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Original Article

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Evaluation of the Analegesic Effect of Caudal Dexamethsasone with Bupivicaine in Paediatric Genitourinary Surgeries

Bhaarat Maheshwari[1], Parul Goyal[2], Namrata Kapadia[3], Parimal Kashiram Patel[4]

Author's Affiliation:

[1]Assistant Professor, Anaesthesiology, [2]2nd YR Resident, Anaesthesiology, [3]1st Year Resident, Anaesthesiology, [4]Senior Resident, Naesthesiology, BJMC, Haripura, Asarwa, Ahmedabad, Gujarat 380016, India.

Abstract

Caudal epidural block is one of the most common regional techniques in pediatric anaesthesia. Epidural route of dexamethasone prolongs analgesic effect. Bupivacaine acts mainly by blockade of voltage gated NA+channel in the axonal membrane. Dexamethasone have a local anesthetic effect on nerve by direct membrane action.

Methodology: A randomized, prospective, interventional study.80 paediatric patients were allocated into two equal groups. BD group received 1.0 ml/kg of 0.25% bupivacaine with 0.1mg/kg of dexamethasone and B group received 1.0ml/kg of 0.25% bupivacaine. Patients more than 6 years were excluded from the study.

Results: In our study FLACC scores in group BD was reduced as compared to group B. Mean duration of analgesia was 279.8±11.54 minutes in group B was increased by adding Dexamethasone to 486.07±3.72 minutes in group BD.

Conclusion: The study was conducted in 80 children, aged 6months to 6 years of ASA I AND II undergoing elective Genitourinary surgeries under general anaesthesia. It is found that addition of Dexamethasone to Bupivacaine in caudal analgesia significantly increases the duration of postoperative analgesia without much side effects.

Key words : Caudal Anaesthesia; Pediatrics patients.

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Aims and Objectives

1. Intraoperative hemodynamic parameters.
2. Intraoperative concentration of inhalation agent required.
3. Perioperative and postoperative complications.
4. Comparison of duration of analgesia between the two groups.
5. To assess the requirements of supplemental analgesics, if any.
6. To study the side effects, if any.

Materials and Methods

After obtaining approval from institutional ethical committee, written informed consent was taken. Total 80 paediatric patients were randomly

Corresponding Author: Parul Goyal, 2nd Year Resident, Anaesthesiology, BJMC, Haripura, Asarwa, Ahmedabad, Gujarat 380016, India.

E-mail: parulgoyal4@gmail.com

allocated into two equal groups (n= 40 in each group) using random number, the allocation ratio was 1:1. BD group received 1.0 ml/kg of 0.25% bupivacaine with 0.1 mg/kg of dexamethasone and B group received 1.0 ml/kg of 0.25% bupivacaine.

Inclusion criterias

1. Age between 6 months to 6 years.
2. Genders: Both.
3. ASA physical status I, II.
4. Elective Genitourinary surgeries.
5. Duration of surgery not more than two hours.

Exclusion criterias

1. ASA status III, IV, V.
2. Emergency surgeries.
3. Local infection of the caudal area.
4. History of allergic reactions to local anaesthetics, bleeding diathesis.
5. Pre-existing neurological or spinal diseases, mental retardation, neuromuscular disorders.

Preoperative assessment: In pre-operative assessment of the patient's birth history, general examination, systemic examination, immunization, allergy, operative history with all required investigations (Hb%, complete blood count, random blood sugar, blood urea, serum creatinine, liver function test, ECG, chest X-ray) done a day before operation. Patient was advised to remain NBM for 6 hours. Informed and written consent was taken.

Preparation in OT: Baseline vitals like ECG, Pulse, Blood pressure, SpO2, Temperature was recorded in all patients.Patients was monitored with ECG, NIBP, SpO2, EtCO2, and Temperature. Then an intravenous line was secured with 24 or 22 gauge intravenous cannula and started i.v. fluids.Patients was Premedicated with Inj. Glycopyrrolate 4µg/kg, Inj. Ondansetron 0.15mg/kg. Preoxygenation was done with 100% oxygen at 5-7 L/Min for 3-5 mins via Jackson-Rees circuit. Induction was done using inhalation method with 50% oxygen and 50 % nitrous oxide with sevoflurane 2-7% Airway was secured with I-gel or ET tube after the effect of I.V. succinylcholine 2 mg/kg.

Caudal epidural was performed with a 22-gauze caudal epidural needle under complete aseptic precaution. Child was put in a left lateral position with their both hips and knees flexed. The sacral hiatus and caudal space was identified by the pop up felt when penetrating the sacrococcygeal ligament, sudden loss of resistance and after correct placement of needle in the caudal space and after negative aspiration for cerebrospinal fluid or blood and then 1 ml/kg of the blinded study solution injected.

Group BD - 1.0 ml/kg of 0.25% bupivacaine with 0.1 mg/kg of dexamethasone.Group B - 1.0 ml/kg of 0.25% bupivacaine.

The patients wasrepositioned supine. Patients was maintained with 50% O2 and 50% N2O mixture with sevoflurane 2-4%.Patient's hemodynamic parameters i.e. NIBP, HR, SpO2, EtCO2, Temperature will be recorded pre-op, at the time of premedication, induction, laryngoscopy, after caudal then every five minutes till 30 minutes after intubation and then every 15 minutes till 90 minutes. Intraoperative ringer lactate or DNS solution was infused as per the requirement of surgery.

During surgery adequate analgesia was evaluated by hemodynamic parameters like change in heart rate and systolic blood pressure at +/- 15% of baseline values and requirement of sevoflurane concentration. An increase in heart rate and systolic blood pressure within 15-20 minutes of skin incision was considered as a failure of caudal anaesthesia. Extubation: After oropharyngeal suction, patient was extubated when patient has established protective airway reflexes with adequate tidal volume and hemodynamic stability.

Post-operative period: Postoperative pain was evaluated by FLACCscore (maximum score of 10) using faces, legs, activity, cry, and consolabilitytool at 30 minutes interval up to first 2 hours ,one hour interval for next three hours and thereafter every 2 hours interval. As an when FLACC score was >4 rescue analgesic was given.

Sedation was assessed by using sedation score (0-spontaneous eye opening, 1-eye open on speech, 2-eye open on shake, 3-unarousable).

Results

Table 1 and graph 1 shows the comparison of postoperative pain (FLACC) scores at 0, 6, 12, 24 hours postoperatively.

Table 1: Postoperative Pain Score (FLACC).

Pain score	Group BD (n=40)	Group B (n=40)	P value
Immediate	0	0	0
06 hr	1.08±0.27	2.08±0.27	<0.001
08 hr	1.13±0.33	4.13±0.33	<0.001
12 hr	2.13±0.33	5.58±0.5	<0.001
24 hr	8.08±0.27	8.48±0.68	1

Adding Dexamethasone significantly reduce the FLACC scores in group BD as compared to group B. Higher FLACC scores were observed in plain Bupivacaine group (group B). Table 2 and graph 2 shows postoperative sedation score.

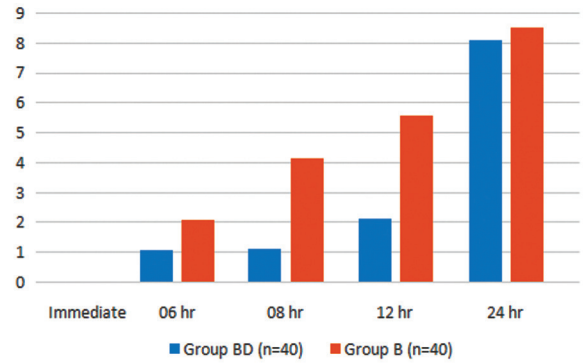
Table 2: Postoperative Sedation Score.

Sedation Score	Group BD (n=40)	Group B (n=40)	P value
Immediate	1.1±0.30	1.15±0.36	0.1
06 hr	0	0	0
12 hr	0	0	0
24 hr	0	0	0

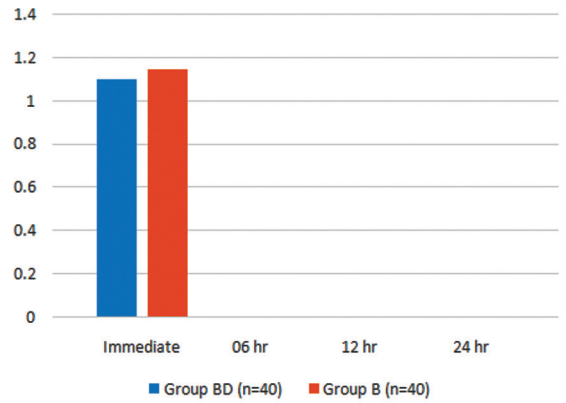
Table 3: Mean Duration of Analgesia.

	Group BD (n=40)	Group B (n=40)	P value
Duration of analgesia	486.07±3.72	279.8±11.54	<0.0001

Graph 1: Postoperative Pain Score.

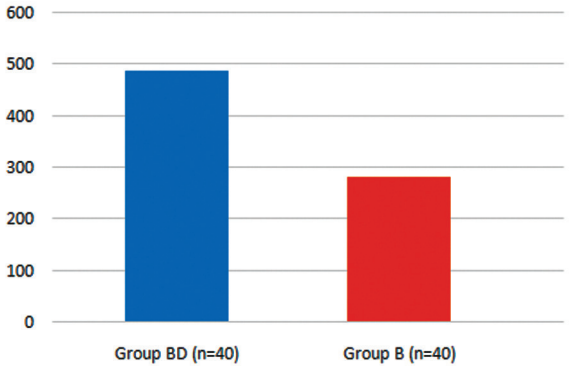


Graph 2: Postoperative Sedation Score.



There was no significant difference observed in postoperative sedation score between two groups (p>0.05). Table 3 and graph 3 shows the mean duration of caudal analgesia in two groups. This duration was significantly prolonged by addition of Dexamethasone to Bupivacaine (group BD) in comparison to Bupivacaine alone (group B). There was statistically significant difference in duration of caudal analgesia between both the groups (p<0.05).

Graph 3: Mean Duration of Analgesia.



Discussion

Caudal block has been found to be an excellent and safe technique for providing postoperative analgesia in paediatric population with a high success rate.

Bupivacaine is an amide type, long acting local anesthetic agent. It reversibly binds to specific sodium ion channels in the neuronal membrane, resulting in a decrease in voltage dependent membrane permeability to sodium ions and membrane stabilization. It also inhibits the depolarization and nerve impulse conduction and causes a reversible loss of sensation.

Dexamethasone is commonly used in the perioperative period to reduce postoperative nausea and vomiting.(1)Additionally, it has been reported to have analgesic effects(2). Dexamethasone might have a local anaesthetic effect on nerve by direct membrane stabilizing action . Therefore, dexamethasone might potentiate the effect of bupivacaine and prolong the duration of analgesia. Another possible mechanism involves the effect of dexamethasone on the spinal cord. The transcription factor, nuclear factor-κ B (NF-κB) is expressed throughout the nervous system and plays an important role in the development of pathological pain. Dexamethasone could regulate NF-κB. More specifically, epidural injection of corticosteroid has been reported to inhibit development of hyperalgesia with associated reduction in NF- κB levels (3)

In present study dexamethasone 0.1mg/kg combined with bupivacaine 0.25% 1ml/kg was given caudally to evaluate intraoperative hemodynamic changes, requirement of inhalational agent, perioperative complications, evaluate the

efficacy of analgesic effect of dexamethasone with bupivacaine and requirement of rescue analgesics.

Conclusion

This study was conducted in 80 children, aged 6 months to 6 years of ASA I & II, undergoing elective urogenital surgeries under general anaesthesia. The patients were assigned randomly into two groups of 40 patients each. Caudal epidural was given in all patients according to their group after giving general anaesthesia. Group B: Bupivacaine 0.25% 1.0ml/kg and group BD: Bupivacaine 0.25% 1.0ml/kg with Dexamethasone 0.1 mg/kg. The patients were observed for intraoperative hemodynamic parameter, intraoperative concentration of inhalation agent required, perioperative complications and postoperatively for duration of caudal analgesia (using FLACC score). It was found that addition of dexamethasone to bupivacaine in caudal analgesia significantly increases the duration of postoperative analgesia without much side effects.

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Comparative Study of Ondansetron versus Low Dose Ketamine in Prevention of Intra Operative Hypotension and Shivering in Patients Undergoing Subarachnoid Block

Aslam.K.A[1], Chandra Sekhar.T[2], Rajay Raghunath[3], K. Rameswra Reddy[4], Janakiraman.P[5]

Author's Affiliation:

[1]Senior Resident, [2]Assistant Professor, [5]Biostatistician, Department of Community Medicine, [4]Post Graduate, Department of Anaesthesiology, PES Institute of Medical Sciences and Research, Kuppam, Andhra Pradesh 517425, India. [3]Consultant, Department of Anaesthesiology, Rajiv Gandhi Speciality Hospital, Agatti Lakshadweep 682553, India.

Abstract

Context: Subarachnoid block (SAB) is a safe anesthestic technique commonly practiced worldwide. It is associated with hypotension (33%), bradycardia (13%), and shivering due to hypovolemia, sympathetic blockade, and Bezold- zarisch reflex. Hypotension is managed with vasopressors and crystalloids, while drugs and physical methods are useful to control shivering.

Aims: The study aims to evaluate the efficacy of ondansetron versus low dose ketamine to prevent hypotension and shivering during SAB.

Settings and Design: A prospective, randomized comparative study.

Methods: The studywas conducted on 120 patients undergoing elective lower abdominal surgeries under SAB. Patients were randomly allocated into two groups of 60 each. Group K received 0.25 mg/kg ketamine, while Group O received 4 mg of ondansetron as a slow intravenous infusion (IV) 5 min before SAB. Mean arterial pressure (MAP) and Heart rate (HR) were studied at 2 min intervals for the first ten minutes and once in 5 minutes for the next thirty minutes. Shivering scores were measured at 5 min interval for 40 min.

Statistical Analysis: Mean Arterial pressure and heart rate were compared and analyzed using unpaired t-tests. Shivering was compared using contingency tests.

Results: A decrease in HR is significantly lower in group K than in group O after 2 min ($p < 0.001$), 8 min ($p < 0.001$), 15 min ($p < 0.0031$), 25 min ($p < 0.0115$) and 40 min ($p < 0.0037$) of SAB. MAP was increased at 2 min time interval in the Ketamine group comparative with the Ondansetron group with a p-value <0.05 showing a high statistical significance. Group K had grade I ($p < 0.001$) shivering in 70% (42) of the patients compared with 36.7% (22) of patients in group O.

Conclusion: Administration of IV ondansetron and ketamine prevents SAB induced hypotension and shivering effectively.

Keywords: hypotension, ketamine, Ondansetron, shivering, subarachnoid block.

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Corresponding Author: Chandra Sekhar.T, Assistant Professor, Department of Anaesthesiology, PES Institute of Medical Sciences and Research, Kuppam, Andhra Pradesh 517425, India.

E-mail: dr.chandu24@gmail.com

Introduction

Spinal anesthesia is a simple, reliable, and most common anesthetic technique practiced worldwide.[1] Despite its popularity and ease of use, it is frequentlyassociated with hemodynamic instability and shivering. The incidence of hypotension and bradycardia in non-obstetric patients is 33% and 13%, respectively.[2] Vasopressors are highly effective in preventing hypotension but may result in cardiac arrhythmias and myocardial ischemia.

Due to the relative safety and beneficial effects on cardiovascular function, ketamine is an anaesthetic agent of choice for hemodynamically unstable patients. Ketamine increases HR and blood pressure due to sympathetic activation, therefore reduces hypotension and bradycardia following SAB. Ondansetron is a selective 5-hydroxytryptamine 3(5-HT3) receptor antagonists and thus may be beneficial for preventing bradycardia and hypotension.[3]

Shivering is the "big little problem" during anesthesia. The serotonergic system playsan essential role in the pathogenesis of perioperative shivering.4Apart from physical warming, drugs such as tramadol and pethidine are being used to prevent shivering. Ketamine is used for preventing shivering during anaesthesia in doses of 0.5 to 0.75mg /kg,5The primary outcome of this study was to evaluate the efficacy of low dose ketamine (0.25 mg/kg) and ondansetron (4 mg) to prevent hypotension and shivering during SAB. The secondary outcome was was to evaluate the side effects of ondansetron and ketamine.

Methods

This prospective randomized comparative study was conducted in a tertiary care hospital from January 2018 to July 2019. After approval from the institutional ethics committee (No: PESIMSR/IHEC/75/28/12/2017), 120 adult patients of ASA physical status I & II aged 18 – 60 years, undergoing elective lower abdominal surgical procedures under SAB were included in this study. Exclusion criteria were patients with thyroid disorders, epilepsy, bronchial asthma, cardiopulmonary, liver and kidney diseases, pregnancy, patients with severe bradycardia and hypotension, allergic to the agents used, and contraindications to SAB.

After explaining the procedure and obtaining written informed consent, the pre-anaesthetic evaluation was done, and patients allotted into two groups (Group K and Group O) of sixty each. The allocation to each group was done randomly using randomization through the random number generator application method. (Random number generator application, Jess tucker, version 1.1.3.2013). Group- K received 0.25mg/kg of IV ketamine and Group- O received 4mg of IV ondansetron five minutes before SAB. All patients received tablet Alprazolam 0.5 mg pre-operative day at night time.Patients were fasting for 8 hours before surgery for solids and 2 hours for clearliquids. The Patients underwent scheduled surgery next day under spinal anaesthesia. The routine monitoring protocols were as per our institution department protocol. Baseline vitals recorded, the operating room temperature maintained at 21°C to 22°C. administered Irrigation and IV Fluids at room temperature (24°C - 26°C) without inline warming. Ringer lactate solution is given at 500 ml/20 min as rapid infusion when spinal anaesthesia was induced and then at 7 ml/kg/h.Instituted subarachnoid block at the L3/4 or L4/5 interspace with 3 ml of 0.5 % hyperbaric bupivacaine.

Patients received respective drugs intravenously just before initiation of SAB. All patients covered with one layer of paper surgical drapes and one layer of a cotton blanket positioned over the thighs and calves. Besides, one layer of a cotton blanket is placed over the chest and arms. No other warming devices were used.

The MAP and heart rate of the patients were studied at different intervals, once in 2 minutes for the first ten minutes and once in 5 minutes for the next thirty minutes. Hypotension was defined as a fall in blood pressure by 20% from the baseline or an absolute mean arterial pressure (MAP) <60 mmHg, managed by increments of intravenous Mephentermine 6 mg. Bradycardia is defined as a decrease in HR by 20% from the baseline value or an absolute HR <50 beats/min, managed by 0.6 mg IV bolus of atropine. Patients with refractory nausea or vomiting were treated with 10 mg metoclopramide IV as a rescue medication. Shivering was graded based on the Bedside Shivering Assessment Scale (BSAS).[6] (Table: 1).

Table: 1 Bedside Shivering Assessment Scale (BSAS).

BSAS 0	None	No Shivering
BSAS 1	Mild	Shivering localized to neck/thorax may be seen only as an artefact on ECG or felt by palpation
BSAS 2	Moderate	Intermittent involvement of the upper extremities +/- thorax
BSAS 3	Severe	Generalized shivering or sustained upper/lower extremity shivering

The incidence and severity of shivering were recorded every five min for the first 40 minutes intraoperatively. If scores were three or higher at 15minutes after spinal anaesthesia, the prophylaxis was regarded as ineffective and were treated withpethidine 0.5 mg/kg IV as a rescue medication.

Power analysis was based on the results of a previous study conducted by Shakya et al. They have shown that hypotension was lowest in the ketamine group (10%) in comparison to the ondansetron group (22.5%) and saline group (20%).[7] The sample size was calculated based on these findings, with a value of 0.055 and an expected prevalence of 0.1(10%). It was calculated that 114 subjects are required for the study. We included (120 subjects) 60 patients in each group for better validation of results. Data were analyzed using STATA 14. Numerical data like MAP and HR were compared and analyzed using unpaired t-tests between the groups. Shivering was compared using contingency tests. The data collected were presented as Mean & SD with 95% confidence intervals for quantitative observations and proportions (%) for qualitative observations.A statistical probability value of <0.05 is considered to be statistically significant. To reject the null hypothesis, the significant level was taken as $p < 0.05$.

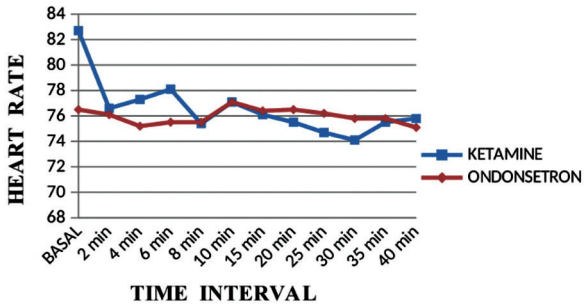
Results

The study was conducted on 120 patients who were posted for elective surgical procedures. The demographic characteristics, such as age, gender, and weight, were comparable in both groups (p> 0.05) (Table: 2). There was no statistical significance in both groups.

Table: 2 Demographic data of study groups.

Variables	Group K (Mean ± SD)	Group O (Mean ± SD)	P value
Age	42.1±10.8	38.6±12.4	0.1128
Weight	61.1±8.3	61.5±9.6	0.8009
Gender (M/F)	29/31	30/30	0.8550

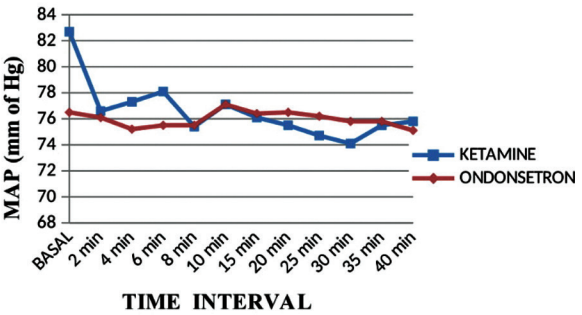
Graph: 1 Comparison of HR between studied groups.



Comparison of heart rate between study groups.

A decrease in HR issignificantly lower in group K than in group O after 2 min (0.001), 8 min (0.001), 15 min (0.0031), 25 min (0.0115) and 40 min (0.0037) of SAB (Graph: 1).Decreases in MAP were significantly lower in group K than group O. patients in group K had significantly fewer vasopressor requirements. There were no statistically significant differences between the two groups after 2 min of SAB. MAP was increased at 2 min time interval in the Ketamine group comparative with the Ondansetron group with a p-value <0.05 showing a high statistical significance (Graph: 2).

Graph: 2 Comparision of MAP between two groups.



Comparison of MAP between study groups.

Table: 3 Comparisonof Shivering Scale.

Shivering Scale	Group					p-value
	Keta Mine		Ondansetron			
	n	%	n	%		
BASAL	0	60	100	60	100	-
5 min	0	60	100	60	100	-
10 min	0	60	100	60	100	-
15min	0	60	100	60	100	-
20 min	0	60	100	60	100	-
25 min	0	18	30	38	63.3	*<0.001
	1	42	70	22	36.7	
30 min	0	30	50	28	46.7	0.715
	1	30	50	32	53.3	
35 min	0	38	63.3	44	73.3	0.239
	1	22	36.7	16	26.7	
40 min	0	30	50	42	70	0.025
	1	30	50	18	30	

* Significant difference

Shivering was not observed in any patient in both the groups within 20 min time interval. While 70 % (42) of patients in group K had shivering with grade 1 ($p< 0.001$) compared to 36.7 % (22) of patients in group O (Table: 3).

Discussion

Hypotension is the most common complication of SAB with an incidence of 20% in the elderly.8 Spinal induced hypotension and bradycardia are multifactorial due to the Bezold–Jarisch reflex, mediated by serotonin receptors within the ventricle wall in response to systemic hypotension. The stimulation of these peripheral 5 hydroxytryptamine subtype 3 (5 HT3) receptors resulted in increased parasympathetic activity and decreased sympathetic activity, resulting in bradycardia, vasodilatation and hypotension.

Ketamine is an NMDA receptor antagonist known to produce dissociative anaesthesia and has a strong analgesic effect. Its acts by noncompetitive antagonism at N-methyl D-aspartate (NMDA) receptors and has a local anaesthetic effect. It increases the blood pressure by central stimulation of the sympathetic nervous system and inhibition of norepinephrine reuptake. Many medical centers use ketamine as an induction agent for potentially hypovolemic trauma patients undergoing rapid-sequence intubation. Ondansetron has been safely used to blunt the Bezold–Jarisch reflex resulting in less bradycardia and hypotension.

Our study investigated the comparative efficacy and safety of a low prophylactic dose of ketamine and ondansetron (with a different mechanism of action) to prevent hypotension and shivering during the subarachnoid block. There was no difference between the two groups concerning hemodynamic parameters. These results were consistent with previous studies by Sagiret al.[9] and Kelsakaet al.10Nallam S R et al.11 found that 4 mg IV ondansetron to be effective in preventing hypotension and bradycardia under neuraxial blockade. In the study conducted by Marashiet al.1 they compared two different doses of ondansetron 6 mg, 12 mg with the placebo group. 12% of patients in the control group had hypotension and required vasopressors. 45% had to shiver, 14% had bradycardia.

In line with our results, Sahoo et al.[12] concluded that IV ondansetron at 4 mg given prophylactically could attenuate decreased blood pressure following spinal anesthesia. Owczuket al.[13] reported that 8 mg IV ondansetron attenuates the fall of systolic and mean blood pressure but does not influence diastolic BP or HR. A study conducted by Rashad14 and Farmawy on 60 parturient females undergoing elective cesarean section concluded that patients who received IV ondansetron 4 mg before SAB significantly decreased both the hypotension and the dose of vasopressors consumption ($p= 0.005$).

Most studies have quoted that shivering incidence varies 30%–40%15and 40–60%16 following regional anesthesia. During the perioperative period, core body temperature was maintained between 36.5°C–37.5°C because shivering occurs as a response to hypothermia. Under regional anesthesia, shivering may occur in normothermic patients.[17] Several factors, including age, level of sensory block, type and volume of infusion solution, and operating room temperature, are risk factors for developing hypothermia in regional anesthesia.[18] Our study demonstrates a statistically significant incidence of shivering in Group K compared to Group O ($p = 0.001$) after 25 min of SAB.

In this study, shivering is graded using a scale that was validated by Tsai and Chu.[19] Our results were similar to the findings of Shakya et al.[8] who suggested that the prophylactic administration of low dose ketamine (0.25 mg/kg) and ondansetron (4 mg) produces the significant anti-shivering effect in comparison with placebo.They also opine that ketamine (0.25 mg/kg) is significantly more effective than ondansetron (4 mg). Kelsaka et al. study said that 8mg of IV ondansetron effectively prevents the postspinal shivering compared to the control group, which was very similar to our results. Sagiret al. concluded that prophylactic use of ketamine and granisetron separately and in combination, effectively prevented shivering developed during regional anesthesia.

The results of the study were consistent with the study of Mushtaq Waniet al.[20] they evaluated the role of prophylactic low dose ketamine and ondansetron for the prevention of shivering during spinal anesthesia. Rama wasonet al.[21] also found ketamine 0.5 mg/kg IV to be effective in controlling shivering under neuraxial blockade.

In our study, the very low dose of ketamine (0.25mg/kg) was used to minimize the side effects. We found that it was significantly effective, and only grade 1 shivering was observed after 25 min initial dose in 42 patients out of 60 (70%). Sayed ADM[22]showed significant results with ketamine 25 mg IV to prevent shivering under SAB. Dal et al[5] showed that ketamine 0.5mg/kg effectively prevented post anaesthetic shivering in patients receiving general anaesthsia. In our study, 0.25mg/

kg of ketamine was as effective as 0.5mg/kg of ketamine. Sharma. S P et al[23] and Botros. JM et al[24] concluded that 8 mg ondansetron effectively prevented SAB induced shivering. A study conducted by Trabelsiet al,[25] on 80 parturients posted for elective cesarean section found that vasopressor consumption is significantly more in the saline group as compared with the ondansetron group ($p< 0.0001$).

In our study, the primary outcome is low dose IV ketamine effectively prevents the SAB induced hypotension compared with ondansetron andondansetron more efficacious than ketamine in preventing SAB induced shivering, the secondary outcome is the usage of these drugs at the said doses free of adverse effects.

One limitation of our study was that we used a fixed dose of ondansetron 4 mg in all patients irrespective of patients' weight. Another limitation was that we monitored NIBP; probably, invasive blood pressure monitoring would have been more reliable. Effects of low dose ketamine on other anaesthetic parameters such as pain and recovery time was also not studied. The use of sympathomimeticsuch as mephenteramine for hypotension treatmentwhich tends to increase both BP and HR, would have masked the incidence of bradycardia. Hence, this could be one reason for not getting significant values in the incidence of bradycardia.

Conclusion

Based on the present comparative study between ondansetron and low dose ketamine we conclude that IV ketamine 0.25mg/kg resulted in better prophylaxis against hypotension. A single-dose of Ondansetron 4mg intravenous bolus resulted in better prophylaxis against shivering. No significant side effects were observed for both groups during the study.

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Comparative Study between Dexmedetomidine and Midazolam in Inducing Conscious Sedation in Patients Undergoing Cataract Surgery

Mamatha M.K[1], Swetha Rajoli[2], Shreyavati R[3]

Author's Affiliation:

[1]Senior Consultant, [3]Professor, Department of Anaesthesiology, Chikkaballapura District Hospital, Chikkaballapura, Karnataka 562101. [2]Senior Resident, Department of Anaesthesiology, ESI Post Graduate Institute of Medical Science, Bengaluru, Karnataka 560010, India.

Abstract

Background: Cataract surgery are usually done in elderly patients. Dexmedetomidine is a potent non-opiod sedative and analgesic devoid of respiratory depression. Midazolam is the most commonly used sedative which is commonly associated with respiratory depression specially in elderly patients.

Objectives: To compare the effects of intravenous dexmedetomidine and midazolam on the haemodynamic stability, sedation and intraocular pressure and to study the safety profile of the drug

Methodology: After obtaining permission from institutional ethical committee and patient informed consent, study was conducted at BMCRI from November 2016 to May 2018 in ASA Grade 1 and 2 patients of 40 to 70 year age undergoing cataract surgery. Patients were randomly allocated to two Group D and M of 32 each. Group D received inj. dexmedetomidine 0.25mcg/kg, Group M received inj. midazolam 0.02mg/kg diluted to 10ml over 10 minutes as intravenous injection. Peribulbar block was given with 8-10ml of injection 2% lignocaine with adrenaline with hyaluronidase. Haemodynamic parameters like Heart Rate, Mean Arterial Pressure and SpO2, Intra Ocular Pressure in non-operating eye, Ramsay Sedation Score, Visual Analogue Score and Modified Aldrete Score were recorded.

