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The Indian Journal of Anesthesia and Analgesia is published Six times a year.

Volume 7 (6 issues) will be published in 2020
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INDIAN JOURNAL OF ANESTHESIA AND ANALGESIA

January – February 2020
Volume 7 Number 1 (Part - I)

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Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 9-14
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.1

A Correlation of Preoperative Ultrasound Parameter to Cormack-lehane Classification in Predicting Difficult Laryngoscopy

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Abstract

Background: Prediction of difficult airway is a challenging task. Commonly used airway assessment screening tests has high interobserver variability and low predictability in detecting difficult airway. Ultrasound could be a helpful tool in the prediction of these difficulties. *Objectives:* The purpose of this study was to evaluate the ability of preoperative ultrasound assessment of anterior neck soft tissue thickness in predicting difficult laryngoscopy in patients undergoing during elective surgery requiring tracheal intubation. *Design:* Prospective; Double blind; Observational study. *Patients:* A total of 100 patients aged more than 18 years, without neck pathologies undergoing general anesthesia and tracheal intubation were included in the study. *Outcome Measures:* Ultrasound distance from skin surface to anterior commissure of vocal cord (DSVC) was recorded with a linear 6 to 13 MHz ultrasound transducer preoperatively. Postoperative anesthesia record was analyzed for Cormac Lehane grades during laryngoscopy. *Results:* The DSVC cutoff value of 0.51 cm was the best predictor of Cormack Lehane grade more than 2 at direct laryngoscopy and of difficult intubation, (sensitivity 78.3%, specificity 74%). The mean (SD) of DSVC was 0.53 (0.12) cm in the difficult laryngoscopy group and 0.40 (0.14) cm in the easy laryngoscopy group, ($p < 0.001$). *Conclusion:* The noninvasive prediction of difficult laryngoscopy can be done by airway ultrasound. The distance of 0.51 cm or more at the level of vocal cord can predict potential difficult laryngoscopy in patients undergoing anesthesia with endotracheal intubation.

Keywords: Ultrasonography; Difficult airway; Direct laryngoscopy.

How to cite this article:
Avani Shah, Hitendra Kanzariya, Neeta Bose. A Correlation of Preoperative Ultrasound Parameter to Cormack-lehane Classification in Predicting Difficult Laryngoscopy. Indian J Anesth Analg. 2020;7(1 Part -I):9–14.

Introduction

Anticipated as well as unanticipated difficult airway remained a challenge for clinician. The incidence of difficult intubation was reported ranging from about 5% to 11% in different settings, such as patients under general anesthesia and critically ill patients in the emergency department and intensive care unit.[1–3] Failed or delayed intubation is associated with significant morbidity and mortality.[4] The incidence of failed intubation is about 1 in 1 to 2000 in elective surgical cases[5,6] and about 1 in 50 to 100 in the emergency scenarios.[7,8]

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Received on 17.10.2019, **Accepted on** 28.11.2019

Careful assessment, planning and preparation before the procedure can help in avoiding airway complications.

Classic prediction criteria essentially deal with surface anatomy. They scan for some factors that are associated with difficult intubation but fails to address others. A meta-analysis reported that only 35% of difficult intubations had a Mallampati score of III or IV.[9] Ultrasound imaging provides a simple and noninvasive technique for the clinical assessment of the patient's airway. Currently multiple parameters are being investigated for preintubation airway assessment, but it has remained unclear as to which sonographic parameters can be useful as predictors of difficult laryngoscopy and intubation.[10]

Of available ultrasound parameters for prediction of difficult intubation, anteriorneck soft tissue thickness at the level of vocal cord is of importance. There is very limited literature available evaluating this parameter for predicting difficult laryngoscopy. In the current study, we evaluated performance of ultrasonographic and clinical parameters in predicting difficult laryngoscopy.

Materials and Methods

A prospective, double-blinded observational study enrolling patients undergoing elective surgery under general anesthesia was conducted at the preoperative area and the operation theatre complex of a tertiary care hospital. After institutional ethics committee approval and informed consent, adult patients with age of 18 years or above, who were scheduled for elective surgery requiring general anesthesia with direct laryngoscopy and tracheal intubation, were included in the study.

Patients were excluded if they had contraindications for a proper direct laryngoscopy including limited mouth opening, head and neck pathologies, underwent tracheostomy, had limited neck extension (< 30°) or refused to participate in the study. The age, sex, body height, body weight, body mass index and the Mallampati (MP) classification (Appendix 1) of the patients were recorded.

Measurements and image acquisitions

All the sonographic measurements were done in the preoperative holding area by a single operator. The operator was anesthesiology resident and had acquired the basic operating technique in using ultrasonography. The operator spent one month practicing the technique for obtaining the standard ultrasound image under qualified radiologist before initiating the study.

Data were collected using the Sonosite portable ultrasound system, and the linear transducer (7–13 MHz) was employed with small part preset. The patient was positioned in supine position with active maximal head extension. Ample amount of gel was applied. The probe was placed in the midline and the neck is scanned in the transverse plane from cephalad to caudal direction until the scanning plane section through both the vocal cords, (Fig. 1). The thickness of anterior neck soft tissue was measured from skin to anterior commissure of the vocal cord (DSVC).

Fig. 1: Measurement of soft tissue neck thickness at the level of vocal cord

After receiving the patient in the operating room, patient was monitored with routine intraoperative monitors, including pulse oximetry, noninvasive blood pressure and electrocardiography. The technique of anesthesia was standardized for all the patients in the study. After anesthesia induction with injection propofol 2–2.5 mg/kg, fentanyl l–2 µg/kg and muscle relaxant vecuronium 0.1 mg/kg intravenously, direct laryngoscopy and endotracheal intubation was carried out by an anesthesiologist with atleast two years of experience of performing the procedure. All the patients were put in neutral position without neck overextension or overbending. The Macintosh blade size 4 was to for laryngoscopy and no external laryngeal pressure was used to facilitate the view.

During the intraoperative laryngoscopy, the Cormack and Lehane (CL) grading was recorded.[11] In patients with a difficult airway, intubation was performed according to the Difficult Airway Society 2015 guidelines.[12] The anesthetists, who performed airway assessment for the patients in the operation, were blinded to our ultrasound assessment result.

The anesthetic records of the patients were reviewed for the grade of laryngoscope view using the Cormack and Lehane classification after the scheduled elective operations (Appendix 2).

Patients with a class III or IV view were assigned to the difficult laryngoscopy group, and those with a class I or II view were assigned to the easy laryngoscopy group.

The Statistical Package for Social Sciences (SPSS) version 22.0 for Windows was used for analysis. The Receiver Operating Characteristic (ROC) curve was drawn to assess the performance of the test, and the cut-point of DSVC for the most appropriate prediction the CL grades was determined. The sensitivity, specificity, positive and negative predictive values were calculated using the determined DSVC were compared with the Mallampati classification.

Results

Totally, 112 patients were scanned during the study period. Twelve cases were excluded from analysis due to the use of supraglottic airway device ($n = 9$), regional anesthesia ($n = 2$), postponement of surgery ($n = 1$). One hundred patients were included in the final analysis. Demographic parameters are shown in (Table 1).

Table 1: Demographic data of the patients

Parameters	Range	Mean	SD
Age (years)	20–78	54.2	13.6
Weight (kg)	41.2–109.5	64.7	11.8
Height (cm)	119.5–182.1	161.4	10.2
Body mass index (BMI)	16.8–48.5	23.9	5.4

No difference was noted in age, sex, BMI, ASA status and MP grades (MPG) among easy and difficult laryngoscopy group. MP grades and CL grading distribution are shown in Table 2 and 3 respectively.

Table 2: Mallampati grading of the patients

MP grade	Percentage (%)
Grade 1	47
Grade 2	36
Grade 3	15
Grade 4	2

Table 3: Cormack-Lehane grading of the patients

CL grade	Percentage (%)
Grade 1	40
Grade 2	37
Grade 3	21
Grade 4	2

For the airway assessment results by the anesthetists, 77% of patients had CL classification grade either 1 or 2 and 23% patients had potential difficult laryngoscopy (CL classification Grade 3, or 4). The average time taken to complete the US examination of the patient's airway was about 1.2 min. A correlation was computed to assess the relation between DSVC with Cormack Lehane grading. There was a weak positive correlation of DSVC with CL grading with a regression coefficient of $r = 0.395$ ($p < 0.01$) found, (Fig. 2).

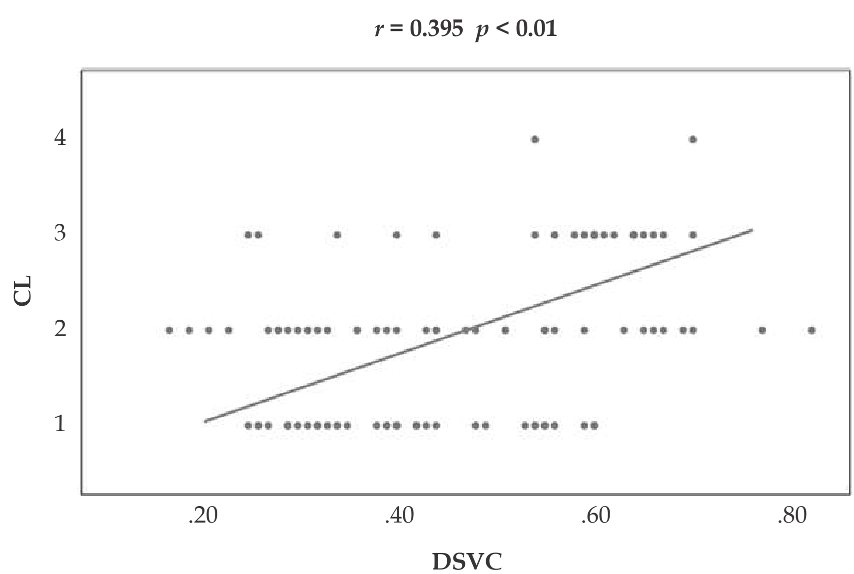

Fig. 2: Scattered diagram of DSVC *vs* Cormac-Lehane grades

The ultrasonographic measurement in difficult and easy laryngoscopy group are compared in (Table 4).

The mean value of DSVC was 0.53 ± 0.12 mm in difficult laryngoscopy group and 0.40 ± 0.14 mm in easy laryngoscopy group which was statistically significant with p - value < 0.001. The distribution of the DSVC in the patients with easy laryngoscopy and in those with potential difficult laryngoscopy were demonstrated in the boxplot, (Fig. 3). The ROC curves for MP grades and DSVC are shown in (Fig. 4).

Table 4: Ultrasonographic measurements comparison

Parameater (mm)	Difficult Laryngoscopy (n = 23)		Easy Laryngoscopy (n = 77)		p - value
	Mean	SD	Mean	SD	
DSVC	0.53	0.12	0.40	0.14	<0.001

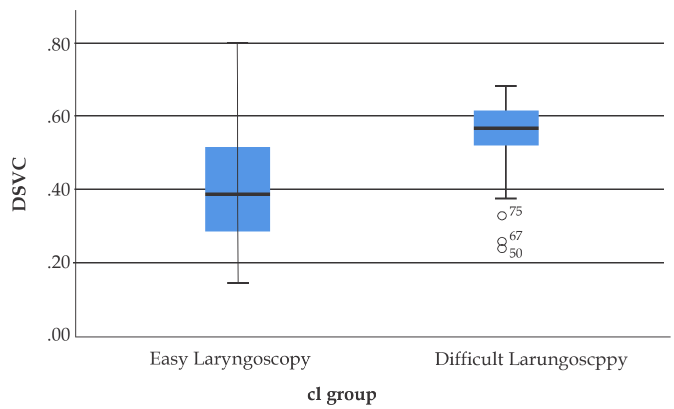

Fig. 3: Boxplot for the distribution of DSVC in the patients with easy and difficult laryngoscopy group.

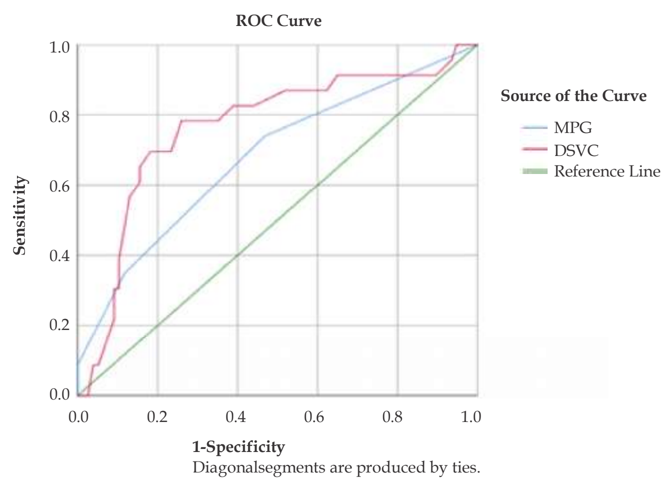

Fig. 4: Receiver Operating Characteristic (ROC) analyses for DSVC (pink line) and Mallampati grading (blue line). Cormack–Lehane grading of glottis exposure over II was considered the threshold of difficult laryngoscopy during the study. Green diagonal line = reference line.

The area under the ROC curves (AUCs) of DSVC and MPG was 0.763 and 0.679 respectively. The AUC of DSVC is more closure to 1 as compared to AUC of MPG indication more validity than MPG. The cut-off of DSVC of 0.51 mm was determined at the point on the ROC curve nearest to the upper left corner of the ROC curve. The sensitivity and specificity of adopting the cut-off of DSVC of 0.51 mm were 78.3% and 74.0% (p < 0.001) which is considered fair in the prediction of difficult laryngoscopy, (Table 5).

Table 5: Performance of DSVC and MPG

Test	AUC	Sensitivity	Specificity	PPV	NPV	*p* - value
DSVC	0.763	78.3%	74%	47.4%	91.9%	< 0.001
MPG	0.679	39.1%	88.3%	50%	82.9%	0.03

Discussion

The management of the airway remains a critical skill for anesthesiologist. Failed to secure airway is a major contributing factor for patients' morbidity and mortality.[13] Currently used traditional indices of difficult airway are not 100% sensitive or specific.[14] Ultrasound has recently emerged as a new tool for airway assessment and prediction of difficult laryngoscopy.[15] The role of ultrasound is still in the primitive phase in airway assessment. Some authors have used ultrasound for predicting difficult airway, but till now, there has been little evidence about which ultrasound assessments are best predictors.[16–18]

In our study, we evaluated the distance from skin to vocal cords by ultrasound preoperatively and compared it with Cormack Lehane assessment during direct laryngoscopy. We also compared the performance of the ultrasound parameter with Mallampati grading in the prediction of difficult airway. The incidence of difficult laryngoscopy as assessed by Cormack Lehane grading was 23% in our study. This incidence was higher than the reported. In the current study, the comparative correlation of DSVC with CL grading for predicting difficult laryngoscopy showed moderate positive correlation.

In the present study, it was found that the measurement of the DSVC is a potential tool in airway assessment and a thickness of more than 0.51 cm correlated with the prediction of difficult intubation. In a study done by Alessandri et al.[19] the sonographic measurements of anterior neck soft tissue were greater in the difficult laryngoscopy group as compared to the easy laryngoscopy group. They compared the distance from skin to the hyoid bone, epiglottis, vocal cord, thyroid isthmus and trachea. they found distance from skin to vocal cord of 0.81 ± 0.20 cm was associated with difficult laryngoscopy.

In a similar study, that was conducted by Ezri et al.[16] comprising a Middle Eastern population, the investigators found that the amount of pretracheal soft tissue in the easy and difficult laryngoscopy groups was mutually exclusive. Patients in whom laryngoscopy was difficult had more pretracheal soft tissue (mean [SD] 28 [2.7] mm *vs* 17.5 [1.8] mm; $p < 0.001$). However, in another study conducted in an American population, it was found that the anterior neck soft tissue thickness was not a good predictor of difficult laryngoscopy.[17] Population in both these studies were of different ethnic group and the incidence of obesity was also different from our study population. In our study, we found that MP was also a good predictor of difficult intubation. DSVC had high sensitivity in predicting difficult intubation than that of the MP class. The specificity and PPV were lower than the physical parameters. Ultrasound measurements of anterior neck soft tissue at the level of the VC could improve the predictive power of current standard clinical screening tests when combined with a Mallampati score. However, Adhikari et al.[20] demonstrated that the Mallampati clinical screening test did not correlate with ultrasound measurements.

We included only 100 adult patients of Indian/ Asian origin. Only 8% of our subjects were obese (BMI ≥ 30 kg/m^2). We have evaluated only one sonographic parameter however, predicting difficult laryngoscopy with a set of parameters will become more valuable. All these are potential limitations of this study. Further, investigations can be done involving a more diverse study population including patient groups having factors known to cause difficult intubation such as pregnancy, obesity and syndromes involving the airway.

Conclusion

Ultrasonographic measurement of the DSVC is a potential predictor of difficult laryngoscopy. A value of more than 0.51 cm correlates well with Cormack Lehane grades for difficult laryngoscopy. It is also more sensitive than the physical parameters such as MP class. The growing interest in the use of ultrasound in airway assessment will be helpful in developing new predictors for difficult laryngoscopy.

Appendix 1: Mallampati classification.

Class 1	Full visibility of tonsils, uvula, and soft palate
Class 2	Visibility of hard and soft palate, and upper portion of tonsils and uvula

Class 3 Soft and hard palate and base of uvula

Class 4 Only hard palate visible

Appendix 2: Cormack–Lehane classification

Grade Laryngoscopic view

1. Full view of the vocal cords
2. Partial view of the glottis or arytenoids
3. Only epiglottis visible
4 Neither glottis nor epiglottis visible

References

1. Shiga T, Wajima Z, Inoue T. Predicting difficult intubation in apparently normal patients: A meta-analysis of bedside screening test performance. Anesthesiology 2005;103(2):429–37.
2. Combes X, Jabre P, Jbeili C. Prehospital standardization of medical airway management: Incidence and risk factors of difficult airway. Acad Emerg Med 2006;13(8):828–34.
3. De Jong A, Molinari N, Terzi N. Early identification of patients at risk for difficult intubation in the intensive careunit: Development and validation of the MACOCHA score in a multicenter cohort study. Am J Respir Crit Care Med 2013;187(8):832–39.
4. Cook TM and MacDougall-Davis SR. Comlications and failure of airway management. Br J Anesth 2012;109(Suppl. 1):i68–i85.
5. Samsoon GL and Young JR. Difficult tracheal intubation: A retrospective study. Anesthesia 1987;42(5):487–90.
6. Rose DK and Cohen MM. The incidence of airway problems depends on the definition used. Can J Anesth 1996;43(1):30–34.
7. Sakles JC, Laurin EG, Rantapaa AA. Airway management in the emergency department: A one-year study of 610 tracheal intubations. Ann Emerg Med 1998;31(3):325–32.
8. Nolan JP and Kelly FE. Airway challenges in critical care. Anesthesia 2011;(66) Suppl 2:81–92.
9. Lee A, Fan LTY, Gin T, et al. A systematic review (meta-analysis) of the accuracy of the Mallampati tests to predict the difficult airway. Anesth Analg 2006;102(6):1867–878.
10. Chan SMM, Wong WY, Lam SKT. Use of ultrasound to predict difficult intubation in Chinese population by assessing the ratio of the pre-epiglottis space distance and the distance between epiglottis and vocal folds. Hong Kong J Emerg Med 2018;25(3):152–59.
11. Cormack RS, Lehane J. Difficult tracheal intubation in obstetrics. Anesthesia 1984;39:1105–111.
12. Frerk C, Mitchell VS, McNarry AF. Difficult Airway Society guidelines for management of unanticipated difficult intubation in adults. Br J Anesth 2015;115(6):827–48.
13. Apfelbaum JL, Hagberg CA, Caplan RA. American Society of Anesthesiologists Task Force on Management of the Difficult Airway. Practice guidelines for management of the difficult airway: An updated report by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway. Anesthesiology 2013 Feb;118(2):251–270.
14. Tamire T, Demelash H, Admasu W. Predictive values of preoperative tests for difficult laryngoscopy and intubation in adult patients at tikuranbessa specialized hospital. Anesthesiol Res Pract 2019(Article ID 1790413):13.
15. Kundra P, Mishra SK, Ramesh A. Ultrasound of the airway. Indian J Anesth 2011 Sep;55(5):456–62.
16. Ezri T, Gewurtz G, Sessler DI. Prediction of difficult laryngoscopy in obese patients by ultrasound quantification of anterior neck soft tissue. Anesthesia 2003 Nov;58(11):1111–114.
17. Komatsu R, Sengupta P, Wadhwa A. Ultrasound quantification of anterior soft tissue thickness fails to predict difficult laryngoscopy in obese patients. Anesth Intensive Care 2007 Feb;35(1):32–37.
18. Rana S, Verma V, Bhandari S, et al. Point-of-care ultrasound in the airway assessment: A correlation of ultrasonography-guided parameters to the Cormack–Lehane Classification. Saudi J Anesth 2018 Apr-Jun;12(2):292–96.
19. Alessandri F, Antenucci G, Piervincenzi E. Ultrasound as a new tool in the assessment of airway difficulties: An observational study. Eur J Anesthesiol 2019;36(7):509–515.
20. Adhikari S, Zeger W, Schmier C. Pilot study to determine the utility of point of-care ultrasound in the assessment of difficult laryngoscopy. Acad Emerg Med 2011 Jul;18(7):754–58.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 15-20
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.2

A Comparative Study of Attenuation of Hemodynamic Responses to Laryngoscopy and Intubation with and without Oral Clonidine

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Abstract

Introduction: Endotracheal intubation is the translaryngeal placement of endotracheal tube into the trachea. Hypertension and tachycardia, usually accompany larynogoscopy and tracheal intubation. *Aims:* A comparative study of attenuation of hemodynamic responses to laryngoscopy and intubation with and without oral clonidine. *Materials and Methods:* This study was done in Fifty patients were selected for the study with the age group ranging between 20–60 years belonging to ASA Group-I. Patients undergoing elective surgical procedures were included in the study. The fifty patients were randomly divided into Two Groups: Control Group and Study Group. Each Group consisted of 25 patients. *Results:* Preinduction and postinduction hemodynamic values were significantly lower in study (clonidine) group, when compared with those of control (without clonidine) group. The difference was statistically significant. *Conclusions:* The stability of heart rate and blood pressure could be achieved by using clonidine 5 ug/kg as a premedicantly useful in management and can prevent instances of 'alpine anesthesia'(attempt to delineate the role of intraoperative hypotension and blood pressure variability).

Keywords: Ultrasonography; Difficult airway; Direct laryngoscopy.

How to cite this article:
B Keshavanarayana, B Sunitha. A Comparative Study of Attenuation of Hemodynamic Responses to Laryngoscopy and Intubation with and without Oral Clonidine. Indian J Anesth Analg. 2020;7(1 Part -I):15–20.

Introduction

Endotracheal intubation is the translaryngeal placement of endotracheal tube into the trachea. Rapid and dramatic hemoldynamic changes, which may adversely affect the patient, may occur during the perioperative period. Hypertension and tachycardia, usually accompany larynogoscopy and tracheal intubation. Failure to blunt the response to intubation may have disastrous consequences in certain patient population like coronary artery disease, systemic arterial hypertension, aneurysmal vascular disease and increased intracranial compliance.

Strategies to circumvent these changes have included minimizing the duration of laryngoscopy

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Received on 11.10.2019, **Accepted on** 28.11.2019

to less than 15 seconds, the use of intravenous narcotics, the use of intravenous Lidocaine, vasodilators, long acting beta-blockers and alpha 2 agonist agents. Each technique has both advantages and disadvantages. The prevention often outlasts the stimulus. Clonidine is an alpha 2 agonist agent used as a premedicant, as well as to maintain the hemodynamic stability preoperatively and intraoperatively.[1,2] The aim of the study is the attenuation of hemodynamic response to laryngoscopy and intubation.

Materials and Methods

This prospective study was done at VRK Medical college in Department of Anesthesiology. Fifty patients were selected for the study with the age group ranging between 20–60 years belonging to ASA-I. Both the sexes were included in the study. Study was done after taking informed consent. Patients undergoing elective surgical procedures were included in the study. After preoperative assessment (history, clinical examination and investigations), patients with airway problems and systemic diseases were excluded from this study.

The fifty patients were randomly divided into Two Groups: Control Group and Study Group. Each Group consisted of 25 patients.

All the patients were given tab, diazepam 5 mg orally night before surgery. Patients in study group were given 200–300 μg (5 mg/kg) tablets of clonidine orally ninety minutes before surgery. The control group was given two tablets of antacid (placebo) ninety minutes before surgery. All the patients were premedicated with inj. Tramadol hydrochloride 1 mg/kg plus promethazine 0.5 mg/kg intramuscularly forty-five minutes before induction.

The patients were preoxygenated with 100% oxygen for five minutes. Pulse Rate (PR) systolic and diastolic blood pressures were recorded. All the patients were monitored with pulse oximeter and electrocardiogram. Induction was done with Thiopentone sodium 2.5% (5 mg/kg body weight) and intubated with Suxamenthonium (2 mg/kg body weight). Maintenance of anesthesia was done with nitrous oxide 66% and oxygen 33% and Pancuronium bromide (0.1 mg/kg) using intermittent positive pressure ventilation.

At the end of the surgery patients were reversed with Neostigmine (0.05 mg/kg) and Atropine (0.02 mg/kg).

Parameters observed were Pulse rate, systolic, diastolic, mean arterial blood pressures and rate pressure product at different intervals as Preinduction, Postinduction, at laryngoscopy and intubation, 1, 2, 5 minute after intubation. The changes in pulse rate and blood pressures were continuously monitored during intraoperative period and postoperatively, patients were observed for six hours.

Rate Pressure Product (RPP) = Heart Rate (HR) * Systolic Blood Pressure (SBP)

With the units for the Heart Rate being beats per minute and for the Blood Pressure mm Hg.

Results

Total 50 patients participated in study with 25 in each group, (Table 1).

The control group comprised of fourteen males and eleven females and study group comprised of sixteen males and nine female patients. Age range was between 20–60 years and 21–60 years in control and study groups respectively. The weight range was between 44–66 kilograms and 43–63 kilograms in control and study groups respectively. There was no statistically significant difference. There was no statistically significant difference in the parameters

Table 1: Demographic details in study

	Control (n = 25)	Study (n = 25)	p - Value
Age (years)	41.7 (20–60 years)	43.0 (21–60Y)	> 0.05
Male/Female	14/11	16/9	> 0.05
Weight (kg)	53.0 (44–66)	54.0 (43–63)	> 0.05
HR (Beats/min)	90.68	92.33	> 0.05
SBP (mm Hg)	120.12	118.40	> 0.05
DBP (mm Hg)	85.28	83.25	> 0.05

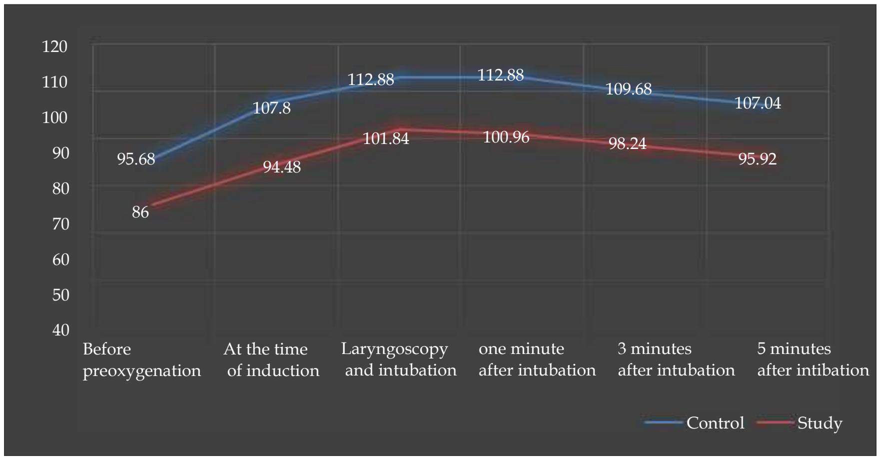

Fig.1: Heart rate in present study on various periods.

between the Two Groups (p less than 0.05), (Fig. 1).

Heart rate is significantly lower in study group than in control group, (p greater than 0.05), (Fig. 2).

Systolic blood pressure in Study group is significantly lower when compared to control group, (Fig. 3).

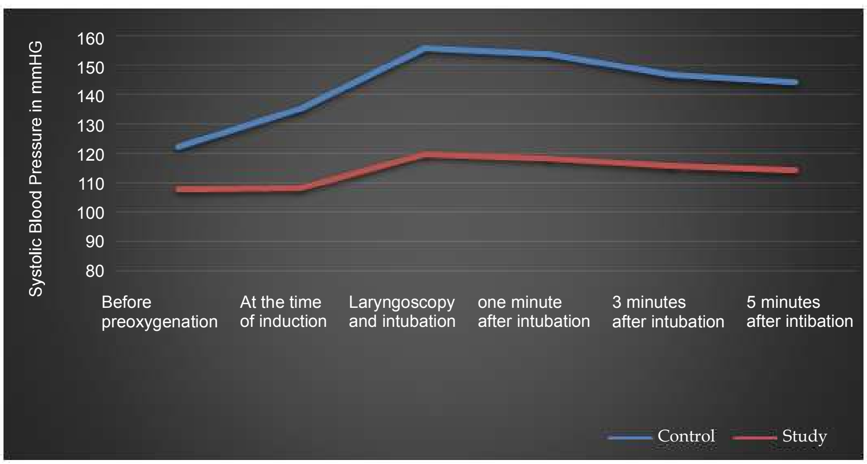

Fig. 2: Systolic blood pressure in present study on various periods.

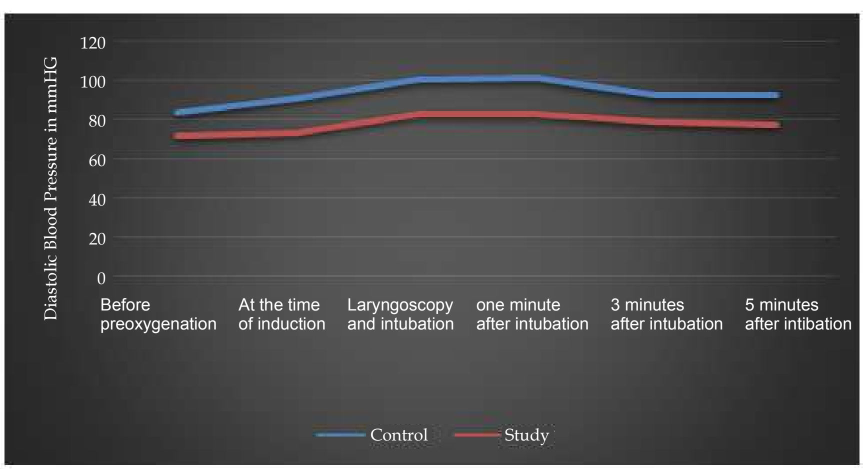

Fig. 3: Diastolic blood pressure in present study on various periods

Diastolic blood pressure in Study group is significantly lower when compared to control group. (p greater than 0.05), (Table 2).

All the parameters of study group significantly lower than when compared to control group.

Table 2: Mean arterial blood pressure and Rate pressure product in present study

Mean Arterial pressure in mm Hg	**Mean Value in control group**	**Mean Value in study group**	***p* - Value**
Before preoxygenation	96.17	84.48	< 0.05
At the time of induction	106.37	84.92	< 0.05
Laryngoscopy and intubation	118.56	94.65	< 0.05
one minute after intubation	118.54	94.82	< 0.05
3 minutes after intubation	113.21	91.36	< 0.05
5 minutes after intubation	109.78	89.86	< 0.05
Rate pressure product in mm Hg*bpm			
Before preoxygenation	11750.88	9,322.72.	< 0.05
At the time of induction	13,610.40	10,213.60	< 0.05
Laryngoscopy and intubation	16,927.66	12,201.28.	< 0.05
One minute after intubation	17,351.20	11,985.28	< 0.05
3 minutes after intubation	16.128	11,434.88	< 0.05
5 minutes after intubation	15,487.20	11,053.28	< 0.05

Discussion

Laryngoscopy and endotracheal intubation may provoke a marked hemodynamic response. This may have insignificant effect in young healthy individuals but may have disastrous consequences in certain patient populations including those with coronary artery disease, systemic arterial hypertension, aneurysmal vascular disease and increased intracranial pressure.

Strategies to blunt marked hemodynamic responses to laryngoscopy and intubation while minimizing the duration of laryngoscopy to less than fifteen seconds can avoid these disastrous consequences. Intravenous lidocaine, vasodilators, narcotics, beta-blockers and alpha 2 adrenoceptor agonists have been used to attenuate the hemodynamic responses to laryngoscopy and intubation. Each technique has both advantages and disadvantages.

Clonidine is an alpha 2 agonist with several desirable properties. As a premedicant it is an effective anxiolytic, sedative and anti-sialogogue. Oral clonidine in a single dose used as a premedicant produces cardiovascular stability. In our study, single dose of oral clonidine 5 μg/kg body weight given preoperatively produced significant and sustained reduction of preoperative systolic and diastolic blood pressures and heart rate and attenuated cardiovascular response to laryngoscopy and endotracheal intubation.[3]

Preinduction and postinduction hemodynamic values were significantly lower in study (clonidine) group, when compared with those of control (without clonidine) group. The difference was statistically significant. Tracheal intubation initiates significant increase in arterial pressures and has been suggested that clonidine modified this response. Similar increases in arterial pressures were recorded in the clonidine group and control (without clonidine) groups, but the lower postintubation values in clonidine group were a reflection of the preexisting hypotension.

Clonidine reduced heart rate and this was observed in our study. The central adrenergic system modulates pain sensation and the alpha 2 adrenergic agonists have been shown either to provide analgesia or to enhance the analgesic effectiveness of opioids. This is possibly one explanation for the observation of more stable hemodynamics in the study group. Three major published studies had addressed the influences of oral preoperative administration of clonidine on course of anesthesia with particular reference to hemodynamic response to laryngoscopy, intubation and surgery.[4]

Recent studies oral clonidine premedication could attenuate the hemodynamic changes associated with laryngoscopy and endotracheal intubation.[5] Study group patient received oral clonidine 5 ug/kg ninety minutes before surgery and control group did not receive clonidine. They found that the increase in mean blood pressures from baseline value following laryngoscopy and intubation in clonidine group was significantly smaller as compared with that of the control group. (20± *vs* 31± 4 mm Hg mean±SD, *p* less than 0.05). There was significant differences between the two groups in the incidence of systolic blood pressure increase above 180 mm Hg following laryngoscopy and intubation (0% *vs* 26%, *p* less than 0.05%). They concluded that oral clonidine of 5 ug/kg as a premedicant could attenuate the pressor response associated with laryngoscopy and endotracheal intubation.

Laurito CE et al. used clonidine 200 μg as premedicant ninety minutes before surgery to attenuate the hemodynamic response to laryngoscopy and intubation.[6] Clonidine 0.2 mg decreased systolic, mean and diastolic blood pressures, but not heart rates. Clonidine 0.2 mg also blunted the increase in systolic blood pressure accompanied laryngoscopy.

The attenuating effect of clonidine has previously been documented by many studies.[7] Control patients showed a significant increase in heart rate and blood pressure. They were significantly lower in patients who were treated with clonidine, immediately after intubation (*p* less than 0.001). The study concluded that oral clonidine 5 μg/kg. ninety minutes before surgery can attenuate hemodynamic response to laryngoscopy and intubation.

Raval DL *et al.* observed reductions in SBP and DBP following premedication with oral clonidine 0.2 mg by 7.63%.[8] In postintubation period, SBP and DBP remained below baseline value producing significant attenuation of rise in SBP due to laryngoscopy and intubation. These findings may be favorably compared with the findings of the present study. Singh S et al. also showed that premedication oral clonidine 150 μg resulted in better hemodynamic stability and less anesthetic requirement.[9] The attenuating effect of clonidine on hemodynamic responses to airway manipulation has previously been documented by many studies. Talebi H et al.[10] have documented that orally administered clonidine in preanesthetic period attenuates the stress response to laryngoscopy and intubation. The findings of the present study are well correlated with studies done by workers like Yokota S et al.,[4] and Singh S et al.[9] Results of our study using clonidine as premedicant consistent with the above studies in attenuation hemodynamic responses to laryngoscopy and intubation.

Conclusion

Oral clonidine as a dose of 5 μg/kg, administered ninety minutes before surgery, attenuated hemodynamic responses to laryngoscopy and endotracheal intubation. Preinduction and postinduction hemodynamic values were significantly lower in study group, when compared with those of control group. The difference was statistically significant. No patient from the study group had severe bradycardia (heart rate less than 50 beats/min), severe hypotension or a combination of the two in the perioperative period. No rebound hypertension was observed in any patient in the study group. Therefore, we conclude that a single premedication dose never resulted in rebound hypertension. By extrapolating our results to hypertensive patients, we suggest that oral clonidine may be particularly useful in management and can prevent instances of ‘alpine anesthesia’.

References

1. Marashi SM, Ghafari MH, Saliminia A. Attenuation of hemodynamic responses following laryngoscopy and tracheal intubation - comparative assessment of clonidine and gabapentin premedication. Middle East J Anaesthesiol. 2009;20(2):233–237.
2. Shrestha GS, Marhatta MN, Amatya R. Use of gabapentin, esmolol or their combination to attenuate haemodynamic response to laryngoscopy and intubation. Kathmandu Univ Med J (KUMJ). 2011;9(36):238–243. doi:10.3126/kumj.v9i4.6336.
3. Talebi H, Nourozi A, Fateh S, et al. Effects of oral clonidine premedication on haemodynamic response to laryngoscopy and tracheal intubation: a clinical trial. Pak J Biol Sci. 2010;13(23):1146–1150. doi:10.3923/pjbs.2010.1146.1150
4. Yokota S, Komatsu T, Yano K, et al. Effect of oral clonidine premedication on hemodynamic response during sedated nasal fiberoptic intubation. Nagoya J Med Sci. 1998;61(1-2):47–52.
5. Talebi HA, Nourozi S Fateh, Mohammadzadeh A, et al. Effects of oral clonidine premedication on hemodynamic response to laryngoscopy

and tracheal intubation: A clinical trial. Pak J Biol Sci. 2010 Dec 1;13(23):1146–150.

6. Laurito CE, Baughman VL, Becker GL, et al. Cavananza: The effectiveness of oral clonidine as a sedative/anxiolytic and a drug to blunt the hemodynamic responses to laryngoscopy. J Clin Anesth 1991:3(3):186–93.
7. MeMIs D, Turan A, KaraManlIoglu B, et al. Gabapentin reduces cardiovascular responses to laryngoscopy and tracheal intubation. Eur J Anaesthesiol. 2006 Aug;23(8):686–90.
8. Raval DL, Mehta MK. Oral clonidine for attenuation of pressor response. Indian J Anesth 2002;46(2):124–29.
9. Singh S, Arora K. Effect of oral clonidine premedication on perioperative hemodynamic response and postoperative analgesic requirement for patients undergoing laparoscopic cholecystectomy. 2011 Jan-Feb; 55(1):26–30.
10. Talebi H, Nourozi A, Fateh S, et al. Effects of oral clonidine premedication on hemodynamic response to laryngoscopy and tracheal intubation: A clinical trial. Pak J Biol Sci. 2010 Dec 1;13(23):1146–150.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 21-27
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.3

A Clinical Study on Correlation of Ultrasonographic Measurement of Caval Index with Central Venous Pressure

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Abstract

Background: Central Venous Pressure (CVP) has been used for fluid resuscitation and to check intravascular volume status. A rapid bedside sonographic examination can be instrumental in guiding management of trauma and critically ill patients. This study evaluated the Ultrasonographic (USG) measurement of Inferior Vena Cava (IVC) diameter and caval index to identify intravascular volume status and its correlation with CVP. We also investigated the association of caval index of ≥ 50% and CVP ≤ 8 mm Hg. *Aims:* This study was designed to evaluate Ultrasonographic (USG) measurement of Inferior Vena Cava (IVC) diameter and caval index could identify intravascular volume status and its correlation with CVP. Also, investigating the association of caval index of ≥ 50% and CVP ≤ 8 mm Hg. *Materials and Methods:* A hundred patients aged 18 years and above were enrolled in this prospective, observational study. IVC inspiratory and expiratory diameters were measured by USG. The correlation of CVP and caval index was calculated. Participants were stratified by their CVP ≤ 8 mm Hg and > 8 mm Hg. *Results:* In 100 participants of the study, 68 had a CVP ≤ 8 mm Hg with caval index > 50%. The efficacy of caval index predicting the low CVP (CVP ≤ 8) between the Two Groups was statistically significant. The caval index ≥ 50% predicting a CVP ≤ 8 mm Hg had sensitivity, specificity, positive and negative predictive value of 97%, 96%, 99% and 93% respectively. *Conclusions:* Bedside USG measurement of caval index greater than or equal to 50% is strongly associated with a low CVP and caval index could be a useful tool to determine CVP.

Keywords: Central venous pressure; Inferior vena cava; Caval index; Emergency department; Intensive care unit.

How to cite this article:

Balaji Thiyagarajan, Sharanu Patil, Alagu Annamalai, et al. A Clinical Study on Correlation of Ultrasonographic Measurement of Caval Index with Central Venous Pressure. Indian J Anesth Analg. 2020;7(1 Part -I):21–27.

Introduction

Adequate fluid resuscitation is extremely vital in acutely ill patients, as under correction of intravascular volume is associated with increased morbidity and mortality. Appropriate volume resuscitation optimizes the preload, improves Cardiac Output (CO) and tissue perfusion. But overzealous resuscitation can lead to increased morbidity and mortality.[1–5] Studies have shown that only about half of the critically ill patient's exhibit preload responsiveness.[6]

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Received on 26.10.2019, **Accepted on** 06.12.2019

The methods of determining the adequacy of volume resuscitation have relied on static and dynamic parameters. The static parameters include Central Venous Pressure (CVP), Pulmonary artery wedge pressure, right and left ventricular end-diastolic volume index. However, all of them require invasive access and none of these are accurate in predicting preload responsiveness.[6–8] There has been a paradigm shift in the approach to predicting hypovolemia with the use of USG.

The dynamic parameters are respiratory variation in CVP, diameter of Inferior Vena Cava (IVC), Superior Vena Cava (SVC), Arterial blood pressure waveform, Passive Leg Raising (PLR) and an actual fluid challenge. Dynamic parameters outperform the static ones in predicting hypovolemia and responsiveness to volume resuscitation.

Some studies propose that in fundamentally sick patients, CVP may not correlate with the successful intravascular volume.[9] Moreover, invasive hemodynamic monitoring has not been found to have a great advantage in sick patients.[10] Pulmonary artery catheters and CVP catheters are time-consuming, intrusive and have major adverse effects. The use of sonography has led to better noninvasive evaluation of intravascular volume status. A quick bedside sonographic examination can be instrumental in directing therapeutic administration.

The absolute IVC diameter changes broadly among healthy adults and by itself may not be diagnostic, the maximal IVC diameter has been found to be lower in patients with hypovolemia.[11] A better indicator of intravascular volume is collapsibility of the IVC. The IVC collapsibility index, also known as the caval index, it is calculated by difference between the maximal (expiratory) and minimal (inspiratory) IVC diameters divided by the maximal IVC diameter. The caval index has been used in spontaneously breathing patients to estimate right atrial pressure.[12,13] Measurements taken during normal respiration have been found to be reasonably accurate.[14] Recent guidelines from the American Society of Echocardiography back the use of IVC diameter and collapsibility of IVC in evaluation of volume status.[15]

We conducted this study to determine if noninvasive, bedside ultrasonographic measurement of the inferior vena cava diameter and caval index could identify intravascular volume status among acutely ill patients and also correlation of Caval Index (CI) of ≥ 50% witch ≤ 8 mm Hg.

Materials and Methods

After obtaining approval from the hospital institutional review board the study was conducted on 100 consecutive cases admitted to the hospital during the study period, satisfying the inclusion and exclusion criteria and consenting to participate in the study. Patients presenting to the ER with trauma or admitted to the ICU with sepsis, septic shock were included in the study. Written informed consent was obtained from the patients before ultrasonographic examination and central vein placement. The inclusion criteria were patients older than 18 years, unintubated and spontaneously breathing. The exclusion criteria were II/III trimester pregnancy, presence of peumothorax/hemothorax, ascites and raised intraabdominal pressures.

Ultrasonographic guided measurements of inferior vena cava during inspiration and expiration were taken while patients were supine. A low-frequency phased array transducer (3.5–5 MHz) was used to evaluate the IVC. There exists considerable variability in the literature regarding the location at which the IVC diameter should be measured. Most studies agree that the measurement should be distal to the junction with the right atrium and within 3 cm of that point,[12–18] Other studies measure the IVC at or near the junction with the hepatic veins.[19–25] Guidelines from the American Society of Echocardiography recommend an assessment of the IVC just proximal to the hepatic veins, which lie approximately 0.5 to 3 cm from the right atrium, (Fig. 1).[15]

Fig. 1: Sagittal view of the inferior vena cava.

To image the IVC, the probe was placed in the subxiphoid 4-chamber position with the probe marker oriented laterally to identify the right ventricle and right atrium. Then, the probe was aimed toward the spine and the convergence of the IVC with the right atrium was visualized. The IVC was then visualized inferiorly, specifically looking for the confluence of the hepatic veins with the IVC. Inspiratory vena cava and expiratory vena cava diameters were measured just proximal to the hepatic veins, which lie approximately 0.5 to 3 cm from the right atrium, (Fig. 2). Measurements were taken during a normal respiratory cycle. M-mode Doppler sonography of the IVC was used to graphically document the absolute size and dynamic changes in the caliber of the vessel during the patient's normal respiratory cycle. The Caval index (CI) was calculated as CI (%) = (IVC expiratory diameter - IVC inspiratory diameter) × 100.

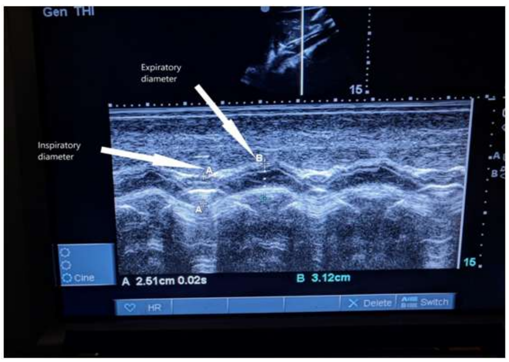

Fig. 2: Sagittal view of the inferior vena cava showing inspiratory and expiratory diameters in M mode.

Simultaneously a right internal jugular catheter was inserted and central venous pressure measurements obtained by digital transduction of the pressure tracing of the distal port the central line after confirmation from a supine chest radiograph that the catheter tip is at the distal aspect of the SVC. Parameters studied included heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, central venous pressure, and inspiratory vena caval diameter. Expiratory vena caval diameter and Caval Index.

Statistical Analysis

Summary statistics were generated for the participants characteristics (age, sex) vital Signs (pulse rate, systolic blood pressure, diastolic blood pressure), and study measurements (central venous pressure, inspiratory vena cava diameter, expiratory vena cava diameter, inferior vena cava and Caval Index percentage.

Sample size calculation

The sample size was calculated taking into consideration the number of admissions in ICU being 6800/year and the number of cases with hypotension 420/year. The incidence being 6.2%, sample size of 89.4 patients was calculated by setting a confidence level at 95%. In order to compensate for loss of data a sample size of 100 used for the study. Data analysis was done with the help of computer using Epidemiological Information Package (EPI 2010) developed by Centre for Disease Control, Atlanta. Using this software range, frequencies, percentages, means and standard deviations, Chi-square and 'p' values were calculated. Kruskal Wallis and Chi-square test were used to test the significance of difference between quantitative variables, Fisher's test was used for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship. Sensitivity, specificity, accuracy, positive predictive value and negative predictive values were calculated.

Results

A hundred patients were enrolled in this study. The mean age of the patients was 45.52 ± 14.42 years. There were 58 males and 42 females in the final analysis, shows in (Table 1). The number of patients having MAP ≤ 70 mm Hg CVP ≤ 8 cm H_2O and Caval Index ≥ 50 is shown in (Table 2).

Table 1: Demographic parameters (mean ± standard deviation)

Parameter	Mean ± SD
Age (years)	45.52 ± 14.42
Weight (kgs)	60.97 ± 12.46
Sex	Males 58
	Females 42

Table 2: Hemodynamic parameters in patients

Hemodynamic parameter	Number of patients
MAP ≤ 70 mm Hg	54
CVP ≤ 8 cm H_2O	72
Caval Index ≥ 50	72

Participants in the study were stratified by their central venous pressure measurement ≤ 8 mm Hg and > 8 mm Hg. The mean heart rate in the CVP ≤ 8 mm Hg group and CVP > 8 mm Hg group was 113.4 ± 7.9 per minute and 97.6 ± 5.8 per minute. On comparing between the groups p value was < 0.001 which was statistically significant. The Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and the Mean Arterial Pressure (MAP) was significantly lower in the patients with CVP of ≤ 8 mm Hg group compared to the patients with CVP > 8 mm Hg group. The mean SBP in the CVP ≤ 8 mm Hg group and CVP > 8 mm Hg group at was 86.1 ± 6.0 mm Hg and 108.6 ± 7 mm Hg. On comparing between the groups p value was < 0.001 which was statistically significant. The mean DBP in the CVP ≤ 8 mm Hg group and CVP > 8 mm Hg group was 62.0 ± 3.3 mm Hg and 69.8 ± 4.5 mm Hg. On comparing between the groups p value was < 0.001 which was statistically significant. The mean MAP in the CVP ≤ 8 mm Hg group and CVP > 8 mm Hg group was 69.8 ± 3.6 mm Hg and 80.3 ± 5.6 mm Hg. On comparing between the groups p value was < 0.001 which was statistically significant, shows in (Table 3).

The mean inspiratory vena caval diameter between CVP ≤ 8 mm Hg group and CVP > 8 mm Hg group was found to be 0.54 cm and 1.24 cm and was statistically significant. The mean expiratory venacaval diameter between CVP ≤ 8 mm Hg group and CVP > 8 mm Hg group at was found to be 1.78 cm and 2.23 cm and was statistically significant. The mean caval index between CVP ≤ 8 mm Hg group and CVP > 8 mm Hg group was found to be 70.3% and 44.3 % and was statistically significant (Fig. 3). There is a positive correlation between caval index and a hypovolemic state (patients with CVP ≤ 8 mm Hg), (Table 3).

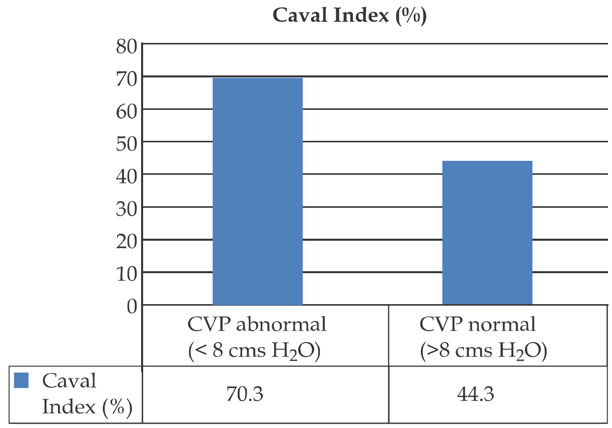

Fig 3: Graph showing correlation of Caval index with central venous pressure (CVP).

Table 3: Hemodynamic variables stratified by their central venous pressure (CVP) ≤ 8 mm Hg and > 8 mm Hg at 0 min

Variable	CVP abnormal (≤ 8 mm Hg) Mean ± SD	CVP normal (>8 mm Hg) Mean ± SD	'*p* value'
Heart rate (beats/minute)	113.4 ± 7.9	97.6 ± 5.8	< 0.001
Systolic BP (mm/Hg)	86.1 ± 6.0	108.6 ± 7.1	< 0.001
Diastolic BP (mm/Hg)	62.0 ± 3.3	69.8 ± 4.5	< 0.001
MAP (mm/Hg)	69.8 ± 3.6	80.3 ± 5.6	< 0.001
Inspiratory IVC dia (cm)	0.54 ± 0.2	1.24 ± 0.23	< 0.001
Expiratory IVC dia (cm)	1.78 ± 0.26	2.23 ± 0.36	< 0.001
Caval Index (%)	70.3 ± 7.7	44.3 ± 2.8	< 0.001

The efficacy of ultrasound guided measurement of caval index in predicting central venous pressure in our study was found to have a sensitivity of 97%, specificity of 96%, accuracy of 97%, positive predictive value of 99% and negative predictive of 93%. We found to have that caval index a higher sensitivity, specificity, accuracy, negative predictive value and positive predictive value when compared to inspiratory and expiratory vena caval diameter, shows in (Table 4).

Table 4: Comparative efficacy of IVC diameter and Caval Index in predicting central venous pressure

	Sensitivity	Specificity	Accuracy	PPV	NPV
Inspiratory IVC diameter	94	82	91	93	85
Expiratory IVC diameter	93	86	91	94	83
Caval Index	97	96	97	99	93

Discussion

The usage of ultrasound in anesthesia and critical care/emergency care has seen a rapid upsurge in recent times. Estimation of hypovolemic by ultrasound has become a routine in many centres because it is rapid, less time consuming, noninvasive and costeffective. Currently there are many parameters to evaluate hypovolemic state by ultrasound method and the most promising being caval index. Caval index has shown to be most sensitive, specific, and has a high positive predictive value, high negative predictive value when compared to inspiratory, expiratory vena caval diameter or CVP when these were used alone. Caval index being a dynamic parameter takes multiple factor into consideration in determining the volume status and the trend of caval index has found to be more reliable indicator of adequate resuscitation than a single value at any point of time. The complexity and complications of CVP can be overcome by simple noninvasive measurement of inferior vena caval diameter and calculating the Caval Index by ultrasonography. This makes ultrasonographic guided fluid resuscitation most appropriate mode of monitoring intravascular volume status in critically ill patients and in emergency situations. The sonographic evaluation of the IVC has been found to the improve the precision of diagnosis in patients with undifferentiated hypotension.[26]

In a recent study, point-of-care sonography assessing cardiac contractility and IVC collapsibility in patients with suspected sepsis it was found to improve the physician certainty of diagnosis and modify more than 50% of treatment plans.[27] Inadequate dilatation of the IVC after a fluid challenge has been found to be more sensitive than blood pressure for identification of hypovolemia in trauma patients.[28] A study in trauma patients has shown bedside caval sonography extremely useful in assessment of fluid status and resuscitation of critically sick patients.[29] In another study, intensely dyspnoeic patients presenting to the emergency department, IVC sonography quickly recognized patients with congestive heart failure and volume overload.[30] Instead of depending on a single estimation of the IVC, it may be more valuable to take after changes in vessel diameter and collapsibility over time, in relation to an intervention. Studies have shown a decrease in the IVC diameter and increased collapsibility after blood loss and fluid removal during hemodialysis.[31] In hypotensive patients, volume resuscitation was associated with increments within the IVC diameter and lower inspiratory collapsibility.[32]

In our study, we found to have that caval index a higher sensitivity, specificity, accuracy, negative predictive value and positive predictive value (Table 4) when compared to inspiratory and expiratory vena caval diameter. We also found that ultrasound guided measurement of Caval Index could predict the low intravascular volume status in 96% of the cases in the study and their difference with the central venous pressure between the Two Groups were statistically significant ($p < 0.01$). It implies that noninvasive ultrasound guided dynamic measurement of caval index which is obtained by measuring the IVC diameters is reliable to assess the intravascular volume status of the patient and will aid the physician towards goal directed treatment of resuscitation.

Conclusion

We conclude that noninvasive, bedside ultrasonographic measurement of Caval Index is a quick, safe, and reliable method to identify patients with low intravascular volume.

Key Messages

Currently there are many parameters to evaluate hypovolemic state; the ultrasound method is most promising. Caval index being a dynamic parameter has found to be more reliable indicator of adequate resuscitation than a single value at any point of time. Ultrasound guided measurement of caval index could predict the low intra-vascular volume status and thus a low central venous pressure. This technique is noninvasive, easy to measure, inexpensive, fast, and reproducible and also guides the treatment plan.

Abbreviation

MAP = Mean Arterial Pressure

CVP = Central Venous Pressure

IVC = Inferior Vena cava

Caval Index = Maximal (expiratory) - Minimal (inspiratory) IVC diameters/maximal (expiratory) IVC diameter

References

1. Murphy CV, Schramm GE, Doherty JA, et al. The importance of fluid management in acute lung injury secondary to septic shock. Chest. 2009 Jul;136(1):102–109.
2. Boyd JH, Forbes J, Nakada TA, et al. Fluid resuscitation in septic shock: A positive fluid balance and elevated central venous pressure are associated with increased mortality. Crit Care Med 2011;39(2):259–65.
3. Alsous F, Khamiees M, DeGirolamo A, et al. Negative fluid balance predicts survival in patients with septic shock: A retrospective pilot study. Chest 2000;117(6): 1749–754.
4. Vincent JL, Sakr Y, Sprung CL, et al. Sepsis in European intensive care units: Results of the

SOAP study. Crit Care Med. 2006 Feb;34(2):344–53.

5. Reichley RM, Gajic O, Afessa B, et al. National Heart, Lung, and Blood Institute Acute Respiratory Distress Syndrome (ARDS) Clinical Trials Network. Comparison of two fluid-management strategies in acute lung injury. N Engl J Med 2006;(354):2564–575.
6. Marik PE, Cavallazzi R, Vasu T, et al. Dynamic changes in arterial waveform derived variables and fluid responsiveness in mechanically ventilated patients: A systematic review of the literature. Crit Care Med 2009;37(9):2642–647.
7. Marik PE, Baram M, Vahid B. Does central venous pressure predict fluid responsiveness? Chest 2008;134(1):172–78.
8. Michard F, Teboul JL. Predicting fluid responsiveness in ICU patients: A critical analysis of the evidence. Chest 2002; 121(6):2000–2008.
9. Marik PE, Baram M, Vahid B. Does central venous pressure predict fluid responsiveness a systematic review of the literature and the tale of seven mares. Chest. 2008 Jul;134(1):172–78.
10. Shah MR, Hasselblad V, Stevenson LW, et al. Impact of the pulmonary artery catheter in critically ill patients: meta-analysis of randomized clinical trials. JAMA. 2005;294(13):1664–1670.
11. Brennan JM, Ronan A, Goonewardena S, et al. Handcarried ultrasound measurement of the inferior vena cava for assessment of intravascular volume status in the outpatient hemodialysis clinic. Clin J Am Soc Nephrol. 2006;1(4):749–753.
12. Jue J, Chung W, Schiller NB. Does inferior vena cava size predict right atrial pressures in patients receiving mechanical ventilation?. J Am Soc Echocardiogr. 1992;5(6):613–619.
13. Yildirimturk O, Tayyareci Y, Erdim R, et al. Assessment of right atrial pressure using echocardiography and correlation with catheterization. J Clin Ultrasound. 2011;39(6):337–343.
14. Brennan JM, Blair JE, Goonewardena S, et al. Reappraisal of the use of inferior vena cava for estimating right atrial pressure. J Am Soc Echocardiogr. 2007;20(7):857–861.
15. Rudski LG, Lai WW, Afilalo J, et al. Guidelines for the echocardiographic assessment of the right heart in adults: a report from the American Society of Echocardiography endorsed by the European Association of Echocardiography, a registered branch of the European Society of Cardiology, and the Canadian Society of Echocardiography. J Am Soc Echocardiogr. 2010;23(7):685–788.
16. Feissel M, Michard F, Faller JP, Teboul JL. The respiratory variation in inferior vena cava diameter as a guide to fluid therapy. Intensive Care Med. 2004;30(9):1834–1837.
17. Sefidbakht S, Assadsangabi R, Abbasi HR, Nabavizadeh A. Sonographic measurement of the inferior vena cava as a predictor of shock in trauma patients. Emerg Radiol. 2007;14(3):181–185.
18. Nagdev AD, Merchant RC, Tirado-Gonzalez A, et al. Emergency department bedside ultrasonographic measurement of the caval index for noninvasive determination of low central venous pressure. Ann Emerg Med 2010;55(3):290–95.
19. Marcelino P, Borba A, Fernandes AP, Marum S, Germano N, Lopes MR. Non invasive evaluation of central venous pressure using echocardiography in the intensive care--specific features of patients with right ventricular enlargement and chronic exacerbated pulmonary disease. Rev Port Pneumol. 2006;12(6):637–658.
20. Barbier C, Loubières Y, Schmit C, et al. Respiratory changes in inferior vena cava diameter are helpful in predicting fluid responsiveness in ventilated septic patients. Intensive Care Med. 2004;30(9):1740–1746.
21. Sakurai T, Ando Y, Masunaga Y, et al. Diameter of the inferior vena cava as an index of dry weight in patients undergoing CAPD. Perit Dial Int 1996;16:183–85.
22. Akilli B, Bayir A, Kara F, Ak A, Cander B. Inferior vena cava diameter as a marker of early hemorrhagic shock: a comparative study. Ulus Travma Acil Cerrahi Derg. 2010;16(2):113–118.
23. Mintz GS, Kotler MN, Parry WR, Iskandrian AS, Kane SA. Real-time inferior vena caval ultrasonography: normal and abnormal findings and its use in assessing right-heart function. Circulation. 1981;64(5):1018–1025.
24. Mitaka C, Nagura T, Sakanishi N, Tsunoda Y, Amaha K. Two-dimensional echocardiographic evaluation of inferior vena cava, right ventricle, and left ventricle during positive-pressure ventilation with varying levels of positive end-expiratory pressure. Crit Care Med. 1989;17(3):205–210.
25. Moreno FL, Hagan AD, Holmen JR, Pryor TA, Strickland RD, Castle CH. Evaluation of size and dynamics of the inferior vena cava as an index of right-sided cardiac function. Am J Cardiol. 1984;53(4):579–585.
26. Jones AE, Tayal VS, Sullivan DM, Kline JA. Randomized, controlled trial of immediate versus delayed goal-directed ultrasound to identify the cause of nontraumatic hypotension

in emergency department patients. Crit Care Med. 2004;32(8):1703–1708.

27. Haydar S, Moore ET, Higgins GL III, et al. Effect of bedside ultrasonography on the certainty of physician clinical decision-making for septic patients in the emergency department. Ann Emerg Med 2012 Sep;60(3):346–58.
28. Yanagawa Y, Sakamoto T, Okada Y. Hypovolemic shock evaluated by sonographic measurement of the inferior vena cava during resuscitation in trauma patients. J Trauma. 2007;63(6):1245–1248.
29. Ferrada P, Anand RJ, Whelan J. Qualitative assessment of the inferior vena cava: useful tool for the valuation of fluid status in critically ill patients. Am Surg 2012 Apr;78(4):468–70.
30. Blehar DJ, Dickman E, Gaspari R. Identification of congestive heart failure *via* respiratory variation of inferior vena cava diameter. Am J Emerg Med 2009 Jan;27(1):71–75.
31. Krause I, Birk E, Davidovits M. Inferior vena cava diameter: A useful method for estimation of fluid status in children on hemodialysis. Nephrol Dial Transplant 2001 Jun;16(6):1203–206.
32. Weekes AJ, Tassone HM, Babcock A, et al. Comparison of serial qualitative and quantitative assessments of caval index and left ventricular systolic function during early fluid resuscitation of hypotensive emergency department patients. Acad Emerg Med. 2011;18(9):912–921.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 28-32
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.4

Effect of Preoperative Information on Perioperative Anxiety of the Patients Posted for Elective Surgery: A Prospective Randomized Comparative Study

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Abstract

Context: Patients without information of surgery and anesthesia are supposed to have high anxiety level in the perioperative period which may have adverse hemodynamic effects and higher incidence of postoperative pain. Overall information regarding anesthesia may attenuate the perioperative anxiety. *Aims:* Our aim and objective was to observe and compare the perioperative anxiety level in patients undergoing elective surgery using Beck Anxiety Inventory (BAI) scale. *Materials and Methods:* One hundred patients of either sex aged between 18 and 80 years conforming to ASA physical Status I to III posted for elective surgery were randomly allocated into Two Groups to receive either baseline information during preanesthetic check up according to Institutional protocol (Group A, $n = 50$) or additional information based on a questionnaire regarding the process of anesthesia (Group B, $n = 50$). The levels of anxiety were assessed using BAI score at 4 time points namely, just after PAC (reading 0), at waiting room before entry to operation theatre (reading 1), on operation table just prior to administering anesthesia (reading 2) and again at four hours after the surgery (reading 3). *Results:* Patients of Group A has much higher anxiety level than Group B ($p < 0.05$). In both the groups anxiety level was the highest just prior to anesthesia but the degree of anxiety was less in Group B (17.28 ± 4.69) than group A (25.88 ± 6.82) p value < 0.0001. *Conclusion:* Combination of preanesthetic check up with additional information to the patient regarding anesthesia based on a questionnaire is better than only check up to reduce perioperative anxiety.

Keywords: Anesthesia; Anxiety; Knowledge; Questionaire.

How to cite this article:
Debanjali Ray, Ishita Saha, Anuradha Mitra, et al. Effect of Preoperative Information on Perioperative Anxiety of the Patients Posted for Elective Surgery: A Prospective Randomized Comparative Study. Indian J Anesth Analg. 2020;7(1 Part -I):28–32.

Introduction

Lack of knowledge regarding anesthesia in addition to surgery is seen as stressors that trigger preoperative anxiety. This may be associated with adverse hemodynamic effects, higher incidence of postoperative pain, altered immune system and contribute to development of infections.[1] The goal of Preanesthetic Check-up (PAC) is to obtain relevant information regarding the patient's current and past medical history and formulate anesthetic plan based on risk assessment.[2,3] The anesthesiologist's attention can greatly reduce anxiety even without

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Received on 15.10.2019, **Accepted on** 11.12.2019

using medicines[4] and enhance their confidence in the anesthetic procedure.[5] In recent years, it has been posited that written material, such as a simple leaflet, could be useful in increasing patients' knowledge of anesthesia and anesthesiologists.[6] There are studies concerning the effect of preoperative information tools on postoperative status of the patient.[7,8] Effect of reading information brochure prior to operation have also been studied.[9] But study regarding the effect of preoperative information in conversation format on perioperative anxiety of the patient using proper scale has not yet been done. Hence, aim of our study was to observe perioperative anxiety with and without additional information regarding anesthesia based on questionnaire and compare the level of perioperative anxiety using Beck Anxiety Inventory (BAI) scale between the groups.

Materials and Methods

This study was undertaken in a teaching hospital in West Bengal in the period from January 2017 to May 2017. After approval from Institute's Ethics Committee and obtaining informed consent 130 patients were recruited for this randomized comparative study. Inclusion criteria were patients of either sex, aged 18 to 70 years, American Society of Anesthesiologists (ASA) physical status I to III, posted for elective surgery. Exclusion criteria were patients having pregnancy, mental retardation, carcinoma, speech problem and psychiatric disorder. Based on a previous study, the mean difference and the pooled standard deviation were calculated and the sample size was determined (65 in Each Group), with power of study being 80% and confidence interval being 95%.[4] Patients were randomly allocated into Two Groups by Stat Trek random number table, where one patient had every chance to get allocated in any group. Patients were randomly allocated into Two Groups either to receive formal information as per institute's protocol during PAC (Group A, *n* - 65) or to receive additional information based on interview using the questionnaire (Group B, *n* - 65). A team of one nursing personnel and two anesthesiologists were formed to run the study smoothly and without any bias. The nursing personnel in the PAC clinic performed the group allocation using the computer-generated random numbers placed in sequentially numbered sealed opaque envelopes. One anesthesiologist performed the PAC as per institute's protocol providing baseline information in Group A or reinforcing with additional information based upon the questionnaire in Group B. The questionnaire comprised of 10 multiple choice questions such as working fields of anesthesiologists, different anesthesia techniques and the patient's own fears related to anesthesia, etc. This questionnaire was prepared according to the study of Demir et al.[10] The patient's response against each question was recorded and any doubt about anesthesia and role of anesthesiologists were clarified. After completion of the PAC, the patients' levels of anxiety according to Beck Anxiety Inventory (BAI) scale[11] were evaluated by another anesthesiologist who was blinded to the study protocol. The BAI scale consists of 21 items, each describing a common symptom of anxiety like numbness or tingling, feeling hot, wobbliness in legs, unable to relax, fear of the worst happening, dizzy, heart pounding, unsteady, terrified, nervous, feeling of choking, hands trembling, shaky, fear of losing control, difficulty breathing, fear of dying, scared, indigestion, faint, face flushed, sweating. The respondent is asked to rate how much he or she has been bothered by each symptom on a 4-point scale ranging from 0 (Not at all) to 3 (Severely - I could barely stand it). The items are summed to obtain a total score that can range from 0 to 63. Where score 0–21= low anxiety, score 22–35 = moderate anxiety and score 36 and above = potentially concerning level of anxiety.[11] Observation at this time point was coded as reading 0. The patient's anxiety levels were further assessed at other time points namely, in preoperative waiting room (reading 1), just prior to administration of anesthesia on operating table (reading 2) and again four hours after operation in either recovery room or in ward (reading 3).

Questionnaire

1. Have you ever experienced anesthesia? *Y/N*
2. Why is the patient examined by an anesthesiologist?

   To give information about their illness/to give information about their allergies/to give information about their medicines/for pain relief/to receive information about operation and anesthetic procedure/all of them/I don't know.
3. Where does an anesthesiologist work?

   Clinic/operating room/intensive care unit/pain therapy centre/kidney stone breaking centre/ Extracorporeal shock wave lithotripsy/Endoscopy unit/ catheter angiography unit/ Radiology unit/I don't know.
4. Which anesthesia techniques do you know?

   General anesthesia/local anesthesia/Regional anesthesia/I don't know

5. What are the responsibilities of an anesthesiologist during an operation?

   Pain relief/Patient's consciousness and awareness under general anesthesia/Patient's blood pressure/ Patient's heart rate/Patient's oxygen level in blood/Replacement of fluid and blood loss/all of them/I don't know.

6. According to your information who applies anesthesia?

   Surgeon/Nurse/Anesthesiologist/Anesthesia Technician/I do not know.

7. What are your fears about general anesthesia?

   Feeling pain during operation/Nausea and vomiting/Unable to wake up after anesthesia/ Remaining unconscious/Sore throat/unable to sleep completely during operation/saying undesirable words unconsciously/Dying/I don't have any.

8. Do you know anything about regional anesthesia? *Yes/No*

9. According to your information who performs regional anesthesia?

   Anesthesiologist/Surgeon/Anesthesia technician/ Nurse/I don't know.

10. What are your fears about Regional anesthesia?

    Feeling pain during operation/Becoming paralyzed/Being aware of operation/I don't have any.

The anesthesiologist blinded to the study protocol, was involved with collection, compilation and analysis of data.

Statistical analysis

Data were plotted on Microsoft excel sheet. Numerical variables were compared between groups by Student's independent samples '*t*' test. Categorical variables were compared between groups by Fisher's exact probability test. Repeated measures ANOVA were employed for intra-group comparison of numerical variables. All analyses were 2-tailed. $p < 0.05$ was considered statistically significant.

Results

One thirty patients were recruited for the study of which 30 could not complete the trial. Those were excluded from our study and calculation was done with fifty patients (Group A, *n* - 50 and Group B, *n* -50) in Each Group. No significant differences were observed in demographic parameters between the Two Groups showing in (Table 1). But regarding the anxiety scale, patients of Group A were much more anxious than Group B in all the four readings. Even there was difference in baseline anxiety level (Group A 5.32 ± 3.97, Group B 3.74 ± 2.80, *p* – value = 0.0237), (Table 3). The difference of anxiety in rest of the readings are shown in Tables 3, 4 and 5 respectively.

The Intra Group and Inter Group variability of anxiety of both the groups showed that the highest level of anxiety occurred just prior to administration of anesthesia. But it is less in Group B (17.28 ± 4.69) compared to Group A (25.88 ± 6.82), *p* - value < 0.0001.). Anxiety level reduced in postoperative period and the degree of reduction of anxiety is more in Group B (11.08 ± 4.61) than in Group A (14.52 ± 5.69), *p* - value being 0.0013.

Table 1: Comparison of demographic characteristics and anesthesia techniques

	Group A (*n* - 50)	Group B (*n* - 50)	*p* - Value
Age (years)	38.84 ± 11.590	38.94 ± 10.958	0.697
M:F	24:26	27:23	0.550
GA: Regional	20:30	23:27	0.546
ASA Status	1.46 ± 0.645	1.52 ± 0.677	0.765

Table 2: Comparison of baseline anxiety between the groups (Reading 0)

Anxiety Score	Group A	Group B
Minimum score	0	0
Maximum score	16	10
Mean ± SD	5.32 ± 3.971	3.74 ± 2.805
	p - Value = 0.0237	

Table 3: Comparison of anxiety between groups (Reading 1)

Anxiety Score	Group A	Group B
Minimum score	4	1
Maximum score	34	22
Mean ± SD	18.1 ± 7.251	11.56 ± 4.903
	p - value < 0.0001	

Table 4: Comparison of anxiety between groups (Reading 2)

Anxiety Score	Group A	Group B
Minimum score	11	6
Maximum score	38	25
Mean ± SD	25.88 ± 6.820	17.28 ± 4.699
	p - value < 0.0001	

Table 5: Comparison of anxiety between groups (Reading 3)

Anxiety Score	Group A	Group B
Minimum score	3	2
Maximum score	24	23
Mean ± SD	14.52 ± 5.690	11.08 ± 4.610
	p - value = 0.0013	

Discussion

This study reveals that patients not receiving additional information about anesthesia through questionnaire were more anxious than those receiving additional information. Among the four readings such as in the PAC clinic, in the preoperative waiting room, just prior to administration of anesthesia in the operating room and four hours after surgery in either recovery room or in ward, the highest level of anxiety was found just prior to administration of anesthesia, i.e. in the operating room. Only check up and fitness declaration is not enough to allay anxiety in patients preparing for surgery. It is the anesthesiologist's responsibility to give detailed information and to be certain that the patient understands explanations about procedures and associated risks.[12]

Klopfenstein CE. et al. studied Two Groups of 20 patients who had anesthetic evaluation before hospitalization and after hospitalization, evening before the procedure and found that anesthetic evaluation as out patient basis prior to admission reduces preoperative anxiety compared to consultation on evening before procedure.[13] Kiyohara LY et al. studied the effect of surgery information on preoperative anxiety and concluded that knowledge of surgery reduces their state-anxiety level, regardless of knowlwdge of diagnosis.[4] Guo P et al. studied 153 patients and reported that an information leaflet and verbal advice reduced preoperative anxiety and depression among Chinese cardiac surgery patients significantly.[14]

In the study of Van Zuuren FJ et al. a single information brochure was reported to have reduced preprocedure anxiety on patients undergoing gastrointestinal endoscopy.[15] The above mentioned four studies more or less corroborated to the outcome of our study.

On the contrary Gillies MA et al. studied the attitude of patients to an information leaflet provided prior to admission and reported 35% of patients found it worried them. They warned against providing inappropriate form of information.[6] The merit of our study was higher patient satisfaction level in those who were given with prior information regarding anesthesia. Limitations of the study is, there are few demographic variables like literacy level, gender and occupation which should have been taken into account, were not included.

Conclusion

Patients' poor knowledge of anesthesia and surgery is an important health problem and a simple information leaflet along with preoperative check up can improve patients' knowledge and reduce anxiety levels significantly in the perioperative period.

Key Messages

Additional information regarding anesthetic procedure based on questionnaire during preanesthetic check up reduces perioperative anxiety in patients undergoing elective surgey.

References

1. Punjabi G, Khokari U, Prajapati G. Effect of Preanesthetic Assessment in outpatient consultation clinic in decreasing anxiety of patient undergoing elective surgery. IOSR-JDMS 2014;13(7):74–77.
2. Lew E, Pavlin DJ, Outpatient preanesthesia evaluation clinics, Singapore Med J 2004;45(11): 509–516.
3. Roizen MF. Preoperative evaluation. In: Miller RD, editor. Miller's Anesthesia, 5th edition. New York: Churchill-Livingstone; 2000. pp.824–83.
4. Kiyohara LY, Kayano LK, Oliveira LM, et al. Surgery information reduces anxiety in the preoperative period. Rev Hosp Clin Fac Med Sao Paulo 2004 Apr;59(2):51–56.
5. Moerman N, van Dam FS, Muller MJ, et al. The Amsterdam Preoperative Anxiety and Information Scale (APAIS). 1996 Mar;82(3):445–51.
6. Gillies MA, Baldwin FJ. Do patient information booklets increase perioperative anxiety? Eur J Anesthesiol 2001 Sep;18(9):620–22.
7. Sagun A, Birbicer H, Yapici G. Patients', who applied to the anesthesia clinic, perceptions and knowledge about anesthesia in Turkiye. Saudi J Anesth 2013;7:170–74.
8. Gercek E, Dal NA, Dag H, et al. The information requirements and self-perceptions of Turkish women undergoing hysterectomy. Pak J Med Sci 2016 Jan-Feb;32(1):165–70.
9. Uysal Aİ, Altıparmak B, Güner Ö. The effect of an informative leaflet on preoperative anxiety and patient's knowledge of anesthesia and anxiety. J Clin Anal Med 2017 April;1–5. DOI: 10.4328/JCAM.4875.
10. Demir A TS, Balaban F, Karadeniz Ü, et al. Anestezi uygulamaları ile ilgili olarak preanestezik değerlendirme sırasında hastalarda yapılan anket çalışması. Turk J Anesthesiol Reanim 2009;37(4):225–33.
11. Beck AT, Epstein N, Brown G, et al. An inventory for measuring clinical anxiety: Psychometric properties. Journal of Consulting and Clinical Psychology 1988 Dec;56(6):893–97.
12. Edward GM, vd Naald N, Oort FJ, et al. Information gain in patients using a multimedia website with tailored information on anesthesia. Br J Anaesth. 2011 Mar;106(3):319–24.
13. Klopfenstein CE, Forster A, Van Gessel E. Anesthetic assessment in an outpatient consultation clinic reduces preoperative anxiety. Can J Anesth 2000;47(6):511–15.
14. Guo P, East L, Arthur A. A preoperative education intervention to reduce anxiety and improve recovery among Chinese cardiac patients: A randomized controlled trial. Int J Nurs Stud. 2012 Feb;49(2):129–37.
15. Van Zuuren FJ, Grypdonck M, Crevits E, et al. The effect of an information brochure on patients undergoing gastrointestinal endoscopy: A randomized controlled study. Patient Educ Couns. 2006 Dec;64(1-3):173–82.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 33-40
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.5

A Study on the Effect of Lateral and Sitting Positions in Spinal Anesthesia for Cesarean Sections

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Abstract

Background: Spinal anesthesia has become the choice in obstetric patients awaiting cesarean section for its characteristics in providing rapid onset of anesthesia, allowing the mother to immediately interact with her baby. We were going to investigate the effect of the sitting and the lateral decubitus positions in the performance of spinal anesthesia for elective cesarean sections. The objective was to compare the onset time of anesthesia, the total requirement of ephedrine and hemodynamic changes in the Two Groups. *Materials and Methods:* After ethics committee approval, this comparative observational study was conducted in the Department of Anesthesiology at Sri Manakula Vinayagar Medical College and Hospital, Puducherry. A total of 72 parturients who met the inclusion criteria were enrolled into the study and were alternatively prepared for spinal anesthesia either in the sitting or in the left lateral position. The onset time taken for anesthesia to reach T4 level, the total requirement of ephedrine and hemodynamic parameters were recorded. *Results:* The Two Groups were comparable with regards to age, weight, gestational period and ASA grade. The mean and SD of onset time - Sensory Blockade in minute after Injection in sitting position group was 3.833 ± 2.049. Similarly it was 4.75 ± 2.089 for the lateral position group. The mean and SD of Ephedrine requirement in milligram in sitting position group is 8.5 ± 6.313. Similarly it was 7.5 ± 6.934 for the lateral position group. There were no significant difference between the groups. *Conclusion:* Our results showed no significant differences between the sitting and left lateral positions regarding the time taken to achieve T4 dermatomal level of anesthesia, the incidence of hypotension depicted by the total requirement of injection ephedrine and overall hemodynamic variables. We concluded that the sitting or the left lateral decubitus position in the performance of spinal anesthesia for cesarean section does not influence on the onset time of anesthesia and incidence of hypotension.

Keywords: Cesarean section; Spinal anesthesia; Sitting position; Lateral position.

How to cite this article:

D. Dinesh Babu, Vidjai Vikram S, S. Bala Subramanian, et al. A Study on the Effect of Lateral and Sitting Positions in Spinal Anesthesia for Cesarean Sections. Indian J Anesth Analg. 2020;7(1 Part -I):33–40.

Introduction

Subarachnoid block has become the choice of anesthesia in obstetric patients for its characteristics in providing very rapid onset of anesthesia, allowing the mother to immediately interact with her baby. And in obstetrics, it is also safer than general anesthesia. So, the complications following

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Received on 08.10.2019, **Accepted on** 13.11.2019

neuraxial anesthesia has become of great interest either to the anesthesiologist and to the patient.[1,2]

Spinal and epidural block may lead to complications in the acute form such as of pain on injection, high or total spinal anesthesia and hypotension or postoperative complications as backache, Post Dural Puncture Headache, urine retention, meningitis and nerve injury.[3] Many studies were done to detect and analyze incidence, pathophysiology and effective measures to minimize or prevent these complications.

The majority of the physiologic effects of spinal anesthesia and essentially all the cardiovascular effects, are mediated by preganglionic sympathetic blockade. Sympathetic nervous system fibers are more peripherally located in the nerve roots than are the sensory fibers. The level of sympathetic fiber blockade is produced at two or more dermatomes higher than the sensory blockade. These facts are clinically confirmed by the loss of cold sensation and an increase in skin temperature (thermography).[4]

Maternal hypotension is the most frequent complication of spinal anesthesia for cesarean section. Most clinicians define hypotension as a maternal systolic blood pressure below 70–80% of baseline recordings and/or an absolute value of < 90–100 mm Hg. Hypotension is often associated with nausea and vomiting and, if severe, ends in serious risks to mother (unconsciousness, pulmonary aspiration) and baby (hypoxia, acidosis and neurological injury).[5,6]

Cesarean sections are either performed under combined spinal-epidural, spinal anesthesia alone, or under general anesthesia. Indeed in our institute, they are done usually under spinal anesthesia alone. The effects of spinal anesthesia are sympathetic blockade to leading hypotension and bradycardia depending on the spread of the anesthetic agent in the subarachnoid space, followed by sensory and motor blockade.[7] The gravid uterus compressing the inferior vena cava, leads to low venous return so reduced cardiac output and finally accounts to further hypotension. So, hypotension is an important factor to consider during cesarean sections performed under spinal anesthesia.[8]

Spinal anesthesia is achieved either in sitting or lateral decubitus positions according to the patient's condition and the anesthetist's preference. The two positions are routinely used for administration of spinal anesthesia and there is no side effects specific to the positions. However, researchers have been giving conflicting opinions about the incidence of hypotension and the need of vasopressors after the execution of spinal anesthesia in different positions. While some stated high incidence of hypotension and the need of vasopressors in the lateral position, others concluded the same in the sitting position.[9]

Therefore in this study, we are going to investigate the effect of the sitting and the lateral decubitus positions in the performance of spinal anesthesia for elective cesarean sections, in our institute. The study will seek to a better performance of the spinal anesthesia technique, optimum operative conditions and high standard perioperative care of the patient.

Materials and Methods

An observational comparative study was carried out at Sri Manakula Vinayagar Medical College and Hospital, Puducherry during the period of November 2015–August 2017 as per Good Clinical Practice (GCP) guidelines of WHO. Sample size (n = 72) was calculated using the statistical software Open Epi version 3.03, considering the mean difference of 1.7 min, 95% of confidential interval and 80% power. Parturients undergoing elective cesarean section with prior written, informed valid consent were allocated alternatively into Sitting group with 6 Parturients and Left Lateral group with 36 Parturients.

Inclusion criteria

Women posted for elective cesarean section, Gestational age more than 37 weeks, Aged 18 to 35 years, having weight between 50 and 80 kg.

Exclusion criteria

Patients of ASA status III and IV, Patients with severe cardiopulmonary diseases, Uncontrolled diabetes mellitus, Thyroid disorders, Neurologic, psychiatric, neuromuscular diseases, Renal or hepatic disease, Other contraindications of spinal anesthesia.

Procedure

Tablet ranitidine 150 mg will be given orally the night before surgery and Injection ranitidine 50 mg IM; Injection metoclopromide 10 mg IM in the morning as premedication before shifting to operation theater. In the preoperative room, intravenous access was secured with 18-G cannula on the non-dominant upper limb and intravenous crystalloid fluid (Ringer's lactate) was started. Preloading of 10 mL/kg was done.[7] Baseline parameters such as Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP) and oxygen saturation (SpO_2) were observed and noted. All patients received the routine method of spinal anesthesia in our institute: Midline approach in the L3-L4 inter-space, with 10 mg (2 mL) hyperbaric 0.5% bupivacaine, using a 25 gauge Quincke spinal needle. Sitting Group received spinal anesthesia in the sitting position and the Lateral group received it in the left lateral decubitus position. Women in the sitting group were placed with their feet resting on a stool. Patients in the lateral group were positioned in the full left lateral position with a pillow supporting the head. Immediately after the procedure, the patient was immediately positioned in the supine position and a wedge was placed under the right side of the hip. Anesthesia was considered successful when fine touch sensation (cotton wool test) was lost at the dermatomal level of T4 bilaterally. If after 20 minutes, surgical anesthesia was not achieved, the surgery was performed under general anesthesia and patient excluded from the study. Heart rate of less than 50 bpm was managed with injection atropine 0.6 mg bolus intravenously, hypotension considered as mean arterial pressure less than 60 mm Hg, was managed with injection ephedrine 6 mg bolus intravenously.

The following parameters were studied:

Onset time of sensory blockade–sensory blockade upto T4 bilaterally (level of nipples) was achieved by checking the level every 2 minutes, by cotton wool test, scored according to a two point scale. Score 1: present, Score 0: absent.

Hemodynamic parameters: Systolic blood pressure (mm Hg), Diastolic blood pressure (mm Hg), Mean arterial pressure (mm Hg), Heart rate (bpm) and saturation of oxygen (%) were recorded 10 minutes before the procedure and then every 2 minutes until baby delivery and thereafter, every 5 minutes until end of surgery.

Results

In our study a total of 72 patients were enrolled and finally analyzed. Each group consisted of 36 patients who were comparable in age, weight, gestational age, ASA status, obstetric code, sensory blockade and hemodynamic parameters. All the values were expressed as Mean ± Standard deviation, except ASA grading and obstetric code of the patients. All the patients in both the groups belong to ASA Grade II and majority of the patients, sitting (24) & lateral (27) out of 36 were multi in their obstetric code distribution.

The two groups showed similar onset time of anesthesia and the same incidence of hypotension. There were no statistically significant differences in patient demographics with respect to age, weight and the operative time. Similarly, there were no statistically significant clinical differences regarding the obstetric code and gestational age of patients. All patients had a sensory block reaching at least T4, but the onset time to reach the dermatomal level was shorter for the sitting group (3.83 ± 2.05 min) in contrast to the lateral group (4.75 ± 2.09 min). Nevertheless, these values did not establish statistical significance (Table 1).

Table 1: Demographic data of the patients

Parameters	Sitting Group	Left Lateral Group
Age (years)	25.333 ± 2.229	26.083 ± 3.263
Weight (Kg)	66.755 ± 7.186	69.444 ± 8.265
Gestational Age (weeks)	38.194 ± 0.709	38.222 ± 0.831
ASA status (Grade II)	36	36
Obstetric code (primi / multi)	12/24	9/27
Sensory blockade (minutes)	3.833 ± 2.049	4.75 ± 2.089
Requirement of Ephedrine (mg)	8.5 ± 6.313	7.5 ± 6.934

Baseline Systolic blood pressures were almost similar in both groups (121.97 ± 12.86 mm Hg *versus* 119.47 ± 10.94 mm Hg in the sitting and lateral group, respectively. The incidence of hypotension, represented by the requirement of injection ephedrine intraoperatively, was apparently higher in the sitting group (8.5 ± 6.31 mg) than the lateral group (7.5 ± 6.93 mg), but this difference did not achieve statistical significance. There were no significant difference observed between the Systolic BP, Diastolic BP, Mean arterial pressure (Tables 2–3) and Heart rate (Figs. 1–2) between the two study groups.

Table 2: Systolic and Diastolic blood pressure at various time intervals in both the study groups

Sl No	Group	Time in Minutes	Systolic Blood Pressure		Diastoli Blood Pressure	
			Sitting	Left Lateral	Sitting	Left Lateral
1	Before Delivery	Baseline	121.972 + 12.859	119.472 + 10.943	76.028 + 7.264	75.639 + 10.023
		2	105.528 + 12.934	111.5 + 13.179	65.472 + 11.58	66.278 + 13.073
		4	102.889 + 16.381	103.75 + 16.013	61.083 + 13.174	61.25 + 14.393
		6	98.222 + 18.32	100 + 15.853	55.444 + 14.709	55.167 + 13.704
		8	109.69 + 13.779	105.933 + 14.851	69.517 + 9.753	63.4 + 14.952
		10	111.8 + 11.1	112 + 14.549	72.333 + 7.933	69.65 + 15.291
		12	113.778 + 8.511	118.444 + 9.926	75.444 + 5.876	77.444 + 13.343
		14	122.75 + 12.5	129 + 0	77 + 6	80 + 0
2	After Delivery	5	113.056 + 7.856	116.694 + 8.847	69.667 + 8.291	69.833 + 9.388
		10	114.917 + 6.72	114.611 + 9.241	70.583 + 9.281	67.639 + 9.418
		15	115.556 + 11.244	116.083 + 12.258	72.25 + 11.315	67.167 + 12.963
		20	117.139 + 8.513	112.611 + 10.53	71.278 + 10.366	65.333 + 12.24
		25	116.556 + 6.199	105.972 + 23.777	72.5 + 7.173	65.944 + 9.639
		30	117.528 + 9.173	111.222 + 7.838	76.528 + 8.477	68.75 + 10.349
		35	114.885 + 18.098	112.414 + 9.187	74.5 + 14.295	67.69 + 11.641
		40	106.333 + 28.525	111.174 + 11.42	71.083 + 20.215	67.522 + 12.915
		45	117 + 6.141	112 + 11.328	75.5 + 8.384	64.526 + 13.176
		50	113 + 4.243	111.75 + 11.72	70 + 5.657	65.125 + 13.185
		55	–	99 + 0	–	49 + 0
		60	–	–	–	–

Table 3: Mean Arterial blood pressure at various time intervals in both the study groups

Sl No	Group	Time in Minutes	Mean Arterial Blood Pressure	
			Sitting	Left Lateral
1	Before Delivery	Baseline	89.75 + 7.145	89.028 + 8.45
		2	76.389 + 12.07	79.917 + 12.374
		4	74.194 + 13.386	76.778 + 17.003
		6	69.333 + 16.357	72.972 + 16.841
		8	80.552 + 11.073	77.667 + 12.962
		10	85.095 + 7.911	83.05 + 13.926
		12	87.111 + 5.6	90.444 + 11.759
		14	89.75 + 6.5	93 + 0
2	After Delivery	5	82.028 + 10.525	116.694 + 8.847
		10	82.278 + 11.252	114.611 + 9.241
		15	86.583 + 9.998	116.083 + 12.258
		20	86.028 + 10.429	112.611 + 10.53
		25	86.611 + 7.624	105.972 + 23.777
		30	89.056 + 9.384	111.222 + 7.838
		35	88.154 + 16.151	112.414 + 9.187
		40	83.5 + 23.57	111.174 + 11.42
		45	89.375 + 7.425	112 + 11.328
		50	84.5 + 4.95	111.75 + 11.72
		55	–	99 + 0
		60	–	–

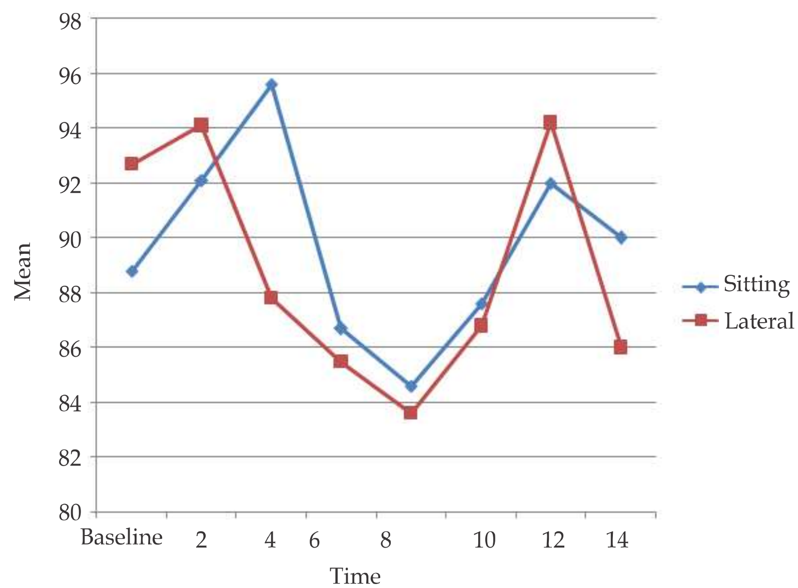

Fig. 1: Mean Heart Rate of the patients before delivery.

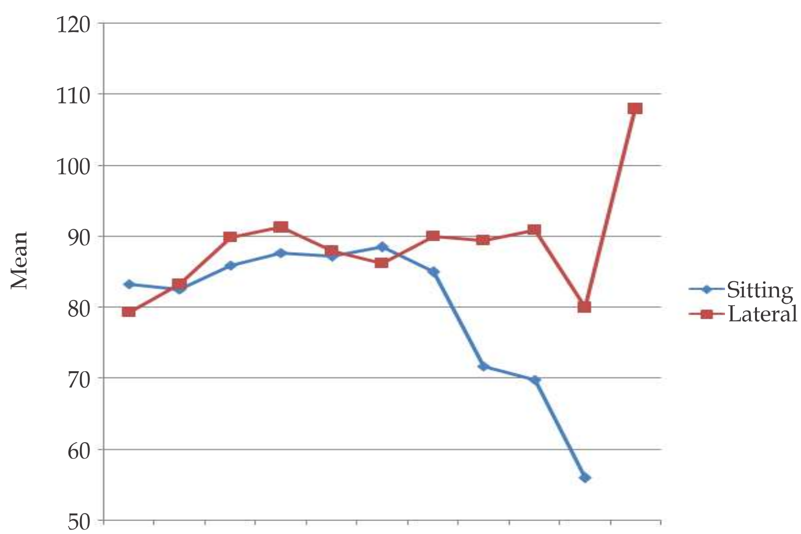

Fig. 2: Mean Heart Rate of the patients after delivery.

Discussion

Studies comparing the left and right lateral position were unable to find a final preference. The first investigators evaluating the sitting *versus* the lateral position during induction of spinal anesthesia placed patients back in the supine position immediately after a single-dose intrathecal injection.[10,11] Because of the extremely short interval between injection and resuming the supine position, it is not surprising that the block characteristics did not differ significantly.

Similarly, Inglis A et al. Found that onset time to T4 was the same in both groups.[11] This result correlates with the onset time to T4 in our study which in turn reflected the identical requirement of ephedrine in the two groups.

Similar to our study Ortiz-Gomez JR et al.[12] evaluated the effect of different positions for the induction of spinal anesthesia for cesarean section on the hemodynamic changes and side effects, their findings are in accordance with our results regarding same incidence of hypotension as well as requirement of ephedrine and phenylephrine perioperatively. They clearly posited that the position did not influence the arterial hypotension and need of vasopressors.

Chevuri SB et al. found same hemodynamic stability in both the groups studied on induction of spinal anesthesia for cesarean section and an easier placement of the spinal needle in the sitting group[9] and these results are consistent with our results as seen in the sitting position *versus* in the left lateral position which showed statistically similar hemodynamic variations throughout the anesthetic procedure and perioperative period.

Kharge ND et al. made a comparison of the lateral and sitting positions for performing combined spinal anesthesia for elective cesarean section[13] and their results are in accordance with our results regarding absence of influence of the induction position on hemodynamic parameters and anesthetic block characteristics.

Despite the authors with their respective studies mentioned above show similar results to the outcome of our study, there are other studies presenting antithetical conclusions. So, here we stand in the need of elaborating the theory behind the intrathecal drug spread which is responsible for differential aspects of hemodynamic variations as well as sensory and motor blockade characteristics.

As the local anesthetic solution is injected, it will spread initially by displacement of CSF and as a result of any currents created within the CSF. The next stage, which may well be the most crucial, is spread due to the interplay between the densities of both CSF and local anesthetic solution under the influence of gravity. Gravity will be 'applied' through patient position (supine, sitting, etc.) and, in any horizontal position, by the influence of the curves of the vertebral canal. Many factors are said to affect these mechanisms,[14] with some having greater impact than others.

The key ones are the physical characteristics of CSF and the solution injected, the clinical technique used and the patient's general features. These interrelate in complex ways and it is important that comparative studies are designed in such a way that two groups of patients receive a technique that differs in one factor only. That is what we intended to perform in our study by comparing two different induction postures of spinal anesthesia.

CSF is an isotonic, aqueous medium with a constitution similar to interstitial fluid. The terms density, specific gravity and baricity define its physical characteristics, but are often used loosely and interchangeably, causing confusion. Precise definitions are as follows: The factors affecting intrathecal drug spread are mutilple. The baricity of the drug solution injected plays an important role. Hyperbaric solutions are more predictable, with greater spread in the direction of gravity[15] and less interpatient variability.[16] In contrast, most plain solutions exhibit greater variability in effect and are less predictable.[16–18]

The volume and concentration of the local anesthetic solution has an appreciable impact on the intrathecal spread. Both CSF and local anesthetics exhibit a curvilinear decrease in density with increasing temperature. CSF is at core body temperature whereas local anesthetic solutions are administered at room temperature. There will be some local decrease in CSF temperature immediately after injection,[19,20] but the core temperature is restored within 2 min, so solution density should be reported at body temperature.

This factor of viscosity of the injected solution has received little attention, but addition of glucose to an aqueous solution changes viscosity as well as density. Studies of a wide range of local anesthetic drugs indicate that intrathecal spread is the same, no matter which one is used, as long as the other factors are controlled.[21,22]

The patient position during and after induction is a very important clinical factor determining the drug spread. It is widely believed that injection of a hyperbaric solution in a seated patient will result in a more restricted block. However, a number of studies have shown that the block, while initially more restricted, eventually extends to a level equivalent to that which would have been obtained had the patient been placed supine immediately after injection.[23–25]

Other clinical factors are the level of injection, the needle type and alignment, intrathecal catheters, fluid currents, epidural injection and finally patient characteristics such as age, weight, height, sex, intraabdominal pressure, spinal anatomy, lumbosacral CSF volume and pregnancy.[26]

Nevertheless, it should be known that obstetric patients awaiting cesarean section under spinal anesthesia are destined to receive smaller doses of spinal local anesthetic than nonpregnant patients due to their smaller CSF volume, the cephalad movement of hyperbaric local anesthetic in the supine pregnant patient and greater sensitivity of nerve fibers to the local anesthetic during pregnancy.[8]

Conclusion

We conclude that the sitting position or the left lateral decubitus position in the performance of spinal anesthesia for cesarean section does not influence either the onset time of anesthesia or the incidence of hypotension.

It was found that the sitting position facilitated the procedure of spinal anesthesia on the part of the anesthesiologist. The lateral position was found to be more comfortable for patients. Hence, the choice of posture for the performance of spinal anesthesia for elective cesarean section could be granted to the anesthetist's preference or the patient's option.

References

1. Ranasinghe JS, Steadman J, Toyama T, et al. Combined spinal epidural anesthesia is better than spinal or epidural alone for Cesarean delivery. BJA Br J Anesth 2003 Aug 1;91(2):299–300.
2. Shaikh JM, Memon A, Memon MA, et al. Postdural puncture headache after spinal anesthesia for cesarean section: A comparison of 25 g Quincke, 27 g Quincke and 27 g Whitacre spinal needles. J Ayub Med Coll Abbottabad JAMC. 2008 Sep;20(3):10–3.
3. RKS MD, RDM MD. Basics of Anesthesia. 4 edition. New York: Churchill Livingstone; 2000.p.528.
4. Halaszynski TM, Hartmannsgruber MWB. Anatomy and physiology of spinal and epidural anesthesia. J Crit Care 1998 Mar 1;17(1):24–37.
5. Emmett RS, Cyna AM, Andrew M, et al. Techniques for preventing hypotension during spinal anesthesia for cesarean section. Cochrane Database Syst Rev. 2001;(3):CD002251.
6. Coppejans HC, Hendrickx E, Goossens J, et al. The sitting *versus* right lateral position during combined spinal-epidural anesthesia for cesarean delivery: block characteristics and severity of hypotension. Anesth Analg 2006 Jan;102(1):243–47.
7. Ronald D. Miller, Lars I. Eriksson, Lee A Fleisher et al. Miller's Anesthesia, 2-Volume Set, 8 edition. Philadelphia, PA: Saunders; 2014.p.3576.
8. David H. Chestnut, Cynthia A Wong, Lawrence C Tsen, et al. Chestnut's Obstetric Anesthesia: Principles and Practice: Expert Consult - Online and Print, 5th edition. Philadelphia, PA: Saunders; 2014.p.1328.
9. Babu Chevuri S, Subba Rao J, Chandergutti V, et al. A Comparative study of effects of sitting and lateral positions on quality of block during induction of Spinal Anesthesia in Patients undergoing Cesarean Section, 2015;(3):93.
10. Bembridge M, Macdonald R, Lyons G. Spinal anesthesia with hyperbaric lignocaine for elective cesarean section. Anesthesia 1986 Sep;41(9):906–909.
11. Inglis A, Daniel M, McGrady E. Maternal position during induction of spinal anesthesia for cesarean section. A comparison of right lateral and sitting positions. Anesthesia. 1995 Apr;50(4):363–65.
12. Ortiz-Gómez J, Javier Palacio-Abizanda F, Morillas-Ramirez F, et al. Effect of position on maternal hemodynamics during elective cesarean delivery under spinal anesthesia. Anestezjol Ratow Anesthesiol Rescue Med 2015 Feb 16;22–29.
13. Kharge ND, Mali A, Gujjar P. Comparison of hemodynamic effects of lateral and sitting positions during induction of spinal anesthesia for elective cesarean section. Int J Res Med Sci 2017 Feb 20;5(3):851–56.
14. Greene NM. Distribution of local anesthetic solutions within the subarachnoid space. Anesth Analg 1985 Jul;64(7):715–30.
15. Tetzlaff JE, O'Hara J, Bell G, et al. Influence of baricity on the outcome of spinal anesthesia with bupivacaine for lumbar spine surgery. Reg Anesth 1995 Dec;20(6): 533–37.
16. Brown DT, Wildsmith JA, Covino BG, et al. Effect of baricity on spinal anesthesia with amethocaine. Br J Anesth 1980 Jun;52(6):589–96.
17. Stienstra R, van Poorten JF. Plain or hyperbaric bupivacaine for spinal anesthesia. Anesth Analg 1987 Feb;66(2):171–76.
18. Vercauteren MP, Coppejans HC, Hoffmann VL, et al. Small-dose hyperbaric *versus* plain bupivacaine during spinal anesthesia for cesarean section. Anesth Analg 1998 May;86(5):989–93.
19. Davis H, King WR. Densities of common spinal anesthetic solutions at body temperature. Anesthesiology 1952 Mar;13(2):184–88.
20. Ernst EA. *In vitro* changes of osmolality and density of spinal anesthetic solutions. Anesthesiology 1968 Feb;29(1):104–109.
21. Alley EA, Kopacz DJ, McDonald SB, et al. Hyperbaric spinal levobupivacaine:A comparison to racemic bupivacaine in volunteers. Anesth Analg 2002 Jan;94(1):188–93
22. Glaser C, Marhofer P, Zimpfer G, et al. Levobupivacaine *versus* racemic bupivacaine for spinal anesthesia. Anesth Analg 2002 Jan;94(1):194–98.
23. Mitchell RW, Bowler GM, Scott DB, et al. Effects of posture and baricity on spinal anesthesia with 0.5% bupivacaine 5 ml. A double-blind study. Br J Anesth 1988 Aug;61(2):139–43.

24. Povey HM, Jacobsen J, Westergaard-Nielsen J. Subarachnoid analgesia with hyperbaric 0.5% bupivacaine: Effect of a 60 min period of sitting. Acta Anesthesiol Scand 1989 May;33(4):295–97.

25. Veering BT, Immink-Speet TT, Burm AG, et al. Spinal anesthesia with 0.5% hyperbaric bupivacaine in elderly patients: Effects of duration spent in the sitting position. Br J Anesth 2001 Nov;87(5):738–42.

26. Hocking G, Wildsmith J a W. Intrathecal drug spread. BJA Br J Anesth 2004 Oct 1;93(4):568–78.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 41-45
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.6

A Comparative Study of 0.1% Ropivacaine with Fentanyl and 0.1% Bupivacaine with Fentanyl for Epidural Labor Analgesia

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Abstract

Objective: A randomized, double blind study to compare the analgesic efficacy, maternal and neonatal outcome of ropivacaine 0.1% and bupivacaine 0.1% both with fentanyl for labor epidural analgesia. *Methods:* Sixty term parturient of ASA Grade I & II with singleton pregnancy in vertex presentation and adequate cervical dilatation requesting painless labor were divided into two groups of 30 each. Group BF parturient received bupivacaine 0.1% with fentanyl 20 μg and Group RF parturient received ropivacaine 0.1% with fentanyl 20 μg as intermittent bolus doses epidurally. After written informed consent, epidural catheter was placed in L3-4/4-5 space followed by study drug administration and top up doses intermittently. Maternal hemodynamics, Visual Analogue Score (VAS), Foetal heart rate, sensory analgesia, motor block, neonatal APGAR score at 1 and 5 min and labor characteristics were recorded. *Results:* The groups were comparable in demographic and obstetric characteristics. Two patients in Group BF developed motor block of Grade 1 while none of the patient in Group RF had motor block. VAS score and quality of analgesia was comparable in both the groups. Onset of sensory block was longer in Group RF. No significant difference was found in both groups with regards to hemodynamics. *Conclusion:* We conclude that ropivacaine 0.1% with fentanyl produced excellent analgesia comparable to bupivacaine 0.1% with fentanyl and can be used safely for labor epidural analgesia.

Keywords: Epidural; Labor analgesia; Ropivacaine; Bupivacaine.

How to cite this article:

Firoz Satpathy, Archana Tripathi, Mukesh Somvanshi, et al. A Comparative Study of 0.1% Ropivacaine with Fentanyl and 0.1% Bupivacaine with Fentanyl for Epidural Labor Analgesia. Indian J Anesth Analg. 2020;7(1 Part -I):41–45.

Introduction

Epidural labor analgesia is the widely used labor analgesic technique and become a 'Gold Standard' in obstetrics.[1] Because of excellent sensory block provided during labor and delivery, bupivacaine is the most commonly used local anesthetic agent for epidural labor analgesia. But bupivacaine is prone to cause motor blockade development, cardiovascular and central nervous system toxicity. However, risk of these side effects reported to be reduced by using smaller concentrations of bupivacaine.[2]

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Received on 08.10.2019, **Accepted on** 13.11.2019

Ropivacaine is another amide local anesthetic agent and its chemical structure is related to bupivacaine. In various studies ropivacaine has been found to produce less motor blockade, thereby reduces the incidence of instrumental deliveries[3,4] with more vaginal deliveries. Furthermore, ropivacaine has been found to produce less incidence of cardiovascular and central nervous system toxicity as compared to bupivacaine.[5–9] Because of these advantages, ropivacaine is gaining popularity in epidural labor analgesia. Although epidurally administered local anesthetic agent alone provides good analgesia during labor, the addition of fentanyl further improves the quality of analgesia.[1]

Looking to the above facts, we had compared the analgesic efficacy, maternal and neonatal outcome of equal concentrations of ropivacaine and bupivacaine both with fentanyl for epidural labor analgesia with intermittent top up doses.

Materials and Methods

After approval of institutional ethical committee and written informed consent, the present study was conducted on 60 term parturient of ASA Grade I & II with singleton pregnancies in vertex presentation and cervical dilatation 3–6 cm, requesting painless labor. All parturient in this study were subjected to detailed preblock evaluation. Parturient who were morbidly obese, having bleeding disorders, history of allergy to local anaesthetics, hypovolemia, thrombocytopenia, local sepsis, antepartum hemorrhage, severe eclampsia and cephalopelvic disproportion and cervical dilatation > 6 cm were excluded from the study. After confirming the active first stage of labor and cervical dilatation 3–6 cms, parturient were randomly divided by sealed envelope method into two groups of thirty parturient each. In Group BF, parturient received 0.1% bupivacaine 10 ml with fentanyl 20 μg and in Group RF parturient received 0.1% ropivacaine 10 ml with fentanyl 20 μg. An independent anesthesiologist prepared the study drugs in coded syringes. Neither the parturient nor the anesthesiologist, who was recording the parameters, knew what drug was being used in given patient.

An intravenous line with 18 G cannula was established and at least 500 ml of Ringer's lactate solution was given. Standard monitoring were applied using multiparameter monitor for heart rate, Noninvasive arterial Blood Pressure (NIBP), pulse oximetry (SpO_2) and ECG. Parturient were placed in the left lateral position and under strict aseptic precautions, midlumbar epidural space L3-L4/ L4-L5 was identified by using a loss of resistance to saline technique with a 16 G Touhy needle. A 20 G single orifice epidural catheter was inserted and the parturient were turned to supine position. To exclude intravascular or intrathecal placement, a test dose of 2 ml of 2% lignocaine with adrenaline was used. First dose of 10 ml study drug bolus was injected according to group allocated. Following 10 minutes parturient were asked to lift legs straight, without flexing knees. When parturient were able to lift legs easily without bending knees, they were asked to take a trial walk. All parturient were given the following instructions:

1. Pass urine every hour
2. Do not walk barefooted

The onset time for analgesia was recorded. Pain intensity was noted using 0–10 cm Visual Analog Scale (VAS), where 0 = no pain and 10 = worst pain. A VAS score of < 3 was considered to be satisfactory. Both sensory and motor blockade were assessed by alteration in temperature sensation to ice and modified Bromage score, shown in Table 1 respectively. Measurements were continued until return of normal sensation and motor function (Bromage score 0). If analgesia was inadequate (VAS > 3), top up dose was repeated up to maximum of 10 ml at a time. Before giving each top up, aspiration was done. In the second stage of labor, top up was given in the sitting position. The study was ended at the time of vaginal delivery, assisted or not, or when the decision was made to perform a cesarean delivery.

Table 1: Modified Bromage score

Grade	
0	Normal movement in hip, knee and foot, No motor block
1	Weakness in hip muscles, Inability to raise extended leg
2	Weakness in knee muscles, Inability to flex knee
3	Motor block of hip, knee, Inability to flex ankle joint

Parturient were assessed every 5 min for half an hour and thereafter, every 30 min for maternal heart rate, NIBP, SpO_2, VAS score and degree of motor block. Subsequent top up doses were given after assessing pain relief (when VAS reached > 3). Following every top up dose, parturient were monitored carefully for 10 minutes to detect any weakness or inadequate analgesia. In addition sensory and motor block levels, duration of first and second stage of labor, mode of delivery (normal, forceps assisted or cesarean), total amount of rescue doses, foetal heart rate, neonatal APGAR score at 1 and 5 min, complications and side effects were studied. Hypotension was defined as systolic blood pressure < 90 mm Hg and was treated by positioning the patient on her left side and if necessary, administering inj ephedrine. After delivery epidural catheter was removed. Parturient were interviewed a day after delivery for satisfaction level and quality of analgesia on four point scale (Excellent, Good, Fair and Poor). Statistical analysis of data was done using Student's '*t*' test and Chi-square test. A p - value ≤ 0.05 was considered as statistically significant.

Results

Demographic and obstetric characteristics were comparable in both the groups (Table 2). Onset of analgesia was significantly longer in group RF as compared to Group BF ($p < 0.05$), (Table 1). The VAS Score was comparable in both the groups for each time interval at which it was assessed (Fig. 1). None of the parturient in Group RF developed motor block while two parturient in Group BF developed motor block (Grade 1) and the difference was statistically insignificant, (Table 3).

Table 2: Demographic and obstetric characteristics

Variables	Group BF	Group RF
Age (yr)	23 ± 3.15	24.26 ± 3.62
Weight (kg)	67.73 ± 3.87	69.76 ± 4.53
Height (cm)	158.96 ± 2.72	158.20 ± 2.36
Duration of labor (min)		
First stage	226 ± 42.18	242 ± 43.39
Second stage	45 ± 14.57	47 ± 14.51
Onset of analgesia (min)	17.93 ± 1.55	23.53 ± 1.67*
Level of sensory block	T8 (T7-T9)	T8 (T7-T9)
Mode of delivery, no (%)		
Vaginal delivery	28 (93.33)	29 (96.66)
Forceps delivery	1 (3.33)	1 (3.33)
Cesarian delivery	1 (3.33)	0
Total dose of		
Study drug (mg)	21.17 ± 2.15	24.67 ± 2.6
Fentanyl (μg)	42.33 ± 4.3	49.33 ± 5.21
APGAR Score at		
1 min	8.06 ± 0.69	8.33 ± 1.06
5 min	10 ± 0	9.83 ± 0.74
Patient satisfaction, no (%)		
Excellent	24 (80)	25 (83.33)
Good	5 (16.66)	5 (16.66)
Fair	1 (3.33)	0
Poor	0	0

Values are expressed as mean ± SD, no (Percentage) and median (range) *$p < 0.05$ Group RF *vs* BF

Table 3: Motor block

Bromage score Grade	Group BF no (%)	Group RF no (%)
0	28 (96.66)	30 (100)
1	2 (6.66)	0
2	0	0
3	0	0

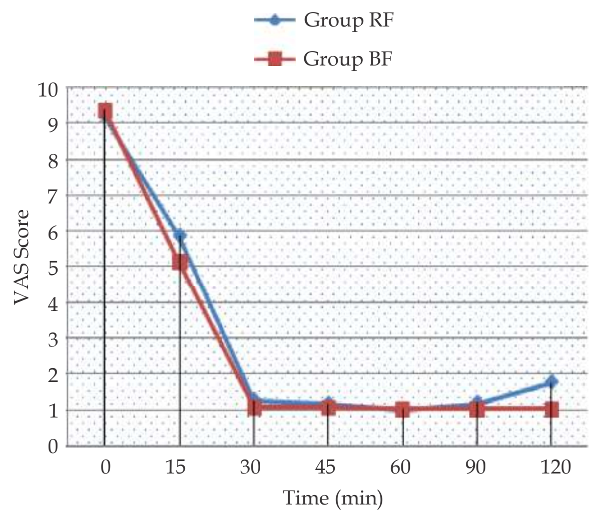

Fig. 1: VAS Scores.

The duration of Stage I and II of labor was comparable in both the groups (Table 1). One parturient in Group RF had forceps delivery. None of the parturient in Group RF required cesarean section. While in Group BF, one delivery was assisted by outlet forceps and one parturient required cesarean section due to prolong second stage of labor, (Table 1).

There was no significant difference between two groups with regard to total dose of study drug administered during first and second stage of labor, (Table 1). Maternal heart rate and arterial blood pressure were comparable in both the groups. No difference was found in neonatal APGAR score at 1 and 5 minutes after delivery in both the groups, (Table 1). None of the parturient in either group had hypotension or bradycardia. Two parturient in each group developed vomiting. One parturient in Group RF had pruritis. However, incidence of side effects in both the groups showed no statistical difference. One day after delivery, all parturient in both groups satisfied and judged the analgesia to be fair to excellent. None of the parturient judged the analgesia to be poor.

Discussion

We had compared 0.1% bupivacaine and 0.1% ropivacaine, both with fentanyl 20 micrograms for epidural labor analgesia with intermittent topup doses. In our study, we used fentanyl with local anesthetic agent to improve the analgesic efficacy of local anesthetic agent without increasing the motor block, as opiods are reported to reduce the effective concentration of local anesthetic agent in a dose dependent manner.[1]

Ropivacaine is a local anesthetic agent with high differential sensory: motor block ratio and reported to cause less motor blockade compared with similar concentration of bupivacaine. However, in our study motor blockade produced by ropivacaine was comparable to bupivacaine. Paddalwar S et al.[1] compared the efficacy of ropivacaine 0.125% and bupivacaine 0.125%, both with fentanyl in epidural labor analgesia and did not find any significant difference in motor block between two groups. In the present study, we did not find any difference in the sensory levels, motor block, VAS score, analgesic potency, duration of labor, mode of delivery and side effects among both groups. Equal concentration of bupivacaine and ropivacaine for epidural labor analgesia has been compared in various studies. Some studies compared 0.25% bupivacaine and 0.25% ropivacaine and did not observe any significant difference either in quality of analgesia or in motor block.[4,10–13] While comparing 0.125% bupivacaine and 0.125% ropivacaine for epidural labor analgesia, Owen et al.[14] failed to observe any significant clinical difference between two drugs. Similar results were also reported by Gautier P et al.[15] In another study, Meister et al.[16] used 0.125% bupivacaine and 0.125% ropivacaine with fentanyl 2 mcg/kg for epidural labor analgesia and they found that both drugs were equipotent. Their results are consistent with our observations although mode of drug delivery was different. Comparable VAS scores, observed in both groups in our study, suggests that there was no difference in the potency of study drug solution, which was also noted in other studies.[13,17–18]

Epidurally administered local anesthetics may cause motor block that may lead to increased rate of instrumental delivery or cesarean section as motor block developed after epidural block may decrease maternal motility, reduces maternal efforts during second stage of labor and may also cause inadequate rotation of presenting foetal part due to the relaxation of pelvic floor muscles.[19–20] Local anesthetic induced motor block can be reduced by decreasing the concentration of agent and also by adding the opiods like fentanyl as demonstrated in Comparative Obstetric Mobile Epidural Trial.[3] This trial shows a lesser incidence of forceps delivery with bupivacaine 0.1% plus fentanyl 0.0002%. In our study also, the incidence of forceps delivery was much less as we used local anesthetic agent in reduced concentration. Although there was no statistically significant difference in degree of motor block, there were a higher number of women who had spontaneous delivery in ropivacaine group.

As shown in Table 2, total drug requirement for labor epidural analgesia (bupivacaine or ropivacaine plus fentanyl) was comparable in both groups. Similar results were reported by Writer et al.[4] and Campbell et al.[18] Traditionally, neonatal condition has been assessed with the APGAR scoring system. The mean APGAR score of neonates was within normal range and comparable in both groups. The results of our study are in accordance with Chopra et al.[21], who also found normal neonatal APGAR score in bupivacaine and ropivacaine groups.

Conclusion

We conclude that 0.1% ropivacaine with fentanyl produced excellent labor analgesia without detriment to foetus, comparable to 0.1% bupivacaine with fentanyl. However, ropivacaine may offer some advantage over bupivacaine with regard to less tendency to cause cardiovascular and CNS toxicity and can be used safely in parturient requesting painless labor.

References

1. Paddalwar S, Nagrala M, Chandak A, et al. A randomized double blind controlled study comparing bupivacine 0.125% and ropivacaine 0.125% both with fentanyl 2 ug/ml, for labor epidural analgesia. Ind J Pain 2013;27:147–53.
2. Fernandez-Guisasola J, Serrano ML, Cobo B, et al. A comparison of 0.625% bupivacaine with fentanyl and 0.1% roivacaine with fentanyl for continuous epidural labor analgesia. Anesth Analg 2001;92:1261–265.
3. Comparative Obstetric Mobile Epidural Trial (COMET) Study Group UK. Effect of low-dose mobile *versus* traditional epidural techniques on mode of delivery: A randomized controlled trial. Lancet. 2001 Jul 7;358(9275):19–23.
4. Writer WD, Stienstra R, Eddleston JM, et al. Neonatal outcome and mode of delivery after epidural analgesia for labor with ropivacaine and bupivacaine: A prospective meta-analysis. Br J Anaesth. 1998 Nov;81(5):713–17.
5. Scott DB, Lee A, Fagan D, et al. Acute toxicity of

ropivacaine compared with that of bupivacaine. Anesth Analg. 1989 Nov;69(5):563-69.

6. Knudsen K, Beckman Suurküla M, Blomberg S, Sjövall J, Edvardsson N. Central nervous and cardiovascular effects of i.v. infusions of ropivacaine, bupivacaine and placebo in volunteers. Br J Anaesth. 1997;78(5):507–514.
7. Bader AM, Datta S, Flanagan H, Covino BG. Comparison of bupivacaine- and ropivacaine-induced conduction blockade in the isolated rabbit vagus nerve. Anesth Analg. 1989;68(6):724–727.
8. Feldman HS, Corino BG. Comparative motor blocking effects of bupivacaine and ropivacaine, a new amino amide local anesthetic in the rat and dog. Anesth Analg 1988;67:1047–1052.
9. Zaric D, Nydahl PA, Philipson L, Samuelsson L, Heierson A, Axelsson K. The effect of continuous lumbar epidural infusion of ropivacaine (0.1%, 0.2%, and 0.3%) and 0.25% bupivacaine on sensory and motor block in volunteers: a double-blind study. Reg Anesth. 1996;21(1):14–25.
10. Muir HA, Writer D, Douglas J, Weeks S, Gambling D, Macarthur A. Double-blind comparison of epidural ropivacaine 0.25% and bupivacaine 0.25%, for the relief of childbirth pain. Can J Anaesth. 1997;44(6):599–604.
11. Owen MD, Thomas JA, Smith T, et al. Ropivacaine 0.075% and bupivacaine 0.075% with fentanyl 2µg/ml for labor epidural analgesia. Anesth Analg 2002;94(1):179–83.
12. McCrae AF, Jozwiak H, McClure JH. Comparison of ropivacaine and bupivacaine in extradural analgesia for relief of pain in labor. Br J Anaesth. 1995 Mar;74(3):261–65.
13. Stienstra R, Jonker T, Bourdrez P, et al. Ropivacaine 0.25% *versus* bupivacaine 0.25% for continuous epidural analgesia in labor: A double-blind comparison. Anesth Analg. 1995 Feb;80(2):285–89.
14. Owen MD, D'Angelo R, Gerancher JC, et al. 0.125% ropivacaine is similar to 0.125% bupivacaine for labor analgesia using patient-controlled epidural infusion. Anesth Analg. 1998;86(3):527–531.
15. Gautier P, De Kock M, Van Steenberge A. A double blind comparison of 0.125% ropivacaine with sufentanil and 0.125% bupivacaine with sufentanil for epidural labor analgesia. Anesthesiology 1999 Mar;90(3):772–78.
16. Meister GC, D'Angelo R, Owen M, et al. A Comparison of epidural analgesia with 0.125% ropivacaine with fentanyl *versus* 0.125% bupivacaine with fentanyl during labor. Anesth Analg. 2000 Mar;90(3):632–37.
17. Campbell DC, Zwack RM, Crone LA, Yip RW. Ambulatory labor epidural analgesia: bupivacaine versus ropivacaine. Anesth Analg. 2000;90(6):1384–1389..
18. Beilin Y, Guinn NR, Bernstein HH, Zahn J, Hossain S, Bodian CA. Local anesthetics and mode of delivery: bupivacaine versus ropivacaine versus levobupivacaine. Anesth Analg. 2007;105(3):756–763.
19. Stoddart AP, Nicholas KE, Popham PA. Low dose Bupivacaine/fentanyl epidural infusions in labor and mode of delivery. Anesthesia 1994;49:1087–1090.
20. Goodfellow CF, Hull MG, Swaad DF, et al. Oxytocin deficiency at delivery with epidural analgesia. Br J Obstet Gynaecol. 1983 Mar;90(3):214–19.
21. Chopra I and Hussain I. Comparision of 0.1% Ropivacaine–Fentanyl with 0.1% Bupivacine–Fentanyl Epidurally for Labor Analgesia. Advances in Anesthesiology 2014; Article I D 237034, Pages 4.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 46-52
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.7

Comparison of Dexmedetomidine as an Adjuvant to Levobupivacaine Versus Levobupivacaine (Plain) in Supraclavicular Brachial Plexus Block: A Clinical Study

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Abstract

Context: Adjuncts to local anesthetics for brachial plexus block may enhance the quality and duration of analgesia. Dexmedetomidine, an α-2 adrenergic agonist is known to produce anti-nociception and enhance the effect of local anesthetics in various peripheral nerve blocks. *Aims:* To evaluate the effects of the addition of Dexmedetomidine (1μ/Kg) to Levobupivacaine (0.5%) for supraclavicular brachial plexus block in upper limb surgeries. *Study Design:* A prospective, randomized double-blinded study. *Methods:* The patients included in the study were randomized into two equal groups. Patients in Group L (n = 30) were administered 29 ml of 0.5% of Levobupivacaine and 1ml of normal saline and Group LD (n = 30) were given 29 ml of 0.5% Levobupivacaine with Dexmedetomidine (1μ/Kg). The onset and duration of sensory and motor block, Hemodynamic variables, Visual Analog Score (VAS), Patient Satisfaction Score (PSS) were recorded for 24 hours postoperatively. *Statistical analysis used:* Chi-square test and Student's unpaired *t*-test. *Results:* Onset of sensory block and motor block in Group LD was (5.30 ± 1.02 min) and (7.87 ± 1.33 min), whereas in Group L (10.83 ± 1.05 min) and (13.87 ± 1.33 min) respectively. Duration of sensory block and motor block in Group LD was (11.42 ± 0.6 hrs) and (10.10 ± 0.68 hrs), whereas in Group L (8.01 ± 0.64 hrs) and (6.69 ± 0.65 hrs) respectively. Mean Pulse rate and mean Blood Pressure was lower in Group LD ($p < 0.05$). VAS was lower in Group LD ($p < 0.05$). PSS was higher in Group LD ($p > 0.05$). *Conclusion:* Dexmedetomidine (1μ/kg) in combination with Levobupivacaine (0.5%) has early onset of sensory and motor block and prolonged duration of sensory and motor block with minimal hemodynamic variables.

Keywords: Supraclavicular brachial plexus block; Dexmedetomidine; Levobupivacaine.

How to cite this article:

Hassaan Muhammed, Shishir KR. Comparison of Dexmedetomidine as an Adjuvant to Levobupivacaine Versus Levobupivacaine (Plain) in Supraclavicular Brachial Plexus Block: A Clinical Study. Indian J Anesth Analg. 2020;7(1 Part -I):46–52.

Introduction

Brachial plexus block provides a useful alternative to general anesthesia for upper limb surgeries by achieving ideal operating conditions with muscular relaxation maintain stable hemodynamics intraoperatively and sympathetic block. It is gaining popularity over general anesthesia due to its effectiveness in terms of cost, performance and good postoperative profile. Brachial plexus block can be performed using several approaches and its preference is determined by innervations of the

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Received on 21.10.2019, **Accepted on** 28.11.2019

surgical site, risk of regional anesthesia-related complications as well as preference and experience of an anesthesiologist. A supraclavicular approach to brachial plexus can provide excellent anesthesia. Compared to the axillary approach it provides an additional advantage of blockage at a level where brachial plexus are tightly grouped which facilitates a single-point injection using less local anesthetic and is believed to result in very rapid onset gives the most effective block for upper extremity.[1]

Levobupivacaine a long-acting amide local anesthetic with good clinical profile, lesser neurotoxicity, and cardiotoxicity compared to bupivacaine is being favored Local anesthesia for regional anesthesia.[2]

Various adjuvants such as midazolam, dexamethasone, clonidine, opioids, have been employed to local anesthetics in search of ideal agents to prolong analgesia with variable results and advantages.[3] Recently, α_2 agonists, dexmedetomidine is eight times more selective towards α_2 adrenergic receptors than Clonidine.[4] It has shown to prolong the duration of block and postoperative analgesia when added to local anesthetics in various regional blocks.

Materials and Methods

A double-blinded randomized prospective study was carried out on 60 patients undergoing upper limb surgeries aged between 18–55 years under the paresthesia technique supraclavicular block in Medical College Hospital after obtaining ethical committee approval. The objective was to compare the effects of the addition of Dexmedetomidine (1μ/Kg) to Levobupivacaine (0.5%) for supraclavicular brachial plexus block in upper limb surgeries. The effects were studied in terms of onset and duration of sensory and motor block; hemodynamic variables; visual analog score (VAS); Patient Satisfaction Score (PSS).

Patients between the age group of 18–55 years weighing 55–82 kgs with ASA1 and ASA2 undergoing elective upper limb surgeries were included in the study. Patients with known allergy to local anesthetic drugs, anticoagulant medications, those with neuromuscular disorders, bleeding disorders, hepatic/renal/respiratory/cardiac diseases, pregnant individuals were excluded from the study. Patients having an infection at the site of block, those who refused to give consent for regional technique, ASA3, ASA4 were also excluded.

A total of 60 patients were randomized into two groups of 30 each by using "slips in the box technique" and assigned as Group LD and Group L. Patients in Group LD received 29 ml of mixture of Levobupivacaine (0.5%) and dexmedetomidine (1μ/Kg), Group L received 29 ml of Levobupivacaine (0.5%) and 1 ml normal saline.

The preanesthetic check-up was done for all patients which included basic demographic characteristics, history, general physical and systemic examination. The relevant investigations are done and patients were kept nil per oral 8 hours before surgery. Patients were shifted to the operating room with written informed consent for regional anesthesia and confirming nil per oral status. IV cannula was secured in the non-operating arm of the patient and ringer lactate started half an hour before surgery. In the operating room, patients baseline pulse rate, blood pressure, SpO_2, heart rate were noted. Heart rate, mean blood pressure and oxygen saturation were recorded after the block every 5 min, 10 min, 15 min, 30 min, 45 min, 60 min, 90 min, 2 hrs, 6 hrs, 12 hrs, 24 hrs. Adverse events such as bradycardia, hypotension, hypoxia, perioperative nausea, and vomiting were recorded.

The patient placed in the supine position with the head slightly turned to the opposite side from the site to be blocked, arm abducted to form an approximately 90° angle at the elbow joint. With aseptic precautions in supraclavicular area, at a point 1.5 to 2 cm posterior and cephalad to midpoint of clavicle, subclavian artery pulsations felt and skin wheal was raised with local anesthetic, next a 22 gauge 5 cm needle mounted on 10 ml syringe passed through same point parallel to head and neck, in a caudad, slightly medial and posterior direction until paresthesia is elicited in the arm or hand. If the rib is encountered needle moved over the first rib until paresthesia is elicited. After eliciting paresthesia and negative aspiration of blood local anesthetic medication is injected.

The sensory block was assessed each minute using a 23 G hypodermic needle by pinprick method along the C4-T2 dermatomes till complete sensory blockade. Sensory onset was considered when there was a dull sensation to pinprick along the above-said dermatomes. A complete sensory block was considered when there was a complete loss of sensation to pinprick. Sensory block graded as Grade 0 (sharp pain felt), Grade 1 (analgesia, dull sensation felt), Grade 2 (Anesthesia, no sensation felt). Assessment of motor block was carried out at each minute till complete motor block after drug injection.

The onset of motor block was considered when there was a Grade 1 motor block. Peak motor blockwas considered when there was a Grade 2 motor block. Motor block was determined according to the Bromage scale for upper extremities on a three-point scale. Motor block graded as, Grade 0 (normal motor function; full flexion and extension of the elbow, wrist, fingers), Grade 1 (decreased motor strength with the ability to move fingers only), Grade 2 (complete motor block with the inability to move fingers).

The pain was assessed by Visual Analog Scale (VAS) i.e., 0-no pain; 2-annoying (mild pain); 4-uncomfortable (moderate pain); 6-dreadful (severe pain); 8-horrible (very severe pain); 10-agonising (worst possible pain).

The duration of sensory block was considered from the onset of sensory block (VAS Score 0) until the patient feels pinprick (VAS Score 2). The duration of motor block was considered from the onset of motor block and complete recovery of motor power

Statistical analysis was done using a student's unpaired *t*-test for quantitative data, Chi-square test for qualitative data. A *p* - value of less than 0.05 was considered statistically significant.

Results

The study was carried out in Sixty ASA 1 and ASA 2 of either sex aged between 18 and 55 years, posted for upper limb surgeries under supraclavicular brachial plexus block by paresthesia technique to evaluate efficacy of Dexmedetomidine (1 μg/kg) as adjuvant to Levobupivacaine (0.5%) in comparison with plain Levobupivacaine (0.5%). The minimum age of patients selected for study was 18 years and the maximum age was 55 years. The mean age of patients in Group L was 33.87 ± 9.86 and in group LD was 33.67 ± 11.59 years. Age incidences between the two groups were comparable. There were 24 patients in Group L and 23 patients in Group LD belonging to ASA Grade 1, and 6 patients in Group L and 7 patients in Group LD belonging to ASA Grade 2. There was no statistically significant difference between the two groups with respect to age distribution and ASA grading ($p > 0.5\%$).

The mean time for onset of sensory and motor block was 5.30 ± 1.02 min and 7.87 ± 1.33 min respectively in Group LD when compared to 10.83 ± 1.05 and 13.87 ± 1.33 min respectively in Group L. Thus, the onset of both sensory and motor block was significantly faster in Group LD than with Group L ($p < 0.001$), (Table 1).

Table 1: Time of onset of sensory and motor block (min)

Study Group	Onset Time; Mean ± SD		*p* - Value	Significance
	Sensory	Motor		
L	10.83 ± 1.05	13.87 ± 1.33	$p < 0.001$	HS
LD	5.30 ± 1.02	7.87 ± 1.33	$p < 0.001$	HS

Statistical analysis: Student's Unpaired *t*-test; HS - Highly Significant; SD - Standard Deviation.

The mean duration of sensory block and motor block was 11.42 ± 0.6 hours and 10.10 ± 0.68 hours respectively in Group LD when compared to 8.01 ± 0.64 hours and 6.69 ± 0.65 hours respectively in Group L. Thus, the duration of sensory block and motor block was significantly longer in Group LD compared to Group L ($p < 0.0001$), (Table 2).

Table 2: Duration of sensory and motor block (hrs)

Study Group	Duration of Block; Mean ± SD		*p* - Value	Significance
	Sensory	Motor		
L	8.01 ± 0.64	6.69 ± 0.65	$p < 0.001$	HS
LD	11.42 ± 0.6	10.10 ± 0.68	$p < 0.001$	HS

Statistical analysis: Student's Unpaired *t*-test; HS - Highly Significant; SD - Standard Deviation.

The mean pulse rate in Group L ranged from 72.36 ± 5.95 to 75.41 ± 4.80 beats/min and in Group LD ranged from 61.36 ± 4.77 to 73.03 ± 5.34 beats/min which showed a significant statistical difference between two Groups ($p < 0.05$) from 10 mins after the block that extended till 2 hours of the block. Bradycardia (HR < 60) was observed in 4 patients in Group LD with none requiring treatment, (Fig. 1).

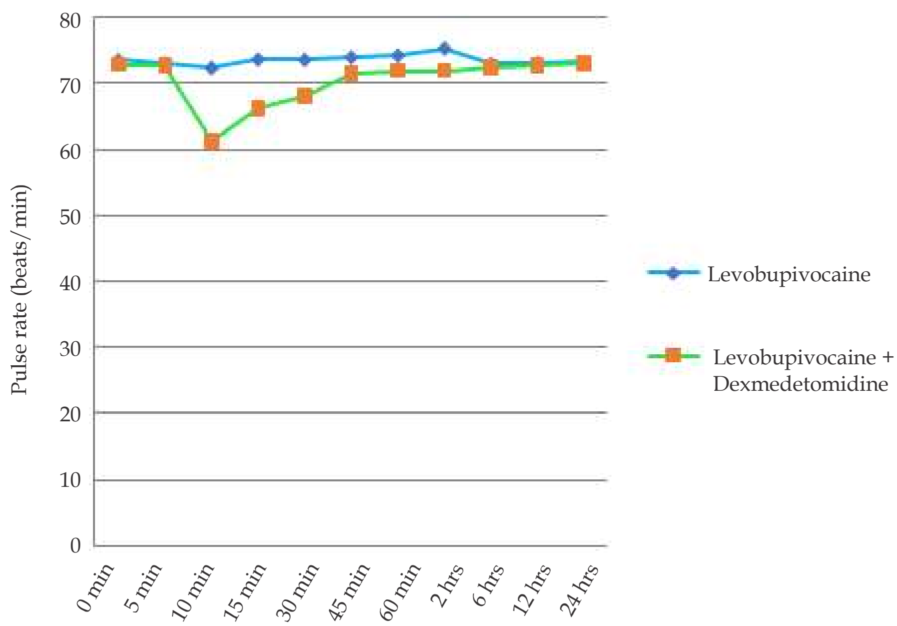

Fig. 1: Pulse rate (beats/min)

The mean systolic blood pressure in Group L ranged from 115.93 ± 8.00 to 117.87 ± 9.39 mm of Hg and in Group LD ranged from 102.27 ± 9.37 to 116.93 ± 8.08 mm of Hg which showed a significant statistical difference between two groups ($p < 0.05$), (Fig. 2).

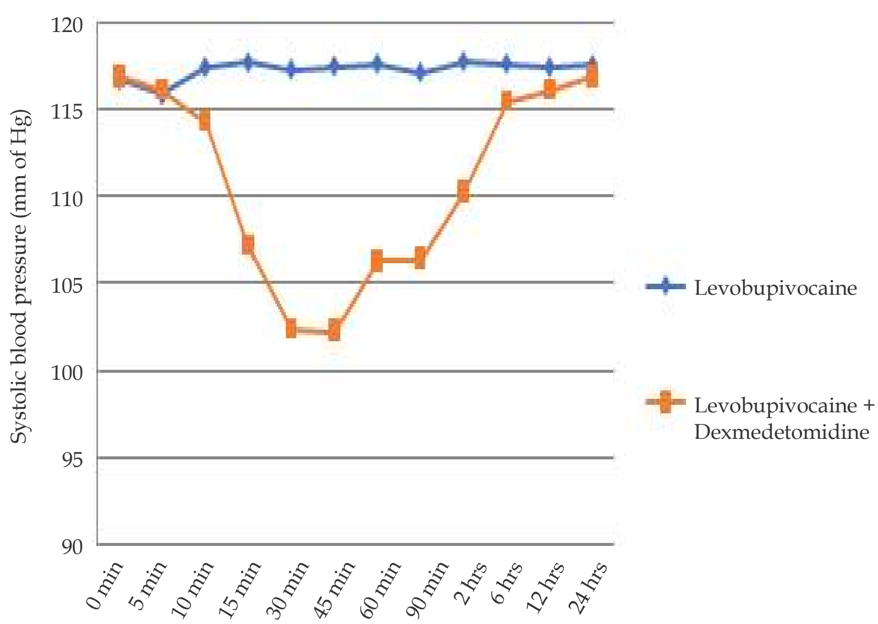

Fig. 2: Systolic blood pressure (mm of Hg)

The mean diastolic blood pressure in Group L ranged from 74.00 ± 6.17 to 74.60 ± 6.08 mm of Hg and in Group LD ranged from 62.26 ± 5.82 to 74.60 ± 5.10 mm of Hg which showed a significant statistical difference between two Groups ($p < 0.05$), (Fig. 3).

VAS SS Scores were less in Group LD at each interval and statistically significant ($p < 0.05$) at 1 hr, 2 hr, 24 hrs, (Table 3). In Group LD 69% of patients had a PSS of 5, whereas Group L 63% had a PSS of 5. Though more number of patients in Group LD had a greater PSS, it was statistically insignificant ($p > 0.05$), (Table 4).

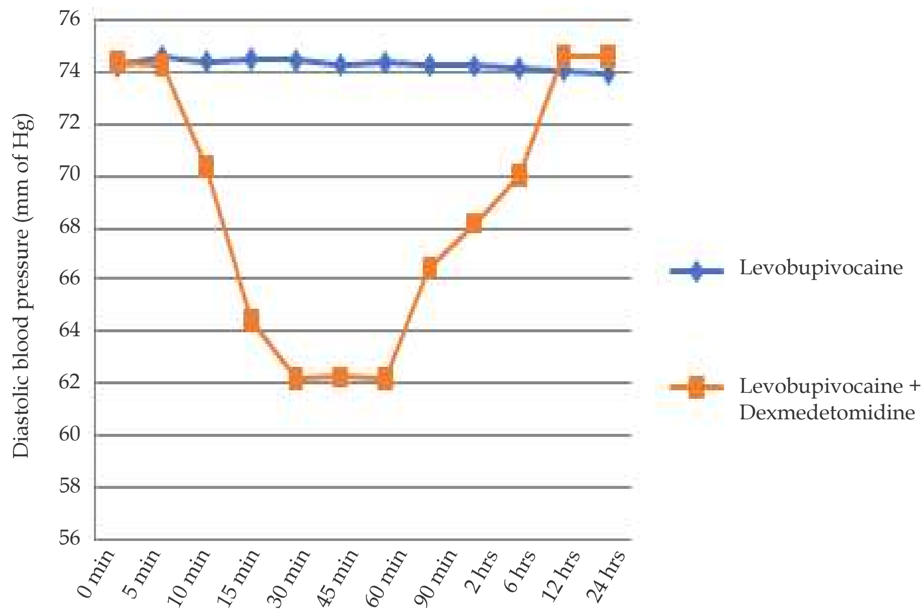

Fig. 3: Diastolic blood pressure (mm of Hg)

Table 3: Visual Analog Scale (VAS) score

Time (hrs)	Mean VAS ± SD		*p* - Value
	Group L	Group LD	
1 hour	2 ± 0.53	1.57 ± 0.57	0.006
2 hours	2.07 ± 0.58	1.63 ± 0.60	0.003
6 hours	2.23 ± 0.77	1.8 ± 0.66	0.11
12 hours	2.53 ± 1.33	2 ± 1.08	0.05
24 hours	3.63 ± 1.49	2.8 ± 1.18	0.01

Statistical analysis: Student's Unpaired *t*-test; SD - Standard Deviation.

Table 4: Patient Satisfaction Score (PSS).

PSS	Group L (n = 30)	Group LD (n = 30)	*p* - value
4	9 (27%)	7 (21%)	0.559
5	21 (63%)	23 (69%)	

Statistical analysis: Chi-square test; $p > 0.05$ not significant.

Discussion

Local anesthetic agent selection, dose, concentration, volume and physical modification can affect the onset, spread, quality and duration of anesthesia. Considering greater toxicity potential and cardiovascular effects of the racemic mixture, levobupivacaine seems a good indication for brachial block.[5] Various adjuvants such as opioids, α_2 agonists, steroids were added to local anesthetics to improve the block quality. Clonidine, the prototype of α_2 agonists which was synthesized in early 1970 when added to local anesthetics improved the block quality. Dexmedetomidine a new α_2 agonist that received USFDA approval in 1999 was reported to be safe and effective in peripheral nerve blocks when compared to clonidine.[6] The brachial plexus block is one of the commonly used peripheral nerve block techniques. The supraclavicular approach provides a successful blockade as it causes the homogenous spread of anesthetic agents throughout the plexus.

In our study, we observed that the onset of sensory and motor block was earlier in patients who received a combination of Dexmedetomidine and Levobupivacaine. Which was similar to the study conducted by Grewal[7] and FW Abdallah who demonstrated that this could be due to a local direct action of dexmedetomidine and its synergistic action with local anesthetics.

In our study, duration of sensory and motor block was prolonged when dexmedetomidine was added to levobupivacaine. The studies of Kosugi et al. on the sciatic nerve of the frog demonstrated that high concentrations of dexmedetomidine inhibit Compound Action Potential (CAP) without α^2 adrenoceptor activation. Dexmedetomidine reduced the peak amplitude of CAPs reversibly and in a concentration-dependent manner. This action was not antagonized by α_2 adrenoceptor antagonists such as yohimbine and atipamezole. The studies of Brumett et al. showed that dexmedetomidine enhances the duration of bupivacaine anesthesia and analgesia of sciatic nerve block in rats without any damage to the nerve. Histopathological evaluation of nerve axon and myelin were normal in control and dexmedetomidine + bupivacaine Groups at 24 hours and 14 days. Atul Dixit et al.[8] evaluated the effect of adding Dexmedetomidine (1 mcg/kg) to 0.5% Levobupivacaine for supraclavicular brachial plexus block in upper limb surgeries. They concluded that the addition of dexmedetomidine to Levobupivacaine for supraclavicular brachial plexus block shortens sensory, motor block onset time and prolongs their duration. Kaygusuz et al. evaluated the effect of adding dexmedetomidine (1 μg/mg) to 0.5% Levobupivacaine for axillary brachial plexus block and observed significantly decreased sensory block onset time, increase in sensory and motor block duration. Our results are comparable with the above studies, hence, we conclude that the addition of dexmedetomidine to Levobupivacaine has a faster onset and longer duration of sensory and motor block compared to Levobupivacaine alone.

In our study mean, pulse ratein Group LD was lower compared to Group L from 10 mins of initiation of blockup to 2 hours of administrating the block which was statistically significant. However, four patients who received Dexmedetomidine in our study group developed clinically significant bradycardia, with none of them requiring treatment. Aliye Esmaoglu et al. evaluated the effect of adding dexmedetomidine (100 μg) to 0.5% Levobupivacaine for axillary brachial plexus block. They observed that Heart rate levels in Group LD were significantly lower than those in Group L. In Group LD bradycardia was observed in 7 patients who required treatment although no bradycardia in Group L. Sarita S Swamy et al.[9] and Haramritpal Kaur et al.[10] evaluated effect of adding dexmedetomidine (1 mcg/kg) to Levobupivacaine for supraclavicular brachial plexus block and they observed that statistically significant difference in Heart rate between two groups from 10 minutes after block. Bradycardia (HR < 60) was observed in two patients of the Dexmedetomidine Group. Our results with respect to changes in Heart rate in both groups were similar to findings of Sarita S Swamy et al. and Haramritpal Kaur et al. The incidence of bradycardia was lesser in our study than that of Aliye Esmaoglu et al. as their study used a higher concentration of dexmedetomidine (100 mcg).

In our study mean, blood pressure in Group LD was lower compared to Group L for 20 minutes of initiation of block time up to 2 hours of administrating block, which were statistically significant. However, none of the patients in Group LD developed significant hypotension. Postsynaptic activation of α_2 adrenoceptors in the central nervous system inhibits sympathetic activity and thus decreases blood pressure and Heart rate. Our results with respect to changes in mean systolic and diastolic blood pressure were similar to findings of Atul Dixit et al, and Sarita S Swamy et al. The mean heart rate and blood pressure were lower in Group LD but it did not warrant any medical intervention. Hence, we conclude that hemodynamic parameters were relatively stable in our patients of both groups throughout the intraoperative and postoperative period.

In our study, we found that the VAS scores were less on the dexmedetomidine group at each interval compared to the levobupivacaine (plain) group, and none of the patients required opioids. The duration of analgesia was statistically longer in the dexmedetomidine group. In our study, PSS was higher in the dexmedetomidine group compared with the control group which was not statistically significant. VAS and PSS scores of our study correlated with observations of Haramritpal Kaur et al.[10]

Conclusion

From our study, we conclude that the addition of dexmedetomidine (1 μ/kg) to 0.5% levobupivacaine 29 ml in supraclavicular brachial plexus block significantly decreases onset time of sensory and motor block, prolongs the duration of sensory and motor block. It is a good alternative to other additives due to its profound anesthetic and analgesic properties combined with minimal side effects. Dexmedetomidine will expand the scope and improve the reliability and efficacy of regional anesthesia.

Acknowledgement: None.

Conflict of interest: Nil.

Abbreviations

ASA - American Society of Anesthesiologists

Inj - Injection

mg - milligram

cm - centimeter

ml - milliliter

μg - microgram

G - Gauge

HR - Heart Rate

HS - Highly Significant

VAS - Visual Analog Scale

mm of Hg - millimeter of mercury

Min - Minutes

Hrs - Hours

PSS - Patient Satisfaction Score

SD - Standard Deviation

References

1. Chun Woo Yang, Hee Uk Kwon, Choon Kyu Cho, et al. A comparison of infraclavicular and supraclavicular approaches to the brachial plexus using neurostimulation. Korean J Anesthesiol 2010;58(3):260–66.
2. Foster RH, Markham A. Levobupivacaine: A review of its pharmacology and use as local anesthetic. Drugs. 2000 Mar;59(3):551–79.
3. Murphy DB, Mccartney CJ, Chan VW. Novel analgesic adjuncts for brachial plexus block: A systemic review. Anesth Analg. 2000 May;90(5):1122–128.
4. Raimo V, Juha M, Veijo S, et al. Characterization of selectivity, specificity and potency of dexmedetomidine as α_2 adrenoceptor agonist. Eur J Pharmacol. 1988 May 20;150(1-2):9–14.
5. Ohmura S, Kawada M, Ohta T. Systemic toxicity and resuscitation in bupivacaine, levobupivacaine or ropivacaine infused rats. Anesth Analg. 2001 Sep;93(3):743–48.
6. Kataria AP, Jarewal V, Singh G, et al. Comparison of Dexmedetomidine and clonidine as an adjuvant to Levobupivacaine in supraclavicular brachial plexus block. Int J Med Res Rev 2017;5(04):399–404.
7. Grewal A. Dexmedetomidine: New avenues, Journal of anesthesiology clinical pharmacology 2011;27(3):297–301.
8. Atul Dixit, Shakti Singhal, Charu Neema, et al. An evaluation of the addition of Dexmedetomidine to Levobupivacaine for supraclavicular brachial plexus block in upper limb orthopedic surgeries. Asian Pacific J Health Sci 2015;2(2):148–53.
9. Sarita S Swami, Varshali M Keniya, Sushma D Ladi, et al. Comparison of dexmedetomidine and clonidine as an adjuvant to local anesthesia in supraclavicular brachial plexus block: A randomized double-blind prospective study. Indian Journal of Anesthesia 2012 May–Jun; 56(3):243–49.
10. Haramritpal Kaur, Gurpreet Singh, Sunita Rani, et al. Effect of dexmedetomidine as an adjuvant to levobupivacaine for supraclavicular brachial plexus block. Journal of Anesthesiology and Clinical Pharmacology 2015 Jul–Sep;31(3):333–38.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 53-57
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.8

Incidence of Sore Throat with Endotracheal Intubation Using Mcintosh Blade Versus Video Laryngoscope

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Abstract

Introduction: Postoperative Sore Throat (POST) is an undesirable common complaint following general anesthesia. The objective of this study was to compare the incidence of sore throat and hoarseness of voice following endotracheal intubation using McIntosh laryngoscope or king vision video laryngoscope. *Methodology:* It was a prospective randomized control trial in which 200 ASA 1 and 2 patients, scheduled for elective surgery requiring endotracheal intubation were randomly allocated to VCL (Video laryngoscope) and MCL (McIntosh laryngoscope) Group. Endotracheal intubation was performed using McIntosh Laryngoscope in MCL Group and kingvision video laryngoscope in VCL Group. POST and hoarseness was assessed at 6, 12, 24 and 48 hours. Incidence of sore throat, hoarseness of voice, laryngoscopy time and ease of insertion was noted and compared. *Results:* There was no significant difference in the incidence of sore throat and hoarseness of voice between the Two Groups . However, duration of laryngoscopy was longer in VCL Group. *Conclusion:* Incidence of Postoperative sore throat and hoarseness of voice does not alter when Kingvision video laryngoscope as compared to McIntosh laryngoscope is used for endotracheal intubation, however the time taken for laryngoscopy and intubation is longer with kingvision video laryngoscope

Keyword: Hoarseness; Sore throat; Laryngoscope; Peroperative complications; Endotracheal intubation.

How to cite this article:
Nischala Dixit, Karthik Jain, Robin George, et al. Incidence of Sore Throat with Endotracheal Intubation Using Mcintosh Blade Versus Video Laryngoscope. Indian J Anesth Analg. 2020;7(1 Part -I):53–57.

Introduction

Postoperative sore throat and hoarseness of voice are major airway complications after general anesthesia with Endotracheal Intubation (ETI) with overall incidence varying from 14.4% to 50%.[1] Although postoperative sore throat usually resolves within a week, it is considered as one of the leading patient complaints after tracheal intubation. Factors responsible for these are pharyngotracheal tissue damage secondary to laryngoscopy and intubation, use of lubricants, longer duration of intubation etc. Different laryngoscopic blades used can have varied extent of tissue damage and hence the incidence of these can be different. Several identified independent risk factors for POST include larger ETT size, age, female sex, prolonged intubation, and trauma during airway manipulation.[2] There is a strong evidence that female patients are at

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Received on 28.10.2019, **Accepted on** 28.11.2019

1.5 fold risk for POST than men.[3] Although video laryngoscope is better for difficult intubation in terms of success rate than McIntosh laryngoscope, the airway trauma because of the same needs a better assessment. We plan to assess the incidence of postoperative sore throat and hoarseness of voice comparing both devices McIntosh and king vision video laryngoscope used for endotracheal intubation. The primary objective of our study was to assess the incidence of sore throat and hoarseness of voice following endotracheal intubation using king vision video laryngoscope in comparison with McIntosh laryngoscope. Secondary objective was to assess the laryngoscopy time and ease of insertion of the endotracheal tube.

Materials and Methods

Based on the power analysis of the study done by Atabak Najafi et al.[4] considering proportion of 0.28 in Group MCL and 0.54 in Group VDL, with 5% level of significance and 80% power, the sample size required was 82. However, we decided to conduct the study with 100 subjects in each group. A Prospective randomized controlled trial was carried out. After Institutional ethical committee approval two hundred patients aged between 18 and 60 years, American Society of Anesthesiology (ASA) Grade I and II posted under general anesthesia were chosen for the study. Randomization was done using computer generated table. Patients with difficult airway, pregnancy, obesity (with BMI > 30), duration of surgery more than 4 hours were excluded from the study. Written informed consent was obtained and patients were allotted to one of the study groups Endotracheal intubation was performed using McIntosh Laryngoscope in MCL Group and using king Vision video Laryngoscope in VCL Group.

On the operation table, monitors including ECG, Pulse oximetry (SpO_2), NIBP were connected to the patient. Baseline vital parameters including heart rate, blood pressure and SpO_2 were noted. Intravenous access was secured and premedicated with injection Glycopyrollate 0.2 mg, injection Midazolam 0.02 mg/kg, injection Fentanyl 2 microgram/kg induction with injection Propofol 1–2 mg/kg, paralyzed with injection atracurium 0.5 mg/to facilitate endotracheal intubation. Endotracheal intubation was performed by anesthesiologist with more than 5 years of experience using McIntosh Laryngoscope in MCL Group and Video Laryngoscope in VCL Group. Laryngoscopy time (from the time of start of insertion till removal of the laryngoscope blade) and ease of insertion (easy/difficult, graded as difficult if external laryngeal manipulation was needed and number of attempts were more than one) were noted. Patients with unanticipated difficult airway in whom change of laryngoscope blade was needed for intubation were excluded from the study. Postintubation vitals including heart rate, blood pressure and SpO_2 were noted. During extubation care was taken to prevent patient from coughing on the tube. Duration of anesthesia was noted. Postoperatively, sore throat (no, mild, moderate and severe) and hoarseness of voice were assessed at 6 hours, 12 hours, 24 hours and 48 hours. Incidence of sore throat (with grading) and hoarseness of voice, laryngoscopy time and ease of insertion in both groups were noted and compared. Patients with persistent sore throat and hoarseness of voice were planned for further evaluation and follow-up till they resolved.

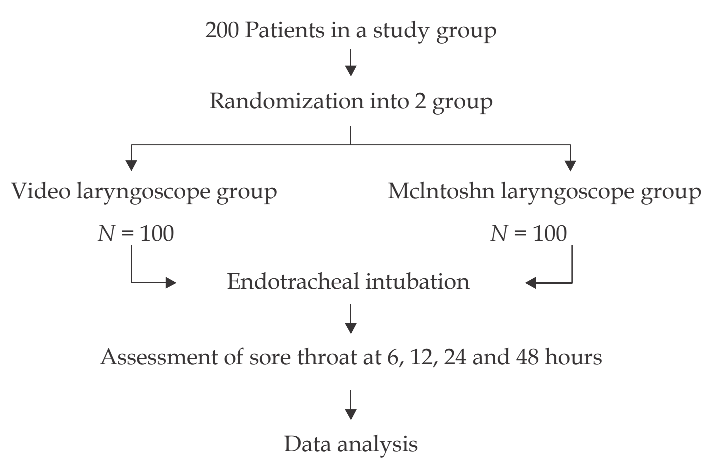

Fig. 1: Data-flow diagram

Statistical Analysis

Following data entry results were analyzed using SPSS 23 version software. Descriptive statistics were reported using mean and SD for the continuous variables, number and percentages for the categorical variables. Proportion of existence of postoperative sore throat and hoarseness were reported using number and percentages. Chi-square test was used to test the significance for the categorical variables. Student's *t*-test was used for comparison of means for the continuous variables. A p - value of < 0.05 was considered as statistically significant.

Results

The mean age and weight were similar in both the groups (Table 1). Distribution of sex and ASA grading were comparable (Table 1). The average duration of anesthesia in Group I and II were 108 ± 32 minutes and 102 ± 38 minutes respectively with no significant difference (p – value = 0.237) between groups.

Comparison of vital parameters between the study group is given in Table 2. There was no significant difference in basal heart rates between groups. Heart rates increased in both groups and the increase was more in the direct laryngoscopy group ($p = 0.03$). There was no significant difference in mean blood pressure readings between groups before induction of anesthesia. The change in blood pressure seen during laryngoscopy in video laryngoscopy group was slightly higher as compared to direct laryngoscopy group ($p = 0.09$). Similarly, Basal SpO_2 and postintubation SpO_2 was not significantly different between the two groups.

The number of cases with difficult laryngoscopy in MCL was two and in VDL was three ($p = 0.6$). Duration of laryngoscopy was significantly longer in VDL group compared to MCLgroup with 34 seconds in MCLgroup and 47 seconds in VDL group ($p < 0.001$).

Incidence of sore throat and hoarseness is presented in Table 3. Postoperatively the incidence of sore throat and hoarseness of voice was similar in both groups across all the times.

Table 1: Demographic details

Parameters	MCL	VDL	p - value
Age (years)	38.7 ± 11.9	38.5 ± 11.3	0.905
Sex	53/47	59/41	0.360
Weight (kg)	65.7 ± 11.1	66.3 ± 9.0	0.636
ASA Grading/II	67/33	72/28	0.416

Table 2: Comparison of vital parameter

Parameters	MCL	VDL	p - value
Basal Heart rate (beats/ minute)	70.8 ± 11.3	68.4 ± 9.7	0.100
Post intubation Heart rate (beats/min)	81.1 ± 10.8	78.1 ± 9.1	0.035
Basal Mean BP (mm Hg)	87.7 ± 7.9	87.7 ± 8.7	0.989
Post intubation Mean BP (mm Hg)	79.9 ± 8.4	78.1 ± 6.8	0.093
Basal SpO_2 (%)	99.6 ± 0.54	99.6 ± 0.57	0.478
Postintubation SpO_2 (%)	100	100	–

Table 3: Comparison of incidence of sore throat and hoarseness between the two groups

Parameters	MCL (n = 100)	VDL (n = 100)	p - value
Sore throat at 6 hr			
No	86	88	0.869
Mild	10	7	
Moderate	3	4	
Severe	1	1	
Sore throat at 12 hr	97	97	0.990
No	3	3	
Mild			

Parameters	MCL (n = 100)	VDL (n = 100)	p - value
Sore throat at 24 hr			
No	100	100	–
Hoarseness at 6 hr			
Present	5	6	0.769
Absent	95	94	
Hoarseness at 12 hr			
Present	2	1	0.555
Absent	98	99	
Hoarseness at 24 hr			
Present	0	0	–
Absent	100	100	

Discussion

POST is a common undesirable complication of endotracheal intubation, which can result in patient discomfort, delay in recovery and increase in expenditure of health care.[5] Video laryngoscope reduces the number of failed intubations, improves glottis view and reduces laryngeal/airway trauma. But there is no evidence to indicate that the use of VLS reduces the number of intubation attempts or the incidence of hypoxia or respiratory complications and no evidence indicates that use of VLS affects the time required for intubation.[6] Risk factors for POST include female sex, younger age, longer duration of ET intubation, and injury to oropharyngeal structures during laryngoscopy and intubation POST can be prevented by adequate relaxation, careful technique, use of soft suction catheters, smaller tracheal tubes, monitoring cuff pressure intraoperatively and avoiding Local Anesthesia/steroid lubricants[7] King vision video laryngoscope consists of a Macintonsh blade design with a video chip at the tip of the blade with an extended optical axis in the vertical plane connected to a video display monitor.

In our study patients we assessed patients for POST at 6, 12, 24 and 48 hours of surgery. Our results showed that the incidence of postoperative sore throat was similar in VDL and MCL Group at 6 hrs (p = 0.869) and 12 hrs (0.990) and none of the patients had sore throat at 24 hrs and 48 hrs. Hoarseness was noticed among five patients in MCL Group and 6 in VDL Group without statistical significance (p = 0.769). At 12 hrs 2 patients in MCL Group and 1 in VDL Group complained of hoarseness (p = 0.555). However, none of the patients complained of hoarseness at 24 hrs. Duration of laryngoscopy was longer (47 seconds) in VDL Group as compared to MCL Group (34 seconds) which was statistically significant (p < 0.001). We made sure that laryngoscopy and intubation was performed by Anesthesiologists with minimum 5 yrs of experience and the average duration of surgery was 100 to 150 minutes. Our study showed a greater incidence of sore throat at 6 hrs and 12 hrs which was similar to a study conducted by Najafi et al, however, they found that the incidence of POST was less in VDL group. This could be because of the time taken for laryngoscopy and intubation was less in VDL Group as compared to our study.

In a study conducted by Hayashi et al., the incidence of hoarseness was found to be 49%.[8] However, in our study the incidence of hoarseness was 5.5%. This is because we used cuff pressure monitor which reduces mucosal damage and we used air in place of Nitros oxide.