Results: We concluded that in our study demographic data were comparable. Patients of Dexmedetomidine group had reduction of IOP after drug injection (p=0.001) and at post bulbar block (p=0.002) which is statistically significant compared to Group M patients and also there was statistically significant difference in RSS Score between two groups.

Conclusions: Dexmedetomidine provides same conscious sedation as Midazolam. Dexmedetomidine reduces intraocular pressure and maintains SpO2 when compared to Midazolam in cataract surgery.

Key words: Cataract surgery; Dexmedetomidine; Midazolam; Intra ocular pressure.

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Corresponding Author: Swetha Rajoli, Senior Resident, Department of Anaesthesiology, ESI Post Graduate Institute of Medical Science, Bengaluru, Karnataka 560010, India.
E-mail: Swethasaritha1091@gmail.com

Introduction

For intraocular procedure such as extraction of cataract it is desirable to achive a normal or reduced IOP.[1] Anaesthesiologist can optimize the conditions for cataract surgery by providing an immobile uncongested field, decreasing IOP and thus minimizing the danger of expulsion of intraocular contents when the eye is opened.[2]

Dexmedetomidine is a selective alpha[2] adrenoreceptor agonist, which provides "conscious sedation" with adequate analgesia, without causing respiratory depression.[3]

It is sedative-hypnotic, anxiolytic and sympatholytic that can attenuate the stress response to surgery (mitigating tachycardia, hypertension) and also decreases IOP during ophthalmic surgery under local anaesthesia. It also allows patients to respond to verbal commands during the sedation. Easy conversion from sleeping to awakening is possible.[4,6,7]

Midazolam is most commonly used benzodiazepine, causes oversedation, respiratory depression, disorientation, confusion and prolonged recovery after long term or high dose use. It has no analgesic component.[6]

Cataract surgery is most commonly done under local anaesthesia with sedation. Several drugs have been used for sedation during this procedure including benzodiazepines, propofol and opiods. However, propofol may cause oversedation and disorientation. Benzodiazepines may result in oversedation, respiratory depression and confusion particularly when administered to elderly patients. Opiods are associated with increased risk of respiratory depression and oxygen desaturation.[6]

The purpose of the current study is tocompare between dexmedetomidine and Midazolam in inducing conscious sedation in Patients undergoing cataract surgery.

Aims and objectives

- To compare the effects of dexmedetomidine and midazolam on the haemodynamic stability, sedation and intraocular pressure.
- To study the safety profile of the above drugs.

Materials and Methods

A total of 64 Inpatients at hospitals attached to Bangalore Medical College and Research Institute, Bangalore, scheduled to undergo cataract surgery under regional anaesthesia.During the period of Nov 2016 – May 2018 will be taken for study, satisfying the inclusion and exclusion criteria

Sample size: With reference to the previous study, a minimum sample size of 42, with 21 per group was calculated based on considering 5% alpha error, 90% power 2 SD in each group of change in haemodynamic parameters and intraocular pressures,and to be sensitive enough to identify difference of 2 mm Hg ofIOP reduction. For better result, a sample size of 64 with 32 in each group has been chosen.

Inclusion Criteria:

1. Patients aged 40-70 yrs of either sex.
2. Patients posted for cataract surgery under regional anaesthesia.
3. Patients with ASA (American society of Anaesthesiologists) Grade 1 & 2.

Exclusion criteria:

1. Patients with baseline heart rate less than 60 per minute.
2. Patient with COPD,chronic renal failure and hepatic dysfunction.
3. Patients with glaucoma

Methodology

After obtaining clearance and approval from Institutional Ethical Committee, patients who were posted for cataract surgery under regional anaesthesia, fulfilling inclusion and exclusion criteria who give informed written consent will be included in the study.

Patients were randomly allocated using a computer generated number to one of the two groups: Dexmedetomidine group (Group D) and Midazolam group (Group M)(n = 32each).

Group D - received injection Dexmedetomidine 0.25µgm/kg diluted in 10ml NS, slow IV over 10 minutes.

Group M -received injection Midazolam 0.02mg/kg diluted in 10ml NS, slow IV over10 minutes.

Preoperative evaluation of all patientswas done, which includes medical history, physical examination and laboratory tests like CBC, RFT, LFT, ECG. The patient will be premedicated with tablet alprazolam 0.5mg the night before surgery. In the pre-operative room, patient will be put on standard monitors like non-invasive blood pressure,pulse oximetry and electrocardiogram. All basal parameters were recorded including IOP

in non-operating eye by using schiotz tonometer.

In Group D, patients were received 0.25 µg/kg of dexmedetomidine diluted in 10ml of NS over 10 minutes as IV injection. In Group M, patients were received 0.02 mg/kg of midazolam diluted in 10 ml of NS over 10 minutes as slow IV injection. Under aseptic precations in supine postion, peribulbar block was given with injlignoadrenaline(8-10 ml) with hyaluronidase10 minutes after the injection of drug and all vital parameters were recorded including IOP in non-operating eye using schiotz tonometer.

Level of sedation is assessed by Ramsay Sedation Score and level of analgesia by Visual Analogue Scale. Modified Alderet Score is used to assess the readiness for discharge post-operetively.HR, MAP, SpO_2, RSS and VAS score were recorded pre-operatively every 5th minute till 30th minute. Post-operatively HR, MAP, SpO_2, RSS, VAS and MAS score were recorded. Adverse effects like hypotension, bradycardia and decrease in saturation(desaturation) were recorded.

We defined

Hypotension: as 20-30% decrease in MAP and treated with fluid bolus followed byinjmephentramine.

Bradycardia: as heart rate <60 beats per minute and is treated with inj atropine.

Decrease in saturation (Desaturation): as SpO_2<90% and is treated with administration of oxygen.

Statistical Analysis

Statistical analysis will be performed as follows: Student t test to compare the nominal data between the groups, Chi-square test to compare categorical data between the groups.P<0.05 will be significant. All the analysis will be done using SSPS 16 version.

Results and Analysis

Age and sex distribution

The mean age for Group D was 58.53±7.34years and for Group M was 59.44±6.72years. The p value is 0.6 which is not significant.46.9% female and 53.1% male patients were there in Group D and 50% of female and 50% male were there in Group M with p=0.6 which is not significant.On comparison of age and sex distribution was similar in both groups which is statistically not significant. Therefore age and sex distribution was comparable in both groups.

Table 1: Age Distribution.

	Group D		Group M	
	Mean	SD	Mean	SD
Age	58.53	7.34	59.44	6.72

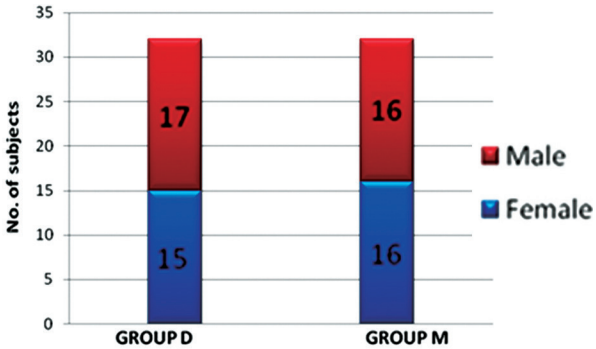

Fig. 1: Gender Distribution of Patients Studied.

Table 2: ASA Grade distribution of patients in both the groups.

	GROUP D		GROUP M	
	Count	Column N %	Count	Column N %
Grade 1	17	53.1	22	68.8
Grade 2	15	46.9	10	31.3

In Group D, ASA Grade 1 patients were 53.1% and ASA Grade 2 were 46.9%. In Group M ASA Grade 1were 68.8% and ASA Grade 2 were 31.3% with the p value of 0.2

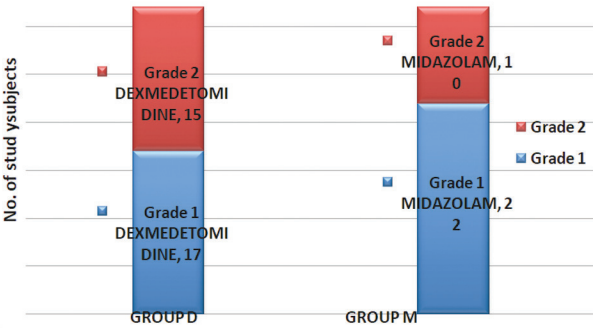

Fig. 2: ASA Grade Distribution.

Table 3: BMI distribution of patients studied.

	GROUP D		GROUP M		
	Mean	SD	Mean	SD	p
BMI	23.63	1.37	23.87	2.00	0.6
Weight	60.59	5.11	61.75	6.52	0.4
Height	160.09	4.75	160.75	4.66	0.6

BMI for Group D was 23.63±1.37 and for Group M was 23.87±2.00 with p value of 0.6 which is not significant.

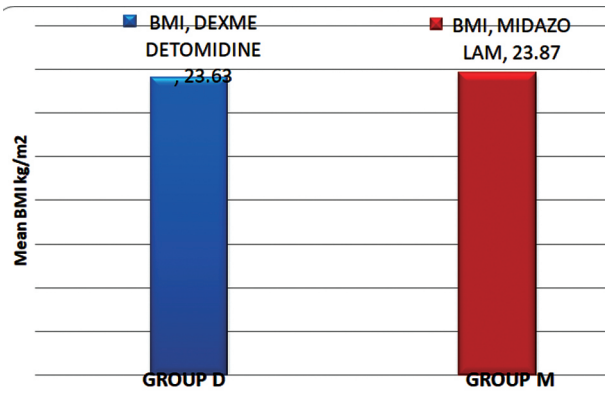

Fig. 3: BMI distribution between 2 groups.

Table 4: Duration of surgery in both the groups.

	Group D		Group M	
	Mean	SD	Mean	SD
Duration of surgery in minutes	26.66	2.32	27.31	1.62

p=0.2

The mean duration for surgery for Group D was 26.66±2.32 minutes and for Group M was 27.31±1.62 minutes with the p value of 0.2 which is not clinically and statistically significant.

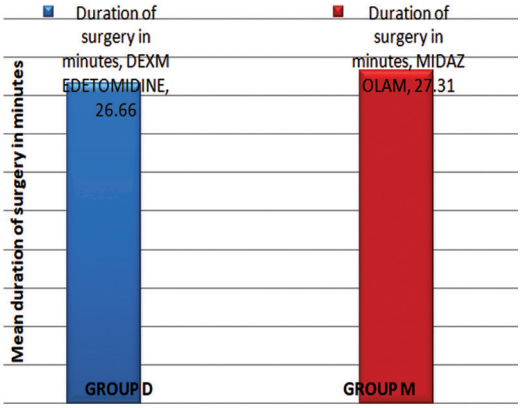

Fig. 4: Duration of surgery between two groups.

Table 5: Baseline HR, MAP, SpO_2, IOP distribution in both the groups.

	GROUP D		GROUP M		
	Mean	SD	Mean	SD	P
Base HR	86.00	11.25	81.97	9.88	0.2
Base MAP	92.00	9.61	89.41	7.20	0.2
Base SPO_2	97.75	1.67	97.94	1.74	0.6
Base IOP	16.63	2.20	16.28	1.99	0.5

There was no statistically significant difference in baseline HR, MAP, SpO_2, IOP between both the groups.Mean baseline HR in Group D was 86±11.25 and in Group M was 81.97±9.88 with p value of 0.2 which is not significant.

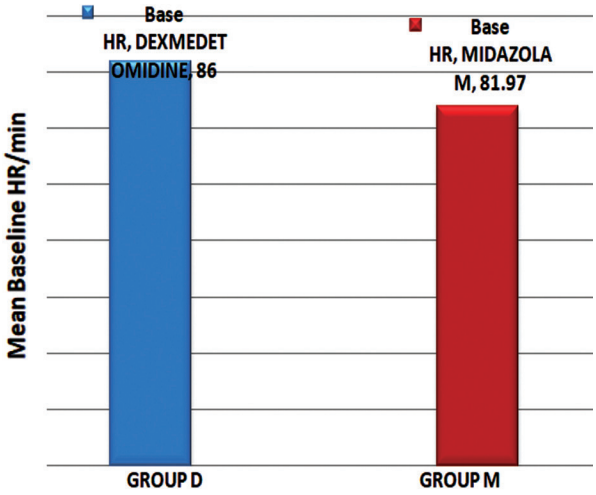

Fig. 5: Comparison of heart rate, Mean arterial pressure, Spo_2 and IOP in both groups.

Table 6: Comparison of HR in both the groups.

	GROUP D		GROUP M		
	Mean	SD	Mean	SD	P
Baseline	86.00	11.25	81.97	9.88	.133
Post drug injection	81.94	9.67	81.19	9.04	.750
Post bulbar block	80.03	8.79	80.53	9.09	.824
Intra-op 5thmin	77.97	9.61	80.38	8.99	.305
Intra-op 10th min	76.66	8.91	80.28	9.14	.113
Intra-op 15th min	75.78	8.87	80.38	8.80	.042
Intra-op 20th min	76.91	9.19	80.44	8.86	.172
Intra-op 25th min	77.16	9.05	80.31	9.05	.069
Intra-op 30th min	75.56	8.75	79.90	8.92	.060
Post-op 5th min	76.09	8.49	80.19	8.59	.160
Post-op 10th min	77.38	8.64	80.44	8.60	.107
Post-op 15thmin	77.00	8.44	80.53	8.85	.133

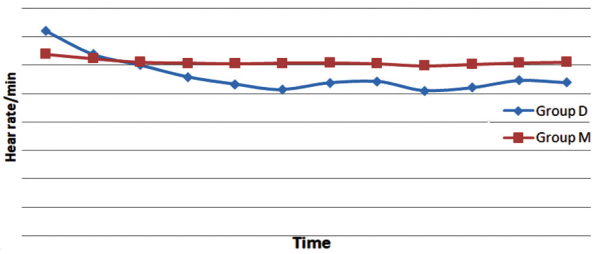

Fig. 6: Comparison of HR in both the groups.

Group D patients had decrease in heart rate when compared to Group M patients at intra-operative 5th minute to post-operative 15th minute.

Table 7: Comparison of MAP in both the groups.

	GROUP D		GROUP M		
	Mean	SD	Mean	SD	P
Baseline	92.00	9.61	89.41	7.20	.226
Post drug injection	87.81	8.21	86.41	5.91	.435
Post bulbar block	86.16	6.91	87.03	8.20	.646
Intra-op 5thmin	86.56	9.79	87.38	6.11	.692
Intra-op 10th min	86.53	7.86	88.25	6.04	.330
Intra-op 15th min	85.94	8.06	86.88	5.54	.590
Intra-op 20th min	86.13	8.48	85.75	4.91	.829
Intra-op 25th min	85.30	6.42	86.91	4.91	.271
Intra-op 30th min	85.15	5.63	86.30	4.79	.408
Post-op 5th min	86.16	5.75	86.78	4.34	.625
Post-op 10th min	85.72	6.11	85.97	5.10	.860
Post-op 15thmin	86.50	6.37	85.88	4.44	.650

Group D patients had lower MAP when compared to Group M patients at post bulbar block to post-operative 15th minute which is not significant.

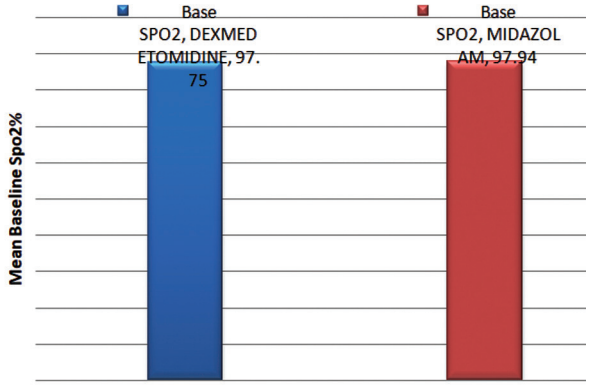

Fig. 7: Comparison of MAP between two groups.

Table 8: Comparison of SpO_2 in both the groups.

	GROUP D		GROUP M		
	Mean	SD	Mean	SD	p
Baseline	97.75	1.67	97.94	1.74	0.7
Post drug injection	97.78	1.68	96.09	2.66	0.003
Post bulbar block	97.78	1.60	95.72	2.87	0.001
Intra-op 5thmin	97.78	1.58	94.81	2.55	<0.0001
Intra-op 10th min	97.69	1.65	94.66	2.15	<0.0001
Intra-op 15th min	97.81	1.64	94.38	1.58	<0.0001
Intra-op 20th min	97.63	1.72	94.69	1.97	<0.0001
Intra-op 25th min	97.68	1.78	94.81	1.89	<0.0001
Intra-op 30th min	97.74	1.53	94.40	1.87	<0.0001
Post-op 5th min	97.87	1.60	94.78	2.61	<0.0001
Post-op 10th min	97.78	1.58	95.00	1.81	<0.0001
Post-op 15thmin	97.84	1.59	95.03	1.69	<0.0001

The mean SpO_2 in Group M was lower when compared to mean SpO2 in Group D at all the time which is statistically significant.

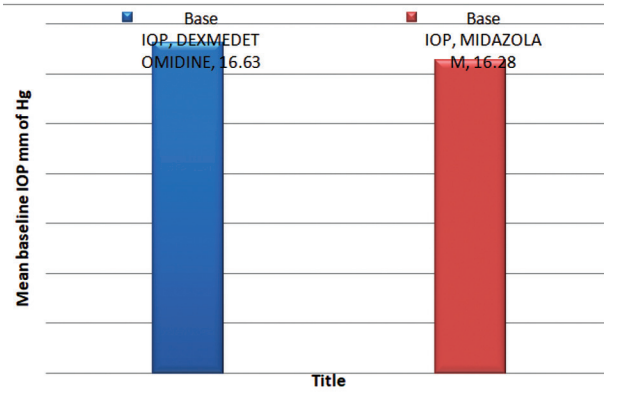

Fig. 8: Comparison of Spo_2 in both the groups.

Table 9: Comparison of IOP in both the groups.

	GROUP D		GROUP M		
	Mean	SD	Mean	SD	P value
Base IOP	16.63	2.20	16.28	1.99	0.5
post drug injection IOP	14.40	2.25	16.24	2.03	0.001
Post bulbar block IOP	12.58	2.12	14.26	2.01	0.002
		0.0001		0.0001	0.002

Mean IOP in Group D is 14.40±2.25mmof Hg at post drug injection and is 12.58±2.12mm of Hg at post bulbar block which is lower when compared to mean IOP in Group M at post drug injection and post bulbar block with statistically and clinically significant p value of 0.002.

Table 10: Comparison of RSS Score in both the groups.

	GROUP D		GROUP M		
	Mean	SD	Mean	SD	p
Post drug injection	2.56	.50	2.47	.51	.461
Post bulbar block	2.84	.37	2.72	.52	.273
Intra-op 5thmin	2.91	.30	2.81	.47	.344
Intra-op 10th min	2.94	.25	3.03	.59	.413
Intra-op 15th min	2.97	.18	3.13	.55	.133
Intra-op 20th min	2.97	.18	3.28	0.52	.002
Intra-op 25th min	2.94	.25	3.22	.55	.011
Intra-op 30th min	2.81	.40	3.20	.55	.004
Post-op 5th min	2.78	.42	3.09	.59	.017
Post-op 10th min	2.66	.48	3.03	.59	.007
Post-op 15thmin	2.47	.51	3.03	.54	.000

RSS score in Group D is lower than Group M at intra-operative 15th minute to post-operative 15th.

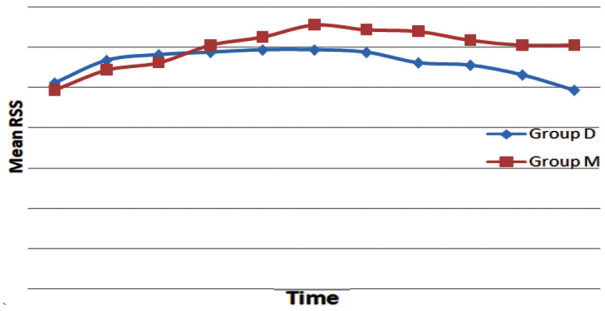

Fig. 9: Comparison of RSS score between two groups.

Table 11: Comparison of VAS score in both the groups.

	GROUP D		GROUP M	
	Mean	SD	Mean	SD
Post drug injection	.00	.00	.00	.00
Post bulbar block	.00	.00	.00	.00
Intra-op 5thmin	.00	.00	.00	.00
Intra-op 10th min	.00	.00	.00	.00
Intra-op 15th min	.00	.00	.00	.00
Intra-op 20th min	.00	.00	.00	.00
Intra-op 25th min	.00	.00	.00	.00
Intra-op 30th min	.00	.00	.00	.00
Post-op 5th min	.00	.00	.00	.00
Post-op 10th min	.00	.00	.00	.00
Post-op 15th min	.06	.25	.19	.40

VAS Score was comparable between both the groups

Table 12: Comparison of MAS Score in both the groups.

	GROUP D		GROUP M		
	Mean	SD	Mean	SD	P
Post-op 5th min MAS	9.22	.42	9.06	.44	0.15
Post-op 10th min MAS	9.34	.48	9.13	.42	0.06
Post-op 15th min MAS	9.50	.51	9.06	.44	<0.0001

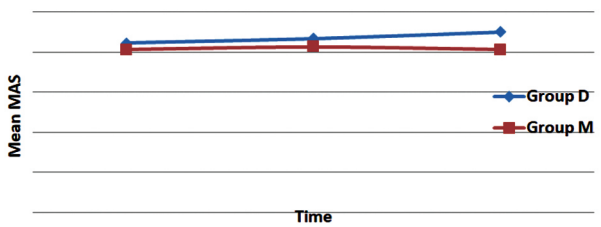

Fig. 10: Comparison of MAS Score in both the groups.

Mean MAS score in Group D is 9.22±0.42 at post-operative 5th minute with p value of 0.15, 9.34±0.48 at post-operative 10th minute with p value of 0.06, and 9.50±0.51 at post-operative 15th minute with p value of <0.0001. This p value was statistically significant, but not clinically as all the patients had MAS Score of 9-10.

Discussion

Patients of Group D received injection 0.25µg/kg dexmedetomidine diluted in 10ml of NS over 10 minutes and patients of Group M received injection 0.02mg/kg midazolam diluted in 10ml of NS over 10minutes. HR, MAP, SpO_2, IOP in non-operating eye were recorded. Peribulbar block was given with injection ligno-adrenaline and hyaluronidase. HR, MAP, SpO_2 and IOP in non-operating eye were recorded. HR, MAP, SpO_2, RSS and VAS score were recorded intra-operatively every fifth minute. Post-operatively, HR, MAP, SpO_2, RSS, VAS and MAS score were recorded every fifth minutes till fifteenth minute. Incidence of bradycardia, hypotension and decrease in SpO_2 were recorded.

Hypothesis made before starting the study

We hypothesized that dexmedetomidine compared to midazolam provides good sedation, reduces IOP, provides hemodynamic stability and can be used safely in patients undergoing cataract surgery.

Demographic Data

Demographic data comparing the age, gender, weight, height, BMI, ASA grade and duration of surgery [Table 1,2,3 and Figure 1,2,3] were comparable between both the groups and did not show any significant statistical difference.

In our study we observed a decrease in heart rate [Table 6 and Figure 6] in Group D when compared to Group M at intra-operative 5th minute to post-operative 15th minute but was not statistically significant and did not require any intervention. This was in accordance with the study done by J AAlhashemi et al[6] in 2006. They also observed decrease in heart in patients receiving dexmedetomidine but did not require any interventions.

In our study we observed that MAP[Table 7 and Figure 7] was comparable between both the groups. The study conducted by Hyo-Seok Na et al[7] in 2011, patients receiving dexmedetomidine had decrease in systolic blood pressure when compared to those patients receiving propofol alfentanyl combination. In this study patient of group D had received 0.6µg/kg/hr infusion, but in our study patients of Group D had received inj dexmedetomidine 0.2µg/kg diluted in 10ml NS over 10minute as single injection.

In our study we observed that there was a statically significant (p=<0.0001) reduction in SPO_2[Table 8 and Figure 8] in Group M when compared to Group D all the time, but it is not clinically significant as most of them have maintained SpO_2>90%. 4 patients of Group M had decrease in SpO_2 and required administration of oxygen via nasal prongs. This is in accordance with the study conducted by J AAllhashemi et al[6] in 2006 and Hoda H et al9 in 2016.

In our study we observed that patients of Group D had reduction of IOP [Table 9] at post drug injection (p=0.001) and at post bulbar block (p=0.002) which is statistically significant compared to Group M patients. This is in accordance with the study conducted by H Ayoglu et al[7] in 2007. They also observed significant reduction in IOP in patients receiving dexmedetomidine.

In our study we observed statistically significant difference in RSS Score[Table 10 and Figure 9] between Group D and Group M at intra-operative 20th, 25th and 30th minute, but it was not clinically significant as the RSS score is between 2 to 3, which indicates moderate (conscious) sedation. This was in accordance with the study conducted by DevangiA Parikh et al[8] in 2013.

VAS score [Table 11] was comparable between both the groups in our study, which was against the study conducted by Hoda H et al[9] in 2016.

In our study MAS score [Table 12 and Figure 10] post-operatively at the 5th and 10th minute was comparable between both the groups, but at 15th minute (p=<0.0001) there was a statistically significant difference between both the groups, and was not clinically significant, as both the groups patients had MAS score of 9, which indicated the readiness for discharge. This was in accordance with the study conducted by Hoda H et al[9] in 2016.

Conclusion

In conclusion, our study demonstrates that dexmedetomidine provides same conscious sedation as midazolam. Dexmedetomidine reduces intraocular pressure and maintains SpO_2 when compared to midazolam in cataract surgery.

Limitation

Sample size was small and single centre study and there is lack of correlation between causes of acute kidney injury and severity of hypomagnesemia

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(Dinesh Kumar Kashyap)

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A Comparative Study of Intrathecal 0.5% Bupivacaine and 0.5% Bupivacaine with Fentanyl in Patients Undergoing LSCS

Nafasat Tasneem Abroo[1], Vijaykumar T.K[2]

Author's Affiliation:

[1]MD, [2]Professor, Department of Anaesthesiology, B.L.D.E. (deemed to be university), Shri.B.M.Patil Medical College, Hospital and Research centre, Vijayapura 586103, Karnataka, India.

Abstract

This study was conducted to compare the effects of hyperbaric bupivacaine 0.5% alone versus hyperbaric bupivacaine 0.5% + fentanyl 25mcg in spinal anaesthesia in patients undergoing LSCS.

Objective: A prospective randomised comparative study, conducted to compare the onset and duration of analgesia and hemodynamic changes, side effects like nausea, vomiting, respiratory depression, shivering, pruritis, etc. if any.

Method: After institutional committee approval and obtaining written informed consent. 64 patients posted for LSCS were randomly divided into two groups with 32 patients in each group. All patients were examined before the surgery and thoroughly investigated as per institution protocol and counselled about the anaesthesia and procedure. Patients were instructed to fast for 6-8 hours before surgery. Baseline blood pressure, heart rate and oxygen saturation were recorded. Lumbar subarachnoid block was performed. After confirming free flow of CSF the drug was injected. Features assessed :The time of onset of sensory analgesia at T10 segment, maximum level of analgesia, degree of motor blockade, duration of effective analgesia, hemodynamic parameters and complications.

Results: Addition of fentanyl to bupivacaine can be safely administered in patients undergoing caesarean section without significant hemodynamic changes and adverse effects. It markedly improves intraoperative anaesthesia and significantly reduces need for postoperative analgesia. Total duration of analgesia with bupivacaine alone was 176.6 +/-31.9 mins versus 276.7+/- 31.4 mins with added fentanyl.

Conclusion: The addition of 25 micro gram of fentanyl to 2ml (10mg) of hyperbaric bupivacaine intensified and prolonged the duration of bupivacaine induced sensory block without affecting motor blockade.

Key words: Bupivacaine; Fentanyl; Intrathecal opoids; Obstetric anaesthesia; Post-operative pain management; Spinal anaesthesia.

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Corresponding Author: Nafasat Tasneem Abroo, MD, Department of Anaesthesiology, B.L.D.E. (deemed to be university), Shri.B.M.Patil Medical College, Hospital and Research Centre, Vijayapura 586103, Karnataka, India.
E-mail: me.naffu@gmail.com

Introduction

Surgical intervention in obstetric practice is becoming increasingly common. Intrathecal analgesia in labour has become an established technique, and various local anaesthetics and opioids have been used either alone or in combination.[1]

Spinal anaesthesia consists of the temporary interruption of nerve transmission within the subarachnoid space produced by injection of a local anaesthetic solution into subarachnoid space.

Spinal anaesthesia confers numerous advantages with smaller doses of local anaesthetic. It is simple to perform with rapid onset of action and good muscle relaxation. One main disadvantage is its limited duration of action, hence insufficient postoperative analgesia. To address this problem and to improve the quality of subarachnoid block, intrathecal Opioids are used as adjuvants to Bupivacaine. Among the manufactured narcotics, fentanyl is better due to higher potency, quicker beginning of activity and fast redistribution reducing its plasma concentration. Thus, improving the early postoperative analgesia.

So this study was undertaken to examine the effect of adding fentanyl to hyperbaric bupivacaine for spinal anaesthesia in patients undergoing elective LSCS.

Materials and Methods

Source of data: This study was carried out in the Department of Anaesthesiology, B.LD.E (Deemed to be University) Shri B. M. Patil Medical College, Hospital and Research Centre, Vijayapur.

Study Design: Prospective randomised comparative study

Study Period: One and half years from December 2018 to September 2020.

Sample Size: Total sample size 32+32=64

with anticipated mean difference of mean duration of analgesia between the study groups as 45.3 min and Anticipated SD as 40.1 min the minimum sample size per group was 32 With 95% power and 1% level of significance.