Although video laryngoscopy has a higher success rate compared to direct laryngoscopy, time taken for intubation is longer. One of the reasons for Video Laryngoscope taking a longer time is due to difficulty in introducing the blade inside the patient's mouth. In our study, time taken for laryngoscopy and intubation was longer in VDL Group as compared to MCL Group which is similar to a study conducted by Sun et al.[9] In most patients, the Glidescope® provided a laryngoscopic view equal to or better than that of direct laryngoscopy, but it took an additional 13 seconds (average) for tracheal intubation.

Time taken for intubation using VDL is usually longer as the easy visualization of the glottis does not guarantee the easy passage of endotracheal tube.[10] This is termed as laryngoscopy paradox. Another problem with VDL is obscuration of view by fogging and the presence of blood or secretions causes' loss of depth perception causing significant airway injury. In a study conducted by Tosh et al [11] concluded that there was a reduced incidence of POST in VDL Group. They had used 60^0 angled stylet which aids in faster orotracheal intubation as compared to 90° angled stylet. However, we intubated all our patients without stylet. Repeated attempts, longer intubation time, and greater force exerted for performing the scopy are some of the important contributing factors for POST. Use of the king vision video laryngoscopy does not significantly reduce the incidence of postoperative sore throat when compared to traditional intubation techniques

Conclusion

We conclude that the incidence of post operative sore throat following laryngoscopy and endotracheal intubation is similar in Video Laryngoscope and McIntosh laryngoscope Groups. However, the time taken for endotracheal tube placement is longer with Kingvision video laryngoscope when compared to McIntosh Laryngoscope.

References

1. McHardy FE, Chung F. Postoperative sore throat: Cause, prevention and treatment Anesthesia perioperative medicine and critical care, 1999 May;54(5):444–45.
2. Lee JY, Sim WS, Kim ES, et al. Incidence and risk factors of postoperative sore throat after endotracheal intubation in Korean patients. J Int Med Res. 2017;45(2):744–752.
3. Higgins PP, Chung F, G Mezei. Postoperative sore throat after ambulatory surgery. BJA: British Journal of Anesthesia 2002 April;88(4):582–84.
4. Najafi A, Imani F, Makarem J, et al. Postoperative sore throat after Laryngoscopy with Macintosh or Glide Scope Video Laryngoscope blade in normal nirway natients. Anesth Pain Med 2014 Feb;4(1):e15136.
5. Narinder P Singh, Jeetinder K Makkar, Vincent Wourms et al. Role of topical magnesium in postoperative sore throat: A systematic review and meta-analysis of randomized controlled trials. IJA 2019;63(7):520–29.
6. Lewis SR, Butler AR, Parker J, et al. Videolaryngoscopy versus direct laryngoscopy for adult patients requiring tracheal intubation: a Cochrane Systematic Review. Br J Anaesth. 2017;119(3):369–383.
7. Aziz MF, Dillman D, Fu R, Brambrink AM. Comparative effectiveness of the C-MAC video laryngoscope versus direct laryngoscopy in the setting of the predicted difficult airway. Anesthesiology. 2012;116(3):629–636.
8. Yamanaka H, Hayashi Y, Watanabe H, et al. Prolonged hoarseness and arytenoid cartilage dislocation after tracheal intubation. Br J Anesth 2009 Sep;452:(3)103–55.
9. Sun DA, Warriner CB, Parsons DG, et al. The Glide Scope® Video Laryngoscope: Randomized clinical trial in 200 patients. BJA: British Journal of Anesthesia 2005 March;94(3):381–84.
10. Van Zundert A, Maassen R, Lee R, et al. A Macintosh laryngoscope blade for video laryngoscopy reduces stylet use in patients with normal airways. Anesthesia and Analgesia 2009 Sep;109(3):825–31.
11. Pulak T, Sunil R, and Lakshmi K. Ease of intubation with C-MAC Video laryngoscope: Use of 60° angled styletted endotracheal tube versus intubation over Bougie. Anesth Essays and Res 2018 Jan–Mar;12(1):194–98.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 58-63
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.9

A Comparative Study of Neuromuscular Blocking Effects and Reversibility of Cisatracurium and Vecuronium

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Abstract

Context: Cisatracurium is a cis isomer of parent compound atracurium, devoid of histamine release, thus possessing hemodynamic & cardiovascular stability. *Aims:* We compared the intubating conditions, hemodynamic stability & recovery of atracurium & vecuronium. *Settings and Design:* We carried out prospective, double blind randomized study after approval of ethical committee. 100 adult patients of ASA 1 & 2 with comparable demographic data were selected. Divided in Two Groups C (Cisatracurium) & V (Vecuronium). Standard monitoring was done & following routine premedication & induction agents, patients were intubated at 2 mins after administration of cisatracurium 0.15 mg/kg & vecuronium 0.1 mg/kg respectively, maintained on intermittent dose of cisatracurium: 0.03 mg/kg & vecuronium: 0.02 mg/kg. Intubation conditions were assessed according to Time to 25% recovery of t1/tc following initial doses, Time to 25% recovery of t1/tc following repeated boluses, Time to 25% recovery of t1/tc following last dose, Return of t4/t1 ratio 0.8 spontaneous recovery at end of operation. *Statistical analysis used:* The results were evaluated by applying paired *t*-test and *p* - value using SPSS Statistical Software. *Results:* Intubating conditions at 2 mins following administration appeared satisfactory & laryngoscopy condition was good in 98% in Group C & 97% in Group V, Time taken for 25% recovery following First Dose & Subsequent Doses was longer for Group C than Group V. Time taken to 25% recovery of t1/tc following Last Dose was shorter in Group C patients as compared to Group V, duration of action of Group C was longer than Group V, both demonstrated equal hemodynamic & cardiovascular effect. *Conclusions:* Cisatracurium is intermediate onset nondepolarizing muscle relaxant devoid of histamine release with longer duration of action & faster recovery.

Keywords: Cisatracurium; Vecuronium; Intubating conditions; Recovery; Hemodynamic profile.

How to cite this article:
Divya N Kheskani, Heena S Chhanwal, Bhakti S Jain. A Comparative Study of Neuromuscular Blocking Effects and Reversibility of Cisatracurium and Vecuronium. Indian J Anesth Analg. 2020;7(1 Part -I):58–63.

Introduction

Rapid and safe endotracheal intubation is of prime importance in general anesthesia. The role of muscle relaxant serves to facilitate endotracheal intubation and provides surgical relaxation.[1–3] The ease of performing endotracheal intubation depends on the degree of muscle relaxation, depth of anesthesia and skill of anesthesiologist.[2] The onset time, duration of muscle relaxation, type of patient and surgery are factors in choosing the appropriate muscle relaxant to achieve rapid, successful

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Received on 12.09.2019, **Accepted on** 23.10.2019

tracheal intubation.[4] Cisatracurium is a cis isomer of parent compound atracurium. However, it is more appealing as it is devoid of histamine release and thus possessing hemodynamic and cardiovascular stability. It possesses organ independent Hoffman elimination and intermediate duration of action. Vecuronium is nondepolarizing muscle relaxant with intermediate duration of action, metabolizes in liver and hepatorenal organ dependent clearance. Hence, forth considering the above properties of cisatracurium in this study we compared the intubating conditions, hemodynamic stability and recovery of these two agents.

Materials and Methods

We carried out prospective, double blind randomized study after approval of ethical committee. Written and informed consent was obtained from all the participating patients. We studied 100 adult patients of physical status ASA 1 and 2, of either sex, age ranging from 18 to 65 years, weighing 40 to 70 kg, posted for elective surgeries under General anesthesia lasting for maximum of 2 to 3 hours. A detailed and formal airway evaluation was done preoperatively and patients with mpg 1 and mpg 2 were included.

Patients excluded were with grading score 3 and 4 according to Sampson and young modification of mallampati grading, anticipated difficult mask ventilation and airway, Patient refusal, patients of ASA 3 and 4, on therapy with drugs known to interfere with neuromuscular transmission, suspected pregnancy, liver or renal disease, prolonged preoperative bed rest, Uncontrolled hypertension, History of reactive airway disease, history of allergy or sensitivity to any medication, latex or egg, emergency surgical intervention or obesity (BMI ≥ 25). All patients were given T Alprazolam 0.5 mg on night prior to the surgery and were kept nil by mouth for 8 hrs.

Patients will be randomly divided into 2 Groups of 50 each:

- Group C (50 patients) for Cisatracurium;
- Group V (50 patients) for Vecuronium.

A written and informed consent was taken from the patient. On the day of surgery, In the preoperative room base line vital parameters (pulse, blood pressure, respiratory rate, SpO_2 and temperature) were recorded. A large bore 18 gauge IV peripheral line was secured, a slow infusion of lactated Ringer's solution was started. All resuscitation equipments were kept ready. Standard monitors were connected and the preinduction Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Heart Rate (HR), Oxygen Saturation (SpO_2), ECG were recorded. In the operation theatre the patients were premedicated with Inj ondansetron 4 mg IV Inj Glycopyrollate 0.2 mg IV, Inj midazolam 0.1 mg/kg IV, Inj fentanyl 10 microgram/kg IV, just before induction. Patient were preoxygenated with 100% oxygen at 10 litre/min fresh gas flow for 3 minutes using closed circuit, induced with IV propofol 2 mg/kg followed by cisatracurium or vecuronium and IPPV wih 100% oxygen on bag and mask after they were randomly allocated to Group C (Cisatracurium) or Group V (Vecuronium). After adequate relaxation for 2 minutes patient were intubated with appropriate sized endotracheal tube and was fixed after checking equal air entry bilaterally.

Grroup C: Cisatracurium intubating dose 0.15 mg/kg;

Group V: Vecuronium intubating dose 0.1mg/kg.

Intubation conditions were assessed according to the criteria: Laryngoscopy condition, vocal cord position, vocal cord movement all being excellent or scarce and if there was reaction to Endotracheal tube insertion of cuff inflation by limb movement or cough shown in (Table 2). Patient were maintained on controlled mechanical ventilation with 50% oxygen, 50% nitrous oxide (N_2O) Inhalational agent (sevoflurane 3%) and maintainance dose of nondepolarizing muscle relaxant (Cisatracurium: 0.03 mg/kg and Vecuronium: 0.02 mg/kg). The Adductor Policies muscle evoked response (AP), Train of Four (TOF) stimulation after supramaximal ulnar nerve stimulation were measured. With TOF the time for recording baseline response was standard 5 mins prior to administration of muscle relaxant. Repeated consequent doses were administered when AP response recovered to 25% of control twitch height, at the end of surgery monitoring was continued until 95% of T1 and T4/T1 (80% at the end of surgery).

At the end of the operation, anesthetic agents were discontinued and adequate oral suctioning was done. Pt were then reversed with inj Glycopyrollate (0.008 mg/kg) and inj neostigmine (0.05 mg/kg) and extubated after regains consciousness and responded to verbal command. All patients were monitored for HR (Heart Rate), SBP (Systolic Blood Pressure), DBP (Diastolic Blood Pressure), S_PO_2, $ETCO_2$ and fluid requirement was calculated and replaced accordingly. The following variables were recorded in minutes: (1) Time to 25% recovery of t1/tc following initial doses (2) Time to 25%

recovery of t1/tc following repeated boluses (3) Time to 25% recovery of t1/tc following last dose (4) Return of t4/t1 ratio 0.8 spontaneous recovery at end of operation (Spontaneous Complete Recovery, (SCRT).

Results

After studying 100 cases, observation and results are summarized in tabulated form and described below. Both groups comprised of 50 patients, (Table 1). No significant difference was seen in male-female ratio,weight and age of patients between both the groups. Intubating conditions at 2 mins following administration appeared satisfactory & laryngoscopy condition wasgood in 98% in group C & 97% in Group V, shown as in Figs. 1–2, both demonstrated equal hemodynamic & cardiovascular effect, Figs. 3–4, Time taken for 25% recovery following first dose & subsequent doses was longer for Group C than Group V, Time taken to 25% recovery of t1/tc following Last Dose was shorter in Group C patients as compared to Group V, duration of action of Group C was longer than Group V, (Table 2).

Table 1: Demographic Data

Parameters	Group C (*n* = 50)	Group V (*n* = 50)	*p* - value	Inference
Sex (M/F)	38:12	40:10	> 0.05	NS
Age (Years)	30.96 ± 7.68	32.4 ±10.01	> 0.05	NS
Weight (kg)	56.72 ± 8.5	60.04 ± 6.943	> 0.05	NS
Height (cm)	165.6 ± 4	168 ± 7.1	> 0.05	NS
ASA Grade 1				
ASA Grade 2	44:6	40:10	–	–
Duration of surgery (min)	100 ± 10	110 ± 15	–	–

Table 2: Recovery characteristics of both groups (*n* -100)

Parameters	Group C	Group V	*p* - value
Time (mins) to 25% recovery of t1/tc following initial doses	57.3 ± 11.2	41.2 ± 7.0	< 0.0001
Time (mins)to 25% recovery of t1/tc following repeated boluses	35.5 ± 8.49	30.02 ± 3.9	< 0.0002
Time (mins) to 25% recovery of t1/tc following last dose	36.75 ± 4.8	31.6 ± 4.71	< 0.0001
Return of t4/t1 ratio 0.8 spontaneous recovery at end of operation (mins)	43.5 ± 4.6	46.5 ± 7.25	< 0.015

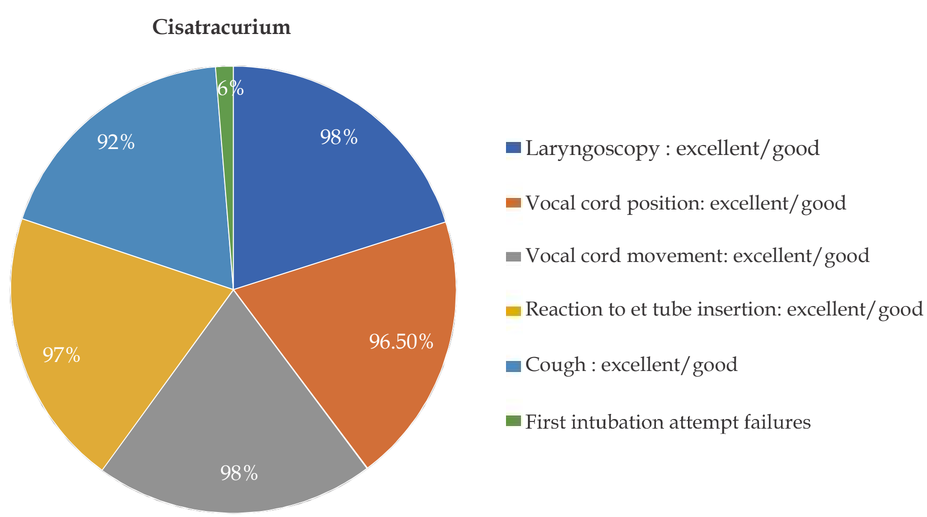

Fig. 1: Cisatracurium-intubating conditions.

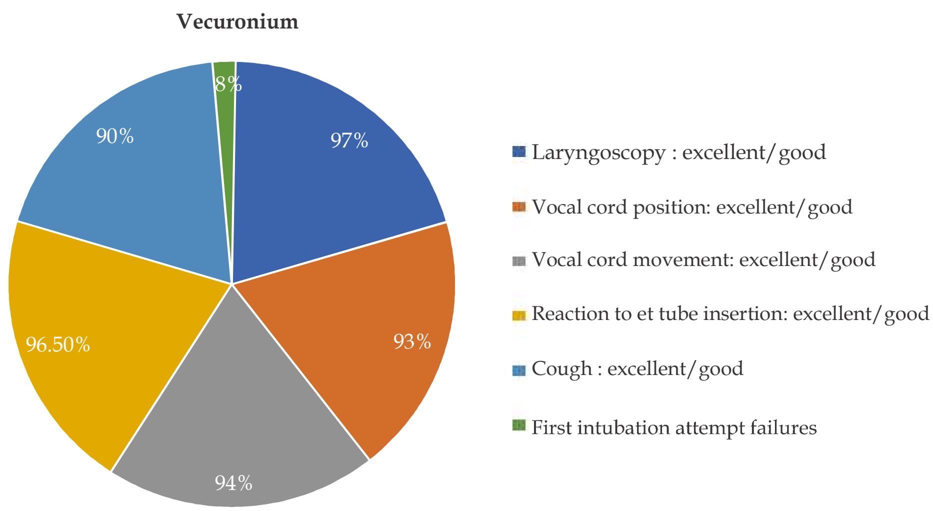

Fig. 2: Vecuronium-intubating conditions.

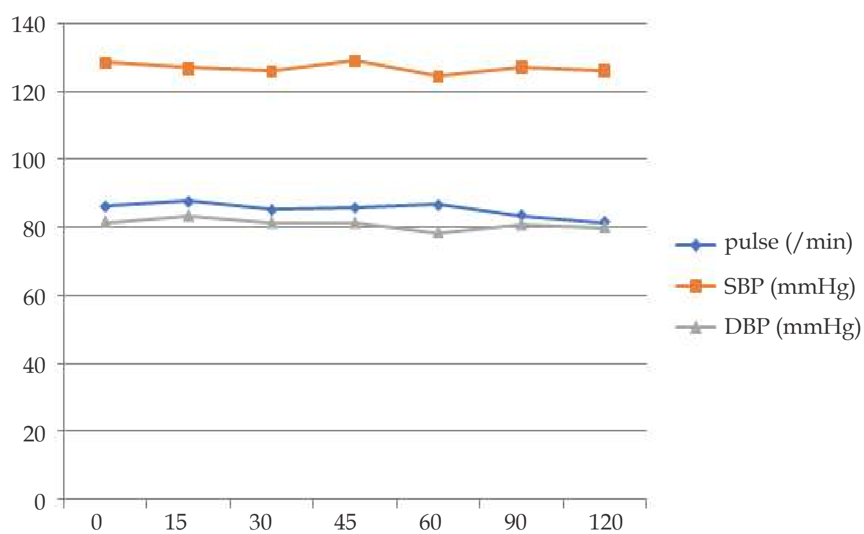

Fig. 3: Cisatracurium vitals (pulse, systolic blood pressure, diastolic blood pressure).

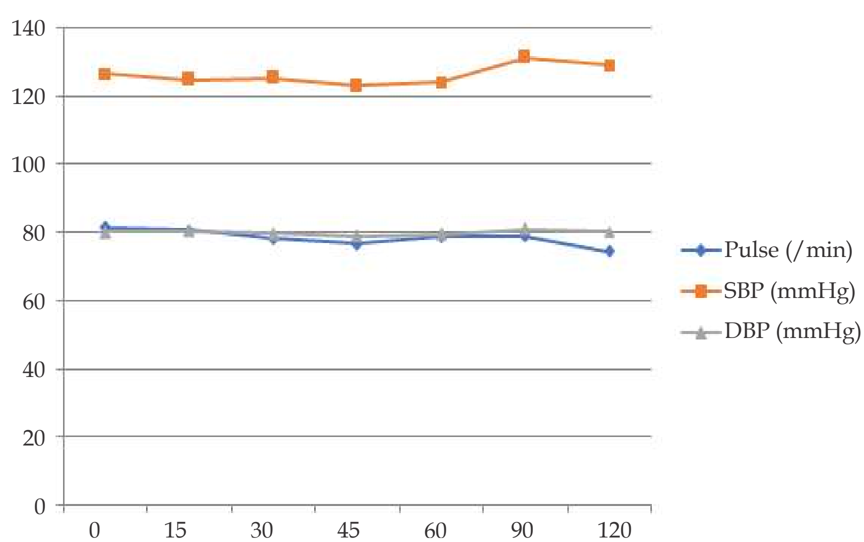

Fig. 4: Vecuronium vitals (pulse, systolic blood pressure, diastolic blood pressure).

Discussion

In our study, Intubating conditions at 2 mins following both drugs administration appeared satisfactory and laryngoscopy conditions - excellent/good in 98% cases in Group C and 97% in Group V respectively.

C Melloni's study "Cisatracurium *versus* vecuronium: A comparative, double blind study, randomized in adult patient under propofol/ fentanyl/*n* 20 anesthesia." Revealed similarly the intubating conditions to be 97.7% satisfactory in Group C and 96.4% in Group V respectively.[10]

Time taken for 25% recovery following First Dose and Subsequent Doses was longer for Group C than Group V. However, the time taken to 25% recovery of t1/tc following Last Vose was shorter in Group C patients as compared to Group V. Thus, duration of action of Group C was longer than Group V. C Melloni has made the similar observation in his study while comparing cisatracurium and vecuronium in the above parameters.[10]

The return of t4/t1 ratio of 0.8-spontaneous recovery at end of operation for Group C was shorter than Group V in our study. Hence, forth proving that recovery from Group C was speedy than Group V in similar conditions. "Cisatracuriumbislate, a review of its pharmacology and clinical potential in anesthetic practice" entitled study by Bryson HM concluded similarly that cisatracurium was associated with significantly faster recovery offered more predicitive recovery profile after continuous infusion than vecuronium.[11]

Moreover, cisatracurium as well as vecuronium demonstrated hemodynamic and cardiovascular stability in all patients.[10,12] Bencini stated that: The short duration of vecuronium may be due to its rapid distribution kinetics such that recovery occurs largely during distribution phase, in contrast to which cisatracurium rapidly degrades by pathway which is independent of hepatic and renal and thus its pharmacological recovery occurs during the elimination phase of the drugs metabolism. The above reason could thus explain the faster recovery of ciatracurium as compared to vecuronium at the end of operation in our study.[13]

Wright P et al. mentioned in his research that cisatracurium would be superior to vecuronium as it does not exhibit even the slightest or minimal trend towards the minimal accumulation as evidenced by atracurium and prolonged effect of vecuronium prior to recovery might be due to its accumulation of metabolites which possess NMB properties on repeated subsequent doses.[14] This observation was supported by studies of Hughes MA and positively explains the results of our study also.[15]

AMEl-Kasaby studied "Cisatracurium in different doses *versus* atracurium during general anesthesia for abdominal surgery" and observed that cisatracurium at larger doses (4*ED95) as compared to atracurium doses had slow onset time as compared to atracurium but possessed longer duration of action and excellent intubating condtions at 2 mins with stable hemodynamic profile."[16]

Conclusion

Both the compared drugs were safe and effecacious under the conditions of the study. In a nutshell cisatracurium is the latest intermediate onset nondepolarizing muscle relaxant devoid of histamine release with longer duration of action and faster recovery.

Key Messages

Thus, Cisatracurium is latest intermediate acting nondepolarizing muscle relaxant preffered now-a-days for induction and maintenance in general anesthesia.

Abbreviations

ASA - American Society of Anesthesiologists

IPPV - Intermittent Positive Pressure Ventilation

SBP - Systolic Blood Pressure

DBP - Diastolic Blood Pressure

$EtCO_2$ - End Tidal CO_2

NMB - Neuromuscular Blocking

Acknowledgement: Nil.

Conflict of Interest: Nil.

References

1. Somani M, Sharma P, Sachdev S, et al. A comparative study between vecuronium and rocuronium for intubating condition and hemodynamic changes. IOSR 2014 Jam;13(6):33–39.
2. Aparna S, Dubey KP, Sharma MS. Comparative evaluation of hemodynamic effects and intubating conditions after the administration of ORG 9426 (rocuronium) and succinylcholine. Indian J Anesth 2004 Jan;48(6):476–79.

3. Misra MN, Agarwal M, Pandey RP, et al. A comparative study of rocuronium, vecuronium and succinylcholine for rapid sequence induction of anesthesia. Indian J Anesth 2005;49:469–73.

4. Fuchs Buder T, Tassonyi E. Intubating conditions and time course of rocuronium-induced neuromuscular block in children. Br J Anesth 1996;77:335–38.

5. Doenicke A, Soukup J, Hoernecke R, Moss J. The lack of histamine release with cisatracurium: a double-blind comparison with vecuronium. Anesth Analg. 1997;84(3):623–628.

6. Lien CA, Belmont MR, Abalos A, et al. The cardiovascular effects and histamine-releasing properties of 51W89 in patients receiving nitrous oxide/opioid/barbiturate anesthesia. Anesthesiology. 1995;82(5):1131–1138.

7. Welch RM, Brown A, Ravitch J, et al. The in vitro degradation of cisatracurium, the R, cis-R'-isomer of atracurium, in human and rat plasma. Clin Pharmacol Ther. 1995;58(2):132–142.

8. Hunter JM, Parker CJ, Bell CF, et al. The use of different doses of vecuronium in patients with liver dysfunction. Br J Anaesth. 1985;57(8):758–764.

9. Vecuronium Bromide drug information I Drugs Update India. www.drugsupdate.com/generic/view/568

10. Melloni C, Devivo P. Cisatracurium *versus* vecuronium: A comparative, double blind, randomized, multicenter study in adult patients under propofol/fentanyl/N_2O anesthesia. Minerva Anestesiol 2006 May;72(5):299–308.

11. Harriet M Bryson. Cisatracurium besilate, A review of its pharmacology and clinical potential in anesthetic practice, Adis Drug evaluation 1997 May;53(5):848–66.

12. Keleş GT et al. Assessment of neuromuscular and hemodynamic effects of cisatracurium and vecuronium under sevoflurane-remifentanil anesthesia in elderly patients. Randomized controlled trial. Eur J Anesthesio 2004 Nov;21(11):877–81.

13. Lien CA, Belmont MR. Dose response relationship of Nimbex under nitrous oxide-opoid-barbiturate anesthesia. Anesthesiology 1993:79(3A)A948 .

14. Hunter JM, Jones RS, Utting JR. Comparison of vecuronium, atracurium and tubocurarine in normal patients and in patients with no renal function. Br J Anaesth 1984 Sep;56(9):941–51.

15. Bencini A, Seaf AHJ, Sohn YJ, et al. Disposition and urinary excretion of vecuronium bromide in anesthetized patients with normal renal function or renal failure. Anesth Analg 1986 Mar;65(3):245–51.

16. Am El Kasaby, HM Alef. Cisatracurium in different doses *versus* atracurium during general anesthesia for abdominal surgery, Saudi Journal of Anesthesia 2010;4(3):152–57.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 64-69
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.10

Easy Method of Ryles Tube Insertion in Laparoscopic Surgeries under General Anesthesia: A Simple, Non fussy and Practical Approach

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Abstract

Background: Insertion of Ryles Tube (RT) or orogastric tube and deflating the gastric contents is often required in patients of laparoscopic surgeries. Passing the RT into the stomach is always difficult in an anesthetized and intubated patients as they cannot follow the commands. Various techniques have been tried with variable success. *Aim*: We describe here a simple and easy technique of RT or orogastric tube insertion in paralyzed and intubated patients and compared with the conventional method in terms of success rate, attempts, time taken for insertion and adverse effects. Patients in our study included were those coming for laparoscopic surgeries under general aesthesia. *Methods:* A total of 60 patients undergoing laparoscopic surgeries, requiring RT placement of either sex, between the age group 25 and 55 yrs. were enrolled for our study. Patients were allotted into Two Groups. Group C (control) the RT was passed through the mouth, and in Group ET (study) RT was passed through the red rubber endotracheal tube. Demographic parameters, required number of attempts, placement time and adverse events were noted. *Results and Conclusions*: Our method of passing RT into the stomach in anesthetized and paralyzed patients- through the endotracheal tube is very simple and easy. The attempts and the time taken for insertion of the RT was much less in our method. The adverse effects were negligible with this method as compared to the conventional method.

Keywords: Ryles Tube (RT); Insertion; Endotracheal tube; Gastric contents; and Laparoscopy.

How to cite this article:
Ramsali Manjula V, Vanagondi Sivakumar, CG Raghuram, et al. Easy Method of Ryles Tube Insertion in Laparoscopic Surgeries under General Anesthesia: A Simple, Non fussy and Practical Approach. Indian J Anesth Analg. 2020;7(1 Part -I):64–69.

Introduction

Decompression of the stomach and GIT is requested quite often by the laparoscopic surgeon to facilitate a better laparoscopic view of the abdominal contents. A request is often made to the Anesthesiologist at the head end to pass a RT in the anesthetized, intubated patients. RT insertion is difficult with first attempt of failure rates of nearly 50–60%[1,2] by conventional method with the head in an intubating position. Anesthetized intubated patients cannot follow the instructions

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Received on 03.09.2019, **Accepted on** 02.11.2019

to swallow like awake patients so may not help in the easy insertion of the RT. This procedure is very challenging in anesthetized patients. The RT passed through nasal or oral route in anesthetized and paralyzed patients coils at piriform sinuses and the arytenoids cartilages.[3]

The distal part of the RT with multiple apertures becomes the weakest part of the tube and thus susceptible to kink, coil, knot or false passage.[4,5] Several modifications have been tried for insertion of the RT but with less success at the cost of complication such as mucosal bleeding, sympathetic stimulation with rise in heart rate and blood pressure. These adverse effects may be not acceptable in high-risk patients.

Many a times attempts to pass the Ryles tube through the nose ends in a fiasco as the Ryles tube either refuses to go down the oesophagus or curls out of the oral cavity or coils into knots in the oral cavity. Repeated attempts through both the nostrils ultimately can lead to a messy situation in the oral cavity with epistaxis and bruising of nasal and oral pathways. A simple and easy technique is described here to ensure a successful RT passage into the stomach in laparoscopic surgeries in anesthetized patients.

Materials and Methods

The present study was conducted in our institute after receiving the permission from ethics committee. Sixty patients posted for laparoscopic surgeries under general anesthesia, aged between 18 and 55 yrs with ASA Grade I/II and MP Grade ½ were included in our study. Airway abnormality, upper airway lesions, skull base lesions, bleeding and clotting disorders, platelet disorders, oesophageal varices or stenosis or history of radiotherapy of head and neck region were excluded from the study. All the patients were examined one day before surgery. The study procedure and the expected complications were discussed with the patients and informed consent was taken. On the day of the surgery in the operation theatre after all the monitors are connected, premedication was done with glycopyrrolate (0.01 mg/kg), midazolam (0.03 mg/kg) and ondansetron 4 mg intravenously. Fentanyl (2μ/kg) was given and then induced with propofol (2 mg/kg) after which muscle relaxant vecuronium (0.1 mg/kg) was injected once we could ventilate the patient. After adequate muscle relaxation, intubation was done with appropriate sized endotracheal tube and then connected to the ventilator after confirming the tube position. Anesthesia was maintained on intermittent positive pressure ventilation with N_2O and O_2, isoflurane and intermittent vecuronium.

Patients were randomly allocated to two groups: Group C (control) and Group ET (study). In control group the RT was passed through the mouth along the side ofintubated endotracheal tube, and in study group-first the plain red rubber endotracheal tube of (size 7) was passed then RT was introduced through that (Fig. 1). In both the groups the RT used was made stiff by keeping in the freezer compartment of refrigerator for minimum 3–4 hrs.

The time taken for insertion was noted in seconds from the insertion of RT or endotracheal tube at the angle of the mouth to successful placement and verified by epigastric auscultation or aspiration of gastric contents.

The following data were recorded and calculated:

1. Success rates of the selected technique for the first attempt, second attempt, and overall;
2. Time required for the successful first attempt;
3. Adverse events during the procedure - coiling, kinking and bleeding.

Fig. 1a: Passing of endotracheal tube into the oesophagus.

Fig. 1b: Passing of Ryles Tube through the endotracheal tube into the stomach.

Statistical analysis

The sample size was calculated by using effect size of 0.99, α = 0.05, 1-β = 0.90. The total sample size was 46 that is 23 in each group for using '*t*' test for two independent groups. However, because of possibility of dropout cases, we have taken total of 60 cases 30 in each W groups.

Observed data were entered in the Microsoft excel sheet. Demographic data (age, height, weight) were presented in mean and standard deviation and analyzed with unpaired *t*-test. ASA physical status, MP Grades, gender distribution, insertion attempts and adverse events were presented as frequency and analyzed by Chi-square test. Time required for insertion was analyzed again by unpaired *t*-test. Results with *p*-value < 0.05 were considered statistically significant.

Results

The study was conducted in total of 60 patients. The demographic parameters like age, sex, height, weight, ASA and MP Grade were comparable in both the Groups.

As shown in Table 2 the RT insertion in the first attempt was 26 (86.7%) in the study group. Second and third attempt requirement was more with the conventional method which is statistically significant. The procedure time for RT placement was least (Fig. 2) in the study (ET) Group (31.68 ± 14.96 seconds) in comparison to the control group (44.63 ± 23.80 seconds) and is significant.

Adverse effects like coiling, kinking and bleeding were negligible in our method as in Table 3. Coiling and Kinking was significantly higher in control group and compared to the study group (p = 0.015 and 0.030).

Coiling of the RT was observed in 6 (20%) patients only in the conventional technique and did not occur in the study group. Kinking occurred in 7 (23.33%) and 1 (3.33%) patients in control and ET assisted group respectively resulting in statistically significant difference. Four patients in control group and 2 in study group were observed to have mucosal bleeding.

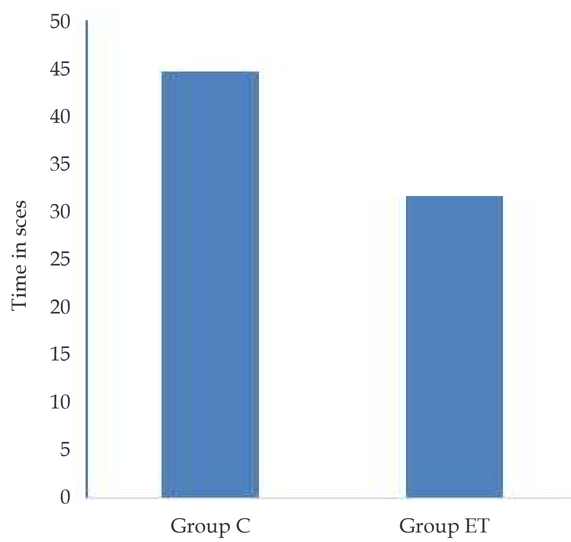

Fig. 1: RT Insertion Time

Table 1: Demographic Parameters

Parameters	Group C (Mean ± SD)	Group ET (Mean ± SD)	*p* - value
Age	34.8 ± 10.61	40.67 ± 15.55	0.093
Height	155.53 ± 9.11	156.73 ± 8.46	0.599
Weight	58.40 ± 10.28	56.33 ± 8.01	0.388
ASA Grade I/II	13/17	16/14	0.067
MP Grade I/II	18/12	21/09	0.293
Sex Ratio M/F	19/11	20/10	0.787

p - value < 0.05 is statistically significant

Table 2: Procedure Variables

Insertion Parameters		Group C	Group ET	*p* - value
Attempts	First	17 (56.7%)	26 (86.7%)	
	Second	10 (33.3%)	3 (10%)	0.001*
	Third	3 (10%)	1 (33.33%)	
Time (Mean ± SD)		44.63 ±23.80	31.68 ±14.96	0.014*

*p - value < 0.05 is statistically significant

Table 3: Adverse events of Ryles Tube insertion

Adverse Events	Group C	Group ET	*p* - value
Coiling	7 (23.33%)	0 (0)	0.015*
Kinking	8 (26.67%)	1 (3.33%)	0.030*
Bleeding	4 (13.33%)	2 (6.67%)	0.667

*p - value <0.05 is statistically significant

Discussion

The number of laparoscopic procedures are increased with the improvement in the laparoscopic skills and the facilities available. Anesthetists are required to pass the RT to decompress gastric contents, which obscures the view of camera and during laparoscopic surgery and chances of gastric perforation. The RT passed through nasal or oral route in anesthetized and paralyzed patients coils at piriform sinuses and the arytenoids cartilages.[3] The weak part of the tube due to multiple apertures makes it susceptible to kink, coil and knot.

The whole concept is simple and straight forward. An appropriate sized endotracheal tube is passed through oral cavity either with the aid of a laryngoscope or blindly (after sufficiently lubricating ET tube) into the oesophagus. RT is then guided through the ET. This technique is almost always easy as already an endotracheal tube is in the trachea and the second ET can only be guided like an endoscope into oesophagus.

The oral, proximal end of the tube's lumen is filled with a small amount of jelly lubricant and through this, a RT is guided down the endotracheal tube to emerge out of the bevel and then into the stomach. Later, the endotracheal tube is pulled out over the RT till it comes out of the oral cavity. The RT is anchored just like an endotracheal tube till the end of the surgery.

Tail piece

In most of the laparoscopic surgeries, at the end of the surgery, the Ryle's tube is almost always removed either before or after extubation. Hence, there is no need to resort to a nasal route for passing a Ryle's tube and also persist with that, when it has turned out to be messy. What all is needed is only decompression of GIT and that can be precisely and easily achieved by passing a Ryle's tube through an oral endotracheal tube stationed in the oesophagus. This Ryle's tube can obviously go only into the stomach and not elsewhere, as already an endotracheal tube is *in situ* in the trachea.

Insertion of the RT by conventional method in paralyzed, anesthetized and intubated patients usually a difficult task requiring repeat attempts leading to frustration and agony. The tube may get impacted into the pyriform sinus, arytenoids cartilage or trachea. The impaction of kinking, coiling and entanglement sometimes complicates the situation.[6–8] Even in unintubated patients, the tube may coil around the epiglottis and lead to chocking, respiratory distress, tachypnoea and cyanosis leading to morbidity.[9]

Several methods have been described for RT insertion with varying degree of success. The most common technique practiced in day to day practice is blind nasal insertion while maintaining external laryngeal manipulation or under direct vision using a laryngoscope followed by instrumentation with Magill's forceps. The nasogastric tube has been inserted with reliable and success rate (94% and 98% in first and second attempts respectively) with the help of stylet tied together at the tips by the slipknot.[2] in the literature different methods and their combinations have been reported. The method of rightward pull of the cricoid cartilage while maintaining mild flexion of the patients neck has found helpful for unconscious intubated patients.[10] Oesophageal guidewire-assisted nasogastric tube insertion was done in anesthetized and intubated patients with manual displacement of larynx (reverse sellick's) and found to have highest success rate of 99.2% in comparison to the technique of head flexion and lateral neck pressure.[11] In conscious and cooperative patients RT insertion either oral or nasal route is usually performed with 'push and swallow' technique.[12]

Our technique of RT insertion through ET showed to have more success rate on a first attempt insertion as compared to conventional method. Similar results were observed with Kwon et al.[13] who studied insertion of orogastric tube through ET assistance. They studied to have favourable outcome with ET assisted orogastric tube placement as compared to conventional method of nasogastric tube insertion. Orogastric tube insertion using the new gastric tube guide study was done in manikin by Alflen et al.[14] They concluded that, use of gastric tube guide to place orogastric tube in a simulation manikin had a higher success rate.

Total time of successful placement was much less in our study (ET) group than the control group (Fig. 2) . Significantly shorter time was required for orogastric tube placement time in manikins in another study.[14] The results coincides with our study results. Kwon et al.[13] found to save more time in orogastric tube placement with ET assisted technique. This was the study done in emergency department where the patient required placement of orogastric tube for getting access to the stomach for diagnostic and therapeutic purposes, medication administration, GI feeding, gastric lavage after poisoning or overdose, gastrointestinal decompression for small bowel obstruction and also for evaluating GI bleeds. Gastric tube placement in unconscious and anesthetized patients was difficult and traumatic and so several modified technique were tried with neck flection along with application of lateral pressure, a tied intubation stylet to an nasogastric tube or inserting a urethral guidewire or angiography catheter into the nasogastric tube.[4,7,15] Some authors also suggested stiffening the RT by keeping in the refrigerator.[16–18]

The chances of adverse events like coiling and kinking were much less in Group ET than in the Group C. This was mainly because the longer length of the ET tube, the passage of RT was easy probably avoiding coiling and kinking. Various other studies have observed that complications like coiling and kinking were common with nasogastric tube insertion without instrumentation.[4–6] Repeated attempts have been reported to increase with incidences of bleeding. The same was observed in our study with less incidences of multiple attempts and bleeding. Kwon et al.[13] concluded in their study to have to have mucosal bleeding with ET assisted placement of the orogastric tube than the control method. These results were in contrary to our study results. In guidewire assisted technique, there are less chances of coiling and no kinking according to Mohan Chandra Mandal et al.[15] but more chances of bleeding. With flexion of neck and reverse Sellick's approach, there were very less chances of kinking and bleeding with shorter time for insertion.

Conclusion

Our technique of RT insertion showed higher success rate and less time of placement. Even the adverse events were much less compared to the conventional method. So, we conclude that our method of RT insertion into the stomach in anesthetized and paralyzed patients through assisted endotracheal tube is simple, non-fussy and faster with lesser adverse events.

References

1. Bong CL, Macachor JD, Hwang NC. Insertion of the nasogastric tube made easy. Anesthesiology 2004 Jul;101(1):266.
2. Tsai YF, Luo CF, Illias A, Lin CC, Yu HP. Nasogastric tube insertion in anesthetized and intubated patients: a new and reliable method. BMC Gastroenterol. 2012;12:99.
3. Ozer S, Benumof JL. Oro- and nasogastric tube passage in intubated patients: fiberoptic description of where they go at the laryngeal level and how to make them enter the esophagus. Anesthesiology. 1999;91(1):137–143.
4. Appukutty J, Shroff PP. Nasogastric tube insertion using different techniques in anesthetized patients: A prospective, randomized study. Anesth Analg 2009 Sep;109(3):832–35.
5. McConnell EA. Inserting a nasogastric tube. Nursing 1997 Jan;27(1):72.
6. Illias AM, Hui YL, Lin CC, et al. A comparison of nasogastric tube insertion techniques without using other instruments in anesthetized and intubated patients. 2013 Sep-Oct;33(5):476–81.
7. Hung CW, Lee WH. A novel method to assist nasogastric tube insertion. Emerg Med J 2008 Jan;25(1):23–25.
8. Tai CM, Wang HP, Lee CT, et al. Esophageal obstruction by a tangled nasogastric tube. Gastrointest Endosc 2010 Nov;72(5):1057–1058.
9. Agarwal A, Gaur A, Sahu D, Singh PK,

Pandey CK. Nasogastric tube knotting over the epiglottis: a cause of respiratory distress. Anesth Analg. 2002;94(6):1659–660.

10. Ghatak T, Samanta S, Baronia AK. A new technique to insert nasogastric tube in an unconscious intubated patient. N Am J Med Sci 2013 Jan;5(1):68–70.
11. Kirtania J, Ghose T, Garai D, et al. Esophageal guidewire-assisted nasogastric tube insertion in anesthetized and intubated patients: A prospective randomized controlled study. Anesth Analg 2012 Feb;114(2):343–48.
12. Fakhari S, Bilehjani E, Negargar S, et al. Split endotraceal tube as a guide tube for gastric tube insertion in anesthetized patients: A randomized clinical trial. J Cardiovasc Thorac Res 2009;1:17–22.
13. Kwon OS, Cho GC, Jo CH, et al. Endotracheal tube - assisted orogastric tube insertion in intubated patients in an ED. Am J Emerg Med 2015 Feb;33(2):177–80.
14. Christian Alflen, Marc Kriege, Irene Schmidtmann, et al. Orogastric tube insertion using the new gastric tube guide: First experiences from a manikin study. BMC Anesthesiology 2017 Apr 4;17(1):54.
15. Mandal MC, Dolai S, Ghosh S. Comparison of four techniques of nasogastric tube insertion in anesthetized, intubated patients: A randomized controlled trial. Indian J Anesth 2014;58:714–18.
16. Ratzlaff HC, Heaslip JE, Rothwell ES. Factors affecting nasogastric tube insertion. Crit Care Med. 1984;12(1):52–53.
17. Flegar M, Ball A. Easier nasogastric tube insertion. Anesthesia 2004 Feb;59(2):197.
18. Gombar S, Khanna AK, Gombar KK. Insertion of a nasogastric tube under direct vision: Another atraumatic approach to an age-old issue. Acta Anesthesiol Scand 2007 Aug;51(7): 962–96.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 70-78
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.11

Comparison of Volume Controlled Ventilation with Pressure Controlled Ventilation During Lumbar Spine Surgery in Prone Position: A Randomized Controlled Study

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Abstract

Background: Different modes of mechanical ventilation such as volume controlled ventilation (VCV) and Pressure Controlled Ventilation (PCV) are deployed to balance respiratory mechanics, gas exchange and hemodynamics in patients undergoing lumbar spine surgeries in prone position. *Methods:* This prospective study included 72 patients undergoing lumbar spine surgeries in prone position. They were randomized to two Groups – Group V (who received volume controlled ventilation) and Group P (who received pressure controlled ventilation). The ventilation and hemodynamic parameters were statistically analyzed at 5 min after intubation in supine (S5), 60 min after prone (P60) and 180 min after prone (P180) position. Oxygenation parameters were assessed from ABG in supine (baseline) and at the end of surgery in prone position. Chi-square, independent *t*-test and ANOVA were used to compare the data between the two groups. *Results:* Demographics, oxygenation and hemodynamics were comparable between the two groups. P peak and P mean increased from supine to prone position in both the groups. The P peak in VCV was higher than PCV in prone position and the difference was significant at first hour [$p = 0.008$] . The dynamic compliance (Cdyn) decreased in both PCV and VCV from supine to prone position. There was significant increase in Cdyn in PCV at the end of first hour in prone position ($p = 0.005$). Vte, MV, PEEP, RR, $EtCO_2$ and V_D/V_T did not show any significant difference between the groups ($p > 0.05$). *Conclusion:* Both VCV and PCV can be safely used to ventilate patients in prone position undergoing lumbar spine surgeries.

Keywords: Prone position; Mechanical ventilation; Volume controlled ventilation; Pressure controlled ventilation; Hemodynamics.

How to cite this article:
M Manjuladevi, Surekha G, Surbhi Gupta, et al. Comparison of Volume Controlled Ventilation with Pressure Controlled Ventilation During Lumbar Spine Surgery in Prone Position: A Randomized Controlled Study. Indian J Anesth Analg. 2020;7 (1 Part -I):70–78.

Introduction

Prone position is needed for surgical exploration during spine surgeries done by posterior approach. During general anesthesia, changing from supine to prone position may have adverse effects on oxygenation, ventilation and circulation. Prone position interferes with lung mechanics by decreasing the pulmonary compliance and increasing the airway pressure.[1–3] High airway pressure may in turn impair venous return to heart, decrease cardiac output and increase the systemic venous pressure. High pressure in epidural veins increases surgical bleeding which can be accentuated if patient is improperly positioned.[4]

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Received on 25.09.2019, **Accepted on** 02.11.2019

In anesthetized patients, different modes of mechanical ventilation such as Volume Controlled Ventilation (VCV) and Pressure Controlled Ventilation (PCV) are deployed to balance respiratory mechanics, gas exchange and hemodynamics. Ventilator induced lung injury could be triggered by volutrauma, atelectrauma and biotrauma. This has been more significant in obese, laparoscopic surgeries, one lung ventilation and specific patient positions.[3,5,6] Very few studies have compared the two Modes – PCV and VCV in surgeries conducted in different positions.[1,7,8] The advantage of PCV over VCV in improvement of oxygenation and ventilation has shown inconsistent results. In our study, primary aim was to compare the effects of PCV with VCV on lung mechanics and gas exchange using ventilation and oxygenation parameters till the end of surgery. Secondary objective was to evaluate the effect of these two modes of ventilation on hemodynamic changes. We hypothesized that the PCV is a superior ventilation mode to VCV in lumbar spine surgeries done in prone position.

Materials and Methods

This prospective, unblinded randomized controlled study was conducted from November 2013 to November 2015 in a tertiary care hospital. The study protocol was approved by the Institutional Review Board (148/2013) and was registered at CTRI.gov.nic.in (CTRI/2018/01/011216).

Seventy two American Society of Anesthesiologists (ASA) Physical Status I and II patients, aged 18–65 years belonging to either sex scheduled for lumbar spine surgeries to be conducted in prone position under General Anesthesia [GA] were included in the study. Patients who were unwilling for study, with Body Mass Index (BMI) > 30, documented autonomic neuropathy, obstructive or restrictive lung diseases, serum creatinine > 1.5 mg%, received steroid supplementation and who were having repeat spine surgeries were excluded from the study. Preanesthetic evaluation was done on the previous day of surgery. All patients were fasted overnight and premedicated with Tab. Pantaprazole 40 mg and Tab. Alprazolam 0.5 mg on the night before surgery. Randomization was done using computer generated table and opaque sealed envelope was used for allocation (Figure 1). Patients were categorized to Group V – (patients who received volume controlled ventilation or Group P –(patients who received pressure controlled ventilation). The required sample size was derived based on a pilot study that estimated mean difference in peak airway pressure (P peak) of 5 cm H_2O in the two desired Groups (mean ± standard deviation in Group V was 21.4 ± 4.16 cm H_2O and Group P was 19.2 ± 2.41 cm H_2O). With 80% power and 5% level of significance, the sample size was estimated to be 36 patients in each group, (Table 1).

In the operation theatre, patients were connected to standard monitors (electrocardiography,

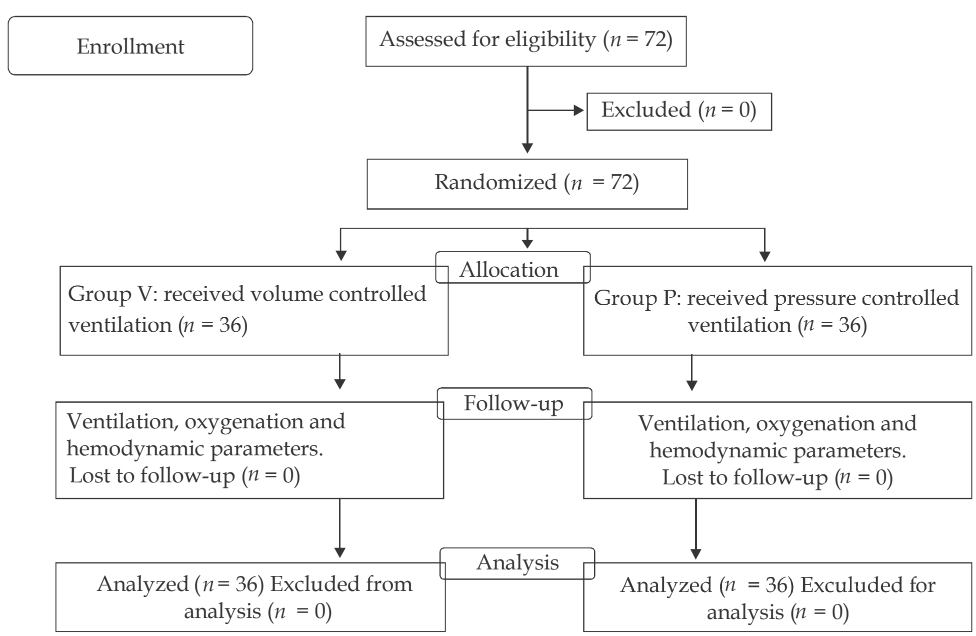

Fig. 1: Consort diagram

Table 1: Descriptive statistics

Variables	Group P (*n* = 36)	Group V (*n* = 36)	*p* - value
Age (years)	47.6 ± 12.4	45.6 ± 10.7	0.52
Sex, *n* (%)			
Male	16 (44.4)	13 (36.1)	0.47
Female	20 (55.6)	23 (63.9)	
BMI (kg/m^2)	24.5 ± 3.8	24.4 ± 4.2	0.97
Duration of surgery (minutes)	193.14 ± 64.47	195.42 ± 64.82	0.88

BMI- Body mass index

noninvasive blood pressure, capnography and pulse oximetry) and an intravenous (IV) access was secured. After optimal preoxygenation, they were premedicated with IV midazolam 1 mg, glycopyrrolate 0.2 mg and fentanyl 2 μg/kg. Induction was done with propofol 2 mg/kg or till the loss of verbal contact and atracurium 0.6 mg/kg. Appropriate sized endotracheal tube was placed, position confirmed and secured. Patients were then ventilated with oxygen - nitrous oxide - isoflurane mixture and received either VCV or PCV. An Arterial Blood Gas (ABG) was done and the same was considered as baseline for comparison with ABG on prone position.

We used longitudinal bolsters which partially compressed the chest, abdomen was kept free, pelvis was partially supported and legs were positioned at heart level. Eyes and peripheral pressure areas were adequately padded. All patients were ventilated with Anesthesia workstation (Datex Ohmeda Aestiva/5®; GE Healthcare, Finland), tidal volume (Vt) in VCV and P peak in PCV were adjusted to deliver Vt of 8 ml/kg ideal body weight and Respiratory Rate [RR] in both Groups were adjusted to keep end tidal carbon oxide ($EtCO_2$) between 33–36 mm Hg. Both the Groups had standardized ventilatory settings with Fractional inspired oxygen concentration (FiO_2) of 0.4, Positive End Expiratory Pressure (PEEP) of 5 cm H_2O and Inspiratory: Expiratory time (I:E) of 1:2 ratio. Anesthesia was maintained with Nitrous oxide - oxygen, Isoflurane, atracurium and morphine. Inhalational agents and fluids were titrated to keep mean arterial pressure within 20% of baseline. Hourly urine output and estimated blood loss during surgery were noted. Normothermia was maintained throughout surgery. Ventilation, oxygenation and circulation variables were measured every 10 min for first half hour and then every 30 min until end of surgery. At the end of surgery, ABG was taken and the patient repositioned to supine position. Adequate reversal was done with IV neostigmine 50 mcg/kg and glycopyrrolate 10 mcg/kg and the patient was extubated. The patient was monitored in the recovery room and shifted to the ward once stable.

The following variables were recorded during the study:

(a). Ventilation and Oxygenation parameters –

Peak airway pressure (P peak), mean airway pressure (P mean), PEEP, $EtCO_2$, exhaled tidal volume (Vte), RR, Minute Ventilation (MV), dynamic compliance of the respiratory system (C_{dyn}). The partial pressure of arterial oxygen (PaO_2), the ratio of PaO_2 to fractional inspired oxygen concentration (PaO_2/FiO_2) and ratio of alveolar dead space to tidal volume ratio (V_D/V_T) were derived from the ABG.

(b). Hemodynamic data – Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP), Heart Rate (HR) were recorded.

Data was tabulated in excel sheet and the parameters were statistically analyzed at 5 min after intubation (S_5) in supine position (baseline) and at one hour (P_{60}) in prone position and at three hours (P_{180}) of prone position. Statistical analysis was done using SPSS version 18 (SPSS Inc, Chicago, Illinois, USA). Descriptive statistics were summarized for continuous (mean and standard deviation) and categorical (counts with percentages) variables. Chisquare test was used to test the association between the categorical variables. Data between groups were compared using an independent t-test. Respiratory and hemodynamic changes after prone position within the group were compared using paired t-test. Repeated measures ANOVA were used to compare the hemodynamic parameters between the two Groups over time. $p < 0.05$ was considered statistically significant.

Results

The demograhics (Age, Sex, BMI) and duration of surgery were comparable in both the groups. P peak and P mean increased from supine to prone position in both the groups. The P peak in VCV was higher than PCV in prone position and the difference was significant at first hour ($p = 0.008$) and stabilised by end of surgery ($p = 0.29$). The Cdyn decreased in both PCV and VCV from supine to prone position. In prone position, there was significant increase in Cdyn in PCV at the end of first hour ($p = 0.005$) and stabilized thereafter, ($p = 0.59$). However, Vte, MV, PEEP, RR, $EtCO_2$, and V_D/V_T did not show any significant difference between the groups ($p > 0.05$). The oxygenation parameters (PaO_2, PaO_2/FiO_2) and hemodynamics (HR, SBP, DBP and MAP) were also comparable in both the Groups. There was no significant difference in estimated blood loss between the Groups.

Discussion

Optimization by various modes of ventilation such as VCV, PCV and pressure controlled ventilation with volume guarantee (PCV-VG) has been a topic of debate. Hemodynamics, gas exchange, mechanical properties of lung and chest wall are considered to guide the mechanical ventilation strategies.[9] Traditionally, VCV has been used in the OT for all types of surgeries. The recent availability of anesthesia ventilators with pressure control modes has made effective ventilation possible even in noncompliant lungs such as chronic obstructive lung diseases (COPD) patients, thoracic surgery or intensive care unit (ICU) patients with respiratory diseases.

VCV uses a constant flow to deliver Vt resulting in high airway pressure, decreased compliance in chest wall and lung, reduced functional residual capacity impairing alveolar ventilation as in laparoscopic surgeries and leading to acute lung injury.[5,10] It does not compensate for leaks and varies with changes in airway resistance, lung compliance and integrity of the ventilator circuit. In comparison, PCV maintains the pressure gradient in proximal airway and alveoli with initial high speed flow which allows recruitment of even the unstable alveoli. The deceleration following this keeps inspiratory pressure constant and allows redistribution of Vt in alveoli with different time constants.[11] PCV provides a lower P peak and higher P mean. It reduces intrathoracic pressure and pulmonary vascular resistance and improves right ventricular function.[12] Thus, PCV has advantage of improving ventilation perfusion ratio and oxygenation. However, it does not guarantee minute ventilation, and therefore, requires more monitoring by the operator. P peak reflects the dynamic compliance of the respiratory system whereas, the plateau pressure reflects the static compliance. P mean is the average pressure of the respiratory system throughout inspiration and determines recruitment of collapsed alveoli and redistribution of blood flow and adds as a critical factor for gas exchange.

In anesthetized patients, mechanical ventilation maintains adequate gas exchange through out the intraoperative period. Prone position during general anesthesia interferes with respiratory mechanics and improves oxygenation.[13] The results in our study, showed that when compared to supine, P peak was increased by 4.6% in prone position at first hour and by 3% in third hour in VCV Group and was comparable at both time points in PCV Group. However, the increase in P peak was lesser in PCV compared to VCV and showed statistical significance at first hour $p = 0.008$. When compared to supine position, Cdyn decreased by13.9% in first hour and 10.4% in third hour of prone position in VCV Group. The decrease was 10% in first hour and by 13% in third hour of prone position in PCV Group. The decrease was more in VCV compared to PCV and showed statistical significance at first hour between the two groups ($p = 0.005$). Between the groups, none of them showed any clinical significance in oxygenation, elimination of carbon dioxide and the physiological dead space ($p > 0.05$). At 30 min after prone position, Jo et al. found decrease of Cdyn by 17% in VCV and 23% in PCV and a similar (< 2%) increase in P peak and P mean in both the groups.[1] Palmon et al. found increase in P peak and decrease in Cdyn and attributed the change in pulmonary mechanics to the frame used for positioning rather than body habitus. Greater compromise in ventilatory function was seen more on Wilson frame and chest rolls rather than Jackson table.[14] Results were similar in one lung ventilation in prone position for robot assisted esophagectomy[8], anterior cervical discectomy and fusion surgery in supine position[15] and laparoscopy cholecystectomy in reverse trendenlenberg position.[16] Tan et al. found PCV beneficial for one lung ventilation during radical resection of pulmonary carcinoma by video assisted thoracoscopic procedure. It reduced P peak and levels of proinflammatory markers thereby reducing airway injury.[17] Significant advantage of Cdyn with PCV was noted in different positions. In steep trendelenburg position for robot assisted laparoscopic radical prostatectomy, the Cdyn (mean ± SD) in PCV was 18.6 ± 3.6 ml/cm H_2O and in VCV was 15.5 ± 1.8 ml/cm H_2O.[7] The surgeries with prone position as in robot assisted radical esophagectomy during one lung ventilation, the Cdyn was 24.3 ± 6.6 ml/cm H_2O in PCV and 22.9 ± 4.3 ml/cm H_2O in VCV and in lumbar spine surgeries 44 ± 8.2 ml/cm H_2O in PCV and 39.1 ± 6.8 ml/cm H_2O in VCV.[1,8] However, pooled analysis of seven studies in meta-analysis showed no significant difference in dynamic compliance (WMD, 2.81 ml/cm H_2O, 95% CI – 1.68–3.95; $p <$ 0.05) between the two groups.[18]

The p peak (mean ± SD) was 29 ± 5.8 cm H_2O in PCV and 35.7 ± 4.7 cm H_2O in VCV in steep Trendelenburg position and 26.5 ± 6.06 cm H_2O in PCV and 29.5 ± 5.9 in VCV in prone position in the robot assisted surgeries.[7,8] In prone position of spine surgeries, it was 14.4 ± 2.3 cm H_2O in PCV and 16.9 ± 2.5 cm H_2O in VCV.[1] These studies favored PCV over VCV. PCV reduced the p peak and Plateau airway pressure (WMD, -1.16 cm H_2O, 95% CI -2.11 to -0.20; $p = 0.02$). The pooled analysis of 25 studies in the meta-analysis also showed a significant difference between the groups (WMD, -4.34 cm H_2O, 95% CI -5.25 to -3.42; $p < 0.05$).[18]

Meta-analysis showed PCV is more efficient in eliminating carbon dioxide as it facilitates the recruitment of unstable alveoli and allows equitable distribution of Vt thereby, recruiting more alveoli in gas exchange. The high Vt to maintain acceptable $PaCO_2$ in VCV on the other hand may overdistend the lung region not involved in gas exchange. The newer mode PCV-VG used in the recent times has the benefits of both PCV and VCV. It's a variant of PCV (decelerating flow with constant pressure) which changes to constant flow ventilation (VCV) when the targeted Vt is not achieved in PCV.[15] The compliance of the lung is calculated and the lowest possible pressure to deliver set targeted Vt is achieved.[16]

Provhilo trial did not show any benefit with low and high PEEP in lower abdominal surgeries.[19] In our study, we had standardized PEEP to 5 cm H_2O in all patients and did not find any difference at any time points in both the groups. The driving pressure (Δ P) of the respiratory system is defined as the difference of plateau pressure of airway at end inspiration and PEEP (Δ P = P plat – PEEP). In a retrospective data on 109, 360 adults, postoperative pulmonary complications (reintubation, pulmonary edema, pulmonary failure and pneumonia) was associated more with PCV compared to VCV due to more varied driving pressures and tidal volumes exacerbated by low or no PEEP (Odds ratio with driving pressure ≤ 19 cm H_2O was 1.37, $p < 0.001$ and in Δ P ≥ 19 cm H_2O was 1.16 , $p = 0.011$ with a relative risk of 1.18, $p = 0.016$)[20] Since, Δ P indicates severity of lung disease and is associated with complications and mortality, Pelosi et al. recommended to use Δ P to individually optimize mechanical ventilation.[9]

Oxygenation parameters

Oxygenation depends on inspired oxygen concentration, alveolar ventilation and intrapulmonary shunts which were all well maintained in the prone position in our study.

P mean determines the distribution of ventilation and recruitment of collapsed alveoli and is important factor for gas exchange.[21] There was statistical significance observed in the P mean ($p < 0.05$) between the two groups at one hour after prone position. The PEEP remained insignificant at all time points. However, there was no beneficial clinical effect on oxygenation between the groups observed in our study (PaO_2/FiO_2 and PaO_2 showed no significance). Though, no extrinsic PEEP was added to their subjects on lumbar spine surgeries in prone position, Jo YY et al. did not observe any significance.[1] In anterior spine surgeries, the PaO_2/FiO_2 ($p = 0.8$) and oxygenation index ($p = 0.6$) were comparable in both groups.[15] The oxygenation was well-maintained in patients in laparoscopic cholecystectomy (head up position) irrespective of VCV, PCV, PCV-VG mode of ventilation.[16] In contrast, PCV showed better oxygenation than VCV in obese patients with bariatric surgeries.[22,23] This maybe attributed to the higher ventilation perfusion mismatch in obese patients with pneumoperitoneum. PCV mode did not show any superiority over VCV to improve oxygenation in radical resection of pulmonary carcinoma by video assisted thoracoscopic surgery, indicating that body position, anesthetic drugs (hypoxic pulmonary vascular constriction) and anesthetic methods used are also responsible to the events of intraoperative or postoperative hypoxemia.[17] Though meta-analysis on twenty two studies showed significant difference in P mean in both the groups, the sub-group analysis on different positions such as steep trendelenberg and prone position did not show any significant difference.[18]

Hemodynamic parameters

Along with mechanical ventilation strategies, currently other preoperative and intraoperative techniques are also used to reduce blood loss and transfusion requirements such as cell saver, recombinant factor VIIa, and perioperative antifibrinolytic agents (such as aprotinin, tranexamic acid, epsilon-aminocaproic acid).[24] Hemodynamic changes occur from supine to prone position which is attributed to raised intraabdominal pressure (IAP) causing decreased venous return and ventricular compliance. Raised IAP causes epidural venous system congestion, increases blood loss and prolongs surgical time during spine surgery.[4,25] Also, the high venous pressure may result in decreased spinal cord perfusion pressure (MAP - Spinal venous pressure) and increases the risk of neurological complications.[14]

The increase in P peak, and P plateau maybe noticed in improper position and obese individuals. Koh et al. concluded such increase may predict and correlate to intraoperative surgical blood loss (p peak $R^2 = 0.405$ and P plat R^2 is 0.489).[4] Increase in Peak inspiratory pressure is attributed not only to decrease in lung and chest compliance, but also increase in airway resistance caused by drainage of secretive fluids due to gravity from change in body position, location and kink of endotracheal tube.[2] Respiratory dynamics using P peak, and Cdyn were evaluated between the two modes of ventilation in our study. There was a decrease in P peak and increase in Cdyn in PCV compared to VCV at the end of 1 hour which was statistically significant between the groups, (Table 2).

Table 2: Ventilatory parameters

Variables	Time (minutes)	Group P	Group V	p - value
P peak ($cm\ H_2O$)	S5	17.8 ± 3.2	17.5 ± 3.5	0.75
	P60	19.2 ± 2.4	21.4 ± 4.2	0.008**
	P180	19.5 ± 2.4	20.5 ± 3.6	0.29
P mean ($cm\ H_2O$)	S5	9.6 ± 3.2	8.4 ± 2.4	0.08
	P60	10.4 ± 2.4	9.2 ± 2.8	0.05*
	P180	9.9 ± 2.4	9.0 ± 2.6	0.22
PEEP ($cm\ H_2O$)	S5	4.43 ± 0.91	4.03 ± 1.05	0.09
	P60	4.43 ± 0.94	3.97 ± 1.05	0.06
	P180	4.45 ± 0.96	3.92 ± 1.08	0.22
C dyn ($ml/cm\ H_2O$)	S5	40.4 ± 11.1	37.8 ± 11.1	0.33
	P60	33.9 ± 7.5	29.3 ± 5.8	0.005**
	P180	31.7 ± 6.7	30.4 ± 8.1	0.59
Vte (ml)	S5	510.9 ± 78.5	499.0 ± 58.3	0.47
	P60	482.9 ± 108.7	503.8 ± 59.6	0.32
	P180	484 ± 58.0	458.4 ± 115	0.36
MV (L/min)	S5	6.18 ± 1.08	6.13 ± 1.16	0.19
	P60	6.09 ± 1.25	5.88 ± 1.10	0.76
	P180	5.94 ± 1.11	5.83 ± 1.25	0.31
RR (rpm)	S5	12.5 ± 1.3	12.6 ± 1.2	0.63
	P60	12.4 ± 1.16	12.0 ± 1.9	0.34
	P180	12.3 ± 1.4	12.2 ± 1.8	0.96
$EtCO_2$ (mm Hg)	S5	32.7 ± 3.6	32.8 ± 5.0	0.98
	P60	30.7 ± 3.6	29.9 ± 3.1	0.32
	P180	31.0 ± 3.8	31.4 ± 3.6	0.47

*Peak airway pressure (P peak), *Mean airway pressure (P mean), Positive End Expiratory P (PEEP), *Dynamic Compliance of the Respiratory system (C_{dyn}), Exhaled Tidal Volume (V_{te}), Minute Ventilation (MV), Respiratory Rate (RR), End Tidal Carbon Oxide ($EtCO_2$). S5 - 5 minutes in Supine Position, P60 - 60 minutes in Prone, P180 – 180 minutes in Prone Position.

Table 3: Hemodynamic parameters

Variables	Time	Group P	Group V	p - value
HR (bpm)	S5	86.0 ± 17.4	91.2 ± 17.7	0.21
	P60	73.6 ± 17.5	78.1 ± 11.7	0.21
	P180	69.3 ± 14.2	75.3 ± 14.6	0.17
SBP (mm Hg)	S5	110.3 ± 17.0	111.1 ± 20.6	0.86
	P60	101.6 ± 15.6	98.8 ± 10.2	0.37
	P180	106.8 ± 18.2	102.4 ± 17.5	0.42

Variables	Time	Group P	Group V	p - value
DBP (mm Hg)	S5	70.37 ± 11.98	68.81 ± 10.34	0.55
	P60	66.5 ± 14.9	68.3 ± 7.5	0.52
	P180	69.1 ± 8.7	68.4 ± 8.5	0.77
MAP (mm Hg)	S5	80.9 ± 15.0	84.6 ± 14.5	0.30
	P60	79.6 ± 12.5	78.9 ± 7.8	0.77
	P180	79.2 ± 8.6	76.8 ± 7.6	0.34

Heart Rate (HR), Systolic BloodP (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP)

Table 4: ABG derived parameters

Variables	Position	Group P	Group V	p - value
PaO_2 (mm Hg)	Supine	217.26 ± 83.69	244.08 ± 119.72	0.27
	Prone	235.51 ± 99.99	211.05 ± 94.81	0.29
$PaCO_2$ (mm Hg)	Supine	38.31 ± 7.12	38.03 ± 5.96	0.85
	Prone	35.88 ± 5.17	37.66 ± 4.89	0.13
PaO_2/FiO_2	Supine	426.15 ±182.12	428.87 ± 132.51	0.94
	Prone	454.46 ± 212.46	406.9 ± 157.79	0.29
V_D / V_T	Supine	0.136 ± 0.09	0.149 ± 0.11	0.60
	Prone	0.198 ± 0.14	0.163 ± 0.11	0.26
Hb gm%	Supine	12.31 ± 1.86	12.45 ± 2.19	0.78
	Prone	11.06 ± 1.82	11.05 ± 1.68	0.98

Comparison of parameters in Supine at 5 min (baseline) and end of surgery in prone position. Partial pressure of arterial oxygen (PaO_2), partial pressure of arterial carbon dioxide ($PaCO_2$), ratio of partial pressure of arterial oxygen to fractional inspired oxygen concentration (PaO_2/FiO_2) and ratio of alveolar dead space to tidal volume ratio (V_D /V_T).

In our healthy patients, there was no clinical and statistical difference in hemodynamic parameters, (Table 3), estimated blood loss (mean ± SD, Group P - 457.35 ± 206.75 ml, Group V 504.29 ± 191.5 ml; p = 0.33), or Hemoglobin in both the groups. The alterations may produce a significant hemodynamic effect in patients with limited cardiac reserve[26] (Table 4).

The transthoracic echocardiography (TTE) findings in positioning prone with longitudinal bolsters showed that the inferior vena cava compression decreased the venous return and increased intrathoracic pressure and decreased the left ventricular compliance.[27] Sreenivasa et al. in their Transesophageal Echocardiography (TEE) study comparing five different positioning systems (Siemens frame, Andrews frame, Wilson frame, Jackson frame and the bolster system) found the Jackson frame and bolsters had the least effect on cardiac performance. Cardiac output decreased with Wilson, preload decreased with Andrews, cardiac index and stroke volume decreased in Siemens,Wilson and Andrew frames. They also found that adequate fluid resuscitation after a presurgical fast reduced changes in blood pressure and heart rate after prone position.[26] Based on this, all patients were also given 500 ml crystalloid before they were turned prone in our study. Inspite of longitudinal bolsters which had partial pressure on the chest, the hemodynamic changes did not show any significance between the two modes of ventilation in this study.

Cardiac, hemodynamic and respiratory variables are thus used to predict intraoperative surgical blood loss. Proper positioning with no/minimal compression on abdomen and chest is mandatory. Vigilant monitoring of adequate tidal volume, respiratory rate, peak airway pressure and lung compliance is therefore, required by the clinician irrespective of the ventilator mode (volume *vs* pressure controlled ventilation). The limitations in our study was that ours was a single centre study done on patients with normal lungs. We did not follow up for postoperative pulmonary complications or oxygenation index either. The same results cannot be extrapolated to diseased lung patients. More randomized studies involving not only indices but also postoperative clinical outcomes are needed to make conclusions on which mode is superior. Currently, lung protective strategies using low Vt, longer inspiration time, appropriate PEEP and recruitment manoeuvres are conducive to improve respiratory mechanics in surgical patients.

Though beneficial effect of P peak, P mean and dynamic compliance was noted in PCV group in our study, there was no significant clinical difference of respiratory, oxygenation and hemodynamic parameters between PCV and VCV. In conclusion, both the modes can be safely used to ventilate patients in prone position undergoing lumbar spine surgeries.

References

1. Jo YY, Kim JY, Kwak YL, et al. The effect of pressure-controlled ventilation on pulmonary mechanics in the prone position during posterior lumbar spine surgery: A comparison with volume-controlled ventilation. J Neurosurg Anesthesiol 2012 Jan;24(1):14–18.
2. Nam Y, Yoon AM, Kim YH, et al. The effect on respiratory mechanics when using a Jackson surgical table in the prone position during spinal surgery. Korean J Anesthesiol 2010 Nov;59(5):323–28.
3. Tusman G, Böhm SH, Warner DO, et al. Atelectasis and perioperative pulmonary complications in high-risk patients. Curr Opin Anesthesiol 2012 Feb;25(1):1–10.
4. Jae Chul Koh, Jong Seok Lee, Dong Woo Han, et al. Increase in airway pressure resulting from prone position patient placing may predict intraoperative surgical blood loss. Spine 2013 May 15;38(11):E678–82.
5. Eichen berger A, Proietti S, Wicky S, et al. Morbid obesity and postoperative pulmonary atelectasis: An underestimated problem. Anesth Analg 2002 Dec;95(6):1788–792.
6. Manna EM, Ibraheim OA, Samarkandi AH, et al. The effect of prone position on respiratory mechanics during spinal surgery. Middle East J Anesthesiol 2005 Oct;18(3):623–30.
7. Choi EM, Na S, Choi SH, et al. Comparison of volume-controlled and pressure-controlled ventilation in steep Trendelenburg position for robot-assisted laparoscopic radical prostatectomy. J Clin Anesth 2011 May;23(3):183–88.
8. Choi YS, Shim JK, Na S, et al. Pressure-controlled versus volume-controlled ventilation during one-lung ventilation in the prone position for robot-assisted esophagectomy. Surg Endosc 2009 Oct;23(10):2286–291.
9. Paolo Pelosi and Lorenzo Ball. Should we titrate ventilation based on driving pressure? Maybe not in the way we would expect. Ann Transl Med 2018 Oct;6(19): 389.
10. Davis K Jr, Branson RD, Campbell RS, et al. Comparison of volume control and pressure control ventilation: Is flow waveform the difference? J Trauma 1996 Nov;41(5):808–814.
11. Campbell RS and Davis BR. Pressure-controlled versus volume-controlled ventilation: Does it matter? Respir Care 2002 Apr;47(4):416–24.
12. Al Shehri AM, El-Tahan MR, Al Metwally R, et al. Right ventricular function during one-lung ventilation: Effects of pressure-controlled and volume-controlled ventilation. J Cardiothorac Vasc Anesth 2014 Aug;28(4):880–84
13. Pelosi P, Croci M, Calappi E, et al. The prone positioning during general anesthesia minimally affects respiratory mechanics while improving functional residual capacity and increasing oxygen tension. Anesth Analg 1995 May;80(5):955–60.
14. Palmon SC, Kirsch JR, Depper JA, et al. The effect of the prone position on pulmonary mechanics is frame-dependent. Anesth Analg 1998 Nov;87(5):1175–180.
15. Moningi S, Elmati PK, Rao P, et al. Comparison of volume control and pressure control ventilation in patients undergoing single level anterior cervical discectomy and fusion surgery. Indian J Anesth 2017 Oct;61(10):818–25.
16. Kothari A, Baskaran D. Pressure-controlled volume guaranteed mode improves respiratory dynamics during laparoscopic cholecystectomy: A Comparison with conventional modes. Anesth Essays Res 2018 Jan–Mar;12(1):206–212.
17. Tan J, Song Z, Bian Q, et al. Effects of volume-controlled ventilation vs pressure-controlled ventilation on respiratory function and inflammatory factors in patients undergoing video-assisted thoracoscopic radical resection of pulmonary carcinoma. J Thorac Dis 2018 Mar;10(3):1483–489.
18. Jiang J, Li B, Kang N, et al. Pressure-controlled versus volume-controlled ventilation for surgical patients: A Systematic review and meta-analysis J Cardiothorac Vasc Anesth 2016 Apr;30(2):501–514.
19. Hemmes SN, Gama de Abreu M, Pelosi P, et al. High versus low positive end-expiratory pressure during general anesthesia for open abdominal surgery (Provhilo trial): A multicentre randomized controlled trial. Lancet 2014 Aug 9;384(9942):495–503.
20. Bagchi A, Rudolph MI, Ng PY, et al. The association of postoperative pulmonary complications in 109,360 patients with pressure-controlled or volume-controlled ventilation. Anesthesia 2017 Nov;72(11):1334–343.
21. Movassagi R, Montazer M, Mahmoodpoor A, et al. Comparison of pressure vs volume controlled ventilation on oxygenation parameters of obese patients undergoing laparoscopic cholecystectomy. Pak J Med Sci

2017 Sep–Oct;33(5):1117–122.

22. Cadi P, Guenoun T, Journois D, et al. Pressure-controlled ventilation improves oxygenation during laparoscopic obesity surgery compared with volume-controlled ventilation. Br J Anesth 2008 May;100(5):709–716.
23. Gupta SD, Kundu SB, Ghose T, et al. A comparison between volume-controlled ventilation and pressure-controlled ventilation in providing better oxygenation in obese patients undergoing laparoscopic cholecystectomy. Indian J Anesth 2012;(56):276–82.
24. Elgafy H, Bransford RJ, McGuire RA, et al. Blood loss in major spine surgery: Are there effective measures to decrease massive hemorrhage in major spine fusion surgery? Spine 2010 Apr 20;35(9 Suppl):S47–56.
25. Park CK. The effect of patient positioning on intraabdominal pressure and blood loss in spinal surgery. Anesth Analg 2000 Sep;91(3):552–57.
26. Dharmavaram S, Jellish WS, Nockels RP, et al. Effect of prone positioning systems on hemodynamic and cardiac function during lumbar spine surgery: An Echocardiographic Study. Spine 2006;31(12):1388–393.
27. Toyota S, Amaki Y. Hemodynamic evaluation of prone position by transesophageal echocardiography. J Clin Anesth 1998 Feb;10(1):32–35.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 79-86
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.12

Comparing Effect of 0.25% Bupivacaine and 0.5% Ropivacaine in Transversus Abdominis Plane Block for Postoperative Analgesia in Lower Abdominal Surgeries

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Abstract

Introduction: Wall of abdomen is a source of pain after abdominal surgeries. Even an operation such as inguinal herniorrhaphymay lead to chronic pain in patients. Lower abdominal surgeries are common surgical procedure with a rare postoperative morbidity. However, chronic pain and continuous neuralgia have been accepted as complications after lower abdominal surgeries. *Aims:* To compare Effect of 0.25% Bupivacaine and 0.5% Ropivacaine in Transversus abdominis plane block for postoperative analgesia in lower abdominal surgeries. *Materials and Methods:* This is was a prospective study conducted at during the period from June 2017 to May 2018. Sixty patients with ASA Grade I and II of 20 to 60 years age, undergoing inguinal hernia surgeries under spinal anesthesia were randomly alocated into Two Groups of 30 each, Group B - Bupivacaine 0.25% and Group R- Ropivacaine 0.5%. *Results:* Thus, the effect of Bupivacaine and Ropivacaine was comparable to each other suggesting that Bupivacaine and Ropivacaine have hemodynamic stability in TAP block. The duration of postoperative analgesia was for more than 24 hrs in Ropivacaine Group comparative to Bupivacaine has a postoperative analgesia for 8 hrs. *Conclusion:* TAP bock performed by landmark technique in patients undergoing lower abdominal surgeries with 0.5% ropivacainesingle injection of 0.5% ropivacaine gives prolonged postoperative analgesia, Reduces the doses of rescue analgesics in postoperative period.

Keywords: Abdomen; Ropivacaine; Bupivacaine; Inguinal hernia.

How to cite this article:

P Anand Vijaya Bhasker, Ramakrishna Shatagopam. Comparing Effect of 0.25% Bupivacaine and 0.5% Ropivacaine in Transversus Abdominis Plane Blockfor Postoperative Analgesia in Lower Abdominal Surgeries. Indian J Anesth Analg. 2020;7(1 Part -I):79–86.

Introduction

The wall of abdomen is a main source of pain after abdominal surgery. Even an operation such as inguinal herniorrhaphy may lead to chronic pain in patients, with clinically significant effects on daily tasks if postoperative pain is not taken care of. The pain perceived by patients after abdominal surgery is derived from the anterior abdominal wall incision. The anterior abdominal wall is innervated by nerve afferents that course through the transverses abdominis neurovascular fascial plane.