By using the formula:

$$n = \frac{(Z_\alpha + Z_\beta)^2 \, 2 \, SD^2}{MD^2}$$

Where Z= Z statistic at a level of significance

MD= Anticipated mean difference

SD= Anticipated Standard deviation

Hence 32 cases were included in each group.

The statistical analysis between the two groups will be compared using student's 't' test and chi-square test.

Randomization: The study population of 64 patients age and weight matched were randomly divided by computer generated slip into two groups with 32 patients in each group.

Group I received 0.5% Bupivacaine 2ml.

Group II received 0.5% Bupivacaine 2ml + Fentanyl 25 mcg.

Results were recorded using a preset performa.

Study group: After institutional committee approval and written informed consent, 64 patients posted for caesarean section were selected. A complete physical examination and routine investigations were done for all patients. Heart rate, non invasive blood pressure, Spo2 were monitored and recorded.

After taking informed consent. The cases were divided into 2 groups with 32 patients in each group by computer generated slip. Group I received Hyperbaric bupivacaine 0.5% 2ml (10mg). Group II receivedHyperbaric bupivacaine 0.5% 2ml (10mg) + fentanyl citrate (25mcg)

Inclusion criteria: Patients undergoing elective LSCS, Patients belonging to ASA grade I and II.

Exclusion criteria: Patients in whom regional anaesthesia is contraindicated, patients with foetal abnormalities, patients with known allergy to study medication, patient with history of hypertension, epilepsy, cardiac illness.

Investigations Required: Hemoglobin, total count, Platelet count, Random blood sugar, Blood Urea, Serum Creatinine, ECG, Others (if required).

Procedure: All patients were examined the day before surgery and thoroughly investigated according to institute protocol and counselled with regards to anaesthesia as well as procedure. Patient's meeting the above criteria were asked to participate in the study and informed consent was obtained. All resuscitation and monitoring equipments like bag-valve-mask system, laryngoscope, endotracheal tubes and emergency drugs were kept ready in the operation theatre for management of any adverse event.

On the day of operation, patient were taken to the operation theatre. Baseline values of blood

pressure, heart rate and oxygen saturation were recorded. Intravenous line was secured with 20G cannula and premedication i.e Inj.ondensetron 4mg given. The patients were placed in the left lateral position on the operating table. The back was cleaned with betadine and spirit.

The area draped with a sterile towel, L3 – L4 space identified and lumbar subarachnoid block was performed, using a 26 guage Quincke-Babcock spinal needle. After confirming free flow of CSF the drug was injected slowly at a rate of 0.25 ml per second.

Anaesthesia Features Assessed

- The time of onset of sensory analgesia at T10 segment. This is the time taken to achieve analgesia at T10 dermatome assessed by pin prick method.
- Maximum level of analgesia. This is the highest level of sensory block as assessed by pinprick method.
- Degree of motor blockade. Motar blockade is assessed using modified Bromage score.
- Duration of effective analgesia. This was taken as the time interval between injection of spinal drug to first reports of pain.Pain was assessed using visual analogue scale.

Rescue analgesia was given with injection diclofenac 1.5mg/kg IV infusion in 100ml normal saline and time of rescue analgesia was noted.

- Cardiovascular/hemodynamic status. After the block patient was monitored for pulse rate and blood pressure every 2 mins initially for 10 min and then every 15 min up to one hour and every 30 min thereafter, till the sensory block regresses to L1.

Bradycardia: A pulse rate of less than 60 beats per minute was considered bradycardia and it was treated with injection atropine 0.6mg IV bolus.

Hypotension: A systolic blood pressure of less than 90 mmHg or decrease in 20% below the base line systolic blood pressure was considered hypotension. It was treated with rapid infusion of IV fluids. Oxygenation via face mask, foot end elevation and injection ephedrine in incremental doses of 6mg IV bolus.

- Any complications or side effects like nausea, vomiting, respiratory depression, shivering, pruritus, etc. if any, were noted.

Results

	Group I	Group II
Mean age (years)	25.3+/-4.6	23.9 +/- 4.20
Mean weight (kgs)	52.0 +/- 1.6	51.0 +/- 2.1
Mean duration of surgery (min)	61.6 +/- 9.8	62.0 +/- 7.7
Mean time of onset of sensory analgesia (min) at T10	2.2 +/- 0.7	1.7 +/- 0.5
Mean height of analgesia (range)	T4 (T3 – T6)	T4 (T3 – T6)
Mean time for highest sensory level (min)	5.3 +/- 2	4.1 +/-1.7
Mean time for two segment regression from the highest sensory level (min)	93.8+/-15.7	129.5+/-33.1
Mean time for sensory regression to L1 from the highest sensory level	170.8+/-30.9	263.8 +/-29.6
Mean time for complete sensory recovery (min)	183.0+/- 31.9	274.5 +/-30.0
Mean time of total duration analgesia (min)	176.6+/- 31.7	276.7 +/-31.4
Mean time of onset to Grade III motor block (min)	3.0 +/-0.9	2.6 +/- 0.8
Mean time of duration of Grade III motor block (min)	112 +/- 21.3	133.3 +/-39.0
Complication: Hypotension(%)	43.8%	34.4%
Bradycardia (%)	15.6%	12.5%
Nausea and vomiting (%)	15.6%	12.5%
Shivering (%)	9.4%	6.3%
Itching (%)	0	6.3%
Respiratory depression (%)	0	0
Post dural puncture headache and neurological complication	0	0

Discussion

1. Onset of sensory analgesia was achieved in 2-3 minutes in a majority of patients in Group I and 1-2 minutes in a majority of patients in Group II which was significant ($p < 0.05$). The mean height of sensory analgesia range was T4 (T3-T6) in both the groups. The time taken to achieve the highest sensory level was 5.3 +/- 2.0 minutes in Group I and 4.1 +/- 1.7 minutes in Group II which was significant ($p<0.05$).
2. Time for two segment regression, time for sensory regression to L1 and time for complete sensory recovery was significantly prolonged in bupivacaine with fentanyl combination when compared to bupivacaine alone.

3. Time of onset to Grade III motor block was not significant (3.0 +/- 0.9 minutes in Group I and 2.6 +/- 0.8 minutes in GroupII).
4. The total duration of analgesia was significantly more in bupivacaine with fentanyl combination, i.e. 273.9 +/- 33.7 minutes when compared to bupivacaine alone group, i.e. 172 +/- 42.9 minutes.
5. The addition of fentanyl 25 mcg to bupivacaine 2 ml (10 mg) was not associated with any significant haemodynamic changes.
6. Hypotension, bradycardia, nausea-vomiting, shivering, pruritus were observed. These were significantly more in bupivacaine alone group. The incidence of hypotension (43.8%) was more in Group I compared to (34.4%) in group ll (bupivacaine and fentanyl)but it was not significant. p>0.05.
7. No cases of respiratory depression, post dural puncture headache or neurological complication were observed during 24 hours postoperativeperiod.

Conclusion

Spinal anaesthesia is the most versatile block available and is used for various surgeries on the lower half of the body. It is ideal in situations when rapid onset of action and profound motor blockade is required. The use of neuraxial opioids has gained popularity over the last few years. Administration of fentanyl intrathecally is an established method for intraoperative anaesthesia and to supplement postoperative analgesia Fentanyl is more lipid soluble than morphine. Thus it is readily eliminated from the CSF than morphine, making late respiratory depression less likely. Intrathecal use of fentanyl is advantageous due to its extremely rapid onset of action, getting desired level of analgesia and anaesthesia with minimum dosage of fentanyl as well as bupivacaine.

This study showed that fentanyl 25mcg prolongs the duration and intensity of bupivacaine induced sensory blockade block without affecting the onset and intensity of motor blockade. This suggests a potential synergism between fentanyl and bupivacaine.

We thus conclude that a combination of fentanyl and bupivacaine can be safely administered for patients who undergo caesarean section, without significant haemodynamic changes and adverse effects. It would markedly improve intraoperative anaesthesia and significantly reduce the demand for postoperative analgesic with good maternal satisfaction.

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A Comparative Study of Intrathecal Hyperbaric Bupivacaine 0.5% with Fentanyl versus Hyperbaric Bupivacaine 0.5% with Buprenorphine in Lower Limb and Lower Abdominal Surgeries

Nithyashree N[1] , Vijay V Katti[2]

Author's Affiliation:

[1]MD, [2]Associate Professor, Department of Anaesthesiology , B.L.D.E (Deemed to be university) Shri B. M. Patil Medical College, Hospital and Research Centre , Vijayapur 586103, Karnataka, India.

Abstract

Background: Various adjuvants have been added to bupivacaine to shorten the onset of block and prolong the duration of block. Present study was undertaken to compare the efficacy of intrathecal fentanyl or buprenorphine with bupivacaine for all infraumbilical surgeries.

Materials and Methods: 60 ASA I and II patients posted for various infraumbilical surgeries were chosen for the study and the patients were divided into two groups of 30 each. Group F received 3ml of 0.5% bupivacaine with 25µg of fentanyl and group B received 3ml of 0.5% bupivacaine with 60µg of buprenorphine.Sensory block was tested with pinprick method and motor block was assessed by onset of Bromage scale 3.

Results: Patient in Buprenorphine group showed a significantly prolonged duration of motor and sensory block than patients in fentanyl groyp and also postoperative VAS scores were significantly low for the buprenorphine group when compared with fentanyl.

Conclusion: To summarise, buprenorphine has higher efficacy with intrathecal bupivacaine with prolonged duration of sensory and motor blockade with decreased incidence of side effects, better haemodynamic stability and also analgesic sparing effect in the postoperative period when compared to fentanyl.

Key words: Bupivacaine; Buprenorphine; Fentanyl; Spinal Anaesthesia.

Introduction

Spinal anesthesia is the most commonly used technique for lower abdominal surgeries as it is very economical and easy to administer. The advantages of subarachnoid block are limited by its short duration of action, limited side effects and minimal hospital stay which makes it to be the choice of anaesthesia technique for various surgeries.[1]

However, postoperative analgesia is the main concern as spinal anaesthesia with local anaesthetics alone has short duration of action and hence requires early analgesic supplementation in postoperative period.Many adjuvents have been added to local anaesthetic such as morphine, midazolam, clonidine, fentanyl, buprenorphine and others to prolong duration of postoperative analgesia.[2,3]

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Corresponding Author: Vijay V Katti, Associate Professor, Department of Anaesthesiology, B.L.D.E (Deemed to be university) Shri B. M. Patil Medical College, Hospital and Research Centre, Vijayapur 586103, Karnataka, India.

E-mail: drvijaykatti@gmail.com

Fentanyl, a lipophilic opioid, has rapid onset of action following intrathecal administration. Addition of fentanyl to spinal anesthesia produces synergistic analgesia for somatic and visceral pain without increased sympathetic block.[7] Therefore, fentanyl provides better intraoperative analgesia and a safer alternative than morphine for management of early postoperative pain.

Buprenorphine is a centrally acting lipid soluble analogue of alkaloid thebaine. It exhibits analgesic property both at spinal and supraspinal level, when used intrathecally in combination with bupivacaine it has known to improve the quality and duration of postoperative analgesia compared to bupivacaine alone.[8]

Material and Methods

After taking written and informed consent,this clinical trial was done on 60 patients aged between 18-60 yrs belonging to ASA grade 1 and 2 who were posted for elective urological, lower abdominal, lower limb and gynecological procedure under spinal anaesthesia after getting clearance from ethical committee of the institution over a period of one and half year.

Patients were randomly assigned into two groups by a slip generated by computer with 30 patients in each.

Group "BB"- 0.5% hyperbaric bupivacaine 3ml +60µg Buphrenorphine.

Group "BF" -0.5% hyperbaric bupivacaine 3ml + 25µg Fentanyl.

Incusion Criteria

- Patients aged between 18 to 60 yearsof both sex planned for lower limb and lower abdominal surgeries.
- Patients belonging ASA grade 1 and 2.

Exclusion Criteria

- Patient refusal, infection at site of injection, hypersensitivity to study drugs, coagulopathy or other bleeding disorders, patients with heart blocks and patients with peripheral neuropathy, cardiac, hepatic, pulmonary, renal failure.

Procedure

After shifting of the patient to the OT table IV access with 18 guage cannula was obtained on the forearm and RL infusion started IV before the block. The monitors were attached to the patient which include NIBP,pulse oximeter and baseline PR, BP, RR and SpO_2 were recorded.

The patients were placed in left lateral or sitting position. Under all aseptic precautions,lumbar puncture was done by midline approach using disposable Quincke spinal needle (25G) at L3-L4 intervertebral space and study drug was injected after confirming CSF free flow. Patients were monitored intraoperatively using NIBP, pulse oximeter and ECG. Oxygen (5L/min) by facemask was given after spinal anaesthesia and fluid therapy was maintained with RL.

Hypotension defined as a decrease of systolic blood pressure by more than 20% from base line, was treated with IV bolus of ephedrine 5mg and IV fluids as required. Bradycardia was defined as heart rate less than 50 beats/minute, treated with IV atropine 0.6mg. Incidence of other side effects were noted and treated accordingly. Onset of sensory blockade was assessed by loss of pin prick sensation to hypodermic needle and highest level of dermatomal spread and time for two segment regression of sensory level and duration of sensory blockade was noted. Onset of motor blockade was assessed by modified bromage scale and duration of motor block was noted. Postoperatively pain was evaluated using visual analogue pain scale score at 3, 6, 12 hours. Injection Diclofenac 75mg in 100ml NS was given IV as rescue analgesia when VAS was ≤ 4.

The data obtained were entered in a Microsoft Excel sheet, and statistical analysis was performed using statistical package for the social sciences (Verson 17). Results are presented as drawings, Mean±SD, counts and percentages. Results were compared using Independent t test, Mann Whitney U test and Friedman test with Dunn's post hoc test.

For all tests, significant was achieved at $p<0.05$.

Results

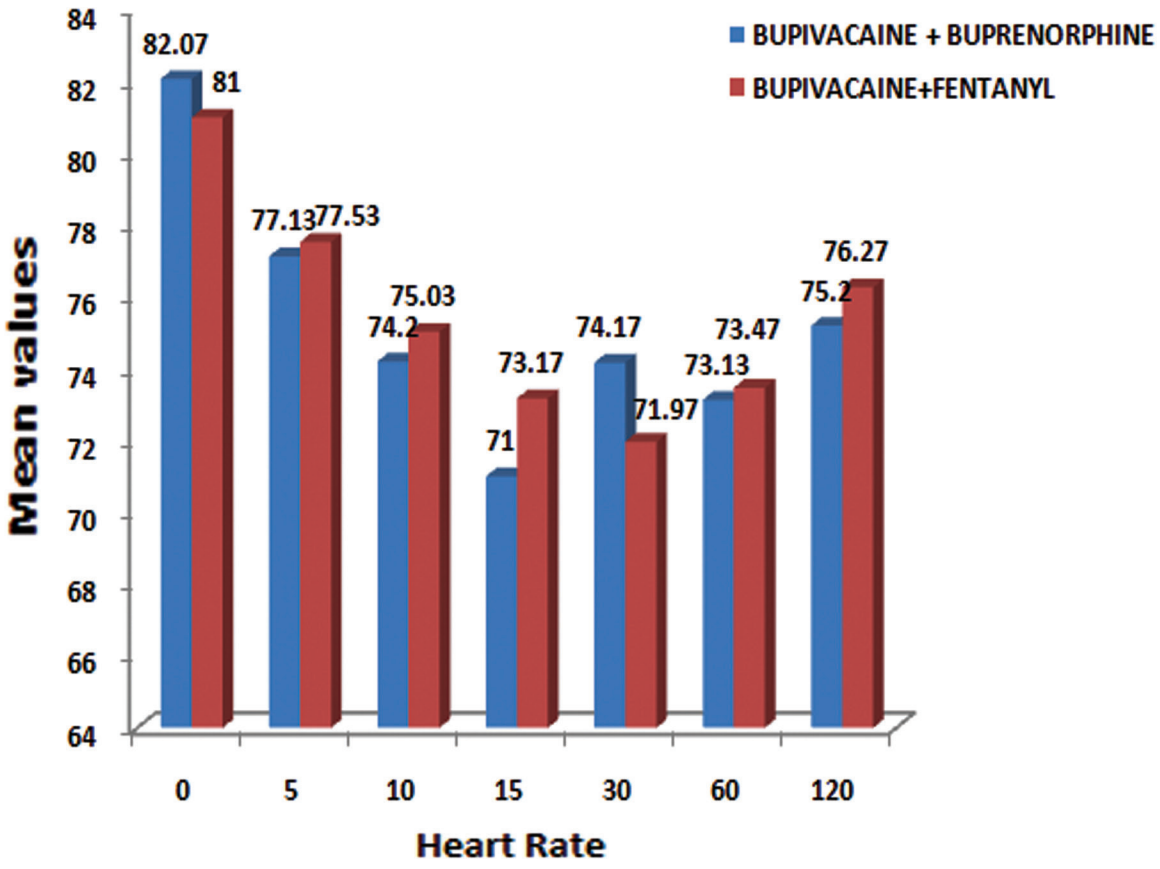
Both the groups were comparable with respect to age, gender, height and weight as shown in table 1, which shows no significant difference. The mean time for onset of sensory block in Group BB was 3.27±0.98 and group BF 3.23±0.728. The mean time for onset of motor block in Group BB was 6.67±1.36 and Group BF was 5.70±1.11. There was no statistical significance in both the groups with regards to onset of motor and sensory block. The time for two segment regression was considerably slower in Group BB with 118.87±6.99 compared to Group BF which was 101.97±7.97 which was statistically significant. The mean duration of

Table 1: Demographic Profile.

Basic variables	Bupivacaine + Buprenorphine		Bupivacaine+Fentanyl		Unpaired t test/ Mann Whitney U test	P value
	Mean	±SD	Mean	±SD		
Age(Years)	35.43	12.461	38.03	11.801	t=0.810	P=0.410
Height	5.53	.507	5.43	.302	U=415.000	P=0.595
Weight	58.13	7.394	57.53	8.460	t=0.292	P=0.771
			Insignicant			

Table 2: Recovery Parameters.

Basic variables	Bupivacaine + Buprenorphine		Bupivacaine+ Fentanyl		Mann Whitney U test	P value
	Mean	±SD	Mean	±SD		
Time for two segment regression	118.87	6.996	101.97	7.972	U=42.000	P=0.001*
Time to complete Motor recovery	247.33	15.522	179.07	11.209	U=0.500	P=0.001*
Time to complete Sensory recovery	281.23	16.245	207.50	14.248	U=0.000	P=0.001*
*:Statistically significant						



sensory block (time for complete sensory recovery) in Group BB was 281.23±16.2 and in Group BF was 207.50±14.23 which was statistically significant (table 2). The mean duration of motor recovery in Group BB was 247.33±15.52 and Group BF was 179.07±11.209. The mean duration of complete analgesia in Group BB was 300±17.01 and Group BF was 179.9±19.59 which was statistically significant. First rescue analgesia was given after 307 minutes in Group BB and in Group BF after 207 minutes which was significant statistically. At any interval the two groups did not differ statistically with respect to heart (Fig. 1). In group BB 3 patients had bradycardia which was treated with Inj. Atropine 0.6mg IV successfully. In Group BB 3.3% had nausea and 16% had hypotension and Group BF 6.66% had nausea and vomiting, 6.66% had hypotension.

Discussion

Spinal opioids and local anaesthetics have been shown to act synergistically at the spinal level in animal studies.[6] The advantage of combining the two types of agents in this manner is thought to be explained by their different analgesic properties and their ability to block pain at two different sites. Opioids produce analgesia by specifically binding and activating the opiate receptors in the substantia gelatinosa, whereas local anaesthetics provide analgesia by blocking impulse transmission at the nerve roots and dorsal root ganglia.[7]

Fentanyl, a lipophilic opiod agonist when used as an adjuvant prolongs the duration of spinal anaesthesia. Fentanyl is a lipophilic μ-receptor agonist opioid. Intrathecally fentanyl exerts its effect by combining with opioid receptor in the dorsal horn of spinal cord and may have supra-spinal spread and action.

Buprenorphine is a mixed agonist-antagonist type of opioid with a long duration. The high lipid soluability, high affinity for opioid receptors end prolonged duration of action makes buprenorphine a suitable choice for intrathecal and peripheral nerve site administration.

In our study, the intrathecal dose of Buprenorphine and Fentanyl was selected based on previous study conducted by Bhukya N et al. Our study showed, addition of 2mcg/kg Buprenorphine with hyperbaric bupivacaine significantly increased duration of both sensory and motor block. Bhukya N et al[8]. had studied the effect of addition of 2mcg/kg buprenorphine and 0.5mcg/kg fentanyl intrathecal to 3 ml hyperbaric bupivacaine for lower limb and lower abdominal surgeries concluded that duration of sensory block, motor block, analgesia and time to first rescue analgesia was significantly longer in buprenorphine group compared to fentanyl group, our results correlate with this study. Rashmi Pal, K.K. Arora, N.S. Doneria et al[9] conducted study on about 90 patient to evaluate the effect of adding clonidine, fentanyl and buprenorphine to intrathecal bupivacaine on spinal block and concluded that time for complete sensory recovery and motor recovery in buprenorphine group was slower compared to fentanyl group and the duration of analgesia and time for first rescue analgesia was significantly longer in buprenorphine group compared to fentanly group,our results correlate with this study.

In our study there is no significant difference with respect to change in mean systolic blood pressure in both the groups. But with regard to DBP there is statistical significant difference in reduction of mean DBP but not clinically (to become clinically significant, reduction in BP should be more than 20% of baseline).

Hence based on our clinical comparative study, we thus conclude that the addition of 60μg buprenorphine to hyperbaric Bupivacaine for spinal anaesthesia is a good alternative compared to 25μg Fentanyl. It provides longer duration of both sensory and motor blockade, good quality of both Intraoperative and postoperative analgesia. It had minimal side effects and better hemodynamic stability.

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A Comparision of Nitroglycerine and Dexmedetomidine for Controlled Hypotension in Endoscopic Resection of Juvenile Nasopharyngeal Angiofibroma

P. Indira[1], Seema[2], Deepraj Singh[3], Rajola Raghu[4]

Author's Affiliation:

[1,4]Associate Professor, [2]Post graduate, [3]Professor & Head of the Department, Department of Anaesthesiology, Osmania Medical College/Hospital , Hyderabad, Telangana 500095, India.

Abstract

Background: Juvenile nasopharyngeal angiofibroma(JNA) is a locally invasive benign vascular tumor, controlled hypotension is used to facilitate endoscopic resection. Nitroglycerine and Dexmedetomidine were compared as hypotensive agents in this study.

Methods : Ethics Committee has approved the study which was conducted at Government ENT hospital, Hyderabad during 2016 – 2018.Study included 40 patients divided into two groups, Group D (Dexmedetomidine) n=20,1µg/kg over 15 min followed by a maintenance infusion at 0.5µg/kg/hr,GroupN(Nitroglycerine) n=20- Nitroglycerine @ 0.5µg/kg/min and titrated in doses 0.5-5µg/kg/min for target blood pressure respectively.

Results : A statistically significant difference was observed in the study in mean pulse rate between two groups Group D-66.09±2.83, Group N-86.59±4.24, p value 0.0001. Blood loss was lower in Group D-310.71±140.58 compared to Group N 482.61±141.42 , and is statistically significant (p value 0.0004). SBP, DBPand MAP were comparatively lower in Group D throughout the surgery.

Conclusions: Dexmedetomidine is a better hypotensive agent with favourablehemodynamics and significantly less blood loss when compared to Nitroglycerine .

Key words: Controlled Hypotension; Dexmedetomidine; Endoscopy; Juvenilenasopharyng ealangiofibroma; Nitroglycerine; Massive Hemorrhage.

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Introduction

Juvenile nasopharyngeal angiofibroma (JNA) is a highly vascular, locally invasive benign tumor exclusive of male adolescents, incidence of 1:150,000 it was first described by Hippocrates in 5th century B.C., Friedberg (1940) called it juvenile angiofibroma[1] JNA arises from posterolateral wall of nasal cavity, anatomical location of tumor is readily accessible for transnasal endoscopic resection[2,3] which is gold standard of care. The tumor has vascular supply from external carotid system, potential risks exist throughout

Corresponding Author: Rajola Raghu, Associate Professor, Department of Anaesthesiology, Osmania Medical College/Hospital, Hyderabad, Telangana 500095, India.
E-mail: raghu.rajula@gmail.com

anesthesia- intraoperative massive bleeding, bronchoaspiration and airway obstruction after extubation.[4] Intraoperative bleeding[5] interferes with surgical field visibility, poses a challenge for both surgeon and anaesthesiologist. Controlled hypotension[6] provides a relatively bloodless field improves visibility of anatomical landmarks, minimizes blood loss and facilitates safe, rapid and effective tumor resection.Various pharmacological agents are used to achieve controlled hypotension. In this study we compared nitroglycerine (NTG) versus dexmedetomidine for inducing controlled hypotension with primary objective-monitoring haemodynamic parameters and secondary objective amount of intraoperative blood loss.

Patients and Methods

A prospective randomized single blinded study was conducted at Governement ENT Hospital, Osmania Medical College, Hyderabad. Institutional ethics committee has approved the study which included 40 patients in age group of 10-20 years posted for transnasal endoscopic resection of NPA. At pre-anaesthetic evaluation all patients were explained about surgery and written informed consent was obtained and were thoroughly investigated for comorbid conditions and cleared for surgery.

Patients were randomized into two groups- Group D(n=20), Dexmedetomidine -200µg in 100 ml of normal saline (2µg/ml), administered as iv infusion in pediatric volumetric burette set, dose 1µg/kg over 10 mins followed by maintenance infusion 0.5µg/kg/hr.

Group N(n=20)-Nitrogly cerine-25mg in 100ml normalsaline, infusion dose 5µg-1kg-1min-1 and titrated in the dose 0.5-5µg-1kg-1min-1to achieve desired mean arterial pressure.

Intraoperatively effects of both agents on hemodynamic parameters and blood loss during surgery were noted in a preset proforma.

Inclusion Criteria:	**Exclusion Criteria:**
ASA Grade I or II	ASA Grade III or IV H/o Coagulopathy
Age 10-20 yrs	Anticoagulants, H/o Drug sensitivity

Standard General anaesthesia technique was used in both groups, Glycopyrrolate 0.04mg/kg, Ondansetron 0.08mg/Kg, Thiopentone @ 3-5mg/kg and vecuronium 0.08mg/kg, Intubated with appropriate sized cuffed ET tube and throat packed. IPPV, 33:66 ; O2/N2O, desflurane 4-6%, Ventilation adjusted to maintain EtCO2: 30-35 mm Hg. Two 16 G venflon were secured on forearms, one for fluids, one for blood and another 20G venflon on dorsum of hand for infusion of hypotensive agents. A 15° Head up position used to facilitate venous drainage.

Monitoring: ECG-V5 lead with ST segment analysis to detect is chemia[7] NIBP, SPO_2, $EtCO_2$ Urine output. Before start of surgery, MAP was decreased to achieve a target MAP of 60-70 mmHg in both groups, baseline SBP, DBP, MAP, HR and SPO_2 were recorded and every 10min till end of surgery. Fluid therapy included–fasting fluid deficit was replaced during first 1 or 2 hr. maintenance, 5 to 6 mL/kg-hr of Ringer's lactate. Intraoperatively blood loss was measured by blood volume in suction bottles and swabs, if blood loss exceeds 20% to 25% of patient's total blood volume it was replaced with blood. Total duration of surgery was 150 mins in all patients. Severe hypotension (MAP<55mmHg) corrected by stopping inhalation agent, Mephentermine 6mgiv bolus.Bradycardia(HR<50bpm) corrected by Atropine 0.5mg iv. Hypotensive agent was stopped 10 minutes before anticipated end of surgery, residual neuromuscular block antagonized with neostigmine 50µg/kg & glycopyrrolate 10µg/kg. After recovery, patients were transferred to post anesthesia care unit (PACU).

Statistical Analysis was done using :

1. Mean
2. Standard deviation
3. Independent t test (for hemodynamic parameters)

Data was entered using MS Excel software and analysed using SPSS 16 version software for determining statistical significance. p values < 0.05 are considered statistically significant.

Observations and Results

Study included 40 patients posted for endoscopic resection of NPA, divided into two groups, Group N(n=20) received NITROGLYCERINE, Group D(n=20) received Dexmedetomidine respectively for controlled hypotension. Intraoperatively hemodynamics (HR, SBP, DBP, MAP) were observed in both groups and recorded in a tabular form for statistical analysis, amount of blood loss between two groups was compared.

Table 1: Distribution of mean age & weight of study groups.

	GroupN (Mean±S.D.)	**GroupD(Mean±S.D.)**	**'p' value**
Age	15.33±2.64	15.94±2.26	0.4373
Weight	45.29±9.75	45.29±9.75	0.8192

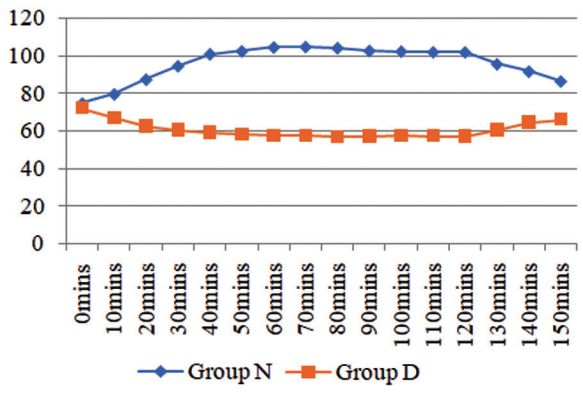
All patients were males in the age group 10-20 years and weight in the range of 28-60Kg and no statistically significant difference was noted between both groupss (p>0.05) (Table.1).

Hemodynamic Variables

Table 2: Intraoperative Pulse Rate variations.

Time (mins)	Group N	Group D	't' value	'p' value
	Mean±S.D.	Mean±S.D.		
0	74.86±8.39	72.05±6.07	1.2135	0.2324
10	79.74±7.81	67.05±5.85	5.8159	0.0001
20	87.53±7.11	62.62±5.49	12.4015	0.0001
30	94.83±5.69	60.49±4.49	21.1878	0.0001
40	100.98±4.94	59.10±3.44	31.1132	0.0001
50	102.53±4.96	58.11±3.23	33.5618	0.0001
60	104.56±6.64	57.47±2.92	29.0325	0.0001
70	104.81±6.6	57.45±3.42	28.4928	0.0001
80	104.20±6.69	57.05±3.36	28.166	0.0001
90	102.72±6.23	57.34±3.45	28.4977	0.0001
100	102.40±5.8	57.48±3.6	29.1922	0.0001
110	102±5,66	57.39±3.54	29.8841	0.0001
120	101.99±5.98	57.35±3.34	29.146	0.0001
130	95.69±5.59	60.63±2.92	24.8613	0.0001
140	91.77±3.8	64.49±2.72	26.1065	0.0001
150	86.59±4.24	66.09±2.83	17.9844	0.0001

Graph 1: Intraoperative Heart rate variations.

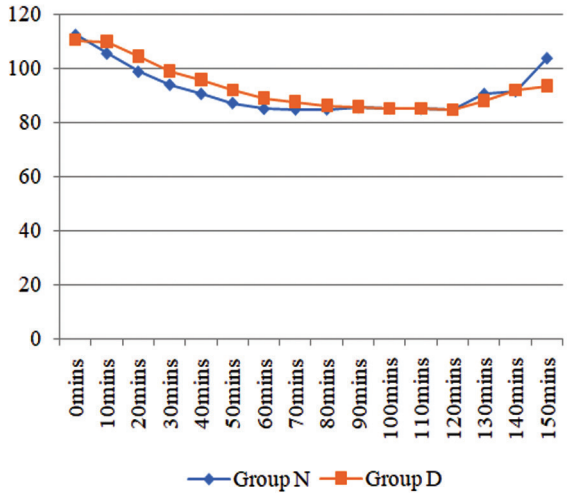


Heart rate was observed in both study groupsat specified intervals and the difference was highly significant (p<0.0001) statistically (Table. 2), with lower pulse rates recorded in group D (Graph.1) from 10 minutes of starting test drug infusions to stopping infusion (57.05±3.36 and 67.05±5.85) when compared with nitroglycerine group (79.74±7.81 and 104.81±6.6).

Table 3: Systolic Blood Pressure variations.

Time (mins)	Group N	Group D	t value	P value
	Mean±S.D.	Mean±S.D.		
0	112.47±10.02	110.37±11.11	0.6277	0.5339
10	105.62±9.65	109.79±9.72	1.3615	0.1814
20	98.91±8.95	104.30±9.33	1.8644	0.07
30	94.11±7.86	99.02±8.33	1.8241	0.07
40	90.74±7.24	95.85±8.28	2.0017	0.0525
50	87.37±6.15	91.96±7.17	2.0145	0.0511
60	85.24±5.02	89.01±6.08	1.9961	0.0531
70	85.03±4.52	87.71±5.48	1.6127	0.1151
80	85.05±4.42	86.33±5.17	0.8336	0.0497
90	85.73±4.39	85.89±4.65	0.1122	0.9113
100	85.34±3.99	85.33±4.53	0.007	0.9945
110	85.26±4.18	85.23±4.69	0.0222	0.9824
120	84.95±5.98	84.87±3.34	0.0569	0.9549
130	90.71±3.94	88.10±4.22	2.0217	0.0503
140	91.77±3.8	91.99±4.42	0.1688	0.8669
150	103.89±5.88	93.56±4.14	6.4241	0.0001

Graph 2: Intraoperative Systolic blood pressure variations.



The mean systolic blood pressure, mean diastolic blood pressure and mean arterial pressure recorded in group D were marginally less when compared with Group N from 90mins of starting test drug infusion to stopping infusion.

The mean SBP, DBP and MAP recorded were significantly lower in Group D (Table.6) after stopping test drug infusion ('p' value 0.0001)

Table 4: Diastolic Blood Pressure variations.

Time (mins)	Group N	Group D	t value	'p' value
	Mean±S.D.	Mean±S.D.		
0	74.91±6.14	71.88±7.01	1.4493	0.1555
10	69.14±5.53	72.25±7.26	1.524	0. 1358
20	64.22±4.9	67.98±6.75	2.016	0.0509
30	60.04±4.52	63.27±6	1.9229	0.062
40	57.85±3.41	59.12±3.12	1.2288	0.2267
50	54±3.38	55.25±3.34	1.1764	0.2467
60	52.75±3.23	53.74±2.6	1.0678	0.2924
70	52.51±3.15	52.85±2.38	0.3851	0.7023
80	52.82±2.82	53.25±3.26	0.4461	0.658
90	52.98±2.79	52.92±2.95	0.76	0.452
100	52.58±2.83	52.57±2.87	0.00111	0.9912
110	52.48±2.83	52.42±2.89	0.0663	0.9475
120	52.79±2.43	52.54±2.41	0.3267	0.7457
130	57.72±3.01	56.49±2.54	1.3967	0.1706
140	62.56±3.36	60.96±2.12	1.8011	0.0769
150	70.75±4.8	63.02±1.95	6.6724	0.0001

Graph 3: Intraoperative Diastolic Blood pressure variations.

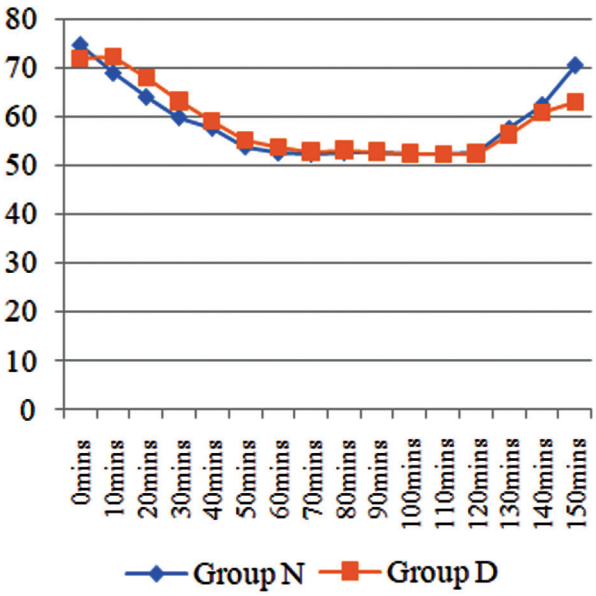
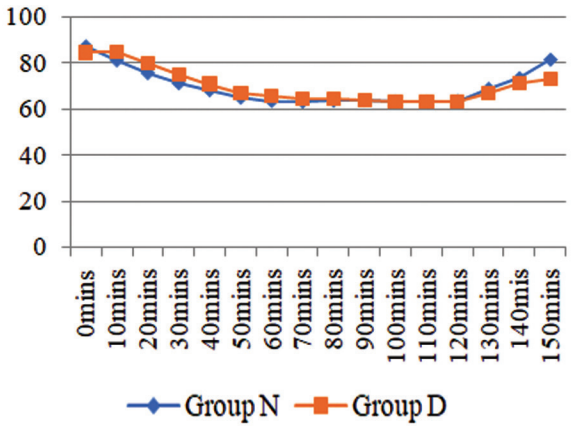


Table 5: Intraoperative Mean Arterial Pressures between study groups.

Time (mins)	Group N	Group D	t value	P value
	Mean±S.D.	Mean±S.D.		
0	87.48±7.04	84.73±8.12	1.1444	0.2596
10	81.51±6.4	84.92±7.72	1.5208	0. 1366
20	75.88±5.89	79.89±7.23	1.923	0.062
30	71.41±5.32	75.08±6.5	1.954	0.0581
40	68.33±4.87	71.05±3.75	1.979	0.0551
50	65.11±4.27	67.18±4	1.5822	0.1219
60	63.64±3.09	65.61±4.27	1.737	0.0905
70	63.36±3.34	64.48±3.01	1.114	0.2723
80	63.67±3.3	64.42±3.3	0.4461	0.4767
90	63.92±3.16	63.87±3.3	0.7187	0.9612
100	63.52±3.16	63.52±3.28	0	1
110	63.48±3.05	63.47±3.18	0.0101	0.992
120	63.58±2.97	63.38±2.99	0.2122	0.8331
130	68.89±2.91	67.14±2.82	1.9313	0.0609
140	73.62±3.34	71.35±2.66	2.3776	0.0226
150	81.7±5.01	73.2±2.55	6.762	0.0001

Graph 4: Intraoperative Mean arterial pressure variations.



(Graph. 5) Attributed to spectrum of effects of dexmedetomidine extending into postoperative period.

Table 6: Blood pressure variations after stopping the study drug infusion.

Time -150 mins	Group N	Group D	't' test	'p' value
SBP	103.89±5.88	93.56±4.14	6.4241	0.0001
DBP	70.75±4.8	63.02±1.95	6.6724	0.0001
MAP	81.7±5.01	73.2±2.55	6.762	0.0001

Graph 5: Blood pressure variations after stopping test drug infusion in both study groups.

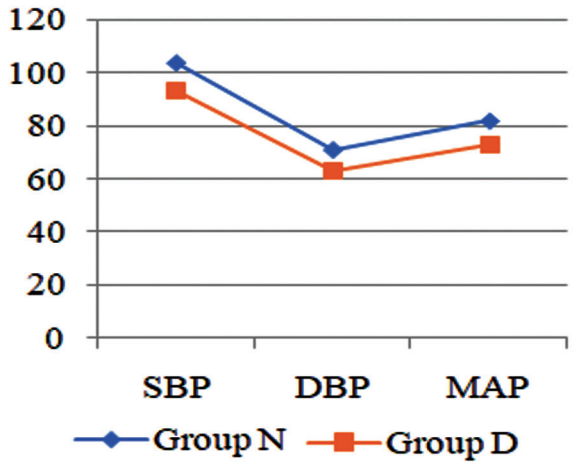
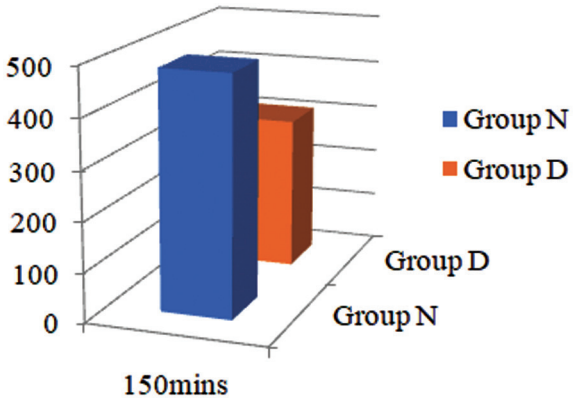


Table 7: Intraoperative Blood Loss.

Mean ± S.D.	Blood loss	't'test	'p' value
482.61±141.42	Group N	3.8553	0.0004
310.71±140.58	Group D		

Graph 6: Comparision of intraoperative blood in both study groups.



Intraoperatively blood loss was less in Group D when compared with Group N (Table. 7) and difference is statistically significant ('p'value0.0004) (Graph. 6), because of favourable hemodynamic profile induced by dexmedetomidine.

Discussion

In 1918, Canon and his colleagues introduced concept of permissive hypotension[8] as a resuscitation strategy used in acute phase of traumatic hemorrhagic shock and its variation known as controlled or induced hypotension (IH) were used in various specialities to create a clearer surgical view, reduce intraoperative blood loss and facilitate surgery.

The etiology of JNA is unknown, anaesthesia management[8] of these tumors is a challenge owing to vascularity, adjacent anatomical structures and intraoperative bleeding, transnasal endoscopic[53] resection is gold standard of care, with controlled hypotension tumor removal is easier, quicker and satisfactory.

Definition of controlled hypotension takes into account level of hypotension required toproduce effect, same time limited by safety(ECKENHOFF & RICH'1966).

Harvey Cushing(1917) proposed deliberate hypotension to provide a bloodless field and better operative conditions for neurosurgery.[9]

Enderby[10] used ganglionic blocking drugs for controlled hypotension in maxillofacial surgery. Schalberg, 1976[11] reported using sodium nitroprusside for hypotensive anaesthesia and blood loss in orofacial corrective surgery.

A mean arterial pressure 30% below a patient's usual MAP, with a minimum of 50 mm Hg in ASA Class I patients and 80 mm Hg in elderly, is clinically acceptable[12], hypotension should be considered satisfactory when bleeding is minimal with adequate organ perfusion (urine out put>0.5ml/kg/min). In theory, as long as mean arterial pressure exceeds sum of colloid osmotic pressure and venous pressure, circulation should be adequate for tissue needs, theoretically a pressure of 32 mm Hg should be sufficient, in practice it is below the safe limit due to specific blood flow requirements of different organs. Controlled hypotension rarely results in vital organ damage as autoregulation maintains their perfusion over a wide range of blood pressures.

The use of dexmedetomidine for providing hypotensive anaesthesia during septoplasty and tympanoplasty[13,14] was studied by Durmus M et al and Ayoglu H et al.

Hypotensive anesthesia should be induced in relation to patient's preoperative blood pressure rather than specific target pressure and limited to level necessary to provide a bloodless field , within safety limits of cerebral and coronary blood flow.

Techniques of Hypotensive Anaesthesia: The key equation is Mean Arterial Pressure=Cardiac Output x Systemic Vascular Resistance (SVR).Thus MAP can be decreased by reducing SVR, CO or both. A reduction in cardiac output for hypotensive anaesthesia is not ideal because maintenance of tissue blood flow is essential. SVR can be reduced by peripheral vasodilation whilst cardiac output can be reduced by lowering venous return, heart

rate, myocardial contractility or a combination of these.

Strategies for Inducing Controlled Hypotension.

Category	Strategy	Examples
Decrease cardiac output	Reduce blood volume	Arteriotomy
	Dilate capacitance vessels	Nitroglycerin
	Decreasecardiac contractility	Inhalation anesthetics (eg, halothane), β-blockers (eg, esmolol)
	Decrease heart rate	Inhalational agents, β-adrenergic blockers
Decrease peripheral vascular resistance	Block autonomic ganglia	Methonium compounds, Pentolinium, Trimethaphan
	α-adrenergic receptor blocker	Phentolamine, Labetalol
	Vascular smooth muscle relaxation	Direct-acting vasodilators (eg, nitroprusside), Calcium-channel blockers (eg, nicardipine), Purines (eg, adenosine), prostaglandin E1, Inhalational anesthetics (eg,Isoflurane)

Measures such as changing position of patient, adjusting airway pressure, adding other drugs to complement activity of primary hypotensive agent(eg., N-acetylcysteine) facilitate induced hypotension. Various drugs are used to achieve controlled hypotension-eg., Nitroglycerine, α-adrenergic receptor blockers, volatile anaesthetics, autonomic ganglion-blockers, β-adrenergic blocking agents, prostaglandin E1, $MgSO_4$ and Ca2+channel blockersand alpha2 agonists eg., dexmedetomidine[15]. Drugs used to produce controlled hypotension must be easy to administer, have a short onset time, an quick offset time on discontinuation, a rapid elimination without toxic metabolites, negligible effects on vital organs, and predictable dose-dependent effects.

Nitroglycerine (NG) was discovered in 1847 by Ascanio Sobrero in Turin, following work with Theophile-Jules Pelouze. Nitrovasodilators[16], (NTG) predominantly dilate capacitance vessels , reduce venous return with concomitant decrease in stroke volume and cardiac output, resulting in hypotension. NTG is frequently used to produce controlled hypotension as it is easily titratable, onset of action is rapid within 1 min and t½ is 2 min. Intravenous infusion is started at 1-2µg/kg/min, there is no upper limit to rate of infusion no toxic metabolites are reported, reversal is spontaneous after stoping infusion. Disadvantages are tachyphylaxis, reflex tachycardia and venous congestion leading to increased blood loss and dose related increase in bleeding time.

Dexmedetomidine is a dextrorotatory S-enantiomer of racemate medetomidine (50:50),((+)-4- (2,3-dimethyle phenyl) ethyl-1 H-imidazole monohydrochloride) (Kuusela et al. 2001)[7]. Itis a highly selective α2-adrenoceptor agonist , with spectrum of beneficial effectslike anxiolysis sedation, analgesia,central sympatholytic effect with a decrease in serum norepinephrine[17,18,19] levels which makes it a good agent for hypotensive anaesthesia. It enhances anaesthesiaby stimulating central α2 and imidazoline receptors, has opioid sparing effects.[20] A biphasic cardiovascular response has been described after i.v.bolus of 1µg/kg dexmedetomidine, initially a transient hypertension and reflex bradycardia are noticed ,due to peripheralα2β-adrenoceptor stimulation of vascular smooth muscle , this is attenuated by a slow infusion over 10 or more minutes.[21,22] Dexmedetomidine exhibits linear pharmacokinetics distribution phase is rapid, with a t½ of distribution 6 min(approx.).[23] Advantages of dexmedetomidine are no reflex tachycardia and no rebound hypertension.

Hypotensive anaesthesia in total hip arthroplasty significantly decreased intraoperative blood loss and operating times compared to normotensive group, Gale Thompson et.al., (Anesthesio -logy;48;91-96;1978), efficacy of dexmedetomidine in providing better surgical field and less blood loss during controlled hypotension was reported by Durmuset.,al,[24] intympanoplasty, septoplasty and maxillofacial surgeries. A single dose of dexmedetomidine 0.5µg/kg/min iv,10mins before induction produced a significant fall in MAP and Heart rate as reported by., Basaret., al,[25] In patients who received dexmedetomidine no other analgesic or anxiolytics were used because of inherent properties.[26,27] Controlled hypotension with dexmedetomidine in middle ear and maxillofacial surgeries provided an ideal surgical field with predictable hemodynamic effectsresults of this study concluded the same. Ulger et al.,[28] comparednitroglycerine with dexmedetomidine as hypotensive agents (MAP 65-75mmHg) in middle ear surgery, conclude dhypotension and hemodynamic stability was better with dexmedetomidine, results in present study are in accordance with this study. In Group D dose of thiopentone used for induction was lower correlates with study of Peden et al.[29] Dexmedetomidine shows better hemodynamic

stability, clear surgical field, lower(VAS) pain scores and few side effects in FESS, Guven et al., and Goksu et al.[30,31] Cincikas and Ivaskevicius[32] used nitroglycerine infusion (0.79 ± 0.34 µg/kg/min) during FESS to maintain MAP-50-60 mmHg, observed reduced surgical bleeding and improved endoscopic vision. In this prospective randomized study, Dexmedetomidine and Nitroglycerine were equally effective as hypotensive agents (MAP of 60-70mmHg). It was observed dexmedetomidine ensured ideal surgical conditions and average blood loss was less when compared with NTG. In Group N, Fentanyl was used @ 2µg/kg, NTG infusion (0.5-5ug/Kg/min) started after intubation and before surgical incision and titrated dose to maintain mean pressure range of 60-70mmHg. Induction of controlled hypotension with NTG depends on intravascular fluid volume.

Excessive decreases in diastolic blood pressuredecreases coronary blood flow and mayevoke baroreceptor-mediated reflex increases in sympathetic nervous system activity result in tachycardia and increased myocardial contractility. Nitroglycerin produces a dose-related prolongation of bleeding time thatparallels hypotension, it may also be due to direct effect of nitroglycerin on vascular tone resulting in vasodilation. Karl-Erik Karlberg associates[33] assessed effect of iv NTG and concluded NTG inhibits plateletaggregationin higher doses due to glyceryl dinitrate formation.

In this study throughout surgery ,difference in mean heart rates in,GroupD: (60.61 ± 4.49) and Group-N(95.58 ± 9.41) (Table.2), and which is statistically significant from 10mins of starting the test drug infusions (p value < 0.0001) (Graph.1).

The mean SBP(GroupD-92.73 ±8.58, GroupN-91.86±8.77) (Table.3) (Graph.2), DBP (GroupD-58.40±7.03, Group N-58.33±7.48) (Table. 4) (Graph. 3), MAP(GroupD-69.85 ± 7.47, Group N-69.54 ± 7.91) (Table.5) (Graph. 4) between two groups shows no statistically significant difference.

Infusion of hypotensive agent was stopped 10mins before end of surgery. Intraoperatively mean blood loss in Group N-482 ± 141.42 and Group D-310.71±140.58 (Table. 7) (Graph. 6) respectively, the 'p' value was 0.0004.

Results in this study suggests that both Nitroglycerine and Dexmedetomidine are equally good for inducing controlled hypotension in endoscopic resection of NPA. Intraoperative blood loss in Group D, the increased blood loss in Group D was significantly less when compared with Group N" with nitroglycerin can be due to increased heart rate, prolongation of bleeding time by NTG due to inhibition of platelet aggregation partially off settingbeneficial effects of hypotension.

Limitations

1. Rare incidence of tumor.
2. Lack of Cardiac output monitoring.
3. Inability to measure bleeding tendencies with NTG.
4. Small sample size, cannot be concluded the results of present study are definitive.
5. More studies are required to conclude results.

Further recommendations

1. There is scope for further studies related to this topic.
2. Different doses of dexmedetomidine can be compared and studied.
3. Synergism of combination of dexmedetomidine with other drugs to be evaluated.

Conclusion

Dexmedetomidine was safe and equally effective in producing controlled hypotension when compared with Nitroglycerine, Dexmedetomidine has advantage of cardiovascular stability and less blood loss. The inherent properities of anxiolysis, sedation, analgesia, opioid and anaesthetic sparing effects, easy administration, predictability with anesthetic agents and lack of toxic side effects while maintaining adequate perfusion of vital organs makes dexmedetomidine a safe and near ideal agent for hypotensive anaesthesia."

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Comparative Evaluation between Ropivacaine versus Ropivacaine with Dexmedetomidine in Ultrasound Guided Parasagittal Brachial Plexus Approach in Upper Limb Orthopedic Surgeries

Karthik GS[1], Sudheer R[2], Mahima KB[3], Shivasharn K Hosalli[4], S. Rangalakshmi[5], Nivedha P[6]

Author's Affiliation:

[1,2]Professor, [5]Professor and HOD, [3,4,6]Junior Resident, Department of Anaesthesiology, Rajarajeswari Medical College and Hospital, Bangalore, Karnataka 560074, India.

Abstract

Background: Ropivacaine has been used for brachial plexus block because of its safety profile. Dexmedetomidine is one of the adjuvants added to Ropivacaine as it is known to potentiate sensory and motor blockade.

Aim: Our aim was to compare and assess the effectiveness of adding Dexmedetomidine as an adjuvant to 0.75% ropivacaine in supraclavicular brachial plexus block using parasagittal approach for duration of analgesia primarily. Onset and duration of sensory and motor blockade were also the variables compared.

Materials and methods: A prospective single blinded randomized comparative clinical study was carried out among in eighty patients of ASA Grade I and II between the ages of 20-60yrs, scheduled for elective upper limb orthopedic surgeries involving the forearm under supraclavicular brachial plexus block using parasagittal approach. Group R received 20ml of 0.75% ropivacaine along with 1ml of normal saline while Group RD received 20ml of 0.75% ropivacaine along with 0.5mcg/kg dexmedetomidine constituted to 1ml. Sensory, motor blockade & analgesic efficacy was determined.

Statistical Analysis: Student t-test was used for demographic and hemodynamic data analysis. Unpaired t-test was used for evaluation of data which consisted of onset, duration of sensory and motor blockade along with duration of analgesia. The results were statistically significant if p-value <0.05. P-value <0.001 was considered highly significant.

Results: Duration of analgesia lasted longer in Group RD (991.09 ± 16.34) when compared to Group R (542.57 ± 18.37). Onset time for sensory and motor blockade were rapid in Group RD (7.71 ± 1.23, 13.66± 1.03) when compared to Group R (10.14 ± 1.00, 18.60 ± 1.54). Duration of sensory blockade was prolonged in Group RD (780.26 ± 31.43) when compared to Group R (455.57± 20.28). Duration of motor blockade was also enhanced in Group RD (725.57 ± 25.18) when compared to Group R (397.74 ± 24.92).

Conclusion: Addition of Dexmedetomidine to Ropivacaine provided superior analgesia along with faster onset and longer duration of sensory and motor blockade.

Key Word : Brachial Plexus; Supraclavicular; Parasagittal; Ultrasound; Ropivacaine; Dexmedetomidine.

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Corresponding Author: Mahima KB, Junior Resident, Department of Anaesthesiology, Rajarajeswari Medical College and Hospital, Bangalore, Karnataka 560074, India.
E-mail: mahimabalakrishnaiah@gmail.com

Introduction

Brachial plexus block has evolved as a safe alternative to general anesthesia for upper limb surgery and for relief of perioperative pain. Advancements in regional anesthesia techniques in terms of local anesthetic drugs, newer adjuvant drugs and use of ultrasound for safe and successful conduct of block has increased its popularity. It helps in reduced hospital stay, less financial burden and also leads to avoidance of undesirable side-effects of general anesthesia.[1]

Ropivacaine is a local anaesthetic effective for both intraoperative anaesthesia and post-operative analgesia by binding to open voltage-gated Na+ channels thereby increasing the frequency of nerve depolarization in a reversible and concentration-dependent manner. Lower lipid solubility of ropivacaine causes greater sensory and motor differential blockade, which is advantageous.[2,3]

Several adjuvants may increase the duration of nerve block. Adjuvant drugs such as alpha-2 adrenergic receptor agonists, opioids, ketamine, dexamethasone and others can be used to increase block duration. Dexmedetomidine is a highly selective alpha-2 adrenergic receptor agonist,[4] its action in peripheral nerve blockade is due to increase in hyperpolarization activated cation current that prevents the nerve from returning to resting membrane potential.[1]

Methods

After obtaining institutional ethical committee clearance, patients belonging to ASA status I & II, aged between 20-60 yrs scheduled for elective upper limb (forearm) orthopedic surgeries under ultrasound guided supraclavicular brachial plexus block using parasagittal approach at Rajarajeswari Medical College and Hospital, were recruited for a prospective randomized single blinded study. Patients with bleeding disorders, uncontrolled diabetes mellitus, renal and liver diseases, pregnant and lactating women, patients with epilepsy, neurological diseases & known hypersensitivity to local anesthetics were excluded from the study. The patients in whom block was not found effective were excluded from the study and given general anaesthesia.

Patients were randomly allocated into two groups based on open envelope method, Group R and RD. Based on a previous study conducted by Kathuriaet.al, with a confidence level of 80% and keeping the mean time of duration of analgesia as one of the primary variables at the p value of < 0.05, we selected 40 patients in each group for our study. Group R - patients received 20ml of 0.75% ropivacaine along with 1ml of normal saline. Group RD - patients received 20ml of 0.75% ropivacaine along with 0.5 mcg/kg of dexmedetomidine constituted to 1ml.

All patients were subjected to detailed pre-anesthetic workup and evaluation. On the day before surgery patients were attended, examined, explained regarding the procedure and taught to interpret the visual analogue scale (VAS). Written informed consent was taken.

Routine fasting guidelines were maintained. Premedication was given with oral alprazolam 0.25 mg and ranitidine 150 mg night before surgery and inj. Ondansetron 4mg & inj. Ranitidine 50mg, 30 minutes prior to surgery.

After shifting the patient to operation theatre, standard anesthesia monitoring in the form of baseline measurement of heart rate, non-invasive arterial blood pressure, ECG and oxygen saturation (SpO2) were started. Intravenous line was secured with 18G cannula in the unaffected limb and I.V. Fluids were given according to the requirement.

The tray containing all necessary drugs and equipments for giving brachial plexus block was prepared. Both groups receiving the block were unaware of the composition of the drugs used. Patients were positioned supine on the table with pillow under the shoulder with the head turned 45 degrees to the contralateral side to make the landmarks more prominent.

An ultrasound machine (sonosite) and a 7-13 MHz linear type probe used, after strict aseptic skin preparation probe was placed in parasagittal plane in the anterior part of supraclavicular fossa, after local anesthetic infiltration with lignocaine, a 23G spinal needle was advanced from the anterior border of the trapezius muscle.

A 10cm extension was attached to the needle. Using an in-plane technique the needle was advanced till the tip entered the sheath of plexus, and then volume of prepared local anesthetic mixture either with 1ml of normal saline or 0.5mcg/kg of dexmedetomidine constituted to 1ml was injected after negative aspiration.

Sensory and motor blocks were assessed soon after the block was given. Post operatively the patients were followed up for the duration of analgesia and other block characteristics at regular intervals.

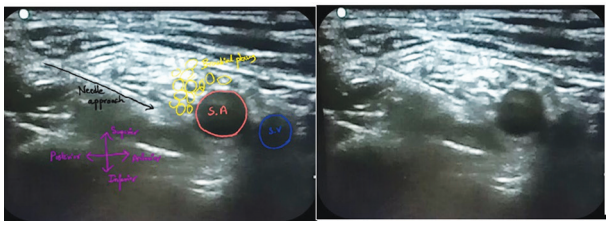

Fig. 1: Ultrasound image of brachial plexus in parasagittal approach.

Since we used Dexmedetomidine as an adjuvant, sedation score was assessed according to the Ramsay Sedation Scale (RSS) intra-operatively & post-operatively.

Any adverse events like bradycardia, hypotension, hypoxemia, sedation, respiratory depression, nausea and vomiting were noted. Bradycardia was defined as heart rate <50 bpm, and hypotension was defined as decline in blood pressure <20% from the baseline recordings. Hemodynamics were assessed intra-operatively and post-operatively. Visual Analogue Scale was used to assess pain and if VAS>4, rescue analgesic was considered. Rescue analgesic used in the post-operative period was inj. paracetamol 1g i.v slow infusion and its requirement in 24 hours post operative period was noted in both groups and computed accordingly.

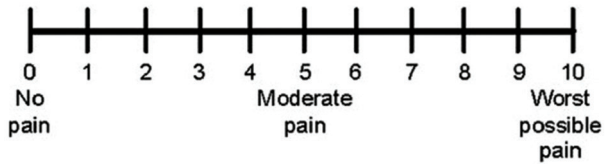

Fig. 2: Visual analogue scale.

Data was computed and entered in MS excel/ analyzed using SPSS software version 16. Student t-test was used for demographic and hemodynamic data analysis. Unpaired t-test was used for evaluation of data which included onset, duration of sensory and motor blockade along with duration of analgesia. The results were statistically significant if p-value <0.05. P-value <0.001 was considered highly significant.