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Received on 04.10.2019, **Accepted on** 13.11.2019

Lower abdominal surgeries are common surgical procedure with a rare postoperative morbidity. However, chronic pain and continuous neuralgia have been accepted as complications after lower abdominal surgeries. The prominent factors linked with chronic pain that develop after inguinal hernia repair are asearly postoperative severe pain, repeated hernia operations and surgical technique.[1,2] The most important issue of interest among chronic pain developing mechanisms after lower abdominal surgeriesas a consequence of all these factors is damaged sensory nerves at the surgical site. Therefore, chronic pain originates after lower abdominal surgeries were accepted to be neuropathic. Pain after surgeries is more pronounced in the first two postoperative days pain is aggravated during mobilization or coughing, than during rest.

Many analgesic modalities are recommended to relieve the postoperative pain. The usual trend is to prescribe an opioid or a Nonsteroids Antiinflammatory Drugs (NSAID) for postoperative analgesia. Nonsteroid ant inflammatory drugs also have certain side effects like hemostasis alteration, renal dysfunction, gastrointestinal hemorrhage etc. Intravenous Opioids although provide satisfactory analgesia, but are associated with unwanted side-effects like respiratory depression, postoperative nausea and vomiting, prolonged sedation and immobilization. Epidural analgesia is generally used regional technique to alleviate pain but it need added care has it's own complications like total spinal anesthesia, intravascular injections, epidural hematoma and epidural abcess. The physiological side effects include hypotension, motor blockade, and urinary retention. It can also result in delayed mobilization and might be contraindicated in certain situations like coagulopathy, infection at the site of injection and raised intracranial pressure.[3] However, in regional analgesic technique, drugs have peripheral site of action, hence minimum systemic side effects.

Hence, regional analgesic technique has gained widespread acceptance as paramount component of postoperative analgesia regimen. Transversus Abdominis Plane Plock (TAPB) is gaining demand as one of such regional blocks. The Transversus Abdominis Plane (TAP) block is a regional anesthesia technique that lend analgesia to the parietal peritoneum as well as the skin and muscles of the anterior abdominal wall. It has been shown to be a safe and potent postoperative adjunct analgesia method in a variety of surgical procedures and it is proposed as part of the multimodal anesthetic approach to promote recovery after lower abdominal surgeries.[4]

Transversus Abdominis Plane Block (TAPB) can be performed through the lumbar triangle of Petit formed by external oblique muscle anteriorly, latissimus dorsi muscle posterior, iliac crest inferiorly and is usually identified as a defect 1 cm above the iliac crest in midaxillary line. The technique involves injection of local anesthetic towards the plane between the Transverses Abdominis Muscle (TAM) and internal oblique muscles. It allows sensory blockade of plexus of nerves supplying lower abdominal wall, muscles and skin *via* local anesthetic drug deposition above the TAM. The present study is to compare the duration of postoperative analgesia dealthby 0.25% bupivacaine and 0.5% ropivacaine used in TAPB for lower abdominal surgeries.

Materials and Methods

This prospective study was conducted during the period from June 2017 to May 2018. A total number of 60 patients undergoing elective lower abdominal surgeries (Unilateral inguinal hernia and open appendectomy) were studied.

Inclusion Criteria

Age between 20–60 years of either gender, American Society of Anesthesiologist (ASA) Grade I and II Patients posted for elective lower abdominal surgeries (Unilateral inguinal hernia and open appendectomy)under spinal anesthesia.

Exclusion Criteria

ASA Grade III and above, allergy to study drugs, history of abdominal surgeries, hematological disorders and emergency surgeries. All the patients were randomly allocated into Two Groups of 30 each using computer generated random numbers by simple randomization technique. In each Group of 25 members were posted for elective unilateral inguinal hernia surgeries and 5 members were posted for elective appendicectomy surgeries. Patient will be observed for 48 hours postoperatively. After the institutional ethics committee approval and written informed consent sixty ASA one or two patients aged between 20 and 60 years scheduled to undergo lower abdominal surgeries (Unilateral inguinal hernia and open appendectomy surgeries). Following a comprehensive preanesthetic evaluation all patients were told about visual analogue scale for pain (0-no pain,10-worst imaginable pain) in their own local language.

All patients were kept nil by mouth from midnight before surgery and tablet alprazolam (0.01 mg/kg) was administered at bed time, the day before surgery. All the patients were reexamined, reassessed and weighed preoperatively on the day of surgery. Intravenous access was established with a 18G intravenous cannula and preloading was done with 15 ml/kg lactated ringer's solution 30 minutes before procedure. Anesthesia machine and accessory anesthetic equipments were checked and drugs, including emergency drugs were kept ready. A multi parameter monitor for monitoring Heart Rate (HR), Noninvasive Blood Pressure (NIBP), Electro Cardiogram (ECG) and oxygen saturation (SpO_2) were attached to each patient on arrival to the operating room and baseline parameters were recorded.

All the patients were randomly divided into Two Groups of 30 each using computer generated random numbers by simple randomization approach. In Each Group 25 members were posted for elective unilateral inguinal hernia surgeries and 5 members were posted for elective appendicectomy surgeries–

Group B : Bupivacaine 0.25%;

Group R : Ropivacaine 0.5%.

Under strict aseptic conditions, with the patient in the lateral position, a lumbar puncture was performed at L3-L4 intervertebral space through midline approach using a 25-gauge Quincke spinal needle. After ensuring free flow of CSF, 0.5% heavy bupivacaine 3 ml was administered intrathecally in both the groups, the spinal injection rate of bupivacaine 0.5% was 1 ml in 3–4 seconds in all patients. Without any additive in lateral position without any table tilt.

At the end of the surgery Petit's triangle will be identified on the side of surgery as a defect of 1 cm above the iliac crest in midaxillary line between the fibers of external oblique and latissimus dorsi muscles. Under all aseptic precautions the block will be given through Petit' triangle with 23G spinal needle attached to a 20 ml syringe containing the drug as per the group allocation.

Needle will be introduced perpendicular to skin and advanced until two "POPS" or "give way" were felt. Then the drug will be injected in the fascial plane after aspiration.

Assessment of block was done by pinprick. Target height was T6. Patients were monitored intraoperatively. Hypotension was taken as fall in systolic blood pressure > 20% of baseline and was treated with incremental doses of Ephedrine 6 mg and bolus of 200 ml of Ringer Lactate. Bradycardia was taken as heart rate < 60 beats per minute and treated accordingly with intravenous glycopyrolate 0.2 mg. No analgesic or sedation was given to any patient intraoperatively. The anesthesiologist who observed the patients in postoperative ward was blinded to the drug injected in TAPB. Patient was monitored every 5 minutes for half an hour, then every 15 minutes till 2 hours and then at 4, 6, 12, 24, 48 hours postoperatively for heart rate, systolic blood pressure, diastolic blood pressure, pain and complications if any. Pain was assessed according to visual analog score from 0 to 10.

Patient was given rescue analgesia in the form of intramuscular diclofenac 75 mg at a visual analog pain score of ≥ 4 (i.e. minimal pain). The duration of analgesia in TAPB was treated to be from the time of recession of sensory level below T10 on the nonoperated side to pain score of 447 (i.e. minimal pain). Patient was also observed for any other postoperative complications like hematoma, flank fullness, etc.

Statistical Analysis

The mean of a collection of numbers is their arithmetic average, derived by adding them up and dividing by number of samples. The standard deviation is the root mean square deviation of the values from their arithmetic mean. In the present study, we used student's unpaired *t*-test for statistical analysis. It was used because two sets of population were compared which were independent and identically distributed. '*p*'-Value: It indicates the probability of error and a value less than 0.05 is considered statistically significant.

Results

Following were the observations and results of present study.

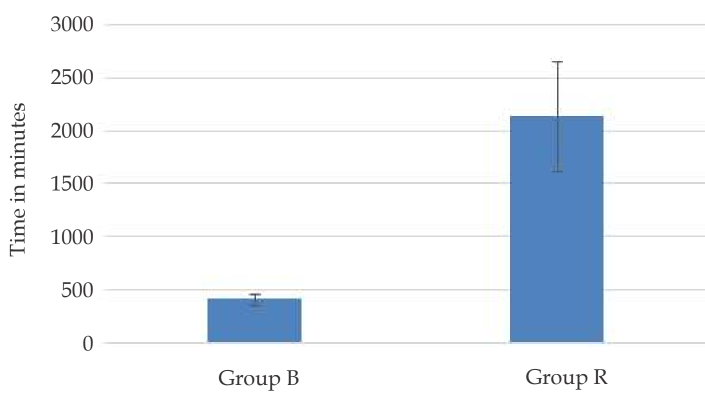
Age wise, weight wise, height distribution is similar in both the groups, Mean age, weight and height is comparable between both the groups (Table 1).

Duration of postoperative analgesia in Group B is 419 ± 49.95 minutes where as in Group R it is 2140 ± 511. 12 minutes which is highly significant compared to Group B. Difference in duration of postoperative analgesia between Two Groups is significant. (p–Value <0.0001). Duration of analgesia

Table 1: Demographic distribution in present study

Age in year	Group B (n = 30)	Group R (n = 30)
20–30	2 (6.67%)	3 (10.00%)
31–40	5 (16.67%)	4 (13.33%)
41–50	7 (23.33%)	8 (26.67%)
51–60	16 (53.33%)	15 (50.00%)
Mean age in years	51 + 9.6	50 + 9.4
p-Value	>0.05	
Weight in Kilograms		
40–50	10 (33.33%)	9 (30%)
51–60	10 (33.33%)	10 (33.33%)
61–70	5 (16.67%)	6 (20%)
71–80	5 (16.67%)	5 (16.67%)
Mean weight in years	56.6 + 8.98	57 + 8.9
p-Value	>0.05	
Height wise distribution in cms		
155–160	12 (40%)	14 (46.67%)
161–165	18 (60%)	16 (53.33%)
Mean weight in years	159.2 ± 3.16	159.5 ± 3.01
p–Value	>0.05	

p-value <0.05 is taken as significant.



p-value <0.05 is taken as significant.

Fig. 1: Comparison of duration of analgesia (mean±sd) in both.

is prolonged in Group R (ropivacaine) (Fig. 1).

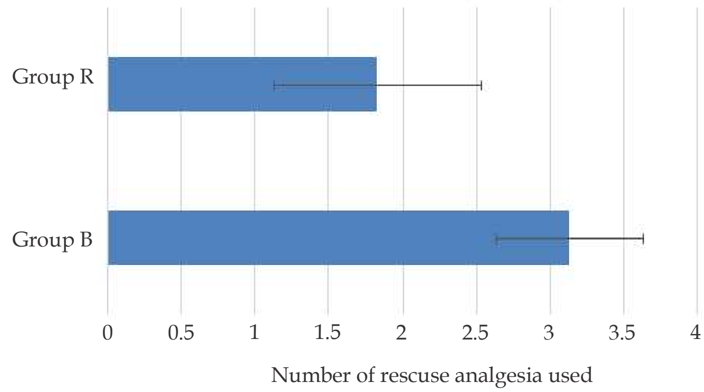
The patient were assessed for postoperative analgesia by visual analog scale. At visual analog pain score of 4 (i.e. minimal pain) patient received rescue analgesic in the form of intramuscular diclofenac 75 mg. Patients in Group B had pain relief for minimum period of 8 hrs postoperatively. Patients in Group R had postoperative analgesia for more than 24 hours (Table 2).

Table 2: Comparsion of VAS pain scores in Two Groups

Time	Group B Mean + SD	Group R Mean + SD	p-Value
0 min	0 ± 00	0 ± 00	.000
15 min	0 ± 00	0 ± 00	.000
30 min	0 ± 00	0 ± 00	.000
1 hr	0 ± 00	0 ± 00	.000
2 hr	0 ± 00	0 ± 00	.000
4 hr	0 ± 00	0 ± 00	.000

Time	Group B Mean + SD	Group R Mean + SD	*p*-Value
8 hr	3.4 ± 0.67	0 ± 00	.000
16 hr	4.33 ± 0.54	0 ± 00	.000
24 hrs	5.06 ± 0.63	2.76 ± 0.77	0.107
48 hr	6.26 ± 1.14	6.6 ± 0.89	0.213

p-value <0.05 is taken as significant.



p-value <0.05 is taken as significant.

Fig. 2: Comparision of number of rescue analgesics used (Mean ± SD) in Two Groups in 48 hours.

Patients in Group B required more rescue analgesics compared to Group R (Fig. 2).

Mean heart rates, systolic blood pressures and diastolic blood pressures are comparable between both the groups. They are not significant in between Groups (Table 3).

Table 3: Comparison of heart rate (Mean ± SD) in both groups

Time	Group B Mean+SD	Group R Mean + SD	*p*-Value
0 mins	77.86 ± 9.12	81.63 ± 1.63	.134
15 min	78.53 ± 9.13	82.33 ± 2.33	.113
30 min	78.86 ± 9.15	82.23 ± 2.23	.172
1 hr	81.13 ± 9.60	83.18 ± 3.10	.413
2 hr	79.86 ± 7.42	82.13 ± 2.13	.239
4 hr	79.33 ± 7.05	82.46 ± 2.46	.113
8 hr	81.4 ± 6.54	83.66 ± 3.66	.181
16 hr	79.33 ± 9.33	81.66 ± 1.66	.290
24 hr	79.26 ± 9.26	81.58 ± 1.50	.342
48 hr	78.47 ± 8.40	81.56 ± 1.56	.108
Systolic blood pressures			
0 mins	126.66 ± 10.07	125.93 ± 9.12	.770
15 min	127.33 ± 9.17	126.13 ± 9.13	.636
30 min	127.53 ± 9.67	125.86 ± 9.15	.535
1 hr	126.8 ± 8.82	124.86 ± 9.60	.453
2 hr	124.06 ± 7.33	123.33 ± 7.42	.649
4 hr	125.6 ± 8.01	125.53 ± 7.05	.821
8 hr	128 ± 6.43	127.06 ± 6.54	.615
16 hr	129.7 ± 7.80	128.8 ± 9.05	.592
24 hr	130.6 ± 8.37	129.6 ± 9.62	.610
48 hr	130.13 ± 7.44	128.46 ± 7.58	.521

Time	Group B Mean+SD	Group R Mean + SD	*p*-Value
Diastolic blood pressure			
0 mins	81.63 ± 10.07	77.86 ± 9.12	.134
15 min	82.33 ± 9.17	78.53 ± 9.13	.113
30 min	82.23 ± 9.67	78.86 ± 9.15	.172
1 hr	83.1 ± 8.82	81.13 ± 9.60	.413
2 hr	82.13 ± 7.33	79.86 ± 7.42	.239
4 hr	82.46 ± 8.01	79.33 ± 7.05	.113
8 hr	83.66 ± 6.43	81.4 ± 6.54	.181
16 hr	81.66 ± 7.80	79.33 ± 9.05	.290
24 hr	81.50 ± 8.37	79.26 ± 9.62	.342
48 hr	81.50 ± 8.37	79.26 ± 9.62	.521

p-value <0.05 is taken as significant.

Discussion

The gain of enough postoperative analgesia are clear and comprise a reduction in the postoperative stress response, postoperative morbidity and in certain types of surgery, bettered surgical outcome. Effective pain control also facilitates rehabilitation and hasten recovery from surgery. Other advantages of competent regional analgesic techniques include reduced pain intensity, reduced incidence of side effects from analgesics and improved patient comfort.

Dr. Reid renders two points, first refers to anatomy of the triangle of Petit. Dr. Rafi, an early collaborator with the first author (JMcD) in establish this block, was incorrect in stating that the floor of the triangle is set by the internal oblique muscle.[4,5] As stated the floor of the triangle of Petit is composed of fascial extensions of the external and internal oblique muscles.[5] The needle does not extend the external oblique muscle, but rather the fascial extensions of this muscle and the internal oblique. It is these fascial layers which present the "pop" sensation described when achieving the block. The needle then lies just lateral to the transversus abdominis, which is the correct position for the performance of the block.

The second point concerns the performance of the block in obese patients. We acknowledge that the triangle of Petit can be more difficult to locate in these patients. However, we have a high success rate with the block even in this group. However, we do recommend initially performing this block in patients with a normal body habitus, in order to gain experience with the block prior to moving onto patients that one might find more challenging. A number of maneuvers may aid palpation of the triangle in these patients. There is usually tenting of the adipose tissue at the pelvic rim, so that, this adipose fold can be "displaced" superiorly. Palpation can be further aided by having the patient lift their head off the bed which tenses the abdominal wall and makes the triangle easier to palpate. It is also worth remembering that palpation of the triangle of Petit can cause some discomfort, which can be used to confirm the location of the triangle. We are presently characterizing the utility of ultrasound, which may assist in locating the triangle, particularly in obese patients.

We agree with Dr. Tornero-Campello that the clinical utility of the transversus abdominis plane block can usefully be compared to epidural analgesia.[7] There is directly no reason to contend that the transversus abdominis plane block would provide superior analgesia to epidural blockade. There are number of patients undergoing abdominal surgery for epidural blockade is not adopted, due to contraindications such as sepsis or coagulopathy or to logistical issues such the lack of availability of the required postoperative monitoring. Therefore, epidural analgesia cannot be considered "standard care," but rather is the 'gold standard' for provision of postoperative analgesia. Furthermore, the transversus abdominis plane block can provide unilateral analgesia, an advantage in patients undergoing nonmidline abdominal incisions. In our study, we demonstrated that the transversus abdominis plane block substantially improves patient comfort when compared to patients who receive opioid-based postoperative analgesia. Therefore, at present we would recommend the transversus abdominis plane block for patients in whom epidural analgesia is not feasible for the reasons discussed earlier.

Using local anesthetic agents in Transverses Abdominis Plane Block (TAPB) is a simple and competent analgesic technique, applicable for surgical procedures where parietal pain is a significant component of postoperative pain. The ease of the procedure can also provide an advantage for clinical use.

In this study local anesthetic agents like 0.5% ropivacaine and 0.25% bupivacaine used in TAPB produced effecient and prolonged postoperative analgesia. The finding that a single-shot TAP technique using drugs like ropivacaine can produce effective analgesia for up to 48 h. The reasons for the prolonged duration of analgesic effect after TAP blockade are not entirely elucidated. However, this may relate to the fact that the TAP is relatively poorly vascularized, and therefore drug clearance may be slowed.[6]

Over the past 3 yrs, a series of studies have highlighted the value of efficacy of various local anesthetic agents in Transverses Abdominis Plane (TAP) block, after the initial description of the technique by Dr. Rafi.[5] TAP Block as described by Dr. Rafi involves identifying the neurovascular plane of the abdominal musculature and injecting a local anesthetic agent there in. He performed abdominal field block *via* the lumbar triangle without any untoward sequelae.

With the procedure of ultrasound guided nerve blockade gaining popularity, this technique was also practiced to injection of bupivacaine and ropivacaine in the TAP block.[6] However, injection *via*Petit's triangle using double POP technique resulted in reliable deposition into the transverses abdominis plane.[6] Moreover, it may not always be possible to use ultrasound guided techniques for administering TAPB where such facilities are not available. The landmark-based technique for the TAP block, have been performed without difficulty in the children. Alternative procedures to the TAP block using ultrasound guidance have newly been described in series of case in children undergoing inguinal hernia repair.[8] There are new variety of techniques for the TAP block and the analgesic merit of each will beclarified in ongoing studies. Although it is possible to ultrasonically visualize the three muscle layers of the abdominal wall, there variance in these muscle layers that can impede the use of ultrasound over the triangle of Petit.[9]

As a result, the point of insertion of needle as described in the ultrasound studies, which is dependent on the adequate identification of the 3 muscle layers, can vary. This will vary the location of the injectate as will the angle of the insertion of needle to skin, which deviate to the landmark approach's description. Although there is an ever-increasing access to ultrasound, it is far from universal and there is a continuing interest in marker techniques.[10]

Epidural ropivacaine was found to be significantly less effective than bupivacaine by a factor of 0.4, ropivacaine was 60% as potent as bupivacaine when used for epidural pain relief in labor analgesia. The analgesic potency of ropivacaine was 0.6 relative to bupivacaine.[11] So, the present study used 20 ml of either 0.25% bupivacaine or 0.5% ropivacaine drugs under study for use in unilateral TAPB considering ropivacaine to be approximately half as potent as bupivacaine (Table 2).

In the present study, mean age in the bupivacaine and ropivacaine groups was 51±9.6 and 50±9.4 years respectively. Mean age among the groups was comparable (Table 1). The mean age of patients in bupivacaine and ropivacaine groups of the present study is in accordance with those of Neha Fuladi 201434 (44.28 ± 16.04 and 47.56 ± 15.48) and Venkatesh Murthi et al. 201636 (57 ± 8.9 and 60 ± 9.3).[12,13]

In the present study, mean weight in the bupivacaine and ropivacaine groups was 56.6 ± 8.98 and 57.27 ± 8.94 kilograms respectively. Mean weight among the groups was comparable.

The mean weight of the patients in bupivacaine and ropivacaine groups of present study is in accordance with those Neha Fuladi 201434 (52.04±10.65 and 52.56 ± 6.87), Shradha et al. 201635 (54.15 ± 7.64 and 55.25 ± 6.45).[12]In the present study, mean height in the bupivacaine and ropivacaine groups was 159.2 ± 3.16 and 159.5 ± 3.01 centimeters respectively. Mean height among the groups was comparable (Table 1).

Mean height of patients in bupivacaine and ropivacaine groups of present study is in accordance with the studies of Shradha et al. 201635 (156 ± 7.64 and 155 ± 6.45).[12]

In present study, mean duration of analgesia in bupivacaine and ropivacaine groups was 419 ± 49.95 and 2140 ± 511.12 minutes respectively and it is prolonged in Ropivacaine group which is statistically significant ($p<0.05$) (Figure 1). The mean duration of analgesia in present study is in accordance with Neha Fuladi et al. 201434 (420.06 ± 14.1 and 2187 ± 1011.09).[12] Thus, it is seen that mean duration of analgesia is prolonged in Ropivacaine group as compared to control group.

The difference between the mean heart rate, mean systolic and diastolic blood pressure were found to be statistically nonsignificant between Group B and Group R at all periods of time (Table 3). Thus, the effect of bupivacaine and ropivacaine was found to be comparable suggesting that bupivacaine and ropivacaine have comparable hemodynamic stability in TAP block (Figure 2).

The findings of present study are in accordance to the study conducted by, Belavi et al. (2009), Neha fuladi (2014) and Venkatesh Murthi et al. (2016) stated that hemodynamic parameters were comparable and statistically in significant (p>0.05) in all the groups at any point of time with no statistical variation.[14,12,13]

The reasons for the prolonged duration of analgesia and hemodynamic stability after TAP blockade are not entirely elucidated. However, this may relate to the fact that the TAP is relatively poorly vascularized, and therefore, drug clearance may be slowed. In present study, no complications such as LA toxicity, liver trauma, local infection or hematoma were seen in any of the Two Groups. Present study with accordance to Neha fuladi (2014) and Shradhasinha et al. (2016) who also did not encounter any complications in their study.[12,15]

Conclusion

From the present study, we conclude that TAP bock performed by landmark technique in patients undergoing lower abdominal surgeries (unilateral inguinal hernia and open appendicectomy surgeries) with 0.5% ropivacaine has following advantages than 0.25% bupivacaine:

Single injection of 0.5% ropivacaine gives prolonged postoperative analgesia. Reduces the doses of rescue analgesics in postoperative period. Both the groups were hemodynamically stable. No complications were seen.

References

1. Callesen T, Bech K, Kehlet H. Prospective study of chronic pain after groin hernia repair. Br J Surg. 1999;86(12):1528–1531.
2. Cunningham J, TempleWJ, Mitchell P, et al. Cooperative hernia study: Pain in the postrepair patient. Ann Surg. 1996 Nov;224(5):598–602.
3. Christie IW, McCabe S. Major complications of epidural analgesia after surgery: Results of a six-year survey. Anesthesia 2007;62(4):335–41.
4. Reid SA. The transversus abdominis plane block. Anesth Analg. 2007 Jul;105(1):282.
5. Rafi AN. Abdominal field block: A new approach *via* the lumbar triangle. Anaesthesia. 2001 Oct;56(10):1024–1026.
6. McDonnell JG. The analgesic efficacy of transversus abdominis plane block after abdominal surgery: Aprospective randomized controlled trial. AnesthAnalg 2007;104:193–97.
7. Tornero-Campello G. Transversus abdominis plane block should be compared with epidural for postoperative analgesia after abdominal surgery. Anesth Analg. 2007 Jul;105(1):281–82.
8. Carney J, Finnerty O, Rauf J, et al. Ipsilateral transversus abdominis plane block provides effective analgesia after appendectomy in children: A randomized controlled trial. AnesthAnalg October 2010;111(4):998–1003.
9. Fredrickson M, Seal P, Houghton J. Early experience with the transversus abdominis plane block in children. PediatrAnesth 2008;18:891–92.
10. Loukas M, Tubbs RS, El-Sedfy A, et al. The clinical anatomy of the triangle of Petit. Hernia. 2007 Oct;11(5):441–44.
11. Capagna G, Celleno D, Fusc P, et al. Relative potencies fbupivacaine and ropivacaine for analgesia in labor. Br J Anesthesia 1999;82(3):371–73.
12. Fuladi Neha, Deshmukh Shubhada, Bhure Anjali. Comparative study of bupivacaine 0.25% *versus* ropivacaine 0.5% in transversus abdominis plane block for postoperative analgesia in lower abdominal surgeries. Journal of Evolution of Med and Dental Sci 2011;3(17):22784748.
13. Murthy K Thimmarayappa Venkatesh, MJ Sowmya, Maya D Sahajanandah. et al. Comparative study of injection 0.5% Bupivacaine and injection 0.75% Ropivacaine for their duration of anesthesia/analgesia in transversus abdominis plane block for unilateral inguinal hernia repair, Indian Journal of Clinical Anesthesia 2016;3(3):329–34.
14. Belavy D, CowlishawPJ, Howes M and Phillips F. Ultrasound-guided transversus abdominis plane block for analgesia after Cesarean delivery. British Journal of Anesthesia 2009;5(103):726–30.
15. Eichenberger U, Greher M, Kirchmair L, et al. Ultrasound-guided blocks of the ilioinguinal and iliohypogastric nerve: Accuracy of a selective new technique confirmed by anatomical dissection, Br JAnesth 2006;(97)238–43.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 87-92
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.13

Addition of Dexamethasone to Bupivacaine for Brachial Plexus Block in Patients Undergoing Upper Limb Surgeries

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Abstract

Introduction: Prolongation of analgesia after single shot Brachial Plexus Block (BPB) with local anesthetic remains a challenge. Dexamethasone prolongs duration of action of local anesthetic when used as an adjuvant. We aimed to determine the efficacy of dexamethasone after addition to bupivacaine for prolongation of analgesia & motor block in BPB. *Methods:* A prospective, randomized, double blind study was carried out in a tertiary care hospital during the period of May 2016 to January 2019. Patients (n = 50) between 18 and 70 years of age of either sex undergoing upper limb surgery were enrolled. Patients in Group I (n = 25) received 0.5% bupivacaine plus dexamethasone 8 mg and Patients in Group II (n = 25) received 0.5% bupivacaine plus 0.9% normal saline. Mean duration of analgesia, mean duration of motor block, onset of sensory block & onset of motor block were recorded. 'p' value less than 0.05 was taken as significant. *Results:* Demographic characteristics were comparable in both the study groups. The mean duration of analgesia was significantly longer in Group I as compared to Group II (748.5 ± 65.57 mins *vs* 555.4 ± 35.20 mins: $p < 0.05$). Group I showed significantly longer mean duration of motor block compared to Group II (814.3 ± 100.81 mins *vs* 690.3 ± 81.36 mins: $p < 0.05$). Similarly, the onset of motor block was significantly rapid in Group I as compared to Group II (13.04 ± 2.09 mins *vs* 14.52 ± 2.29 mins: $p < 0.05$). *Conclusion:* Dexamethasone as an adjuvant to bupivacaine in brachial plexus block significantly prolongs the duration of analgesia and motor block in patients undergoing upper limb surgery.

Keywords: Brachial Plexus Block; Bupivacaine; Dexamethasone; Local anesthetic.

How to cite this article:

Raj Kumar Pradhan, Janmejaya Sahoo, Ashwini Patil, et al. Addition of Dexamethasone to Bupivacaine for Brachial Plexus Block in Patients Undergoing Upper Limb Surgeries. Indian J Anesth Analg. 2020;7(1 Part -I):87–92.

Introduction

The Joint Commission on Accreditation of Healthcare Organizations has coined the phrase "Pain: The 5*th* Vital Sign" to elevate awareness of pain management among healthcare professionals.[1]

From time immemorial, attempts were made to relieve the pain of surgical intervention by various means. But it is only during the last few decades that great advances have been made in the management of surgical anesthesia and analgesia using different modalities like systemic opioids,

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Received on 13.10.2019, **Accepted on** 02.11.2019

cyclooxygenase inhibitors, patient controlled analgesia, Transcutaneous Electrical Nerve Stimulation and continuous central and Peripheral Nerve Block (PNB) etc. Despite these technical advances, many patients continue to suffer due to inadequate control of pain, major causes of which include inadequate knowledge regarding effective dosing and also under treatment with opioids due to fear of respiratory depression and addiction.[2] The role of PNB has expanded from the operating suite into the arena of postoperative and chronic pain management. Typical features of PNB include rapid onset, predictable, dense anesthesia and postoperative analgesia. Among the various PNB, Brachial Plexus Block (BPB) is one of the most commonly practiced blocks, as it offers an excellent operative field for surgeries of the upper extremities. One of the common approaches to blockade of brachial plexus is the supraclavicular approach as it has a favorable safety profile, ease of performance, high patient acceptability and broad applicability for hand, wrist and forearm procedures.[3,4]

Single shot BPB can provide analgesia only for the period of action of the local anesthetic used, which is very short and unlikely to provide postoperative pain relief for a long-time. Keeping this in mind, various opioids as well as other drugs have been used as adjuvants with local anesthetics with a view to increase the analgesic efficacy and concept of extending the duration of analgesia.[5-7] But there has been a concern regarding safety profile and adverse effects of these additives. Corticosteroids such as dexamethasone added to bupivacaine microspheres have been proven to prolong peripheral nerve block in animals. Undesirable side effects with single dose of dexamethasone seem to be minor and previous studies have demonstrated safe short-term (< 24 hour) use of dexamethasone.[8]

A review conducted on adjuvants in peripheral nerve blockade and effect of additives on duration of analgesia, neurotoxicity and safety concerns concluded that more data is required prior to undertaking the widespread use of dexamethasone as an additive for peripheral nerve blocks.[9] Hence, the current clinical study was planned with the objective to assess efficacy of dexamethasone after addition to local anesthetic agent for prolongation of analgesia & motor block for BPB in patients undergoing upper limb surgeries.

Materials and Methods

The present study was carried out in a tertiary care hospital during the period of May 2016 to January 2019. It was a prospective, randomized, double blind study of 50 patients undergoing upper extremity surgeries below shoulder joint. The study was approved by institutional ethical committee and patients were enrolled in the study after taking written informed consent.

Patients were randomly allocated using a standard randomization code into one of the following Two Groups depending upon the drugs, they received for brachial plexus block. Anesthesiologist prepared study drugs, who was involved in randomization process not involved further in the study. Thus, the patient and the observer were blinded to the study drug.

Group I (n = 25): Patients in this group received 1.5% adrenalized xylocaine (20 ml) and 0.5% bupivacaine (16 ml) plus dexamethasone 8 mg (2 ml) making a total volume of 38 ml.

Group II (n = 25): Patients in this group received 1.5% adrenalized xylocaine (20 ml) and 0.5% bupivacaine (16 ml) plus 0.9% normal saline (2 ml) making a total volume of 38 ml.

Patients between 18 and 70 years of age of either sex and of physical status, American Society of Anesthesiologists (ASA) Class I and II posted for upper limb surgery and with normal sensory and motor function in affected limb were selected. Patients with ASA Grade 3 and 4, any bleeding disorder and patient on anticoagulants, severe respiratory disease, neuro deficit involving brachial plexus, local infection at the injection site, history of allergy to local anesthetic, patients with a history of peptic ulcer disease, diabetes mellitus, hepatic or renal failure (contraindication to steroids), pregnant women, failed block, patchy block were excluded from the study.

Drug solution and dosages used were:

a. Xylocaine 5% ampoule. 6 ml of it was diluted to 20 ml with 0.9% normal saline to make it 1.5%. Xylocaine was used in a dose not exceeding 7 mg/kg.
b. Adrenaline 100 μg i.e. 0.1 ml of 1:1000 Adrenaline to make a dilution of 1:200000 or 5 µg/ml was taken with tuberculin syringe and added to xylocaine solution.
c. Bupivacaine 0.5% ampoule was used. 16 ml of it was taken in 20 ml syringe. It was used in the dose not exceeding 2 mg/kg.
d. Dexamethasone ampoule (4 mg/ml; 2 ml). 2 ml was added to xylocaine in Group I patients.

An intravenous drip started before undertaking the procedure which continued throughout the surgery. Vital parameters were recorded throughout the procedure and oxygen at the rate of 2l/min administered through oxygen mask.

The brachial plexus block was carried out after thorough explanation of the procedure and emphasising the need for patient cooperation. The classical approach to supraclavicular block using a single-injection, nerve-stimulator technique was used. The patient was asked to be in the dorsal recumbent position without a pillow, arms at his/her sides and head turned to side opposite to the one being blocked. This manoeuvre allowed for detection of any subtle finger movement produced by nerve stimulation. Part of neck was aseptically cleaned and draped. The operator stood on the same side to be blocked. With the patient in the above described position and the shoulder down, the lateral (posterior) border of the Sternocleidomastoid (SCM) muscle was identified and followed distally to the point where it met the clavicle. The point of needle entrance was about 1 in (2.5 cm) lateral to the insertion of the SCM in the clavicle or one "thumb breadth" lateral to the SCM. Palpation of the subclavian artery at the site confirms the landmark. The palpating index finger was placed at this site. Local infiltration of 1 ml of 2% lignocaine was given at the proposed puncture site. The needle was connected to nerve locator by the electrodes and was properly grounded with the help of ECG lead. The stimulation was started with an intensity of 2.0 mA and a pulse width of 100 μs. Once the desired response was obtained (muscle twitch of the fingers) current was decreased gradually upto 0.6 mA. After getting desired response the drug solution was injected. It was aimed to elicit an isolated muscle twitch in all fingers either in flexion or extension. Injection area was massaged, to help the solution to track along the plexus. The site of injection was sealed with tincture benzoin seal. During the conduct of block and thereafter, the patient was observed vigilantly for any complications of the block and for the toxicity of the drugs injected.

Onset of sensory block i.e. the time from injection to onset of analgesia in each of the major peripheral nerve distributions was assessed by pinprick. Sensory block was graded as per the following scale: 0 = no block (normal sensation), 1 = partial block (decreased sensation), and 2 = complete block (no sensation). Onset of motor block i.e. the time from injection to the inability of the patient to move his/her fingers or raise their hand was measured at 0, 10, 20, and 30 min by assessing the following motor functions: flexion at the elbow (musculocutaneous nerve), extension of the elbow and the wrist (radial nerve), opposition of the thumb and index finger (median nerve), and opposition of the thumb & small finger (ulnar nerve). Motor block was graded according to the following scale: 0 = no block (full muscle activity), 1 = partial block (decreased muscle activity), and 2 = complete block (no muscle activity). Duration of analgesia was considered satisfactory if the patient did not complain of any pain or discomfort and if no sedation was necessary. Postoperative follow-up was carried out in the recovery and postoperative ward. The duration of analgesia was noted according to 0–10 Visual Analog Score (VAS) for pain at every half an hour for first 10 hours and then hourly till 24 hours. When the patients began to experience the worst pain (VAS = 8–10), it was considered that analgesic action of the drugs was terminated and rescue analgesic (IM Diclofenac 1–1.5 mg/kg or tab Tramadol) was given. Duration of motor block was assessed hourly.

Possible side effects of brachial plexus block like incidence of drowsiness, pruritus, nausea/vomiting, Horner's syndrome, phrenic nerve palsy, pneumothorax, respiratory depression and sign and symptoms for local anesthetic toxicity were noted. In the circumstance of inadequate or patchy action of the block, the block was supplemented with general anesthesia and excluded from the study. If in case surgery was unduly prolonged and the effect of the block wore off, rescue analgesia with IV propofol or IV ketamine was given. For statistical analysis, association among the study groups were assessed with the help of Fisher test, student '*t*' test and Chi-square test. '*p*' value less than 0.05 was taken as significant.

Results

Demographic characteristics were comparable in both the study groups (Table 1). The mean duration of analgesia was significantly longer in Group I as compared to Group II (748.5 ± 65.57 mins *vs* 555.4 ± 35.20 mins). This difference was statistically significant ($p < 0.05$). The mean duration of motor block was significantly longer in Group I as compared to Group II (814.3 ± 100.81 mins *vs* 690.3 ± 81.36 mins: $p < 0.05$). The onset of sensory block in Group I was earlier as compared to Group II (8.48 + 1.58 mins *vs* 9.60 + 1.73 mins: $p < 0.05$) and was statistically significant. Similarly, the onset of motor block was rapid in Group I as compared to Group II

(13.04 ± 2.09 mins *vs* 14.52 ± 2.29 mins: $p < 0.05$) as mentioned in (Table 2). 7 (28%) patients in Group I required 50 mg of Tramadol while 1 (4%) patient required 100 mg of Tramadol. 17 (68%) patients in Group I did not require rescue analgesic. 10 (40%) patients in Group II required 50 mg of Tramadol while 11 (44%) and 1 (4%) patients required 100 mg and 200 mg of Tramadol respectively. 6 (12%) patients in Group II did not require rescue analgesic. It was observed that significantly higher number of patients in Group II required rescue analgesic and at higher dosages ($p < 0.05$) (Fig. 1). Postoperative complications between groups were comparable and most common complications were nausea & vomiting.

Table 1: Demographic data

Parameters	Group I (n = 25)	Group II (n = 25)	p - value
Age (in years, Mean ± SD)	38.9 ± 12.59	39.6 ± 12.28	> 0.05
Sex (Male: Female)	15:10	14:11	> 0.05
Weight (in kg, Mean ± SD)	64.1 ± 10.57	64.8 ± 10.07	> 0.05

(n = Number of Patients, SD = Standard Deviation)

Table 2: Efficacy Parameters

Parameters	Group I	Group II	p - value
Mean duration of analgesia (min)	748.5 ± 65.57	555.4 ± 35.20	< 0.05
Mean duration of motor block (min)	814.3 ± 100.81	690.3 ± 81.36	< 0.05
The onset of sensory block (min)	8.48 + 1.58	9.60 +1.73	< 0.05
The onset of motor block (min)	13.04 ± 2.09	14.52 ± 2.29	< 0.05

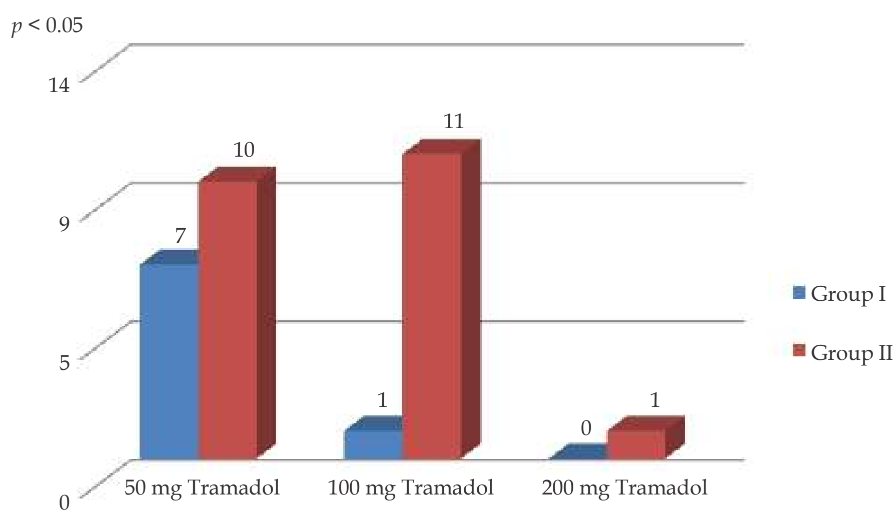

Fig. 1: Number of patients required rescue Analgesia (Tramadol).

Discussion

Pain experienced during and after orthopedic upper limb traumatic surgeries is pivotal to be treated. Regional anesthesia in the form of Brachial plexus nerve block for these surgeries has widespread acceptance due to improved postoperative pain relief, decreased need of postoperative rescue analgesia, less incidence of nausea, reduced recovery time with the benefit of patients resuming ambulation sooner and faster discharge from hospital when compared with General Anesthesia,[10] leading to improved patient satisfaction. Besides, brachial plexus block remains the sole substitute to GA for surgeries of the upper limb and can be used effectively in patients with significant comorbidities. Supraclavicular Brachial plexus block is conducted with anesthetic agents for upper limb surgeries and is not only an anesthetic method that allows easier homeostasis control during surgery, but also allows easier postoperative pain control.

Dexamethasone is a nonparticulate steroid that has been shown in animal studies to be nonneurotoxic[11,12] and may even be cytoprotective.[13] One exception to these findings is that Williams BA et al.[14] found that bathing isolated rat sensory neurons in a solution of ropivacaine combined with high-dose dexamethasone (133 mcg/ml), clonidine and buprenorphine exacerbated the neurotoxicity associated with ropivacaine. They reported that dexamethasone alone or in combination with ropivacaine had no influence on cell death after 24 hours of exposure. This study suggested that although individual adjuvants may not be neurotoxic, combinations may be and urges caution. The relevance of this *in vitro* study to clinical practice remains unknown, but certainly warrants further study on the neurotoxicity of combinations of agents.

Persec et al. as well as Kim et al. showed that dexamethasone in addition to local anesthetic significantly prolonged duration of postoperative analgesia and decreased requirement of rescue analgesia in 24 hours.[15–16] The mechanism of corticosteroids related to their analgesic activity is not yet fully understood. It has been reported that corticosteroids induce a degree of vasoconstriction, that results in reducing absorption of local anesthetic, and they modulate nuclear transcription after attachmentto the intracellular receptor. Stan et al. concluded that corticosteroids suppress the synthesis & secretion of various inflammatory mediators, which extends the period of analgesia. Attardi et al. reported that dexamethasone increases the activity of inhibitory potassium channels on nociceptive C-fibers by acting on glucocorticoid receptors, but more research on the action of steroids on peripheral nerve fiber as well as its mechanisms is necessary.[17,18]

Persec et al. conducted randomized controlled study, by assessing 70 patients undergoing upper-limb surgeries using single-shot supra-clavicular blockade. They investigated the analgesic efficacy of low-dose dexamethasone added to levobupivacaine and concluded that single-shot low-dose dexamethasone in addition to levobupivacaine results in prolonged duration of analgesia and less rescue analgesic consumption compared with levobupivacaine alone.[19] In our study, 17 patients from Group I compared to 3 patients from Group II did not require rescue analgesia in 24 hours postoperatively.

Conclusion

Adding dexamethasone to local anesthetic agents in brachial plexus block significantly prolongs the duration of analgesia and motor block and is a remarkably safe and cost effective method of providing postperative analgesia. We conclude that dexamethasone could be a promising adjuvant, which significantly prolongs the duration of analgesia in brachial plexus nerve blockade. As such, large, well-designed, randomized controlled trials would be needed to either support or refute its adoption into mainstream clinical practice with particular attention to comparison with systemic administration.

References

1. Asdourian CP. Acute pain management. In: Warfield CA, Fausett HJ. Manual of Pain Management: 2*nd* edition. Philadelphia: Lippincott Williams and Wilkins; 2002.p.215–22.
2. Hurley RW, Wu CL. Acute postoperative pain. In: Miller RD. Miller's Anesthesia: 7*th* edition. Philadelphia: Churchill Livingstone; 2010.p. 2757–781.
3. Wedel DJ, Horlocker TT. Nerve Blocks. In: Miller RD. Miller's Anesthesia: 7*th* edition. Philadelphia: Churchill Livingstone; 2010.p. 1639–674.
4. Mayfield JB, Rosow CE. Anesthesia for the outpatient. In: Wylie and Churchill Davidson's A Practice of Anesthesia: 7*th* edition. London: Arnold; 2003.p.1021–1036.
5. Khosa DS, Thind SS, Gupta HK, et al. Effects of adding potassium chloride to lignocaine and bupivacaine solutions on the onset time and duration of brachial plexus block. Indian Journal of Anesthesia 1990;38(8):119–22.
6. Candido KD, Franco CD, Khan MA, et al. Buprenorphine added to the local anesthetic for brachial plexus block to provide postoperative analgesia in outpatients. Regional Anesthesia and Pain Med 2001;26(4):352–56.
7. Bazin JE, Massoni C, Bruelle P, et al. The addition of opioids to local anesthetics in brachial plexus block: The comparative effects of morphine, buprenorphine and sufentanil. Anesthesia 1997;52(9):858–62.
8. Chawda PM, Sharma G. A clinical study comparing epinephrine 200 µg or clonidine 90 µg as adjuvants to local anesthetic agent in brachial plexus block *via* supraclavicular approach. J Anesthesiol Clin Pharmacol 2010;26(4):523–27.

9. Brummett Williams B. Additives to local anesthetics for peripheral nerve blockade. International Anesthesiology Clinics 2011;49(4):104–116.

10. McCartney C, Brull R, Chan V, et al. Early but no long-term benefit of regional compared with general anesthesia for ambulatory hand surgery. Anesthesiology 2004;101(2):461–67.

11. Benzon HT, Chew TL, McCarthy RJ, Benzon HA, Walega DR. Comparison of the particle sizes of different steroids and the effect of dilution: a review of the relative neurotoxicities of the steroids. Anesthesiology. 2007;106(2):331–338.

12. Kroin JS, Schaefer RB, Penn RD. Chronic intrathecal administration of dexamethasone sodium phosphate: Pharmacokinetics and neurotoxicity in an animal model. Neurosurgery 2000 Jan;46(1):178–82.

13. Ma R, Wang X, Lu C, et al. Dexamethasone attenuated bupivacaine-induced neuron injury in vitro through a threonine-serine protein kinase B-dependent mechanism. Neuroscience. 2010;167(2):329–342.

14. Williams BA, Hough KA, Tsui BY, Ibinson JW, Gold MS, Gebhart GF. Neurotoxicity of adjuvants used in perineural anesthesia and analgesia in comparison with ropivacaine. Reg Anesth Pain Med. 2011;36(3):225–230.

15. Persec J, Persec Z, Kopljar M, et al. Low-dose dexamethasone with levobupivacaine improves analgesia after supraclavicular brachial plexus blockade. International Orthopedics 2013;38(1):101–105.

16. Kim Y, Lee G, Kim D, et al. Dexamathasone added to levobupivacaine improves postoperative analgesia in ultrasound guided interscalene brachial plexus blockade for arthroscopic shoulder surgery. Korean J Anesthes 2012;62(2):130–34.

17. Stan T, Goodman E, Cardida B, et al. Adding methylprednisolone to local anesthetic increases the duration of axillary block. Reg Anesth Pain Med. 2004 Jul-Aug;29(4):380–81.

18. Attardi B, Takimoto K, Gealy R, et al. Glucocorticoid induced upregulation of a pituitary K+ channel mRNA *in vitro* and *in vivo*. Receptors Channels. 1993;1(4):287–293.

19. Persec J, Persec Z, Kopljar M, et al. Low-dose dexamethasone with levobupivacaine improves analgesia after supraclavicular brachial plexus blockade. International Orthopedics 2013;38(1):101–105.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 93-98
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.14

Analysis of Delayed Extubation among Surgical Patients: A One-year Prospective Observational Study

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Abstract

Context: Endotracheal intubation is the gold standard of a secure airway under general anaesthesia and extubation at the end of surgery is a norm. However this does not happen in all the patients. Delayed extubation after surgery occurs in small percentage of patients due to various reasons which would have been decided preoperatively or sometimes intraoperatively. But sometimes its unexpected due to unanticipated complications in perioperative period. *Aim:* This study was conducted to analyze prevalence and causes of delayed extubation among surgical patients. *Setting and Design:* It was a one year prospective observational study of patients with delayed extubation after surgical procedures. *Results:* Prevalence of delayed extubation among surgical patients operated under anesthesia was 4.32%. Preoperative variable which showed higher percentage of delayed extubation were age above 40 years, male gender, ASA PS II and above. Among operative variables, delayed extubation was seen more in surgical procedures like intraabdominal surgeries and head and neck surgeries and patients under general anesthesia. Delayed extubation was planned in 70.32% of surgical patients. Intraoperative events like hypotension, blood loss, starting of inotropes and duration of surgery also has an influence on delayed extubation. *Conclusion:* Delayed extubation, though not frequent, will be required in some surgical patients. It has its own morbidity and mortality. Prolonged intubation and mechanical ventilation after delayed extubation is more harmful as it is associated with complications.

Keywords: Delayed extubation; General anesthesia; Surgical patients.

How to cite this article:
Raveendra Ubaradka, Siri Kandavar. Analysis of Delayed Extubation among Surgical Patients: A One-year Prospective Observational Study. Indian J Anesth Analg. 2020;7(1 Part -I):93–98.

Introduction

Endotracheal intubation is the gold standard of maintaining patent and protected airway under general anesthesia and extubation after surgery is the norm. However, this may not be possible in all surgical cases, as in a small percentage of surgical patients extubation has to be delayed. Delayed extubation is removal of the endotracheal tube outside the operative room in the postoperative period after surgical procedure. Such patients are shifted to the postanesthesia care unit (PACU) or

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Received on 10.10.2019, **Accepted on** 28.11.2019

Intensive Care Unit (ICU) with endotracheal tube for postoperative care.

The need for delayed extubation cannot always be predicted in the preoperative period as it also depends on the perioperative events. Mortality and morbidity can occur during anesthesia and they are influenced by many nonanesthetic factors as well.[1] Prevalence of delayed extubation depends on the level of care, expertise and facilities. It is associated with its own complications like postoperative pulmonary complications, increased length of stay in hospital and increased cost burden on patients.

Delayed extubation is routinely seen in cardiac and neurosurgical cases and studies are reported on delayed extubation in these specialties. Literature is scanty with regard to the prevalence, causes and outcome of delayed extubation among other surgical specialties. Hence, we conducted a clinical audit in our hospital to find out the prevalence and analyze causes and outcome of delayed extubation among surgical patients.

Materials and Methods

This is a prospective observational study conducted in the department of anesthesiology from February 2018 to January 2019. After institutional ethical committee clearance for study, all adult surgical patients who had delayed extubation were included. We excluded patients aged below 18 years. Cardiac and neurosurgery patients were also excluded as these patients are routinely shifted to ICU with endotracheal tube after the surgery. We divided the variables into preoperative, intraoperative, postoperative and outcome variables.[1, 2]

Preoperative variables were age, gender, American society of anesthesiologist physical status (ASA PS). Operative variables were elective or emergency surgery, type of surgical procedure and anesthesia, airway related issues like difficult intubation, duration of surgery. Intraoperative events like hypotension, blood loss, inotropes, arrhythmias, intraoperative myocardial infarction and cardiac arrest, if any were also noted.

Postoperative events like delayed recovery from anesthesia and neuromuscular blockade, inadequate reversal or residual neuromuscular blockade, inadequate respiratory efforts, stridor, laryngospasm, postthyroidectomy nerve injury or tracheomalacia if any were noted. We also noted the reason for shifting with an endotracheal tube and whether it was planned or unplanned in the preoperative period. The decision of shifting the patients with the endotracheal tube was taken only by the treating consultant and we did not have any influence over it.

Data was analyzed using SPSS software version 20. Mean and standard deviation was used for continuous data and number and percentage for categorical data was used.

Results

Prevalence of delayed extubation was around 4.32% among surgical patients. Among 3587 patients who underwent surgery after meeting the inclusion and exclusion criteria, we had 155 delayed extubation. Preoperative variables are described in Table 1. The median age of the patients was 55 years with the youngest patient of 19 years and the eldest patient of 85 years. We had 35 (22.58%) patients belonging to age below 40 years and 120 (77.41%) patients in above 40 years of age. Percentage of delayed extubation was higher in male patients (67.1%) in our study. Patients belonging to ASA PS class II and above were around (68.38%) in the delayed extubation group.

We saw delayed extubation more common among elective surgical procedures. The type of surgical procedures done in patients with delayed extubation were intraabdominal surgeries or intraabdominal with transthoracic approach surgery in 63 (40.64%) patients, head and neck and maxillofacial surgeries in 61 (39.35%) patients and 31 (20%) patient underwent other procedures such as orthopedic surgery, hernioplasty, debridement's, Transurethral Resection of Prostate (TURP) and laparoscopic surgery.

Surgical procedures were done under general anesthesia with or without epidural anesthesia in 151 patients. In four patients, surgery was started under regional anesthesia but later patients were intubated due to intraoperative complications. Airway management in 44 (39.8%) patients were difficult and delayed extubation was anticipated here as these patients were either undergoing head and neck surgery or maxillofacial surgeries.

Duration of surgery was less than 4 hours in 57 (36.77%) patients, was between 4 and 8 hours in 83 (53.54%) patients and was more than 8 hours in 15 (9.67%) patients, (Table 2).

Table 1: Preoperative variables

S. No	Preoperative variables	No of cases (cohort = 155)	
1.	**Age** (years) (median)	55 (19–85)	
2.	**Distribution of age**	***n* (%)**	
	< 40 years	35 (22.58)	
	> 40 years	120 (77.41)	
3.	**Gender**	***n* (%)**	
	Male	104 (67.1)	
	Female	51 (32.9)	
4.	**ASA PS**	**Elective *n* (%)**	**Emergency *n* (%)**
	I	31 (20)	18 (11)
	II	63 (40)	14 (9)
	III	14 (9)	13 (8.4)
	IV	0	2 (1.3)

Delayed extubation was planned in 109 (70.32%) patients and 46 (29.67%) patients had unplanned delayed extubation. Patients who had planned or unplanned delayed extubation were shifted to either ICU or PACU. All the ICU patients were mechanically ventilated. Eighteen (11.6%) patients were shifted to PACU where they were connected to T-piece and spontaneous ventilation.

Table 2: Operative variables

S. No		No of patients	Percentages (%)
1.	**Type of surgery**		
	Elective	108	69.67
	Emergency	47	30.32
2.	**Type of Surgical procedure**	***n* = 155**	
	Intraabdominal/intrathoracic surgery	63	40.64
	Head and neck/maxillofacial surgery	61	39.35
	Others	31	20.00
3.	**Type of anesthesia**	***n* = 155**	
	GA+ETT+IPPV with or without EA	138	89.03
	GA+DLT+IPPV with or without EA	13	8.38
	SA	4	2.58
4.	**Airway management**	***n* = 155**	
	Easy	107	69.03
	Difficult	44	28.38
	Nil	4	
5.	**Duration of surgery**	***n* = 155**	
	< 4 hours	57	36.77
	4–8 hours	83	53.54
	> 8 hours	15	9.67
6.	**Type of delayed extubation**	*n* = 155	
	Planned	109	70.32
	Unplanned	46	29.67
7.	**Shifted to**	***n* = 155**	
	ICU	137	88.38
	PACU	18	11.61

Intraoperative events which lead to delayed extubation were the risk of airway oedema (42.58%) which was anticipated in most of the head and neck surgery and maxillofacial surgery, hypotension (31.6%), blood loss > 1000 ml (18.1%), starting of inotropes (20%) in the intraoperative period. Other cardiovascular related causes were arrhythmias (4.5%), intraoperative cardiac arrest (2.6%) and intraoperative myocardial infarction (1.3%), (Table 3). In few cases, delayed extubation was decided at the time of extubation when there were complications like delayed recovery from anesthesia (10.3%), stridor (3.9%), residual neuromuscular blockade (3.9%), laryngospasm (3.2%), postobstruction pulmonary oedema (1.9%), postthyroidectomy nerve injury (3.2%) and tracheomalacia (1.9%). Delayed extubation was done due to long duration surgery in 10.3% of patients.

Table 3: Problems during the intraoperative period

Problems encountered	Present	Percentages (%)
Airway oedema	66	42.58
Hypotension	49	31.60
Blood loss > 1000 ml	28	18.10
Inotropes	31	20.00
Arrhythmias	7	4.50
Cardiac arrest	4	2.64
Laryngospasm	5	3.20
Stridor	6	3.90
Nerve injury	5	3.20
Residual NM blockade	6	3.90
Tracheomalacia	3	1.90
Pulmonary oedema	3	1.90
Delayed recovery from anesthesia	16	10.30
Intraoperative MI	2	1.30
Unanticipated difficult airway	1	0.64
Long duration surgery	15	9.70

There were 10 (6.45%) deaths among the delayed extubation patients. Tracheostomy was required in six patients. Reintubation was required in nine patients within 24 hours of extubation, (Table 4). Causes of reintubation were drowsiness, tachypnea and hemodynamic instability postextubation. We did not follow up on whether there was readmission, any complications or death after discharge from ICU or PACU. We also noted how long it took to extubate the patients in the postoperative period, 25 (17.9%) patients were extubated in less than 24 hours, 86 (61.8%) patients took between 24 and 48 hours for extubation and 28 (20.1%) patients took more than 48 hours to extubate, (Table 5). Causes of delay of more than 48 hours to extubate were reduced level of consciousness in 12 (42.85%) patients, hemodynamic instability in 8 (28.57%) patients, pneumonia in 5 (17.85%) patients and sepsis in 3 (10.7%) patients.

Table 4: Outcome of delayed extubation

		Percentages (%)
Extubated	139/155	89.67
tracheostomy	6/155	3.87
Death	10/155	6.45
Reintubation required in 24 h	9/142	6.25
Time to extubate	n = 139	%
< 24 h	25/139	17.98
24–48 h	86/139	61.87
> 48 h	28/139	20.14

Table 5: Showing time taken to extubate patients

Time to extubate	n = 139	Percentages (%)
< 24 h	25/139	17.98
24–48 h	86/139	61.87
> 48 h	28/139	20.14

Discussion

In this prospective observational study, the prevalence of delayed extubation was around 4.32%. Delayed extubation was seen in higher percentage in age above 40 years, male patients, and ASA PS class II and above. Studies show that age, gender and ASA PS has an influence on ICU admission and mortality among surgical patients.[2,3] In a study done by Anastasian et al. found that age, ASA PS class and long duration of surgery had an influence on the decision to delay extubation in multilevel spine surgery. They noted that there was an association with long duration of surgery and large volume of crystalloid infusion in prone position which lead to airway and tissue oedema due to which extubation was delayed in these patients.[4] Our study showed higher percentage of delayed extubation among male patients. Head and neck malignancies and intraabdominal surgeries being more common among male patients might be one of the reasons.

Advancing age is associated with comorbidities like hypertension, diabetes mellitus and cardiovascular diseases along with lesser physiological reserves to deal with postoperative complications.[2] We had higher percentage of delayed extubation among patients with age above 40 years. Delayed extubation was more commonly seen in intraabdominal surgery (40.64%) and head and neck surgeries (39.35%) under general anesthesia. Planned delayed extubation was when intraoperative events like blood loss and hypotension and risk of airway oedema were anticipated and planned in the preoperative period. Unplanned delayed extubation was if there were any adverse events in the intraoperative period.

Duration of surgery had an effect on delayed extubation. We noted 63.21% of surgeries which lasted more than four hours had delayed extubation. In a study done among spine surgeries by Li F et al., intraoperative factors like long duration surgery, significant blood loss and blood transfusion, larger volume of crystalloid and colloid infusion are risk-factors for delayed extubation. Early blood transfusion may also increase the risk of delayed extubation. It was also noted patient factors did not affect extubation time and it is intraoperative factors which had an impact on extubation time.[5]

In our study, 70.3% of the patients were planned delayed extubation and only 29.7% of the patients had unplanned delayed extubation. There is an association between type of surgery and anesthesia and delayed extubation. Misal US et al. said the selection of anesthetic technique and anesthetic drugs determines the duration of unconsciousness. Time to emergence increases with increasing duration of anesthesia.[6] Exposure to general anesthetic drugs for long duration is associated with longer time to recover from anesthesia which would have led to delayed extubation in few cases.

In head and neck surgery or maxillofacial surgery extubation was delayed due to risk of airway oedema and difficult airway. Singh et al. in the study reported that primary tracheostomy should be considered for patients who have maxillofacial free-flap reconstruction and bilateral neck dissection, or those with oropharyngeal tumors who need additional access procedures. Delayed extubation is safe after free-flap reconstruction and unilateral neck dissection in patients who do not have conditions such as obstructive sleep apnoea or poor lung function.[7] Coyle et al. said overnight intubation patients in head and neck surgery had better results like shorter mean stay in the intensive care unit than tracheotomized patients.[8] Most of the extubation in head and neck surgeries were done over airway exchange catheter. Twohig EM et al. suggested that staged extubation is always better in head and neck surgeries.[9]

Lanuti et al. said restricted intraoperative fluid balance, limited blood loss anesthetic technique and epidural use permit most patients undergoing oesophageal resection to be safely extubated immediately postresection in the operating room. We had 15 cases of oesophagostomies who had delayed extubation due to blood loss and prolonged duration of surgery and one lung ventilation and required elective postoperative mechanical ventilation.[10]

In a study done by Anastasian et al. said that handoffs by treating anesthesiologists in case of surgeries extending beyond duty hours were associated with delayed extubation after general anesthesia for a broad range of surgical procedures. End time of surgery in odd hours has led to delayed extubation among surgical patients. As the number of anesthesiologist present during odd hours are less in number, extubation is delayed among long duration surgery to avoid complications.[4]

In a study done by Schurner et al. anesthesia related complications were 37%, which were intubation-related and extubation related. In our study, 20 % of patients had extubation related complications which caused unplanned delayed extubation. Extubation related problems in our study were stridor, laryngospasm, postthyroidectomy nerve injury, residual neuromuscular blockade or postobstructive pulmonary oedema.[11]

Quinn et al. investigated factors associated with unplanned postoperative admissions to the Intensive Care Unit (ICU). They suggested higher ASA PS class, case duration of more than four hours and advanced age are associated with unplanned ICU admission.[12] The preoperative, operative and postoperative variables are interrelated in causing delayed extubation and ICU admissions among surgical patients. Manjula et al. said factors which served as significant predictors of anesthesia intensive care unit admissions were males aged more than 60 years, ASA Grading III or IV, abdominal explorations, emergency operations, history of intraoperative arrhythmias, major blood loss, hypotension requiring inotropic support. They concluded that ICU admission and patient outcome depends on multiple factors.[13] Delay in extubation can lead to complications like postoperative complications, increased length of stay and financial burden on the patients. Zettervell et al. said delay in extubation in aortic aneurysm repair lead to postoperative respiratory complications, increased length of stay and increased cost on patients.[14] Delayed extubation can be due to various reasons which are unavoidable but prolonged mechanical ventilation and ICU stay is more dangerous as it can lead to complications and morbidity.

Conclusion

In conclusion, our findings suggest that delayed extubation is seen mainly in the age above 40 years, male gender, with ASA PS II and above coming for head and neck or maxillofacial and intraabdominal surgeries and when there are intraoperative complications. Delayed extubation is multifactorial. But most of our patients could be extubated in the postoperative period. It is done mainly to avoid postoperative airway-related complications and hemodynamic instability. Delayed extubation can reduce mortality and morbidity, however prolonged intubation and mechanical ventilation is associated with complications like postoperative pulmonary complications, increased length of stay in ICU and hospital and increased cost on patients.

References

1. Bhat SA, Shinde V, Chaudhari L. Audit of intensive care unit admissions from the operating room. Indian J Anesth 2006;50(3):193–200.
2. Patel SK, Kacheriwala SM, Duttaroy DD. Audit of postoperative surgical intensive care cnit admissions. Indian J Crit Care Med 2018;22(1):10–15.
3. Anastasian ZH, Gaudet JG, Levitt LC, et al. Factors that correlate with the decision to delay extubation after multilevel prone spine surgery. J Neurosurg Anesthesiol 2014;26(2):167–71.
4. Anastasian ZH, Kim M, Heyer EJ, et al. Attending handoff is correlated with the decision to delay extubation after surgery. Anesth Analg 2016;122(3):758–64.
5. Li F, Gorji R, Tallarico R, et al. Risk-factors for delayed extubation in thoracic and lumbar spine surgery: A retrospective analysis of 135 patients. J Anesth 2014;28(2):161–66.
6. Misal US, Joshi SA, Shaikh MM. Delayed recovery from anesthesia: A postgraduate educational review. Anesth Essays Res 2016;10(2):164–72.
7. Singh T, Sankla P, Smith G. Tracheostomy or delayed extubation after maxillofacial free-flap reconstruction? Br J Oral Maxillofac Surg 2016;54(8):878–82.
8. Coyle MJ, Main B, Hughes C, et al. Enhanced Recovery After Surgery (ERAS) for head and neck oncology patients. Clin Otolaryngol 2016;41(2):118–26.
9. Twohig EM, Leader R, Shaw RJ, et al. Staged extubation to manage the airway after operations on the head and neck. Br J Oral Maxillofac Surg 2016;54(9):1030–1032.
10. Lanuti M, de Delva PE, Maher A, et al. Feasibility and outcomes of an early extubation policy after esophagectomy. Ann Thorac Surg 2006;82(6):2037–2041.
11. Schürner AM, Manzini G, Bueter M, et al. Perioperative surgery- and anesthesia-related risks of laparoscopic Roux-en-Y gastric bypass: A single centre, retrospective data analysis. BMC Anesthesiol 2018;18(1):190.
12. Quinn TD, Gabriel RA, Dutton RP, et al. Analysis of unplanned postoperative admissions to the intensive care unit. J Intensive Care Med 2017;32(7):436–43.
13. Manjula S, Lalita D, Rao S. Analysis of anesthetic intensive care unit admissions: Anesthesiologists' perspective. J Anesthesiol Clin Pharmacol 2007;23(3):283–89.
14. Zettervall SL, Soden PA, Shean KE, et al. Early extubation reduces respiratory complications and hospital length of stay following repair of abdominal aortic aneurysms. J Vasc Surg 2017;65(1):58–64.e1.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 99-105
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.15

A Prospective Observational Study on Ultrasonographic Measurement of Optic Nerve Sheath Diameter as a Bedside Tool in Detecting Findings of Increased Intracranial Pressure in Neuro Critical Care Patients

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Abstract

Context: Posttraumatic intracranial hypertension might be detrimental. Bedside ultrasound measurement of optic nerve sheath diameter helps in early diagnosis of increased intracranial pressure. *Aims:* To determine the accuracy of detecting the raised intracranial pressure by ultrasonographic measurement of Optic Nerve Sheath Diameter (ONSD). To correlate ONSD with the Computer Tomography (CT) findings of increased intracranial pressure and the average time taken to measure ONSD with ultrasound. *Settings and Design:* A Prospective, double blinded Observational Study. *Methods and Materials:* To determine the accuracy of detecting the raised intracranial pressure by ultrasonographic measurement of Optic Nerve Sheath Diameter (ONSD). To correlate ONSD with the Computer Tomography (CT) findings of increased intracranial pressure and the average time taken to measure ONSD with ultrasound. *Statistical Analysis:* Descriptive Analysis - Sensitivity, Specificity and Predictive values. *Results:* The sensitivity for the mean binocular optic nerve sheath diameter ultrasonography in detecting elevated intracranial pressure was 99.42% and the specificity was 82.43% with an odds ratio of 0.3547. The positive predictive value was 92.97% and the negative predictive value was 98.39% with an p - value of < 0.0001 which was significant. The average time taken to measure the ONSD was 19.8 secs. *Conclusions:* The evaluation of optic nerve sheath diameter is a simple noninvasive procedure, which is a potentially useful tool in the assessment and monitoring of raised intracranial pressure.

Keywords: Bedside ultrasound; Optic nerve sheath diameter; Intracranial hypertension.

How to cite this article:

Ravi Saravanan, Krishnamoorthy Karthik, Kanirajan Yogalakshmi, et al. A Prospective Observational Study on Ultrasonographic Measurement of Optic Nerve Sheath Diameter as a Bedside Tool in Detecting Findings of Increased Intracranial Pressure in Neuro Critical Care Patients. Indian J Anesth Analg. 2020;7(1 Part -I):99–105.

Introduction

Early detection of intracranial hypertension and proper treatment to reduce Intracranial Tension (ICT) protects cerebral perfusion and better neurological recovery.[1] Clinicians need an accurate tool to distinguish those with elevated intracranial pressure from a vast majority of patients with a head injury who have no elevated intracranial pressure. Direct measurement of CSF pressure by placing intraventricular or intraparenchymal catheters and transducing them is the gold standard

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Received on 18.10.2019, **Accepted on** 07.12.2019

in the measurement of intracranial pressure. These procedures are highly invasive with complications like hemorrhage, infection, also require technical expertise and availability.[2–5]

Other noninvasive methods available to assess intracranial hypertension are neuroimaging (CT and MRI brain), transcranial Doppler, tympanic membrane displacement, intraocular pressure measurement, venous opthalmodynamometry and changes in optic nerve sheath diameter (ONSD) using orbital ultrasound.[6]

Neuroimaging techniques like CT scan and MRI are most commonly used to predict intracranial hypertension, but these techniques are expensive, require long acquisition times, have limited availability and require patient transport which might be harmful in unstable patients.

Ultrasonography is emerging as a simple bedside tool widely used in emergency departments. The cost of the procedure is low and the equipment is widely available. Ultrasonography of ONSD has been developed in recent times as a possible indicator of intracranial hypertension. The optic nerve is a part of the central nervous system and is surrounded by CSF (Cerebro Spinal Fluid), which is continuous with the intracranial subarachnoid space. Elevation of intracranial pressure is transmitted through this subarachnoid space, especially the retrobulbar segmentas shown in (Fig. 1). Dilatation of the optic nerve sheath is shown to be a much earlier manifestation of ICP rise.[7–10] CSF pressure variations influence the optic nerve sheath diameter in patients with head injuries, children with ventriculoperitoneal shunts, postmortem specimens, intrathecal gelatin infusion models. Bedside measurement of Optic Nerve Sheath Diameter (ONSD) using orbital ultrasound is an effective tool in early diagnosis of intracranial hypertension.

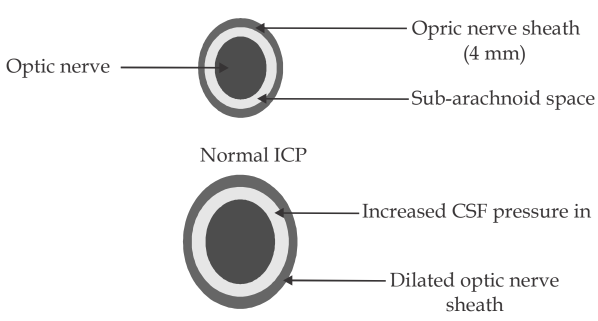

Fig. 1: A cross section of the optic nerve. The subarachnoid spaceseparates the optic nerve from the optic nerve sheath (a) the normal state. (b) After dilatation of the optic nerve sheath as a consequence of increased cerebrospinal fluid pressure in the subarachnoid space. CSF: Cerebrospinal Fluid, ICP: Intracranial Pressure.

The procedure is relatively simple, less time consuming, can be done at the bedside, easily reproducible and with least interpersonal variability in measurements. The patient is placed in the supine position. A layer of gel is applied over the closed upper eyelid. The linear high-frequency 5–10 Hz probe is placed on the gel over the eyeball to get axial images of the globe and optic nerve as in Fig. 2. The diameter of the optic nerve sheath was measured 3 mm behind the globe as in Fig. 3

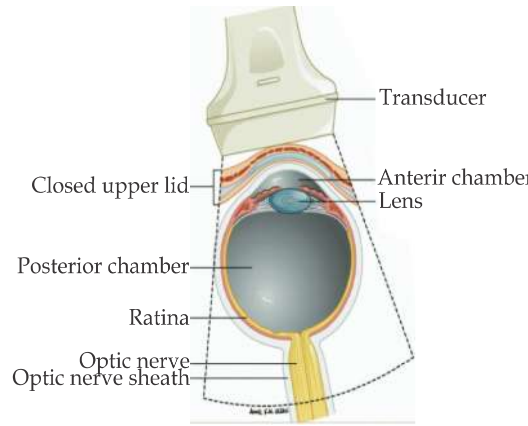

Fig 2: Diagram of sonographic evaluation through closed eyelid of eye and optic nerve sheath diameter.

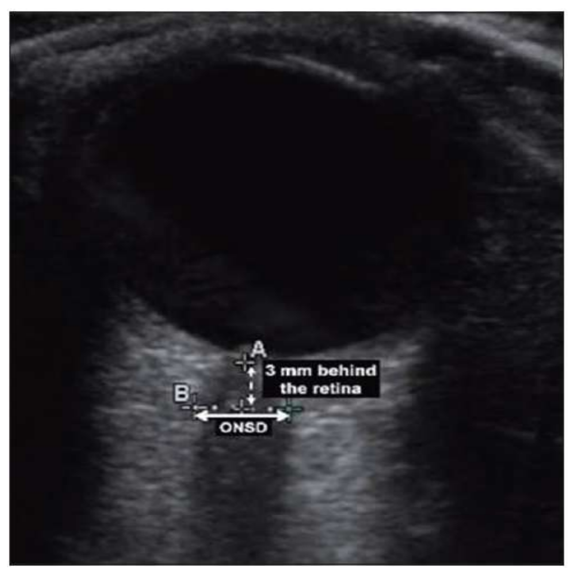

Fig. 3: Ultrasound image showing optic nerve sheath diameter.

Aims and Objectives

The aim is to determine the accuracy of detecting the raised intracranial pressure by ultrasonographic measurement of Optic Nerve Sheath Diameter (ONSD). The primary objective is to correlate ONSD with the Computer Tomography (CT) findings of increased intracranial pressure and the average time taken to measure ONSD with ultrasound.

Materials and Methods

The study is a prospective observational study. After institutional ethical committee approval (IEC NO:1354/2018) and Clinical Trial Registry India registration (CTRI No- 2018/11/022261), this study was done in 233 patients admitted at the emergency department and neurosurgery department meeting the inclusion criteria after getting proper consent. Patients of both sexes between age group 18 and 65 years with a head injury and suspected to have raised ICT and subjected to CT brain evaluation were included in the study. Patients with orbital and ocular injuries and diseases affecting the optic nerve like neuro-inflammatory and degenerative disorders were excluded.

Ocular ultrasound is performed with a linear high frequency 5–10 Hz probe placed over the eyeball to get axial images of the globe and optic nerve. The diameter of the optic nerve sheath was measured 3 mm behind the globe. Binocular ONSD was measured to derive the mean. ONSD values > 5 mm signified increased ICT. The measurements were done by anesthesiologists experienced with ultrasound examination. The time taken for the measurement was noted which is the time from placing the probe over the eyeball to time of arriving the value.

Interpretation

ONSD more than 5 mm is suggestive of increased intracranial pressure and the values were compared with the CT findings of intracranial hypertension. The patients were followed up subsequently. If the patients undergo repeat CT scan after medical or surgical intervention, ultrasonographic measurement of ONSD was repeated and compared with the new CT findings.

Results

The CONSORT flowchart for the flow of patients is represented in Fig. 4. Two hundred and thirty-three patients were enrolled in the study, 185 Male patients and 48 Female patients were considered for the study. All data were entered in the MS Excel spreadsheet and a descriptive analysis was used as in Table 1. Fig.5 represents the distribution of ONSD among the study patients. The sensitivity for the mean binocular optic nerve sheath diameter ultrasonography in detecting elevated intracranial pressure was 99.42% (95% CI 96.82% to 99.99%) and the specificity was 82.43% (95% CI 71.83% to 90.30%) with odds ratio of 0.3547. The positive predictive value was 92.97% (95% CI 88.98% to 95.59%) and the negative predictive value was 98.39% (95% CI 89.6% to 99.77%) as noted in Table 2. The ONSD correlates well with the CT findings of intracranial tension as represented in the bar diagram in Fig. 7. The average time taken for a single ONSD measurement was 19.8 secs. The scatter diagram for the time taken to measure ONSD is shown in Fig. 6.

Table 1: Table representing the correlation between ONSD and CT findings of raised ICT

	Raised ICT	**Normal ICT**
ONSD > 5 mm	172 (True positive)	13 (False positive)
ONSD < 5 mm	1 (True negative)	47 (False negative)

Table 2: Stanalysis

Statistics	**Value**	**95% CI**
Sensitivity	99.42%	96.82% to 99.99%
Specificity	82.43%	71.83% to 90.30%
Positive Likelihood		
Ratio	5.66	3.45 to 9.27
Negative Likelihood		
Ratio	0.01	0.00 to 0.05
Disease prevalence	70.04%	63.91% to 75.68%
Positive Predictive		
Value	92.97%	88.98% to 95.59%
Negative Predictive		
Value	98.39 %	89.60% to 99.77%
Accuracy	94.33%	90.67% to 96.8

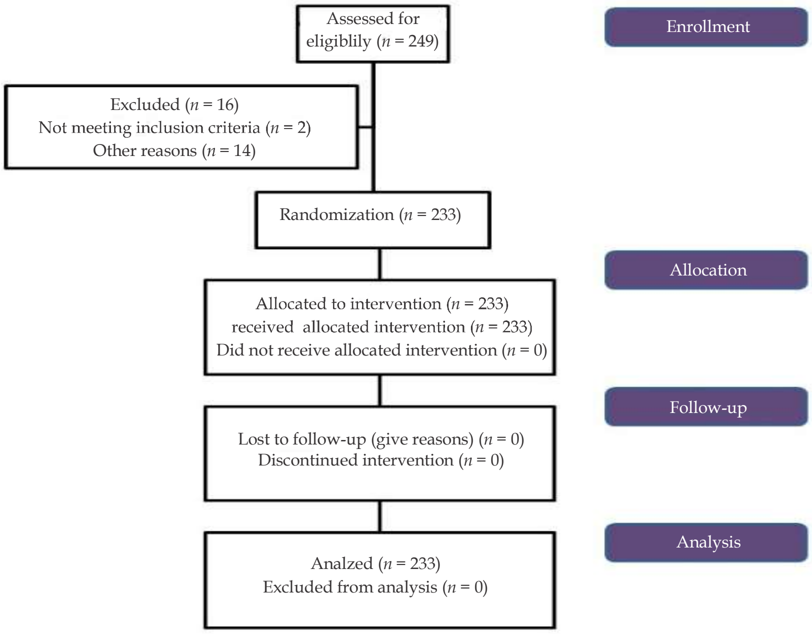

Fig. 4: CONSORT diagram representing the flow of patients in the study.

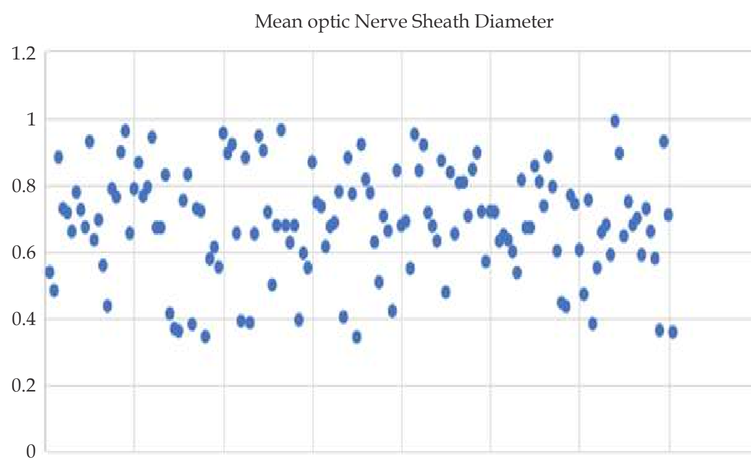

Fig. 5: Scatter diagram representing the distribution of ONSD among study patients.

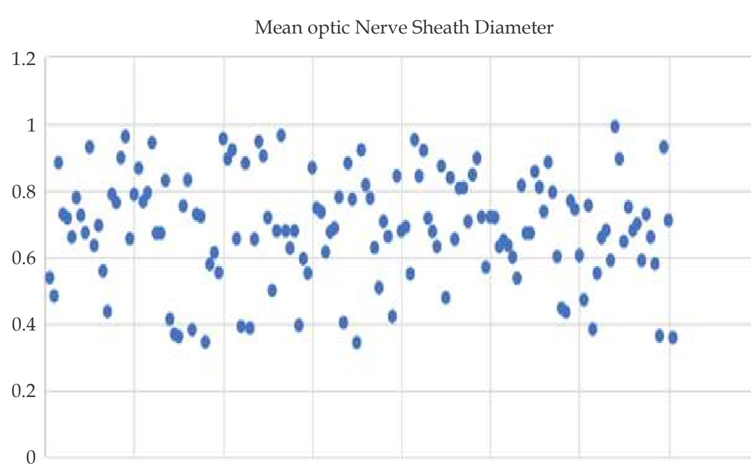

Fig. 6: Scatter diagram representing the time taken for ONSD measurement.