Results

Eighty patients were enrolled for the study as per the study protocol mentioned above, we did not have any dropouts of patient's in our study. There was no block failure noted among patients in any of the groups. Both the groups R and RD were comparable with respect to age, sex distribution, weight, height (demographic variables), ASA grading and duration of surgery (Table 1). Duration of analgesia lasted longer in Group RD (991.09 ± 16.34) when compared to Group R (542.57 ± 18.37) (p-value <0.001) (Table 2). As per the observation noted in Table 3, the onset time for sensory and motor blockade were rapid in Group RD (7.71 ± 1.23, 13.66± 1.03) when compared to Group R (10.14 ± 1.00, 18.60 ± 1.54) with p-value <0.05. By adding Dexmedetomidine to Ropivacaine in our study, we noted early occurrence of sensory and motor blockade.

Duration of sensory blockade was prolonged in Group RD (780.26 ± 31.43) when compared to Group R (455.57 ± 20.28) with p-value of <0.001(Table 4). Duration of motor blockade was also enhanced in Group RD (725.57 ± 25.18) when compared to Group R (397.74 ± 24.92) (p-value <0.001) (Table 4).

Sedation scores were higher in Group RD when compared to Group R (Figure 10). VAS scores were less in patients of Group RD which led to reduced total analgesic requirement in Group RD (0.74 ± 1.12) when compared to Group R (2.34 ± 1.45) (p-value <0.001) (Table 4) (Figure 9).As per the observations noted in Figure 6,7,8 hemodynamic stability was maintained in patients of both the groups without any significant variations.

Two patients in Group RD had bradycardia which responded well to inj. glycopyrrolate. One patient in Group RD had transient hypotension.This patient responded to i.v fluids and 6mg bolus of i.v mephentramine. We did not notice hypoxemia, nausea, vomiting and respiratory depression in any of the patients among both the groups (Table 5).

Table 1: Demographic Profile.

Demographic Profile	Group R	Group RD	P-value
Age (in yrs)	38.62 ± 13.20	39.22 ± 15.31	0.411
Height (in cms)	158.74 ± 5.71	159.6 ± 5.14	0.527
Weight (in kgs)	60.27 ± 9.04	61.69 ± 8.93	0.483
Sex (male/ female)	21(52.5%)/ 19(47.5%)	20(50%)/ 20(50%)	0.832
ASA distribution (I/II)	18(45%)/ 22(55%)	21(52.5%)/ 19(47.5%)	0.636
Duration of Surgery (in mins)	68.29± 19.42	63.57± 19.54	0.315

P-value not significant

Table 2: Duration of Analgesia.

Variables	Group R	Group RD	P-value
Duration of Analgesia (in min)	542.57 ± 18.37	991.09± 16.34	<0.001
Rescue analgesia-paracetamol (g)	2.34 ± 1.45	0.74 ± 1.12	<0.001

P-value <0.001, statistically significant

Table 3: Onset time of Sensory and Motor block.

Variables	Group R	Group RD	P-value
Onset of sensory block (in min)	10.14 ± 1.00	7.71± 1.23	<0.001
Onset of motor block (in min)	18.60 ± 1.54	13.66± 1.03	<0.001

P-value <0.001, statistically significant

Table 4: Duration of Sensory and Motor block.

Variables	Group R	Group RD	P-value
Duration of sensory block (in min)	455.57± 20.28	780.26± 31.43	<0.001
Duration of motor block (in min)	397.74 ± 24.92	725.57 ± 25.18	<0.001

P-value <0.001, statistically significant

Table 5: Side effects.

Variables	Group R	Group RD
Hypotension	0	1
Nausea	0	0
Vomiting	0	0
Bradycardia	0	2
Hypoxemia	0	0
Respiratory Depression	0	0

P value >0.05, insignificant

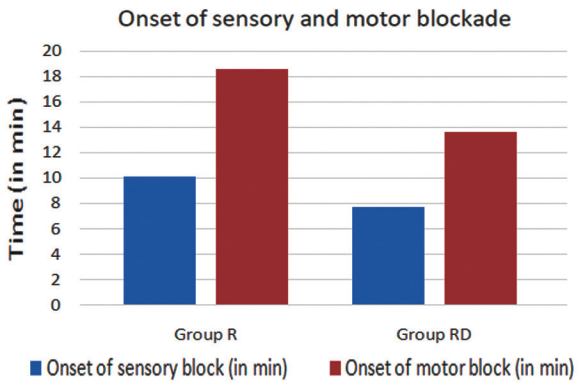

Fig. 3: Graphical representation of onset of sensory and motor blockade.

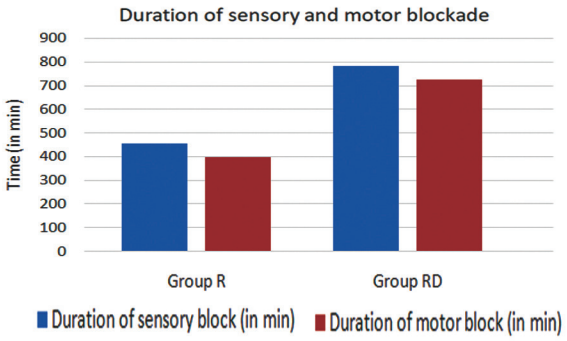

Fig. 4: Graphical representation of duration of sensory and motor blockade.

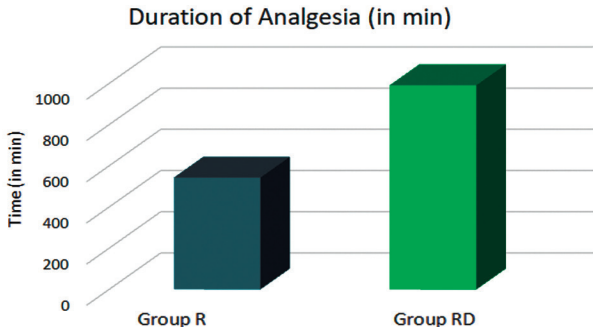

Fig. 5: Graphical representation of duration of analgesia.

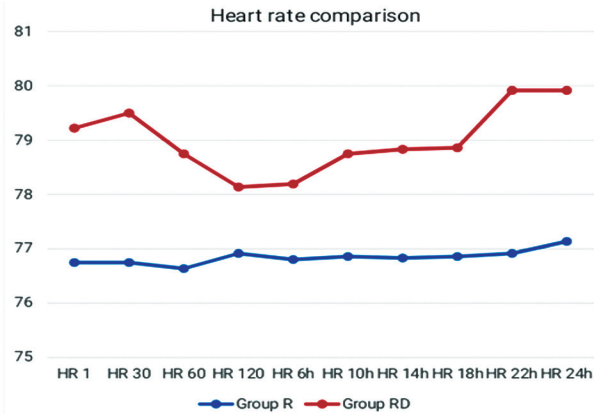

Fig. 6: Graphical Representation of Heart rate comparison between groups.

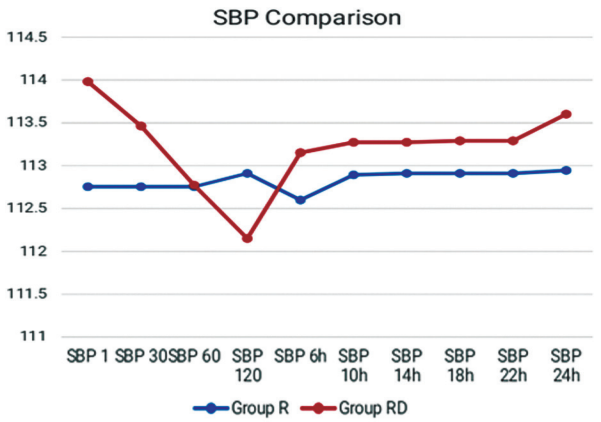

Fig. 7: Graphical representation of Systolic blood pressure comparison between groups.

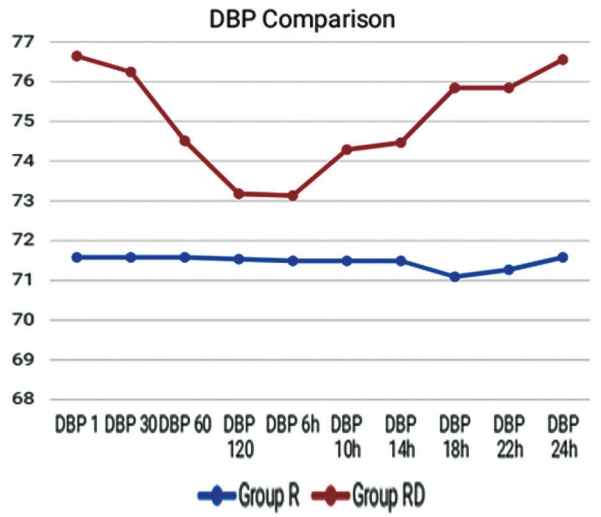

Fig. 8: Graphical Representation of Diastolic blood pressure comparison between groups.

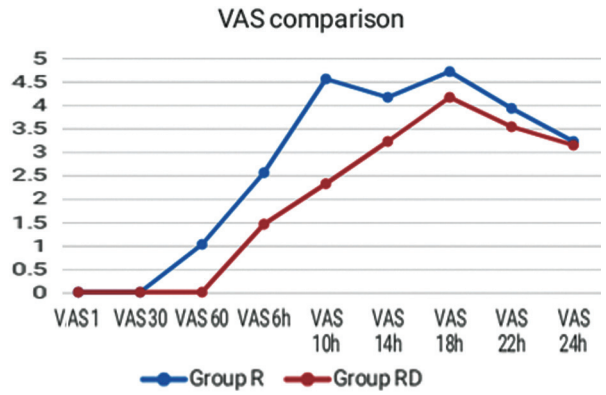

Fig. 9: Graphical representation of VAS comparison between groups.

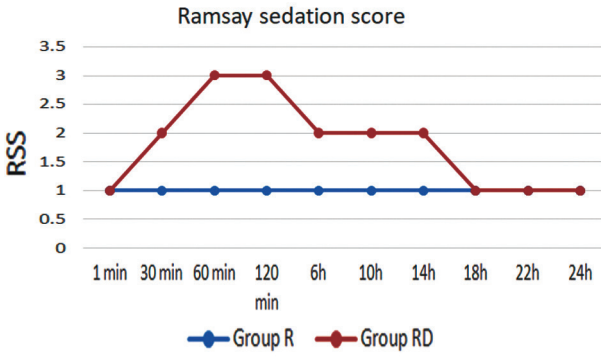

Fig. 10: Graphical representation of Ramsay sedation score comparison between groups.

Discussion

Supraclavicular blocks are performed at the level of the brachial plexus trunks. Ultrasound guided blocks provides rapid onset, predictable and dense anesthesia along with high success rate. Local anesthetics alone for supraclavicular brachial plexus block provide good operative conditions but have a shorter duration of postoperative analgesia.[5]

General anesthesia when used for patients undergoing upper limb surgeries results in significant hemodynamic disturbances along with accompanying adverse effects including nausea, vomiting and respiratory insufficiency, toavoid all these adverse effects brachial plexus block is commonly used. With the advent of ultrasound, the nerve clusters can be easily imaged and block quality is also impressive. Intra-arterial injection and pneumothorax can be easily avoided.

Ropivacaine is a local anaesthetic effective for both intraoperative anaesthesia and post-operative analgesia by binding to open voltage-gated Na+ channels thereby increasing the frequency of nerve depolarization in a reversible and concentration-dependent manner. Lower lipid solubility of ropivacaine causes greater sensory and motor differential blockade. It is considered to be a cardio stable local anesthetic without accompanying neurotoxicity.[2,3]

Several adjuvants may increase the duration of nerve block. Adjuvant drugs such as alpha-2 adrenergic receptor agonists, opioids, ketamine, dexamethasone and others can be used to increase block duration. Dexmedetomidine is a highly selective alpha-2 adrenergic receptor agonist,[4] its action in peripheral nerve blockade is due to increase in hyperpolarization activated cation current that prevents the nerve from returning to resting membrane potential.[1]

Supraclavicular approach described by Chan et.al[8] with a probe resting posterior to clavicle, with posterolatero-anteromedial orientation provides a very stable location in terms of anatomical delineation.

Similar to the study conducted by Adrian Searle et.al[6] in our study, we have used posterior parasagittal approach to the brachial plexus at the supraclavicular level, utilizing the arc of the first rib to provide a deep limit to needle transit, and probe stability by resting against the scalene muscles medially, and clavicle anteriorly.[6] In this approach, subclavian vein is well-separated from the brachial plexus and the subclavian artery, with the plexus positioned posterior to the artery.

Injury to major structures before the needle approaches the brachial plexus is almost prevented. This technique ensures that the needle tip does not trespass the first rib or the pleural dome eliminating the risk of pneumothorax. So, we used this approach.

Lot of studies are being done using Dexme detomidine as an adjuvant to local anesthetics, accordingly superiority has been established by using Dexmedetomidine perineurally in various studies.

In our study, we used 0.5mcg/kg of Dexmedetomidine as an additive to Ropivacaine and we found that Dexmedetomidine prolonged the duration of sensory and motor blockade. Moreover, even the duration of analgesia was also enhanced (which was our primary objective). The rescue analgesic medication used in the post-operative period was of lesser doses in the group which received Dexmedetomidine as an adjuvant (Group RD). These observations in our study correlates to a similar study which was conducted by Gurajala et.al.[2] They used 50mcg of Dexmedetomidine as an adjuvant to 0.5% Ropivacaine and found that onset of motor block was earlier and durations of analgesia, sensory and motor blockade were significantly prolonged in group who received Dexmedetomidine.

In a study conducted by Suneet Kathuria et.al[1] they found that sensory and motor block onset was earlier in group who received Dexmedetomidine. The duration of sensory and motor block, duration of analgesia was also prolonged in group who received Dexmedetomidine perineurally when compared with group who received intravenous Dexmedetomidine.

Our study correlates with the study conducted by Faraj et.al[18] wherein they randomized patients into three groups, Dex-P, Dex-IV and control group, duration of analgesia was 10.9 hours on addition of 0.5 mcg/kg Dexmedetomidine to 0.5 % Ropivacaine (Dex-P). Dexmedetomidine also reduced the 24-hour cumulative morphine consumption to 63.9mg (Dex-P) compared to Group Dex-IV.

In one of the studies conducted by Srinivasa Rao et.al[17] they randomly allocated patients into Group LD50 and Group LD100. Group LD50 received 0.5% levobupivacaine plus 50mcg of dexmedetomidine. Group LD100 received 0.5% levobupivacaine plus 100mcg of dexmedetomidine. They concluded that 100mcg dose of dexmedetomidine in brachial plexus block hastens the onset and prolongs the duration of sensorimotor blockade and analgesia, but with higher incidence of bradycardia and sedation. Keeping this in consideration, we have used 0.5mcg/kg of Dexmedetomidine rather than 1mcg/kg dosage. In a study conducted by Ranjit et.al[16] they concluded that perineural dexmedetomidine prolonged the analgesic duration and reduced 24-hour postoperative analgesic consumption (8h 36min +/- 1h 36min and 10h 42min +/- 1h 36min) when used as an adjuvant to bupivacaine in fascia iliaca compartment block. They concluded that intravenous dexmedetomidine is less efficacious than perineural dexmedetomidine in terms of evaluating block characteristics.When intravenous analgesics were used for patients for postoperative analgesia in comparison to perineural administration of Dexmedetomidine, it was derived that perineural adjuvant added to local anesthetic was more efficacious in terms of analgesia.

Sarita et.al[11] conducted a study to compare the efficacy between the two alpha-2 agonists, dexmedetomidine and clonidine in supraclavicular brachial plexus block, they found out that the patients who had received Dexmedetomidine had prolonged duration of analgesia (456+/-97min) when compared to patients who received clonidine (289+/-62 min), thus they derived that Dexmedetomidine when compared to clonidine provided superior quality of block.

Dexmedetomidine when used perineurally was associated with bradycardia and hypotension as reported by Esmagolu et.al[15] wherein they used 100mcg of dexmedetomidine to levobupivacaine for brachial plexus block. Hence, we chose 50mcg of Dexmedetomidine, we did not notice any significant bradycardia or hypotension.

As postulated by Guo TZ et.al[12] alpha-2 agonists prevent the release of norepinephrine in the locus coeruleus causing sedation and hypnosis, they also terminate propagation of pain signals leading to pain relief. They were of the opinion that stimulation of alpha-2 receptors brings about sedation, analgesia, and anxiolysis.

Eisenach JC et.al[13] in their clinical review emphasized the importance of alpha-2 agonists in reducing the anesthetic drug requirements by virtue of their sedative, analgesic, antihypertensive and antiemetic effects.

Dexmedetomidine has emerged as an adjuvant for local anesthetics in epidural, intrathecal and other peripheral nerve blocks as suggested by Ribeiro RN et.al.[14] The sedation caused by alpha-2 agonists is taught to be due to central inhibition of substance P release in the nociceptive pathway and it has well been documented that patients are easily arousable. There were no problems when side effects were taken into consideration, as we did not notice any major adverse effects. Dexmedetomidine in the dose of 50 mcg prolongs analgesic duration. Analgesic requirements were minimal in patients in whom Dexmedetomidine was used.

Dexmedetomidine, thus acted as a good additive to Ropivacaine. Our study has provided superior block characteristics along with prolonged post-operative analgesia with addition of Dexmedetomidine as an adjuvant to 0.75% Ropivacaine when compared to Ropivacaine alone in supraclavicular brachial plexus block. Our study had some limitations, we chose 50mcg of dexmedetomidine as earlier studies had a mention of bradycardia and hypotension with higher doses. Hence,we evaluated the efficacy of lower dose concentration of dexmedetomidine in block keeping in view of not causing any adverse effects. However, further studies need to be carried out with larger samples to validate our observations using different dosage protocols.

Conclusion

We conclude from our present study that addition of 0.5mcg/kg of Dexmedetomidine to 0.75% Ropivacaine enhanced the quality of block as the duration of analgesia was significantly prolonged and onset of both sensory and motor blockade was rapid. It also prolonged the duration of sensory and motor blockade, making it as one of the potential adjuvants for ropivacaine in upper limb forearm orthopedic surgeries.

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Conflicts of Interest: No conflicts of interest.

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Comparative Study between Intubating Laryngeal Mask Airway and Macintosh Laryngoscope in Patients with Simulated Cervical Spine Injury

Panidapu Nagarjuna[1], Barsha Sen[2], Mrunalini Parasa[3]

Author's Affiliation:

[1]Senior Resident, Department of Cardiac Anaesthesiology, SCTISMT, (Sree Chitra Tirunal Institute) Trivandrum 695011, Kerala, [2]Senior Resident, Department of Cardiac Anaesthesiology, Amrita Institute of medical sciences, Kerala 682041, [3]Professor, Department of Anaesthesiology, NRI Medical College & GH, Guntur, Andhra Pradesh 522003, India.

Abstract

The aim of this prospective randomized study is to compare intubating laryngeal mask airway (ILMA) with Macintosh laryngoscope (ML) in patients with simulated cervical spine injury, to compare the hemodynamic variables and to see any complications associated with their use in the peri-operative period.

Methods: We selected 60 ASA physical status 1 and 2 patients posted for elective surgeries under general anaesthesia. These patients were randomly allocated into two groups of 30 each: Group ML was intubated using Macintosh laryngoscope and Group ILMA was intubated using ILMA. Baseline hemodynamic parameters (BP, HR), 3 min and 5 min post intubation readings and number of attempts taken for successful intubation were recorded.

Results: The mean duration of intubation was more in Group ILMA (28.93 +/-8.98 seconds in Group ML vs 74.83 +/-16.03 seconds in Group ILMA) with a P value of <0.01. The rise in hemodynamic parameters was comparatively higher in Group ILMA than in Group ML but it was statistically insignificant.

Conclusion: Macintosh laryngoscope is a faster method to secure tracheal intubation than Intubating Laryngeal Mask in patients with cervical collar. The success rate of intubation through Intubating Laryngeal Mask is similar to that of Macintosh laryngoscope.

Key-words: Intubating Laryngeal Mask airway; Macintosh Laryngoscope; Cervical spine injury; Difficult intubation.

Key Messages: ILMA can be safely used for intubation in patients with cervical spine injuries.

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Corresponding Author: Panidapu Nagarjuna, Senior Resident, Department of Cardiac Anaesthesiology, SCTISMT, (Sree Chitra Tirunal Institute) Trivandrum 695011, Kerala, India.

E-mail: drarjun83@gmail.com

Introduction

Endotracheal intubation in a patient with limited cervical spine movement is always a challenge even to the most experienced anaesthesiologist 1. Laryngoscopy requires flexion of the lower cervical spine and atlanto-occipital extension for alignment of the oral, pharyngeal and laryngeal axes & to create a direct line of vision from the mouth to the vocal cords. In patients with cervical spine injury, airway management poses a bigger challenge due to risk of neurological damage related to neck movements; thus manual-in-line stabilization is commonly applied to minimize neck movement during tracheal intubation. Such immobilization can render intubation under direct laryngoscopy more difficult.

The intubating laryngeal mask airway (ILMA) is a modified version of the Laryngeal mask airway (LMA) which, in addition to permitting ventilation, is designed to facilitate blind tracheal intubation with a tracheal tube in an anaesthetized patient. ILMA is an alternative device to direct laryngoscope and can be used to secure an endotracheal tube in patients with cervical collar.[2]

Various reports have shown that ILMA has advantage over conventional laryngoscope guided tracheal intubation especially in patients with cervical trauma and difficult airways. It does not require head and neck manipulation for insertion and facilitate better alignment of tracheal tube. It is an effective means of maintaining ventilation and oxygenation.[3] Studies using ILMA in patients with cervical spine injuries were very less which prompted us to use this device for intubation. Hence, we compared the efficacy & feasibility of ILMA to secure an endotracheal tube in patients with simulated cervical spine immobility using a cervical collar.

Aims

The aim of this prospective randomized controlled study is to compare ILMA with Macintosh laryngoscope in patients with simulated cervical spine injury, to compare the hemodynamic variables and to see any complications associated with their use in the peri-operative period

Settings and Design

The study was conducted in a tertiary care hospital, operating around 2500 cases in a year.

Methods and Material

The institutional ethical committee approved the study protocol and written informed consent was obtained from each patient preoperatively. Sixty ASA physical class 1 and 2 patients undergoing various procedures under general anaesthesia were randomly allocated into two groups using computed generated randomized chart. Inclusion criteria were patients with ASA physical status 1 and 2, age group of 20-60 years, Mallampati grades 1-2, thyro-mental distance of >4 cm & inter-incisor distance of >4 cm. Exclusion criteria were patient refusal, upper airway pathologies, ASA physical status 3 and 4 patients, emergency surgeries, patients with H/o asthma, COPD & morbid obesity.

After shifting the patient to operation theatre, peripheral line secured under local anaesthesia and standard ASA recommended monitors were connected. Cervical collar was placed in position after explaining to the patient. All patients were premedicated with Glycopyrrolate 5mcg/kg and Midazolam 0.05mcg/kg, induced with Fentanyl 2mcg/kg, Propofol till the loss of verbal response. Vecuronium 0.1mg/kg was administered after checking adequacy in bag mask ventilation to facilitate muscle relaxation and tracheal intubation in both the groups.

Group ML were intubated routinely using Macintosh laryngoscope. Group ILMA were intubated using ILMA and Parker flex tube. Backup plan for intubation was kept ready in case of any desaturation or difficulty encountered during the study process. If patient desaturated (SpO_2 <92%) or could not be intubated using ILMA then cervical collar was taken out and patient was intubated using Macintosh laryngoscope in case of ILMA group and using Bougie in case of ML group.

Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial pressure (MAP), Heart rate (HR) were recorded at baseline, immediately after intubation, 3min and 5min after intubation in Group ML. Similarly, SBP, DBP, MAP, HR were recorded in Group ILMA after inserting ILMA, after passing Parker flex tube through ILMA and 3 min, 5 min thereafter. Time taken for intubation, ease of intubation, number of attempts taken for successful intubation was also recorded. Insertion time is calculated as time taken from the time of insertion of ILMA to the visibility of proper et CO_2 curve, while Intubation time is the time taken from the insertion of parker flex tube through ILMA till the visibility of et CO_2 curve. Total intubation time was calculated by adding insertion time and intubation time. A maximum of 3 attempts were considered before declaring the case as a failure.

Statistical Analysis used

Assuming the overall intubation success rate in the patients without neck immobilization would be 95%,[2] we decided that a 20% difference in overall intubation success rate between the groups would be clinically important. Thirty patients in each group would thus be necessary with α=0.05 and β=0.2. We therefore enrolled 30 patients per group.

Unpaired scored data were examined and compared using Mann–Whitney U-tests. The incidence of intubation complications, number of ILMA insertion attempts, and overall intubation success rate were tested by Fisher's exact tests or χ2-tests, as appropriate. Other descriptive data were compared using unpaired t-tests. Statistical analysis was performed using StatView version 5.0 (SAS Institute Inc., Cary, NC, USA) and Sample Power 2.0 (SPSS, Chicago, IL, USA). Values are expressed as mean and standard deviation (SD) unless otherwise stated; P<0.05 was considered statistically significant

Results

The demographic data, Mallampati classes & types of surgeries were comparable in both the groups (Table 1).

Table 1: Comparison of demographic variables between the two groups.

	GROUP ML	GROUP ILMA	P value
Male	19	16	0.272
Female	11	14	0.228
Age (yrs)	39.86+/-14.71	41.13 +/-13.6	0.731
Weight (kg)	62.2 +/- 8.87	63.23 +/- 8.68	0.532
Mallampati Class 1	21	22	0.682
Mallampati class 2	9	8	0.712
ASA 1	24	22	0.569
ASA2	6	8	0.627

Abbreviations: ASA – American Society of Anaesthesiologists, ML – Macintosh laryngoscope, ILMA – Intubating Laryngeal Mask Airway.

Ease of Intubation

Tracheal intubation was successful in all the 30 cases in both the groups.

In group ML 28 patients were intubated in the first attempt while 2 patients were intubated in the second attempt using a Bougie. In group ILMA 26 patients could be intubated during the first attempt, 3 were intubated in the second attempt after specific manoeuvres and 1 patient in the third attempt (Table 2). Success rate of intubation in first attempt and second attempt was almost same in both the groups while in one case it required a third attempt for successful intubation in group ILMA (Table 2).

Table 2: Comparison of attempts taken to intubate between two groups.

	1st attempt	2nd attempt	3rd attempt
Group ML	28 (93.3%)	2 (6.6%)	0
Group ILMA	26 (86.6%)	3 (10%)	1 (3.33%)

ML – Macintosh laryngoscope, ILMA – Intubating Laryngeal Mask Airway

Time Taken for Intubation

Mean time taken for intubation in Group ML was 28.9 +/- 8.98 seconds while it was 74.83 +/- 16.03seconds in group ILMA and the P value was found to be <0.01 which was statistically very much significant (Table 3)

Table 3: Comparison of total time taken for intubation between two groups.

	GROUP ML	GROUP ILMA	P value
Duration of intubation(sec)	28.9 +/- 8.98	74.83 +/- 16.03	<0.01

Abbreviations: ILMA – Intubating Laryngeal Mask Airway, ML – Macintosh Laryngoscope.

Haemodynamics

Baseline systolic, diastolic and mean blood pressures were similar in both the groups and the difference was not statistically significant (Table 4,5,6).

Table 4: Comparison of systolic blood pressure between the two groups at various time intervals.

Systolic Blood Pressure	GROUP ML (mm of Hg)	GROUP ILMA (mm of Hg)	P value
Baseline	130 +/- 12.5	133.26+/-15	0.3942
After ILMA insertion	-	143.76+/-21.35	-
After Intubation	139 +/- 17.3	145.4+/-16.16	0.1441
After 3min	121 +/- 16.8	122.46+/-14.16	0.8953
After 5min	115 +/- 11.8	117.16+/-14.8	0.6246

Abbreviations: ILMA – Intubating Laryngeal Mask Airway, ML – Macintosh Laryngoscope.

Table 5: Comparison of diastolic blood pressure between the two groups at various time intervals.

Diastolic Blood Pressure	GROUP ML (mm Hg)	GROUP ILMA (mm Hg)	P value
Baseline	77.8	78.66	0.731
After ILMA	-	90.56	-
After Intubation	85.46	89.23	0.257
After 3min	74.56	78.36	0.153
After 5min	70.83	76.36	0.170

Abbreviations: ILMA – Intubating Laryngeal Mask Airway, ML – Macintosh Laryngoscope.

Table 6: Comparison of mean arterial pressures between the two groups.

Mean Blood Pressure	GROUP ML (mm of Hg)	GROUP ILMA (mm of Hg)	P value
BASELINE	88.36	90.16	0.528
After ILMA	-	102.46	-
After intubation	96.16	100.2	0.105
After 3min	84.23	87.3	0.281
After 5min	79.2	84.46	0.217

Abbreviations: ILMA – Intubating Laryngeal Mask Airway, ML – Macintosh Laryngoscope.

Heart Rate

The rise in heart rate was higher in group ILMA than that of group ML after intubation and at 3 min post intubation. However, this rise was statistically insignificant in both the groups (Table 7).

Table 7: Comparison of heart rates between the two groups.

	GROUP ML (mm Hg)	GROUP ILMA (mm Hg)	P value
BASE LINE	90.16	84.46	0.621
After ILMA	-	101.86	-
After intubation	97.1	100.10	0.197
After 3min	89	90.42	0.606
After 5min	83.16	87.75	0.07

Abbreviations: ILMA – Intubating Laryngeal Mask Airway, ML – Macintosh Laryngoscope.

Table 8: Comparison of post-operative complications between the two groups.

	GROUP ML (n)	GROUP ILMA (n)
Lip injury	-	2
Sore throat/ Hoarseness	1	2

Abbreviations: ILMA – Intubating Laryngeal Mask Airway, ML – Macintosh Laryngoscope.

Discussion

In our study we compared the total time taken for intubation using a Macintosh laryngoscope and ILMA in patients with simulated cervical spine immobility using a rigid cervical collar.

Demographic data, ASA physical status and Mallampati classes were similar in both the groups. Also types of surgeries were nearly same in both the groups. The mean duration of intubation was more in ILMA group than the Macintosh group, with a mean duration of 28.93+/-8.98 seconds in Group ML, while it was 74.83+/-16.03 seconds in Group ILMA and P value was found to be <0.001, which was statistically significant.

The mean duration of intubation found in our study was similar to Kavitha et al[4] and Sharma VS et al.[3] The success rate of intubation was 100% in both the groups; however, it was 93.33% (28/30) in first attempt in group ML while 86.6% (26/30) in group ILMA. These findings were similar to studies conducted by Ruchi bola et al1, Komatsu et al[2] and Choyce et al.[5]

In our study, hemodynamic response to intubation was more in ILMA group but the variation in hemodynamic response was not statistically significant. But when looked at individual steps of intubation, it was observed that insertion of ILMA and passing of Endo-Tracheal Tube (ETT) through ILMA generates more pressor response compared to laryngoscopy and intubation with Macintosh laryngoscope. All the changes in HR and MAP remained within acceptable 20% from the baseline values in both the groups. These findings were in accordance with studies conducted by Nakazawa et al[7], Naveed et al[6], Joo et al[8] and Singh et al[9] who also had similar hemodynamic variations in using ILMA but they are also statistically insignificant.

Our findings were in contrast with Kihara et al[10], who showed that during insertion and intubation with ILMA there was no significant increase in MAP, and HR. To prevent accidental extubation during removal of ILMA we tend to advance a tracheal tube towards the carina by pushing with the stabilizing rod. Movement of the tracheal tube probably provides the stimulus[11] which produces the magnitudes of hemodynamic responses with the use of ILMA.

Our incidence of oesophageal intubation and mucosal trauma was comparable to previous studies.[5,12] Higher incidence of mucosal trauma was seen in ILMA group compared to that of Macintosh group, this may be because of high pressure exerted by ILMA against pharyngeal mucosa.[12] However,

there was no statistically significant difference in the incidence of sore throat or hoarseness of voice during postoperative period in both groups.

Conclusions

Macintosh laryngoscope is a faster method to secure tracheal intubation than Intubating Laryngeal Mask in patients with cervical collar. The success rate of intubation through Intubating Laryngeal Mask is similar to that of Macintosh laryngoscope.

Acknowledgement

None

Conflict of Interest

None

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Relationship between Preoperative Maternal Abdominal Circumference Measurement and the Level of Sensory Block in SAB in Cesarean Section : Prospective Observational Study

Ramachandraiah R[1], Vyshnavi N Rao[2]

Author's Affiliation:

[1]Professor and Hod, [2]Post Graduate, Department of Anesthesia, Bangalore Medical College and Research Institute, Fort Road, Bangalore 560004, Karnataka, India.

Abstract

Background and aims: Inferior venacaval compression during pregnancy causes extradural venous engorgement which may reduce the lumbar cerebrospinal fluid volume. A subsequent greater cephalad spread of sensory block is observed. We hypothesized that maternal abdominal circumference measurement can reflect the compressive effect of uterus and investigated the relationship between maternal abdominal circumference and the level of sensory block, the maximum level of sensory block, incidence of hypotension, nausea, vomiting, requirement of ephedrine in term parturients undergoing cesarean section under spinal anasethesia.

Methods: Abdominal circumference of 40 term parturientswere measured before performing subarachnoid block. 0.5% hyperbaric bupivacaine (2ml, 2.2ml, 2.4ml) was injected into L3-L4 subarachnoid space according to parturients height .The level of sensory block was assessed at various time intervals. The statistical tests applied were Onewayanova, product moment correlation and independent sampleT Test.

Results: The correlation coefficient between abdominal circumference and the level of sensory block was significantly positive at various time intervals ($p<0.05$) following spinal anesthesia. There was a positive correlation between abdominal circumference and highest level of sensory block. No significant correlation was found between abdominal circumference and incidence of hypotension, requirement of ephedrine, nausea and vomiting after spinal anaesthesia ($p>0.05$).There was a significant positive correlation between BMI and the level of sensory block ($p<0.05$).

Conclusion: Parturients with greater abdominal circumference value have a higher level of sensory blockade after spinal anaesthesia. Abdominal circumference cannot predict the incidence of hypotension, nausea, vomiting and the dose of ephedrine required.

Key words: Abdominal Circumference; Subarachnoid block; Level of sensory block.

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Corresponding Author: Vyshnavi N Rao, Post Graduate, Department of Anesthesia, Bangalore Medical College and Research Institute, Fort Road, Bangalore 560004, Karnataka, India.

E-mail: vyshnavinrao@gmail.com

Introduction

Spinal anaesthesia is a safe, simple, rapid, effective and easy to apply anaesthetic technique for cesarean section. Despite the advantages of spinal anaesthesia, hypotension is a common complication with an incidence of 70% to 85% in parturients.[1-4]

Many factors including the Characteristic of injected solution, Patient position, Height, Pregnancy, Intra abdominal pressure, Lumbosacral cerebrospinal fluid volume determine the intrathecal spread of local anaesthetics.In obstetric patients physiological changes due to pregnancy includingchanges of spinal curvature,venous pooling secondary to progesterone induced decrease in vascular tone,aortocaval compression by the gravid uterus contribute to hypotension during cesarean section under spinal anesthesia.[1-6]

Abdominal circumference (AC) correlates with intra abdominalvolume. Maternal abdominal circumference increases during pregnancy and it is influenced by fetus size,amniotic fluid volumeand size of the uterus.

This study was undertaken to determine the relationship between preoperative maternal abdominal circumferencemeasurement, level of sensory block and the maximum level of sensory block achieved and the incidence ofhypotension, nausea and vomitingand requirement of Injection ephedrinefollowing spinal anaesthesia with 0.5% hyperbaric bupivacaine in parturients undergoing cesarean section.

Materials and Methods

We conducted this prospective observational study between June 2020 and December 2020 among 40 parturients who belonged toASA Grade I and Grade II in the age group of 20-40 years, with uncomplicated, singleton and term pregnancy, undergoing elective and emergency cesarean section under spinal anesthesia and willing to give informed written consent.

Those parturients not willing to give informed consent, contraindication to spinal anaesthesia, Preeclampsia, diabetes mellitus, cardiac diseases, Pre term, multiple gestation, Morbid obesity (BMI>35), height <155cm or > 170 cm, Placental, fetal abnormalities, oligohydramnios, polyhydramnios were excluded from the study.

After obtaining approval and clearance from the institutional ethics committee, the parturients fulfilling the inclusion criteria were enrolled for the study after obtaining informed consent.

All study participants were informed about the purpose of the study and the method used to measure the level of sensory blockade prior to anaesthesia.

When the parturient arrived at the operating room, abdominal circumference was measured with the parturient in supine position at the level of the umbilicus. Injection Ranitidine 50mg iv and Injection Metoclopramide 10mg iv were given 30 minutes before surgery. Intravenous hydration of 20 mL/kg crystalloids was given. Standard monitors were installed, including an automated noninvasive blood pressure device, a pulseoximetry monitor, and an electrocardiography monitor. Baseline blood pressure, heart rate and oxygen saturation were recorded.

Parturient was turned to the right lateral decubitus position on a horizontal operating table for spinal anaesthesia. Under strict aseptic precautions spinal anaesthesia was performed using the median approach through the L3-L4 intervertebral space. A Quincke 27-gauge spinal needle was inserted with its bevel oriented parallel to the dural fibers and then rotated to direct the bevel cephalad. Then, 0.5% hyperbaric bupivacaine was injected into the subarachnoid space. The dose of bupivacaine was determined by the parturient's height. Thus, 0.5% hyperbaric bupivacaine 2.0 mL was administered when the height was between 156 cm and 160 cm; 0.5% hyperbaric bupivacaine 2.2 mL was administered when the height was between 161 cm and 165 cm; and 0.5% hyperbaric bupivacaine 2.4 mL was administered when the height was between 166 cm and 170 cm.

After the spinal injection, the parturients were immediately turned to the supine position. A left uterine displacement of about 15 degree was maintained by inserting a folded blanket placed under the patient's right hip. No attempt was made to influence the level of sensory blockade by manipulating the operating table. A proforma was used to collect the data which includes patient details, diagnosis, surgery proposed, anaesthesia details etc. The blood pressure, heart rate and oxygen saturation was measured at 1minute, 3minutes, 5 minutes and thereafter every 10 minutes till the completion of the surgery.

Drop in systolic blood pressure to below 100mmHg, or a decrease of more than 30% in the baseline mean arterial blood pressure (MAP) was considered as hypotension and treated with Injection ephedrine (6 mg) iv. Intravenous atropine (0.6 mg) was given when the heart rate wasless

than 60 beats/min. Level of sensation loss for cold will be checked by using an ice cube at 1 minute, 5 minutes, 10 minutes, 15 minutes and 20 minutes after spinal anaesthesia. The level of sensory blockade at 20 minutes after spinal injection was defined as the level of maximum sensory blockade. Loss of cold sensation was assessed by asking the patient to report when the cold stimulus appears similar to a reference point (forehead skin).

The dermatomal level below the detected stimulus was recorded as the level of sensory blockade. Time taken to achieve maximum level of sensory block was noted. The doses of ephedrine given and the incidence of nausea and vomiting were recorded. Nausea and vomiting was treated with injection ondansetron4mg iv.

Statistical Analysis

The sample size was calculated using the formula.

$$n = \frac{(Z\alpha + Z\beta)\ X(SD)^2}{(d)^2}$$

The probability of falsely rejecting a true null hypothesis (α)=0.05, Zα= 1.96. The probability of failing to reject a false null hypothesis (β) = 0.80, Zβ= 0.84, Standard deviation = 6.8.

Data was entered into Microsoft excel sheet and analysed using Inc. SPSS 20 India software. The statistical tests applied were: One way Anova, Product moment correlation, Independent sample T Test. P value < 0.05 was considered as statistically significant. The clinical characteristics of the study participants are presented as means and standard deviation for continuous variables .

Results

40 parturients were enrolled for the study. The demographic characteristics of the parturients is shown in table 1. The mean age of the parturients was 25.18±4.8 years. The mean BMI was 27.13 ± 3.18kg/m^2 and the mean abdominal circumference was 117.70±20.58 cm. Table 2 and graph1 shows that higher the abdominal circumference more is the level of sensory block.

The highest median level of sensory blockade achieved was T3 in parturients with abdominal circumference in the range of 151- 155 cm as shown by Table 3. Table 4 shows the relation between BMI and the level of sensory block – more the BMI, higher is the level of sensory block.

Table 1: Demographic characteristics of parturients.

	N	Minimum	Maximum	Mean	S.D.
Age	40	20	35	25.18	4.888
Height (cm)	40	156	170	160.15	3.697
Weight (kg)	40	57	92	69.43	9.974
BMI (kg/m2)	40	22.80	34.60	27.1375	3.18012
Gestational age(wk)	40	30.00	40.00	37.9250	1.63907
Abdominal circum-ference(cm)	40	86	155	117.70	20.589
Baseline SBP(mmhg)	40	114	150	129.85	8.711
Baseline DBP(mmhg)	40	68	100	80.25	9.857
Baseline MAP(mmhg)	40	83	115	95.80	8.358
Baseline SpO2	40	97	100	99.18	0.712
Baseline RR	40	12	20	15.28	2.160
Baseline HR	40	72	110	93.48	8.840
Ephedrine dose(mg)	40	0	18	4.20	6.256

SBP – systolic blood pressure, DBP- diastolic blood pressure, MAP- mean arterial pressure, RR – respiratory rate, HR- heart rate.

Table 2: Level of sensory block V/S abdominal circumference at different time intervals.

AC (cm) Mean±SD	Level of Sensory Block and Mean Abdominal Circumference							
	T2	T4	T5	T6	T8	T10	T12	p Value
1Min	-	-	-	-	136±13.4	104±2.8	99.5±11.5	<0.001
5Min	-	142.2±14.7	-	128.9±13.8	98.8±8.2	94.8±4.6	-	<0.001
10Min	-	134±12.4	104	108.8±18.3	95.2±5.2	-	-	<0.001
15Min	151.3±5.5	131.6±9.9	104	102.2±13.6	-	-	-	<0.001
20Min	151.3±5.5	132.5±10.3	105±1.4	99.5±9.0	-	-	-	<0.001

AC – abdominal circumference

Graph 1: Level of sensory block v/s abdominal circumference at different time intervals.

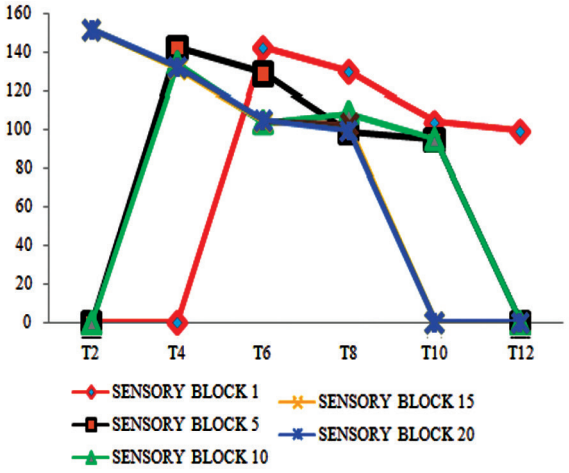

Table 3: Abdominal circumference and the maximum level of sensory block.

S. no.	Abdominal Circumference (in cm) Groups	Highest level of Sensory Block Achieved (median)
1.	85-90	T 7
2.	91-95	T6
3.	96-100	T6
4.	101-105	T5
5.	106-110	T5
6.	111-115	T5
7.	116-120	T5
8.	121-125	T4
9.	126-130	T4
10.	131-135	T4
11.	136-140	T4
12.	141-145	T4
13.	146-150	T4
14.	151-155	T3

As per the above tabulations we can infer that Higher the BMI, Higher is the level of sensory block

There was no significant correlation between the values of abdominal circumference, incidence of hypotension, nausea vomiting and the ephedrine requirement as shown by the descriptives in the study analysis (p>0.05).

Table 4: Relationship between BMI and level of sensory block at different time intervals.

Time	Level of Sensory Block	BMI mean ± SD	p value
1min	T6	30±4.41	0.008
	T8	28±2.9	
	T10	25.3± 1.9	
	T12	25.5 ±2.3	
5min	T4	30 ±4.41	0.004
	T6	28± 2.7	
	T8	25.5 ±2.45	
	T10	24.4± 1.37	
10min	T4	29.3± 3	<0.01
	T5	26	
	T6	25.9± 2.2	
	T8	23.9± 0.8	
15min	T2	32.4± 0.5	<0.01
	T4	28.6 ±2.8	
	T5	26.0	
	T6	25.2± 2	
20min	T2	32.4 ±0.5	<0.001
	T4	28.5± 2.7	
	T5	26± 0.5	
	T6	25± 2	

Discussion

The purpose of this study is to investigate the relationship between maternal abdominal circumference and the level of sensory blockade following spinal anaesthesia. Kuok CH7 et al conducted a study in 2016 in cesarean section and the spinal bupivacaine dosage was fixed according to parturients height.Hence in our study bupivacaine dose used was fixed according to parturients height. In this study we demonstrated significant correlation between abdominal circumference and the level of sensory blockade at 1min, 5mim,10min, 15min and 20min time interval after spinal anaesthesia.Zhou QH 9et al in their study in 2014 also found a strong positive correlation between abdominal girth and the cephalad spread of spinal anaesthesia similar to our study.

We also found a positive correlation between abdominal circumference measurement and the highest level of sensory blockade achieved. Parturients with greater abdominal circumference have greater IVC compression and greater epidural venous plexus distension.This results in less CSF volume which causes higher level of sensory

blockade. In this study we also found a significant correlation between BMI and the level of sensory block similar to the study conducted by Taivainenet al.[11]

The higher spread of local anesthetic in obese patients may be due to compression of inferior vena cava by the weight of the abdominal mass causing engorgement of epidural venous plexus. This causes reduction in the spinal canal volume and increased spread of the local anesthetic in the CSF. The amount of extradural fat surrounding and possibly compressing the dural sac might also be a factor responsible for spread of local anaesthetics in CSF. This study failed to demonstrate significant correlation between the values of abdominal circumference, incidence of hypotension, nausea vomiting and the ephedrine requirement .This may be due to the fact that hemodynamic response to spinal anaesthesia is influenced by various factors like Hydration, Venous capacitance, Baseline peripheral vascular tone, Blood volume, Cardiac output and degree of aortocaval compression. Hence abdominal circumference measurement can be used as a reliable predictor for the spread of local anesthetic in parturients undergoing cesarean section under spinal anaesthesia.

Limitations of this study are:Symphysiofundal height and vertebral column length which are found to correlate with the level of sensory block were not measured.

Conclusion

Parturients with greater abdominal circumference value tend to have higher level of sensory block but no correlation was noted with the incidence of hypotension, nausea / vomiting and the requirement of ephedrine. Abdominal circumference and BMI provide a simple way to predict the effect of spinal anaesthesia.

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Original Article

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Comparison of Efficacy of Two Different Dose Regimens of Intravenous Dexmedetomidne for Awake Transnasal Fibreoptic Intubation

Sandeep V D[1], Kiran N[2]

Author's Affiliation: [1]Post Graduate Resident, [2]Professor, Department of Anaesthesiology, Sri Devaraj Urs Medical College, R L Jalappa Hospital, SDUAHER, Tamaka, Kolar, Karnataka 563101, India.

Abstract

Background and Objectives: Nasal Fibreoptic intubation (NFI) is the recommended technique in patients with difficult airway like facial defects, limited mouth-opening and cervical instability but it requires the patient to be awake. The usage of an ideal sedative agent and stabilizing the intubating condition was essential for this. In this study we compare efficacy of different doses of dexmedetomidine for conscious sedation facilitating NFI.

Materials and Methods: This is a prospective, blinded-randomized-trial to correlate the effectiveness of different loading and maintenance doses of dexmedetomidine during NFI on 60 patients, 30 in each group, aged between 20 and 60 years with ASA grade I or II enrolled for elective surgery.

All patients received 2 mg Midazolam as premedication before transferring to operating room. Group A patients received Dexmedetomidine 1 mcg/kg I.V bolus slowly over 10 minutes then 0.8 mcg/kg/h as maintenance throughout the procedure. Group B patients received Dexmedetomidine 0.8 mcg/kg I.V. as bolus and 0.2 mcg/kg/h as maintenance dose.

Primary outcomes were assessment of sedation level and comfort of each patient by Total Comfort Scale (TCS). The difference in quantitative measures was done using student 't' test and difference in proportions by 'Chi' square test. $P<0.05$ was considered statistically significant.

Results: With respect to comfort scores and optimal conditions during NFI, Group A people showed significantly lower scores when compared to Group B.

Conclusion: Dexmedetomidine with loading 1µg/kg and higher maintenance dose 0.8µg/kg/h were better for NFI with better patient tolerance, patient comfort, patient satisfaction, good sedation and preserved upper airway with spontaneous breathing.

Key words: Comfort scale; Dexmedetomidine; Fibreoptic intubation.

Key Message: Dexmedetomidine at higher maintenance dose of 0.8 mcg/kg provides better comfort level to the patients and optimal conditions with less side effects during awake trans nasal fibreoptic endotracheal intubation.

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Corresponding Author: Kiran N, Professor, Department of Anaesthesiology, Sri Devaraj Urs Medical College, R L Jalappa Hospital, Kolar, Karnataka 563101, India.
E-mail: dr.nkiran@gmail.com

Introduction

Mortality and morbidity in anaesthesia commonly are from difficult airways. It is predicted that one third of all anaesthetic deaths are because of the inability to ventilate and intubate. 3 – 18% of the population are expected to have difficulties during endotracheal intubation during general anaesthesia1.

Intubation with McIntosh laryngoscope can be tough in certain conditions where there are restricted jaw movements, obese individuals with short neck, cervical spine injuries and inadequate mouth opening e.g. - inter-maxillary fixation,Temporomandibular joint trauma, rheumatoid arthritis.

A breakthrough technique for successful Intubation in the above-mentioned patients with difficult airway is the Awake Fibreoptic Intubation (AFOI) which has been in practice since 1960's and gaining wider popularity in managing difficult airways. Nowadays, the Fibreoptic intubation has become the instrument of first choice in difficult intubation cases particularly after the publication of the American society of Anaesthesiologists (ASA) guidelines in Difficult Airway Management2. Further Awake Fibreoptic Intubation is safe with a higher success rate because of the following reasons.

1. Preserved Muscle tone avoids airway collapse and keeps the airway patent.
2. Spontaneous breathing on command can open the obstructed airway passages.
3. Chances of desaturation is minimal in awake state/spontaneous breathing.[3]

Endotracheal Intubation using a Fibreoptic bronchoscope in the Awake State, if performed without proper sedation, can be an extremely unpleasant and discomforting experience for the patient. Numerous drugs have been used for producing conscious sedation such as Benzodiazepines, opioids, propofol which can be either Used alone or in combination.Midazolam administration results in amnesia and sedation. Propofol has fast onset of action and reduced context sensitive half-life with profound amnesia. ***Opioids example:*** Fentanyl and Remifentanil administration results in attenuating hemodynamic response and in reduction of discomfort during the passage of FOB through vocal cords.

All of the above drugs result in favorable intubating conditions, the incidence of oxygen desaturation is high. Therefore, an ideal agent for conscious sedation should ensure Spontaneous ventilation with adequate airway patency, patient Cooperation favorable intubating conditions and stable hemodynamics and should not produce respiratory depression.[4]

Dexmedetomidine when compared to fentanyl had better tolerance to intubation and upper airway obstruction hence it is more effective than fentanyl.

Dexmedetomidine when used at doses of 1 mcg/kg bolus was safe and beneficial even without airway blocks, nerve blocks or topical anaesthesia. Dexmedetomidine on comparison with Midazolam provided better satisfaction and pain score during procedural sedation and less respiratory depression effects. In this study we will be comparing two groups, one with higher maintenance dose of 0.8mcg/kg infusion and the later with lower maintenance dose of 0.2mcg/kg infusion of dexmedetomidine so that the marked reduction in BP and HR which may occur in patients with higher maintenance dose can be reduced.

Aims and Objectives

To administer a bolus of 1 mcg/kg followed by 0.8 mcg/kg intravenous infusion of dexmedetomidine for patients requiring awake trans nasal fibreoptic endotracheal intubation (group A).

To administer a bolus of 0.8mcg/kg followed by 0.2 mcg/kg intravenous infusion of dexmedetomidine for patients requiring awake trans nasal fibreoptic endotracheal intubation (group B).

To compare and document the degree of sedation, adequacy of analgesia and adverse effects if any, between the above two group of patients.

Methods

After obtaining institutional ethical committee approval. 60 patients belonging to ASA I and II, aged between 20 to 60 of both genders posted for elective surgeries under general anaesthesia with anticipated difficult airway were selected. Patients were segregated into two groups of 30 patients each group based on computer generated randomisation after informed written consent. Exclusion criteria included patients suffering from cardio vascular disease (Hypertension, congestive heart failure, coronary artery disease).

- Respiratory disease
- Cerebrovascular insufficiency
- Coagulation defects/bleeding disorder
- Renal/hepatic insufficiency
- Patients with gastro oesophageal reflux, uncontrolled hypertension, ischemic heart diseases and any type of blocks on ECG.

- Patients who are on benzodiazepines or antidepressants or any sedatives.
- Possibility of pregnancy/known pregnancy.
- A thorough preanesthetic check-up was carried out, history was taken and systemic examination done. Vitals were noted including weight of the patient.

Investigations asked prior to surgery include

- Complete hemogram
- Serum electrolytes
- Blood urea and serum creatinine
- Random blood sugar
- Bleeding time and clotting time
- ECG and Chest x-ray
- Urine analysis for sugar, albumin and microscopy
- No other specific investigations were asked

All patients were assessed 1 day before the surgery, investigation reports were checked, anaesthetic procedure explained and informed consent was taken.

Fasting was ensured for 8hours and patients were premedicated with Tab. Alprazolam 0.5mg and Tab. Rantac 150 mg, which were repeated again on the morning of surgery.

Preparation of drug for infusion

Dexmedetomidine 1ml ampule containing 100mcg was diluted with normal saline till 20cc so that the solution contains drug of 5µg per ml.

The drugs were administered using a syringe pump.

Patients were randomly segregated into two groups by computer generated table.

GROUP A: received Dexmedetomidine 1mcg/kg as a bolus dose slowly over 10

minutes then 0.8mcg/kg/hr. as a maintenance dose by a syringe pump.

GROUP B: received Dexmedetomidine 0.8mcg/kg as a bolus dose slowly over 10 minutes then 0.2mcg/kg/hr. as a maintenance dose by a syringe pump.

Inj.Glycopyrrolate 0.2mg I.V given 45min before intubation. Patient was shifted to the operating theatre. Once the patient was shifted to OT their basal HR, NIBP, SPO 2 were noted and monitoring was started. I.V access was obtained with 18G venflon.4% lignocaine 4 ml was used for nebulizing the upper and lower airway.10% Lignocaine oral spray. Xylometazoline nasal drops were instilled.

Flexible fibreoptic bronchoscopy guided tracheal intubation with appropriately sized endotracheal tubes was done. Intubation conditions was evaluated by Total Comfort Score (TCS).

Adverse effects if noted were treated as follows:

Bradycardia with Inj. Atropine 0.6 mg I.V

Hypotension with IV fluids and Inj.Ephedrine 6 mg I.v bolus. Desaturation managed by connecting oxygen cannula through side port of FOB

Total Comfort Score

Levels of comfort and sedation were assessed by Total comfort score which contains seven parameters and each one is rated from a scale of one to five, one being minimum and 5 being maximum.

	1	2	3	4	5
Alertness	Deeply asleep	Lightly asleep	Drowsy	Fully awake	Hyper alert
Calmness	Calm	Slightly anxious	Anxious	Very anxious	Panicky
Respiratory response	No coughing and no spontaneous respiration	Spontaneous respiration	Occasional cough	Coughing regularly	Frequent coughing or choking
Crying	Quiet breathing, no crying	Sobbing or gasping	Moaning	Crying	Screaming
Physical movement	No movement	Frequent slight movement	Vigorous movement limited to extremities	Vigorous movements including torso and head	Occasional slight movement
Muscle movement	Muscles totally relaxed no movement	Reduced muscle tone	Normal muscle tone	Increased muscle tone and flexing of fingers and toes	Extreme muscle rigidity and flexing of fingers and toes
Facial tension	Facial muscle totally relaxed	No facial tension evident	Tension evident through muscle	Facial muscle contorted	Grimacing

Seven parameters which include alertness, calmness, respiratory response, crying, physical movement, muscle movement and facial tension.

Statistical software: The Statistical software namely SPSS 22.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

Sample Size: Sample was estimated based on total comfort scale during pre-oxygenation, during trans-nasal fibreoptic-scopy (FOS), and during endotracheal tube intubation.

In a study conducted by Sharif kamalarafa and Amirabozikryelsayed, During FOS the average variance of total comfort scale was 3.6 with a mean difference of 1.68 with 95% confidence interval, with 80% power to find an effect size of 0.89(14% different in total comfort scores) the required sample size per group is estimated at 30[5]

Results

Table 1: Age distribution of patients studied between two groups.

Age in years	Group A	Group B	Total
20-30	7(23.3%)	8(26.7%)	15(25%)
31-40	4(13.3%)	8(26.7%)	12(20%)
41-50	5(16.7%)	5(16.7%)	10(16.7%)
51-60	14(46.7%)	9(30%)	23(38.3%)
Total	30(100%)	30(100%)	60(100%)
Mean ± SD	44.47±14.16	41.50±13.22	42.98±13.66

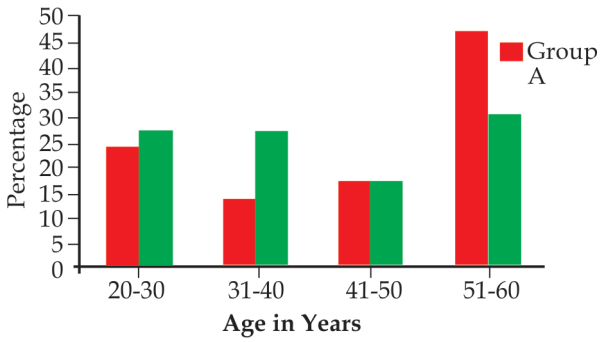

Fig. 1: Bar Diagram Showing Age.

The Mean age of subjects in group A was 44.47±14.16 years and in group B was 41.50±13.22 years. There was no significant difference in mean age between two groups with p value P=0.405. (Fig. 1 & Table 1)

Table 2: Weight (kg) distribution in two groups of patients studied.

Weight (kg)	Group A	Group B	Total
<50	3(10%)	4(13.3%)	7(11.7%)
50-60	10(33.3%)	7(23.3%)	17(28.3%)
61-70	3(10%)	13(43.3%)	16(26.7%)
>70	14(46.7%)	6(20%)	20(33.3%)
Total	30(100%)	30(100%)	60(100%)
Mean ±SD	65.80±12.25	63.27±10.47	64.53±11.37

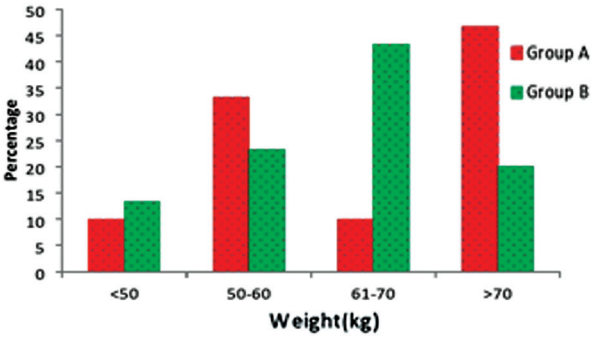

Fig. 2: Bar Diagram Showing Weight Distribution between Two Groups.

Mean weight of subjects in Group A was 65.80±12.25 kgs and in Group B was 63.27±10.47kgs. There was no significant difference in mean weight between two groups.(Figure 2 & Table 2).

Table 3: Gender distribution of patients studied.

Gender	Group A	Group B	Total
Female	12(40%)	12(40%)	24(40%)
Male	18(60%)	18(60%)	36(60%)
Total	30(100%)	30(100%)	60(100%)

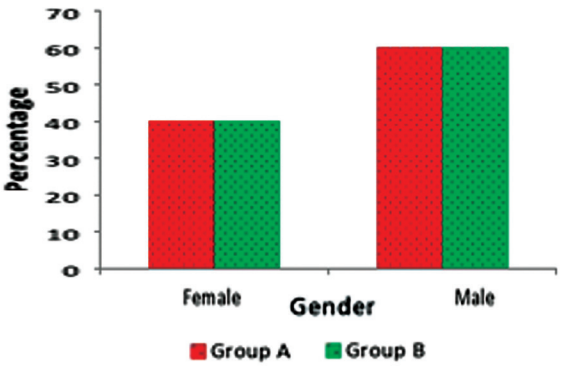

Fig. 3: Bar Diagram Showing Gender Distribution Between Two Groups.