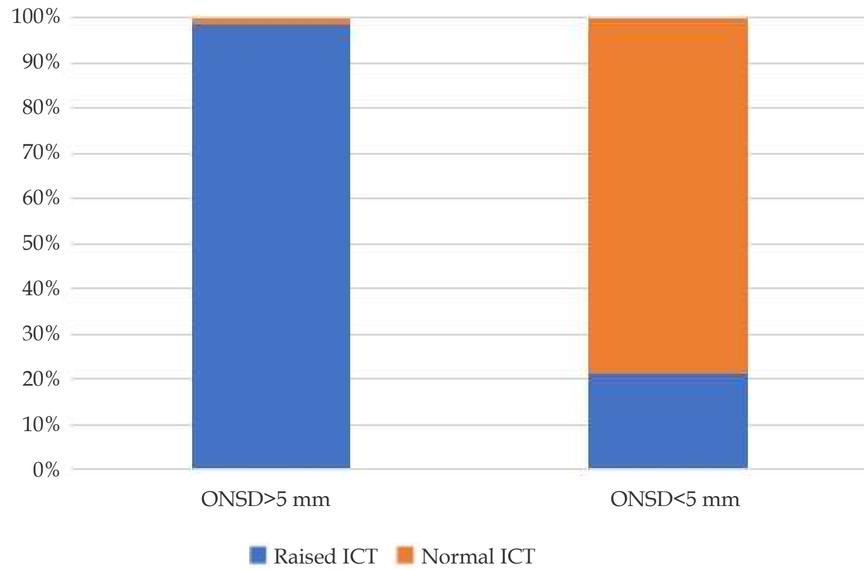

Fig. 7: Bar diagram representing the correlation of ICT with ONSD.

Discussion

Raised intracranial pressure is a consequence of head injury with intracranial bleed which when diagnosed earlier and prompt treatment can avoid cerebral ischemia and its sequel.[1] With this consideration, a test with high sensitivity and specificity with the least time consumption needs to be practiced for early detection of raised ICP.[17,18] ONS anatomically continues with dura mater from the brain.[11] When there is an increase in ICP, the CSF slowly percolates around the nerve sheath causing it to increase in diameter which could be picked up by B scan. A position of 3 mm behind the globe was chosen because the ultrasound contrast is greatest, the results are more reproducible and anatomically the anterior nerve is most distensible. In the present study, the average ONSD in the control group was compared with the group with raised ICP. It was also noted that papilloedema was not found in the acute situation, but that increased ONSD may act as a marker for raised ICP before the development of papilloedema.[7–10]

Using these ultrasonography techniques several groups have investigated the relationship between the optic nerve sheath diameter as measured by A-scan and the ICP. Cennamo[14], Gangemi[15] and Tamburrelli[16] each demonstrated a positive linear relationship between these two variables in neurosurgical patients and in particular, an immediate change in ONSD with the change in ICP.

Liu and Kahn,[13] in a cadaver study, looked at the pressure gradient within the optic nerve sheath in relationship to the ICP and the anatomy of the optic nerve sheath. They noted that the trabeculations were most dense posteriorly being quite sparse anteriorly where the nerve sheath was thinnest and the most distensible. Although they did not measure the optic nerve sheath diameter, they noted that in all of the cadavers the bulbous portion of the optic nerve was seen to bulge or inflate somewhat as the intracranial pressure was created, but there was no obvious change in appearance along the remaining nerve.

Hansen and coworkers in 1994 presented data using a transorbital B-scan approach for the measurement of ONSD.[11,12] This approach allowed them to choose a distance behind the globe to consistently measure the nerve, something difficult to attain with A-scan techniques.

In 1996, Helmke and Hansen[7] went on to demonstrate, again in cadaver studies, that the ONSD increased by up to 60% at a distance of 3 mm behind the globe compared with only 35% at 10 mm thus confirming Liu and Kahn's observations. Furthermore, they went on to show that the optimal experimental scanning position was longitudinal (axial) where the least interobserver variability was found although there was no significant difference in measurement by lateral, axial or transverse projection. This latter observation is of importance because transorbital B-scan ultrasonography looking along the optic nerve longitudinally relies on a poorer lateral resolution of the ultrasound pulse, rather than the high-resolution perpendicular approach of a transverse scan. The average time taken to measure ONSD in our study was 19.8 seconds as in the study done by Venkatakrishna Rajajee et al. who observed the median time required for a cluster of six measurements was from 10 minutes.[19] Direct measurement of CSF pressure by placing intraventricular catheters and transducing them is the gold standard in measurement of intracranial pressure which was not done or compared, is the only limitation of this study.

Conclusion

ONSD is a noninvasive, less time consuming, readily available and easily trainable modality to assess raised ICP in suspected patients. There was a significant correlation between the ONSD measured by ultrasonography and CT findings of increased intracranial pressure. ONSD can be considered as a modality to diagnose raised intracranial pressure along with other imaging modality. Though ONSD has a few advantages compared to intraventricular ICP monitoring, a prospective study with a large study population is required to prove ONSD's unequivocal efficacy over intraventricular ICP monitoring.

Key Messages

Optic Nerve Sheath Diameter (ONSD) measured by bedside ultrasound greater than 5 mm in adults indicates raised intracranial pressure. ONSD measurement is less time consuming and correlates well with the Computer Tomographic findings.

References

1. Sekhon MS, McBeth P, Zou J, et al. Association between optic nerve sheath diameter and mortality in patients with severe traumatic brain injury. Neurocrit Care. 2014;21(2):245–252.
2. Rosenberg JB, Shiloh AL, Savel RH, et al. Noninvasive methods of estimating intracranial pressure. Neurocrit Care. 2011 Dec;15(3):599–608.
3. Binz DD, Toussaint LG 3rd, Friedman JA. Hemorrhagic complications of ventriculostomy placement: A meta-analysis. Neurocrit Care. 2009;10(2):253–56.
4. Lozier AP, Sciacca RR, Romagnoli MF, et al. Ventriculostomyrelated infections: A critical review of the literature. Neurosurgery 2001;51:170–81.
5. Saladino A, White JB, Wijdicks EF, et al. Malplacement of ventricular catheters by neurosurgeons: A single-institution experience. Neurocrit Care. 2009;10(2):248–52.
6. Raboel PH, Bartek J, Andresen M, et al. Intracranial pressure monitoring: Invasive *versus* noninvasive methods: A review. Crit Care Res Pract 2012;2012:14.
7. Helmke H, Hansen HC. Fundamentals of transorbital sonographic evaluation of optic nerve sheath expansion under intracranial hypertension. I Experimental study. Pediatr Radiol 1996 Oct;26(10):701–705.
8. Helmke H, Hansen HC. Fundamentals of transorbital sonographic evaluation of optic nerve sheath expansion under intracranial hypertension. II Patient study. Pedaitr Radiol 1996 Oct;26(10):706–710.
9. Hansen HC, Helmke K. Validation of the optic nerve sheath response to changing cerebrospinal fluid pressure: ultrasound findings during intrathecal infusion tests. J Neurosurg. 1997;87(1):34–40.
10. Hansen HC, Helmke K, Kunze K. Optic nerve sheath enlargement in acute intracranial hypertension. Neuro-ophthalmology 1994;14(6):345–54.
11. Hansen HC, Helmke K. The subarachnoid space surrounding the optic nerves. An ultrasound study of the optic nerve sheath. Surg Radiol Anat. 1996;18(4):323–328.
12. Helmke K, Hansen HC. Fundamentals of transorbital sonographic evaluation of optic nerve sheath expansion under intracranial hypertension II. Patient study. Pediatr Radiol. 1996;26(10):706–710.
13. Liu D, Kahn M. Measurement and relationship of subarachnoid pressure of the optic nerve to intracranial pressures in fresh cadavers. Am J Ophthalmol. 1993;116(5):548–556.
14. Cennamo G, Gangemi M, Stella L. The correlation between endocranial pressure and optic nerve diameter: An ultrasonographic study. Ophthalmic Echography 1987;7:603–606.
15. Gangemi M, Cennamo G, Maiuri F. Echographic measurement of the optic nerve in patients with intracranial hypertension. Neurochirugica 1987 Mar;30(2):53–55.
16. Tamburelli C, Aricle C, Mangiola A. CSF dynamic parameters and changes of optic nerve diameters measured by standardized echography. Ophthalmic Echography 1993;13:101–109.
17. Bäuerle J, Nedelmann M. Sonographic assessment of the optic nerve sheath in idiopathic intracranial hypertension. J Neurol. 2011;258(11):2014–2019.
18. Geeraerts T, Merceron S, Benhamou D, Vigué

B, Duranteau J. Non-invasive assessment of intracranial pressure using ocular sonography in neurocritical care patients. Intensive Care Med. 2008;34(11):2062–2067.

19. Rajajee V, Fletcher JJ, Rochlen LR, Jacobs TL. Comparison of accuracy of optic nerve ultrasound for the detection of intracranial hypertension in the setting of acutely fluctuating vs stable intracranial pressure: post-hoc analysis of data from a prospective, blinded single center study. Crit Care. 2012;16(3):R79.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 106-113
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.16

Crystalloid Preload *Vs* Crystalloid Coloadfor the Prevention of Hypotension During Spinal Anesthesia

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Abstract

Introduction: Hypotension following Spinal Anesthesia (SA) is a common and troublesome Complication. Prophylactic fluid preloading with crystalloids is traditional practice to prevent hypotension. Timing of the infusion of the crystalloid is more important as its shorter intravascular stay. We hypothesized that crystalloid loading just after intrathecal injection compared to preload is more effective. *Methods:* 100 healthy adult patients of ASA 1 & 2, scheduled to undergo lower limb and abdominal surgery under spinal anesthesia, were studied. Patients in preload Group (A) were preloaded with RL at 15 ml/kg over 20 min periods prior to spinal anesthesia while in coload Group (B) received Ringer lactate 15 ml/kg as soon as spinal block is performed over 10 to 15 min. *Results:* The incidence of hypotension was low in coload group than compared to preload group. Mean arterial pressure at before spinal anesthesia was 100 mm Hg and 101 mm Hg, following subarachnoid block at 3 minutes dropped up to 85 mm Hg and 92 mm Hg, after 5 minutes 80 mm Hg and 88 mm Hg after 10 minutes 78 mm Hg and 90 mm Hg in preload and coload group respectively. *Conclusions:* In our study, we found that coload is more effective, than preload solution in prevention of hypotension in patients undergoing elective surgeries for abdomen and lower limb surgery under spinal anesthesia. So, it is unnecessary to spend time to deliver preload and delay surgery for the prevention of SA induced hypotension.

Keywords: Spinal anesthesia; Crystalloid; Preload; Coload.

How to cite this article:
Sameer H Parmar, Bipin M Patel, Ravikumar M Parmar, et al. Crystalloid Preload Vs Crystalloid Coloadfor the Prevention of Hypotension During Spinal Anesthesia. Indian J Anesth Analg. 2020;7(1 Part -I):106–113.

Introduction

Spinal anesthesia is the regional anesthesia obtained by blocking the spinal nerves in the subarachnoid space. The era of regional anesthesia dates back to more than a century ago (1884) when Koller discovered the local anesthetic properties of cocaine.[1] Subarachnoid block is one of the earliest forms of regional anesthetic techniques to be described.[2] The technique is now widely used by anesthetists.[3]

It has been shown that complication occurs during surgery like stress response to surgery, intraoperative blood loss, postoperative

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Received on 22.10.2019, **Accepted on** 06.12.2019

thromboembolism, morbidity and mortality in high-risk patients are reduced by spinal anesthesia.[4] Spinal anesthesia is a popular and well-accepted technique for surgery below umbilicus in adult patients.

Hypotension following Spinal Anesthesia (SA) is a common and troublesome Complication.[6] To reduce the incidence and severity of spinal hypotension various maneuvers have been used which includes preloading the patients with intravenous fluids with either crystalloid or colloid solution, and it is a common and traditional practice.[6]

Recently rapid fluid administration at the time of spinal block have been advocated because it expands intravascular volume at the time of maximum vasodilatation and avoids unnecessary delay in surgery.[7,8] Coload might be physiologically more appropriate because this might maximize intravascular volume expansion during vasodilatation from the sympathetic blockade and limit fluid redistribution and excretion.[9] The present study was undertaken to compare the efficacy of crystalloid (Ringer lactate) preload *versus* coload for prevention of spinal anesthesia induced hypotension.

Materials and Methods

After obtaining institutional ethics committee approval and informed consent, 100 healthy adult patients of either gender, ASA 1 & 2, scheduled to undergo lower limb and abdominal surgery under spinal anesthesia, were included and studied. Patients who refused to give consent, H/o allergy to local anesthetis drugs, neurological problem, chronic hypertention, known stenotic heart disease, hematocrit less than 30%, altered coagulopathy, infection at local site were excluded. This prospective single blinded randomized controlled study was conducted on patients who were admitted at the Gujarat cancer and research institute, Ahmedabad, Gujarat, India.

Patients were admitted one day before the surgery and preoperative evaluation were performed with detailed history, physical examination including height, weight, evidence of spinal deformity and mental status of the patient. All the patients were kept nil per oral since 10 pm on previous day of surgery. Premedication like antacids and anxiolytics were given. Patients were randomly allocated into either preload or coload group with computerized Rendo Software.

Intravenous access was obtained by an 18 G IV cannula. Standard monitors like electrocardiography, pulse oximetry, noninvasive blood pressure were connected to the patient. The baseline Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP) and Oxygen Saturation (SpO_2) were recorded.

Patients in preload Group (A): Were preloaded with RL at 15 ml/kg over 20 min periods prior to spinal anesthesia, after which the IV infusion was slowed to a minimum rate throughout the study period.

Patient in coload Group (B): Received Ringer lactate 15 ml/kg as soon as spinal block is performed over 10 to 15 min and then after IV infusion is continued to minimum rate throughout study period.

With the patients in the left lateral position, under strict aseptic precautions, lumbar subarachnoid block was performed at L2-L3 or L3-L4 interspinous space using 23 G Quincke spinal needle. After the free flow of CSF was confirmed, 0.5% Bupivacaine hydrochloride heavy was injected. The patients were then immediately turned supine and pillow placed under shoulder and head low position given. The time of institution of subarachnoid block was noted. The level of spinal block at various intervals was checked by loss of pinprick sensation and the final level of the block was noted. Surgery was started when the sensory level of block reached to desired level according to surgery. Intraoperative monitoring includes basal heart rate, systolic blood pressure, diastolic blood pressure and mean arterial blood pressure, SpO_2 and respiratory rate. All the above parameters are recorded immediately after giving spinal block, at every 1 minute till 5 minute, than every 5 minute till 30 minute and then every 15 min till completion of surgery.

Hypotension was defined as a decrease in the systolic blood pressure by more than 25% from the initial baseline level. Incidence of hypotension, bradycardia, nausea and vomiting were noted. Total intravenous fluid, Urine Output (UO) and surgical blood loss were also noted. Hypotension is managed with Trendelenberg position, increase in fluid infusion rate and administering 100% oxygen by mask. If hypotension still persists, despite the above measures, Injection mephenteramine sulphate was administered IV 6 mg bolus at 1 minute interval until the blood pressure increased to acceptable levels. Bradycardia was defined as heart rate less than 50 minute. Bradycardia was treated with intravenous injection atropine sulphate 0.6 mg. The number of doses atropine sulphate and mephenteramine sulphate drug was recorded

Statistics

The data were recorded on the patient's case record form and analyzed using MS Excel 2007 and SPSS version (Statistical Package for the Social Sciences). Student '*t*' test for independent group at 5% level of significance and *p*' value < 0.05 was considered significant.

Results

Fifty patients each in preload & coload group of both sex belonging to ASA Grade G I & II between 20 to 60 years of age were scheduled for surgeries under spinal anesthesia (Table 1).

There were no significant differences found in both the groups in relation to types of surgery (Table 2).

Table 1: Showing demographic data of both the group which were comparable and having no differences.

		Preload group	Coload group
Weight in kg			
	41–50	23	24
	51–60	19	19
	61–70	8	7
Sex			
	Male	22	22
	Female	28	28
Age in years			
	21–30	6	7
	31–40	9	9
	41–50	19	17
	51–60	16	17

Table 2: Types of surgery

Type of Surgery	Preload Group	Coload Group
w.l.e. & s.t.g.	4	5
Below knee amputation	3	3
Groin dissection	2	3
Laparotomy	14	12
High inguinal orchidectomy	3	3
Mupit insertion	7	10
T.u.r.b.t.	9	8
Penectomy	2	3
Reduction & internal nailing	3	1
W.l.e. & curettage & cementing	3	2

Data were expressed as Number. Both group were compared by unpaired '*t*' test.

The mean Systolic Blood Pressure (SBP) before spinal anesthesia was 135 mm Hg in both the groups. Following subarachnoid block at 3 minutes SBP dropped up to 103 mm Hg and 122 mm Hg, after 5 minutes 97 mm Hg and 117 mm Hg after 10 minutes 97 mm Hg and 119 mm Hg in preload and coload group respectively. The fall in mean SBP is significant up to 60 minutes from spinal anesthesia. Number of patients in whom decrease in systolic blood pressure was more than 25% in preload group was 25 (50%) as compared to 17 (34%) in coload group, which was clinically significant. Incidence of hypotension in Preload group was higher when compared to Coload Group, which was statistically significant ($p < 0.05$) (Fig. 1 and Table 3).

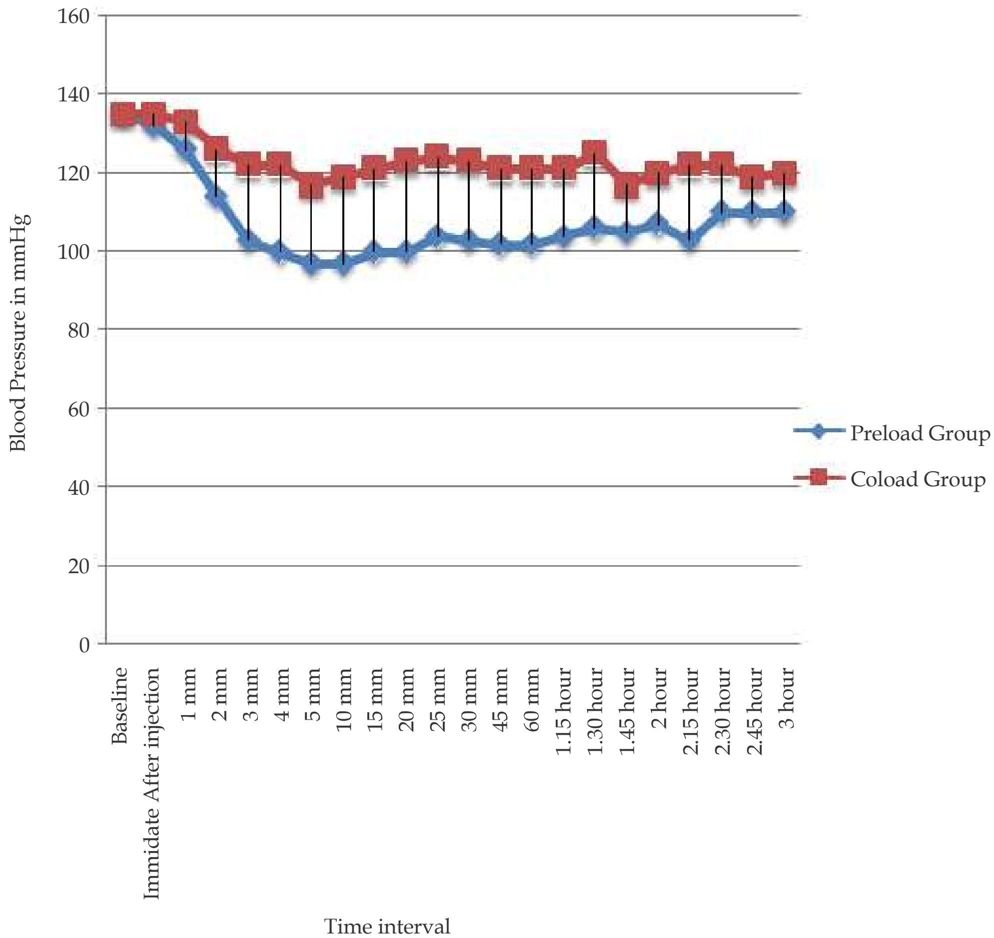

Fig. 1: Showing mean systolic blood pressure.

Table 3: Showing incidence of hypotension (fall in systolic blood pressure > 25% of base line).

Preload Group	Coload Group
25 (50%)	17 (34%)

The mean Diastolic Blood Pressure (DBP) before spinal anesthesia was 83 mm Hg and 84 mm Hg in preload and coload group respectively. Following subarachnoid block at 3 minutes DBP dropped up to 76 mm Hg and 77 mm Hg, after 5 minutes 71 mm Hg and 74 mm Hg after 10 minutes 70 mm Hg and 75 mm Hg and after 15 minutes 66 mm Hg and 75 mm Hg in preload and coload group respectively. The fall in mean DBP is significant up to 60 minutes from spinal anesthesia. There was significant difference in decrease in diastolic blood pressure between the two groups ($p < 0.05$) (Fig. 2).

The Mean Arterial Blood Pressure (MABP) before spinal anesthesia was 100 mm Hg and 101 mm Hg in preload and coload group respectively. Following subarachnoid block at 3 minutes MABP dropped up to 85 mm Hg and 92 mm Hg, after 5 minutes 80 mm Hg and 88 mm Hg after 10 minutes 78 mm Hg and 90 mm Hg in preload and coload group respectively. The fall in mean MABP is significant up to 60 minutes from spinal anesthesia. So, we conclude that there was significant difference in fall in mean arterial blood pressure in both the groups ($p < 0.05$) (Fig. 3).

We conclude that there was no significant change in Heart Rate in between Two Groups.

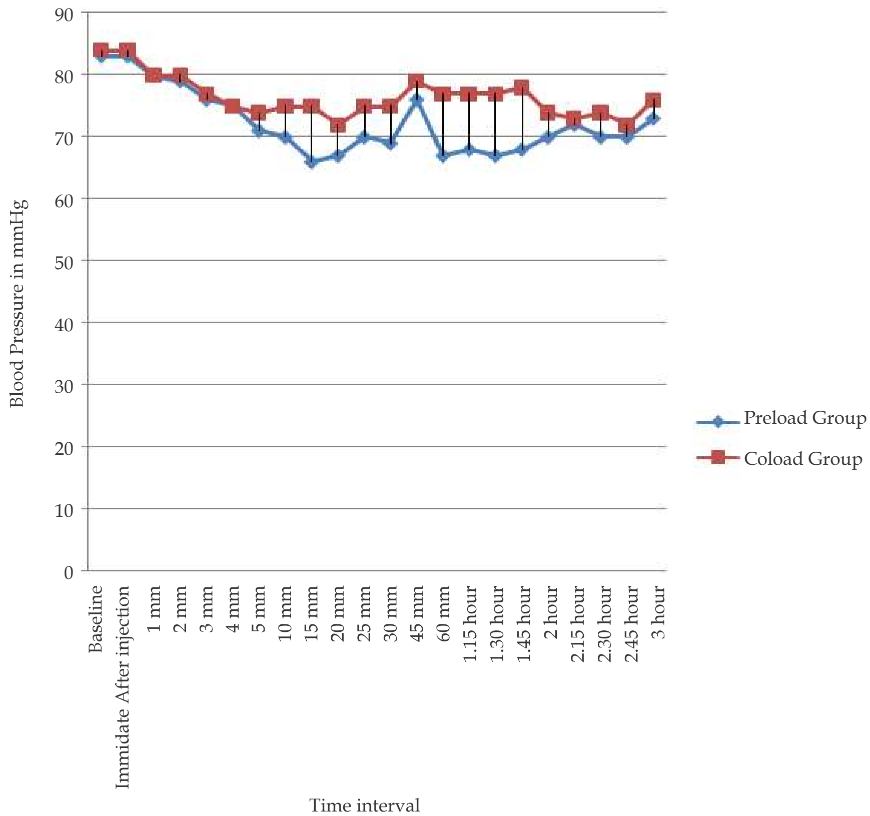

Fig. 2: Mean Diastolic blood pressure.

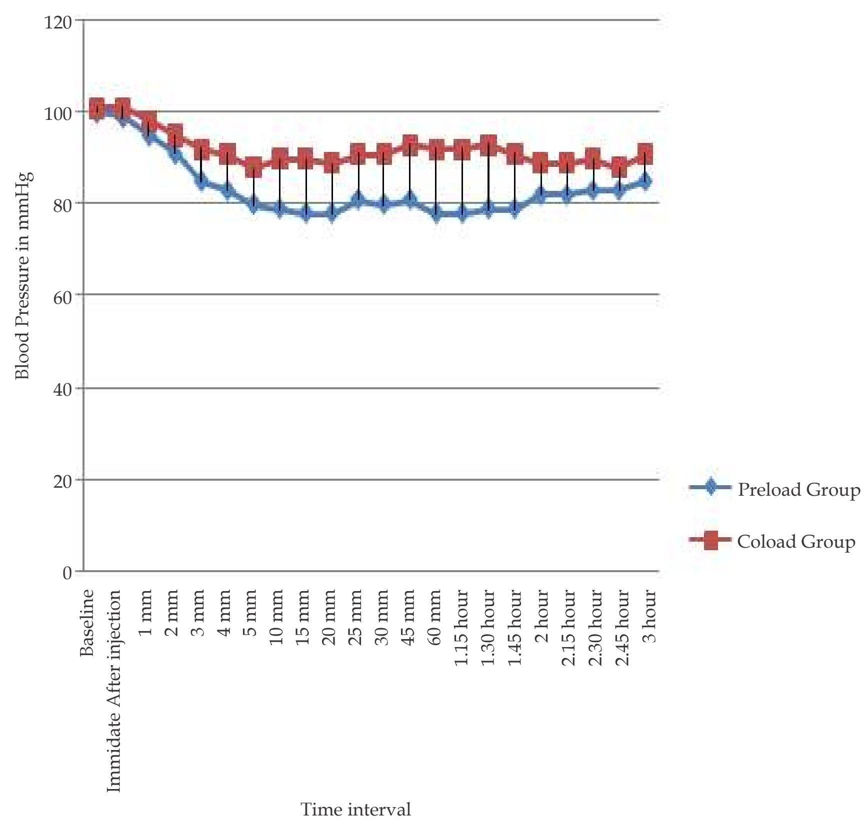

Fig. 3: Mean Arterial blood pressure.

Discussion

With the introduction of safe local anesthetic drugs and consequent reduction in the incidence of neurological complications, SA is still widely used in clinical practice. Due to its advantage such as rapid onset of action, uniformly distributed analgesia, profound muscle relaxation, maintenance of clear mentation intraoperatively, blunting of stress response, good postoperative recovery SA has replaced GA for lower abdominal and lower limb surgeries.[6] SA has proved to be extremely safe when managed well; however, there is still a risk of complications. Some of the complications of SA are hypotension, bradycardia, total spinal anesthesia and accidental intravascular injection. Hypotension is an important complication which may be preventable or avoidable.[7,8]

Various techniques have been used to prevent SA induced hypotension. Some of these are preloading with IV fluids, low-dose local anesthetics in SA with or without additives and use of vasopressors prophylactically.[8]

Of these preloading with IV fluids has been considered safe and effective method. Few studies have evaluated the value of crystalloid administration before spinal block *versus* no crystalloids in general surgical population. They found no significant difference in the incidence of spinal induced hypotension between patients receiving and not receiving crystalloids before spinal anesthesia. We have conducted a comparative study to compare efficacy of preloading and coloading of Ringer lactate solution in prevention of hypotension following spinal anesthesia. After subarachnoid block, there was progressive fall in blood pressure up to 20–30 minutes and maximum hypotension occurred between 5 and 15 minutes. In our study, incidence of hypotension has been found to be in 50% in patients of preload group and 34% in patients of coload group which were clinically significant.

Concept of coloading can be explained by the timing of hemodynamic events after SA. Sympathetic nerve blockade is completed within the first 10 minutes after administration of Bupivacaine hydrochloride in subarachnoid space. There are high chance of hemodynamic changes like hypotension and bradycardia in this period.[10,11] At same time, loading with fluid in intravascular space will decrease the chances of hypotension. Preloading before commencement of SA may be effective but with considerable risk of volume overload. But, coloading makes available extra fluids in intravascular space during period of the highest-risk of hemodynamic changes due to SA.[12] So, it leads to timely compensatory changes in cardiovascular system and limits fluid redistribution and excretion with reduced risk of fluid overload. So, Coloading is physiologically more appropriate and rational approach. Few studies, which compare the effects of preloading and coloading with RL in SA induced hypotension and support our study, are as follows:

In 2012, Siddharthkumar B et al.,[13] studied role of 20 ml/kg of RL as preload and coload in 30 patients in each group. They conclude that Coloading with 20 ml/kg of ringer lactate is as effective as preloading with same volume over 20 minutes in the context of prevention of spinal anesthesia induced hypotension in lower limb surgery. In our study, we found that coload with RL is better than preload for prevention of hypotension during SA.

In 2012 Jacob, et al.,[14] conducted a study of crystalloid preload *versus* coload for hypotension in 100 parturient scheduled for cesarean section under SA and found that incidence of hypotension was 30 in preload and 23 in coload group. They found high incidence of nausea (19 *versus* 10, p = 0.0473) and vomiting (14 *versus* 6, p = 0.0455) in preloading group as compared to coloading group. Frequent monitoring and prompt treatment with vasopressors were recommended. It is concluded that preloading before commencement of SA is not essential and coloading is equally effective for the prevention of SA induced hypotension.

In 2008 Manu Bose, et al.,[15] they conducted a randomized study to compare the effect of preloading against coloading with 15 ml/kg ringer lactate in preventing hypotension and bradycardia following spinal anesthesia in total 54 patients undergoing arthroscopies of lower limb. They found that trend of HR and MBP at various time intervals was comparable for both preloading and coloading groups. Incidence of hypotension was 18.52% for preloading group and 11.11% for coloading group. In our study, we found hypotention 50% in preload group and 34% in coload group.

In 2002 Jose L Mojica et al.,[16] conducted a randomized clinical trial to evaluate the efficacy of crystalloids in preventing spinal-induced hypotension and Cardiovascular Side Effects (CVSE) in total 404 surgical patients. Crystalloid administration at the time of spinal block resulted in an incidence of spinal induced hypotension almost identical to that seen in the Placebo Group, but led to a significant reduction in the risk of CVSE as compared with placebo (RR, 0.23; p = 0.019; number needed to treat, 13) or with crystalloids administered before spinal block (RR, 0.26; p = 0.014; number needed to treat, 14). Administering crystalloids at the time of spinal block had a beneficial effect in preventing CVSE in general and specialty surgery patients undergoing spinal anesthesia as compared with administering crystalloids before spinal block or administering no crystalloids. This study favors the results of our study.

In 2001 Kamenik M et al.,[17] studied the effects of RL solution coload compared with preload on cardiac output after SA. They found that a sustained rise above baseline in coload group, whereas it returned to baseline in preload group and decreased in the group that received no fluid in general surgical population. They conclude that hypotention was more common in preload than soload group. This findings are similar to our study.

In 2001 Ewaldsson CA et al.,[18] found in their kinetic analysis of an IV infusion of RL as preload that a rapid fluid administration over two minutes after induction of spinal or general anesthesia for non-obstetric surgery might prevent hypotension caused by central hypovolemia. Similarly in our study, we found less hypotension in coload group. So, one should not spend valuable time to deliver preload before SA to prevent hypotension specifically in patients with ASA I & II risk patients and unnecessarily delay surgery.[14] Care must be taken for parturient and patients with ASA > III risk.

Conclusion

In our study, we found that coload is more effective, than preload solution in prevention of hypotension in patients undergoing elective surgeries for abdomen and lower limb surgery under spinal anesthesia. Coloading with 15 ml/kg of ringer lactate is more effective than preloading with same volume over 20 minutes in the context of prevention of spinal induced hypotension. So, it is unnecessary to spend time to deliver preload and delay surgery for the prevention of SA induced hypotension. However, we also concluded that incidence of hypotension was only reduced but not completely eliminated in this study.

References

1. Koller C. The use of cocaine for producing anesthesia of the eye (Translated and reprinted). Lancet 1884:990–92.
2. Kennedy F, Effron AS and Perry G. Spinal cord paralysis caused by spinal anesthesia. Surg Gynecol Obstet. 1950 Oct;91(4):385–98.
3. Cirtchley LAH, Stuart JC, Short TG er al. Hemodynamic effects of subarachnoid block in elderly patients. Br J Anesth 1994;73:464–70.
4. Rodgers A, Walker N, Schug S, et al. Reduction of postoperative mortality and morbidity with epidural or spinal anesthesia: Results from overview of randomized trials. BMJ. 2000 Dec 16;321(7275):1493.
5. Spinal anesthesia: A practical guide http:// update. Anesthesio-logists.org/wp-content/ uploads/2009/10/Spinal-Anesthesia-a-Practical-guide.pdf.
6. Bernd Hartmann, Axel Junger, Joachim Klasen, et al. The incidence and risk-factors for hypotension after spinal anesthesia induction: An analysis with automated data collection. Anesth Analg 2002;94(4):1521–529.
7. Kamenik M, Paver-Erzen V. The effects of lactated Ringer's solution infusion on cardiac output changes after spinal anesthesia. Anesth Analg. 2001;92(3):710–714.
8. Ewaldsson CA, Hahn RG. Volume kinetics of Ringers solution during induction of spinal and general anesthesia. Br J Anesth 2001;87:406–414.
9. Dyer RA, Farina Z, Joubert IA, et al. Crystalloid preload versus rapid crystalloid administration after induction of spinal anesthesia (coload) for elective cesarean section. Anaesth Intensive Care. 2004 Jun;32(3):351–57.
10. Somboonviboon W, Kyokong O, Charuluxananan S, et al. Incidence and risk-factors of hypotension and bradycardia after spinal anesthesia for cesarean section. J Med Assoc Thai. 2008 Feb;91(2):181–87.
11. Cook PR, Malmaqvist LA, Bengtsson. Vagal and sympathetic activity during spinal anesthesia. Acta Anaesthesiol Scand. 1990 May;34(4):271–75.
12. Maria Monica, Bliacheriene Sandra, Claudia RC. Preload during spinal anesthesia for cesarean section. Comparison between crystalloid and colloid solution. Rev Bras Anesthesiology 2004;54(6): 781–87.
13. Siddharthkumar. Studied a comparative study of preloading versus coloading of crystalloid to prevent spinal anesthesia induced hypotention. Journal of Evolution of Medical and Dental Sciences 2012;1(5):746–53.
14. Jacob JJ.Crystalloid preload versus crystalloid coload for parturients undergoing cesarean section under spinal anesthesia. J Obstet Anesth Crit Care 2012;2:10–15.
15. Bose Manu. Crystalloid preload versus rapid crystalloid administration after induction of

spinal anesthesia (coload) for elective cesarean section. J Anesth Clin Pharmacol 2008;24(1):53–56.

16. Mojica JL, Meléndez HJ, Bautista LE. The timing of intravenous crystalloid administration and incidence of cardiovascular side effects during spinal anesthesia: the results from a randomized controlled trial. Anesth Analg. 2002;94(2):432–37.

17. Kamenik M. The effect of lactated Ringers solution infusion on cardiac output changes after spinal anesthesia. Anesth Analg 2001;92(3):710–14.

18. Ewaldsson CA. Volume kinetics of RL solution during induction of spinal and general anesthesia. Br J Anesth 2001;87:406–414.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 114-123
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.17

Comparative Study of Magnesium Sulphate Nebulization and Lignocaine Nebulization in Prevention of Postoperative Sore Throat

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Abstract

Introduction: General anesthesia is an integral part of anesthesia and intubation is a necessary step to protect the airway from regurgitation and aspiration. Postoperative sore throat, hoarseness of voice, cough are common sequelae after endotracheal intubation. The present study was conducted to compare the efficiency of preoperative nebulization of lignocaine hydrochloride and magnesium sulphate for reducing the incidence of POST in patients undergoing surgeries in general anesthesia. *Aims and Objective:* The purpose and aim of the study was to compare the efficiency of preoperative nebulization of lignocaine hydrochloride and magnesium sulphate in reducing the incidence of POST following GA with regards to- Postoperative Sore Throat (POST), Cough hoarseness of voice, dysphagia and dysphonia and Complications from possible systemic effects, because of absorption from mucosal surfaces. *Materials and Methods:* 100 patients of Government Medical College, Kota, and attached group of hospitals, scheduled to undergo elective surgery lasting more than 1 hour but less than three hours under GA requiring tracheal intubation within the age group 40–70 years, of both sexes were randomly allocated in two groups by simple randomization using computer generated numbers. Group A: 50 patients received nebulized magnesium sulphate 4 ml. (6.25%). Group B: 50 patients received nebulized lignocaine 4 ml. (2%). *Results:* On Intergroup comparison incidence of sore throat was more common in Lignocaine Group as compared to Magnesium Group but there was no significant difference in both Groups with respect to sore throat at rest ($p > 0.05$). On Intragroup comparison incidence of hoarseness of voice decrease with time in both groups but more faster recovery in Magnesium Group. In Magnesium Group no incidence of hoarseness of voice found at 24 hr after extubation. In Lignocaine group no incidence of hoarseness of voice found at 48 hr after extubation.

Keywords: Sore throat; Hoarseness of voice; Lignocaine; Magnesium Sulphate.

How to cite this article:
Sanjay Kalani, Chiranji Lal Khedia, Gopal Sharma. Comparative Study of Magnesium Sulphate Nebulization and Lignocaine Nebulization in Prevention of Postoperative Sore Throat. Indian J Anesth Analg. 2020;7(1 Part -I):114–123.

Introduction

General anesthesia is an integral part of anesthesia and intubation is a necessary step to protect the airway from regurgitation and aspiration and to provide adequate ventilation in patients undergoing surgery.

Postoperative sore throat, hoarseness of voice, cough are common sequelae after endotracheal intubation. Mucosal injury with resulting inflammation caused by airway instrumentation causes much more distress to patients especially in

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Received on 11.10.2019, **Accepted on** 28.11.2019

presence of abdominal or thoracic incision as any attempt to cough causes significant pain.[1] Among all the complications associated with ET intubation, sore throat and hoarseness are amongst the most common one. Though modern anesthesia has evaluated a lot and is safe and reliable but for satisfactory postoperative outcome, efforts should be made to decrease the incidence and severity of Postoperative Sore Throat (POST), apart from the management of postoperative pain, nausea, vomiting etc.[3]

Measures to reduce POST[4]

1. Nonpharmacological methods for reducing postoperative sore throat are:

- Use of smaller size endotracheal tube, Careful and gentle airway instrumentation, Minimising the duration and number of laryngoscopy attempts, Intubation after the full relaxation of the larynx, Gentle oropharyngeal suctioning, Filling the cuff with an anesthetic gas mixture, Minimizing intracuff pressure < 20 mm Hg and Extubation when the tracheal tube is fully deflated.

2. Pharmacological measures for attenuating postoperative sore throat:

- Nebulization with beclomethasone and fluticasone, Gargling with azulene sulfonate, aspirin, ketamine[5], magnesium, benzydamine, green tea[6], hydrochloride and licorice etc., Local spray of benzydamine hydrochloride, Intracuff administration of alkalized lignocaine[7], Steroid gel application on endotracheal tube1. Topically dexpanthenol, use of video laryngoscope blade[8], Amyl-m-cresol lozenges, and Magnesium lozenges.[9]

Role of Aerosolized Drugs to Reduce POST[10]

For effective and satisfactory postoperative outcomes, medications chosen must reach the site of action and remain active once there, without any systemic toxicity. This could be achieved by the use of aerosolized medications *via* nebulizers or metered dose inhalers which help to increase efficacy and minimize toxicity.

An advantage of using nebulizers over metered-dose and dry powder inhalers is that less patient coordination is needed for optimum drug delivery. In addition, some drugs are only available in solution form and cannot be given through a metered-dose or dry powder inhaler.

The present study was conducted to compare the efficiency of preoperative nebulization of lignocaine hydrochloride and magnesium sulphate for reducing the incidence of POST in patients undergoing surgeries in general anesthesia, because lignocaine being local anesthetic may reduce the local nerve irritation and magnesium being NMDA receptor antagonist was tried as cost effective method to decrease POST. (NMDA has a role in nociception and inflammation associated with POST).

Aims and Objectives

The purpose and aim of the study was to compare the efficiency of preoperative nebulization of lignocaine hydrochloride and magnesium sulphate in reducing the incidence of POST following GA with regards to:

1. Postoperative sore throat (POST);
2. Cough hoarseness of voice, dysphagia and dysphonia;
3. Complications from possible systemic effects, because of absorption from mucosal surfaces.

Materials and Methods

Materials required:

1. Nebulizer (Piston compresser type nebulizer)
2. Anesthesia work station (WATO EX-35, Mindray)
3. Bain's circuit/closed circuit with circle absorber
4. Endotracheal tubes of different sizes (cuffed) with connection
5. Macintosh curved blade laryngoscope
6. Drip sets, IV cannula
7. Sterile syringes and swabs
8. Drip stand
9. Stylet
10. Multiparameter monitor (Bene View T9, Mindray) (Pulse oximetry, NIBP, $EtCO_2$, ECG, Gas analyzer)
11. Suction machine and Catheter
12. Adhesive plaster
13. General anesthesia drugs

    (Midazolam, Glycopyrrolate, Fentanyl, Propofol, Succinylcholine, Halothane, Vecuronium, N_2O, Neostigmine)
14. Emergency drugs

    (Adrenaline, Atropine, Dopamine,

Dobutamine, Deriphylline, Hydrocortisone, Mephentermine, nor adrenaline, Phenylephrine)

15. Drugs for nebulization

(Magnesium sulphate, Lignocaine 2%)

Study Design

This was a prospective, randomized, double blinded, case control study entitled as "Comparative Study of Magnesium Sulphate Nebulization and Lignocaine Nebulization in Prevention of Postoperative Sore Throat" conducted in the department of Anesthesiology, Government Medical College, Kota, in all three attached hospitals.

Sample Size

With the level of significance (alpha) = 0.05 and power of 80%, sample size required was 40 per group. To accommodate any exclusion, 50 patients from each group were selected. 100 patients of Government Medical College, Kota, and attached group of hospitals, scheduled to undergo elective surgery lasting more than 1 hour but less than three hours under GA requiring tracheal intubation within the age group 40–70 years, of both sexes were randomly allocated in two groups by simple randomization using computer generated numbers. The study was carried out with the approval of hospital research and ethical committee, after obtaining informed consent from patient and their relatives. The study remains free from being biased as neither the Patients nor the anesthesiologist who nebulized as well as who anesthetize and recorded the finding knows about the drug group.

Group A: 50 patients received Nebulized Magnesium Sulphate 4 ml. (6.25%);

Group B: 50 patients received Nebulized Lignocaine 4 ml. (2%).

Inclusion Criteria

- Adult normotensive patients, age between 40 and 70 years of both sex;
- Undergoing surgery under general anesthesia with tracheal intubation;
- Mallampatti Grade I and II;
- ASA Grade I and II.

Exclusion Criteria

- Patients allergic to any drugs.
- ASA Grade 3 & 4.
- Pt with compromise renal function.
- Pts with severe neuromuscular disease.
- Pts undergoing head, neck, or laparoscopic surgery.
- Pts having URI, those with NG tube or any nasal or throat packs or who require these intraoperatively.
- Pts with anticipated difficult intubation.
- Pts requiring prone or lithotomy position.
- Surgery lasted more than 3 hrs.

Preanesthesia evaluation included detailed history and physical examination to rule out any systemic diseases like respiratory disease, cardiovascular diseases, neuromuscular diseases, thyroid disease, liver or kidney disease and to know contraindications to drugs and techniques.

All patients were kept fasting overnight and premedicated with oral alprazolam 0.5 mg and ranitidine 150 mg on night before surgery and in the morning of surgery. 30 minute Prior to the induction of anesthesia, patients in Group A were nebulized with 4 ml of 250 mg isotonic nebulized magnesium sulfate (6.25% solution) for 15 min and Group B were nebulized with 4 ml of 2% lignocaine.

The solution for nebulization was administered by an anesthesiologist not associated with the management of the case. The anesthesiologist anesthetizing the case and those recording the scores were blinded to it.

Patients nebulized in sitting position through piston type compresser nebulizer.

Patients were:

A. Refrained from eating or drinking during that period;

B. Educated to "turn over" if vomiting occurs or to spit out the secretions;

C. Advised to take deep inspiration by open mouth.

On arrival of the patient in the operating room, intravenous line was established by 18-gauge intravenous cannula and infusion of ringer lactate was started. The patients head was placed on a soft pillow of 10 cm before induction of anesthesia with the neck flexed and head extended. The patients was connected to multiparameter monitor to record heart rate, noninvasive SBP, DBP, MAP, $EtCO_2$, continuous ECG tracing and oxygen saturation. After recording baseline parameters, the patient was premedicated with injection midazolam

0.02 mg/kg body weight. Then the patient was preoxygenated with 100% oxygen for 3 minutes *via* a face mask with Bain's circuit.

Anesthesia was induced with fentanyl 2 mcg/kg and propofol 2 mg/kg. Once an adequate depth of anesthesia was achived, patient was paralyzed by giving intravenous succinylcholine 1.5 mg/kg body weight. Intermittent positive pressure ventilation given with 100% oxygen for 1 minute with tidal volume of 6–8 ml/kg body weight. One minute after mask ventilation, gentle laryngoscopy and intubation was performed by an experienced anesthesiologist. Patients requiring laryngoscopy and intubation for more than 30 second or requiring more than two attempts for intubation were excluded from the study. Trachea intubated with soft seal cuffed sterile polyvinyl chloride tracheal tube (Sterimed) of 7–7.5 mm inner diameter in female with Mcintosh 3 no. blade and 8–8.5 mm in male patients with Mcintosh 4 no. blade. The tracheal tube cuff was inflated with air (till slight leakage of air is observed on positive pressure on bag). Proper placement of endotracheal tube was confirmed by bilateral symmetrical chest movements, bilateral equal air entry on auscultation, square waveform on capnograph, normal end tidal CO_2. The endotracheal tube was secured with adhesive tape. After assuring the proper placement of endotracheal tube, anesthesia was maintained with 1% isoflurane and vecuronium bromide 0.08 mg/kg body weight. Ventilation was controlled using Bain's circuit or closed circuit with soda lime in circle absorber using ventilator.

Hemodynamic parameters

The following Hemodynamic Parameters were recorded in all patients:

- Heart Rate (HR) in beats per minute;
- Systolic Blood Pressure (SBP) in mm of Hg;
- Diastolic Blood Pressure (DBP) in mm of Hg;
- Saturation $SpO_{2.}$

The above Hemodynamic Parameters were monitored in the following Time Interval:

- Basal before premedication;
- Just after intubation;
- 5 min after intubation;
- 10 min after intubation;
- Just after extubation.

On completion of surgery, anesthetic agents were discontinued allowing smooth recovery of consciousness. The muscle relaxation was reversed with a combination of neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. The trachea was extubated after extubation criteria were met (immediately after recovery of respiration), and the patients were shifted to postanesthesia care unit. The primary aim of this study was to evaluate the postoperative sore throat both at rest and on swallowing. The secondary aim was to identify other laryngeal complaints, such as cough, hoarseness of voice, dysphonia and dysphagia. These symptoms were scored by nursing staff not knowing results of study. Sore throat was defined as pain at the larynx or pharynx. It was asked with a direct questionnaire survey, 'Do you have a pain throat after operation?' Presence of sore throat was noted at rest and on swallowing. Cough was defined as a sudden, strong abdominal contraction. Even a single cough was recorded as 'yes'. Hoarseness was defined as a harsh or stained voice of patients different from his/her normal voice. If a nurse observed the patient's voice change, it was scored as 'yes'. Presence of sore throat, hoarseness and cough was noted:

- Immediately after extubation;
- 2 hr postoperatively, 8 hr postoperatively, 24 hr postoperatively and 48 hr postoperatively.

In the postoperative ward, patients were also monitored for any drug-related side effects like nausea, vomiting, hypotension, respiratory depression etc.

Statistical Analysis

All recorded data were expressed as mean ± SD Unpaired *t*-test was used for numerical data to compare Two Group. Test of normality (Kolmogorov-Smirnov, Shapiro-Wilk) was done for continuous variables (height, weight, age). Categorical data (gender) was expressed as frequency of occurrence. Comparisons of categorical data between groups were done using Pearson Chi-square, continuity correction, likelihood ratio, ($p < 0.05$) and considered statistically significant. IBM SPSS-21 was used for statistical analysis.

Observations and Results

There was even distribution of age in two groups. The patients selected in the present study belonged to the age between 40 and 70 years. Table 1 shown Age distribution of the patients in both the Groups. The mean age was 47 ± 7.8 and 47.9 ± 7.8 in Group A and Group B respectively. There was no significant difference in the age of patients

Table 1: Age distribution

Age (Range) (In years)	Group A (n = 50)	Group B (n = 50)
40–50	18	20
51–60	21	22
61–70	11	8
mean age ± SD (years)	47 ± 7.8	47.9 ± 7.8
p - value	0.999 (NS)	

Table 2: Sex distribution

Sex	Group A		Group B	
	No. of patients	Percentages	No. of patients	Percentages
Male	27	54%	28	56%
Female	23	46%	22	44%
Total	50	100%	50	100%

between the Magnesium Group and Lignocaine Group. Both Groups were similar with respect to age distribution ($p > 0.05$), shows in (Table 2).

Majority of patients were male i.e. 54% and 56% in Magnesium Group and Lignocaine Group respectively. Data were analyzed statistically and results were comparable with no significant difference ($p > 0.05$).

Table 3 shown comparison of mean pulse rate in both the Groups. On Intragroup comparison mean pulse rate increase in both groups at, 1 min, 5 min, 10 min after intubation and just after extubation from the preoperative value, but mean pulse rate more increase in Lignocaine Group as compared to Magnesium Group just after intubation and extubation. On Inter group comparison there was no significant difference in the mean pulse rate between the Lignocaine Group and Magnesium Group.

Table 3: Pulse Rate

Time	Group A		Group B			p - value	Statistical Significance
	Mean	SD	Mean	SD			
Preoperative		81.2	9.25	79	9.4	0.2167	
Intraoperative	1 Min	87.1	8.84	89	9.7	0.2614	
	5 Min	85	11	85	10	0.9770	p – value > 0.05 NS
	10 Min	86	8.8	86	9	0.9463	
Postoperative just after extubation		89.1	8.94	91	8.7	0.3093	

Table 4 shown comparison of mean SBP in both the Groups. On Intragroup comparison mean SBP increase in both Groups at, 1 min, 5 min, 10 min after intubation and just after extubation from the preoperative value, but mean SBP more increase

Table 4: Systolic BP

Time	Group A		Group B			p - Value	Statistical Significance
	Mean	SD	Mean	SD			
Preoperative		126	7.9	128	7.6	0.1309	
Intraoperative	1 Min	131	6.93	134	7.26	0.0514	
	5 Min	127	7.3	129	7.7	0.1130	p – value > 0.05 NS
	10 Min	126	6.1	129	6.6	0.0721	
Postoperative just after extubation		129	6.87	132	6.78	0.0819	

in Lignocaine Group as compared to Magnesium Group just after intubation and extubation. On Inter group comparison there was no significant difference in the SBP between the Lignocaine Group and Magnesium Group.

Table 5 shown comparison of mean DBP in both the Groups. On Intragroup comparison mean DBP increase in both groups at, 1 min, 5 min, 10 min after intubation and just after extubation from the preoperative value, but mean DBP more increase

Table 5: Diastolic BP

Time		Group A		Group B		*p* - value	Statistical Significance
		Mean	SD	Mean	SD		
Preoperative		84	7.2	85	10	0.5766	
Intraoperative	1 Min	86.84	7.06	90	9	0.0627	
	5 Min	82	9	83	8.5	0.6530	*p* - value > 0.05 NS
	10 Min	82	7.3	83	8.2	0.5222	
Postoperative just after extubation		86.5	8.65	89	8.9	0.1290	

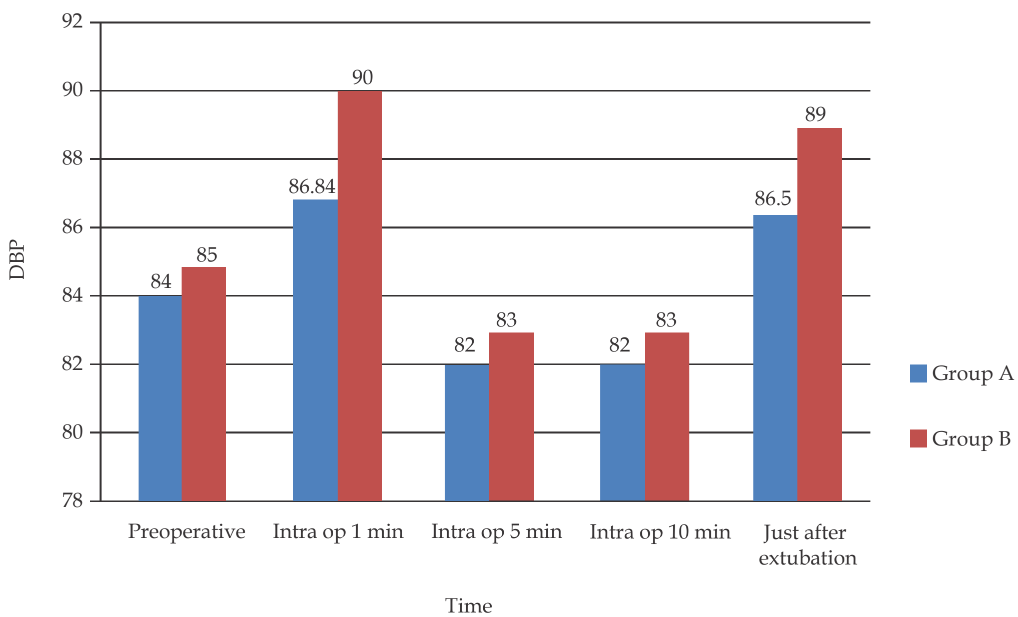

Fig. 1: Diastolic BP.

in Lignocaine Group as compared to Magnesium Group just after intubation and extubation. On Inter group comparison there was no significant difference in the SBP between the Lignocaine Group and Magnesium Group, shows in (Fig. 1).

Table 6 shown comparison of mean SpO_2 in both the Groups. On Intragroup comparison no difference in preoperative, intraoperative and postoperative means SpO_2 in both Groups. There was no significant difference in the mean SpO_2

Table 6: SpO_2

Time		Group A		Group B		*p* - value	Statistical Significance
		Mean	SD	Mean	SD		
Preoperative		98.7	0.93	98	1	0.13	
Intraoperative	1 Min	99.9	0.27	99.9	0.27	0.73	
	5 Min	99.9	0.27	99.9	0.27	0.73	*p* – value > 0.05 NS
	10 Min	99.9	0.27	99.9	0.27	0.55	
Postoperative just after extubation		98	0.7	99	1	0.29	

of patients between the Magnesium Group and Lignocaine Group. Both Groups were similar with respect to mean SpO_2.

Table 7 shown comparison of sore throat at rest in both the groups just after extubation, 2 hours, 8 hours, 24 hours and 48 hours. On intragroup comparison incidence of sore throat was more just after extubation in both groups. Sore throat incidence decrease with time in both groups. After 48 hr no incidence of sore throat found in both groups. On intergroup comparison incidence of sore throat was more common in lignocaine group as compared to magnesium group but there was no significant difference in both groups with respect to sore throat at rest ($p > 0.05$), (Fig. 2).

Table 8 shown comparison of sore throat on swallowing in both the Groups just after extubation, 2 hours, 8 hours, 24 hours and 48 hours. On Intragroup comparison incidence of sore throat on swallowing was more just after extubation in both Groups. Sore throat incidence decrease with time in both Groups. After 48 hr no incidence of sore throat found in both Groups. On Inter group comparison incidence of sore throat was more common in Lignocaine Group as compared to

Table 7: Sore throat at rest

Time	Group A		Group B		*p* - value	Statistical Significance
	Nos. of patients	Percentages	Nos. of patients	Percentages		
Immediate after extubation	7	14	9	18	0.770	
2 hour	4	8	6	12	0.505	*p* - value>0.05 NS
8 hour	2	4	5	10	0.239	
24 hour	1	2	2	4	0.557	
48 hour	0	0	0	0		

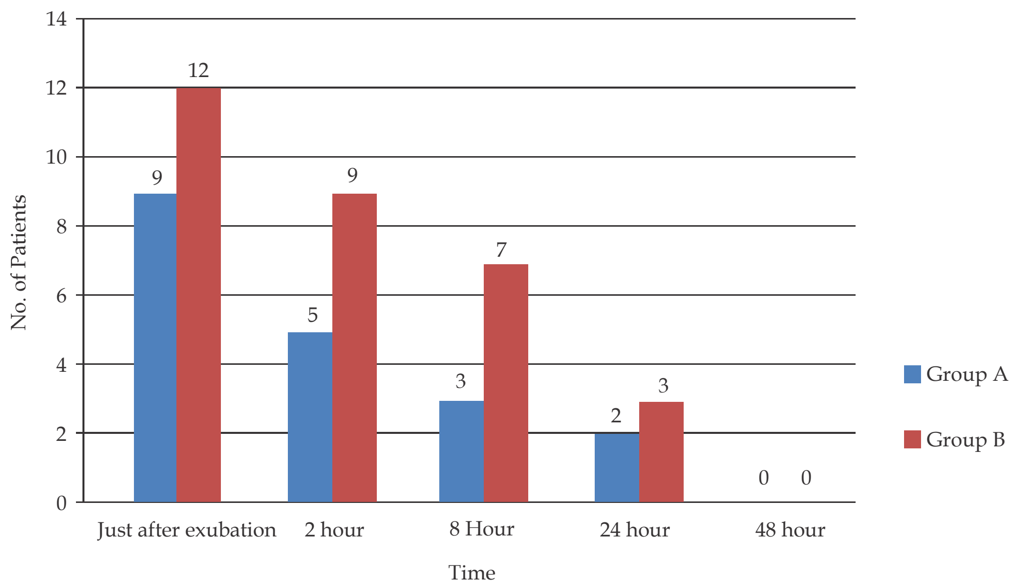

Fig. 2: Sore throat.

Table 8: Sore throat on swallowing

	Nos. of patients	Percentages	Nos. of patients			
Immediate after extubation	9	18	12	24	0.624	
2 hour	5	10	9	18	0.249	*p* - value > 0.05 NS
8 hour	3	6	7	14	0.182	
24 hour	2	4	3	6	0.646	
48 hour	0	0	0	0		

Magnesium Group but there was no significant difference in both Groups with respect to sore throat on swallowing ($p > 0.05$).

Table 9 shown comparison of hoarseness of voice in both the Groups just after extubation, 2 hours, 8 hours, 24 hours and 48 hours. On Intragroup comparison incidence of hoarseness of voice was more just after extubation in both Groups. Incidence decrease with time in both Groups. 24 hr after extubation no incidence of hoarseness of voice found in Magnesium Groups. In Lignocaine Group no incidence of hoarseness of voice found 48 hr after extubation. On Inter group comparison incidence of sore throat was more common in Lignocaine Group as compared to Magnesium Group but there was no significant difference in both Groups with respect to hoarseness of voice ($p > 0.05$).

Table 9: Hoarseness of voice

Time	Group A		Group B		*p* - value	Statistical Significance
	Nos. of patients	percentages	Nos. of patients	Percentages		
Immediate after extubation	4	8	7	14	0.337	
2 hour	3	6	6	12	0.294	*p* – value > 0.05 NS
8 hour	2	4	3	6	0.646	
24 hour	0	0	1	2	0.314	
48 hour	0	0	0	0		

Table 10 shown comparison of cough in both the Groups just after extubation, 2 hours, 8 hours, 24 hours and 48 hours. On Intragroup comparison incidence of cough just after extubation more in Magnesium Group as compare to Lignocaine Group patients thereafter incidence of cough more in Lignocaine Group patients. 48 hr after extubation no incidence of cough noted in both Groups. On Inter group comparison there was no significant difference in the incidence of cough in patients between the Magnesium Group and Lignocaine Group. Both Groups were similar with respect to cough incidence ($p > 0.05$).

Table 10: Comparison of cough

Time	Group A		Group B		*p* - value	Statistical Significance
	No. of patients	Percentages	No. of patients	Percentages		
Immediate after extubation	7	14	5	10	0.538	
2 hour	3	6	4	8	0.695	*p* – value > 0.05 NS
8 hour	2	4	3	6	0.646	
24 hour	1	2	2	4	0.557	
48 hour	0	0	0	0		

Complication and side effect

As observed in Magnesium Group 2 patients (4%) developed nausea, and 2 patients (4%) developed sedation in Lignocaine Group. We conclude that the side effect profile of the both Groups was quite similar as none of the patient in both Groups had profound deep sedation or respiratory depression and does not bring any additional morbidity to patients. Incidence of side effects were comparable ($p > 0.05$) in both the Groups.

Discussion

Postoperative Sore Throat (POST), cough and hoarseness of voice is common, uncomfortable, distressing sequelae after tracheal intubation. It impacts the wellbeing of patients after surgical procedures under general anethesia and leaves the patients with unpleasant memories of surgery.

In our study we used magnesium sulphate nebulization and lignocaine nebulization for reducing postoperative throat complaints. Magnesium acts as a NMDA antagonist and NMDA recepter has a role in nociception and inflammation. Magnesium is easily available, cost effective. Lignocaine act by anti-inflammatory action and reduce local nerve irritation. It is easily available, cost effective, less side effect and no long-term residual effects.

Sore Throat

We found that incidence of sore throat at rest and on swallowing was more in lignocaine group as compare to Magnesium Group and sore throat more common in female patients as compared to male patients during study period, but statistically there was no significant difference in the incidence of sore throat between the Magnesium Group and Lignocaine Group patients. Both Groups were similar with respect to sore throat ($p > 0.05$). On Intragroup comparison sore throat incidence decrease with time in both Groups. 48 hr after extubation there was no incidence of sore throat found in both Groups.

Our study correlated with the study of Christensen AM et al. (1994)[2] in which they found that the incidence of postoperative sore throat in women (17%) was significantly higher than that in men (9%) which was attributed to the tighter fitting of tube in women.

On swallowing incidence of sore throat after magnesium sulphate nebulization at rest just after extubation, 2 hr, 4 hr, 24 hr was 20%, 16%, 12% and 2%. Our findings are also comparable to study done by Gupta SK, Tharwani S et al. 2012.[11] In their study, they concluded that incidence and severity of POST at rest and on swallowing reduced with magnesium sulphate nebulization.

Hoarseness of Voice

It was observed that Incidence of hoarseness of voice was more in Lignocaine Group as compare to Magnesium Group and more incidence in female patients but there was no significant difference in the incidence of hoarseness of voice between the Magnesium Group and Lignocaine Group patients. Both Groups were similar with respect to hoarseness of voice ($p > 0.05$). On Intragroup comparison incidence of hoarseness of voice decrease with time in both Groups but more faster recovery in Magnesium Group. In Magnesium Group no incidence of hoarseness of voice found at 24 hr after extubation. In Lignocaine Group no incidence of hoarseness of voice found at 48 hr after extubation.

Cough

It was observed that on Intragroup comparison initially just after extubation incidence of cough more in Magnesium Group then Lignocaine Group after that incidence of cough decrease in both Groups. Incidence of cough at 2 hr and after that more in Lignocaine Group as compared to Magnesium group. In both Groups incidence of cough was more in female patients. 48 hr after extubation there was no incidence of cough noted in both Groups on Inter group comparison there was no significant difference in the incidence of cough in patients between the Magnesium Group and Lignocaine Group. Both Groups were similar with respect to cough incidence ($p > 0.05$).

Secondary Goals

Endotracheal tube intubation which is integral part of general anesthesia associated with presser response and hemodynamic variation. In cardiac disease patients during the insertion and extubation of endotracheal tube may increase the morbidity and mortality due to presser response. Preoperative nebulization with magnesium sulphate and lignocaine decrease the incidence of perioperative morbidity and mortality due to perioperative hemodynamic stability. The following hemodynamic parameters were recorded in all patients:

Basal before premedication, just after intubation, 5 min., 10 min. after intubation and just after extubation.

Heart Rate

As shown in Table 4, just after intubation, mean pulse rate increased as compared to basal value in both Groups but increase in pulse rate was much more in Lignocaine Group as compared to Magnesium Group and mean pulse rate in Lignocaine Group remained high ($p > 0.05$) as compared to Magnesium Group up to just after extubation. But, none of the patients in both either groups required any treatment for tachycardia or arrhythmia (pulse rate was never less than 60 bpm).

On Inter group comparison difference was statistically not significant ($p > 0.05$). Results suggest that increase in pulse rate in both Groups was due to intubation response.

Systolic and Diastolic Blood Pressure

As shown in Tables 5 and 6, just after intubation, both SBP and DBP increased as compared to basal value in both Groups but increase in blood pressure was much more in Lignocaine Group as compared to Magnesium Group and blood pressure remain high as compared to Magnesium Group up to just after extubation. On Inter group comparison difference was statistically not significant ($p > 0.05$). Results suggest that increase in blood pressure in both Groups was due to intubation response.

SpO$_2$

As shown in Table 7 in both Groups changes in mean oxygen saturation remained statistically insignificant ($p > 0.05$). On Intragroup comparison mean oxygen saturation remained constant.

Side Effects and Complications

As shown in Table 10, in Magnesium Group 2 (4%) patients developed nausea, and 2 (4%) patients developed sedation in Lignocaine Group. Hypotension, Hypertension, Oligourea, seizure, Arrhythmias, respiratory depression, Flushing of skin, Loss of deep tendon reflex, Slurring of speech and any other complications were not observed in any patient of either group.

Our results indicate that as a nebulization, the side effect profile of the both Groups was quite similar as none of the patient in both Groups had profound deep sedation or respiratory depression and does not bring any additional morbidity to patients.

Summary and Conclusions

We conclude that incidence of sore throat, hoarseness of voice and cough was more common in Lignocaine Group as compared to Magnesium Group and more common in female patients in both Groups. So, both drugs can be used for prevention of postoperative sore throat, but magnesium sulphate was better for prevention of POST but statistically nonsignificant. However, further study required with large study group and monitoring of blood concentration of drugs.

References

1. Doukumo DM, Faponle AF, Bolaji BO, et al. Effects of lidocaine and K-Y jellies on sore throat, cough, and hoarseness following endotracheal anesthesia. Journal of the West African College of Surgeons 2011;1(3):3.
2. Edomwonyi NP, Ekere IT, OMO E, et al. Postoperative throat complications after tracheal intubation. Ann Afr Med 2006;5:28–32.
3. Yadav Monu, Chalumuru Nitish Gopinath Ramachandran. Effect of magnesium sulfate nebulization on the incidence of postoperative sore throat. Journal of Anesthesiology Clinical Pharmacology 2016;32:2.
4. Houman Teymourian, Seyed Amir Mohajerani, Alireza Farahbod. Magnesium and ketamine gargle and postoperative pore phroat. Anesth Pain Med. 2015 Jun;5(3):e22367.
5. Jafari H, Ariaeifar MR, Yazdani Charati J, et al. The effect of green tea gargle solution on sore throat after coronary artery bypass grafting: A randomized clinical trial. Anesth Pain Med, 2016 Jun;6(3):e32108.
6. Gaur P, Ubale P, Khadanga P. Efficacy and safety of using air *versus* alkalinized 2% lignocaine for inflating endotracheal tube cuff and it's pressure effects on incidence of postoperative coughing and sore throat. Anesth Essays Res 2017;11(4):1057–1063.
7. Atabak Najafi, Farsad Imani, Jalil Makarem, et al. Postoperative sore throat after laryngoscopy with macintosh or glide scope video laryngoscope blade in normal Airway Patients. Anesth and Pain Med 2014;4(1).
8. David M Kali, Loraine S Silvestro, Paul N Austin. Noval preoperative pharmacologic method of preventing postoperative sore throat due to tracheal intubation. AANA Journal 2014 June;82(3):188.
9. Hung Nan Kai, Ching Tang Chan, Shun Ming, et al. Effect of postoperative sore throat of spraying the endotracheal tube cuff with benzydamine hydrochloride, 10% lidocaine and 2% lidocaine. Anesthesia and Analgesia 2010;111(4):882–86.
10. S Pedersen. Topical Review Inhalers and nebulizers: Which to choose and why? Respiratory Medicine 1996;90:69–77.
11. Michael FM James. Calcium and Magnesium, Wylie and Churchill: Davidson's A Practice of Anesthesia, 7th edition. In: Thomas EJ Healy, Paul R Knight, editor. Edward Arnold: 2003.p. 341.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 124-136
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.18

Elastomeric Infusion Pump: Evaluation of Different Infusion Rates for Postoperative Epidural Analgesia

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Abstract

Introduction: The continuous epidural infusion of local anesthetic and fentanyl using a multirate elastomeric infusion pump provides the good analgesic option to treat the postoperative pain following the major abdominal surgery. The aim of the present study is to compare the different infusion rates of 0.1% bupivacaine with fentanyl as continuous epidural infusion using Baxter's multirate elastomeric infusion pump in patients undergoing laparotomy under general anesthesia. *Materials and Methods:* Seventy five patients, in age group of 25–60 year with ASA Grade I and II undergoing intraabdominal surgery under general anesthesia were randomly divided into three groups. The epidural catheter was placed in L1–2 interspace with six cm of catheter length in epidural space before induction of GA. At the time of closure of peritoneum a bolus of 8 ml of 0.1% bupivacaine with fentanyl 2 mcg/ml was given in epidural space and the continuous infusion was started at specified rate depending upon the group. In Gp I the infusion was @ 5 ml/hr while in Gp II and Gp III infusion rate was 7 ml/hr and 12 ml/hr respectively. An independent observer visited the patient at regular intervals to enquire about VAS score in postoperative period, extending up to 48 hours. *Statistical Analysis:* Parametric and nonparametric data were collected and relevant data of each patient was entered in Microsoft Excel Worksheet© and were analyzed statistically by using IBM SPSS© software. *p* - value < 0.05 was taken statistically significant. *Results:* Analysis of postoperative VAS score showed that all the patients have 0 VAS at the time of extubation. Gp I showed higher VAS scores while Gp II and Gp III had a comparable VAS scores. Mean morphine consumption in Gp I was 0.96 ± 1.136 (total 5.7 mg), in Gp II was 0.48 ± 0.714 (total 2.88 mg) and in Gp III was 0.24 ± 0.663 (total 1.44 mg). All groups demonstrated the height of sensory block at T5 dermatome level in immediate postoperative period and the regression was faster in Gp I and II. The mean height of sensory blockade was much higher in Gp III (T7 dermatome) as compared to Gp I & II (T 9 dermatome). Gp III had mild weakness in hip flexion after 20 hrs of continuous infusion. Statistically higher sedation scores were noted in Gp III, but all patients were responsive to commands at all times. Gp III had higher incidence of bradycardia and hypotension (5/25, 20 %), shivering (13/25, 52%), pruritus (14/25, 56%), nausea and vomiting. The mean hospital stay was 5.106 ± 1.203 days. *Conclusion:* For adequate postoperative pain relief following laparotomy under general anesthesia, the administration of bupivacaine 0.1% with fentanyl 2 mcg/ml @7 ml/hr is ideal rate for continuous epidural infusion. The multi rate elastomeric pump used in the study performed satisfactorily and no mal function was reported.

Keywords: Infusion pump; Epidural analgesia.

How to cite this article:

Sijo C Babu, Girish Sharma, Arati Sharma, et al. Elastomeric Infusion Pump: Evaluation of Different Infusion Rates for Postoperative Epidural Analgesia. Indian J Anesth Analg. 2020;7(1 Part -I):124–136.

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Received on 02.09.2019, **Accepted on** 28.11.2019

Introduction

Pain is an inevitable consequence of surgery and it disrupts the normal physiological and psychological homeostasis. Acute pain after surgery has a distinct patho physiology that reflects peripheral and central sensitization as well as humoral factors.[1] Peri operative pain is a potent trigger for the stress response, activates the autonomic system and is thought to be an indirect cause of adverse effects on various organ systems.[2] Uncontrolled acute pain is associated with the development of chronic pain, prolonged rehabilitation and reduction in quality of life.[3,4] Moreover, failure to relieve pain is morally and ethically unacceptable. Goals for the same are to relieve suffering, achieve early mobilization after surgery, shorten hospital stays, reduce hospital costs and increase patient satisfaction.[5] Laparotomy performed under general anesthesia with a mid line vertical incision is best choice as it provides a rapid and safe entry into the peritoneum and provides relatively bloodless field but is associated with intense pain in the immediate postoperative period. Early postsurgical pain typically peaks on the first postoperative day and shows some improvement over the first 72 hours.[6] This pain has a major impact on patients' satisfaction and may negatively interfere with the postoperative recovery course.[7] Many options are available for treatment of postoperative pain, the main stay of postoperative pain therapy in many settings is still opioids.[8] All opioids have significant side effects limiting their use.[9] Primary opioid-based regimens are being challenged by other agents and approaches to postoperative pain management.[10] Regional neuraxial anesthesia is an effective method of producing effective postoperative analgesia.[11] Effective analgesia for postoperative pain relief after major surgery with epidural administration has been a proposition since early 1980s.[12] The ideal epidural analgesic technique for major surgery would provide effective pain relief with minimal side effects and high levels of patient satisfaction. It would also obtund central sensitization and pain-induced organ dysfunction, leading to improved outcome.[13] Continuous infusion of local anesthetics and opioids in the epidural space helps to maintain a constant level of analgesia while minimizing the cardiovascular and respiratory effects of bolus doses.[14] For this purpose, disposable pumps that use an elastomeric reservoir remain widely used, while the operational complexity of electronic pumps raises concerns about potentially introducing dangerous programming errors.[15]

Potential long-term benefits from reduction in morbidity associated with epidural analgesia may outweigh total costs.[16] Further, studies are needed to identify the full extent of potential benefits from epidural analgesia, optimal techniques and especially the minimum effective dosage with less side effects. Hence, we compared different infusion rates of 0.1% bupivacaine with fentanyl 2 mcg/ml as continuous epidural infusion using elastomeric multirate infusion pump for postoperative analgesia in patients undergoing laparotomy under general anesthesia.

Materials and Methods

After approval by the research ethics committee and written informed valid consent of the patients, the proposed study was carried out over a period of one year, in ASA-I and ASA-II patients, aged between 25 and 60 years of either sex, weight ranging from 40 to 70 kg, posted for intraabdominal surgery. The study was conducted in a prospective, double blind and randomized manner.

Inclusion Criteria

Included ASA Grade I & II patients posted for abdominal surgery under general anesthesia.

Exclusion Criteria

Included Patient refusing consent, patients with ASA Grade III and IV, history of peripheral neuropathy, low backache and spinal pathologies, pregnant women, patients with coagulation disorders, history of drug allergy or hypersensitivity to drugs, infection at the site of epidural injection, patients with psychiatric disorder and patients aged less than 25 years and more than 60 years. All patients underwent a routine preanesthetic check up. Study protocol was explained to all the patients during preanesthetic evaluation and informed consent was taken and signed. The patients were made familiar with visual analog score, VAS (0 for no pain and 10 for the worst imaginable pain). The patients were instructed for a fasting period of 6 hrs.

Patients were divided into Three Groups depending upon the rate of continuous epidural infusion of 0.1% bupivacaine with fentanyl 2 mcg/ml, as follows, Group I: @ 5 mL/hr, Group II: @ 7 mL/hr and Group III: @ 12 mL/hr. The epidural infusion at specified rates was continued for next 48 hrs in postoperative period. The patients were assigned to their respective groups using random allocation software. The number allocated was kept in a sealed envelope and kept under lock and key. The envelope was opened at the time of surgery and the patient was assigned to the respective group. The epidural catheter was placed at L1/2 interspace with 6 cms of catheter in epidural space before giving general anesthesia and test-dose of 3 ml of 2% lidocaine with 1:200000 adrenaline was given to rule out intrathecal or intravascular placement of catheter.

Intravenous fentanyl 2 mcg/kg and ondansetrone 0.1 mg/kg were administered just before induction of anesthesia. All the patients were preoxygenated with 100% oxygen for 3 minutes. Induction of anesthesia was provided by injection Propofol 1–2.5 mg/kg intravenously. Injection Atracurium 0.5 mg/kg was used to facilitate tracheal intubation after 3 minutes of assisted ventilation. Anesthesia was maintained with 1% Isoflurane with 33% oxygen and 66% nitrous oxide. Muscle relaxation was maintained by intermittent boluses of Atracurium 0.1 mg/kg as required. At the time of closure of peritoneum, patients were given a bolus of 8 ml of 0.1% bupivacaine with 2 mcg/ml of fentanyl and thereafter, the continuous epidural infusion was started as per group allocated using elastomeric infusor pump. At the end of the procedure, prior to extubation residual neuromuscular blockade was reversed with intravenous Neostigmine 0.05 mg/kg and Glycopyrrolate 0.01 mg/kg. The time of extubation was considered as 0 minutes. The epidural infusion at specific rate was kept for 48 hrs in postoperative period and patients were observed for pain relief and side effects, if any, at regular intervals. Subsequent refilling of the infusion pump was done by the same anesthetist who started the infusion.

The independent observer visited the patient at regular intervals to monitor and enquire about VAS score in postoperative period extending up to 48 hours; the observer had no access to covered infusion pump.

The quality of postoperative analgesia was assessed according to VAS score at 0, 30, 60 minutes and 2, 4, 6, 8, 10, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48 hrs. It was considered satisfactory if the patient does not complain of any pain or discomfort after surgery. When the patient began to experience pain more than 4 on VAS it was considered that the analgesic action of the drug is inadequate and rescue analgesia was given as injection morphine sulphate 6 mg intravenously, waited for 15 minutes and repeated at a dose of 3 mg, if necessary.

The level of sensory block was assessed postoperatively at above intervals, according to pin prick method. (Grade-0 Sharp pain felt, Grade-1 - dull sensation felt, Grade-2 - no sensation felt). The infusion was stopped if sensory block level reaches above T4. It was restarted after it recedes back to T5 or below. The level of motor block was assessed postoperatively, by asking the patient to move his/her limb in accordance with the Modified Bromage Scale. Sedation score was assessed by using Ramsay Sedation Scale postoperatively at the same time intervals. Monitoring of heart rate, mean arterial pressure, SpO_2 and respiratory rate was done at same time intervals. Side effects were monitored.

Results

Parametric and nonparametric data were collected and were analyzed statistically by using IBM SPSS® software. The following observations were made:

The mean age (in years) was 38.64 ± 9.83, 41.60 ± 8.11 and 38.56 ± 9.81 in Group I, II and III respectively. The mean weight (in kg) was 65.12 ± 5.95 in Gp I, 64.2 ± 7.39 in Gp II and 65.88 ± 6.72 in Gp III. The mean height (in cm) was 167.68 ± 6.26, 166.92 ± 6.38 and 166.00 ± 5.53 in Gp I, II and III respectively. No statistically significant difference was found between the Three Groups with respect to age, weight and height (p - value: > 0.05). In this study, more number of male patients were present in all the Three Groups and the difference was statistically insignificant (p – value > 0.05). Out of the total patients, 18.7% (14/75) were females and 81.3% (61/75) were males. The quality of analgesia was assessed by VAS scoring for 48 hours postoperatively. All the patients at the time of extubation (time 0) recorded a VAS of '0'. There after the VAS values showed a 'rise and fall' trend. When the Gp I and II were compared for pain scores at different points of postoperative period, the VAS recorded were significantly lower in Gp II up to 10 hours and the changes were statistically highly significant (p - value < 0.001). Only at 12^{th} hour (p - value = 0.371) and 16^{th} hour (p - value = 0.346) the groups had comparable pain scores. While comparing Gp I and III for analgesic efficacy, the VAS recorded for Gp III were significantly lower throughout the study period, and the changes were statistically highly significant (p - value < 0.001). No significant changes in VAS scores were noted on comparing pain between Gp II and Gp III except between 8 and 20 hours of postoperative period. The p - values were consistently more than 0.05, except between 8 and 20 hours (p - value < 0.001). During this period Gp III demonstrated a significantly lower pain scores, (Table 1, Fig. 1).

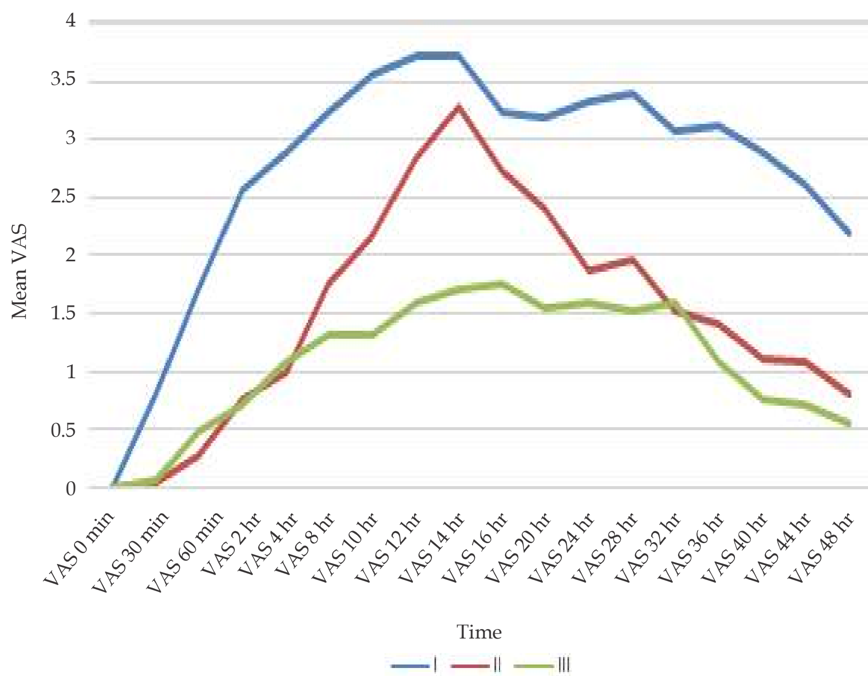

Fig. 1: VAS values in three groups at different point of time

Table 1: VAS values in three groups at different point of time

	Gp I		Gp II		Gp III		*p* - value* (*t*- test)		
	Mean	SD	Mean	SD	Mean	SD	Group I Vs Group II	Group I Vs Group III	Group II Vs Group III
VAS 0 min	0.000	0.0000	0.000	0.0000	0.000	0.0000	–	–	–
VAS 30 min	0.800	0.5000	0.040	0.2000	0.080	0.2769	.000	.000	.914
VAS 60 min	1.720	0.7371	0.280	0.4583	0.480	0.5859	.000	.000	.475
VAS 2 hr	2.560	0.8206	0.760	0.5972	0.720	0.7371	.000	.000	.979
VAS 4 hr	2.880	0.9713	1.000	0.6455	1.080	0.7024	.000	.000	.931
VAS 6 hr	3.240	0.9695	1.760	0.6633	1.320	0.9452	.000	.000	.181
VAS 8 hr	3.560	0.9609	2.160	0.6245	1.320	0.5568	.000	.000	.000
VAS 10 hr	3.720	0.9798	2.840	0.8981	1.600	0.7638	.002	.000	.000
VAS 12 hr	3.720	1.3077	3.280	1.1733	1.720	0.9363	.371	.000	.000
VAS 16 hr	3.240	1.5078	2.720	1.3077	1.760	1.0909	.346	.000	.031
VAS 20 hr	3.200	1.1902	2.400	0.8165	1.560	0.5066	.006	.000	.004
VAS 24 hr	3.320	1.0296	1.880	0.7257	1.600	0.5000	.000	.000	.419
VAS 28 hr	3.400	0.8660	1.960	1.2741	1.520	0.8226	.000	.000	.277
VAS 32 hr	3.080	0.8124	1.520	1.1944	1.600	1.2247	.000	.000	.964
VAS 36 hr	3.120	0.5260	1.400	0.6455	1.080	0.7024	.000	.000	.177
VAS 40 hr	2.880	0.7810	1.120	0.7810	0.760	0.5972	.000	.000	.192
VAS 44 hr	2.600	0.8165	1.080	0.7024	0.720	0.6137	.000	.000	.184
VAS 48 hr	2.200	0.5000	0.800	0.5774	0.560	0.7118	.000	.000	.342

(*p - value inference: > 0.05- insignificant, < 0.05- significant, < 0.001- highly significant)

The mean dose of Inj. Morphine consumed as rescue analgesic in Gp I, Gp II and Gp III was 0.96 ± 1.136, 0.48 ± 0.714 and 0.24 ± 0.663 respectively. Intergroup analysis showed a statistically insignificant p - value of 0.129 between Gp I and Gp II, and 0.591 between Gp II and Gp III. But the difference was statistically significant with a p - value of 0.012 between Gp I and Gp III. The total amount of morphine consumed over 48 hours per patient was 5.76 mg in Gp I, 2.88 mg in Gp II and 1.44 mg in Gp III, (Table 2, Fig. 2).

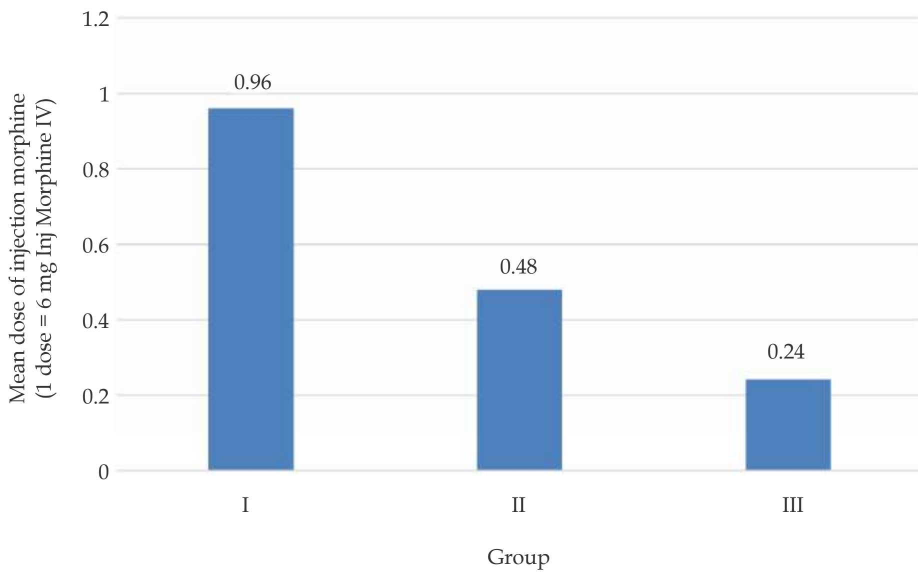

Fig. 2: Comparison of number of rescue analgesic doses (Inj. Morphine sulphate 6 mg IV).

Table 2: Comparison of number of rescue analgesic doses (Inj. Morphine sulphate 6 mg I/V)

Groups	N	Mean dose of Inj. Morphine	SD	Mean consumption of morphine over 48 hours (mg)	*p* - value (*t*- test)
I	25	0.96	1.136	5.76	Group I v/s Group II = 0.129
II	25	0.48	0.714	2.88	Group I v/s Group III = 0.012
III	25	0.24	0.663	1.44	Group II v/s Group III =0.591

At the time of extubation, all the patients demonstrated a comparable sensory block level corresponding to dermatomes T4/T5. Thereafter, the height of the sensory block showed a regression to lower levels in all the Groups. The rate of regression of sensory block height was higher in Gp I. Gp III showed a relatively consistent sensory block level during the study period, (Fig. 3). Gp I and II till 28 hrs showed no significant difference in sensory block height (p value >0.05), but thereafter Gp I showed significant regression of sensory block (p - value < 0.001). At the end of the study period, the mean height of sensory blockade achieved by Gp I and II was dermatome level T9, whereas for Gp III it was T7. While comparing Gp I and III, and Gp II and Group III, the regression of the sensory block observed for Gp III was significantly lower throughout the study period, and the changes were statistically highly significant (p - value < 0.001), (Fig. 3).

The level of motor block was assessed in accordance with the Modified Bromage Scale. Gp I and Gp II consistently demonstrated no motor block. But Gp III after 20 hrs was characterized by Modified Bromage Scale values between 5 and 6, corresponding to mild weakness in hip flexion, and the changes were statistically significant (p - value < 0.05).

In Gp I the patients showed Ramsay sedation scale less than 2 during most of the study period. The sedation scale in Gp II was consistently between 2 and 3, whereas Gp III showed significantly higher levels of sedation. The sedation scores between Gp I and Gp II were comparable throughout the study period (p - value > 0.05). The comparison between All Groups showed a statistically significant high sedation score in Gp III after 12 hrs (p - value < 0.05).

Patient's Heart Hate (HR), Mean Arterial Blood Pressure (MABP), respiratory rate, Oxygen Saturation (SpO_2) were recorded Preoperative mean heart rate were 94.280 ± 6.0520, 95.760 ± 7.8437, and 96.320 ± 7.7175 in Gp I, II and III respectively, with no statistically significant difference in the Three Groups (p - value: > 0.05). Comparison between Gp I and Gp II showed a statistically comparable HR between 8 hours and 32 hours (p - value: > 0.05). Rest of the time period, Gp II showed a significant lower HR compared to Gp I. Whereas the comparison between Gp III with Gp I and Gp II showed a statistically highly significant fall in HR in Gp III throughout the study period (p - value : < 0.001). MABP before induction of anesthesia in Gp I, II and III were 80.480 ± 5.0259, 80.640 ± 2.9844 and 85.200 ± 4.8477 mm Hg respectively, with no statistically significant difference between the groups (p - value: > 0.05). In the postoperative period, Gp I showed a consistently elevated MABP, ranging between 99.440 ± 4.9840 mm Hg to 104.400 ± 6.8496 mm Hg, whereas it was between 83.360 ± 4.8809 mm Hg to 91.000 ± 13.0671 mm Hg in Gp II and 68.720 ± 5.3659 mm Hg to 80.120 ± 10.7017 mm Hg in Gp III. Highly significant fall in MABP was observed within Gp III (p - value: < 0.001).

The mean respiratory rate in the preoperative assessment were 20.320 ± 1.9088, 21.200 ± 1.9365 and 20.560 ± 2.4166 in Gp I, II and III respectively, which was comparable to each other (p - value: > 0.05). Comparison between Gp I and Gp II showed a statistically comparable mean respiratory rate (p - value : > 0.05) between 10 hours and 32 hours of postoperative period. Rest of the time period, Gp II showed a significantly low respiratory rate than that of Gp I. Whereas the comparison between Gp III with Gp I and II showed a statistically highly significant fall in respiratory rate in Gp III throughout the study period (p - value: < 0.001).

Intergroup comparison of mean SpO_2 between the groups revealed comparable values till 24 hours of postoperative time period (p - value: > 0.05). After that the saturation of oxygen showed a significant fall in Gp III compared to Gp I and II (p - value: < 0.05).

Side effects such as postoperative hypoxemia, hypotension, bradycardia, shivering, pruritus, nausea, vomiting, signs of local anesthetic toxicity/ arrhythmia and any other untoward side effect was monitored. Incidence of hypoxia (SpO_2 < 94%) was considerably higher in Gp III (13/25, 52%) whereas in Gp II only 2 patients (8%) and none in Gp I had fall in saturation values (p - value: < 0.001). Five patients (20%) in Gp III suffered hypotension (MABP < 65 mm Hg) and bradycardia (HR < 60 bpm) but no patient in Gp I and II had significant fall in heart rate and blood pressure (p - value: < 0.05). Thirteen patients (52%) reported shivering in Gp III whereas two patients (8%) in Gp I and five patients (20%) in Gp II reported shivering (p - value: < 0.05). Pruritus was present in all the Groups with highest incidence in Gp III (14/25, 56%), followed by Gp II (8/25, 32%) and Gp I (4/25, 16%) (p - value: < 0.05). Gp I showed a less incidence of nausea (4/25, 16%), whereas Gp II (5/25, 20%) and Gp III (10/25, 40%) showed a higher incidence, but the differences were statistically insignificant (p - value:

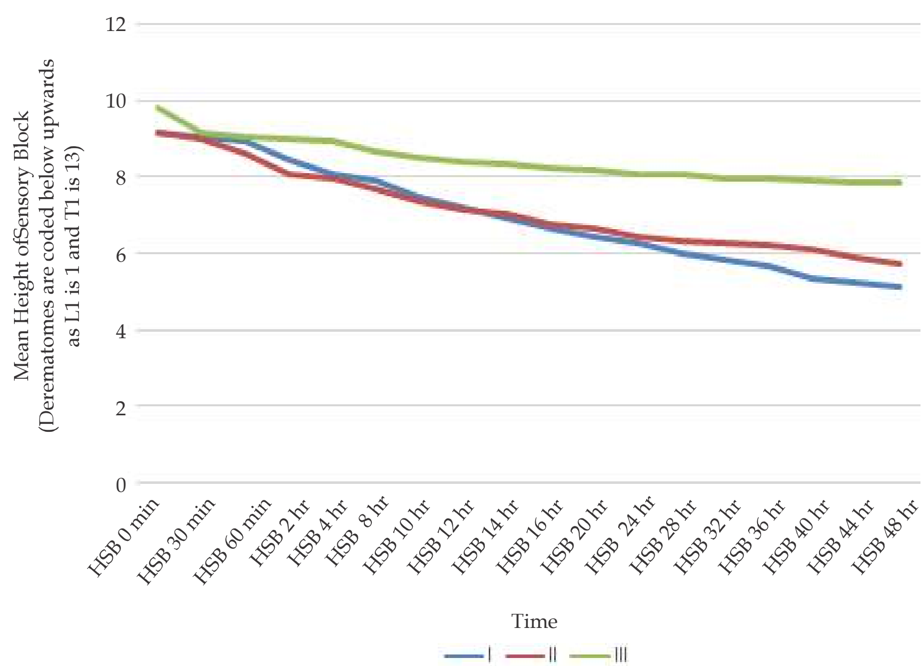

Fig. 3: Mean heights of the sensory block (HSB) in three groups at different point of time

>.05). Incidence of vomiting was highest in Gp III (7/25, 28%), followed by Gp II (4/25, 16%) and Gp I (3/25, 12%) (p - value: > 0.05). None of the patients in the study showed any signs of local anesthetic toxicity or arrhythmia during the study period, (Table 3, Fig 4).

Table 3: Incidence of side effects

	Group						Total		
	I		II		III				
Side effects	**Count**	**% within Group**	**Count**	**% within Group**	**Count**	**% within Group**	**Count**	**Total %**	***p*-value***
Hypoxia (SpO_2 < 94%)	0	0.0%	2	8.0%	13	52.0%	15	20.0%	.000
Hypotension (MAP < 65 mm Hg)	0	0.0%	0	0.0%	5	20.0%	5	6.7%	.005
Bradycardia (HR < 60 bpm)	0	0.0%	0	0.0%	5	20.0%	5	6.7%	.005
Shivering	2	8.0%	5	20.0%	13	52.0%	20	26.7%	.001
Pruritis	4	16.0%	8	32.0%	14	56.0%	26	34.7%	.011
Nausea	4	16.0%	5	20.0%	10	40.0%	19	25.3%	.112
Vomiting	3	12.0%	4	16.0%	7	28.0%	14	18.7%	.312
Signs of LA toxicity/ arrhythmia in first 30 min	0	0%	0	0%	0	0%	0	0%	–

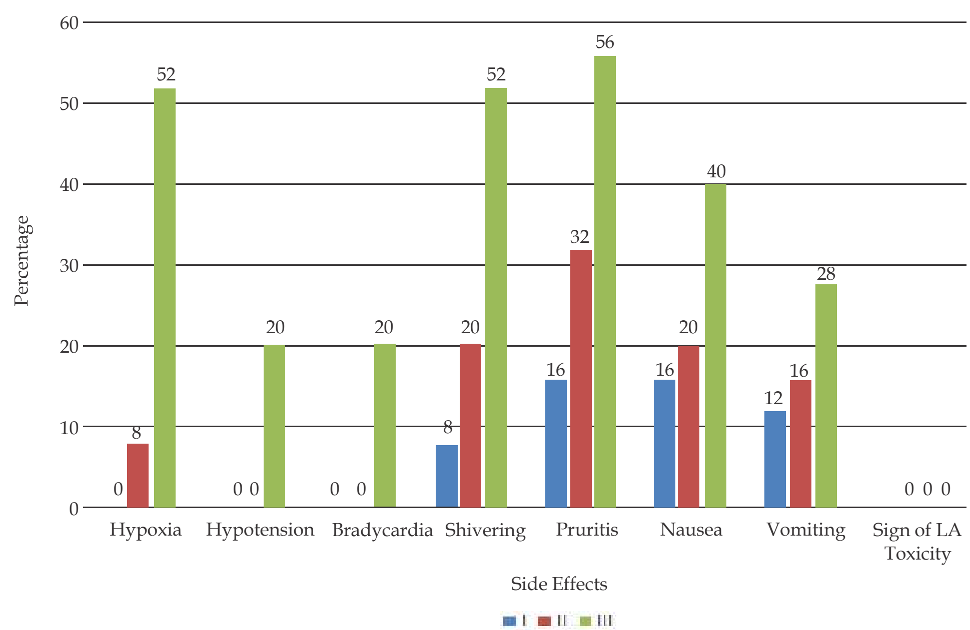

Fig. 4: Incidence of side effects

Apart from the proposed objectives of the study, we also performed a retrospective comparative analysis of mean length of hospital stay between our subjects and 75 other subjects in a similar patient population who were not given CEA. Length of hospital stay was defined as the time period beginning with admission to the Postanesthesia Care Unit (PACU) until the day of discharge. The mean hospital stay of the subjects who have received CEA was 5.106 ± 1.203 days whereas it was 9.106 ± 3.747 days in subjects who received only GA (p - value < 0.001).

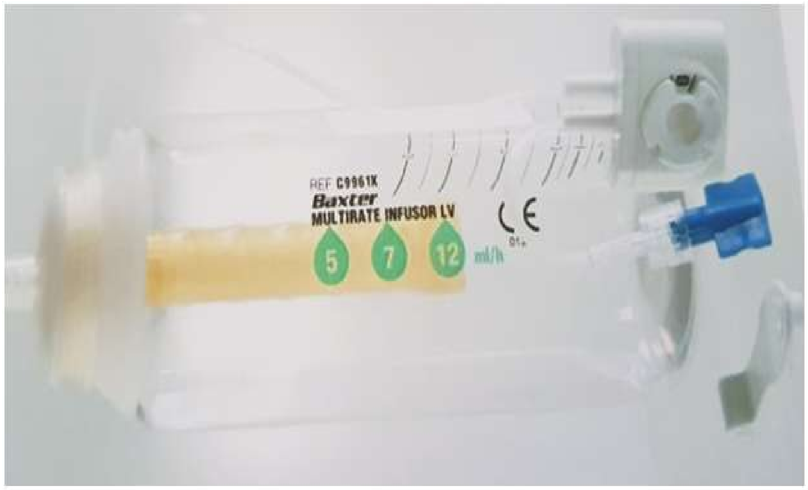

Fig. 5: Baxter's Multirate Elastomeric Infusion Pump

Discussion

Epidural analgesia is a safe and well-established technique, commonly regarded as the gold standard in postoperative pain management.[17] It provides superior pain relief while retaining adequate spontaneous respiration and hemodynamic stability. Christopher L Wu et al.[18] and Salicath JH et al.[19] suggested that an epidural technique provides better pain relief.

Routinely isobaric bupivacaine is used in a concentration of 0.1–0.25% for postoperative analgesia.[20] Addition of fentanyl has synergistic analgesic action and increases the pain free period postoperatively.[21] When administered in combination with opioids and other additives, the minimum effective concentration of bupivacaine can be as low as 0.0625% to 0.1% for epidural analgesia and side effects related to higher concentration of bupivacaine and fentanyl are less.[22,23] The mean VAS score at the time of extubation (0 min) was zero in all the Three Groups and can be attributed to the effect of bolus dose of epidural bupivacaine and fentanyl given at the time of peritoneum closure as well as the residual effect of intraoperative analgesia. Results showed that Gp II and Gp III have better pain relief than Gp I as far as quality of analgesia is concerned. Gp II and Gp III had comparable VAS during most of the study period. This shows that infusion of test solution @ 5 ml/hr was inadequate for postoperative analgesia. A similar pattern of pain scores were observed in a study conducted by SS Patil et al., Neal H Badner and Rakesh Bhandari and Paech MJ et al.[24–26]

The morphine consumption was maximum in Gp I. Intergroup analysis demonstrated a statistically significant difference between Gp I and Gp III. This could be attributed to fact that in Gp III the rate of infusion is 12 ml/hr which covers wide area in epidural space providing better pain control and also due to fact that more amount of fentanyl is being given i.e. 24 mcg/hr resulting in less consumption of morphine. This fentanyl acts locally on opioids receptors present at spinal cord level and also gets absorbed from epidural space and thus acting centrally.

At the time of extubation (0 minute) all Three Groups showed comparable sensory block level reaching up to dermatome T5 as all the patients in our study received a bolus dose of 8 ml of bupivacaine and fentanyl at the time of closure of peritoneum. Thereafter, a steady regression of sensory block was seen throughout the study period in all the groups. The regression was faster in Gp I and Gp II as compared to Gp III. The height of sensory blockade at a given time was much higher in Gp III throughout the study period. At the end of the study period the mean height of sensory blockade achieved by Gp I and Gp II was at dermatome level T9, whereas for Gp III it was at T7. The regression of sensory analgesia always corresponded with an increase in pain score, further supporting the trends in VAS score analysis discussed above.

Our results suggest that when drug is given as a bolus dose, it ascends two to three segments higher as compared to continuous infusion because all patients have sensory block up to T5 dermatome with 8 ml of bolus and then showing gradual regression to various levels depending upon the rate of infusion. Continuous epidural infusion of bupivacaine at a higher rate induces a slower regression of sensory blockade compared with lower infusion rates. Tachyphylaxis in continuous or repetitive epidural anesthesia manifests as either a diminished response to a standardized dose of local anesthetic or an increased dose requirement to maintain a constant level of sensory block. The lipid soluble bupivacaine penetrates the epidural fat and nerve fibers and deposit in the injecting region without diffusing longitudinally. Bigler et al. hypothesized that tachyphylaxis is due to a relative reduction in the efficiency of the neurogenic blockade by local anesthetics secondary to a posttraumatic increase in afferent neurogenic input, thereby overriding the neurogenic blockade.[27] Also, bupivacaine contains parahydroxyl benzoate as a preservative, which might alter the structural integrity of the epidural space, resulting in either a true reduction in effect at the receptor level, or a decrease in the fraction of local anesthetic reaching the receptor, causing a steady regression in sensory block height.[28] In a study conducted by Akifumi Kanai et al. and SS Patil et al.[24,29], a similar pattern of regression of sensory blockade was reported. In the study by SS Patil et al., they demonstrated that bupivacaine with fentanyl maintained a higher level of sensory blockade compared to ropivacaine and fentanyl.

None of the patients in Gp I and Gp II developed motor blockade, whereas Gp III showed a higher incidence after 20 hours of continuous infusion. Motor block is usually not seen with intermittent bolus injections of dilute local anesthetic. However, continuous infusion of anesthetic solution it may become anesthetized with time and this is probably why patients in Gp III developed a motor block. The motor block developed was considered as mild. Moreover the motor blockade developed after a period of time, reflecting the accumulated effect of the local anesthetic used. Christopher L Wu et al.[18] showed the overall incidence of motor block associated with CEA to be 28.3%.

Higher sedation scores were observed in Gp III after 12 hrs but all patients were responsive to commands at all times and it can be due to the systemic effect of fentanyl getting absorbed from epidural space. A Scott et al. and Leonardo Teixeira Domingues Duarte et al.[30,31] demonstrated a rising incidence of sedation with increase in fentanyl concentration.

Preoperative and intraoperative mean HR and MABP were comparable in three groups with no statistically significant difference. Five out of twenty five (20%) patients in Gp III developed bradycardia and hypotension but none in other groups. Epidural blockade causes vasodilatation with decrease in venous return and blockade of sympathetic fibers (T1-4), leading to bradycardia and hypotension depending upon the amount and volume of drug given as continuous infusion. Also, enhanced analgesia may abate the sympathetic discharge associated with pain perception, leading to lower heart rates. Fentanyl also has a vagotonic effect on heart causing decrease in heart rate by itself. This explains the significant decrease in HR in Gp III throughout the study period. The well settled HR in Gp II and III are in concordance with the well-controlled pain profile observed in these groups. Similar results were seen in study by Kumar Lakshmi et al.[32] None of the patient received any blood transfusion or vasopressors in the postoperative period though Inj. Mephentermine 3 mg IV was sometimes given during surgery. A similar study conducted by SS Patil et al.[34] demonstrated a comparable incidence of hypotension (13.3%).

Respiratory depression is one of the most feared adverse effects following CEA with opioids and can be classified as early and late.[35] Due to the different definitions of respiratory depression adopted by the authors, the incidence described in the literature varies considerably.[36] In our study, we defined respiratory depression by a reduction in peripheral oxygen saturation (SpO_2), determined by the pulse oximetry, less than 94%. The mean respiratory rate and mean SpO_2 in the preoperative assessment were comparable to each other. Highly significant fall in respiratory rate in Gp III was observed throughout the study period. The respiratory centre may get depressed due to increased systemic absorption of fentanyl from epidural space or its direct spread as more amount of fentanyl (24 mcg/hr) is being administered in Gp III with higher infusion rate and enhanced analgesia in that group. Also, the incidence of hypoxia was considerably higher in Gp III (52%), whereas Gp II showed 8% and none in Gp I. The difference was statistically highly significant.

Side effects such as shivering, pruritus, nausea, vomiting and signs of local anesthetic toxicity/ arrhythmia and any other untoward side effect were monitored and the incidence was significantly more in Gp III. Epidural anesthesia and analgesia is associated with a high incidence of intra and postoperative shivering, which is sometimes difficult to control. Increased temperature loss induced by the sympathetic block-induced vasodilatation and epidural infusion at ambient atmospheric temperature may lead to shivering.[37] Mild to moderate hypothermia (35.9 to 34°C) during general or regional anesthesia triggers the activation of thermoregulatory mechanisms responsible for decreasing temperature loss and increasing heat generation: Muscle shivering, sympathetic centers hyperactivity promoting vasoconstriction in the area above sympathetic block, increase in enzyme reactions by catecholamines, among others. Abreu MP et al.,[38] conducted a comparative study to analyze the incidence of intra and postoperative shivering and other complications of epidural block. In their study, 41% patients who received epidural bupivacaine/fentanyl solution developed shivering; this is in agreement with our study. They also demonstrated that, addition of fentanyl to LA solution did not abolish shivering but is able to decrease its incidence. Shivering during CEA can be prevented by measures such as warming infused fluids to 37ºC, maintaining room temperature between 21 and 24ºC and using thermal mattresses and blankets to cover the patient. Pharmacological therapy shows varying success rates.[39]

The use of opioids by intrathecal or epidural route frequently results in itching. The incidence of pruritus is 83% in postpartum patients and 69% in nonpregnant patients including males and females.[40] The central mechanism of intrathecal and epidural opioid-induced itching may be related to direct absorption of opioids into blood or due to cephalic spread of the drug in the cerebrospinal fluid and its action on the medullary dorsal horn and a trigeminal nucleus in the medulla.[41] Neuraxial opioids can also cause itching by acting on central 5-HT3 receptors. In our study, pruritus was present in all the groups with highest incidence in Gp III followed by Gp II and Gp I, which was statistically significant. The overall incidence was 34.7%. In a similar study conducted by Saito et al.,[42] the incidence of pruritus with epidural bupivacaine/morphine and bupivacaine/fentanyl was found to be 36% and 10% respectively. In another study conducted by Tan et al.,[43] to compare the analgesic and adverse effects of three commonly used concentrations of thoracic epidural fentanyl with bupivacaine, 41.37% of patients who received bupivacaine 0.1% with 2 mcg/ml fentanyl developed pruritus. These studies are in concordance with our results. Naloxone, the classic μ-receptor antagonist, is effective in preventing or treating intrathecal or epidural opioid-induced itching. Gurkan and Toker[44] have shown that ondansetron reduces the incidence of intrathecal fentanyl–induced pruritus. Because intrathecal or epidural opioids do not produce itching by the release of histamine, H1 blockers (such as diphenhydramine) have little effect on centrally induced itching.

Even though lipophilic opioids such as fentanyl are taken up quickly into the spinal cord, a continuous infusion of the same can cause ascension into medulla, triggering CTZ. Moreover, epidural administration of drugs leads to rapid vascular uptake that provides access to the CTZ Hypotension may lead to brain stem ischemia, which is thought to activate the circulatory, respiratory, and vomiting centers grouped together in the medulla. Consequently, supplemental oxygen and strategies avoiding hypotension can relieve nausea in such circumstances.[45] In our study, incidence of nausea and vomiting was highest in Gp III followed by Gp II and Gp I. Rucci et al.[46] demonstrated the higher incidence of PONV when fentanyl was added to the bupivacaine. Crocker and Vandam[47] found out that hypotension (systolic blood pressure < 80 mm Hg), a block higher than the T5, and the anesthetic mixture increased the incidence of PONV during spinal anesthesia. Young age group and female gender are the other documented risk factors.

The signs of systemic local anesthetic toxicity or arrhythmia during the study period were specifically sought and none were seen. The infusion of a local anesthetic drug over a long-period into the epidural space can lead to potentially toxic plasma concentrations. Felicity Reynolds[48] compared bupivacaine, lignocaine and mepivacaine and found bupivacaine to have the widest safety margin. Moreover, it is possible that toxic signs would be virtually absent in patients receiving CEA with low concentration of local anesthetics because the rise in plasma concentration would be very slow.[49]

All the patients in our study had a urinary catheter *in situ* preoperatively as part of our institute protocol, so, incidence of urinary retention was not able to assess. The causative association between epidural local anesthetics and opioids with Postoperative Urinary Retention (POUR) is well-documented and is probably due to combination of the central and peripheral effect of the opiate involving altered autonomic activity and the effect of epidural local anesthetics on the sacral and lumbar nerve fibers, blocking the transmission of impulses from and to the bladder.[50,51] It can be minimized by using lower concentrations of local anesthetic. Naloxone per se has no effect on normal bladder function; However, it has been shown to reverse the uro dynamic effects associated with epidural opioids.[51]

We also performed a retrospective comparative analysis of mean length of hospital stay between our subjects and 75 other subjects in a similar patient population who were not given CEA. Length of stay was defined as the time period beginning with admission to the Postanesthesia Care Unit (PACU) until the day of discharge. The mean hospital stay of the subjects who have received CEA was 5.106 ± 1.203 days whereas it was 9.106 ± 3.747 days in subjects who received only GA shown in Fig. 5, with a p - value of < 0.001 (highly significant). Baxter's multirate elastomeric infusion pump worked satisfactorily in all Groups without causing any problem regarding flow of anesthetic drug.

In our experience, continuous epidural infusion of 0.1% bupivacaine with fentanyl 2 mcg/ml @7 ml/hr offers the best infusion rate for managing postoperative pain following abdominal operations. It requires careful supervision. A quiet, reliable infusion pump is not cheap. The epidural catheter might penetrate a blood vessel or the duramater, though if this happened it is probable that the patient would be in less danger from a low-concentration of drug delivered slowly by infusion than from a larger mass of drug delivered as a bolus.

References

1. American Society of Anesthesiologists Task Force on Acute Pain Management. Practice guidelines for acute pain management in the perioperative setting: An updated report by the American Society of Anesthesiologists Task Force on Acute Pain Management. Anesthesiology 2012 Feb;116(2):248–73.
2. Kehlet H. Surgical stress: The role of pain and analgesia. British Journal of Anesthesia. 1989 Aug 31;63(2):189–95.
3. Kehlet H, Holte K. Effect of postoperative analgesia on surgical outcome. British Journal of Anesthesia 2001 Jul 1;87(1):62–72.
4. Kehlet H, Jensen TS, Woolf CJ. Persistent postsurgical pain: Risk-factors and prevention. The Lancet 2006 May 13;367(9522):1618–625.
5. Garimella V, Cellini C. Postoperative pain control. Clinics in colon and rectal surgery 2013 Sep;26(3):191.
6. Tolver MA, Rosenberg J, Bisgaard T. Early pain after laparoscopic inguinal hernia repair. A qualitative systematic review. Acta Anesthesiologica Scandinavica 2012 May;56(5):549–57.
7. White PF, Kehlet H, Neal JM, et al. The role of the anesthesiologist in fast-track surgery: from multimodal analgesia to perioperative medical care. Anesth Analg. 2007;104(6):1380–396.
8. Werawatganon T, Charuluxanun S. Patient controlled intravenous opioid analgesia *versus* continuous epidural analgesia for pain after intraabdominal surgery. Cochrane Database Syst Rev 2005 Jan 25;1:CD004088.
9. Barletta JF, Asgeirsson T, Senagore AJ. Influence of intravenous opioid dose on postoperative ileus. Annals of Pharmacotherapy 2011 Jul;45 (7–8):916–23.
10. Zafar N, Davies R, Greenslade GL, et al. The evolution of analgesia in an 'accelerated' recovery programme for resectional laparoscopic colorectal surgery with anastomosis. 2010 Feb;12(2):119–24.
11. Garimella V, Cellini C. Postoperative pain control. Clinics in colon and rectal surgery 2013 Sep;26(3):191.
12. RG Wheatley, SA Schug, D Watson. Safety and efficacy of postoperative epidural analgesia, BJA: British Journal of Anesthesia 2001;87(1):47–61.
13. Rem J, Brandt MR, Kehlet H. Prevention of postoperative lymphopenia and granulocytosis by epidural analgesia. Lancet. 1980 Feb 9;1(8163):283-4.
14. Skryabina EA, Dunn TS. Disposable infusion pumps. American Journal of Health-System Pharmacy 2006 Jul 1;63(13):1260–268.
15. Skryabina EA, Dunn TS. Disposable infusion pumps. American Journal of Health-System Pharmacy 2006 Jul 1;63(13):1260–268.
16. Liu S, Carpenter RL, Neal JM. Epidural Anesthesia and Analgesia their role in postoperative outcome. Anesthesiology: The Journal of the American Society of Anesthesiologists 1995 Jun 1;82(6):1474–506.
17. Feldheiser A, Aziz O, Baldini G, et al. Enhanced Recovery After Surgery (ERAS) for gastrointestinal surgery, part 2: Consensus statement for anesthesia practice. Acta Anesthesiologica Scandinavica 2016 Mar;60(3):289–334.
18. Wu CL, Cohen SR, Richman JM, et al. Efficacy of postoperative patient-controlled and continuous infusion epidural analgesia *versus* intravenous patient-controlled analgesia with opioids: A Meta-analysis. The Journal of the American Society of Anesthesiologists 2005 Nov 1;103(5):1079–1088.
19. Salicath JH, Yeoh EC, Bennett MH. Epidural analgesia *versus* patient-controlled intravenous analgesia for pain following intra-abdominal surgery in adults. Cochrane Database of Systematic Reviews 2018;(8).
20. Málek J, Ševčík P Mladá fronta A S. Postoperative Pain Management, 3rd updated edition. 2017.pp.44–45.
21. Sjöström S, Bläss J. Postoperative analgesia with epidural bupivacaine and low-dose

fentanyl: A comparison of two concentrations. Acta anesthesiologica scandinavica 1998 Aug;42(7):776–782.

22. Miller R. Miller's anesthesia, 8th edition. Philadelphia, PA: Elsevier/Saunders: 2015.p. 1043.

23. ScottDA, BeilbyDS, McClymontC. Postoperative analgesia using epidural infusions of fentanyl with bupivacaine a prospective analysis of 1,014 patients. Anesthesiology: The Journal of the American Society of Anesthesiologists 1995 Oct 1;83(4):727–37.

24. Patil SS, Kudalkar AG, Tendolkar BA. Comparison of continuous epidural infusion of 0.125% ropivacaine with 1 μg/ml fentanyl *versus* 0.125% bupivacaine with 1 μg/ml fentanyl for postoperative analgesia in major abdominal surgery. Journal of Anesthesiology, Clinical Pharmacology 2018 Jan;34(1):29.

25. Badner NH, Bhandari R, Komar WE. Bupivacaine 0.125% improves continuous postoperative epidural fentanyl analgesia after abdominal or thoracic surgery. Canadian Journal of Anesthesia 1994 May 1;41(5):387.

26. Paech MJ, Westmore MD. Postoperative epidural fentanyl infusion: Is the addition of 0.1% bupivacaine of benefit? Anesthesia and intensive care 1994 Feb;22(1):9–14.

27. Berti M, Fanelli G, Casati A, et al. Comparison between epidural infusion of fentanyl/ bupivacaine and morphine/bupivacaine after orthopedic surgery. Canadian Journal of Anesthesia 1998 Jun 1;45(6):545.

28. Covino BG. Physiology and pharmacology of local anesthetic agents. Anesth Prog. 1981 Jul-Aug; 28(4):98–104.

29. Kanai A, Osawa S, Suzuki A, et al. Regression of sensory and motor blockade, and analgesia during continuous epidural infusion of ropivacaine and fentanyl in comparison with other local anesthetics. Pain Medicine 2007 Feb 27;8(7):546–53.

30. ScottDA, BeilbyDS, McClymontC. Postoperative analgesia using epidural infusions of fentanyl with bupivacaine a prospective analysis of 1,014 patients. Anesthesiology: The Journal of the American Society of Anesthesiologists 1995 Oct 1;83(4):727–37.

31. Duarte LT, Fernandes MD, Fernandes MJ, et al. Continuous epidural analgesia: Analysis of efficacy, side effects and risk-factors. Revista brasileira de anestesiologia 2004 Jun;54(3):371–90.

32. Lakshmi K, Kumari MP, Sunil R. A comparison of the analgesic efficacy and safety of epidural bupivacaine with fentanyl and ropivacaine with fentanyl in abdominal surgery. Ain-Shams Journal of Anesthesiology 2015 Oct 1;8(4):623.

33. Holte K, Foss NB, Svensén C, et al. Epidural anesthesia, hypotension, and changes in intravascular volume. Anesthesiology: The Journal of the American Society of Anesthesiologists 2004 Feb 1;100(2):281–86.

34. Patil SS, Kudalkar AG, Tendolkar BA. Comparison of continuous epidural infusion of 0.125% ropivacaine with 1 μg/ml fentanyl *versus* 0.125% bupivacaine with 1 μg/ml fentanyl for postoperative analgesia in major abdominal surgery. Journal of anesthesiology, clinical pharmacology 2018 Jan;34(1):29.

35. Berti M, Fanelli G, Casati A, et al. Comparison between epidural infusion of fentanyl/ bupivacaine and morphine/bupivacaine after orthopedic surgery. Canadian Journal of Anesthesia 1998 Jun 1;45(6):545.

36. Baxter AD. Respiratory depression with patient-controlled analgesia. Canadian Journal of Anesthesia/Journal Canadien D'anesthésie 1994 Feb 1;41(2):87–90.

37. Alfonsi P. Postanesthetic shivering. Drugs 2001 Dec 1;61(15):2193–205.

38. Abreu MP, Vieira JL, Lutti MN, et al. Shivering during epidural anesthesia with and without fentanyl: Comparative study. Revista brasileira de anestesiologia 2004 Apr;54(2):153–61.

39. Golembiewski J. Pharmacological management of perioperative shivering. Journal of Perianesthesia Nursing 2015 Aug 1;30(4):357–59.

40. Kumar K, Singh SI. Neuraxial opioid-induced pruritus: An update. Journal of Anesthesiology, Clinical Pharmacology 2013 Jul;29(3):303.

41. Waxler B, Dadabhoy ZP, Stojiljkovic L, et al. Primer of postoperative pruritus for anesthesiologists. Anesthesiology: The Journal of the American Society of Anesthesiologists 2005 Jul 1;103(1):168–78.

42. Saito Y, Uchida H, Kaneko M, et al. Comparison of continuous epidural infusion of morphine/ bupivacaine with fentanyl/bupivacaine for postoperative pain relief. Acta Anesthesiologica Scandinavica 1994 May;38(4):398–401.

43. Tan CN, Guha A, Scawn ND, et al. Optimal concentration of epidural fentanyl in bupivacaine 0.1% after thoracotomy. British Journal of Anesthesia 2004 May 1;92(5):670–74.

44. Gürkan Y, Toker K. Prophylactic ondansetron reduces the incidence of intrathecal fentanyl-induced pruritus. Anesthesia and Analgesia 2002 Dec 1;95(6):1763–766.

45. Borgeat A, Ekatodramis G, Schenker CA. Postoperative nausea and vomiting in regional anesthesia a review. Anesthesiology: The Journal of the American Society of

Anesthesiologists 2003 Feb 1;98(2):530–47.

46. Rucci FS, Cardamone M, Migliori P. Fentanyl and bupivacaine mixtures for extradural blockade. BJA: British Journal of Anesthesia 1985 Mar 1;57(3):275–84.

47. Crocker JS, Vandam LD. Concerning nausea and vomiting during spinal anesthesia. Anesthesiology: The Journal of the American Society of Anesthesiologists 1959 Sep 1;20(5):587–92.

48. Reynolds F. A comparison of the potential toxicity of bupivacaine, lignocaine and mepivacaine during epidural blockade for surgery. BJA: British Journal of Anesthesia 1971 Jun 1;43(6):567–72.

49. Scott DB. Evaluation of the toxicity of local anesthetic agents in man. BJA: British Journal of Anesthesia 1975 Jan 1;47(1):56–61.

50. Hansen BJ, Rosenberg J, Andersen JT. Urinary retention in connection with postoperative pain treatment with epidural opioids. Ugeskrift for Læger. 1990 May;152(22):1574–577.

51. Baldini G, Bagry H, Aprikian A, et al. Postoperative urinary retention anesthetic and perioperative considerations. The Journal of the American Society of Anesthesiologists 2009 May 1;110(5):1139–157.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 137-142
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.19

Comparison of Granisetron and Ondansetron on the Spinal Anesthesia Induced Hypotension, Bradycardia and Fetal Outcome after Administration Intrathecal Hyperbaric Bupivacaine in Patients Undergoing Cesarean Sections

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Abstract

Background: Spinal anesthesia is easy to perform and provides a rapid-onset, dense surgical block. It is associated with hypotension and bradycardia, which may be deleterious to both mother and baby[1]. Various preventive methods are used to prevent or minimize hypotension including uterine displacement, fluid preloading, and compression stocking the lower extremities.[2]This study compares the effectiveness of Granisetron and Ondansetron on the spinal anesthesia induced hypotension, bradycardia after intrathecal hyperbaric Bupivacaine in patients undergoing cesarean sections. *Materials and Methods:* Sixty full-term patients posted for cesarean section belonging to ASA I or II were randomly assigned to Two Groups each containing 30 patients. Group G received 1 mg Granisetron and Group O received 4mg Ondansetron. Hemodynamic were noted at regularly along with APGAR score. *Results:* Trend observed in heart rate following the administration of the test drugs in both the groups and was not significant. The baseline hemodynamic of the patients were insignificant in both the Groups. This continued to be the case for up to 5 minutes after delivery of the drugs. At 10, 20, 30 and 45 minutes however, all three parameters were higher in Group O than Group G. At 60 mins however, no significant difference is seen between the groups. Similar trend was observed in APGAR score in neonates of both the Groups. *Conclusion:* Ondansetron was more effective in attenuation of spinal anesthesia induced hypotension than in Granisetron. Both the Groups had no significant difference in prevention of bradycardia oxygen saturation and foetal outcome.

Keywords: Cesarean Section; Granisetron; Ondensetron; Hemodynamic; Spinal Anesthesia.

How to cite this article:

Soumya Nath Maiti, Bhavini B. Shah, Himanshu Kiran Khanvelkar. Comparison of Granisetron and Ondansetron on the Spinal Anesthesia Induced Hypotension, Bradycardia and Fetal Outcome after Administration Intrathecal Hyperbaric Bupivacaine in Patients Undergoing Cesarean Sections. Indian J Anesth Analg. 2020;7(1 Part -I):137–142.

Introduction

For a pregnant patient Spinal anesthesia is the most sought after technique as it is cheaper, simple to perform and produces rapid onset of anesthesia and complete muscle relaxation and does not carry the risk of maternal or fetal-risk for toxicity to local anesthetics (Nag et al., 2015). Since, the introduction of smaller diameter, noncutting, pencil point Whitaker's spinal needles

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Received on 29.08.2019, **Accepted on** 13.11.2019

the incidence of postdural puncture headache has become low (<5%).[3] Hyperbaric Bupivacaine is the most commonly used agent for spinal anesthesia when performing cesarean sections. It's duration of action of 1.5 to 2 hours is perfectly matched to duration of surgery in most cases.

Up to 71% of women who receive spinal anesthesia for cesarean delivery experience spinal hypotension.[4] Spinal hypotension can be severe and may occur precipitously, giving rise to perinatal adverse outcomes, such as maternal nausea and vomiting, fetal acidosis and may be an important cause for maternal death related to regional anesthesia.[5] Pregnant patients with depleted intravascular fluid due to dehydration may be at risk of cardiovascular collapse because of the sympathetic blockade induced bradycardia and decreased preload. Considering all the adverse effects, prevention of spinal hypotension is one of the leading research area within the field of obstetric anesthesia.

For the treatment of spinal anesthesia induced hypotension, multiple pharmacological and non-pharmacological methods have been tried, none of the methods are adequate or conclusively superior to others. The nonpharmacological methods commonly used to prevent hypotension are leg compression and elevation using tight fitting elastic stockings and wedge placement under right buttock for avoidance of aorto-caval compression prevents hypotension to some degree, but is of limited use by the cost and moreover they are not stand-alone method to prevent hypotension. For pharmacological methods preloading with fluids and vasopressors are the most common methods used to prevent hypotension. Among Intravenous fluids colloid is significantly more effective than crystalloids.[6] Over infusion of crystalloid can cause dilutional anemia as it has shorter half-life.[7] This patients have a greater chance of developing pulmonary edema. Vasopressors are used to treat hypotension quickly. Directly acting selective $\alpha 1$ receptor agonists, phenylephrine and methoxamine, as well as both directly and indirectly acting drugs, mephentermine, metaraminol and ephedrine are used.[8,9]

Granisetron and Ondansetron are selective 5-hydroxytryptamine 3 (5-HT3) receptor antagonists. These receptors are present as cardiac chemoreceptors on the cardiac vagal afferent located peripherally and centrally in the chemoreceptor trigger zone that mediate Bezold-Jarisch reflex. Bezold-Jarisch reflex cause inhibition of vasomotor centers when stimulated, promoting vasodilatation and hypotension. The receptors of the Bezold-Jarisch reflex located within the walls of the heart respond to systemic responses to hypervolemia and hypovolemia. After spinal blockade, there is decreased venous return of blood to the heart that results in alteration of the cardiac wall and stimulation of cardiac mechanoreceptors, which results in activation of the Bezold-Jarisch reflex, and thus inducing hypotension and bradycardia.[10] The activation of peripheral 5-HT3 receptors located in intracardiac vagal nerve endings by serotonin further elicits the Bezold-Jarisch reflex resulting in hypotension and bradycardia. The stimulation of 5-HT3 receptors located on sensory vagal nerve endings results in a lowered heart rate and an initial short-lasting hypotension followed by a longer lasting hypotension, attributed to the Bezold-Jarisch reflex. Current studies indicate that 5-HT3 antagonism may abolish the BJR response to spinal anesthesia.[11] In this study, we compare effectiveness of Granisetron and Ondensetron on postspinal hypotension, bradycardia in patients posted for cesarean section.

Materials and Methods

After approval of the medical ethics committee and obtaining well-informed written consent from each patient, this comparative study was conducted randomly in 60 patients undergoing cesarean section under spinal anesthesia at DY Patil Medical College and Research Centre. Patients were excluded if they have any contraindications to subarachnoid block, history of hypersensitivity to studied drugs, hypertensive disorders with pregnancy or those receiving selective serotonin reuptake inhibitors or migraine medications or refused to participate. Randomization was done using computer generated random number table as follows-Group O 4 mg Ondensetron and Group G 1mg Granisetron.

All patients were subjected to preanesthetic evaluation with relevant laboratory investigations. Preoperative vitals were noted. Peripheral venous access with 20 gauge intravenous catheter was established. All the patients were preloaded with 10 ml/kg of Ringer Lactate (RL) over 15 minutes and continued thereafter at a rate of approximately 10–15 ml/min throughout the study period. Study medications were prepared and in identical 10 ml syringes and injected 5 minutes prior to spinal anesthesia.

Spinal anesthesia was administered in sitting position under all aseptic precautions.

After painting and draping of the lumbar area, subarachnoid placement of Bupivacaine (2.2 ml of 0.5% Bupivacaine) through the L3-L4 or L2-L3 interspinous spaces was given using 26 G Quinke's spinal needle.

The target block height was equal to or above T8 and the surgeon was asked to proceed. Oxygen was administered at a rate of 3l/min by a Hudson mask to all the patients until the umbilical cord was clamped. Inspite of giving study drugs sudden drop in blood pressure if noted was initially managed with intravenous crystalloid fluid bolus of 4 ml/kg. If not corrected with this, Injection Mephentermine 6 mg IV was given and was repeated after 3 minutes till it is corrected, the patients receiving vasopressors were excluded from the study and the experiment was terminated for them.

Systolic, diastolic and mean arterial blood pressure and heart rate were noted at 2 minutes and every 5 minutes after administration of spinal anesthesia for the first 30 minutes and every 15 minutes till end of surgery. Decrease in heart rate less than 50 beat/min was treated with 0.2 mg intravenous Glycopyrolate and the patients receiving Glycopyrolate were excluded from the study and the experiment was terminated for them.

Vitals were monitored continuously. Apgar score at zero, first, third and fifth minute was noted. Any side effects in the immediate postoperative period was also noted.

Results

The study was conducted on total of 60 patients and were randomly divided into two equal groups, using computer generated random allocation chart. Both the groups were proportional with regards to age, weight, ASA physical status. The mean arterial pressure in the group which was given Granisetron is much lower than the group which was given Ondansetron. There was no significant difference between the two groups as per the calculation of *t*-Test ($p > 0.05$). This continues to be the case for up to 5 mins after delivery of the drugs. However, at 10, 20, 30, 45 minutes Ondansetron attenuates fall in mean arterial pressure compared to Granisetron (p value < 0.05). At 60 mins however, no significant difference is seen between the groups (Fig.1). Similar, trends were observed in heart rate, Fig. 2, oxygen saturation, Fig. 3 and APGAR score shown in Table 1, following the administration of the test drugs in both the Groups.

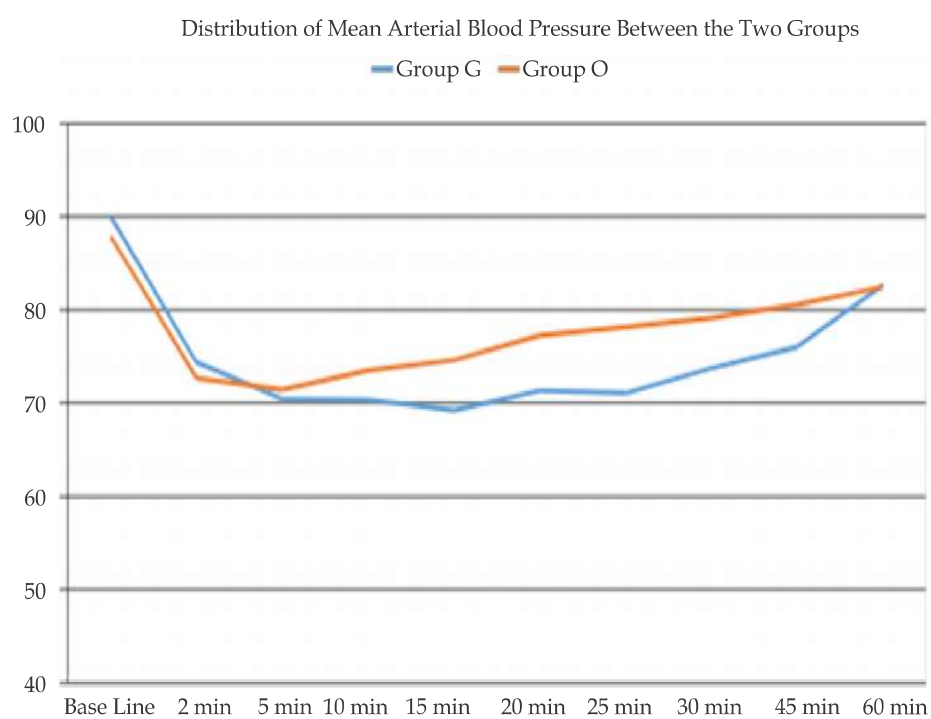

Fig. 1: Line diagram showing comparison of mean arterial blood pressure in Group G and Group O (Baseline mean arterial blood pressure: Group G- 90.02 ± 7.43 mm Hg and Group O -87.86 ± 6.16 mm Hg.)

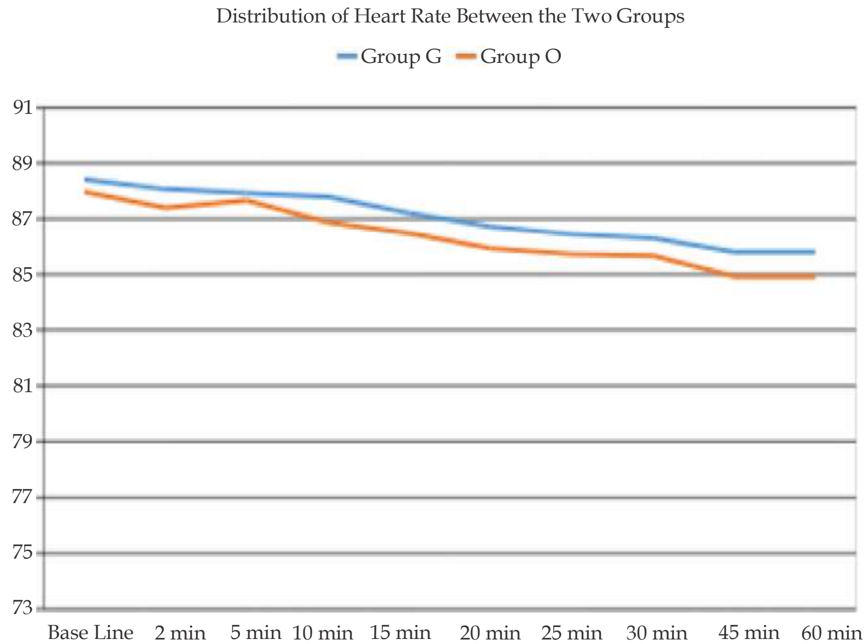

Fig. 2: Line diagram showing comparison of heart rate in Group G and Group O

Fig. 3: Line diagram showing comparison of mean SpO_2 in Group G and Group O

Table 1: APGAR score distribution between Group G and Group O

Apgar Score	Group	Mean	SD	*t*-Test	*p* - Value
	Group G	6.83	.747	.784	.436
0 Mins	Group O	6.97	.556		
1 Mins	Group G	7.47	.681	.366	.716
	Group O	7.53	.730		
3 Mins	Group G	7.83	.699	1.82	.074
	Group O	8.20	.484		
5 Mins	Group G	8.33	.547	1.97	.053
	Group O	8.60	.498		

Discussion

Our randomized controlled study was designed to test the comparison of effectiveness and of pretreatment with intravenous Ondansetron or Granisetron for the prevention of spinal anesthesia induced hypotension and bradycardia and on the fetal outcome.

Our study shows that, prophylactic intravenous administration of 4 mg Ondansetron or 1mg Granisetron 5 min before induction of spinal anesthesia significantly reduces the severity of spinal-induced hypotension with significant differences between Ondansetron and Granisetron in regards to systolic, diastolic and mean blood pressure at 10, 20, 30, 45 minutes with Ondansetron being more efficient in prevention of spinal induced hypotension.

Our results matched with that of Omyma M Khalifa who conducted a study in 2014 “A comparative study of prophylactic intravenous Granisetron, Ondansetron, and Ephedrine in attenuating hypotension and its effect on motor and sensory block in elective cesarean section under spinal anesthesia” on eighty parturient. They reported that the reduction in mean arterial pressure was significantly lower in the therapeutic groups, with the best results recorded in the O group and nearly comparable results in G and E groups.[12]

In contrast, Alaa El Deen Mahmoud Sayed et al. (2017) compared the efficacy of intravenous Ondansetron and Granisetron on hemodynamics, shivering and motor & sensory block in female undergoing elective cesarean section under spinal anesthesia and concluded that prophylactic intravenous administration of 4 mg Ondansetron or 1mg Granisetron 5 min before induction of spinal anesthesia significantly reduces the severity of spinal-induced hypotension compared to saline group by attenuating fall in mean arterial blood pressure with no significant differences on mean arterial pressure between Ondansetron and Granisetron groups.[13]

Comparison of pulse rate at different time intervals using *Z* test showed no statistical difference between the two groups. ($p > 0.05$). The result of our study on the effect of heart rate after spinal anesthesia was comparable to studies conducted by Owczuk R et al. and Rashad and Farmawy in 2008 and 2014 respectively. Owczuk R et al. (2008) conducted a study titled “Ondansetron given intravenously attenuates arterial blood pressure drop due to spinal anesthesia: A double-blind, placebo-controlled study.” and concluded that IV Ondansetron has no effect on heart rate.[14]

Rashad and Farmawy (2013) examined 60 patients undergoing spinal anesthesia for cesarean section and randomly divided them into 3 equal groups. Five minutes prior to spinal anesthesia, Group O (n = 20) Ondansetron 4 mg, Group G (n = 20) Granisetron 1 mg, and Group S (n = 20) normal saline all received their respected doses. MAP was measured at 5-minute intervals in each group. In regards to decreases in mean arterial pressure, there was significant distinctness between Group O and both Groups G and S at 5, 10, 15, 20 and 25 minutes.[15]

Similar trend was observed in Apgar score in neonates of both the groups. The Apgar score was analyzed quantitatively within the groups for each stage and the p - value was found to be statistically not significant. There is scarce literature evidence on the effect of 5 HT3 receptor antagonists on fetal outcome, however, Pasternak et al. (2017) investigated the risk of adverse fetal outcomes associated with Ondansetron in a study that included 608,385 pregnancies from the period of January 2004 through March 2011 and concluded there was no significantly increased risk of adverse fetal outcomes when Ondansetron was taken during pregnancy.[16] Whereas Walid Teabelsi et al. (2015) in the study on efficacy of Ondansetron on spinal induced hypotension and on Neonatal outcome concluded that that Ondansetron can be helpful to improve metabolic and vital parameters of newborns.[17]

Conclusion

To conclude, our study validates the use premedication of 4 mg Ondansetron over 1 mg Granisetron for prevention of incidence of hypotension in healthy parturients undergoing spinal anesthesia with Bupivacaine for elective cesarean delivery as significant difference was noted in the incidence of attenuation of spinal anesthesia induced hypotension in Ondansetron group compared to Granisetron group.

Limitations

The limitations of this study are that we did not compare the need for rescue vasopressor and the effect of these drugs on sensory and motor blockade in parturients undergoing cesarean section. Finally, postoperative nausea and vomiting, pain, and analgesic requirement were not studied.

Financial Support and Sponsorship: Nil

Conflicts of Interest: Nil

References

1. Sahoo T, Sen Dasgupta C, Goswami A, et al. Reduction in spinal-induced hypotension with ondansetron in parturients undergoing caesarean section: a double-blind randomised, placebo-controlled study. Int J Obstet Anesth. 2012;21(1):24–28.
2. Cyna AM, Andrew M, Emmett RS, et al. Techniquesfor preventing hypotension during spinal anesthesia for cesarean section. Cochrane Database Syst Rev 2006;18(4):CD002251.
3. Pal Anirban, Acharya Amita, Dawar Pal Nidhi, et al. A comparative study between pencil-point 25G Whitacre and cutting-beveled 25G Quincke spinal needles in 320 obstetric patientsAnesth Essays Res 2011 Jul–Dec;5(2):162–66.
4. Klöhr S, Roth R, Hofmann T, Rossaint R, Heesen M. Definitions of hypotension after spinal anaesthesia for caesarean section: literature search and application to parturients. Acta Anaesthesiol Scand. 2010;54(8):909–921.
5. Auroy Y, Benhamou D, Bargues L. Major complications of regional anesthesia in France: The SOS Regional Anesthesia Hotline Service, Anesthesiology 2002;97(5):1274–280.
6. Ko JS, Kim CS, Cho HS, Choi DH. A randomized trial of crystalloid versus colloid solution for prevention of hypotension during spinal or low-dose combined spinal-epidural anesthesia for elective cesarean delivery. Int J Obstet Anesth. 2007;16(1):8–12.
7. Carralho JC, Mathias RS, Senra WG, et al. Maternal and foetal and neonatal consequences of acute hydration during epidural anesthesia for cesarean section. Regional Anesthesia 1993;18(25):19.
8. Nagdev S, Samaddar DP, Chatterjee A, et al. Vasopressors in obstetric anesthesia: A current perspective: World Journal of Clinical Cases 2015;3(1):58–64.
9. Mitra JK. Prevention of hypotension following spinal anesthesia in Cesarean Section - then and now. Kathmandu Univ Med Journal 2010;9(32):415–19.
10. Velken R, Swain LL, Di Bona GF. Epidural serotonin receptorsin circulatory control in conscious Sprague-Dawley rats. Am JPhysiol 1990;258:468–72.
11. Yamano M, Ito H, Kamato T, et al. Characteristics of inhibitory effects of serotonin (5-HT) 3 receptor antagonist,YMO60 and YM114 (KAE 393), on von BazoldJarisch reflex induced by 2 methyl 5 HT, veratridine and electrical stimulation of vagus nerves in anesthetized rats. Jpn J Pharmacol. 1995;69(4):351–356.
12. Sh M Khalifa Omyma, A comparative study of prophylactic intravenous granisetron, ondansetron, and ephedrine in attenuating hypotension and its effect on motor and sensory block in elective cesarean section under spinal anesthesia, AinShams Journal of Anesthesiology 2015;08:166–72.
13. Alaa El Deen Mahmoud Sayed1 and Ahmed Shaaban Mohamed. Ondansetron *versus* granisetron effects on hemodynamic instability during spinal anesthesia for cesarean section. European Journal of Pharmaceutical and Medical Research 2017;4(6):758–65.
14. Owczuk R, Wenski W, Polak-Krzeminska A. Ondansetron given intravenously attenuates arterial blood pressure drop due to spinal anesthesia: A double-blind, placebo-controlled study. Reg Anesth Pain Med 2008 Jul-Aug;33(4):332–39.
15. Rashad MM, Farmawy MS. Effects of intravenous ondansetron and granisetron on hemodynamic changes and motor and sensory blockade induced by spinal anesthesia in parturients undergoing cesarean section. Egypt J Anesth 2013;29:369–74.
16. Björn Pasternak, Henrik Svanström, and Anders Hviid. Ondansetron in pregnancy and risk of adverse fetal outcomes. New England Journal of Medicine 2013 Feb 28;368(9):816–23. DOI: 10.1056/NEJMoa1211035.
17. Trabelsi W Romdhani, Elaskri C, Sammoud H, et al. Effect of ondansetron on the occurrence of hypotension and on neonatal parameters during spinal anesthesia for elective cesarean section: A prospective, randomized, controlled, double-blind study. Anesthesiology research and practice 2015 Jan 8;2015:1–7.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 143-149
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.20

A Comparative Study between Thiopental Sodium and Etomidate on Hemodynamic Response in Adult Treated Hypertensives Scheduled for Elective Surgery

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Abstract

Context: Ideal drugs used for anesthesia for induction should counter the response to stress at the same time not affecting the changes in the hemodynamics of the patient. This is required because induction is an important part in anesthesia. *Aim:* To compare hemodynamic response to induction of anesthesia with thiopentone or etomidate in adult treated hypertensive patients. *Settings and Design:* Present hospital based comparative study was carried out at Adichunchanagiri Institute of Medical Sciences, BG Nagar, Bellur. *Methods:* 60 adult treated hypertensive patients of either sex, aged between 29 and 61 years, belonging to ASA I and II who were randomly allotted to Two Groups of 30 each. Group T received 5 mg/kg of thiopentone sodium and Group E received Etomidate 0.3 mg/kg. Pulse rate, systolic, diastolic and mean arterial pressures both after premedication (level 0) and at every minute for five minutes (levels 1–5) postinduction with both drugs were recorded. *Statistical Analysis:* The data was analyzed using *t*-test for comparing mean values between Two Groups. *Results:* SBP fell to 120 ± 28.8 from 131.70 ± 16.03 (level 0) in Group T and fell to 120.80 ± 20.05 from 131.23 ± 16.03 (level 0) in Group E. DBP had a slight fall to 77.73 ± 17.00 at 4 minutes in Group T. MAP fell from 94.52 ± 12.10 (level 0) to 91.72 ± 21.34 in Group T and fell from 96.96 ± 12.96 (level 0) to 90.37 ± 17.51 in Group E. Comparison of variations in heart rate, SBP, DBP and map from level 0 to postinduction recordings at 1–5 levels between Two Groups was insignificant ($p > 0.05$). Patients in both Groups did not have any side effects. *Conclusion:* Both drugs are comparable in efficacy and safety. Thiopentone comparatively has better cost effectiveness and ease of availability.

Keywords: Thiopental sodium; Etomidate; Hemodynamic response; Hypertension; Surgery.

How to cite this article:
V Praveen Kumar, J Hymavathi. A Comparative Study between Thiopental Sodium and Etomidate on Hemodynamic Response in Adult Treated Hypertensives Scheduled for Elective Surgery. Indian J Anesth Analg. 2020;7(1 Part -I):143–149.

Introduction

Hypertension is extremely common, affecting over one billion people worldwide, and is responsible for over seven million deaths annually. In 2000, total number of hypertensive patients were 972 million and by 2025, 1.6 billion will be suffering from hypertension.[1]

When the cause for the hypertension is not known, it is called the essential hypertension. It is a

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Received on 22.10.2019, **Accepted on** 28.11.2019

well-known fact that hypertension is an important risk-factor for cardiovascular diseases. During anesthesia such patients are prone to develop a lot of variations in the blood pressure. During induction the arterial blood pressure falls drastically. They are also prone to hyperresponsiveness to intubation and laryngoscopy.[2]

Ideal drugs used for anesthesia for induction should counter the response to stress at the same time not affecting the changes in the hemodynamics of the patient. This is required because induction is an important part in anesthesia. Thiopentone was the first agent which acts very fast and also aids in increasing the oxygen concentration.[3]

Etomidate is also a fast-acting hypnotic agent but not a barbiturate like thiopentone. It does not cause side effects related to respiratory system and also the cardiovascular system. Studies have proved that it has few adverse effects.

It is a relatively new agent.[4] In routine practice the anesthetic agent of choice is desired which will have minimum adverse effects especially with known cases of hypertension.[5]

Hence, study was undertaken to compare hemodynamic response to induction of anesthesia with thiopentone or etomidate in adult treated hypertensive patients. A note was also made of costeffectiveness of each drug.

Materials and Methods

Study Design

A hospital based comparative study with 60 adult elective surgical hypertensive patients, 30 in Group T (Thiopental) and 30 patients in Group E (Etomidate) was undertaken to study the hemodynamic response to induction of anesthesia with thiopentone or etomidate between January 2011 to September 2012. The number of patients was 22 in general surgical category, 18 in orthopedic and 20 in gynecological category.

Sources of data

Data was randomly collected from 60 ASA II adult treated hypertensive patients aged between 29–61 years scheduled for elective surgeries at Adichunchanagiri Institute of Medical Sciences, BG Nagar, Bellur for a period of two years September (2010–2012).

Inclusion criteria

1. Patients of age 29–61 years;
2. Patients with controlled essential hypertension.

Exclusion criteria

- Patients not willing to participate, ASA III and above;
- End organ damage, emergency surgeries;
- Co-morbid conditions like epilepsy, COPD etc. Obstetric, Pediatric and obese patients;
- Patients with shock;
- Drug allergies.

Methods

Institutional ethical committee permission was taken. Written informed consent was taken from all eligible patients included in the study. Sample size was 60 patients undergoing elective surgeries. This was a prospective comparative study. The patients were divided into Two Groups as follows:

Group E - Inj. Etomidate: 30 patients;

Group T - Inj. Thiopental sodium: 30 patients.

Patients found fit on preanesthetic examination were posted for surgery. A detailed history was obtained. Thorough clinical examination of each and every patient was carried out. Surgical profile was also carried out for all patients. Tablet alprazolam as well as tablet ranitidine was given in the night before surgery. Patients were also advised to continue their antihypertensive drugs.

Hemodynamic parameters before surgery were noted. Then, after giving drugs like glycopyrrolate, midazolam and fentanyl and after giving oxygen and once the patient stabilized, hemodynamic parameters were again recorded and marked as level 0 recording. Group E patients were given general anesthesia with etomidate 0.3 mg/kg body weight. Group T patients were given general anesthesia with thiopentone 5 mg/kg body weight. Both Group patients received vecuronium afterwards.

Later all hemodynamic parameters were observed and noted down at 1, 3, 4, and 5 minutes after induction. Routine ECG monitoring was carried out for all patients. Complications were observed and noted down from induction of anesthesia till 24 hours after.

Statistical Methods

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min./Max.) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance.

Results

Table 1 shows distribution of all the patients as per type of surgery done. Majority of the patients underwent general surgery followed by gynecology surgery and rest orthopedic surgery.

Table 1: Distribution of all the patients as per type of surgery done

Type of surgery	Nos.	Percentage (%)
General surgery	22	36.7
Orthopedic surgery	18	30
Gynecology surgery	20	33.3
Total	60	100

Table 2 shows comparison of Two Groups of patients on different variables. There were 14 male (46.7%) and 16 females (53.3%) in Group –T. There were 14 male (46.7%) and 16 females (53.3%) in Group –E. The mean age, mean weight were comparable in Two Groups of patients. Both the Groups were also comparable in terms of duration of hypertension and also in terms of various age Groups.

Table 2: Comparison of two groups of patients on different variables

Variables		Group T		Group E		Chi-square/ *t*-value	*p*-value
		%	Nos.	%	Nos.		
Gender	Male	14	46.7	14	46.7	0.06696	0.7958
	Female	16	53.3	16	53.3		
Duration of hypertension	< 6 months	22	73.3	26	86.7	3.476	0.4815
	6 months 1 year	4	13.3	3	10.0		
	1–2 years	2	6.7	0	0.0		
	3–5 years	1	3.3	1	3.3		
	> 5 years	1	3.3	0	0.0		
Age (years)	< 30	01	3.3	01	3.3	1.111	0.8925
	31–40	05	16.7	04	13.3		
	41–50	11	36.7	11	36.7		
	51–60	13	43.3	13	43.3		
	> 60	0	0.0	1	3.3		
Mean Weight (kg)		52.43 ± 9.53		50.63 ± 9.40		0.7365	0.4644
Mean Age (years)		48.93 ± 7.80		49.90 ± 8.83		0.4509	0.6537

Table 3 shows comparison of Two Groups of patients for treatment received. 14 patients in the group T and 17 in group E received Calcium channel blockers. Four patients in group E received Calcium channel blockers with Beta blockers. Six patients in each group received beta blockers. Two patients in each group received ACE inhibitors.

Table 3: Comparison of two groups of patients for treatment received

Treatments	Group T (n = 30)		Group E (n = 30)	
	Nos.	%	Nos.	%
Calcium channel blockers	14	46.7	17	56.7
Calcium channel blockers with Beta blockers	0	0.0	4	13.3
Beta blockers	6	20.0	6	20.0
ACE inhibitors	2	6.7	2	6.7
ARB with Diuretics	2	13.3	1	3.3
ARB	3	10.0	0	0.0
Alpha blockers	1	3.3	0	0.0

Table 4 shows comparison of Two Groups of patients on fundus changes. The number of patients with normal study of funds Group T – 5 (16.7%); Group E – 3 (10.0%). The number of patients with hypertensive changes on fundus study – Group-T – 25 (83.3%); Group-E – 27 (90.0%).

Table 4: Comparison of two groups of patients on fundus changes

Fundus	Group T (*n* = 30)		Group E (*n* = 30)	
	Nos.	%	Nos.	%
No change	5	16.7	3	10.0
Change present	25	83.3	27	90.0
Fundus I	11	36.7	9	30.0
Fundus II	14	46.7	18	60.0

Table 5 shows comparison of two Groups of patients on complications. The number of patients with Grade I hypertensive change Group-T – 11 (36.7%); Group –E – 9 (30.0%). The number of patients with Grade II hypertensive changes Group-T – 14 (4.7%); Group –E – 18 (60.0%)

Table 5: Comparison of two groups of patients on complications

Complications	Group T (*n* = 30)		Group E (*n* = 30)	
	Nos.	%	Nos.	%
No complication	30	100.0	29	96.7
Complication present	0	0.0	1	3.3
Vomiting	0	0.0	1	3.3

Table 6 shows comparison of Two Groups of patients on pulse rate. No patient in group T had any complication while one patient in group E had post-operative nausea and vomiting.

Table 6: Comparison of two groups of patients on pulse rate

Pulse rate	Group T	Group E	*p*-value
Level – 0	82.03 ± 15.32	81.47 ± 11.56	0.872
1 minute	90.00 ± 19.24	84.00 ± 14.02	0.173
2 minutes	89.03 ± 19.64	86.83 ± 9.70	0.584
3 minutes	88.43 ± 19.12	87.13 ± 10.22	0.744
4 minutes	87.47 ± 18.43	86.60 ± 11.91	0.829
5 minutes	85.90 ± 17.15	84.03 ± 12.28	0.630

Table 7 shows comparison of Two Groups of patients on Systolic Blood Pressure (SBP). The mean values of SBP in both the Groups were comparable i.e. similar at all levels. Thus, both the drugs exerted similar effect on the SBP in both the group patients.

Table 7: Comparison of two groups of patients on systolic blood pressure (SBP)

SBP mm Hg	Group T	Group E	*p*-value
Level – 0	131.70 ± 20.73	131.33 ± 16.03	0.939
1 minute	122.83 ± 22.5	124.17 ± 21.04	0.813
2 minutes	120.43 ± 25.64	120.80 ± 20.05	0.951
3 minutes	120.67 ± 28.16	126.50 ± 25.67	0.405
4 minutes	120.63 ± 28.8	126.73 ± 22.97	0.368
5 minutes	120.00 ± 28.8	127.47 ± 22.08	0.264

Table 8 shows comparison of Two Groups of patients on Diastolic Blood Pressure (DBP). The mean values of DBP in both the Groups were comparable i.e. similar at all levels. Thus, both the drugs exerted similar effect on the DBP in both the group patients.

Table 8: Comparison of two groups of patients on diastolic blood pressure (DBP)

DBP mm Hg	Group T	Group E	*p*-value
Level – 0	78.30 ± 11.00	79.77 ± 9.76	0.587
1 minute	79.43 ± 18.87	80.07 ± 18.74	0.897
2 minutes	79.67 ± 17.48	77.30 ± 14.53	0.571
3 minutes	78.90 ± 17.99	81.73 ± 17.50	0.539
4 minutes	77.73 ± 17.00	81.80 ± 15.51	0.337
5 minutes	80.13 ± 24.91	81.73 ± 13.07	0.756

Table 9 shows comparison of Two Groups of patients on Mean Arterial Blood Pressure (MAP). All the variations in heart rate, SBP, DBP and MAP remained within acceptable range and tended to return towards level-0 at the end of study period in both Groups. All changes were self-corrective without the need for intervention on our part.

Table 9: Comparison of two groups of patients on mean arterial blood pressure (MAP)

MAP mm Hg	Group T	Group E	*p*-value
Level – 0	94.52 ± 12.10	96.96 ± 12.96	0.396
1 minute	93.22 ± 19.30	93.07 ± 19.72	0.976
2 minutes	92.90 ± 19.97	90.37 ± 17.51	0.604
3 minutes	93.19 ± 21.70	94.50 ± 20.36	0.810
4 minutes	91.06 ± 19.35	94.23 ± 17.71	0.513
5 minutes	91.72 ± 21.34	95.00 ± 15.96	0.503

Discussion

We found that the HR increased from 82.03 ± 15.32 to 90.00 ± 19.24 immediately after induction with thiopentone. These findings are in accordance with those studies done by Roberts CP et al.[6], Arnow JT et al.[7] and Gauss A et al.[8], but not in accordance with the study of Singh R et al.[9] This may be due to peripheral vasodilation leading to reflex tachycardia.

The HR decreased from 81.47 ± 11.56 to 87.13 ± 10.22 with etomidate. These findings are in accordance with those studies done by Singh R et al.[9] but not in accordance with the study of Criado A et al.[10], Gooding JM et al.[11] and Colvin MP et al.[12]

We observed that in terms of heart rate at all levels, both the Groups were not much difference from each other. These findings are in accordance with those studies done by Joyce JT et al.[13], Robert JF et al.[14] and Arnow JT et al.[7] but not in accordance with the study of Arnow JT et al [7] study. In the present study, the SBP ranged from 110–180 mm Hg. None of the patients with an SBP of > 180 mm Hg or DBP of > 110 mm Hg was included in the study.

But Howell SJ et al. study state that a systematic review and meta-analysis of 30 observational studies has shown that patients with preoperative systolic blood pressure of > 180 mm Hg or diastolic blood pressure of > 110 mm Hg, are more prone for perioperative ischemia, arrhythmias and cardiovascular lability.[15]

Hence, the results of our study cannot be extended to a group of population where SBP is > 180 mm Hg or DBP is > 110 mm Hg. In our study, the SBP in both the Groups decreased from 131 ± 20.73 to 120 ± 28.8 in Group T and from 131.23 ± 16.03 to 120.80 ± 20.05 in Group E.

In our study, DBP varied as follows: In group the increase was from 78.30 ± 11.00 to 80.13 ± 24.91 at level 5 and also showed decrease from 78.30 ± 11.00 to 77.73 ± 17.00 at level 4. In Group E, it is increased from 79.77 ± 9.76 to maximum of 81.73 ± 13.07 at level 5 and showed decrease from 79.77 ± 9.76 to 77.30 ± 14.53. These findings are in accordance with those studies done by Roberts CP et al.[6] and Gauss A et al.,[8] Colvin MP et al.[12] and Criado A et al.[10] but not in accordance with that of Gooding JM et al.[11], and Gauss A et al.[8]

In our study, the MAP decreased from 94.52 ± 12.10 at level zero to 91.72 ± 21.34 at 5 minutes in Group T and from 96.96 ± 12.96 at level zero to 90.37 ± 17.51 at 2 minutes in Group E. These findings are in accordance with those studies done by Singh R et al.,[9] Cradio A et al.[10], Colvin MP et al.[12] and Singh R et al.[9] but not in accordance to Gooding JM et al.[11]

We found that HR, SBP, DBP and MAP were similar in both the groups. These findings are in accordance with those studies done by Joyce JT et al.[13], Robert JF et al.[14] and Arnow JT et al.[7] but not in accordance to Gauss A et al.[8] In our study patients in either group did not complain of any pain on injection. This is probably because of use of etomidate Lipuro - an advanced formulation (etomidate in lipid emulsion). Doenicke AW et al.[16] study has shown that lipid formulation of etomidate is associated with much lower incidence of pain on injection, thrombophlebitis and histamine release on injection. Van Eeden AF et al.[17] study has shown that there was 20–25% incidence of pain on injection with etomidate. However, propylene glycol formulation of etomidate has been used in this study.

Hence, our study correlates with that of Doenicke MW et al.[18] However, a comparative study between etomidate in lipid emulsion with etomidate in propylene glycol has to be carried out. One patient in Group E had vomiting which was amenable to treatment. The postoperative nausea and vomiting which is being attributed to etomidate can also be due to fentanyl premedication. Gregory G et al.[19] study showed that among 105 children who received etomidate for rapid sequence intubation, three patients vomited within 10 minutes of injection. Hence, our study correlates with that of Gregory et al. All the patients in the present study were followed up for 24 hours postoperatively and no hemodynamic instability have been noted. The major and well-known side effect of etomidate, adrenocortical suppression has not been studied in the present work.

A word about cost – effectiveness

Thiopentone

500 mg vial of thiopentone (Neon lab) costs about a maximum retail price of ₹40/-. Recommended dose for induction of anesthesia is 5 mg/kg which implies that a two 500 mg vials can be used for 3 patients weighing about 60 kg after reconstitution and storage. Hence, for a total of 30 patients, 20 vials which costs about ₹800/- have been consumed.

Etomidate

Etomidate Lipuro (B Braun) is supplied in a 20 mg (2 mg/ml) ampoule. Each ampoule costs ₹490/. Recommended dose being 0.3 mg/kg which implies one ampoule can be used for only one patient weighing about 60 kgs. Hence, for a total of 30 patients, 30 vials, costing to about ₹14,700/- have been consumed. In our study, considering the number of patients (30 in each Group), we found thiopentone to have better cost effectiveness and ease of availability when compared to etomidate.

Conclusion

We conclude from our study that both thiopentone and etomidate have similar and safe hemodynamic profile when used in adult treated hypertensive patients. Thiopentone comparatively has better cost effectiveness and ease of availability.

Key Messages

Thiopentone due to its costeffectiveness and easy availability should be used in adult treated hypertensives scheduled for elective surgery.

References

1. Sapkota S, Sherpa M, Bhattarai B. Incidence of hypertension in patients undergoing surgery at Dhulikhel Hospital: Kathmandu University Hospital. Kathmandu Univ Med J 2011;34(2):40–43.
2. William B Kennel. Hypertension update, heart disease epidemiology study, National Institute of Health Framingham, Massachussets 1978 June, 1. Dundy.
3. Forman SA. Clinical and Molecular Pharmacology of Etomidate. Anesthesiol 2011; 114(3):695–707.
4. Saddler JM, Devon R, Hospital E. Anesthesia and Hypertension. UK page 11–13.
5. Lundy JS. Intravenous anesthesia: Preliminary report of the use of two new thiobarbiturates. ProcMayo Clinic 1935;10:536–43.
6. Roberts CP, Greene LT, Meloche R, et al. Studies of anesthesia in relation to hypertension II: Hemodynamic consequences of induction and endotracheal intubation. Br J Anesth 1971;43:531–46.
7. Arnow JT, Hess W, Klein W. Etomidate,

alfathesinin and thiopentone as induction agents for coronary artery surgery. Canadian Anesth Soc 1980 July;27(4):338–44.