Samples are gender matched with P=1, Chi-Square test. In this study, 40% were females and 60% were males. There was no significant difference in gender between two groups. (Fig. 3 & Table 3).

Table 4: Comparison of vital parameters in two groups of patients studied.

Variable	Group A	Group B	Total	P value
Pulse Rate	80.1±10.87	80.33±11.35	80.22±11.02	0.935
SBP (mm Hg)	120±10.17	116.33±10.66	118.17±10.49	0.178
DBP (mm Hg)	75±9.74	71.33±10.08	73.17±10	0.157
MAP (mm Hg)	89.93±9.42	86.27±9.89	88.1±9.75	0.147
RR	13.57±1.28	13.6±1.57	13.58±1.42	0.928
Spo2%	98.37±1.13	97.83±1.26	98.1±1.22	0.090+

On comparison of vital parameters between two groups Group A has better hemodynamic stability. (Fig. 4 & Table 4)

Variables that were compared areAlertness, Calmness, Respiratory response, Crying, Physical Movement, Muscle Movement and Facial tension. (Fig. 5 & Table 5).

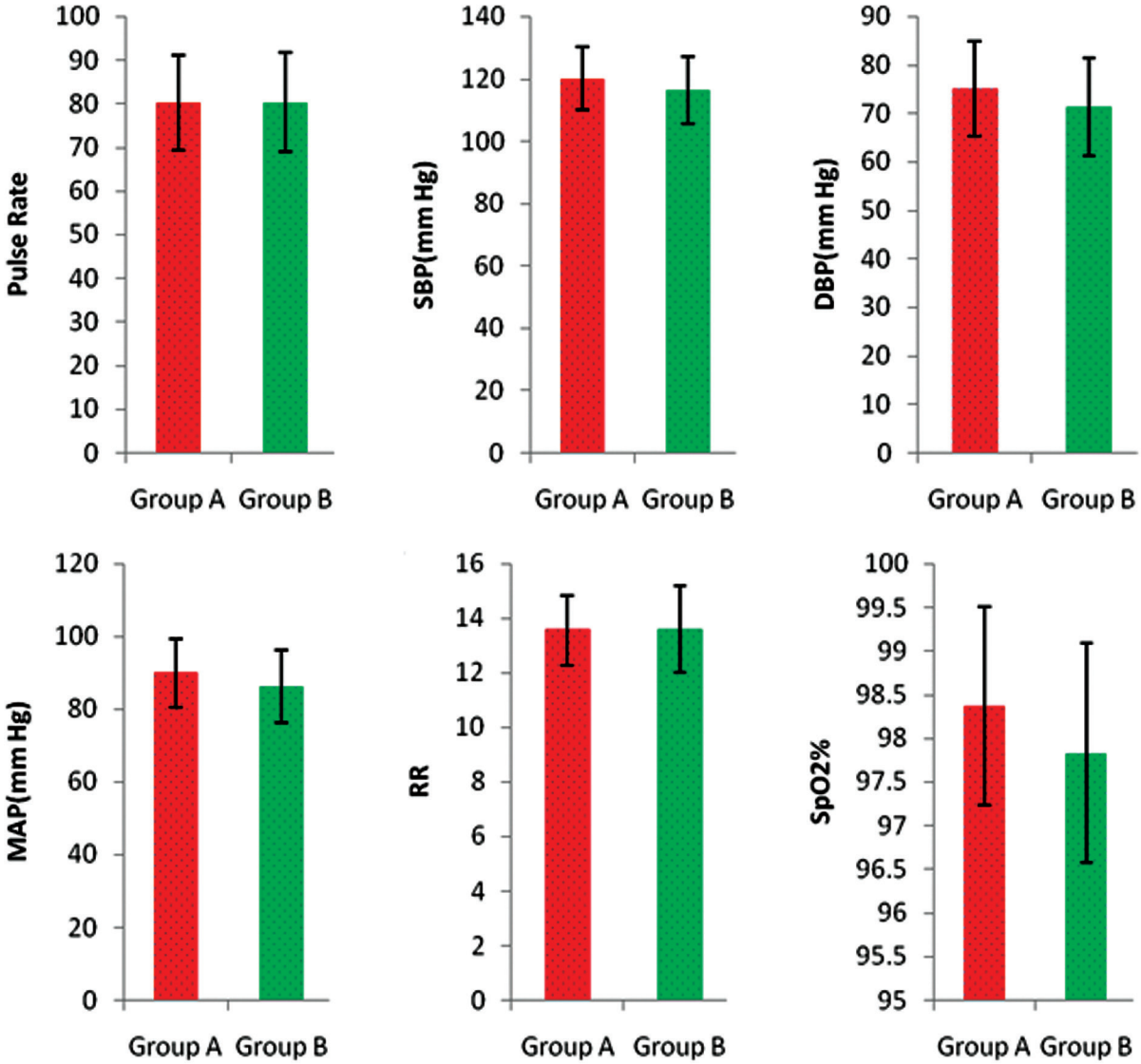

Fig. 4: Bar Diagram Showing Comparision of Vital Parameters between Two Groups.

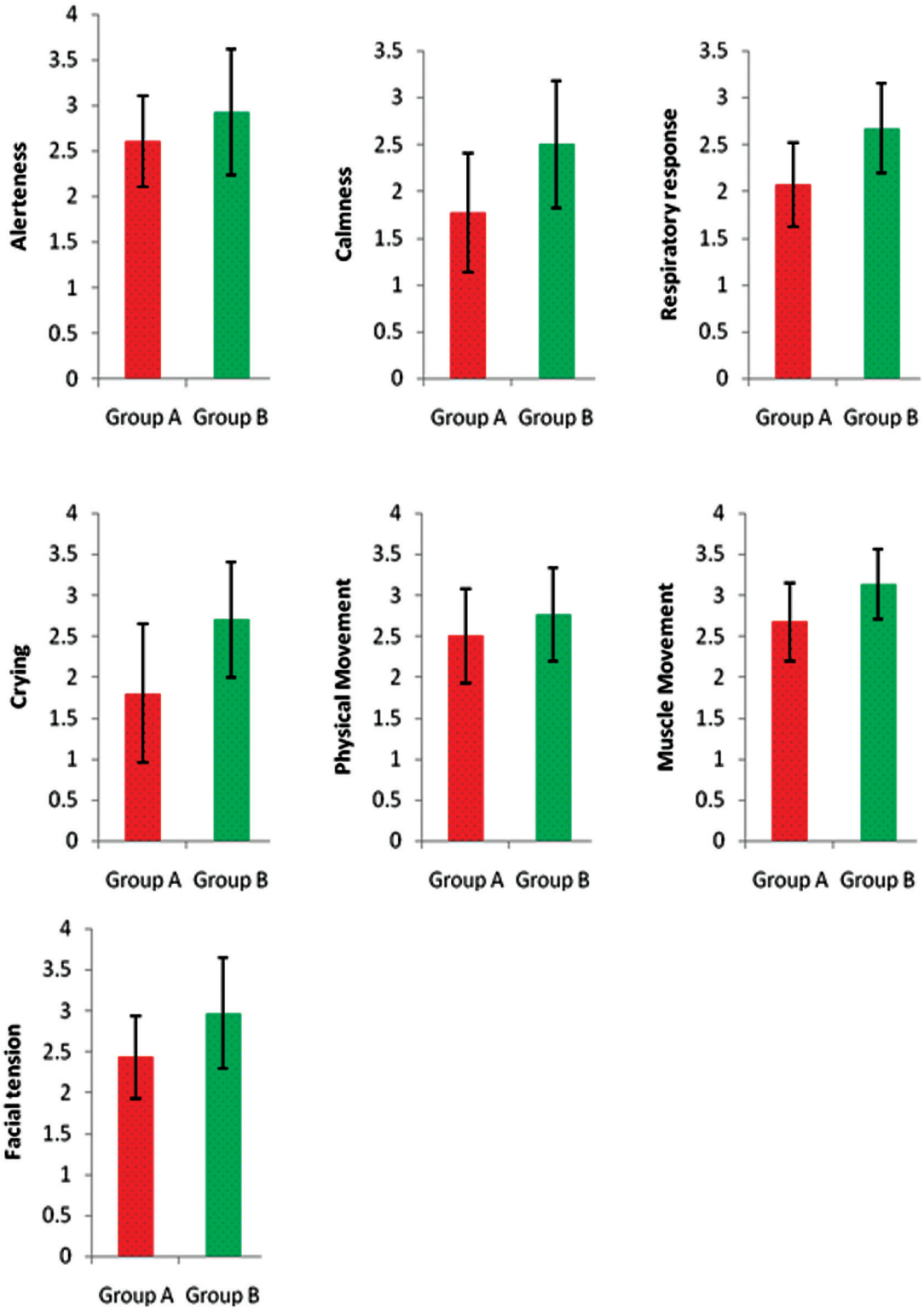

Fig. 5: Bar Diagram Showing Comparision Of Study Variables Between The Two Groups.

Table 5: Comparison of study variables (TCS) in two groups of patients studied.

Variables	Group A	Group B	Total	P value
Alertness	2.60±0.50	2.93±0.69	2.77±0.62	0.036*
Calmness	1.77±0.63	2.50±0.68	2.13±0.75	<0.001**
Respiratory response	2.07±0.45	2.67±0.48	2.37±0.55	<0.001**
Crying	1.80±0.85	2.70±0.70	2.25±0.89	<0.001**
Physical Movement	2.50±0.57	2.77±0.57	2.63±0.58	0.075+
Muscle Movement	2.67±0.48	3.13±0.43	2.90±0.51	<0.001**
Facial tension	2.43±0.50	2.97±0.67	2.70±0.65	0.001**

Table 6: Total Comfort Scores between the two groups.

Total Comfort Score	Group A	Group B	Total
<20	28(93.3%)	14(46.7%)	42(70%)
20-30	2(6.7%)	16(53.3%)	18(30%)
Total	30(100%)	30(100%)	60(100%)

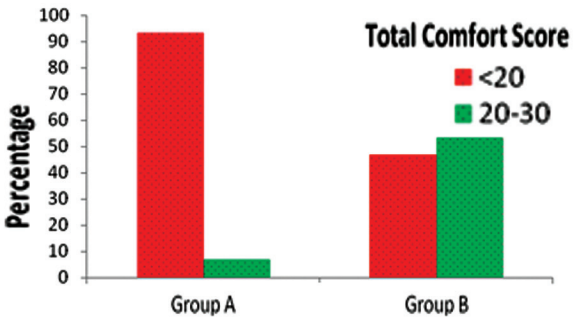

Fig. 6: Bar Diagram Showing Comparision Of Total Comfort Scores Between The Two Groups.

The TCS was scored from 7 to 35 with 7 being minimum and 35 being maximum score and in group A patients the average TCS was 15.84 ± 0.54 and in group B patients the average TCS was 19.67 ± 0.67 with a p value of < 0.001 which was significant using chi square test. (Fig 6 & Table 6)

Significant figures

+ Suggestive significance (P value: 0.05<P<0.10)

* Moderately significant (P value:0.01<P≤ 0.05)

** Strongly significant (P value: P≤0.01)

Discussion

In case of difficult airway scenarios, awake intubation is essential Awake fibreoptic bronchoscope guided intubation is one of the best method to secure airway in a case of anticipated difficult airway. For AFOI, different drugs were used to produce sedation while preserving spontaneous respiration.[6]

Endotracheal intubation in an awake state, if performed without Adequate sedation can be an unpleasant and discomforting experience for the patient. The various drugs used for sedation during AFOI are as

Follows:

1. Benzodiazepine (Midazolam)
2. Propofol
3. Alpha 2 agonists (clonidine &Remifentanil)
4. Ketamine

The above-mentioned drugs can be used alone or in combination with others and in various dosages as per the requirements of the patient, Clinical settings, operative conditions. An ideal sedative regimen for AFOI should provide patient comfort &cooperation, amnesia Anxiolysis, anti-tussive properties/attenuation of airway reflexes Stable hemodynamics and maintenance of a patent airway.[7]

The search for an Ideal sedative regimen for Awake Fibre optic Intubation is being constantly pursued by various clinical studies.[8]

Dexmedetomidine is a highly selective alpha 2 agonist mainly Acting upon the pontine Locus coeruleus nucleus producing sedation. Further, it has Anxiolytic, Analgesic and Anti sialagogue properties. An Important property of Dexmedetomidine is that it produces sedation without respiratory depression; in contrast opioid agonists produce Significant respiratory depression.[9]

This was a comparative two group clinical study carried out at R L Jalappa hospital and research centre, Tamaka, Kolar, during the Academic year from January 2019-June 2020.Sixty patients of age group 20-60 years with ASA grade I, II of both sex undergoing elective surgeries with anticipated difficult airway by general anaesthesia were included. patients were randomly segregated into two groups of 30 each after obtaining informed consent.

In this study we compared two different doses of dexmedetomidine, one with higher maintenance dose and the other with low maintenance dose for sedation during awake trans nasal endotracheal fibreoptic intubation.

GROUP A: received Dexmedetomidine 1mcg/ kg as a bolus dose slowly over 10 minutes then

0.8mcg/kg/hr. as a maintenance dose by a syringe pump.

GROUP B: received Dexmedetomidine 0.8mcg/kg as a bolus dose slowly over 10 minutes then 0.2mcg/kg/hr. as a maintenance dose by a syringe pump.

All patients had been counselled about the procedure and were premedicated with drugs T. Alprazolam 0.5 mg the night before the Surgery, T. Ranitidine 150 mg and T. Ondansetron 4 mg were given 2 Hours before the surgery.Inj.Glycopyrrolate 0.2mg I.V given 45min before intubation. Patient was shifted to the operating theatre. Once the patient was shifted to OT their basal HR, NIBP, SPO2 were noted and monitoring was started. I.V access was obtained with 18G venflon.4% Lignocaine 4 ml was used for nebulizing the upper and lower airway.10% Lignocaine oral spray. Xylometazoline nasal drops were instilled.

Then as per the study and the patient's group, dexmedetomidine loading doses were given before fibreoptic intubation, in group A 1µg/kg over 10 minutes and in group B 0.8µg/kg over 10 minutes.

After this maintenance dose of dexmedetomidine by a syringe pump was commenced in both groups and fibreoptic intubation was started, a well lubricated Fibreoptic bronchoscope preloaded with the appropriate ETT was inserted through the Nasal route and Intubation was successfully performed in all the patients. The infusion is continued till the end of the procedure that is securing the airway by endotracheal tube.

Intubation condition and tolerance to Intubation was assessed by Total Comfort Score (TCS). The Mean Arterial Pressure and the Heart Rate, Oxygen saturation using SpO_2 was monitored throughout the Intubation procedure.

Both the groups were comparable in terms of age, weight, gender and ASA grading in our study. In our study, we observed that there was significant difference in the Total comfort scores among the two groups, in group A the TCS was below 20 in 28 patients out of 30, whereas only 14 patients had a score less than 20 in group with p value <0.001 which was statistically significant. We also observed that TCS above 20 was seen in only 2 patients in group A where as in group B it was seen in 16 patients with a p value of <0.001 which was also statistically significant.

By seeing significant difference in the TCS, we conclude that dexmedetomidine at 1µg/kg bolus with 0.8mcg/kg/hr. Infusion was better at providing optimal sedation and comfort levels for the patient with spontaneous respiratory efforts being preserved; we also didn't observe any significant side effects during the procedure with higher maintenance dose.Peden et al., found that that bradycardia was observed in thePatients of healthy volunteers following dexmedetomidine administration and that can be prevented by administration of Glycopyrrolate before Intubation thereby preventing the side effects of dexmedetomidine.[10]

Bergere et al has observed that Dexmedetomidine in combination with low dose Midazolam is more effective than Midazolam alone for sedation in Awake Fibreoptic Intubation and that Dexmedetomidine at 1ug/kg bolus was safe and of good benefit for patients undergoing Awake Fibreoptic intubation even without airway nerve block or topical Anaesthesia.[11]

Further, Dexmedetomidine has been proved as an effective sedative agent for AFOI in difficult airway scenarios.[12] Venn et al reported unaltered hemodynamics even in higher doses of Dexmedetomidine infusion.[13]

Conclusion

We concluded that dexmedetomidine especially with loading dose 1µg/kg and higher maintenance dose 0.8µg/kg/h was better for fibreoptic intubation with better patient tolerance, patient comfort, patient satisfaction, good sedation and preserved upper airway with spontaneous breathing.

Conflicts of Interest: Nil

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Comparison of oral Midazolam versus Combination of Low Dose Oral Midzolam–Ketamine for Premedication in Paediatric Surgical Patients

Santhosh MCB[1], Umesh NP[2], Shivakumar G[3]

Author's Affiliation: [1]Associate Professor, [2]Assistant Professor, [3]Professor, Department of Anaesthesiology, Mandya Institute of Medical Sciences, Mandya, Karnataka 571403, India.

Abstract

Background and need for study: One of the challenge faced by paediatric anaesthesiologist is the allaying of fear of a child in the preoperative period. Among the commonly used premedicant in children, midazolam is the front runner. A combination low dose of ketamine and midazolam have been tried to overcome the deficiencies of ketamine and midazolam alone.

Aims: This research was planned to compare the effectiveness of combination of low dose midzolam–ketamine with oral midazolam alone as a premedicant in paediatric patients in terms of degree of sedation, separation from parents, mask acceptance, and postoperative recovery

Design: Prospective, randomised, double blind controlled study.

Methods: Sixty children of ASA physical status I or II, aged between 1 and 12 years, who were scheduled to undergo elective minor surgery were randomised into two groups M and MK of thirty children each. Children in group M were administered with oral midazolam 0.5 mg.kg-1 mixed with 2 ml of honey and group MK were administered with combination of low dose oral midzolam (0.25 mg.kg-1) & oral ketamine (3 mg.kg-1) for premedication mixed with 2 ml of honey. Patient was assessed for parental separation anxiety, mask acceptance, level of sedation and emergence delirium.

Statistical Analysis: Difference with respect to anxiety at separation from parents and tolerance to mask between the two groups was analysed using chi-square test . Difference with respect to incidence and severity of emergence delirium between the two groups was analysed using an independent sample t test . The $P < 0.05$ was considered significant.

Results: Parental separation was acceptable in 23 patients (76.7%) in group M and 28 patients in (93.3%) in group MK (Table 2, 3). Mask acceptance was satisfactory in 13 (43.3%) in group M and 19(63.3%) in group MK.

Post-operative delirium was noted in one patient in each group.

Conclusion: The low dose mixture of ketamine and midazolam provides better parental separation and mask acceptance with better cooperation during induction of anaesthesia.

Key words: Midazolam; Ketamine; Premedication; Anxiety; Delirium.

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Corresponding Author: Umesh NP, Assistant Professor, Department of Anaesthesiology, Mandya Institute of Medical Sciences, Mandya, Karnataka 571403, India.
E-mail: drumeshnp@gmail.com

Introduction and need for the study

One of the challenge faced by paediatric anaesthesiologist is the allaying of fear of a child in the preoperative period.[1] Anxiety would lead to violent behaviour and also increased postoperative pain, postoperative agitation.[2,3] The primary goal of preanaesthetic medication in children are to decrease fear associated with parent separation and unknown surroundings, and permit trouble free initiation of anaesthesia.

Among the commonly used premedicant in children, midazolam is the front runner.[4] It has a many of advantages: hypnosis, early onset, and relatively short duration of action.[4] Even with these advantages midazolam is at a distance from an ideal premedicant effects because of associated unwanted effects such as paradoxical reaction, respiratory depression, cognitive impairment, amnesia and restlessness.[5,6] Oral midazolam premedication produces good or excellent results in only 60% to 80% of cases.

Ketamine, a non-barbiturate cyclohexamine derivative, is fat soluble and quickly absorbed after intravenous, intramuscular, oral and intranasal administration. Ketamine when used alone as premedication in a dose of 6 mg.kg-1 was found to have undesirable effects, such as excessive salivation, hallucinations and dysphoria.[6]

So combination low dose of ketamine and midazolam have been tried to overcome the deficiencies of ketamine and midazolam alone.

In view of the above, our research was planned to compare the effectiveness of combination of low dose midzolam–ketamine with oral midazolam alone as a premedicant in paediatric patients in terms of degree of sedation, separation from parents, mask acceptance, and postoperative recovery.

Methodology

This study was an prospective, randomised, double blind controlled study. After obtaining institutional ethical committee clearance, written informed consent from the patient's parents or legal guardian, 60 children of ASA physical status I or II, aged between 1 and 12 years, who were scheduled to undergo elective minor surgery. Children with known allergy or hypersensitive reaction to midazolam or ketamine, cardiac arrhythmia or congenital heart disease, increased intracranial tension, intraocular pressure, chronic illness and mental retardation were not included in the study. Randomisation was done using computer generated table into two groups M and MK of thirty children each. Children in group M were administered with oral midazolam 0.5 $mg.kg^{-1}$ mixed with 2 ml of honey and group MK administered with combination of low dose oral midzolam (0.25 $mg.kg^{-1}$) & oral ketamine (3 $mg.kg^{-1}$) for premedication mixed with 2 ml of honey. Investigator 1 who was not involved in the collection of data prepared the study drug and administered the drugs orally 30 min prior to the surgery. The below parameters were recorded by investigator 2 who was blinded about the drugs given to the patient, Heart rate,respiratory rate and oxygen saturation (SPO_2) were monitored continuously and recorded at 5 min interval in the preoperative period. Anxiety of the patient was assessed by using the Parental Separation Anxiety Score (PSAS).

The Parental Separation Anxiety Scale (PSAS) is a 4-point scale as follows:

- 1 = easy separation
- 2 = whimpers, but is easily reassured, not clinging
- 3 = cries and cannot be easily reassured, but not clinging to parents
- 4 = crying and clinging to parents

A PSAS score of 1 or 2 were considered as an acceptable separation, whereas scores of 3 or 4 were considered difficult separations from the parents.

Level of sedation was assessed using five point scale as follows (sedation score)

1 = Agitated
2 = Alert
3 = Calm
4 = Drowsy
5 = Asleep

In the operation theatre, general anaesthesia was induced with oxygen, sevoflurane 3-5% using Jackson Ree's circuit with face mask.

The patient's ability to accept the anaesthesia mask was measured using the Mask Acceptance Scale (MAS).

The MAS scale (4-point Likert scale)

- 1 = excellent (unafraid, cooperative, accepts mask readily)
- 2 = good (slight fear of mask, easily reassured)
- 3 = fair (moderate fear of mask, not calmed with reassurance)
- 4 = poor (terrified, crying, or combative).

Patients who received a score of 1 or 2 were

considered "satisfactory" acceptance of the anaesthesia mask; scores of 3 or 4 were considered "unsatisfactory."

Once the patient was induced, intravenous (i.v) access was secured. Intravenous Fentanyl 2 $\mu g.kg^{-1}$ was given. Airway was managed with suitable size laryngeal mask airway. Anaesthesia was maintained with sevoflurane. Electrocardiogram, SpO_2 heart rate, end tidal carbon dioxide was monitored continuously and documented at 5 min intervals. Non-invasive blood pressure was recorded at 5 min intervals. Any cardiorespiratory or other adverse effects were noted.

For postoperative analgesia, paracetamol rectal suppositories were inserted near the end of the procedure. In PACU, patients vitals were monitored continuously.

In the PACU, emergence delirium was aanalysed using the Watcha scale

Behaviour	Score
Asleep	0
Calm	1
Crying, but can be consoled	2
Crying, but cannot be consoled	3
Agitated and thrashing around	4

Score higher than 2 indicates presence of emergence delirium.

Patients with delirium score higher than 2 were administered with iv midazolam (0.01- 0.02 $mg.kg^{-1}$).

Statistical Analysis

Difference with respect to anxiety at separation from parents and tolerance to mask between the two groups was analysed using chi-square test . Difference with respect to incidence and severity of emergence delirium between the two groups was analysed using an independent sample t test . The $P < 0.05$ was considered significant.

Results

Both the groups were comparable with respect to demographic data (Table 1). Mean age was 3.41 ± 2.03 years, and mean weight was 13.17± 3.72 kg. There was no significant difference in the surgical and anaesthesia duration. Parameters like heart rate, respiratory rate and oxygen saturation were in the normal range in both the groups. Other parameters like Parental separation was acceptable in 23 patients (76.7%) in group M and 28 patients in (93.3%) in group MK (Table 2, 3). Mask acceptance was satisfactory in 13 (43.3%) in group M and 19(63.3%) in group MK.

Post-operative delirium is noted in one patient in both the groups.

Table 1: Demographic data.

	Group M (30)	Group MK (30)	p value
Age 1- 3years	16	12	0.23
Age 3-5 years	09	11	0.12
Age 5-8 years	05	07	0.24
Sex (Male:Female)	22/8	20/10	0.78
ASA status I/II	29/1	28/2	0.82
Anaesthesia time (min)	52 ± 8.31	50 ± 5.97	0.13
Surgical time	42 ± 10.27	38 ± 11.21	0.37

Table 2: Comparison of parenteral separation, sedation score, mask acceptance and postoperative agitation (mean±SD).

	Group M (n=30)	Group MK (n=30)	p value
Parenteral separation score	3.47±0.43	1.47±0.57	0.028
Sedation Score	4.12±0.21	4.05±0.23	0.65
Mask acceptance score	3.10±0.03	1.8±0.05	0.034
Postoperative agitation	1.23±0.34	1.25±0.6	0.42

Table 3: Number of patients with acceptable sedation and parenteral separation.

	Group M (n=30) (%)	Group MK (n=30) (%)	p value
Parenteral separation score 1 or 2 at 30 min	23 (76.7%)	28 (93.3%)	0.039
Mask acceptance score (1 or 2)	13 (43.3%)	19 (63.3%)	0.042
Postoperative agitation (no)	1 (33.3%)	1 (33.3%)	0.32
Sedation score 3-5 at 30 minutes	24 (80%)	25 (83.3%)	0.46
No. of children asleep at induction	10 (33.3%)	11 (36.7%)	0.53
No of children disturbed at induction	15 (50%)	8 (26.7%)	0.048

Discussion

An anxious fearful fighting child is always stressful for the anaesthesiologists, care givers and parents and may lead to behavioural and psychological disturbances in the child which may affect daily functioning of the child. Children between 1 and 5 years of age appear to be at highest risk for developinganxiety because children under the age of 1 year rarelyexperience separation anxiety.[7]

Perioperative anxiety inchildren can be reduced by pharmacological or behavioural interventions.[8]

All routes of premedication and many premedication drugs have been tried but no single technique or agent has provided complete satisfactory results.

In our study, we have compared effectiveness of oral midazolam (0.5 $mg.kg^{-1}$) and combination of oral midazolam (0.25 $mg.kg^{-1}$) & oral ketamine (3 $mg.kg^{-1}$) in lower dose as premedicants in children undergoing elective surgical procedure. We found that the parenteral separation score (1 or 2) at 30 min, Mask acceptance score (1 or 2), number of children uncooperative at induction was lessin group MK significantly when compared group M. There was no significant difference between the two groups with regard to sedation score 3-5 at 30 minutes, number of children asleep at induction, incidence of postoperative agitation.

Darlong V et al, conducted a study on seventy eight children posted for elective eye surgery. They were divided them into three groups who received oral midazolam 0.5mg/kg or oral ketamine 6mg/kg or combination of lower dose of both midazolam 0.25mg/kg and ketmine 3mg/kg in combination as a premedication. They concluded that combination of oral ketamine and midazolam in low dose had very less side effects and was more effective, faster in onset and had a more rapid recovery when compared to other two groups.[9]

Majidinejad S, Taherian K et al., randomized, double-blinded, clinical trial to compare the combination of oral midazolam and ketamine with oral midazolam alone as sedatives during the procedure among children subjected to computed tomography imaging. The study populationconsisted of patients with age group of 6 months to 6 years with minor head traumamedium-risk, who were advised to undergo brain CT imaging. Patients were randomly divided in to two groups: one group received 0.5 mg/kg midazolam (group OM, n = 33) orally and anothergroup received combination of 0.2 mg/kg midazolam and 5 mg/kg ketamine orally (group OMK, n=33). This study showed that in comparison with Oral midazolam, combination of oral midazolam with ketamine was more effective in providing a satisfactory sedation levelin children undergoing CT examination without any additional side effects; however, both the regimens did not fulfil the clinical needs for sedation during the procedure.[10]

Damle SG, Gandhi M, Laheri V conducted a randomized double-blind study to evaluate the sedative effects of oral ketamine and oral midazolam administered before general anesthesia. Twenty unco-operative children between the age-group of 2 to 6 years were selected after thorough clinical examination and tests. Children were administered eitherwith 0.5 mg/kg oral midazolam or 5 mg/kg ketamine, results showedthat adequate sedation is obtained at the end of 30 min with both the drugs, alsosignificantly better anxiolysisobtained with oral midazolam. Oral ketamine produced slightlyhigher heart rate and respiratory rate. It was noted from the questionnaire that oral midazolam has better response and side effects were more common with oral ketamine.[11]

Darlong V et al conducted a prospective randomised, controlled study in eighty seven children posted forelective ophthalmologic surgeries. One group (M) received oral midazolam 0.5 mg/kg, another group (MKL) received oral midazolam 0.25 mg/kg and ketamine 3 mg/kg, and Group (MKH) received midazolam 0.5 mg/kg and ketamine 6 mg/kg.

Level of sedation and ease of parental separation were noted during general anaesthesia procedure. They concluded that a combination of midazolam and ketamine in lower dose is as equally effective as high-dose midazolam and ketamine for achieving adequateanxiolysis and a rapid recovery, along with lesser incidence of excessive salivation in children undergoing ophthalmic surgery.[12]

With the review of above scientific studies and results of our study is in concordance with the findings of above studies.

Darlong et al had found lesser incidence of salivation and lesser haemodynamic changes in low dose combination group than higher dose combination group. In our study, inspite of administration of ketaminethere was no incidence of excessive salivation or changes in haemodynamic parameters in group MK when compared to group M. Limitation of the study is the number patients studied.