8. Gauss A, Heinrich H, Wilder-Smith OHG. Echo cardio-graphic assessment of the hemodynamic effects of propofol: A comparison with etomidate and thiopentone. Anesth 1991 Feb;46(2):99–105.
9. Singh R, Choudhary M, Kapoor PM, et al. A randomized trial of anesthetic induction agents in patients with coronary artery disease and left ventricular dysfunction. Ann Cardiac Anesth 2010;13(3):217–23.
10. Criado A, Maseda J, Navarro E, et al. Induction of anesthesia with etomidate:hemodynamic study of thirty-six patients. Br J Anaesth. 1980 Aug;52(8):803–805.
11. Gooding JM, Corssen G. Cardiovascular effects of etomidate. Anesth Analg. 1977 Sep-Oct;56(5):717–19.
12. Colvin MP, Savage TM, Newland PE, et al. Cardio respiratory effects of etomidate in patients with cardiac disease. Br J Anesth 1979;51:551.
13. Joyce JT, Roizen MF, Eger EI. Effects of thiopentone induction onsympathetic activity. Anesthesiol 1983;59(1):19–22.
14. Robert JF, Nancy C. Comparison of a newer formulation of etomidate with thiopentone: Side effects and awakening times. Anesthesiol 1979;50:242–44.
15. Howell SJ, Sear JW, Foex P. Hypertension, hypertensive heart disease and perioperative cardiac risk. Br J Anesth 2004;92(4):570–83.
16. Doenicke AW, Roizen MF, Hoernecke R, et al. Solvent for etomidate may cause pain and adverse effects. Br J Anesth 1999;83(3):464–66.
17. Van Eeden AF. Etomidate and; or Anesthetic Induction A Clinical Comparison between Methohexitone. S Afr Med J 1980;57(8):278–79.
18. Mayer M, Doenicke A, Nebauer AE, et al. Propofol and etomidate-Lipuro for induction of general anesthesia. Hemodynamics, vascular compatibility, subjective findings and postoperative nausea. Anesthetist 1996 Nov;45(11):1082–84.
19. Guldner G, Schultz J, Sexton P, et al. Hemodynamic effects and adverse events following etomidate for rapid: Sequence intubation in young children. Acad Emer Med 2003;10:134–39.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 150-154
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.21

Prognosticators of Packed Red Blood Cell Transfusion in Patients Undergoing Off Pump Coronary Revascularization

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Abstract

Background: Coronary revascularization surgery is a procedure associated with higher rate of transfusion. Approximately 20% of all cardiac surgeries require allogeneic blood transfusions. The Red Blood Cells (RBCs) transfusion increases the morbidity and mortality in any surgery. The understanding of preoperative variables pertinent with the Red Blood Cells (RBCs) transfusion will authenticate the risks of transfusion and thus cede the need for productive blood conservancy methods. The intention of this study was to regulate the clinical and demographic variables associated with blood product transfusion in patients undergoing elective off pump coronary revascularization surgery. *Materials and Methods:* This was a single-center retrospective study conducted on 142 patients who had undergone elective off pump coronary revascularization surgery Patients' preoperative clinical and demographic data, were analyzed. The preoperative lab analysis like hemoglobin, hematocrit, renal functions and coagulation profile were cataloged. The primary endpoints of interest was packed red blood cell transfusion. Secondary outcomes analyzes were reoperation rate for bleeding or cardiac tamponed and total postoperative chest tube drainage. Only intraoperative and postoperative (6 days) homologous packed RBC transfusions were recorded. *Results:* A total of 142 patients who underwent isolated off pump coronary revascularization surgery were studied. Blood transfusions were given to 23 of 142 patients (16.19%). Eleven of 41 women (26.8%) needed transfusion, compared with 12 of 101 men (11.9%) ($p < 0.028$). *Conclusion:* In the present study, we conclude preoperative anemia, low hematocrit and female gender were certainly associated with perioperative allogeneic red blood cells transfusion in patients undergoing off pump coronary revascularization surgery.

Keywords: Anemia; Blood transfusion; Cardiac surgery; Hematocrit; Off Pump Coronary revascularization surgery (OPCAB); Red Blood Cells (RBC).

How to cite this article:

Vijaya Kumara, Harshil Joshi, Guru Prasad Rai D. Prognosticators of Packed Red Blood Cell Transfusion in Patients Undergoing Off Pump Coronary Revascularization. Indian J Anesth Analg. 2020;7(1 Part -I):150–154.

Introduction

Coronary revascularization surgery is one of the commonest open cardiac surgeries done latterly. It is associated with momentous blood loss and increased extent of blood transfusion.[1] Over and above 20% of all Coronary revascularization surgeries require blood transfusions in the United States.[2] Customarily, coronary revascularization surgery was done using Cardiopulmonary Bypass

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Received on 10.10.2019, **Accepted on** 28.11.2019

(CPB) which allows the heart to be arrested and provides an immobile and bloodless field to enable optimal and complete revascularization. Today most of the coronary revascularization surgery are done on beating heart without use of CPB (OPCAB). There are inconclusive differences in terms of postoperative mortality, morbidity and adequacy of revascularization between patients undergoing OPCAB and coronary revascularization surgery with CPB, but the studies show that the patients undergoing coronary revascularization surgery with CPB are transfused more blood than those undergone OPCAB.[3,4] The red blood cells transfusion is associated with profound complications wholly related to transfusion like febrile nonhemolytic reactions, infections, TRALI Graft-*Vs*-Host Disease (GVHD), Transfusion-associated circulatory overload etc.[5] There are several blood conservancy techniques, which could result in reduction in superfluous blood transfusion. Routinely consummated are autologous blood donation, red cell salvage, hemostatic and antifibrinolytic agents and normovolemic hemodilution.[6] The understanding of preoperative variables pertinent with the Red Blood Cells (RBCs) transfusion will authenticate the risks of transfusion and thus, cede the need for productive blood conservancy methods. The intent of this study was to determine the clinical and demographic covariates associated with red blood cells transfusion in patients undergoing elective Off Pump Coronary revascularization surgery (OPCAB).

Materials and Methods

The study was conducted at a tertiary care hospital using the clinical data of patients who underwent isolated elective off pump coronary revascularization surgery. This was an observational retrospective study conducted between November 2017 and October 2018. Patients who had undergone emergency coronary revascularization surgery surgeries, concomitant cardiac surgical procedure like coronary revascularization surgery with Mitral Valve Replacement (MVR) or coronary revascularization surgery with Aortic Valve Replacement (AVR) and on pump coronary revascularization surgery (using CPB) were excluded from study. Patient's demographic data, preoperative investigations like hemoglobin, hematocrit, renal functions and coagulation profile and perioperative data were collected from hospital data base.

Preoperative criterion analyzed were age, sex, Body Surface Area (BSA), stenosis of left main coronary artery > 50%, antiplatelet medications within seven days before operation, preoperative heparin therapy, history of recent myocardial infarction (within 6 months), Left Ventricular Ejection Fraction (LVEF), prior cardiac surgery, chronic renal failure, cerebrovascular disease, antifibrinolytic drugs and last preoperative hematocrits. Number of distal anastomoses performed, use of Left Internal Mammary Arteries (LIMA), lowest intraoperative hematocrits and transfusion of blood products were documented intraoperatively.

The primary endpoints of interest was packed red blood cell transfusions, reoperation rate for bleeding or cardiac tamponed and total postoperative chest tube drainage. Only intraoperative and postoperative (6 days) homologous packed RBC transfusions were recorded.

Anesthesia Technique

All patients were given general anesthesia with intravenous induction agents using fentanyl, midazolam and propofol according to patients' clinical requirement. Inhalational agent isoflurane was used for maintenance of anesthesia in all patients. To maintain stable hemodynamics, noradrenaline was used as and when required. One gram of antifibrinolytic agent (inj. tranexamic acid) was given to all patients before the skin incision. OPCAB was done with midline sternotomy incision. Variable number of grafts were anastomosed depending on patients' clinical conditions using left internal mammary artery grafts and saphenous vein grafts. Anticoagulation was achieved with intravenous heparin 200–300 IU/kg to the target Activated Clotting Time (ACT) of 250–350. Anticoagulation was partially reversed with intravenous protamine 1 mg/100 units of heparin after completion of last anastomosis. All patients were electively ventilated for 2–4 hours postoperatively. Postoperative hemodynamics, chest tube drain and allogenic PRBC transfusion if any were charted. Institutional Research Committee and Institutional Ethical Committee clearance were taken prior to conducting the study and the study compiles with current ethical consideration.

Data Analysis

All quantitative data were coded and transformed into an excel master sheet for computer programming. A Chi-square test was used to evaluate categorical variables for analysis. For all practical analyses, $p < 0.05$ was accepted to be statistically significant. Statistical analysis of the data was done using SPSS (version 16) package.

Results

Total 194 patients underwent coronary revascularization surgery November 2017 to October 2018. We excluded 52 patients who underwent concomitant procedures and on pump coronary revascularization surgery leaving 142 patients who underwent isolated off pump coronary revascularization surgery for study. Preoperative patient demographics have been detailed in Table 1. Blood transfusions were given to 23 of 142 patients (16.19%). Eleven of 41 women (26.8%) needed transfusion, in comparison with 12 of 101 men (11.9%) ($p < 0.028$). Preoperative hemoglobin and hematocrit are compared in Table 2, preoperative hemoglobin and preoperative hematocrit were significantly associated with intraoperative blood transfusion. Perioperative details are given in Table 3. Number of distal grafts more than 3 was associated with increased requirement of intraoperative blood transfusion. In present study, diabetes mellitus, hypertension, age of patients, preoperative heparin therapy and recent MI had no association with increase in transfusion requirement in patients undergoing off pump coronary revascularization surgery.

Table 1: Preoperative demography characteristics

Covariates	Without transfusion (*n* = 119)	Transfusion (*n* = 23)	*p* - value
Age (mean)	58	64	
Sex Male	89 (88.1%)	12 (11.9%)	
Female	30 (73.2%)	11 (26.8%)	0.028
Comorbidities			
Diabetes Yes	105 (83.3%)	21 (16.7%)	
No	14 (87.5%)	2 (12.5%)	0.65
Hypertension Yes	110 (84%)	21 (16%)	
No	9 (81.8%)	2 (18.2%)	0.085
Smoking	28 (90.3%)	3 (9.7%)	0.26
CVA	3 (100%)	0	
CKD	6	0	0.27

Table 2: Comparing preoperative hemoglobin and hematocrit

	Without transfusion (*n* = 119)	Transfusion (*n* = 23)	*p* - value
Preoperative Hb			
< 11 gm/%	3	11	0.02
> 11 gm/%	116	12	
Preoperative Hct			
< 34%	10	15	0.03
> 34%	109	8	

Table 3: Perioperative assessment

	Without transfusion (*n* = 119)	Transfusion (*n* = 23)	*p* - value
Recent MI	14 (70%)	6 (30%)	0.071
Preoperative heparin	18 (78.3%)	5 (21.7%)	0.25
Ejection fraction			
> 50%	91 (81.2%)	21 (18.8%)	0.11
35–50%	17 (89.5%)	2 (10.5%)	0.47
< 35%	10 (100%)	0	0.14

	Without transfusion (n = 119)	Transfusion (n = 23)	p - value
Extent of coronary artery disease			
Single vessel disease	3 (75%)	1 (25%)	0.62
Double vessel disease	17 (85%)	3 (15%)	0.86
Triple vessel disease	92 (83.6%)	18 (16.4%)	0.92
LMCA	36 (78.3%)	10 (21.7%	0.89
Nos. of grafts			
1	1 (100%)	0	
2	9 (90%)	1 (10%)	0.86
3	52 (98.1%)	1 (1.9%)	0.92
4	47 (79.7%)	13 (20.3%)	0.13
5	8 (50%)	8 (50%)	0.09

Discussion

Blood transfusion in cardiac surgeries is enormous, followed by orthopedic surgeries. Patients undergoing cardiac surgery require higher rates of transfusions than patients undergoing noncardiac surgeries.[6] Blood transfusion during cardiac surgeries is primarily from hemodilution from pump priming or to correct coagulopathy and blood loss during surgery. This observational retrospective study was undertaken to determine variable risk-factors for allogeneic red blood cell transfusion in patients undergoing off pump coronary revascularization surgery, which is associated with a major blood loss.

According to the guidelines of Society of Thoracic Surgeons and other reports suggests blood transfusion rate diversifies significantly between surgeons and institutions.[7,9] Allogeneic red blood cell transfusion rates of 8–100% have been proclaimed during coronary revascularization surgery in many studies.[10,11] This extensive inconstancy may be explained by a variety of facts which include differences in patient populace among the study centers, preoperative medication with antiplatelet agents and anticoagulants and several surgical and procedure-related factors.[12,13] Many studies have compared the transfusion requirement in on pump and off pump coronary revascularization surgery. Recently off pump coronary revascularization surgeries done more frequently than on pump coronary revascularization surgery because of improvement in surgical skills and technology, but the blood transfusion requirement is still high compared to noncardiac surgeries.

Recent studies have reported anemia as a considerable predictor for requirement of transfusion. However, it is still unclear what hemoglobin level indicates the need for transfusion. The Society of Thoracic Surgeons latest guidelines for blood transfusion and conservation in cardiac surgery recommends a hemoglobin level of < 7 g/dl for PRBC transfusion. However, the level of evidence is 'C' with a recommendation of 'Class 2a', which means that supporting evidence is still insufficient.[14,15] Recent reports have determined poor results when transfusion is due to preoperative anemia or blood dyscrasias.[16,18] In 2014, Engoren et al. evaluated late mortality in 922 patients who underwent isolated coronary revascularization surgery during a 3.5-year period. They established that patients with preoperative anemia who received intraoperative transfusion had an increased rate of death compared with those without anemia and transfusion.[19] Numerous strategies exist for dealing with preoperative anemia in patient undergoing coronary revascularization surgery. In patients with delayed surgery with known risk-factors for transfusion, optimization with erythropoiesis-stimulating agents should begin before surgery.

Limitations

The limitations in this study include, it's a retrospective, descriptive in nature and small cohort size. More prospective long-term studies must be designed to explore the risk-factors of blood transfusion in OPCAB and to validate our current findings.

Conclusion

In denouement, our study showed that preoperative anemia, low hematocrit and female gender wereunquestionably associated with perioperative allogeneic red blood cell transfusion in patients undergoing OPCAB.

Conflict of Interests

The writer declared no conflicts of interest with regards to the analysis, authorship and/or publication of this article.

Acknowledgment

The writer would like to express their acknowledgement to the Hospital Records Department at Kasturba Hospital for providing access to case reports.

Financial disclosure

There is no financial disclosure.

Funding/support

The authors received no financial support for the research, authorship and/or publication of this article.

Institutional ethics committee has been taken (Approval no: IEC 48/2019).

References

1. Chiavetta JA, Herst R, Freedman J, et al. A survey of red cell use in 45 Hospitals in Central Ontario, Canada. Transfusion 1996;36(8):699–706.
2. Parolari A, Alamanni F, Cannata A. Off-pump *vs* on-pump coronary artery bypass: Meta-analysis of currently available randomized trails. Ann Thorac Surg 2003;76:37–40.
3. Sellke FW, DiMaio JM, Caplan LR. Comparing on-pump and off-pump coronary revascularization: Numerous studies but few conclusions. Circulation. 2005 May 31;111(21):2858–864.
4. Raja SG, Dreyfus GD. Off-pump coronary artery bypass surgery: To do or not to do? Current best available evidence. J Cardiothorac Vasc Anesth 2004;18:486–505.
5. Engoren MC, Habib RH, Zacharias A, et al. Effect of blood transfusion on long-term survival after cardiac operation. Ann Thorac Surg 2002;74(4):1180–186.
6. Murphy GJ, Reeves BC, Rogers CA, et al. Increased mortality, postoperative morbidity, and cost after red blood cell transfusion in patients having cardiac surgery. Circulation 2007;116(22):2544–552.
7. SP. The Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists blood conservation clinical practice guidelines. Ann Thorac Surg 2011;91(3):944–82.
8. Karkouti K, Wijeysundera DN, Beattie WS, et al. Variability and predictability of large-volume red blood cell transfusion in cardiac surgery: A multicenter study. Transfusion 2007;47(11):2081–88.
9. Legare JF, Buth KJ, King S, et al. Coronary bypass surgery performed off-pump does not result in lower in-hospital morbidity than coronary revascularization performed on-pump. Circulation 2004;109(7):887–92.
10. Rogers MA, Blumberg N, Saint S, et al. Hospital variation in transfusion and infection after cardiac surgery: A cohort study. BMC Med 2009;7:37.
11. Snyder-Ramos SA, Mohnle P, Weng YS, et al. The ongoing variability in blood transfusion practices, predictors of blood transfusion Sandoughdaran S in cardiac surgery. Transfusion 2008;48(7):1284–299.
12. Slight RD, Bappu NJ, Nzewi OC, et al. Factors predicting loss and gain of red cell volume in cardiac surgery patients. Transfus Med 2006;16(3):169–75.
13. Ferraris VA, Brown JR, Despotis GJ, et al. The Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists blood conservation clinical practice guidelines. Ann ThoracSurg 2011;91(3):944–82.
14. Du Pont-Thibodeau G, Harrington K, Lacroix J. Anemia and red blood cell transfusion in critically ill cardiac patients. Ann Intensive Care 2014;4:16.
15. Acharya D, Gulack BC, Loyaga-Rendon RY. Clinical characteristics and outcomes of patients with myocardial infarction and cardiogenic shock undergoing Coronary Artery Bypass Surgery: Data from the society of thoracic surgeons' national database. Ann Thorac Surg2016;101(2):558–66.
16. Gundling F, Seidl H, Gansera L. Early and late outcomes of cardiac operations in patients with cirrhosis: A retrospective survival-rate analysis of 47 patients over 8 years. Eur J Gastroenterol Hepatol 2010;22(12):1466–473.
17. Engoren M, Schwann TA, Habib RH. The independent effects of anemia and transfusion on mortality after coronary artery bypass. Ann Thorac Surg 2014;97(2):514–20.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 155-163
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.22

A Comparative Study of Fentanyl and Clonidine as an Adjuvant to Bupivacaine for Spinal Anesthesia

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Abstract

Background: Spinal Anesthesia is the regional anesthesia obtained by blocking spinal nerves in subarachnoid space, the aesthetic agents are deposited in the subarachnoid space and act on spinal nerve roots and not on substance of cord. Intrathecal opioids are synergistic with local aesthetic and intensity of sensory block without increasing motor block and offer Hemodynamic stability. Intrathecal opioids like fentanyl citrate is combined with local anesthetics which has milder side effects, also fentanyl citrate is lipophilic drugs. It has rapid onset compared lyophobic morphine. This property may affect onset of sensory block. When fentanyl citrate is added to bupivacaine hydrochloride for subarachnoid block. An intrathecal Clonidine has substantial antinociceptive effect by its action on α^2 Receptor in dorsal Horn of spinal cord and by adding Clonidine with Bupivacaine hydrochloride improves intraoperative analgesia and might prolong the duration of spinal Analgesia. We compared the effects of fentanyl and Clonidine as an adjuvant to Bupivacaine for spinal Anesthesia. *Methods:* The study was carried out by selecting the patients presenting for surgery of lower limb, perineal surgery, lower abdominal surgery etc. Study was done in 50 patients belonging to ASA 1 and 2 selected for the study. Group - BF: Inj. Bupivacaine Hydrochloride (20 mg) (0.5%) + inj. Fentanyl citrate 25 μg. Group - BC: Inj. Bupivacaine Hydrochloride (20 mg) (0.5%) + inj. Clonidine Hydrochloride 50 μg. Time at which sensory and motor blockade reached highest dermatome level & stabilized at highest level. Recording of vital signs was started from the point of injection of drug in CSF. Heart Rate, Blood Pressure, SpO_2, were noted every 1 min for first 10 min, then every 5 min till 30 min and then every 15 min till 60 min. Duration of total sensory and Motor Blockade is noted. Hypotension was defined as Systolic - Blood Pressure less than 90 mm HG or 30% decrease in Systolic Blood Pressure from Base line and Brady cardia was defined as Heart Rate less than 50 min. Patients were observed for following complication during procedure Hypotension, Bradycardia, Sedation, Respiratory depression, Nausea, Vomiting, Rigors, Pruritus. Duration of Motor & Sensory Blockade was noted. *Results:* We studied that mean time for onset of sensory block (sec) and motor block (sec) was shorter in Group - BF as compared to Group - BC. Total duration of motor and sensory block was longer in Group - BC as compared Group - BF. Changes in pulse rate, systolic BP and diastolic BP shows statistical significance in both Group. First analgesic requirement was more prolonged in Group - BC. Group - BF shows some complications like Nausea, Pruritus, and Hypotension. Group - BC shows complications like sedation, Hypotension + Bradycardia. *Conclusion:* Clonidine Hydrocloride caused intense sensory and motor blockade when injected with bupivacaine. Clonidine also didn't show side effects like respiratory depression, pruritus, urinary retention. Which were noted with the use of fentanyl. But onset of action was delayed with use of clonidine and increased chances of more bradycardia, hypotension and sedation compared to fentanyl which required more supportive care.

Keywords: Fentanyl; Clonidine; Bupivacaine; Spinal Anesthesia; Hemodynamic; Sensory and Motor blockade.

How to cite this article:

Sunil Ninama, Visharad Trived. A Comparative Study of Fentanyl and Clonidine as an Adjuvant to Bupivacaine for Spinal Anesthesia. Indian J Anesth Analg. 2020;7(1 Part -I):155–163.

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Received on 21.11.2019, **Accepted on** 05.12.2019

Introduction

"For all the happiness mankind can give is not pleasure but in relief from pain" –Pain is extra ordinary complex sensation which is difficult to define and equally difficult to measure in an accurate objective manner. A Regional Anesthesia may be considered as Anesthesia of an anatomic part produced by application of chemical capable of blocking conduction in nerve tissue Associated with that part. Agent must not damage the tissue permanently and the functional derangement must be reversible" Spinal Anesthesia is the regional anesthesia obtained by blocking spinal nerves in subarachnoid space the anesthetic agents are deposited in the subarachnoid space and act on spinal nerve roots and not on substance of cord.

Spinal Anesthesia has been popular for short and intermediate duration of surgical procedures for decades. Lidocaine has been the local Anesthetics of choice for spinal Anesthesia in ambulatory surgical procedures.[1] This was based on drugs short duration of action which allows timely recovery and discharge, unfortunately recent reports of lidocaine neurotoxicity have created doubt of use of lidocaine. One study reported 37% incidence of "Radicular Symptoms" of pain and/or dysesthesias in buttocks, thigh or lower Limbs after spinal anesthesia with 5% lidocaine in 7.5% glucose for these reasons, Bupivacaine Hydrochloride has become popular for ambulatory short surgical procedure.[2]

Bupivacaine hydrochloride is a potent local Anesthetic. It has propensity to cause severe hypotension in geriatric patients. Intrathecal opioids are synergistic with local anesthetic and intensity of sensory block without increasing motor block and offer Hemodynamic stability. An intrathecal morphine is associated with higher incidence of side effects. So, newer opioids like fentanyl citrate is combined with local anesthetics which has milder side effects, also fentanylcitrate is lipophilic drugs. It has rapid onset compared lipophobic morphine. This property may affect onset of sensory block.

When fentanyl citrate is added to bupivacaine hydrochloride for subarachnoid block.[3] An intrathecal Clonidine has substantial antinociceptive effect by its action on α^2 Receptor in dorsal Horn of spinal cord and by adding Clonidine with Bupivacaine hydrochloride improves intraoperative analgesia and might prolong the duration of spinal Analgesia.[4]

"We compared the effects of fentanyl and Clonidine as an adjuvant to Bupivacaine for spinal Anesthesia."

Aims of Study

" A Comparative study of fentanyl and Clonidine as an adjuvant to Bupivacaine for spinal Anesthesia."

The parameters observed were:

1. To compare the onset of peak sensory blockade;
2. To compare the level of maximum motor blockade;
3. To compare the duration of sensory blockade;
4. To compare the duration of motor blockade;
5. Duration of postoperative analgesia and time to rescue analgesia;
6. Incidence of intraoperative & postoperative complication;
7. To compare adverse effects of procedure & drugs.

Materials and Methods

After getting approval from the ethical committee of our hospital. The study was carried out by selecting the patients presenting for surgery of lower limb, perineal surgery, lower abdominal surgery etc.

Study was done in Gujarat Cancer Research Institute in 50 patients study was done in ASA Grading I & II.

Exclusion Criteria

- Allergic to local Anesthetic;
- Patient refusal;
- Valvular heart disease;
- Surgery of longer duration;
- Bleeding tendency;
- Neurological problem;
- Infection at the site of injection.

Preanesthetic Assessment

All patients were examined preoperatively and history noted. All patients were tested for sensitivity to Bupivacaine by an intradermal skin test.

Investigation

HIV, HBSAG, Hemoglobin, total count, Platelet count, differential count, Renal function test, Serum Electrolytes, Liver function test, Urine

Analysis, Prothrombin time, Activated partial thromboplastin time, Electro–cardiogram, Chest *X*–Ray (P/A view).

Group allocation

50 Patients were randomly allocated in Two Group (n = 25)

Groups	
Group–BF	Inj. Bupivacaine Hydrochloride (20 mg) (0.5%) + Inj. Fentanyl citrate 25 μg.
Group–BC	Inj. Bupivacaine Hydrochloride (20 mg) (0.5%) + Inj. Clonidine Hydrochloride 50 μg

Premedication

Tab. Lorazepam 1 mg at 10.00 pm on previous night of surgery Tab. Diazepam 5 mg at 6.00 am on the day of surgery Spinal Anesthia is given for the surgeries in 50 patients were taken in operation room and monitoring devices, like Noninvasive Blood Pressure Monitoring Electrocardiography SpO_2. 18G Intravenous catheter was inserted in forearm peripheral vein followed by preloading 10 ml/kg of Injection Ringer lactate Solution. Patients were put in left lateral position followed by painting and draping of back taking aseptic precaution after local infiltration. Intrathecal space was identified and spinal needle introduced and drugs were given according to groups allowed. Patients were immediately turned supine. Sensory block was assessed by cotton gauze and level was confirmed. Motor Block was assessed at the time of reaching highest sensory block by bromate score

Bromage Score[5]

Grade–0 : No block full flexion of knee & feet;

Grade–I : Partial block just able to flex knee but full flexion of feet;

Grade–II : Almost complete block unable to flex knee but complete; Flexion of feet possible;

Grade–III : Complete block unable to flex knee & feet.

Time of the peak level of sensory and motor block was calculated. This was calculated from the time of drug injected intrathecal to time at which sensory and motor blockade reached highest dermatome level & stabilized at highest level. Level of dermatome block. Recording of vital signs was started from the point of injection of drug in CSF. Heart Rate, Blood Pressure, SpO_2, were noted every 1 min for first 10 min, then every 5 min till 30 min and then every 15 min till 60 min. Durationof total sensory and Motor Blockade is noted. Hypotension was defined as Systolic Blood Pressure less than 90 mm HG or 30% decrease in Systolic Blood Pressure from Base line and Brady cardia was defined as Heart Rate less than 50 min. Hypotension was treated by increasing the rate of Intravenous fluid, mephentermine 5 mg IV in Incremental doses. Brady cardia was treated by Inj. Glucopyrolate 0.2 mg IV. Patients were observed for following complication during procedure: Hypotension, Bradycardia, Sedation, Respiratory depression, Nausea, Vomiting, Rigors, and Pruritus.

Postoperative

Patient were shifted to postoperative ward and duration of Motor & Sensory Blockade was noted. Total duration of surgery and postoperative complications like headache, Urinary retention, diplopia, and backache was noted. Duration of postoperative first analgesic requirement was noted. Mean & Standard deviation were calculated for each parameter Statistical Analysis was done.

p - value < 0.05 were considered significant.

Results

There was no statistical significance difference between Two Groups (p > 0.05) with respect to age, sex, weight and height, as shown in (Table 1).

Table 1: Demographic details

	Group - BF	Group - BC	p - value
Age (mean ± SD)	50.6 ± 14.4	54 ± 17.1	0.4507
Sex (M/F)	15:5	15:5	
Weight (mean ± SD)	51.5 ± 9.89	52.4 ± 7.98	0.7248
Height (mean ± SD)	168 ± 6.05	166 ± 5.65	0.2330

Table 2 shown that mean time for onset of sensory block (sec) was shorter in Group - BF as compared to Group - BC. p < 0.05 which is statistically significant. Peak height of sensory block was T6 in both Groups. Time to reach peak sensory level (min) showing no statistical significant difference in both Groups.

Table 2: Sensory block

Sr. No.	Sensory Blockade	Group - BF	Group - BC	*p* - value
1	Time of peak sensory height mean	T6	T6	
2	Time to reach peak sensory level (min) Mean ± SD	8.4 ±1.93	8.75 ±1.92	$p > 0.05$
	Motor Block			
3	Time of onset of sensory B. (sec)	36.25 ± 11.3	87 ± 25.7	$p < 0.05$
4	Time of onset of Motor Block (sec) mean ± SD	121.5 ± 59.67	156 ± 29.63	$p < 0.05$

Changes in pulse rate (min) showing $p < 0.05$ statistical significant difference in both Groups at 20 min, 25 min, 30 min, 45 min, shown as in (Table 3).

Table 3: Changes in pulse rate and min

Sr. No.	Time	Group - BF	Group - BC	*p* - value
1	Basal	96.5 ± 15.65	91.1 ± 13.2	0.1935
2	1 min	92.6 ± 21.1	92.2 ± 16.1	0.9402
3	3 min	95.7 ± 15	91.7 ± 16.3	0.3711
4	5 min	93.8 ± 15.1	89.1 ± 15.4	0.2813
5	10 min	91.2 ± 15.14	83.9 ± 16.64	0.1113
6	15 min	90.2 ± 14.89	82 ± 15.94	0.0662
7	20 min	87.9 ± 14.8	78.7 ± 17.3	$p < 0.05$
8	25 min	87.6 ± 14.6	74.8 ± 20	$p < 0.05$
9	30 min	87 ± 14.9	77.2 ± 16.7	$p < 0.05$
10	45 min	86.95 ± 14.48	77.85 ± 15.30	$p < 0.05$
11	60 min	84.95 ± 13.97	77.8 ± 14.37	0.0808

Table 4 shown, Systolic blood pressure changes (mm of Hg) showing $p < 0.05$ in both Group at 15 min, 20 min, 25 min, 30 min, 45 min. There was statistical significance. Difference in both Groups. Changes showing total duration of Motor and Sensory Block, shows in (Table 5). It Shows total duration of motor and sensory block was longer in Group - BC as compared Group - BF. $p < 0.05$ which is statistical significant difference in both Groups.

Table 4: Changes in blood pressure

Sr. No.	Time	Group - BF Systolic BP	Group - BC Systolic BP	*p* - value	Group - BF Diastolic BP	Group - BC Diastolic BP	*p* - value
1	Basal	131.15 ± 15.13	134 ± 11.4	0.4556	84.05 ± 9.13	85.55 ± 7.79	0.5350
2	1 min	126 ± 17.4	126 ± 13.9	1.0000	81.4 ± 9.9	80.1 ± 10	0.6462
3	3 min	122.65 ± 15.89	119 ± 13.7	0.3887	78.6 ± 8.75	75 ± 8.2	0.1399
4	5 min	121 ± 16.6	116 ± 15.5	0.2765	76.9 ± 9.26	73.2 ± 8.3	0.1434
5	10 min	116.9 ± 16.94	109.6 ± 15.02	0.1135	75.5 ± 9.8	70.7 ± 9.36	0.0829
6	15 min	116.5 ± 16.54	108.2 ± 14.41	$p < 0.05$	74.2 ± 10.3	68.3 ± 8.88	$p < 0.05$
7	20 min	114 ± 16.2	106 ± 14.2	$p < 0.05$	73.2 ± 10.4	67.8 ± 8.99	$p < 0.05$
8	25 min	114 ± 17.2	105 ± 16.9	$p < 0.05$	72.9 ± 10.6	66.35 ± 8.4	$p < 0.05$
9	30 min	114 ± 14	105 ± 14	$p < 0.05$	72.5 ± 10.3	67.3 ± 8.49	$p < 0.05$
10	45 min	116.6 ± 14.47	109.4 ± 11.21	$p < 0.05$	74.65 ± 10.4	68.75 ± 7.62	$p < 0.05$
11	60 min	118.6 ± 14.1	113.5 ± 11.07	0.1614	75.55 ± 10.2	72.3 ± 8.19	0.2202

Table 5: Duration of motor and sensory block

Sr. No.	Parameters	Group - BF	Group - BC	*p* - value
1	Total duration of Motor Blockade	177.5 ± 12.9	200 ± 18	$p < 0.05$
2	Total duration of Sensory Blockade	221 ± 20	234 ± 20.49	$p > 0.05$

First analgesic requirement was more prolonged in Group - BC as compared to Group - BF. $p < 0.05$ shows statistical significance between two Groups. Group – BF shows some complications like Nausea, Pruritus, and Hypotension. Group - BC shows complications like sedation, Hypotension + Bradycardia $p < 0.05$. There was statistical significant difference in both Groups in complications like Hypotension + Bradycardia, Sedation, Pruritus, as shown in (Table 6).

Table 6: 1st Analgesic requirement and duration of surgery

Sr. No.	Parameters	Group - BF	Group - BC	*p* - value
1	1st Analgesic Requirement	294 ± 10.32	344 ± 19	$p < 0.05$
2	Total duration of surgery	79 ± 49.96	100 ± 39.3	$p < 0.05$

Discussion

Spinal anesthesia is popular and commonly used worldwide. The advantages of an awake patient, minimal drug consumption, costs and rapid patient turn over has made this method of choice for many surgical procedures. Bupivacaine has been used as a spinal aesthetic since 1966 but has got longer duration of action. It has been well-documented that the combination of opioid with local anesthetics administered intrathecal has synergistic analgesic effect. Addition of fentanyl might potentiate the afferent sensory blockade, therefore, providing better surgical anesthesia. A Kararmaz, S Kaya et al.[6] Studied low-dose bupivacaine with fentanyl in spinal anesthesia for transurethral prostatectomy. Duration of analgesia was prolonged.

This study "A comparative study of fentanyl and clonidine as an adjuvant to bupivacaine in spinal anesthesia" was carried out in patients undergoing different surgical procedures like Lower-Limb Surgeries, Perineal Surgeries & Lower Abdominal Surgeries. This study was carried out in 50 adult patients of different age, sex, height and weight, ASA risk-status I and II, undergoing for lower limb, perineal region, lower abdominal surgeries. In this study, we divided patients into two Groups, having 25 patients in each Group.

Group - BF: Hyperbaric bupivacaine hydrocloride 20 mg + fentanyl citrate 25 μg;

Group - BC: Hyperbaric Bupivacaine Hydrocloride 20 mg + clonidine hydrocloride 50 μg;

Demographic Data

Mean age of patients in Group - BF was (50.6 ± 14.4) and Group - BC was (54 ± 17.1), All patients were of ASA status I/II having sex ratio in Group - BF was (M : F 15 : 5) and Group - BC was (M : F 15 : 5). They were scheduled for different surgical procedures. Mean weight of Group - BF was (51.5 ± 9.89) and Groub - BC was (52.4 ± 7.98). Mean height of Group - BF was (168 + 6.05) and Group - BC was (166 + 5.65). There was no statistical significant difference between Two Groups with respect to age, sex, weight and height ($p > 0.05$)

Ben-David et al.[7] Demonstrated that the use of diluted small dose bupivacaine for spinal blockade is inadequate to provide reliable anesthesia for longer duration of surgery. Addition of fentanyl was made it a reliable aesthetic. The added fentanyl provided an enhanced and increased duration of sensory analgesia without intensifying the motor blockade or prolonging analgesic effect.

Sensory Block

Onset of Sensory Block

In this study, onset of sensory block was earlier in Group - BF (36.25 + 11.3 sec) as compared to Group - BC (87 + 25.7 sec). There was statistically significant difference between Two Groups ($p < 0.05$). It is due to higher lipid solubility of fentanyl citrate thus allowing it to cross biological membranes rapidly and to be taken up by highly perfused tissues quickly. It crosses blood brain barrier so onset of action, sensory blockade was earlier in Group - BF as compared to Group - BC Bano F, Sabbar S et al.[8] Studied that Intrathecal fentanyl as an adjuvant to Bupivacaine in spinal anesthesia for cesarean section. They concluded that addition of fentanyl to intrathecal bupivacaine results in earlier onset of Sensory Blockade.

Peak Sensory Level

In this study mean, height of Sensory Block was T6 level. It was due to addition of fentanyl citrate 25 µg or Clonidine hydrochloride 50 µg mixed with bupivacaine hydrochloride 20 mg. This increased the volume of injection to 4.5 cc. Pramod Patra, et al. (2003)[9] assessed the suitability of intrathecal spinal opioids plus bupivacaine for endoscopic urological surgeries and concluded that the addition of fentanyl to bupivacaine provided adequate surgical anesthesia and ideal peak sensory block height of T8 level.

Dobrydnjov, et al. (2003)[10] studied addition of bupivacaine 6 mg plus Clonidine 30 µg (Group - BC 30) diluted in 3 ml of saline. Which produced highest sensory block up to T6 level. Solokovic N et al. (2010).[11] Studied level of block and basicity of bupivacaine in spinal anesthesia. In (Group - BH) patients receiving hyperbaric bupivacaine (3 ml), highest level of block was upto T1 level in 3.33% of patients and lowest level of block was T7 level in 6.66% of patients. Time to achieve T6 level Sensory Block.

In this study mean, time (min) for onset of Sensory Blockade in Group - BF was (8.4 ± 1.9) and Group - BC was (8.75 ± 1.92). There was no statistical significant difference between both Groups (p > 0.05). Dobrydnjov et al. (2003)[10] studied addition of bupivacaine 6 mg plus Clonidine 30 µg (Group – BC 30) diluted in 3 ml of saline. Which produced highest Sensory Block up to T6 level.

Total Duration of Sensory Block

In this study, total duration of sensory blockade (min) in Group - BF was (221 ± 20) and Group - BC was (234 ± 20.49). There was no statistical significant difference between Two Groups (p > 0.05). Olfa Kaabachi et al. (2007)[12] studied Clonidine 1 µg/kg was safe and effective adjuvant to plain bupivacaine. They concluded addition of Clonidine to bupivacaine prolonged the duration of Sensory Block. Parvin Greval et al. (2003)[13] Did a double blind study, by injecting hyperbaric bupivacaine 15 mg plus fentanyl 25 µg intrathecal in 75 adult patients. Scheduled for lower limb and urological surgeries. They also concluded that duration of motor block is prolonged due to fentanyl administration.

Motor Block

Onset of motor blockade

In this study time (sec) for onset of motor blockade in Group - BF was (121.5 ± 59.67) and Group - BC was (156 ± 29.63). There was statistically significant difference between Two Groups (p > 0.05). Onset of motor block was earlier in patients receiving bupivacaine and fentanyl. It was due to fentanyl lipid solubility and onset of motor blockade was checked by Bromage Score. Bano F, Sabbar S, et al.[5,8] Studied that intrathecal fentanyl as an adjuvant to bupivacaine in spinal anesthesia for cesarean section. They concluded that addition of fentanyl to intrathecal bupivacaine results in earlier onset of motor blockade.

Total duration of motor block

Time (min) for total duration of motor blockade in Group - BF was (177 ± 12.9) and Group - BC was (200 ± 18). There was statistically significant difference between Two Groups (p < 0.05). Total duration of motor block was shorter in Group - BF. Parvin Greval et al. (2003)[13] Did a double blind study, by injecting hyperbaric bupivacaine 15 mg plus fentanyl 25 µg intrathecal in 75 adult patients, Scheduled for lower limb and urological surgeries. They also concluded that duration of motor block is prolonged due to fentanyl administration. Dobrydnjov et al. (2003)[10] addition of bupivacaine 6 mg plus Clonidine 30 µg (Group – BC 30) diluted in 3 ml saline produced prolonged motor blockade. The mean duration of motor block on the dependant side was significantly prolonged (Group – BC 30). Van Tuijl et al. (2006)[14] concluded that addition of 15 µg Clonidine to 5mg of intrathecal hyperbaric bupivacaine prolongs duration of motor block.

Hemodynamic changes

Systolic and Diastolic blood pressure changes

Spinal anesthesia causes hypotension by interruption of efferent sympathetic transmission. Which decreased peripheral resistance (decreased after load), venous dilatation, decreased venous return (decreased preload) & decreased cardiac output. Sympathetic preganglion nerve fibers exit the spinal cord from T1 to L2 level. Vasomotor tone is mediated by sympathetic fibers arising from T5 to L1 innervating arterial and venous smooth muscles. Sympathetic blockade level is two segments higher then analgesic blockade level.

In this study, Table 5 shows changes in systolic blood pressure (mm Hg). There was statistically significant difference at 20 min, 25 min, 30 min, 45 min between both Groups as $p < 0.05$ after statistical analysis. Table 6 shows changes in diastolic blood pressure (mm Hg). Again, there was statistical significant difference at 20 min, 25 min, 30 min, 45 min between both Groups as $p < 0.05$ after statistical analysis. Olfa Kaabachi et al. (2007)[12] studied Clonidine 1 μg/kg intrathecal and found that it was a safe and effective adjuvant to plain bupivacaine. They concluded that during intrathecal anesthesia hypotension developed, which was more frequent in 29% patients of Clonidine Group compared to 17% patients of control Group. Merivitra et al. (2009)[15] studied a comparison between hyperbaric bupivacaine and bupivacaine + Clonidine. They concluded that patient receiving Clonidine needed more vasopressor. There was significant difference in systolic and diastolic blood pressure between Two Groups. Systolic and diastolic blood pressure being lower in patients receiving bupivacaine and clonidine. Erturk E et al. (2010)[16] studied 12 mg Ropivacaine or 8 mg Bupivacaine with fentanyl 20 μg in spinal anesthesia for major orthopedic surgeries. Study showed systolic and diastolic blood pressure was lower in patients receiving bupivacaine and fentanyl. Rajesh Mahajan et al. (2005)[17] studied 24 patients of pregnancy induced hypertension scheduled for cesarean section. Group - B and Group - BF showed mean arterial blood pressure was decreased in both Groups.

Pulse Rate

In this study of Table 3 shown, changes in pulse rate, p was < 0.05 after statistical analysis, suggesting significant difference between Two Groups at 20 min, 25 min, 30 min, 45 min. Bradycardia was expected after spinal anesthesia. Cardiac accelerating fibers are lying from T1 to T4 level. Clonidine cause stimulation of alpha 2 adrenergic receptors of the neurons in the tractus solitaries causes inhibition of the nucleus of sympathetic neurons in the medulla. By this mechanism, alpha adrenergic agonist reduce tonic activity of the bar reflex causing bradycardia. Bradycardia was noted in patients receiving bupivacaine with clonidine. Which was treated by inj. glycopyrolate (0.2 mg) intravenously. Eisenach et al.[18] Studied that bradycardia developed with use of caudal Clonidine in pediatric surgical patients during regional anesthesia. Olfa Kaabachi et al. (2007)[12] studied and found that Clonidine 1 μg/kg was a safe and effective adjuvant to plain bupivacaine. They concluded that the Clonidine 2 μg/kg added to bupivacaine frequently causes severe bradycardia. Incidence of bradycardia was reported in 21% patients. Erturk K et al. (2010)[16] studied comparison of 12 mg of ropivacaine or 8 mg bupivacaine, mixed with 20 μg fentanyl in spinal anesthesia for major orthopedic surgeries in geriatric patients. Heart rate was lower in patients receiving bupivacaine + fentanyl than in patients receiving bupivacaine + clonidine.

Complication

Hypotension developed in 5 patients in Group - BF and 3 patients in Group - BC intraoperatively. There was no statistical significant difference between Two Groups ($p > 0.05$). Olfa Kaabachi et al. (2007)[12] studied Clonidine 1 μg/kg & found that it was a safe and effective adjuvant to plain bupivacaine. They concluded that the addition of Clonidine tobupivacaine causes hypotension which was more frequent 29% of patients in Clonidine Groups and 17% patients in Control Groups.

Merivitra et al. (2009)[15] studied a comparison between hyperbaric bupivacaine and bupivacaine + Clonidine. They concluded that patients receiving Clonidine needed more vasopressor support compared to the Control Group. There was statistically significant difference between Two Groups. Hypotension was noted in patients receiving bupivacaine + Clonidine. Erturk E et al. (2010)[16] studied either 12 mg Ropivacaine or 8 mg Bupivacaine, mixed with fentanyl 20 μg in spinal anesthesia for major orthopedic surgeries. The study showed that systolic and diastolic blood pressure was lower in patients receiving bupivacaine and fentanyl. Rajesh Mahajan et al. (2005)[17] studied 24 patients of pregnancy induced hypertension scheduled for cesarean section. Mean arterial blood pressure decreased in both Groups within 4–6 min of spinal block as compared to baseline However, the fall in MAP was not statistically significant the decrease in MAP was 20% of base line in both Groups. In this study, 3 patients complained of pruritus in fentanyl Group. Pruritus was most common adverse effect in patient who received intrathecal fentanyl citrate. Pruritus was mild and did not require any treatment. Spencer Lui et al.[19] studied intrathecal lidocaine 5% with and without 25 μg fentanyl citrate in 8 volunteers. They concluded that patients receiving fentanyl pruritus was most common. Morgan G Ed Ward et al.[20] studied pruritus is a common complication with intrathecal opioid use, Most likely cause of spinal opioid induced pruritus was direct central effect on opioid receptor in substantia gelatinase.

Hypotension and bradycardia were noted in 5 patients receiving clonidine intrathecal. Olfa

Kaabachi et al (2007) (12) studied Clonidine 1µg/kg intrathecal and said that it was a safe and effective adjuvant to plain bupivacaine. They concluded that addition of Clonidine to bupivacaine leads to hypotension and bradycardia. Sedation was noted in 3 patients receiving clonidine. Lee et al.[21] studied Clonidine 2 µg/kg intrathecal showed longer duration of sedation in patients.

Postoperative analgesia

In this study, 1[st] analgesic requirement (min) in patients of fentatyl + bupivacaine was (294 ± 10.32) and in patients of clonidine + bupivacaine was (344 ± 19). This shows significant difference between Two Groups $p < 0.05$. Addition of Clonidine and fentanyl intrathecal caused prolonged postoperative analgesia. In this study, postoperative analgesic effect was more prolongedin Group - BC compared to Group - BF. I Van Tuijl (2006)[14] study also showed that addition of intrathecal Clonidine to hyperbaric bupivacaine prolonged the duration of spinal analgesia. I Dobrydnjov et al. (2003)[10] study also showed that addition of bupivacaine 6 mg plus Clonidine 30 μg (Group – BC 30) diluted in 3 ml saline prolonged duration of analgesia in inguinal herniorrhaphy. Levand Homme PM et al. (2009)[22] study also showed that intrathecal Clonidine 150 µg combined with bupivacaine caused prolonged postoperative analgesia. Parvin Greval et al. (2003)[13] studied "A double blind study on 75 adult patients scheduled for lower limb and urological surgeries by administration of intrathecal fentanyl 25 μg plus hyperbaric bupivacaine 15 mg." Fentanyl with low-dose bupivacaine prolonged the duration of analgesia. Rajesh Mahajan et al. (2005)[17] studied 24 patients of pregnancy induced hypertension scheduled for cesarean section. Group - B and Group - BF showed prolonged duration of analgesia without hemodynamic and neonatal compromise.

Onset of sensory and motor blockade was earlier in patients receiving fentanyl with bupivacaine compared to the patients receiving Clonidine with bupivacaine. Total duration of sensory and motor blockade was prolonged in groups of patients receiving Clonidine with bupivacaine. Systolic and diastolic blood pressure changes shows statistically significant difference between Two Groups. 1[st] analgesic requirement was prolonged in patients receiving clonidine with bupivacaine compared to patients receiving fentanyl with bupivacaine. Pruritus was noted in patients receiving fentanyl. Sedation, hypotension and bradycardia was noted in patients receiving clonidine with bupivacaine.

Conclusion

Clonidine hydrochloride caused intense sensory and motor blockade when injected with bupivacaine. Clonidine also didn't show side effects like respiratory depression, pruritus, urinary retention. Which were noted with use of fentanyl. But onset of action was delayed with use of clonidine and increased chances of more bradycardia, hypotension and sedation compared to fentanyl which required more supportive care.

References

1. Uma Shrivastava, Aditya Kumar, Surekha Saxena. Studied spinal anesthesia with lidocaine and fentanyl, Indian J Anesthe 2004;48(2):121–23.
2. Fanelli G, Borghi B, Casati A. Studied unilateral bupivacaine spinal anesthesia for outpatient knee arthroscopy: Italian study group on unilateral spinal anesthesia. Can J Anesth 2000;47:746–51.
3. Levand Hoome PM. An evaluation of clonidine of the postoperative antihyperalgesic and analgesic effects of intrathecal clonidine administered during elective ceserian delivary. Anaesth Analg 2008–2009;107(3):948–55.
4. Lt Col Upadhyayk. Studied addition of clonidine with bupivacaine for caudal blockade significantly prolong the duration of analgesia (2005).
5. Bromage. Epidural Analgesia. Philadelphia: WB Saunders; 1978.p.144.
6. Kararmaz A, Kaya S. Studied low-dose bupivacaine-fentanyl spina anesthesia for transurethral prostatectomy. Anesthesia 2003 Jun;58(6):526–30.
7. Ben-David B, Solomon E, Levin H. Studied Intrathecal Fentanyl with small-dose dilute bupivacaine: Better anesthesia without prolonging recovery.Anesth Analg. 1997 Sep;85(3):560–65.
8. Bano F, Sabbar S. Studied that intrathecal fentanyl as an adjuvant to bupivacaine: In spinal anesthesia for ceserian section. J Cool Physicians Surg Pak 2006 Feb 02;16(2): 87–90.
9. Patra Pramod, Chandra Kapoor Mukul. Studied spinal anesthesia with bupivacaine and fentanyl for endoscopic urological surgeries: J Anesth Clin Pharmacol 2005;21(2):147–54.
10. Dobrydnjov I, Axelsson K, Samarutel J, et al. Studied postoperative pain relief following intrathecal bupivacaine combined with intrathecal or oral clonidine. Acta Anesthesiol

Scand 2002;46:806–14.

11. Solakovic N. Level of sensory block and baricity of bupivacaine 0.5% in spinal anesthesia. Med Arh. 2010;64(3):158–160.
12. Olfa Kaabachi. Studied clonidine as an adjuvant to plain bupivacaine in spinal anesthesia in adolescent (2007 April 19).
13. Grewal Parveen, Sunil Katyal Sunil. Studied that addition of fentanyl with bupivacaine prolonged sensory and motor blockade. Anesth Analg 1992;78:918–20.
14. Van Tuijl I, Mj Giezeman. Studied addttion of clonidine to hyperbaric bupivacaine prolongs spinal analgesia and motor blockade. British Journal Oh Anesthesia 2006;97(3);365–70.
15. Merivirta R. A Comparison between hyperbaric bupivacaine and bupivacaine clonidine combination. Acta Anesthesiol Scand 2009 Jul;53(6):788–93. DOI: 10.1111/j.1399-6576.2009.01955.
16. Eurtuk E, Tutuncu C. Comparison of ropivacaine and bupivacaine both with fentanyl in orthopedic surgery: In geriatric patients. Med Princ Pracct, 2010;19(2):142–7.
17. Mahajan Rajesh, Grover VK. Studied intrathecal fentanyl with low-dose hyperbaric bupivacaine for ceserian delivery in patients with pregnancy induced hypertension. Anesth Clin Pharmacol 2005;21(1):51–58.
18. Eisanach Jc. De Cock M, Klimscha W. Studied alpha 2 adrenargic for regional anesthesia; A clinical review of clonidine. Anesthesiology. 1996 Sep;85(3):665–674.
19. Spencer S Liu, Susan B Mcdonald. Studied current issues in spinal anesthesia. Anesthesiology. 2001 May;94(5):888–906.
20. Morgan G Edward. Clinical anesthesiology copyright, 4th edition. Central Neuraxial Blockade and Intraspinal Opioids: 2004.pp. 396–97.
21. Lee S, Chiu Aa, Carpenter Rl. Studied clonidine prolongs sedation in spinal anesthesia with prolonging recovery. Anesth Analg 1995;80:730–34.
22. Levand Hoome PM. An evaluation of clonidine of the postoperative antihyperalgesic and analgesic effects of intrathecal clonidine administered during elective ceserian delivary. Anesth Analg 2008–2009;107(3):948–55.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 164-173
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.23

Efficacy of Seal of Proseal Laryngeal Mask Airway by Using Digital Insertion and Bougie Guided Insertion Techniques

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Abstract

Introduction: The Laryngeal Mask Airway (LMA) was designed to facilitate separation of the gastrointestinal and respiratory tracts, improve the airway seal, enable controlled ventilation and diagnose mask misplacement. A Drain Tube (DT) enables diagnosis of mask misplacement and also aims to attenuate risks of gastric inflation, regurgitation and aspiration of gastric contents. *Aims and Objectives:* Our objective is to compare digital insertion and bougie guided insertion of the ProSeal LMA with respect to the oropharyngeal leak pressure, number of attempts to successful placement, effective airway time, airway trauma insertion, postoperative airway morbidity and hemodynamic response to insertion. *Materials and Methods:* In our study, compared ProSeal LMA insertions using the digital and bougie guided techniques in 40 adult ASA I & II patients randomized into Two Groups of 20 patients. *Results:* The study finds that effective airway time (37.3 ± 3.7 seconds *vs* 20.8 ± 3.0 seconds) and oropharyngeal leak pressure (31.8 ± 1.7 cm H_2O *vs* 24.2 ± 3.2 cm H_2O) are higher in the bougie guided group as compared to the digitally inserted group and that this association is statistically significant. The two techniques are comparable with respect to other parameters. *Conclusion:* The bougie guided technique of insertion of ProSeal LMA is an acceptable alternative to the digital technique. It has advantages of having a higher leak pressure and lesser chance if malposition. The disadvantages include a higher effective airway time and the potential for stimulation and trauma.

Keywords: Laryngeal Mask Airway; Bougie Guided Insertion; Controlled ventilation

Introduction

Airway management is the cornerstone of anesthesia and resuscitation. In spite of tremendous advances in contemporary anesthetic practice, airway management continues to be of paramount importance to anesthesiologists. Till date, the cuffed endotracheal tube was considered the gold standard for providing a safe seal around the glottis region, especially for laparoscopic surgeries under general anesthesia.[1] The disadvantages of endotracheal intubation, which involves laryngoscopy are in terms of concomitant hemodynamic responses and damage to the oropharyngeal structures at insertion. Postoperative sore throat is also a concern. This precludes the global utility of the tracheal tube and requires a better substitute.[2] Over a phase of time, new airway devices have been added to the anesthesiologist's armamentarium.

Laryngeal Mask Airway combines the advantages of a noninvasive face mask and the more invasive endotracheal tube. Initially, LMA

How to cite this article:
Potlapelly Vasu Prakash, Talikota Nagaraju. Efficacy of Seal of Proseal Laryngeal Mask Airway by Using Digital Insertion and Bougie Guided Insertion Techniques. Indian J Anesth Analg. 2020;7(1 Part -I):164–173.

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Received on 10.10.2019, **Accepted on** 28.11.2019

was recommended as a better alternative to the face mask. However, ever since its inception, the LMA has questioned the supposition that tracheal intubation is the only acceptable way to maintain a clear airway and provide positive pressure ventilation. Since, its commercial introduction in the late 1980's, it has been used in over 250 million routine and emergency procedures. Though LMA provides all the above benefits, the danger of gastric insufflation, pulmonary aspiration of stomach contents and fear of insufficient ventilation acts as a deterrent to the widespread use of LMA. To overcome the above difficulties, Archie Brain designed the ProSeal Laryngeal Mask Airway (PLMA)™ in 2000, with an altered cuff to improve seal around glottis. The main aim of the Drain Tube is to enhance the scope and safety of the device, mainly when used with positive pressure ventilation.[3] Adult studies have shown that compared to classic laryngeal mask airway, the PLMA forms an improved seal with both respiratory and gastrointestinal tract and provides easy access to the alimentary tract.[4]

Conventional airway management involves the use of the mask, the direct laryngoscope, and the endotracheal tube, whereas fiberoptic bronchoscope has been the gold standard for an access and intubation in difficult airways. Over the airways, continued incidences of hypoxia during airway management led to efforts to device effective alternatives. Much of the latest advances have been in the form of supraglottic airway devices and video units. Preferably such devices should be easier to use technically, allow early and fast introduction, provide satisfactory cuff seal without alteration of cuff shape, prevent pulmonary aspiration, allow positive pressure ventilation, maintain airway framework, allow easy removal alone or if used for intubation, should be available for all ages, should be able to be reused, should be easy to sterilize, should be cheap and most significantly, should be authenticated for consistent use based on effectiveness in large population.

Materials and Methods

Randomized controlled trial done in Department of Anesthesiology for a period of I year from Aug 2017 to Aug 2018. Patients of either gender of ASA class I& II of age group 20–60 years undergoing surgeries under general anesthesia.

Inclusion Criteria

1. ASA I, II;
2. Age group 20–60 years;
3. Patients posted for surgery under general anesthesia (duration <3 hours).

Exclusion Criteria

1. Patients with clotting and coagulation disturbances due to any reason
2. Patients with an increased risk of aspiration (Hiatus hernia, GERD, obesity, and pregnancy).
3. Patients with an anticipated difficult airway.

Forty ASAI and II patients, of either sex, between 20 and 60 years, scheduled for surgery under general anesthesia (duration <3 hours) were allocated into two groups of 20 patients each.

The sample size for the study was based on a pilot study on 10 patients. The outcome of the pilot study indicated that a sample size of 30 in each group would give enough power of more than 85%. However, the results of the pilot study are not included in the results of the main study.

Preoperative Evaluation

The following parameters will be examined a day before surgery are Age, height, and weight, Airway evaluation, Basal heart rate and blood pressure. Procedure explained and detailed informed consent obtained. Nil per oral 8 hours prior to surgery. Tab. Alprazolam 0.5 mg. Tab. Pantoprazole 40 mg + domperidone 10 mg at 10 pm day before surgery and 6 am on the day of surgery.

Preparation of procedure room

Anesthesia machine and the ventilatorare tested. A flow sensor check is performed. Bain's circuit is tested. A standby of working laryngoscope with appropriate bladesize, endotracheal tubes, stylet, mask, and oropharyngeal airways are kept ready. Bougie and introducer are also kept ready. ProSeal LMA cuff is inflated and checked for leaks and deflated which is selected according to the weight used algorithm advised by the manufacturers, shows as in (Table 1). A water-based jelly is applied over the cuffed portion of the device as per the manufacturer recommendation. All emergency drugs are prepared. The suction apparatus is tested and connected with soft tipped suction catheter.

The patients will be divided into Two Groups:

Group D-ProSealLMA insertion by digital technique.

Group B- ProSeal LMA insertion by the bougie guided technique.

Monitors were Electrocardiogram, Non-invasive blood pressure, Pulse oximeter and Capnogram. Intravenous line with an 18G cannula is obtained in a superficial vein of the dorsum of the hand. The patients will be premedicated with Inj. Midazolam 0.02 mg/kg, Inj. Glycopyrrolate 0.004 mg/kg, Inj. Ondansetron 0.08 mg/kg and Inj. Pentazocine 0.2 mg/kg.

Procedure

The patient's head is supported on a firm pillow of height 10–12 cm. Preoxygenation is given with 100% oxygen for 3 minutes, and anesthesia is induced with Inj. Lignocaine 1.5 mg/kg and propofol 2 mg/kg. On the loss of verbal contact, the anesthetist checks that the patient could be hand-ventilated with a face mask and checked for manual mask ventilation. Only then, Inj. Succinylcholine 2 mg/kg is given intravenously. After an adequate depth of anesthesia and muscle relaxation achieved i.e., after one minute and jaw is relaxed. ProSeal LMA will be inserted by the digital/bougie technique according to the study group which is explained below:

Group D - The Digital Technique

ProSeal LMA will be selected as per body weight chart and insert using index finger as recommended by the manufacturer. Then cuff of the device is inflated not less than 25% of the maximum recommended volume, as this provides the maximum effective seal.

Group B - Bougie guided insertion

The ProSeal LMA will be primed with well lubricated 16F gum elastic bougie with the straightend protruding 30 cm beyond the drain tube. Under the laryngoscopic guidance, the distal portion of bougie will be placed 5–10 cm into the esophagus. The laryngoscope will be removed and ProSeal LMA will be inserted using the digital technique, while an assistant stabilizes the proximal end the bougie. The bougie will be removed while ProSeal LMA is held in position. All insertions will be performed in sniffing position with cuff fully deflated and using midline approach. Then cuff of the device is inflated not less than 25% of the maximum recommended volume, as this provides the maximum effective seal.

Ventilation is judged to be optimal if the following four tests are satisfactory:

- Adequate chest movement;
- Stable oxygenation not less than 95%;
- "Square wave"capnography and
- Normal range end-tidal CO_2.

In both the groups, if it is not possible to ventilate the lungs, the following airway maneuvers are allowed: chin lift, jaw thrust, head extension, or flexion on the neck. After any maneuver, adequacy of ventilation is reassessed. If it is not possible to insert the device or ventilate through it, two more attempts of insertion are allowed.

Three attempts will be allowed before insertion is considered a failure. The time between picking up laryngoscope/ProSeal LMA and successful placement will be recorded. Any episode of hypoxia (SpO_2 < 90%) or other adverse events will be noted. In the event of a failed insertion of the ProSeal LMA after three attempts, the patient will be intubated with endotracheal tube and surgery will be allowed to proceed. Oropharyngeal leak pressure will be measured as the pressure at which audible leak is heard at a constant flow of 6 lit/min with the Adjustable Pressure Leak valve kept closed (Drager workstation). Pulse rate, Systolic blood pressure, Diastolic blood pressure and Mean Arterial Pressurewill be recorded prior to insertion and one, three, fiveminute intervals after insertion.

Variables Measured were First attempt success rate, Oropharyngeal leak pressure, Number of insertion attempts and Effective Airway Time (EAT). After securing the ProSeal LMA, the patients were started on controlled ventilation at tidal volume 6–8 ml/kg and respiratory rate of 12–15 breaths/min. Muscle relaxation is provided with a loading dose of vecuronium 0.1mg/kg. Propofol infusion with $N_2O:O_2$ mixture in a ratio of 4:2 and muscle relaxation with vecuronium 0.02 mg/kg at 15–20 minutes interval is used for maintenance of anesthesia. Analgesics like diclofenac 75 mg or paracetamol 1 gm are started as an intravenous infusion. At the end of surgery, anesthetic agents are discontinued after the effect of last dose muscle relaxant, when the patient begins spontaneous ventilation with adequate tidal volume, suction will be done. N_2O is stopped with the continuation of 100% O_2. Reversal is given with Neostigmine 0.05 mg/kg and glycopyrrolate 0.08 mg/kg. After attaining adequate reversal, the device will be removed under thorough suction. Any visible blood staining on ProSeal LMA orbougie or laryngoscope will be recorded. Mouth, lips, and tongue will be closely inspected for any evidence of trauma.

Statistical Analysis

The results are obtained by statistical analysis. Data isanalyzed using computer software, Statistical Package for Social Science (SPSS) version 10. Physical Status, Mallampati grading classification, mouth opening, size of the device, SpO_2 is analysed using either *t*-test or Chi-square test, depending on their distribution and whether it is a qualitative or quantitative data.

Results

Out of the 40 patients studied, the percentage of patients in each age group and the mean age is comparable and not statistically significant. The percentage of the patients of a gender in each group is comparable even though the sex ratio favors female sex. But it does not affect the outcome of our study. Using Fisher's exact test it was found that, the difference is not statistically significant.

Table 1: Demographic data comparison of the groups

Parameters	ProSeal LMA insertion technique				X^2	*p* - value
	Bougie guided		Digital			
	Count	Percentage	Count	Percentage		
Age						0.629
<30	3	15	2	10	0.49	
30–39	4	20	3	15		
40–49	6	30	9	45		
50–59	7	35	6	30		
Gender						
Male	7	35	10	50		
Female	13	65	10	50	0.92	0.337
ASA						
I	14	70	14	70	0	1.00
II	6	30	6	30		

p -value: <0.05 → Significant.

This study warranted the patients to be within the ASA-PS I & II classes. The percentage of patients within each group are comparable and calculated to be statistically insignificant. The distribution of patients based on weight is comparable. The mean weight is alsocomparable and statistically not significant (Table 1).

The percentage of patients within each group are comparable and calculated to be statistically insignificant. The thyromental distance was measured and two study groups were comparable based on it. But, no significance was noted statistically, (Table 2). Mouth opening among the two groups was comparable and there is no

Table 2: Mouth opening parameters comparison of the groups

Parameters	ProSeal LMA insertion technique				X^2	*p* - value
	Bougie guided		Digital			
	Count	Percentage	Count	Percentage		
Mallampatti grade classification						
I	8	40	9	45		
II	12	60	11	55	0.1	0.75
Thyromental distance						
<6.5	5	25	9	45	3.31	0.191
6.5	2	10	0	0		
>6.5	13	65	11	55		
Mouth opening						
>6	16	80	18	90	0.784	0.376
4–6	4	20	2	10		
ProSeal LMA size based						
3	9	45	7	35	0.42	0.519
4	11	55	13	65		

p -value: <0.05 → Significant.

significance statistically as measured by Fisher exact test. Weight and physical characteristics of the patients, the size of LMA is selected (refer selection guide, (Table 3). The groups were comparable, bears no particular effect on the outcome and are therefore statistically insignificant.

Table 3: Number of attempts for insertion of LMA based comparison of the groups

Number of attempts	ProSeal LMA insertion technique				X^2	*p* - value
	Bougie guided		Digital			
	Count	Percentage	Count	Percentage		
I	18	90	14	70		
II	2	10	5	25	2.786	0.248
III	0	0	1	5		

p-value: <0.05 → Significant.

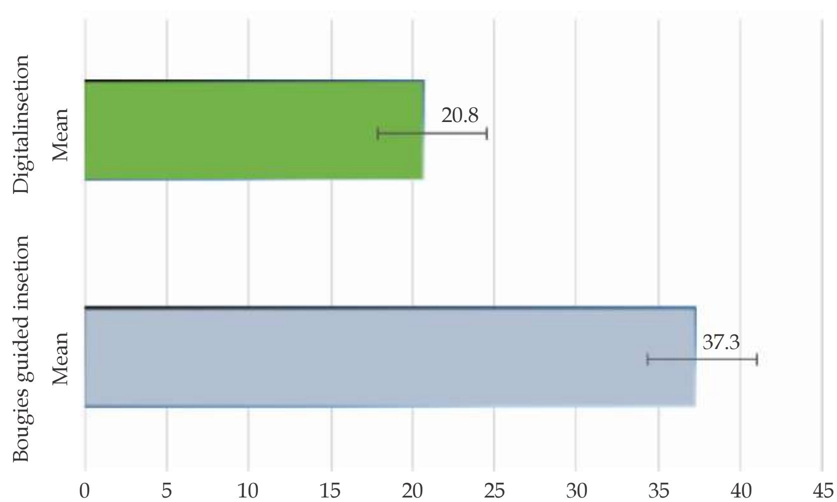

Fig. 1: Graphical comparison of Effective Airway Time based on the group.

Number of attempts in both the groups were comparable and there was no significance statistically.

The effective airway time is longer in patients with bougie-guided insertion compared to digital

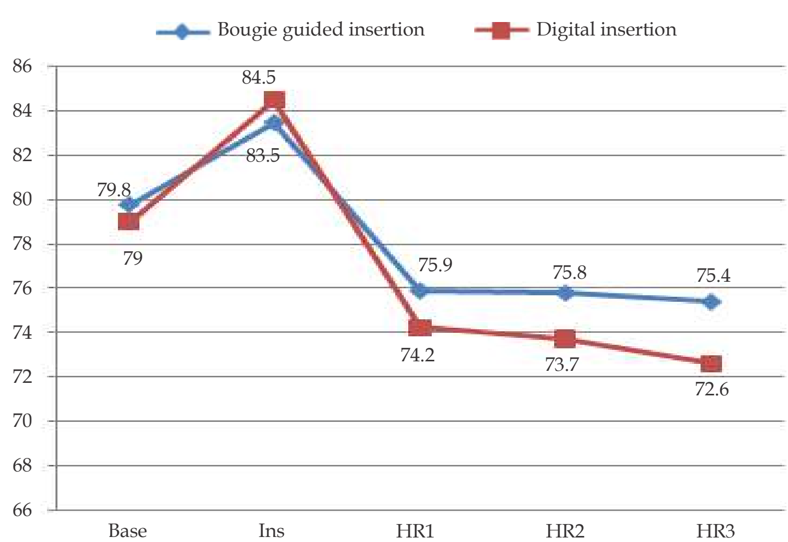

Fig. 2: Graphical comparison of Heart Rate based on the group at different intervals.

insertion. The difference between the two groups is statistically significant (Fig. 1).

With respect to Heart Rate, both the groups are comparable. The mean Heart rate does not show any statistical significance by the different techniques. Also, the mean pulse rate is comparable over the three phases (Fig. 2).

The MAP is more for the bougie guided technique as compared to digital insertion but this is not statistically significant.

There is no statistically significant difference in the incidence of visible blood staining on the LMA device using the two different techniques (Fig. 4).

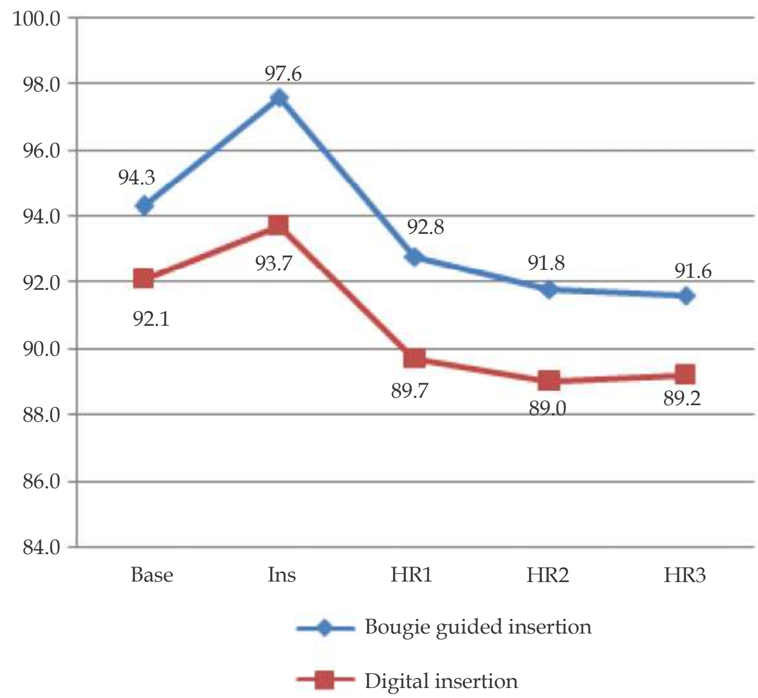

Fig. 3: Graphical comparison of Mean Arterial Pressure based on the group at different intervals.

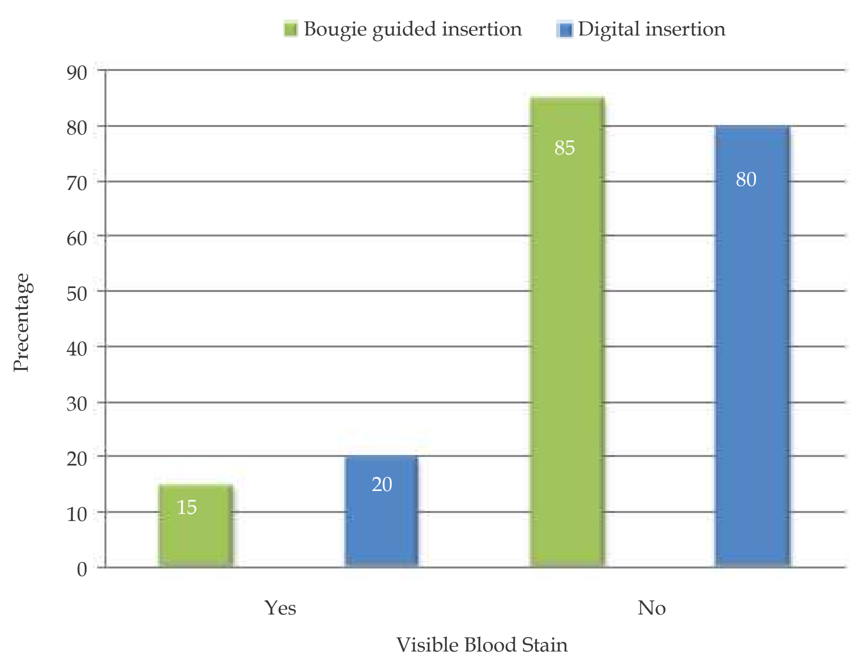

Fig. 4: Graphical comparison of Visible Blood Staining based on the group.

Table 4: Oropharyngeal leak pressure based comparison of the groups

Group	Mean	SD	N	*t*-value	*p* - value
Bougie-guided insertion	31.8	1.7	20	9.36	<0.0001
Digital insertion	24.2	3.2	20		

p -value: <0.05 → Significant.

There is a statistically significant increase in oropharyngeal leak pressure in the Bougie guided group in comparison with the digital insertion group (Table 4).

There is no statistically significant difference in the incidence of sore throat postextubation using the two different techniques. Postextubation incidence of dysphagia between the two groups was comparable and there was no statistical significance. Postextubation incidence of dysphonia between the two groups was comparable and there is no statistical significance.

Table 5: Side effects based comparison of the groups

Sore throat	ProSeal LMA insertion technique				X^2	*p* - value
	Bougie guided		Digital			
	Count	Percentage	Count	Percentage		
Yes	1	5	4	20		
No	19	95	16	80	2.05	0.15
Dysphagia						
Yes	3	15	0	0	3.24	0.072
No	17	85	20	100		
Dysphonia						
Yes	0	0	0	0		
No	20	100	20	100		

p -value: <0.05 → Significant.

Discussion

Demographically the two groups were comparable with respect to age. Of the 40 patients studies (20 in the bougie guided group and 20 in the digitally inserted group), the mean age for bougie-guided insertion group is 43.3 ± 11 years and that for the digitally inserted group is 44.9 ± 9.7 years. ($t = 0.49$, $p = 0.629$). The percentage of patients on each age group is comparable. The samples are comparable with respect to gender. The study population shows a slight female predominance but this is not statistically significant. It does not affect the outcome of this study. Using Fisher's exact test, it was found that the difference is not statistically significant ($p = 0.337$).

The distribution of subjects based on weight is comparable. The mean weight is also comparable. In the bougie guided group the mean weight is 55.9 ± 9 kgs and in the digitally inserted group, the mean weight is 55.1 ± 6.5 kgs. ($t = 0.32$, $p = 0.750$).

The study group included patients in the ASA-PS classification I & II. 70% of the patients are ASA-PS I and 30% of patients are ASA-PS II. ($p = 1.00$). The samples are comparable with respect to ASA-PS classification.

The subjects were comparable with respect to Modified Mallampati classification. Most of the patients studied belonged to MMC - II class (60% in the bougie guided group and 55% in the digitally inserted group). The percentage of patients within each group is comparable and is calculated to be statistically insignificant. Brimacombe[5] in a study of 1500 adult patients undergoing surgery using LMA in which Mallampati grades and fiber optic scores were similarly obtained. Placement failed in 6 patients within 3 attempts (0.4%). 1385 patients were Mallampati I/II, 102 Grade III, and 13 Grade IV. All failed placements occurred in MallampatiGrades I/II. Again there was no correlation between fiber optic scoring and Mallampati grade. Data from the prospective study of Mahiou et al.,[6] looking at 362 patients showed that ease of insertion of the LMA did not correlate with Mallampati grade or Cormack Lehane scoring. The latter finding suggests that the position of the larynx has little bearing on LMA insertion. In a retrospective study by Brimacombe[5] of 272 patients, it was determined that there was no correlation between Mallampati grade and ease of insertion or final fiberoptic position of LMA. This series included 29 Grade III and 3 Grade IV patients. The overall first-time failure rate was less than 2%. All gradings were standardized and performed as originally described by Mallampati.

The thyromental distance was measured and it is found that the two study groups were comparable based on the thyromental distance and there is no significance as measured by Fisher Exact test. 65% of the subjects in the bougie guided group and 55% of the subjects in the digitally inserted group had TMD > 6.5 cm. Thyromental distance, the distance between the bony point of the mentum and the upper border of the thyroid cartilage, when less than 6.5 cm, would correlate with difficult airway.[7] TMD of less than 6.5 cm is generally accepted as a predictor for difficult airway. Arne et al. in an analysis of 1,200 patients, found that using a cutoff point for TMD of 6.5 cm when pooled with a multi-factor evaluation, decreased the incidence of unexpected difficult intubation to 0.2%.[8] El Ganzouri et al.[9] used a TMD of <6 cm as a predictor of the difficult airway.

Mouth opening among the two groups was comparable and there is no significance statistically as measured by Fisher Exact test. 85% of patients had mouth opening >6 cm and 15% had a mouth opening between 4 and 6 cm ($p > 0.05$). The average distance between upper and lower incisor teeth in patients with normal TMJ function is 47mm with a range of 31–55 mm.

Based on weight and physical characteristics the size of the device was selected. This bears no particular effect on the outcome and is therefore statistically insignificant. Size 3 ProSeal LMA was used in 40% of the patients and size 4 was used in 60% of the patients (p - 0.519). This bears no particular effect on the outcome and is therefore statistically insignificant ($p > 0.05$). Kihara et al.[10] in 2003, study of 237 adults, found that size selection for the ProSeal LMA is equally effective using the manufacturer's weight-based formula (size 3 for <50 kg; size 4 for 50–70 kg; size 5 for >70 kg) and the sex-based formula (size 4 for females and size 5 for males), in terms of ease of insertion, ventilation, gas exchange, fiberopticposition, mucosal injury and postoperative pharyngolaryngeal complaints, but Oropharyngeal Leak Pressure was higher with the sex-based formula due to the more frequent selection of larger sizes, shown as in (Table 5).

The first attempt success rate was 90% in the bougie guided group and 70% in the digitally inserted group. The second attempt success rate was 10% in the bougie guided group while it was 25% in the digitally inserted group. One subject in the digitally inserted group needed three attempts (p - 0.248). No statistical difference was seen in the number of attempts to position the device adequately in this study.

The effective airway time is longer in patients with bougie-guided insertion compared to digital insertion. The difference between the two groups is statistically significant. In the bougie guided group, the mean airway time was 37.3 ± 3.7 seconds, while in the digitally inserted group it was 20.8 ± 3.0 seconds ($t = 15.56$, $p < 0.05$). M Lopez Gill et al.[11] contrasted bougie-guided insertion of ProSeal LMA with the digital technique in 120 anesthetized children. They also found that the effective airway time was longer (37 *vs* 32 sec, p < 0.001) for bougie-guided insertion.

Escherttzhuber S et al.[12] in 2008 compared ProSeal LMA insertion in three equal-sized groups using the digital, Introducer or bougie guided techniques and found that the time taken for successful placement was similar among groups at the first attempt, but was shorter for the guided technique after three attempts. In 2009, Taneja et al. evaluated ProSeal LMA insertion in Three Groups, Group G -Bougie-guided insertion, Group I - Introducer guided, Group D - Digital and found that the total insertion time of ProSeal LMA ranged from 18 to 25 seconds in Group G, 17 to 84 seconds in Group I and 16 to 86 seconds in Group D. The mean insertion time in the Three Groups was 22.1 ± 2.1 seconds in Group G, 31.9 ± 18.83 seconds in Group I and 29.6 ± 18.61 seconds in Group D ($p<0.05$).[13]

Anand Kuppusamy and Naheed Azhar in a 2010 study compared the classical digital placement of ProSeal LMA with gum elastic bougie-guided technique in 60 anesthetized adult patients (with 30 patients in each group). The effective airway time for GEB guided insertion was longer than that of digital technique (36.87 ± 11.2 seconds *vs* 22.32 ± 12.09 seconds).[14]

Both the techniques are comparable with respect to the heart rate. The mean pulse rate shows no significant change by the different techniques. Also, the mean pulse rate is comparable over the three phases. Baseline HR was comparable with 79.8 ± 11.2 bpm in the bougie guided group and 79 ± 8.1 bpm in the digitally inserted group. The mean arterial pressure was comparable at baseline, insertion and MAP 1st, 3rd and 5th mints. In 2002, Howarth et al. inserted the ProSeal LMA using a gum elastic bougie and found that there was no substantial change in heart rate or blood pressure.[15] In a 2010 study, Anand Kuppusamy et al. found no noteworthy difference in hemodynamic response to PLMA insertion by digital or GEB technique.[14] There was a statistically significant increase in oropharyngeal leak pressure (31.8 ± 1.7 *vs* 24.2 ± 3.2 cm H_2O) in the bougie-guided insertion group as compared to the digital insertion group. In 2000, Brimacombe J and Keller C[3] studied 60 ProSeal LMA insertions using the digital technique. The mean airway seal pressure in this study was 27 cmH_2O. In a 2003 study, Kihara Sand Brimacombe J evaluated 90 ProSeal LMA insertions using the digital technique. The mean airway seal pressure was 25 cmH_2O[16] (Fig. 3).

Kihara S et al. studied 237 PLMA insertions in 2004 using the digital technique again.[10] The airway seal pressure was 26 ± 8 cm H_2O. In the year 2002, Howarth et al. used the new technique of bougie-guided insertion.[15] 100 ProSeal LMA insertions were studied and the airway seal pressure was higher at 33 cmH_2O (range 17–40 cm H_2O). In 2012, Joffe AM et al. evaluated 48 PLMA insertions (1 size #3, 24 size #4 and 23 size #5) in 25 male and 23 female patients using the bougie guided technique. The mean airway seal pressure was 30 cm H_2O.[17]

The results obtained in our study are in concordance with these earlier findings. There was a statistically significant increase in oropharyngeal leak pressure in the bougie-guided insertion group as compared to the digital insertion group which shows that when the ProSeal laryngeal mask airway is inserted using the bougie guided technique, it gives a better seal in the airway with improved ventilation. Although in another study by Lopez-Gil et al. in which 120 PLMA insertions were studied in the age group of 1–16 years (ASA I, II) there was no statistically significant difference in oropharyngeal leak pressure between the two techniques. The mean airway seal pressure was 33 cm H_2O inboth the cases.[11]

There is no statistically significant difference ($p > 0.05$) in the incidence of visible blood staining on the device using the two different techniques. 15% of the study subjects had visible blood staining on the device at extubation. In a 2006 study, by Lopez-Gil et al. , 120 ProSeal LMA insertions were studied in the age group of 1–16 years (ASA I, II). Visible blood staining was noted in 3 cases out of 60 in the digitally inserted group and in 4 cases out of 60 in the bougie guided group.[11]

In 2012, Joffe AM et al. evaluated 48 PLMA insertions (1 size #3, 24 size #4 and 23 size #5) in 25 male and 23 female patients using the bougie guided technique.[17] Visible blood staining was evident on 8% of the airway devices. In a 2010 study, Anand Kuppusamy et al., comparing bougie-guided insertion of ProSeal LMA vs digital insertion found that the incidence of blood staining on ProSeal LMA was identical in both the groups.[14] There was no statistically significant difference in the incidence of airway trauma between both the groups.

There is no statistically significant difference in the incidence of sore throat postextubation using the two different techniques. 5% of the subjects in the bougie-guided group and 20% of the subjects, in the digitally inserted group, had sore throat in the postextubation period. In a 2006 study, by Lopez-Gil et al., 120 ProSeal LMA insertions were studied in the age group of 1–16 years (ASA I, II). No case of a sore throat were reported in this study.[11]

AnandKuppusamy and NaheedAzhar in a 2010 study, compared classical digital placement ProSeal LMA with gum elastic bougie-guided technique in 60 anesthetized adult patients (with 30 patients in each group).[14] 3 patients in the digitally inserted group complained of sore throat in the postoperative period. In 2012, Joffe et al.[17] evaluated 48 PLMA insertions (1 size #3, 24 size #4 and 23 size #5) in 25 male and 23 female patients using the bougie guided technique. 38% of the patients had sore throat postoperatively. 15% of the patients had pain on swallowing postoperatively. Sore throat was more frequent in digital technique while dysphagia was more frequent with GEB technique.

There is no statistically significant difference in the incidence of dysphagia in the postextubation using the two different techniques. 15% of the subjects in the bougie guided group had complained of dysphagia (p = 0.072). Anand Kuppusamy and Naheed Azhar in a 2010 study compared classical digital placement ProSeal LMA with gum elastic bougie-guided technique in 60 anesthetized adult patients (with 30 patients in each group).[14] 5 patients in the digitally inserted group complained of dysphagia in the postoperative period.

No patient complained of dysphonia in the two groups. Taneja et al. in 2009, compared ProSeal LMA insertion in Three Groups: Group G - Bougie-guided insertion, Group I - Introducer guided, Group D - Digital. There was no incidence of dysphonia in the GEB-guided insertion group, ($p>0.05$).

Conclusion

The first attempt success rate was higher in the bougie guided group in this study. Although this was not statistically significant. Comparison of effective airway time showed that the digital technique was faster than the bougie guided technique. The shorter-time taken to secure the airway using the digital method was statistically significant.

Complications included airway trauma during insertion as evidenced by visible blood staining and postoperative airway morbidity as evidenced by sore throat, dysphagia, and dysphonia. The incidence of sore throat was higher in the digitally inserted group and the incidence of dysphagia was higher in the bougie guided group. Although these complications do not achieve statistical significance. The disadvantages of the bougie guided placement of the PLMA include airway stimulation and trauma.

References

1. Sharma B, Sahai C, Bhattacharya A, et al. ProSeal laryngeal mask airway: A study of 100 consecutive cases of laparoscopic surgery. Indian J Anesth 2003;47:467–72.
2. Misra MN, Ramamurthy B. The ProSeal LMA™ and the tracheal tube: A comparison of events at the insertion of the airway device. Internet J Anesthesiol 2008;16(2):1–6.
3. Khan RM, Maroof M. Airway Management made easy, 2nd edition. Paras; 2007. pp.122–27.
4. Brimacombe J. Keller C. Fullekrug B, et al. A multicentre study comparing the Proseal with the classic laryngeal mask airway in anesthetized and nonparalyzed patients. Anesthesiology. 2002 Feb;96(2):289–95.
5. Brimacombe J. Analysis of 1500 laryngeal mask used by one anesthetist in adults undergoing routine anesthesia. Anaesthesia. 1996 Jan;51(1):76–80.
6. Mahiou P, Narchi P, Veyrac P, et al. Is the laryngeal mask easy to use in case of difficult intubation? Anesthesiology. 1992;77:A1221–228.
7. Savva D. Prediction of difficult tracheal intubation. Br J Anaesth. 1994 Aug;73(2):149–53.
8. Arme J, Descoins P, Fusciardi J, et al. Preoperative assessment of difficult intubation in general and ENT surgery: predictive value of a clinical multivariate risk index. Br J Anesth 1998;82(2):140–46.
9. El Ganzouri AR, McCarthy RJ, Tuman KJ, et al. Perioperative airway assessment: Predictive value of a multivariate risk index. AnesthAnalg 1996;82(6):1197–204.
10. Kihara S, Brimacombe JL, Yaguchi Y, et al. A comparison of sex and weight-based ProSeal laryngeal mask size selection criteria. A randomized study of healthy anesthetized paralyzed adult patients. Anesthesiology 2004;101:340–43.
11. Lopez GilM J, Brimacombe J, Baragan L, et al. Bougie-guided insertion of the ProSeal™ laryngeal mask airway has higher first attempt success rate than the digital technique in children. BrJ Anesth 2006;96(2):238–41.
12. Eschertzhuber S, Brimacombe J, Hohlrieder M, et al. Gum elastic bougie-guided insertion of the ProSeal laryngeal mask airway is superior to the digital and introducer tool techniques in patients with simulated difficult laryngoscopy using a rigid neck collar. Anesth Analog. 2008;107(4):1253–256.
13. Taneja S, Agarwal M, Dali JS, et al. Ease of proseal laryngeal mask airway insertion and its fiberopticview after placement using Gum Elastic Bougie: Acomparison with conventional techniques. 01 May 2009. http://www.thefreelibrary.com/Ease of proseal laryngeal mask airway insertion and its fiberoptic...-a20200779988 accessed 18 November 2013.
14. Anand Kuppusamy, Naheed Azhar. Comparison of bougie-guided insertion of ProSeal laryngeal mask airway with the digital technique in adults. Indian J Anesth 2010 Jan–Feb;54(1):35–39.
15. Howarth A, Brimacombe J, Keller C. Gum elastic bougie-guided insertion of the ProSeal laryngeal mask airway. A new technique. AnesthIntens Care 2002;30: 624–27.
16. Kihara S, Brimacombe J. Sex-based ProSeal laryngeal mask airway size selection: a randomized crossover study of anesthetized, paralyzed male and female adult patients. Anesth Analg. 2003;97(1):280–84.
17. Joffe AM, Schroeder KM, Shepler JA, et al. Validation of the unassisted, gum elastic bougie-guided, ProSeal laryngeal mask airway placement technique in anesthetized patients. Indian J Anaesth. 2012 May;56(3):255–58.

Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 174-182
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.24

Comparative Study of Two Different Doses of Fentanyl Citrate 2 mcg/kg and 4 mcg/kg in Attenuation of Hemodynamic Responses During Intubation

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Abstract

Background: Laryngoscopy and intubation in the lightly anesthetized patient is associated with significant increase in blood pressure and heart rate. These changes occur from reflex sympathetic discharge resulting from pharyngeal and laryngotracheal stimulation with increases in plasma concentration of epinephrine and norepinephrine. This reaction is not prevented by regular premedication. This study was designed to compare the two different doses of fentanyl citrate that is 2 mcg/kg and 4 mcg/kg in attenuation of hemodynamic effects during laryngoscopy and intubation. *Methods:* 80 adult patients 40 in each group ranging from 18–60 years of age and from both sexes undergoing modified radical mastectomy and total and subtotal thyroidectomy and surgeries which include oral intubation were selected for the study. Only patients belonging to ASA 1 and 2 were selected for the study. Group 1: Receives Inj. Fentanyl Citrate 2 mcg/kg. Group 2: Receives Inj, Fentanyl Citrate 4 mc/kg. All the parameters including heart rate, systolic arterial pressure, diastolic arterial pressure, and mean arterial pressure were recorded at the time of intubation and sequencially 1 min, 3 min, 5 min, and 10 minutes after intubation. *Results:* We studied all 4 parameters in both the Groups in all the patients and found out that the heart rate slightly increased during intubation in the Group 1 patients while it was either remained stable or decreased in Group 2 patients. There is consistent decrease in SBP, DBP and MBP in both the Groups from the baseline throughout the study period, and maximum decrease in all the pressures found at 10 minutes interval in Group 2 patients. *Conclusion:* Fentanyl citrate given 5 minutes before intubation produces most attenuation of the hemodynamic effects of stress response. Pretreatment with fentanyl citrate in every normal case would cause attenuation of hemodynamic effects of laryngoscopy and intubation. It will cause minimal change in heart rate, SBP, DBP, MAP, RPP during the first 10 minutes after intubation. Fentanyl citrate in 2 mcg/kg significantly attenuate but fentanyl 4 mcg/kg completely attenuates the hemodynamic responses during laryngoscopy and intubation.

Keywords: Laryngoscopy; Intubation; Fentanyl citrate.

Introduction

Laryngoscopy and intubation in the lightly anesthetized patient is associated with significant increase in blood pressure and heart rate. These increases in the pulse rate and blood pressure are usually of short duration and well-tolerated by healthy patients. However, in patients with hypertension, myocardial infarction and cardiovascular disease, these changes may lead to complications like

How to cite this article:
Visharad Trived, Sunil Ninama. Comparative Study of Two Different Doses of Fentanyl Citrate 2 mcg/kg and 4 mcg/kg in Attenuation of Hemodynamic Responses During Intubation. Indian J Anesth Analg. 2020;7(1 Part -I):174–182.

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Received on 01.11.2019, **Accepted on** 27.11.2019

myocardial infarction, dysrhythmia and cardiac failure, cerebrovascular catastrophes. These changes occur from reflex sympathetic discharge resulting from pharyngeal and laryngotracheal stimulation with increases in plasma concentration of epinephrine and norepinephrine. This reaction is not prevented by regular premedication.

Many methods have been identified to attenuate these responses including intravenous inhalational agents, narcotics, vasodilators, adrenergic and calcium blockers. Fentanyl citrate has been identified as an effective agent in this regard. Fentanyl citrate is effective in blunting the pressure response to laryngoscopy and intubation with different potency with different dose titration. Off course, it would have some side effects like respiratory depression and chest wall rigidity. But with doses used in clinical setting to attenuate this pressure response, side effects are minimal.

This study was therefore designed to compare the two different doses of fentanyl citrate that is 2 mcg/kg and 4 mcg/kg in attenuation of hemodynamic effects during laryngoscopy and intubation.

Materials and Methods

Eighty adult patients ranging from 18–60 years of age and from both sexes undergoing modified radical mastectomy and total and subtotal thyroidectomy and surgeries which include oral intubation were selected for the study.

Patients were assessed preoperatively through history and clinical examination. Investigatons were carried out and analyzed. Only patients belonging to ASA 1 and 2 were selected for the study. We exclude the patients on drugs affecting autonomic nervous system, Significant medical comorbidities, Patients having known allergy to study drug, Airway abnormalities, Expected difficult intubation, Nasal intubation, Surgeries requiring head and neck manipulations and throat packing. After obtaining institutional board approval, written informed consent was obtained from 80 adult patients undergoing thyroidectomy, mastectomy and other surgeries in which oral intubation required and were placed in two different Groups (40 in each Group)

Group 1: Receives Inj. Fentanyl Citrate 2 mcg/kg;

Group 2: Receives Inj. Fentanyl Citrate 4 mc/kg.

Patients were instructed to remain NBM for at least 8 hours before surgery. Patients were premedicated with Tab. Lorazepam Hydrochloride 1 mg night before surgery and Tab. Diazepam Hydrochloride 5 mg in the early morning on the day of surgery. Anesthetic technique was identical in all the patients.

On arrival in the operation theatre patients were monitored with routine noninvasive blood pressure measurement, pulse oxymetry and ECG, HR, SBP, DBP, MAP were recorded as a baseline vale designated as A.

After securing intravenous line all the patients were given inj. Glycopyrrolate 4 mcg/kg. prior to injection of the study drug HR, SBP, MAP, DBP were recorded and designated as B- preinduction value.

Now, patients in Group 1 received study drug Fentanyl citrate in a dose of 2 mcg/kg and Group 2 received Fentanyl citrate in a dose of 4 mcg/kg (0 minute). Then patients were oxygenated with 100% O_2. At 2 minutes inj. Vecuronium was given. Within its half a minute patients were induced with Inj. Thiopentone Sodium 5 mg/kg. Patients were ventilated for 3 minutes following vecuronium bromide injection. At 5 minutes patients were intubated with cuffed endotracheal tube of appropriate size. Tube was fixed and secured tightly. Anesthesia was maintained with O_2 (50%) + N_2O (50%) + Isoflurane (1%–3%) and intermittent dose of inj. Vecuronium bromide 0.1 mg/kg. Ventilation was controlled mechanically and adjusted to maintain an end tidal CO_2 concentration between 30–40 mm of Hg. All the parameters including heart rate, systolic arterial pressure, diastolic arterial pressure, and mean arterial pressure were recorded at the following intervals:

- Immediately after intubation : E
- 1minute after intubation : E + 1
- 3 minute after intubation : E + 3
- 5 minute after intubation : E + 5
- 10 minute after intubation : E + 10

We had defined following parameters for study:

(1) Hypotension was defined as SBP < 25% of baseline value or 90 mm of Hg, whichever was lower;

(2) Hypertension was defined as SBP >25 % of baseline value or 150 mm of Hg, whichever was greater;

(3) Tachycardia was defined as HR > 25 % of baseline value;

(4) Bradycardia was defined as HR < 60 beats per minute;

(5) An arrhythmia was defined as any ventricular or supraventricular premature beat or any rhythm other then sinus.

Incidences of all these parameters were recorded in all the Groups.

If there was hypotension as per definition then fluid challenge was given. If there was hypertension as per definition isoflurane was started. If there was tachycardia associated with hypotension, fluid challenge was given or if associated with hypertension, then isoflurane was started. If there was bradycardia as per definition, that was treated with injection Atropine sulfate. After 15 minutes, if there was hypotension, isoflurane was shut off; if it remained persistent intravenous fluid challenge was given. If there was hypertension, isoflurane was started or increased in incremental doses, still if persisted, bolus dose of injection Esmolol hydrochloride 0.5–2 mg/kg was given.

Results

The present study, includes 80 adult patients belonging to ASA Group 1 and 2 undergoing thyroidectomy and modified radical mastectomy and surgeries involving oral intubation. They were randomly assigned into Two Groups of 40 each. All the patients were given the drug according to methodology of our study and induced accordingly.

Group 1: Receives Inj. Fentanyl Citrate 2 mcg/kg;

Group 2: Receives Inj. Fentanyl Citrate 4 mc/kg.

There was no significant difference in the parameters mentioned above in both the Groups (Table 1).

Table1: Demographic data: Age, Sex and Weight distribution

Parameters	Group 1 (*n* = 40)	Group 2 (*n* = 40)	*p* - value
Age	44.20 ± 11.84	50.87 ± 11.57	0.0128
Male	14	15	1.0000
Female	26	25	1.0000
Weight	50.45 ± 6.16	52.65 ± 7.93	0.1698
Surgery duration	2.04 ± 0.26	1.94 ± 0.36	0.1584

Table 2 shows, the changes in heart rate in each of the Two Groups during the study. It shows that the heart rate slightly increased during intubation in the Group 1 patients while it was either remained stable or decreased in group 2 patients. However in both the groups stress response found to be attenuated significantly throughout the first ten minutes of intubation. These data indicates that in both the Groups heart rates decreased from the baseline value during the study period. Heart rate found significantly decreased in the Group 2 consistently (Fig. 1).

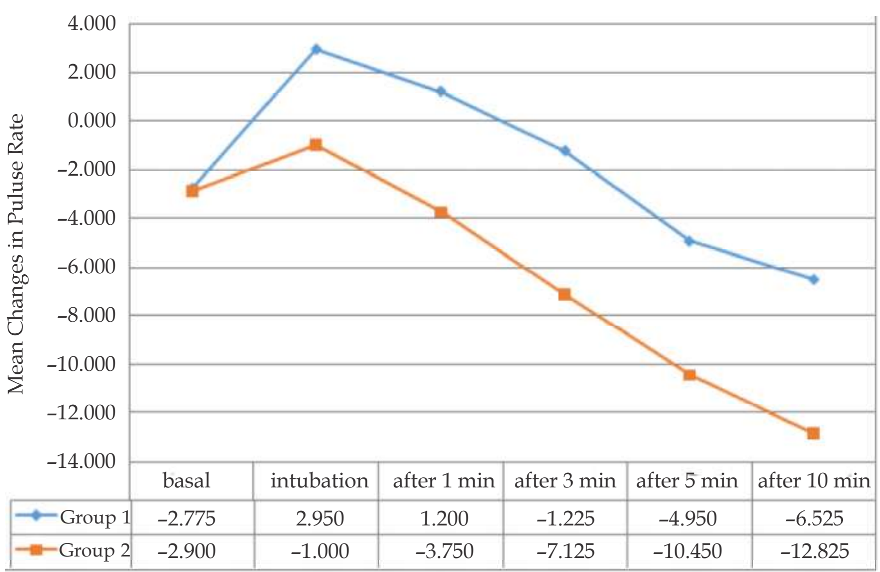


Fig. 1: Changes in Pulse Rate.

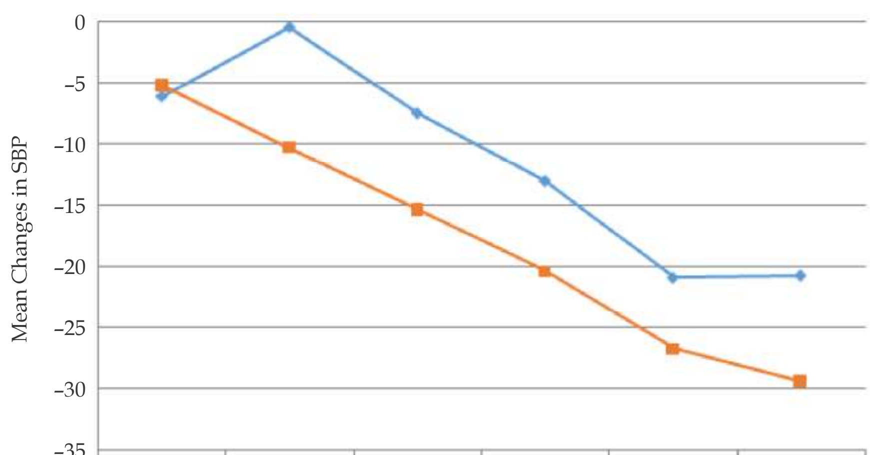
Table 2: Mean Heart rate in Two Groups

Time Interval	Group 1 (n = 40)	Group 2 (n = 40)	p - value
Basal(A)	90.42 ± 11.43	87 ± 12.21	0.1992
Preinduction(B)	87.65 ± 13.06	84.05 ± 11.41	0.1932
E	93.37 ± 10.77	86 ± 10.52	0.0027
E + 1	91.62 ± 10.84	83.25 ± 12.86	0.0027
E + 3	89.2 ± 11.38	79.87 ± 13.34	0.0012
E + 5	85.47 ± 10.67	76.55 ± 12.64	0.0010
E + 10	83.9 ± 11.89	74.17 ± 11.64	0.0004

Table 3 shows, the changes in systolic blood pressure during the study period. Looking from the data in the table we can see that there is consistent decrease in SBP in both the Groups from the baseline throughout the study period. Following chart shows SBP in both the groups were decreased below base line and the maximum decrease noted was in Group 2 patients at 10 minutes interval and that is of approximately 29.5 mm of Hg (Fig. 2).

Table 3: Mean SBP in both Groups

Time Interval	Group 1 (n = 40)	Group 2 (n = 40)	p - value
A	131.42 ± 16.03	132.7 ± 12.33	0.6912
B	125.22 ± 16.64	127.42 ± 12.24	0.5025
E	130.87 ± 20.84	122.32 ± 14.39	0.0359
E+1	123.85 ± 16.285	117.3 ± 13.42	0.0532
E+3	118.32 ± 14.24	112.22 ± 14.43	0.0607
E+5	110.47 ± 12.37	105.87 ± 14.54	0.1316
E+10	110.65 ± 14.90	103.2 ± 12.56	0.0180



	Basal	Intubation	1 min	3 min	5 min	10 min
Group 1	–6.2	–0.55	–7.575	–13.1	–20.95	–20.775
Group 2	–5.275	–10.375	–15.4	–20.475	–26.825	–29.5

Fig. 2: Changes in SBP.

Table 4 shows, the changes in mean arterial blood pressure during the study period. Looking from the data in the table we can see that there is consistent decrease in MAP in both the Groups from the baseline throughout the study period.

Fig. 3 shows, MAP in both the Groups were decreased below base line and the maximum decrease noted was in Group 2 patients at 10 minutes interval and that is of approximately 20.75 mm of Hg. However, it was transiently increased during the time of intubation in thefirstgroup.

Table 4: Mean MAP in both Groups

Time Interval	Group 1 (n = 40)	Group 2 (n = 40)	p - value
A	96.11 ± 10.57	97.17 ± 8.22	0.6209
B	91.61 ± 10.84	92.97 ± 7.19	0.5123
E	97.64 ± 16.58	91.2 ± 11.41	0.0474
E + 1	93.10 ± 14.19	87.7 ± 10.41	0.0569
E + 3	89 ± 11.76	83.1 ± 10.79	0.0228
E + 5	84.76 ± 10.63	78.8 ± 11.43	0.0187
E + 10	83.51 ± 12.70	76.42 ± 10.42	0.0082

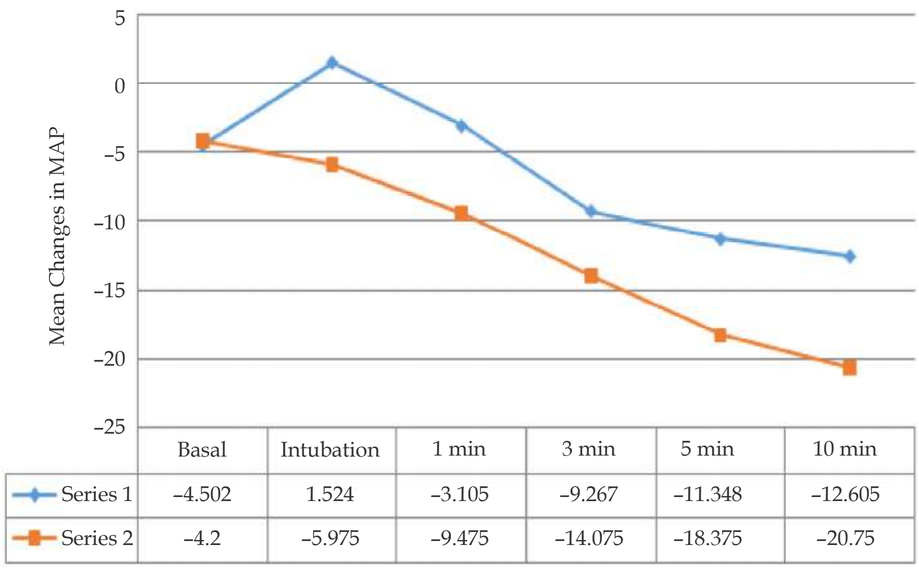


Fig. 3: Changes in MAP.

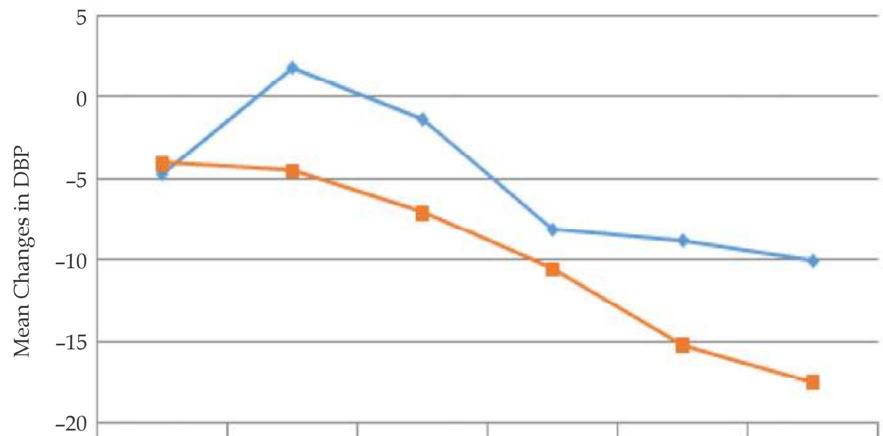
Table 5 shows, the changes in diastolic blood pressure during the study period. Looking from the data in the table we can see that there is consistent decrease in SBP in both the groups from the baseline throughout the study period.

Fig. 4 shows, DBP in both the Groups were decreased below base line and the maximum decrease noted was in Group 2 patients at 10 minutes interval and that is of approximately 17.5 mm of Hg. It was transiently increased during the time of intubation in the first group however.

There are very few adverse drug reactions noted in our patients like only two of our patients in Group 2 had developed hypotension and bradycardia following administration of 4 mcg/kg dose and was treated by infusing crystalloids and inj. Atropine Sulfate for bradycardia 0.6mg. No other side effects have reported in any other patients in both the Groups namely, hypertension or arrhythmias

Table 5: Mean DBP in both Groups

Time Interval	Group 1 (n = 40)	Group 2 (n = 40)	p - value
A	81.9 ± 10.06	82.65 ± 6.90	0.6986
B	77.17 ± 11.76	78.57 ± 6.32	0.5094
E	83.7 ± 14.86	78.12 ± 11.24	0.0622
E + 1	80.52 ± 13.88	75.52 ± 10.32	0.0715
E + 3	73.75 ± 16.06	72.1 ± 9.28	0.5754
E + 5	73.07 ± 9.74	67.45 ± 10.21	0.0137
E + 10	71.82 ± 11.61	65.15 ± 9.71	0.0066



	Basal	Intubation	1 min	3 min	5 min	10 min
Group 1	−4.725	1.8	−1.375	−8.15	−8.825	−10.075
Group 2	−4.075	−4.525	−7.125	−10.55	−15.2	−17.5

Fig. 4: Changes in DBP.

Discussion

The body reacts to external stimuli, ranging from minor to massive insult both locally and generally. The general response is in the form of wide spread endocrinal, metabolic and biochemical reactions throughout the body. The magnitude of response is highly dependent on the severity, intensity and duration of stimulus. For triggering such reflex response and presenting a complex interplay of substances between the hypothalamo and pituitary axis, the classical neuroendocrinal hormone system and autonomic nervous system is brought to action and is called "Stress Response" or "Alarm Reaction".[1]

The stress response leads to secretion of many anabolic and catabolic hormones resulting in hyper metabolism with the acceleration of most of the biochemical reactions. The response plays as a compensatory mechanism and provides maximum chances of survival because of increased cardiovascular functions, fluid preservation and supply of the increased demands for energy generating substances. If the stress response is prolonged, the continuous hyper metabolic state may result in exhaustion of essential components of the body like fat, glucose protein minerals and increase morbidity and mortality sometimes.[1]

Laryngoscopy and intubation result in increased in all the hemodynamic parameters like heart rate, systolic, diastolic and mean blood pressure. To attenuate this response various kind of drugs are in use like beta blockers, calcium channel blockers as well as nitro glycerine, propofol and central sympatholytic drugs such as clonidine, opioids like morphine, fentanyl etc.,[2] Narcotics may block afferent nerve impulses resulting from stimulation of pharynx and larynx during intubation.

It was shown that adequate depth of anesthesia and quick, smooth laryngoscopy is the mainstay for blunting this response. Narcotics have advantage of having perioperative role in anesthesia. They can be used as sole or supplementary agent for induction of anesthesia. Narcotics are very commonly used for intraoperative analgesia; therefore, there is no additional cost involved. Various narcotic drugs like morphine, fentanyl, alfentanil, sufentanil and ramifentanil have been tried for attenuation of pressure response associated with laryngoscopy and ETI.[3–8]

So, we selected the drug fentanyl citrate to attenuate the stress response associated with laryngoscopy and intubation because of its proved analgesic activity. Its duration of action as well as onset of action after intravenous administration are short with respect to other narcotics and so postoperative side effects will be less. Fentanyl citrate is available in our country since 1998 and has various advantages like no histamine release or bronchospasm, cardio stability, rapid onset and short duration of action. So, our study was designed to find out its efficacy for attenuation of pressure response in the dose of 2 mcg/kg and 4 mcg/kg.

In this clinical study, both the Groups were similar with regard to demographic datas, operative procedures & duration. Patients with significant comorbidities, having known allergy to study drug, Airway abnormalities, expected difficult intubation, Nasal intubation, Surgeries requiring head and neck manipulations and throat packing were excluded because of having greater impact on stress response. There are various studies carried out previously to find out the optimum dose of fentanyl citrate to attenuate the stress response.

Kautto[3] found that supplementation of fentanyl 2 μg/kg significantly attenuated and 6 μg/kg completely abolished the arterial pressure and heart rate increases during laryngoscopy and intubation. In addition, decreased the amount of fentanyl needed during the operation. Respiratory depression was not observed during recovery.

Chung[4] showed that when given two minutes before laryngoscopy, fentanyl 2 μg/kg & 5 μg/kg resulted in 24% and 6% rise in maximum SBP during rapid-sequence induction in healthy patients. Black[5] and Kay[6] found complete attenuation of hemodynamic response with 5 μg/kg fentanyl. Cork[8] found that fentanyl 5 μg/kg reduced norepinephrine rise during rapid-sequence induction of anesthesia. Fentany l 6 μg/kg was found to have a useful place in attenuating the cardiovascular effects of fibre optic intubation under general anesthesia.[9] Martin[10] used thiopental, 3 mg/kg, along with fentanyl, 8 μg/kg, for induction of anesthesia. MAP rise was attenuated compared to plain thiopentone sodium 6 mg/kg Group.

Donald E Martin and Henry Rosenberg[10] found that fentanyl 8 mcg/kg used as an adjuct to thiopental for induction of anesthesia to blunt the circulatory response to tracheal intubation caused fall in SAP, DAP, PCWP. Doses of fentanyl that are low enough to cause little postoperativerespiratory depression significantly blunt postintubation hypertension when used as an adjunct to thiopental. Iyer and Russell[11] studied, 80 patients undergoing coronary artery surgery. Patients received, either 0, 2, 5, 10 or 15 μg/kg of fentanyl. Mean MAP fell at all dose levels after induction, the mean fall being about 30 mm Hg at 5 μg/kg and greater. Mean MAP exceeded preinduction values after intubation with 0 and 2 μg/kg, and progressive attenuation of the MAP rise was found as the dose of fentanyl increased. They concluded that, if a minimal fall in mean MAP after induction with no rise above preinduction MAP is the sole criterion, a fentanyl dose of about 3 μg/kg is recommended. So, in our study, we have taken the dosage of fentanyl citrate in as little to attenuate the stress response at the same time it will not produce any side effects postoperatively. So, we try to compare the efficacy of two different doses of fentanyl citrate that is 2 mcg/kg and 4 mcg/kg and we have found the decrease in all the hemodynamic parameters like HR, SBP, MAP, DBP consistently in all the patients. However, in some patients there was a transient rise in parameters during intubation in Group 1 patients while in Group 2 not a single patient found to have increase in parameters.

Ko[12] designed a study to examine the optimal time of injection of fentanyl. Patients received fentanyl (2 μg/kg) 1, 3, 5, or 10 min before tracheal intubation. They concluded that the most effective time to administer fentanyl to protect circulatory responses to laryngoscopy and tracheal intubation is 5 min before tracheal intubation. Fentanyl is often used to reduce the hemodynamic response to tracheal intubation. However, large doses may cause unwanted side effects. Administration of fentanyl at the optimal time reduces the dose required.[13,14,15] So, in our study we administered fentanyl citrate at 5 minutes before intubation and we got the maximum response.

JE Smith[9] studied the effect of fentanyl on the circulatory responses to orotrachealfiberoptic intubation and found that fentanyl 6 mcg/kg suppresses the hypertensive response to fiberopticintubation as effectively as it does to mcintosh intubation. It also attenuates tachycardia associated with intubation.[16–18] So, fentanyl 6 mcg/kg can be recommended as a simple and effective method of minimising the cardiovascular disturbances produced by orotrachealfiberopticintubation under general anesthesia.[19,20]

TE Black[5] had done had done a comparative study between alfentanyl and fentanyl in reducing the hemodynamic responses to tracheal intubation and laryngoscopy and conclude that alfentanyl in low-doses can be used as a supplement during induction to prevent the rise in blood pressure and heart rate associated with laryngoscopy and intubation. The use of fentanyl 5 mcg/kg or alfentanyl 15 mcg/kg were equally effective in preventing a rise in blood pressure but 30 mcg/kg of alfentanyl was required to prevent an increase in heart rate.[21,22] The apparent duration of effect of the induction combination was significantly shorter when using alfentanyl rather than fentanyl.

In our study, we had given the two dose of fentanyl citrate and compared the effects of both the doses in attenuation of hemodynamic responses. We found out that fentanyl citrate decreases the hemodynamic parameters sufficiently and prevent any rise in parameters if given in sufficient doses and at optimum time interval

In our study, we have found out that in Group 1 who received the 2 mcg/kg dose shows some increase in hemodynamic parameters during intubation and it again came back to below baseline 1 minute after intubation. However, in Group 2 patients who received 4 mcg/kg dose did not show any rise in hemodynamic parameters and were continuously below base line throughout study period.

We follow our patients for 10 minutes after intubation and found out the mean decrease in heart rate in Group 1 is 7.77% while in Group 2 its 14%. In Group 1 there was transient rise in heart rate of approximately 3% and then start to decline after 1 minute. The decrease in heart rate was found to be 1% at 1min, 5% at 5 min and maximum 7% at 10 minutes in Group 1 patients. While in Group2 patients decrease in heart rate was sustained and in was 4% at 1 min, 8% at 3 min, 10% at 5 min and maximum at 14% at 10 minutes.[23–25]

Decrease in SBP was sustained throughout these 10 minutes. That is 5% at 1min, 15% at 5 min and 10 minutes as well in Group 1 patients while in Group 2 patients the decrease in SBP.was 11% at 1 min, 19% at 5 min and 21% at 10 minutes. Decrease in DBP was also sustained after initial rise during intubation in Group 1 patients. The maximum decrease in DBP noted was 12% in Group 1 and 20% in Group 2 patients. Decrease in MAP was also sustained in both the Groups and maximum decrease fond at 10^{th} minutes was around 12% in Group 1 and 20% in Group 2 patients. The rate pressure product which is a measure of myocardial oxygen demand was decrease upto 20% in Group 1 and approximately 34% in Group 2 patients. No evidence of any myocardial insult was seen in any of the patients in any Group in our study except two patients showing transient hypotension and bradycardia in Group 2. None of our patients demonstrate the side effect postoperatively.

Conclusion

From our study we conclude that:

- Fentanyl citrate given 5 minutes before intubation produces most attenuation of the hemodynamic effects of stress response.
- Pretreatment with fentanyl citrate in every normal case would cause attenuation of hemodynamic effects of laryngoscopy and intubation. It will cause minimal change in heart rate, SBP, DBP, MAP, RPP during the first 10 minutes after intubation.
- Fentanyl citrate given in dose of 2 mcg/kg resulted in attenuation of response to laryngoscopy and intubation but transient rise in heart rate and blood pressure were noted in this group at the time of intubation. However, thereafter it successfully decreases the hemodynamic parameters.
- Fentanyl citrate given in dose of 4 mcg/kg resulted in complete attenuation of hemodynamic response during laryngoscopy and intubation and none of the recording were above baseline after intubation. So, 4 mcg/kg dose is more suitable and more effeicient in attenuating the stress response during intubation.
- None of our patients had any side effects postoperatively like chest wall rigidity, hypotension, bradycardia, arrhythmia and respiratory depression except for the two patients in Group 2 who developed bradycardia and hypotension transiently.
- So, fentanyl citrate in 2 mcg/kg significantly attenuate but fentanyl 4 mcg/kg completely attenuates the hemodynamic responses during laryngoscopy and intubation.

References

1. Singh Manorama. Stress response and anesthesia alerting peri and postoperative management. Indian JAnesthesia 2003;47(6):427–34.
2. Reid LC, Brace DE, Irritation of the respiratory tract and its effect upon heart. Surg Gynec and Obs 1940;70:157–62.
3. Kautto UM, Attenuation of the circulatory response to laryngoscopy and intubation by fentanyl Acta Anesthesiol Scand 1982;26(3):217–21.
4. Chung KS, Sinatra RS. A comparison of fentanyl, esmolol, their combination for blunting the hemodynamic responses during rapid sequence induction. Can JAnesth 1992;39(8):774–79.
5. Black TE. Reducing the hemodynamic responses to laryngoscopy and intubation. A comparison of alfentanyl and fentanyl. Anesthesia 1984;39(9):883–87.
6. Kay B. Blocking the circulatory responses to tracheal intubation. A comparison of fentanyl and nalbuphine. Anesthesia 1985;40(10):960–63.

7. Dahlgren N. Treatment of stress response to laryngoscopy and intubation with fentanyl. Anesthesia 1981;36(11):1022–1026.

8. Cork RC. Fentanyl preloading for rapid sequence induction of anesthesia. Anesth Analg 1984;63(1):60–64.

9. Smith JE, King MJ, Yanny HF, et al. Effect of fentanyl on the circulatory responses to orotracheal fiberoptic intubation. Anesthesia 1992;47(1):20–23.

10. Marlin DE. Low-dose fentanyl blunts circulatory responses to tracheal intubation. Anesth Analg 1982;61(8):680–84.

11. Iyer V, Russell WJ. Induction using fentanyl to suppress the intubation response in the cardiac patient: What is the optimal dose? Anesth Intensive Care 1988;16(4):411–17.

12. Ko SH, Kim DC, Han YJ et al. Small-dose fentanyl: Optimal time of injection for blunting the circulatory responses to tracheal intubation. Anesth Analg 1998;86:658–61.

13. Weiskopf RB, Eger EI 2nd, Noorani M, Daniel M. Fentanyl, esmolol, and clonidine blunt the transient cardiovascular stimulation induced by desflurane in humans. Anesthesiology. 1994;81(6):1350–1355.

14. Ebert JP, Pearson JD, Gelman S, Harris C, Bradley EL. Circulatory responses to laryngoscopy: the comparative effects of placebo, fentanyl and esmolol. Can J Anaesth. 1989;36(3 Pt 1):301–306.

15. Salihoglu Z, Demiroluk S, Demirkiran, Kose Y. Comparison of effects of remifentanil, alfentanil and fentanyl on cardiovascular responses to tracheal intubation in morbidly obese patients. Eur J Anaesthesiol. 2002;19(2):125–8.

16. Gaubatz CL, Wehner RJ. Evaluation of esmolol and fentanyl in controlling increases in heart rate and blood pressure during endotracheal intubation. AANA J. 1991 Feb;59(1):91–96.

17. Abou-Madi, A method for prevention of cardiovascular reactions to laryngoscopy and intubation. Canadian Anaesthetists Society Journal, 1975 May;22(3):316–29.

18. Fox EJ et al, Complications related pressure response to endotracheal intubation Anaesthesiology, 1977 Dec;47(6):524–5.

19. Helfman SM, Gold MI, DeLisser EA, Herrington CA. Which drug prevents tachycardia and hypertension associated with tracheal intubation: lidocaine, fentanyl, or esmolol? Anesth Analg. 1991; 72(4):482–6.

20. Bachofen M. Suppression of blood pressure increases during intubation: lidocaine or fentanyl? Anaesthesist. 1988;37(3):156–61.

21. Bruder N, Ortega D, Granthil C. Consequences and prevention methods of hemodynamic changes during laryngoscopy and intratracheal intubation Ann Fr Anesth Reanim. 1992;11(1):57–71.

22. Abdallah C, Karsli C, Bissonnette B. Fentanyl is more effective than remifentanil at preventing increases in cerebral blood flow velocity during intubation in children. Can J Anaesth. 2002;49(10):1070–5.

23. Feng CK, Chan KH, Liu KN, et al. A comparison of lidocaine, fentanyl, and esmolol for attenuation of cardiovascular response to laryngoscopy and tracheal intubation. Acta Anaesthesiol Sin. 1996;34(2):61–7.

24. Fusciardi J, Godet G, Bernard JM, et al. Roles of fentanyl and nitroglycerin in prevention of myocardial ischemia associated with laryngoscopy and tracheal intubation in patients undergoing operations of short duration. Anesth Analg. 1986;65(6):617–24.

25. Splinter WM, Cervenko F. Haemodynamic responses to laryngoscopy and tracheal intubation in geriatric patients: effects of fentanyl, lidocaine and thiopentone. Can J Anaesth. 1989;36(4):370–6.

Case Report

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 183-186
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.25

Anesthetic Management of Severe Mitral Stenosis with Left Atrial Clot in a Known Case of Hypothyroidism with Undetected Obstructive Sleep Apnoea Posted for Mitral Valve Replacement

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Abstract

A 55 year old, diabetic, hypertensive female patient diagnosed with rheumatic heart disease and severe mitral stenosis was posted for mitral valve repair surgery. She was a known case of hypothyroidism with seizure disorder. On 2D echo, she had a severely dilated left atrium and a moderate degree of pulmonary hypertension (RVSP 48 mm Hg) She was found to have a left atrial clot on the Trans Esophageal Echocardiography (TEE) performed prior to surgery. On clinical examination, the patient was obese and a candidate for difficult airway. Her pulse was irregularly irregular suggestive of atrial fibrillation which was confirmed on ECG. Patient was taken up for surgery under high-risk with all surgical and anesthetic concerns explained to the family. Although there were no events intraoperatively, patient was difficult to wean off the ventilator postoperatively with one episode of cardiac arrest during a weaning trial. Patient was successfully revived after CPCR as per AHA guidelines. After an elective tracheostomy was performed, various causes of the sudden ventilator dependency that were ruled out included cor pulmonale owing to pulmonary hypertension, an undetected preoperative obstructive sleep apnoea, embolization of the clot to the brain, and chronic hypothyroidism leading to respiratory muscle weakness.

Keywords: Mitral stenosis; Obesity; Hypothyroidism; Obstructive sleep apnoea; Pulmonary hypertension, Cor pulmonale, Respiratory failure.

How to cite this article:
Mihika Divatia, Vishwas Sathe, Balachandran et al. Anesthetic Management of Severe Mitral Stenosis with Left Atrial Clot in a Known Case of Hypothyroidism with Undetected Obstructive Sleep Apnoea Posted for Mitral Valve Replacement. Indian J Anesth Analg. 2020;7(1 Part -I):183–186.

Introduction

Mitral stenosis is one of the most common cardiac anomalies associated with rheumatic heart disease.[1] The normal area of the mitral valve is 4–6 cm^2 with severe mitral stenosis detected when mitral valve area is lesser than 1 cm.[2] Symptoms of mitral stenosis vary with the severity of disease. Milder forms of the disease often tend to go unnoticed since patients are often asymptomatic till the degree of stenosis increases. With progression of the disease, patients start complaining of breathlessness with minimal exertion or even at rest. The decrease in mitral valve surface area reduces left ventricular filling, causes stasis of blood in the left atrium and increase in left atrial pressures which eventually lead to left

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Received on 16.10.2019, **Accepted on** 05.02.2020

atrial dilatation and enlargement which can often be seen on chest radiogram as straightening of the left heart border. The increase in left atrial pressures cause a subsequent increase in pulmonary vascular resistance leading to pulmonary hypertension and pulmonary oedema in severe cases. The stasis of blood in the left atrium can lead to the formation of a left atrial thrombus. In cases that are associated with atrial fibrillation, there is always a risk of embolization of this thrombus into the pulmonary or cerebral circulation.

The goal of anesthetic management in such cases is to achieve rhythm control and prevent tachycardia, hypoxia and hypotension intraoperatively along with judicious use of intravenous fluids.

Patients with obesity and increased body mass index[2] (normal BMI 18.5–24.9 kg/m^2) pose a further challenge to case management. Apart from being difficult airway candidates,[3,4] such patients may have an undetected obstructive sleep apnoea which often complicates the postoperative period. Obstructive sleep apnoea is a chronic disorder leading to partial or complete collapse of the upper airway during sleep with a consequent reduction in airflow. Postoperatively, these patients tend to have increased propensity for airway collapse impairing gas exchange and respiratory function.[5]

Long standing hypothyroidism when combined with the above comorbidities increases the perioperative risk of surgery.[7,8] When the hypothyroidism is not well controlled it leads to a number of complications, mainly by decreasing the body's metabolism of induction agents and causing respiratory muscle weakness hence making postoperative weaning from ventilator difficult.[9]

Case Report

A 55 year old female patient with RHD and severe mitral stenosis was posted for mitral valve replacement. She was a known case of hypertension, diabetes, hypothyroidism and seizure disorder for the last 10 years, on medication for all of the above.

She gave a history of previous hospitalization one month ago, for heart failure and pulmonary oedema wherein she was detected with severe mitral stenosis following rheumatic heart disease. She had since been started on anticoagulation therapy which had now been switched from Warfarin to unfractioned Heparin for the surgery.

She continued to have breathlessness and fatigue on minimal exertion post the hospitalization and hence decided to undergo the surgery as advised. On clinical examination, patient was obese with BMI of 30 kg/m.[2] She had a Mallampati score of three and a thyromental distance of 2 finger breadths and a short neck, making her a difficult airway candidate. Her pulse was irregularly irregular pattern which was suggestive of atrial fibrillation. Her heart rate and blood pressure were within normal limits.

The patient's routine blood work was within normal limits with TSH value of 9.9 mcg/dl. Echocardiography of the patient confirmed the diagnosis of atrial fibrillation with a controlled rate. The 2d echo showed severe dilatation of the left atrium with severe pulmonary artery hypertension (48 mm Hg). A Trans oesophageal Echocardiography (TEE) revealed a left atrial clot (3 × 3.8 cm).

High-risk consent was obtained preoperatively and the patient along with her relatives was explained the risk of anesthesia and surgery owing to her comorbid conditions and the risk- associated with embolization of the clot. The patient was instructed to take her antithyroid and antiepileptic medications as per schedule and avoid all hypoglycemic agents before surgery.

Preoperative vitals were within normal limits, random blood sugar was normal and lungs were clear. A crash cart with all emergency drugs, defibrillator and transcutaneous pacing wires were kept on standby. Calculated infusions of ionotropic and vasopressor agents were made for intraoperative hemodynamic management. Prior to induction, a large bore IV cannula was secured. An arterial line connected to a transducer was inserted in the Rt femoral Artery to monitor fluctuations in blood pressure throughout the surgery. A central venous catheter was secured in the Rt internal jugular vein for monitoring fluid status with calibrated guidewire insertion to avoid arrhythmias and clot embolization.

Patient was preoxygenated using 4 litres of oxygen. Premedication was administered with Inj Midazolam 5 mg and Inj Fentanyl 200 ug intravenously in titrated doses. General anesthesia was administered using Inj Etomidate 20 mg IV slowly over 30 mins to avoid a sudden fall in blood pressure. Succinylcholine 75 mg was given as muscle relaxant of choice and Train of Four (TOF) count was monitored. Patient was intubated after the count reached 0.

Inj Noradrenaline (3/50) was started at a low dose postinduction through the CVC to maintain a target MAP of 70 mm Hg and BP was monitored continuously *via* the arterial line using a transducer.

The patient was kept on an infusion of Inj Atracurium, Midazolam and Fentanyl to maintain the plane of anesthesia along with Sevoflurane as inhalational agent of choice. Postoperatively, the patient was kept intubated and ventilated with ionotropic support overnight. The patient's respiratory efforts remained unsatisfactory the next day due to which weaning from the ventilator was delayed. Extubation was performed 2 days postoperatively after patient had regained motor power and responded to commands satisfactorily. Postextubation, the patient complained of breathlessness and was unable to maintain saturation in spite of supplemental oxygenation.

Bipap ventilation was started following which the patient exhibited decreasing levels of consciousness with serial ABGs showing an increasing trend of hypercapnia. Patient was then electively intubated and put back onventilatory support. Over the next several days, ventilatory settings were changed based on the serial ABGs of the patient and weaning was attempted gradually.

After several unsuccessful weaning attempts over the next 7 days, the patient was scheduled for an elective tracheostomy owing to prolonged need for intubation. Post the tracheostomy, the patient remained on ventilatory support. Weaning attempts were unsuccessful with the patient developing tachycardia and hypoxia if taken off ventilator during one such weaning trial, the patient went into cardiac arrest. The patient was revived successfully after 2 cycles of high quality CPCR as per AHA guidelines. Weaning attempts were then witheld for a few days. Patient was hemodynamically stable postresuscitation and showed no signs of organ damage.

An Indirect laryngoscopy (IDL) performed by the ENT team of doctors showed mobile and functional vocal cords ruling out vocal cord lesion/palsy as a cause of her respiratory distress. On retesting her blood samples, her TSH had increased to 12 mcd/dl. The patient's medications were reviewed by the medicine team and her dose of Thyroxine was increased.

Weaning attempts were restarted after a few days and the patient was given rigorous chest physiotherapy and a high protein diet to increase respiratory muscle strength. Eventually, the patient showed improved ABGs with an acceptable oxygen saturation with 6 litres of oxygen *via t*-piece which was then gradually changed to room air. Serially improving blood gas reports and a better level of consciousness made the patient a candidate for discharge. The patient was sent home after being under observation for a week, with an elective tracheostomy closure planned after two weeks.

Discussion

After discussion with the respiratory medicine team, it was concluded that there could be 4 possible reasons for the acute onset of respiratory distress in this patient–

1. Cor pulmonale owing to pulmonary hypertension:

   Long standing pulmonary hypertension could have lead to remodeling of pulmonary vasculature and increased pulmonary vascular resistance which could have caused dilatation and hypertrophy of the right ventricle.[10]

2. Preexisting, undetected OSA leading to respiratory fatigue and consequent respiratory failure. Respiratory failure, leading to decreased ventilation and accumulation of carbon dioxide leads to hypoxia and hypercarbia which decreases levels of consciousness complicating the weaning process postoperatively.[11]

3. An embolism of a clot to the brain leading to ischemic injury of the respiratory centre or loss of the gag reflex.[12,13]

4. Severe hypothyroidism could be a possible cause of the respiratory failure. Decrease in serum thyroid levels can affect the respiratory system by either decreasing the response to hypoxia/hypercapnea or by causing weakness of the diaphragm and respiratory muscles leading to accumulation of carbon dioxide and consequently leading to hypoxia and decreasing level of consciousness.[14–18]

References

1. Holmes K, Fanzca MBChB, B Gibbison, et al. Mitral valve and mitral valve disease; BJA Education 2017 January;17(1):1–9.
2. M Eckmann David. Anesthesia for Bariatric surgery; Millers Anesthesia, International 8th Edition; US: Elsevier Health; 2014 15 October. pp.2200–216.
3. Seo Suk-Hwan, Lee Jeong-Gil, Yu Soo-Bong, et al. Predictors of difficult intubation defined by the Intubation Difficulty Scale (IDS): Predictive value of 7 airway assessment factors; Korean J Anesthesiol 2012 Dec;63(6):491–97.

4. Crawley SM, Dalton AJ, et al. Predicting the difficult airway; Continuing Education in Anesthesia Critical Care and Pain 2015 Oct;15(5):253–57.
5. Masa JF, Pépin JL, Borel JC, et al. Obesity hypoventilation syndrome. Eur Respir Rev. 2019;28(151):180097.
6. Daniel J Drucker, Gerard N Burrow Cardiovascular Surgery in the Hypothyroid Patient; Arch Intern Med 1985 Sep;145(9):1585–857.
7. Rampur A, Rao V, Anand Kumar PG et al. Hypothyroid patient undergoing Coronary bypass surgery: A nightmare, perioperative management challenge. IJBAR 2014;05(11):571–72.
8. Pandya K, Lal C, Scheinhorn D. Hypothyroidism and ventilator dependency; Arch Intern Med 1989;149(9):2115–116.
9. Datta D, Scalise P. Hypothyroidism and failure to wean in patients receiving prolonged mechanical ventilation at a regional weaning center; Chest 2004 Oct;1307:(4)126–312.
10. Bhattacharya A. Cor pulmonale; JIACM 2004;5(2):128–36.
11. Fouladpour N, Jesudoss R, Bolden N, et al. Perioperative Complications in Obstructive Sleep Apnea Patients; Anesth Analg 2016 Apr;122(4):1228–229.
12. Lynn M Peterson, Darryl Fisher R, Robert L Reis, et al. Cardiac Operations in Patients with Left Atrial Thrombus Incidence and Prevention of Postoperative Embolism; Ann Thorac Surg 1969 Nov;402:(5)8–406.
13. Mac Grory Brian, Chang Andrew, K Atalay Michael, et al. Left Atrial Appendage Thrombus and Embolic Stroke: A Case Study. Stroke. 2018 Sep; 49(9):e286–e289.
14. M Siafakas Nikolaos. Salesiotou Vassiliki, Filaditaki Vassiliki, et al. Respiratory Muscle Strength in Hypothyroidism; Chest Journal 1992 July;102(1):189–94.
15. Ashtyani H, Hochstein M, Bhatia G, et al. Respiratory muscle force in patients with hypothyroidism (abstract). Am Rev Respir Dis. 1988 Aug;138(2):A191.
16. Laroche CM, Cairns T, Moxham J, et al. Hypothyroidism presenting with respiratory muscle weakness. Am Rev Respir Dis. 1988 Aug;138(2):472–4.
17. Sadek SH, Khalifa WA, Azoz AM. Pulmonary consequences of hypothyroidism. Ann Thorac Med. 2017 Jul-Sep;12(3):204–208.
18. Marvisi M, Zambrelli P, Brianti M. Pulmonary hypertension is frequent in hyperthyroidism and normalizes after therapy. Eur J Intern Med 2006;17:267.

Case Report

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 187-190
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.26

Use of Truview Laryngoscope in Patients of Limited Mouth Opening Associated with Panfacial Trauma

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Abstract

Introduction: Panfacial fractures are the biggest challenge for anesthesiologist because of its difficulty in airway management. Different airway securing devices have been used. *Case Report:* A 28 Years old male patient with pan facial fracture posted for open reduction and internal fixation of mandible and left zygomatic arch with a closed reduction of nasal bone fracture. Airway examination showed decreased mouth opening of 1 finger indicating difficulty in mask ventilation and intubation. He was successfully intubated with the help of truview laryngoscope. *Conclusion:* Careful evaluation of fracture, difficult airway predictors are useful in intubating patient with decreased mouth opening in panfacial trauma with the help of truview laryngoscope.

Keyword: Panfacial fracture; Limited mouth opening; Difficult mask ventilation; Difficult intubation; Truview laryngoscope.

How to cite this article:
Rajashri Sonwane Virshid, Akhila L Arakkal, Sayyed M Omar. Use of Truview Laryngoscope in Patients of Limited Mouth Opening Associated with Panfacial Trauma. Indian J Anesth Analg. 2020;7(1 Part -I):187–190.

Introduction

Maxillofacial injuries are on the rise due to increase in vehicular trauma. These injuries do not pose an immediate threat to life unless they compromise airway. Anesthetic management of maxillofacial injuries is a challenge requiring expertise in airway management.[1] Truview has proved to be better device than Macintosh laryngoscope in anticipated difficult intubation.[2] Truview offers a better view of glottis by 1, 2 Cormack lehane grade as compared with conventional Macintosh laryngoscope in anticipated difficult airway. Here we report successful airway management in a case of pan facial trauma with restricted mouth opening whose airway was secured with truview laryngoscope.

Case Report

A 28 years male patient of weight 58 kgs sustained pan facial injuries in a road traffic accident under the influence of alcohol followed by loss of consciousness. General examination was within normal limits. Airway examination revealed a restricted mouth opening of 1 finger (15 mm). Extension & flexion of neck within normal limit. Thyromental & hyomental distance within normal limits. There was a depression in the fronto-nasal

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Received on 15.10.2019, **Accepted on** 28.11.2019

region with deviation of the nose to the right. Routine preoperative biochemical hematological investigations were done and found to be within normal limits. A CT head and neck revealed pneumocephalus, fractures of the left frontal bone, bilateral nasal bone as shown in (Fig. 1), lateral walls of the orbits, anterior wall of the left maxillary sinus, left zygomatic arch (Fig. 2) and the alveolar process of the mandible with mandibular condyles intact (Fig. 3). The patient was posted here for an open reduction, internal fixation of the mandible and zygomatic arch with a closed reduction of nasal bone fracture.

Fig. 1: Showing bilateral nasal bone fracture.

Fig. 2: Showing anterior wall of the left maxillary sinus, left zygomatic arch.

Fig. 3: 3D RECON CT showing fracture of mandible.

We anticipated difficult in mask ventilation as the patient had facial deformity and anticipated difficult laryngoscopy and difficult intubation due to restricted mouth opening. Our plan for intubation was awake oral Fiberoptic Intubation (FOI). Alternative plans for airway management included Truview laryngoscope, retrograde intubation and tracheostomy. The patient was premedicated with injection (inj.) Glycopyrrolate 0.2 mg IV, inj. Midazolam 1 mg IV, inj. Ondensetron 4 mg IV. Airway preparation was done with nebulization by 4% lignocaine 4 ml, gargles 5 ml of 2% Lignocaine viscous and a transtracheal block (2% lignocaine 2 ml) was given. The patient was sedated with inj Nalbuphine 5 mg intravenously and inj. Propofol 30 mg IV Initially fiberoptic laryngoscopy was attempted but due to difficulty in visualization due to defect in lens of fiberoptic bronchoscope we switched to the Truview laryngoscope as an alternative. Laryngoscopy was done using the Truview laryngoscope and vocal cords were visualized as Cormack Lehane Grade II (visualization of posterior part of laryngeal aperture). Intubation was done under vision using a flexo-metallic tube (7.5 Fr) with the help of a stylet. Tube placement was confirmed by capnography and bilateral air entry was confirmed by auscultation. The patient was then given inj. Propofol 2 mg/kg IV and inj. Atracurium 0.5 mg/kg IV.

To facilitate surgical access, a submandibular incision was taken by the surgeon and blunt dissection was done. Using an artery forceps tube was taken out through the submandibular route.

During the procedure, anesthesia was maintained with intermittent positive pressure ventilation using Oxygen, Nitrous oxide, Isoflurane, and inj. Atracurium was given intermittently. The procedure was completed uneventfully, and the patient was reversed with inj. Neostigmine and inj. Glycopyrrolate, extubated *via* the submandibular route. No complications were encountered in the postoperative period.

Discussion

Mouth opening measured as the interincisor distance, that is distance between the upper and lower incisors, is used as a predictor of difficult intubation. Normally it is 46 mm or more, while less than 38 mm predicts a difficult intubation.[3] The Macintosh laryngoscopy blade is one of the most popular blades used for intubation. Generally, Macintosh blades no. 3, 4 are used for intubation in adults.

We measured and found that minimum interincisor distance needed for insertion of a Macintosh blades are 22 mm and 25 mm respectively. A reduction in mouth opening may occur due to microstomia or due reduction in mandibular motility. Acute mandibular hypomobility is most often due to mandibular or facial trauma. Chronic mandibular hypomobility may occur due to temporo-mandibular joint pathology, trauma, surgery or neoplastic disease.

Various techniques have been described for securing airway in case of patients with limited mouth opening. These include blind nasal intubation, fiberoptic intubation, video intubating stylets, glidescope, retrograde intubation and surgical airway (tracheostomy). The use of fiberoptic nasotracheal intubation is a safe & better alternate to classical blind awake nasal intubation technique & tracheostomy.[4] Trochway (video intubating stylet) assisted nasotracheal intubation is also found to be an efficient method compared to FOB in patients with limited mouth opening. Also, the Levitar FPS optical stylet can be used in patients with < 15 mm mouth opening & is advantageous compared to other optical stylets due to its malleable tip. One study found that in patients with < 14 mm mouth opening tracheal intubation was performed significantly faster with a better view & a higher success rate with a glidescope laryngoscope compared to Macintosh. Bonfil fibroscope can be helpful for an awake fiberoptic intubation in very limited mouth opening. Retero graden asotracheal intubation is an effective & useful technique for airway control in patients with limited mouth opening of less than 20 mm & with only a small risk potential. In a retrospective audit of 20 patients with restricted mouth opening, where retrograde intubation was performed, the intubation was easy to perform & had a high success rate & low incidence of complications.

The truview laryngoscopy blade has an optical assembly based on the prism principle to provide image of an object situated at an angle of 45 degree to a straight line of vision and has found to provide a better view of the glottis as compared with Macintosh laryngoscope.[2] It was designed to allow for intubation with the minimal use of force.[5] Due to the anterior refraction it is possible to obtain a better view of the glottis with minimal manipulations of the head and neck.[6] Movements at the cervical spine are also found to be less and this is advantageous in clinical situations where cervical movements are to be avoided.[7] The truview blade also has an integrated oxygen port which prevents misting and provides continuous oxygen insufflation during laryngoscopy which may be beneficial in patients with poor pulmonary reserve.[8]

The truview laryngoscope has a slim 12.8 mm blade[9] and thus, can be used in patients with reduced mouth opening. The use of Truview system has been described for intubation in patient with limited mouth opening under 15 mm. However, some authors suggest that the addition of the optical port increases the overall size of the blade, which may make it more difficult to insert in patients with limited mouth opening.[10]

In our case it was an anticipated difficult intubation due to reduced interincisor distance. Therefore, decision was to go ahead with local preparation of airway & oral or nasal fiberoptic intubation. Due to technical error of fiberoptic laryngoscope (defect in lens), we switched to true view laryngoscope intubation and were successful in securing airway. The tube was brought outside through submandibular route so as to facilitate access to surgeon for carrying out the surgery.

The Glycopyrrolate will decrease secretion, Midazolam will decrease anxiety, ondensetron will decrease postoperative nausea vomiting, airway preparation with lignocaine in the form of nebulization, gargle, spray, transtracheal block provides surface anesthesia to airway, prevent breath holding & prevents breath holding & laryngospasm in response to intubation for smooth induction Propofol can be used. Maintenance of anesthesia is done with isoflurane though sevoflurane can also be used. For muscle relaxant Atracurium and vecuronium. The study of the fracture, counselling of patient, detailed airway assessment, premedication, proper airway preparation helped in formulating the plan of Truview. Though there were multiple fractures, the fracture which contributed to decrease mouth opening was most likely unilateral zygomatic arch fracture.

Conclusion

Proper history regarding mechanism of injury, the details of fracture line and proper airway assessment should all be considered in deciding the plan for intubation. The truview laryngoscope due to slim blade and angled view helps provide a better view of the larynx, and it may be beneficial in patients with decreased mouth opening. It can thus serve as a means of intubation in patients with limited mouth opening.

Acknowledgment

All the authors are extremely grateful to the Department of Oromaxillofacial surgery & the entire staff of Department of Anesthesiology for their active help in this work. We would like to express our gratitude to our patient & his relatives for their consent & cooperation.

References

1. Jayshree S. Maxillofacial and upper airway injuries Anesthetic impact. IJA 2008;52(5 suppl):688–98.
2. Singh I. Evaluation of Truview EVO2 laryngoscope is anticipated difficult intubation: A comparison to Macintosh laryngoscope. IJA 2009;52(2)164–68.
3. Gupta S, Sharma KR, Jain D. Airway assessment: Predictors of difficult airway. Indian J Anesht 2005;49(4)257–62.
4. Salman B. Fiberoptic intubation in limited mouth opening surgeries. World Journal of Dentistry 2011 Oct–Dec;2(11):350–52.
5. Truview EVO2 optical view laryngoscope. Truphatek International Ltd. Available from: http://www.truphatek.com
6. Rai E, Ramamani, Jacob R. Truview EVO2 Laryngoscope. J Anesth Clin Pharmacol 2009;25: 199–202.
7. Bhardwaj N, J Kajal, Rao Madhusudan, et al. Assessement of cervical spine movement during laryngoscopy with Macintosh and Truview laryngoscopes. J Anesthesiol Clin Pharmacol 2013 Jul–Sep;29(3):308–312. DOI: 10.4103/0970-9185.117053.
8. Li JB, Xiong YC, Wang XL, et al. An evaluation of the Truview EVO2 laryngoscope. Anesthesia 2007;62:940–43.
9. Barak M, Philipchuck P, Abecassis P, et al. A comparison of the Truview blade with the Macintosh blade in adult patients. Anesthesia 2007;62:827–31. DOI :10.1111/j.1365-2044.2007.05143.
10. B Bruno Bissonnette, Luginbuehl Igor, Marciniak Bruno, et al., 1st Edition. Rapid recognition and preoperative implication. McGraw-Hill Professional; Education 2006 July 20.p.900. http://www.accessanesthesiology.com

Case Report

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part - I): 191-194
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.27

Anesthetic Management of a Rare Case of Primary Sjogren's Syndrome for a Gynecological Surgery

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Abstract

A 44 years old female patient with primary sjogren's syndrome presented for surgical repair of third degree uterovaginal prolapse with cystocele and rectocele. Other associated medical problems included hypertension, Type II diabetes mellitus and hypothyroidism. Vaginal hysterectomy with colpoperineorrhaphy and levataroplasty was done under lumbar subarachnoid block and the perioperative course was uneventful. Herein, we describe our experience of anesthetic management of a case of primary sjogren's syndrome for an elective surgical procedure.

Keywords: Sjogren's syndrome; Schirmer's test; Immunosuppressants; Spinal anesthesia.

How to cite this article:
Renuka R. Anesthetic Management of a Rare Case of Primary Sjogren's Syndrome for a Gynecological Surgery. Indian J Anesth Analg. 2020;7(1 Part -I):191–194.

Introduction

Sjogren's syndrome is a chronic systemic autoimmune disorder. The overall prevalence of sjögren's syndrome is 0.1% to 0.4% in the general population, with a female to male ratio of 9:1. It is usually diagnosed in the fourth or fifth decade of life eventhough, it can manifest in all age groups.[1] The clinical hallmarks of Sjogren's syndrome are dryness of the cornea and conjunctiva or keratoconjunctivitis sicca and dry mouth or xerostomia due to the lymphocytic infiltration of lacrimal and salivary glands respectively. It is classified either as primary (PSS) when occuring alone or secondary (SSS) when asscociated with other autoimmune diseases.[2] The disease remains fundamentally incurable and treatment is mainly symptomatic.[3] Due to the constantly evolving nature, overlapping qualities of each unique connective tissue disorder along with the multiorgan involvement and associated increased mortality rate the impact of these disorders on different systems and their management needs to be emphasized. Thus, in this case report we discuss about a female patient with primary sjogren's syndrome who underwent an elective gynecological procedure.

Case Report

A 44 years old female patient, homemaker by occupation presented with mass per vagina which was diagnosed to be third degree uterovaginal

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Received on 06.09.2019, **Accepted on** 23.10.2019

prolapse with Grade 2 cystocele and rectocele for which an elective gynecological surgery was planned. Her obstetric score was P4L4.

About 5–6 months back, she had one episode of fever which was completely relieved by antipyretics following which she developed arthralgia involving both small and large joints of upper and lower extremities associated with skin lesions and photosensitivity. Since then she also complains of persistent sensation of gravel in both the eyes for which she had to clear her eyes with water and dryness of mouth which compelled her to take frequent sips of water. Since, last two months, she had pain in the region of both the parotids and difficulty in swallowing solid foods. There was no history of hematemesis or melena. The patient denied any history of cough, hemoptysis or bleeding from any site. There was no history of oral ulceration, alopecia, analgesic abuse or any recent trauma. There was no history of similar or any major illness in her family. Schirmer's test was done for the patient and was found to be positive. Based on history, clinical examination, relevant laboratory investigation reports and as per 2016ACR/EULAR criteria[4] she was diagnosed as primary sjogren's syndrome and was on treatment with wysolone, methotrexate, hydrochloroquine and topical corticosteroids for skin lesions.

She was a diagnosed case of hypertension on treatment with amlodipine tablets since 5 years. She is recently diagnosed with Type 2 diabetes mellitus on oral hypoglycemic agents and borderline hypothyroidism not on any treatment. On personal history, she had no addiction or promiscuous behavior. Sleep, bowel and bladder habits were normal

Laboratory investigations and test reports were:

Investigations	Patient report	Reference ranges
Total leukocyte count (cells/cumm)	3970*	4000–11000
ESR (mm/hr)	47*	Male: < 15 Female: < 20
Thyroid stimulating hormone (μIU/mL)	4.97*	Adults: 0.3–4.5
Glycosylated hemoglobin (HBA1C)	6.7%*	Normal < 5.7 %
USG-abdomen and pelvis	Grade I fatty liver	
2d-ECHO	Hypertensive heart disease*	
Anti-nuclear antibodies	1: 920*	< 1:40
Anti-Ro/SSA	1.45*	< 1.0
Anti-La/SSB	7.25*	<1.0
C3 (mg/dl)	99	90–180
C4 (mg/dl)	21	10–40
Anti-phospholipidantibodies IgG (U/ml)	1.2	< 10
Anti-phospholipidantibodies IgM (U/ml)	0.9	< 10
Anti-smith antibodies	Negative	
Serum ceruloplasmin (mg/dl)	41.5	20–35

*Elevated/abnormal results

Preanesthetic evaluation was done and on examination, she was found to be moderately built with weight 55 kg, height 155 cm and BMI of 22.9 and well nourished. Erythematous skin lesions (mottled hypo and hyperpigmentation type) were seen on cheeks, neck and extensors of the forearm. Other general physical examination findings were within normal limits. Respiratory system and cardiovascular system examination was within normal limits. Central nervous system examination did not reveal any motor, sensory or autonomic neurological involvement. On airway examination, no features suggestive of anticipated difficult airway were found.

Different anesthetic options along with its risks and benefits were explained to the patient. Nil per oral status of 8 hours was confirmed and pantoprazole tablet was given the night prior to surgery as aspiration prophylaxis. After arrival in the operating room, multi-para monitors were connected and base line parameters recorded as heartrate of 78 beats per minute, noninvasive blood pressure 118/71 mm Hg, respiratoryrate 16 per minute, O_2 saturation of 100%. After placing the patient in sitting position, under aspetic precautions lumbar subarachnoid block was performed by mid line approach at L3-L4 intervertebral space using 25 G quincke needle and 18 mg of 0.5% hyperbaric bupivacaine injected after free flow of clear cerebrospinal fluid through the needle was confirmed. Immediately patient was positioned supine, motor block, sensory block assessed using modified bromage score and pinprick method respectively. Maximum sensory block level achieved was T10 within 5 minutes, then the patient was put in lithotomy position for the surgical procedure. Vaginal hysterectomy with colpoperineorrhaphy and levataroplasty was done and the surgical procedure lasted for 2 hours. The patients vital parameters remained stable throughout the perioperative period without any pharmacological intervention and the estimated blood loss was about 500 ml. Humidified O_2 supplemented at 5 liters per minute. Total 1500 mL of crystalloids was transfused intraoperatively. Effect of spinal anesthesia lasted for 4 hours. Postoperatively pain was managed with intravenous injections of tramadol.

Postoperatively, foot exercises were started as soon as the motor block receded. Prophylactic anticoagulation and chest physiotherapy was also initiated. She was discharged on the fifth postoperative day without any complication. The patient was followed up regularly on out patient basis for 6 months and no complications were noted.

Discussion

Sjogren's syndrome is a well-known entity with multiple connective tissue disorders and hypergamma globulinemia.[5] The pathogenetic mechanism underlying these disorders is an inappropriate and excessive immunological reaction by the patients antibodies. It follows an indolent or slowly progressive course with the disease confined to the exocrine glands. However, in 30% of patients, it can involve neurological function (abnormal gait, autonomic dysfunction, seizures, movement disorder, ataxia/incoordination, insensitivity to pain, hyporeflexia, and even paraparesis or quadriparesis), immunological disorder (immune system anomalies, dysfunction autoimmunity), pharyngeal abnormality, respiratory tract modification (interstitial-like disease), chronic atrophic gastritis, celiac like disease, distal renal tubular acidosis, raynaud phenomenon and other skin anomalies. Occurrence of nonhodgkins lymphoma and mortality are higher in these patients. Secondary Sjögren syndrome occurs in 10 to 20% of patients with rheumatoid arthritis, systemic lupus erythematosus, and scleroderma. Various other diseases can imitate this syndrome including sarcoidosis, lipoproteinemia, and amyloidosis.

Preoperative assessment includes evaluation of constitutional illness, associated rheumatoid arthritis, interstitial pneumonitis, nephritis, vasculitis, peripheral neuropathies and lymphomas. Hypothyroidism and sleep disorders are relatively common.[6] Drug history particularly intake of systemic steroids, immunosuppressants and radiotherapy and its associated adverse effects if present should be recorded. Immunosuppressants are continued perioperatively while monitoring patient's leucocytes and platelet counts. Drugs with anticholinergic side effects like atropine, hyosine, phenothiazines, tricyclic antidepressants and antispasmodics should be avoided. Oral premedicants may provoke oesophageal injury by adhering to dryer walls of oesophagus[7], hence avoided. The enlarged parotid and submandibular glands may make the mask ventilation difficult. Laryngoscopy and intubation are complicated by xerostomia, poor orodental hygiene and temporomandibular joint arthritis. Hoarse voice is suggestive of crico-arytenoid joint involvement. Preoperative indirect laryngoscopy or fiberoptic assessment helps to plan intubation strategies or consideration of alternative regional techniques. Anesthesiologist must minimize infection by maintaining equipment cleanliness, using bacterial filters and prophylactic antibiotics. Inspired gases and intravenous infusates are warmed. The administration of anesthetic agents, hypnotics and local anesthetics must be done slowly and in presence of blood pressure monitoring because of the possibility of autonomic nervous system dysfunction. Ocular lubricants should be instilled frequently. Particular care is necessary to prevent positioning trauma associated with rheumatoid deformities. Adhesive tapes and ECG electrodes can cause epidermal ecchymosis or bullous eruptions. Thin and fragile skin makes venous cannulation difficult. Vasospastic irritability may provoke painful cyanotic reaction similar to raynaud's phenomenon.[8] Intraoperative vasodilatation necessitates colloids infusion for hemodynamic stability. Vigilant monitoring of respiratory embarassment due to crico-arytenoid inflammation and glandular enlargement[9] is required. Humidified oxygen facilitates mobilization of tenacious secretions as mucus plug inspissation can lead to bronchospasm and dyspnoea. All the above mentioned precautions were taken care of in our patient. Although, general anesthesia may be the most rapid and appropriate method in emergency surgical situations but in our patient, due to the presence of other associated medical problems and allergic predisposition for which she was on treatment with multiple drugs, we decided to avoid polypharmacy, unnecessary drug interactions and as the neurological examination findings, preoperative reports of coagulation profile were all within normal limits, as there was no surgical emergency conditions, we opted for spinal anesthesia. As the postoperative analgesic requirement in vaginal hysterectomy patients is relatively less, in our institution we do not practice epidural analgesia in these set of patients.

Preoperative aspiration prophylaxis, intravenous steroids administration and optimal preloading enabled us to manage the patient without aggravation of the clinical symptomatology. Effect of spinal anesthesia lasted for four hours, prolonged reversible sensory blockade is expected due to additional binding of local anesthetics and is useful for postoperative analgesia.

Conclusion

Careful preoperative assessment, intraoperative management tailored to the needs of the patient and surgeon reduce the perioperative risk to minimum and improve patient outcome.

References

1. De Carolis S, Salvi S, Botta A, et al. The impact of primary Sjogren's syndrome on pregnancy outcome: Our series and review of the literature. Autoimmun Rev. 2014 Feb;13(2):103–107.
2. Haralampos M, Moutsopoulos. Sjogrens' Syndrome; In: Anthony S Fauci, Joseph B Martin, Eugene Braunwald et al. (Eds). Harrison's Principles of Internal Medicine, 14th edition. NewYork: The McGraw-Hill Book Companies Inc; 1998.pp.1901–904.
3. Robert IF. Sjogren's syndrome. In: William N Kelley, Shaun Ruddy Edward, D. Harris & Clement B Sledge (Eds.) Textbook of Rheumatology, 5th edition. Mosby Year book Inc. 1997.pp.955–68.
4. Shiboski CH, Shiboski SC, Seror R. 2016 American College of Rheumatology/European League against rheumatism classification criteria for primary Sjogren's syndrome: A consensus and data-driven methodology involving three international patient cohorts. Arthritis Rheumatol 2017;69:35–45.
5. Sjogren HS. Zur kenntnis der kerato-conjuctivitis sicca (Keratitis folliformis bei hypofunktion der tranendrusen). Acta Opthalmol 1933;2:1.
6. Moutsopoulos HM, Tzioufas AG and Youinou P. Sjogren's syndrome. In: PJ Maddison, David A Tsenberg, Patricia Woo and David N Glass (Eds.). Oxford Text book of Rheumatology, 2nd edition. New York: Oxford University Press Inc; 1998.pp.1301–314.
7. Kjellen G, Fransson SG, Lindstrom F. Esophageal function, radiography and dysphagia in Sjogren syndrome.Dig Dis Sci. 1986 Mar;31(3):225.
8. Alexander EL, Arnett FC, Provost TT. Sjogren' Syndrome Association of Anti-Ro (SSA) antibodies with vasculitis, hematologic abnormalities and serological hyperactivity. Ann Intern Med. 1983 Feb;98(2):155–9.
9. Phelps JA. Laryngeal obstruction due to cricoarytenoid arthritis. Anesthesiology. 1966 Jul-Aug;27(4):18–22.

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[1] Flink H, Tegelberg Å, Thörn M, Lagerlöf F. Effect of oral iron supplementation on unstimulated salivary flow rate: A randomized, double-blind, placebo-controlled trial. J Oral Pathol Med 2006; 35: 540-7.

[2] Twetman S, Axelsson S, Dahlgren H, Holm AK, Källestål C, Lagerlöf F, *et al.* Caries-preventive effect of fluoride toothpaste: A systematic review. Acta Odontol Scand 2003; 61: 347-55.

Article in supplement or special issue

[3] Fleischer W, Reimer K. Povidone iodine antisepsis. State of the art. Dermatology 1997; 195 Suppl 2: 3-9.

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[4] American Academy of Periodontology. Sonic and ultrasonic scalers in periodontics. J Periodontol 2000; 71: 1792-801.

Unpublished article

[5] Garoushi S, Lassila LV, Tezvergil A, Vallittu PK. Static and fatigue compression test for particulate filler composite resin with fiber-reinforced composite substructure. Dent Mater 2006.

Personal author(s)

[6] Hosmer D, Lemeshow S. Applied logistic regression, 2nd edn. New York: Wiley-Interscience; 2000.

Chapter in book

[7] Nauntofte B, Tenovuo J, Lagerlöf F. Secretion and composition of saliva. In: Fejerskov O,

Kidd EAM, editors. Dental caries: The disease and its clinical management. Oxford: Blackwell Munksgaard; 2003. p. 7-27.

No author given

[8] World Health Organization. Oral health surveys - basic methods, 4th edn. Geneva: World Health Organization; 1997.

Reference from electronic media

[9] National Statistics Online—Trends in suicide by method in England and Wales, 1979-2001. www.statistics.gov.uk/downloads/theme_health/HSQ 20.pdf (accessed Jan 24, 2005): 7-18. Only verified references against the original documents should be cited. Authors are responsible for the accuracy and completeness of their references and for correct text citation. The number of reference should be kept limited to 20 in case of major communications and 10 for short communications.

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