Conclusion

The low dose combination of ketamine and midazolam provides better parental separation and mask acceptance with better cooperation during anaesthesia induction. As there was no difference in the incidence of side effects between the two groups, it can be concluded that low dose combination of ketamine and midazolam can replace midazolam alone as premedicant in children.

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A Comparative Study of Dexmedetomidine as Adjuvant to 0.5% Bupivacaine in Erector Spinae Plane Block for Perioperative Analgesia in Patients Undergoing Percutaneous Nephrolithotomy

Sampreeta S Reddy[1], Swati Bisht[2]

Author's Affiliation: [1]Junior Resident, [2]Professor, Department of Anaesthesiology, Vydehi institute of medical sciences and research centre, Whitefield, Bengaluru 560066, Karnataka.

Abstract

Context: Patients undergoing percutaneous nephrolithotomy (PCNL) experience considerable post-operative pain. Perioperative pain control for PCNL using regional anaesthesia techniques like erector spinae plane block (ESPB) helpsin better outcome in terms of pain, fentanyl requirement. It also indirectly helps in faster recovery and early discharge from hospital.

Aims: To assess and compare perioperative pain control provided by ESPB with 0.5% bupivacaine and dexmedetomidine as adjuvant to it.

Settings and Design: This randomized case control study was undertaken in a tertiary care centre. 60 patientsplanned for elective unilateral PCNL over a period of 15 months. Patients were randomized into two groups (Group B and group D) using envelope method. Patients were compared for fentanyl consumption, duration and effectiveness of analgesia obtained.

Methods and Materials: ESPB was administered pre operatively under ultrasound guidance at the level of 10th thoracic vertebrae. Needle tip was visualised above transverse process of 10th thoracic vertebra. Position was confirmed by hydro dissection on injecting normal saline under ultrasound and drug was injected.Patients were assessed for painat specific time intervals. Total opioid consumption was noted. Data obtained was recorded and analysed.

Statistical analysis used: Statistical analysis was performed by SPSS software v.23.0. One-way analysis of variance, Bonferroni correction, Chi square test was used. P value of <0.05 was considered statistically significant.

Results: Dexmedetomidine as adjuvant to local anaesthetic agent improves the quality and prolongs the duration of analgesia. It also decreases total fentanyl consumption.

Conclusion: ESPB provides adequate analgesia for PCNL. Addition of dexmedetomidine decreases fentanyl and sevoflurane consumption meanwhile increasing duration of analgesia.

Key words: Erector spinae plane block; Dexmedetomidine 0.5 %; Bupivacaine; Peri operative analgesia.

Key message: Ultrasound guided pre-emptive single shot ESPB with dexmedetomidine as adjuvant to 0.5% bupivacaine provides good analgesia, reduces total opioid consumption and facilitates rapid recovery.

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Corresponding Author: Sampreeta S Reddy, Junior Resident, Department of Anaesthesiology, Vydehi institute of medical sciences and research centre, Whitefield, Bengaluru 560066, Karnataka, India.
E-mail: sampreeta.royal@gmail.com

Introduction

PCNL is a minimally invasive endoscopic urosurgical procedure of choice for renal calculi of >2cm, staghorn calculi and multiple calculi.[1] Although PCNL is a minimally invasive procedure, it is associated with considerable pain caused by percutaneous tract, distension of pelvicalyceal system and Gerota's fascia with irrigation fluid and placement of nephrostomy tubes. As with any other surgeries, management of surgery related pain is important in PCNL. Optimal dynamic analgesia, preferably non opioid analgesia is a crucial component in enhanced recovery, length of hospital stay and reversion to daily activities as it also avoids nausea, vomiting and constipation associated with opioids.[2]

Practice of regional anaesthesia techniques have significantly evolved after introduction of ultrasound. Ultrasound guided ESPB is a newly described peri paravertebral regional anaesthesia technique by Forero et al as novel and simple interfascial plane block for thoracic neuropathic pain.[3] Since its description, it has been compared with different regional anaesthetic techniques and is being studied pain management in different surgeries.[4,5] ESPB is reported to be easier, safe in administration and providing extensive and potent analgesia with minimal expectable complications.[6]

Dexmedetomidine, a selective alpha 2 agonist, has been found to have additive effect with local anaesthetic agents by increasing duration of action. Hence it is added as adjuvant for local anaesthetic agent to assess and compare the efficacy and duration of analgesia in this study.

Through this study, we intended to study the efficacy of dexmedetomidine as adjuvant to 0.5% bupivacaine in ultrasound guided single shot pre-emptive ESPB in terms of duration of analgesia, fentanyl and inhalational agent consumption in patients undergoing elective unilateral PCNL.

Methodology

This study was conducted in a tertiary care centre. Institutional ethics committee approval was obtained for the single blinded randomized case control study. 60 patients of American society of Anaesthesiologists (ASA) physical status 1 and 2, aged between 18 to 60 years, undergoing elective unilateral PCNL were enrolled for the study. Patients with deranged coagulation profile, deranged renal function, allergy to local anaesthetic agent, active infection at injection site, spine deformities or the patients who refused ESPB were excluded from the study. Informed written consent was obtained from all participants. Thorough pre anaesthetic evaluation was done for all the patients. They were educated on visual analogue scale (VAS) scoring system for assessment of pain. Patients were randomized into two groups (group B and group D) using sealed envelope method. Pre operatively, patients were kept nil per orally (NPO) for at least 6 hours. During NPO period, patients were hydrated with intravenous fluids as per body weight. Patients were premedicated with injection pantoprazole sodium 40mg on the morning of surgery.

Pre-operatively patient was connected to standard cardiac monitors and was put on right lateral position. For ESPB, skin at the site of procedure was prepared with 5% povidone iodine and 70% isopropyl alcohol. Sterile drapers were covered. A high frequency linear ultrasound transducer [Siemens ACUSON freestyle TM, Germany] was used. Spinous process of 9th thoracic vertebra was palpated and scanned at the corresponding level transverse process of 10th thoracic vertebra was located by moving the probe laterally by 3cm from the midline. The probe was then rotated by 90 degrees clockwise. Skin, subcutaneous tissue, trapezius and erector spinae muscles were identified. [Figure 1] A 22G 80mm facet type sonotap needle [Pajunk, Geisingen, Germany] was introduced in-line cephalocaudally till the needle tip is at the transverse process below erector spinae muscles. Location of needle tip is confirmed by visible hydro dissection on injecting normal saline.

Group B patients received 2mg/kg of 0.5% Bupivacaine. Group D patients received 1mcg/kg dexmedetomidine and 2mg/kg 0.5% bupivacaine. Injection of drug was considered as time T0 and patient was monitored hemodynamically.

General anaesthesia for PCNL in both the groups followed same technique. Patients were pre medicated with glycopyrrolate 0.005mg/kg, midazolam 0.02mg/kg, ondansetron 0.1mg/kg IV. Pre oxygenation with 100% oxygen followed by induction with fentanyl citrate 2mcg/kg, propofol 2mg/kg and atracurium besylate 0.5mg/kg IV. Fentanyl citrate 0.5mcg/kg IV was repeated after every 60minutes and atracurium besylate 0.1mg/kg IV as required. Post-surgery, residual neuromuscular blockade was reversed using neostigmine methyl sulphate 0.05mg/kg and glycopyrrolate 0.01mg/kg IV.

Post operatively patients were assessed for presence and severity of pain during rest and on

cough, total fentanyl requirement and presence of side effects like nausea, vomiting, bradycardia, hypotension, shivering, pruritis etc. Patient was assessed regularly at 2nd houly interval for first 24 hours and 6th hourly thereafter. VAS score more than 4 was considered as intolerable pain and rescue analgesics like paracetamol 1g IV and diclofenac sodium 75mg in 100ml normal saline were administered.

Results

All characteristics were summarized descriptively. For continuous variables, the summary statistics of mean± standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries and diagrammatic presentation. Chi-square ($\chi 2$) test was used for association between two categorical variables. The difference of the means of analysis variables between two independent groups was tested by unpaired t test. If the p-value was <0.05, then the results were considered to be statistically significant otherwise it was considered as not statistically significant. Data were analyzed using SPSS software v.23.0. and Microsoft office 2007.

Table 1: Comparison of study groups in terms of various demographic parameters considered in the study.

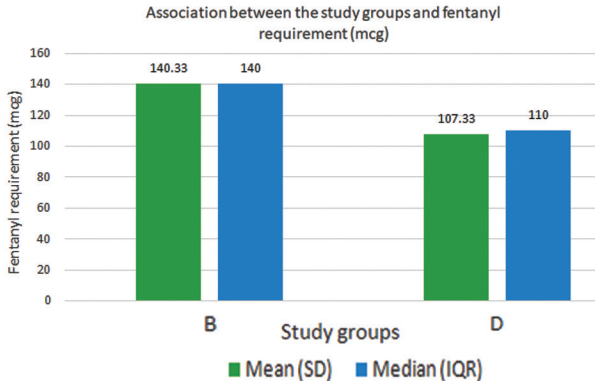
Parameters	Groups		P values
	B	D	
Age (years)	40.90 ± 10.59	38.73 ± 11.82	0.714
Gender [Male: Female] (%)	18:12 (60%: 40%)	16:14 (53.3%:46.7%)	1.000
ASA PS [I:II] (%)	16:14 (53.3%:46.7%)	18:12 (60%: 40%)	1.000
Duration of surgery (Mins) (mean ± SD)	83.17 ± 17.39	81.67 ± 16.63	0.977

Table 2: Comparison of study groups in terms of fentanyl requirement and duration of analgesia.

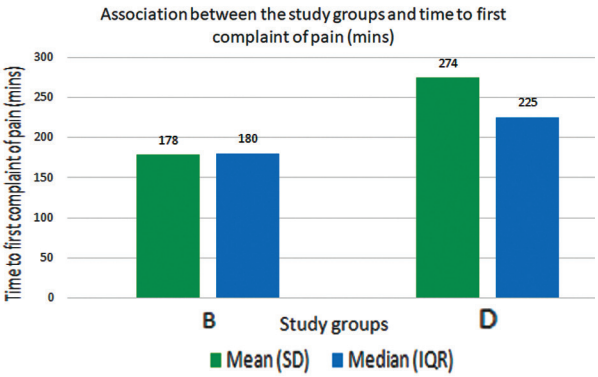
Parameters	Groups		P values
	B	D	
Fentanyl Required (mcg) Mean ± SD	140.33 ± 37.55	107.33 ± 17.80	<0.001
Time to first complaint of pain (min) Mean ± SD	178.00 (28.33)	274.00 (150.05)	<0.001

A total of 60 patients (30 patients in each group) were recruited and all completed the study. The demographic profile such as age and gender distributionwere expressed as mean and standard deviation and both groups were comparable. There was no statistically significant difference among two groups with regard to distribution of ASA physical status 1 and 2 patients, hemodynamic variations and duration of surgery. [Table 1] There was a highly significant statistical variation in regards to the duration of analgesia and opioid requirement in both the groups with p value <0.05. [Table 2, Graph 1 and graph 2]

Graph 1: Mean and median of fentanyl requirement (mcg) and association between study groups.



Graph 2: Mean and median of time to first complaint of pain (mins) and association between study groups.



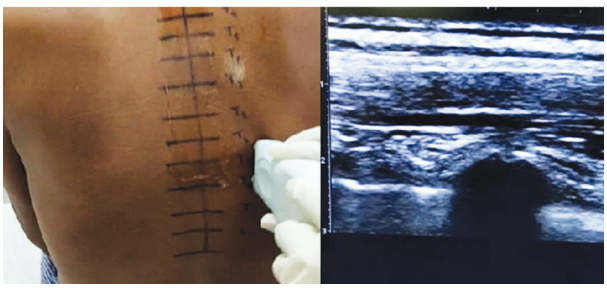


Fig. 1: Image showing surface and ultrasound anatomy of erector spinae muscles at T10 vertebral level.

In group D, 2 patients developed hypotension intraoperatively which was corrected by administration of ephedrine hydrochloride 6mg IV. In group D, 3 patients developed nausea post operatively for which ondansetron 0.1mg/kg IV was administered. None of these complications

were observed in group B patients. Patients in group D required less dose of fentanyl citrate intra and post operatively. Duration of analgesia was prolonged and patients required lesser rescue analgesic agents and was statistically significant.

Discussion

Three muscle bundles namely iliocostalis, longissimus and spinalis together form Erector spinae muscle. They extend bilaterally from spinous process to ribs and the skull to the sacral region and pelvis. It supports the spine in erect posture and is an anti-gravity muscle.[7]

Erector spinae plane block (ESPB) was first described by Forero et al in 2016 as the block administered by injecting the local anaesthetic agent below erector spinae muscle layer and above the transverse process.[3] The drug administered is assumed to produce combined effect of paravertebral, neuraxial, intercostal and retro laminar blocks. It acts both on dorsal and ventral primary rami by interfascial spread. Main mechanism of action is assumed to be the spread towards dorsal primary rami and into paravertebral space.

Patient should either be positioned in sitting or in lateral decubitus or in prone position. The spinous process of 7th cervical vertebra is the most prominent. Hence, the spinous processes can be counted down till the level required to provide analgesia for different surgeries. It is also seen that the drug administered spreads craniocaudally. So, the site of injection should ideally be kept the midpoint of the required level of analgesia. In this study, the block was administered in patients undergoing PCNL. Hence, spinous process of 9th thoracic vertebra was marked which corresponds to transverse process of 10th thoracic vertebra.

The ultrasoundprobe should be placed horizontally on the midline on marked spinous process. Here it was 9th thoracic spinous process. The probe should be moved 2–3 cm laterally to locate transverse process and rotated 90 degree clockwise. In lower thoracic level, only two layers of muscles that is, trapezius and erector spinae muscles can be identified above hump like transverse process of vertebra. At costovertebral junction, the appearance of hump like projection changes to rounded acoustic shadows.[8] The needle should be inserted inline cephalocaudally till the needle tip is visualised at the transverse process. Local anaesthetic agent should be injected on confirming the hydro dissection.

Ultrasound guided regional anaesthesia techniques are safe and accurate in avoiding complications like intravascular injections and nerve injury. Usage of ultrasound also greatly reduces the quantity of drug used in the block.[8]

Dexmedetomidine is a centrally acting selective alpha 2 agonist. It mediates antinociceptive signals via peripheral alpha 2 adrenoreceptors. It results in activation of rectifying potassium channels leading to hyperpolarization of membrane thus decreasing excitability.[9]

In this study, we studied intraoperative and post-operative effects of dexmedetomidine as adjuvant to 0.5% bupivacaine in ultrasound guided single shot pre-emptive erector spinae plane block. Local anaesthetic agents like bupivacaine provide good analgesia for about 4 to 6 hours when used solely in single shot techniques. To prolong the duration, catheter placement and addition of adjuvants are the options. Catheter placement has it's own disadvantages like misplacement, migration and infections etc. Best method to improve the quality and duration of analgesia is by adding opioid or non-opioid adjuvant and comparatively with minimal and predictable complications. Usage of IV opioids and no steroidal anti-inflammatory agents have side effects like sedation, nausea, vomiting, constipation and respiratory depression etc

Regional anaesthesia techniques if used along with other modalities of analgesia, produces excellent pain control intra and post operatively. It reduced the opioid agent requirement intra operatively. It also reduces the pain and morbidity post operatively. ESPB administration for PCNL, showed possibility of early mobilization of patients. This indirectly reduced the duration if hospital stay and expenses for the patients.

ESPB is safer and easier. Complications like motor block and pleural injury were not encountered in our study. The limitations of the study are non-inclusion of paediatric and geriatric patients, exclusion of patients with co morbid conditions and also measurement of plasma levels of drugs are not done.

To conclude, ESPB provides good analgesia in patients undergoing PCNL. Addition of dexmedetomidine as adjuvant to bupivacaine increased the quality of block. Hence it can be included as one of the multimodal analgesic techniques followed under enhanced recovery protocols.

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Comparison of Analgesic Efficacy of Levobupivacaine and Levobupivacaine with Nalbuphine in Inguinal Hernia Surgeries Under Subarachnoid Block

Rajesh Singh Rautela[1], Rashmi Salhotra[2], Shreshtha Jha[3]

Author's Affiliation: [1]Director Professor and Medical Director, [2]Professor, [3]Senior Resident, Department of Anesthesiology and Critical Care, University College of Medical Sciences and Guru Teg Bahadur Hospital, Dilshad Garden, Delhi- 110095, India,

Abstract

Background: Recently there has been an interest to explore the efficacy of nalbuphine as' an adjuvant to local anaesthetic agents. This study was designed to compare its analgesic efficacy when added to levobupivacaine in patients undergoing inguinal hernia surgeries under subarachnoid block.

Methods: Fifty patients belonging to ASA I/II, between 18-65 years of age undergoing inguinal hernia repair were randomly allocated to receive subarachnoid block with either 12.5 mg of 0.5% isobaric levobupivacaine (2.5 ml)+ normal saline (0.5 ml) (Group-LS) or 12.5 mg of 0.5% isobaric levobupivacaine (2.5 ml)+ 1 mg nalbuphine (0.1 ml) + normal saline (0.4 ml) (Group-LN). Onset of sensory block, two segment regression time, time of regression to T12, duration of effective analgesia and intensity of motor block were assessed.

Results: Onset of sensory block was comparable in the two groups (P=0.774). Time of regression of sensory block to T12 dermatome was 161.09 ± 40.50 min in group LS and 167.50 ± 50.17 min in group LN (P=0.633).The duration of effective analgesia was 177.39 ± 43.53 min in group LS and 183.75 ± 56.69 min in group LN (P=0.669).Motor block parameters were also comparable.More number of patients in group LN had a sedation score of one as compared to group LS.No major side effects were seen.

Conclusion: 12.5 mg levobupivacaine with or without nalbuphine is sufficient for conducting inguinal hernia surgeries. Intrathecal nalbuphine 1 mg did not affect the sensory and motor block characteristics of levobupivacaine.

Key words: Nalbuphine; Inguinal hernia; Levobupivacaine; Subarachnoid block.

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Corresponding Author: Shreshtha Jha, Senior Resident, Department of Anesthesiology and Critical Care, University College of Medical Sciences and Guru Teg Bahadur Hospital, Dilshad Garden, Delhi- 110095, India,

E-mail: shreshthajha2410@gmail.com

Introduction

Inguinal hernia surgeries are commonly performed under subarachnoid block because of safety, reliability, good postoperative analgesia and cost effectiveness.[1,2] Since bupivacaine is implicated with high cardiovascular and neurological toxicity[3-5] newer local anesthetics are being explored. Levobupivacaine is the S-isomer of bupivacaine [6]which supposedly has less cardiac and neurological toxicity than racemic bupivacaine.[3,7]

Various 'adjuvants may be added to intrathecal local anaestheticsto improve the quality and intensity of block and to provide post-operative analgesia. Nalbuphine is a mixed opioid i.e. kappa agonist and μ antagonist. So, it provides analgesia without significant sedation, respiratory depression and pruritus.[8,9]

The block characteristics of hyperbaric drugs such as bupivacaine along with nalbuphine have been studied extensively. However, there is limited literature available on the effect of addition of nalbuphine on the block characteristics of isobaric drug such as levobupivacaine when given via the intrathecal route. Hence, this study was planned to compare the analgesic efficacy of nalbuphine as an adjuvant to levobupivacaine in patients undergoing inguinal hernia surgery under subarachnoid block. The primary objective was assessment of analgesic efficacy and secondary objective were assessment of sensory and motor block parameters and side effects.

Materials and Method

This randomized, double blind, prospective study was undertaken after getting clearance from the Institutional Ethical Committee- Human Research (IEC-HR). The trial was registered with Clinical Trials Registry-India (ctri.nic.in) before enrolling the patients.All the procedures followed were in accordance with the Helsinki Declaration of 1975, as revised in 2000. Patients belonging to American Society of Anesthesiologists(ASA) physical status I/II between 18-65 years of age, height between 150 and 180 cm, scheduled for inguinal hernia surgery under subarachnoid block were included. Patients who did not give consent for subarachnoid block, who had infection at injection site, coagulopathy, any space occupying lesion, increased intracranial tension, seizure disorder, spine deformity, hepatic or renal disease, arrhythmias,drug addicts and chronic alcoholics were excluded.

Written informed consent was taken before recruiting the patients. Patients were transferred to operation theatre where non-invasive blood pressure, ECG and pulse oximetry were monitored. An intravenous access was established and preloading was done with ringer lactate 15 ml/kg over 15-30 minutes. Patients were randomly allocated to one of the two groups using a computer generated table of random numbers.

Group-LS: 12.5 mg of 0.5% isobaric levobupivacaine (2.5 ml) [Levo-anawin, Neon pharmaceuticals Ltd]+ normal saline (0.5 ml)

Group-LN: 12.5 mg of 0.5% isobaric levobupivacaine (2.5 ml) [Levo-anawin, Neon pharmaceuticals Ltd] + 1 mg nalbuphine(0.1 ml) [Nacphin, Neon pharmaceuticals Ltd] + normal saline (0.4 ml)

The total volume of intrathecal drug injected was 3 ml in both the groups.

Study drug was prepared by an anesthesiologist who was not involved in the further conduct of the study. Both, the patient and the anesthesiologist who assessed the block characteristics and other parameters were kept blinded to group allocation.

Subarachnoid block was performed under all aseptic precautions in sitting position with midline approach. A 25 G Quincke's spinal needle was introduced at L2-L3/L3-L4 intervertebral space with bevel facing cephalad and 3 ml of the study drug was injected at the rate of 0.5 ml/sec after confirming free flow of cerebrospinal fluid. After removing spinal needle, patient was made supine. Oxygen was given by facemask at the rate of 4 L/min. Heart rate, blood pressure, arterial oxygen saturation, respiratory rate, VAS score, motor block as per Modified Bromage scale (MBS) and sedation score were recorded every 5 min for first 30 min and then every 15 min till the end of surgery. The level of sensory block was assessed by pin prick method in mid clavicular line using a 26G hypodermic needle every 2 min until the level had stabilized for 3 consecutive tests and this sensory level was recorded as the highest level of sensory block following which it was assessed at intervals mentioned above for other parameters.

Any episode of hypotension, determined by fall in systolic blood pressure (SBP) >20% from pre-operative baseline value or SBP<90 mm Hg was managed by rapid infusion of additional intravenous fluids and mephentermine 6 mg I.V.Bradycardia (heart rate less than 50/minute) was treated with atropine 0.6 mg I.V. Intraoperative nausea, vomiting, headache, dizziness, pruritus and any other side effects were noted and treated accordingly. Quality of sensory block was assessed

as the time of onset of block at T10 dermatome, maximum block height, time of two segment regression of sensory block (from the maximum height of block), time of regression of sensory block to T12 dermatome and duration of effective analgesia. Motor block was assessed as per the Modified Bromage Scale[10] as follows:

Grade	Criteria
0	No motor loss
1	Inability to flex the hip
2	Inability to flex the knee
3	Inability to flex the ankle

In case the sensory block level of T10 was not achieved by 20 min after intrathecal injection, patient was given general anaesthesia and was counted as failure.

After completion of surgery, patients were shifted to postoperative ward and all the parameters mentioned above were recorded at every 15 min till the time when the patient first complained of pain (VAS ≥ 3). Pain was evaluated by using a 0-10 cm Visual Analogue Scale (VAS) where '0' represents no pain and '10' represents worst imaginable pain.[11]

Pain was noted at intervals mentioned previously. Duration of effective analgesia was defined as time from giving subarachnoid block to patient's first complaint of pain (VAS ≥ 3). At the time of patient's first complaint of pain, paracetamol 1g I.V.was given as rescue analgesia.

Sedation was assessed as per University of Michigan Sedation Scale as mentioned below.[12]

0	Awake and alert
1	Minimally sedated: tired/sleepy, appropriate response to verbal conversation and/or sound
2	Moderately sedated: somnolent/ sleeping, easily aroused with light tactile stimulation or a simple verbal command
3	Deeply sedated: deep sleep, arousable only with significant physical stimulation
4	Unarousable

Considering a standard deviation of 46.9 min from a previous study7 to estimate a difference of 40 min in time of regression of sensory block to T12 dermatome, at 5% level of significance and 80% power, 22 cases were required in each group. To account for failures, a total of 50 patients were randomized to one of the two groups (25 patients per group).

Statistical analysis was carried out using SPSS, software version 20.0. The quantitative parameters like age, height, weight, time of onset of block, time to two segment regression of sensory block, time of regression of sensory block to the level of T12 dermatome and duration of effective analgesia which were measured at one-time point were compared using unpaired t-test. Level of block and Modified Bromage Scale were represented as median [inter-quartile range] and were compared by Mann-Whitney U-test. Sedation score was analysed using Chi-square test. Repeated measure ANOVA was used to compare the haemodynamic variables. A p-value <0.05 was considered as significant.

Results

A total of 78 patients were enrolled. Twenty eight were excluded for various reasons. A total of 50 patients were randomized into two groups of 25 each to receive allocated intervention (Figure 1). Two patients from group LS and one patient from group LN were excluded due to failure of subarachnoid block. So, a total of 47 patients were analysed.

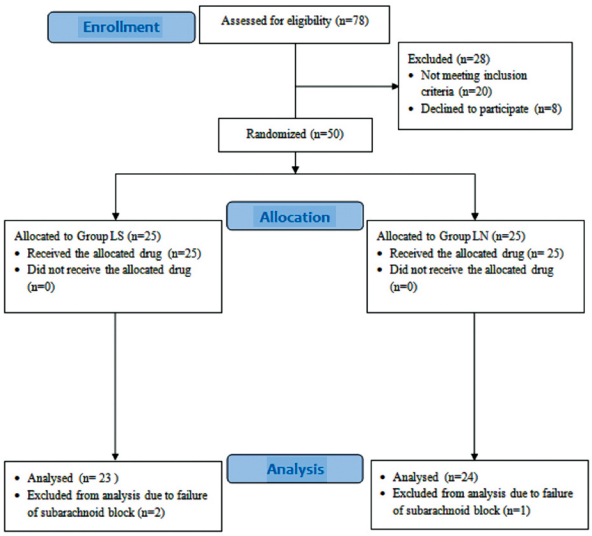

Fig. 1: CONSORT flow diagram.

Table 1: Demographic Profile.

Parameter	Group LS (n=23)	Group LN (n=24)	P
Age (yr)	36.2 ± 13.0	42.0 ± 13.8	0.146
Weight (kg)	61.8 ± 7.2	56.6 ± 6.9	0.015
Height (cm)	163.6 ± 5.5	160.2 ± 4.1	0.021
Duration of surgery (min)	80.87 ± 11.74	70.00 ± 13.75	0.006

Yr=year, kg=kilogram, cm=centimetre, Min=

minutes. P< 0.05 is considered statistically significant, Values are expressed as Mean ± SD.

Table 2: Characteristics of Sensory Block.

Parameter	Group LS (n = 23)	Group LN (n = 24)	P
Maximum Block height*	T6 [T6-T8]	T6 [T6-T8]	0.798
Time of onset of block (min)†	5.30 ± 2.34	5.41 ± 2.07	0.774
Time of two segment regression(min)†	61.09 ± 28.88	54.58 ± 19.33	0.372
Time of regression to T12 (min)†	161.09 ± 40.50	167.50 ± 50.17	0.633
Duration of effective analgesia (min)†	177.39 ± 43.53	183.75 ± 56.69	0.669

* values are expressed as Median [IQR], †values are expressed as Mean ± SD

P < 0.05 is considered statistically significant, min = minutes

Table 3: Motor Block (Modified Bromage Scale (MBS).

Time	Group LS (n = 23)	Group LN (n = 24)	*P*
5 min	2.00 [1.00-2.00]	2.00 [2.00-2.00]	0.342
10 min	2.00 [2.00-3.00]	2.00 [2.00-3.00]	0.924
15 min	3.00 [3.00-3.00]	3.00 [2.00-3.00]	0.220
20 min	3.00 [3.00-3.00]	3.00 [3.00-3.00]	0.912
25 min	3.00 [3.00-3.00]	3.00 [3.00-3.00]	0.956
30 min	3.00 [3.00-3.00]	3.00 [3.00-3.00]	0.176
45 min	3.00 [3.00-3.00]	3.00 [3.00-3.00]	0.322
60 min	3.00 [3.00-3.00]	3.00 [3.00-3.00]	0.322
75 min	3.00 [3.00-3.00]	3.00 [3.00-3.00]	0.322
90 min	3.00 [3.00-3.00]	3.00 [3.00-3.00]	0.322

min = minutes, P< 0.05 is considered statistically significant. values are expressed as Median [Inter-quartile range. Demographic profile and duration of surgery is shown in table 1. There was a statistically significant difference in the mean weight and height of patients between the two groups but these were clinically comparable. The mean duration of surgery also showed a statistically significant difference between the two groups. However, the absolute time difference was approximately 10 min.

The sensory block characteristics are shown in table 2. There was no significant difference between the two groups.

Motor block intensity was also comparable in both groups at all the time points. (Table 3)

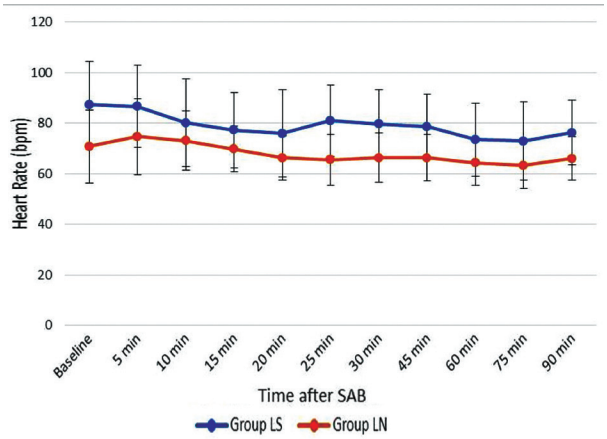

Fig. 2: Heart rate trends in both groups.

Numerical data on which figures are based for figure 2-Heart rate trends in both groups.

Time	Group LS (n = 23)	Group LN (n = 24)	P
Baseline	87.4 ± 17.0	70.8 ± 14.5	
5 min	86.7 ± 16.3	74.7 ± 15.0	
10 min	80.2 ± 17.2	73.1 ± 11.7	
15 min	77.3 ± 14.9	69.8 ± 9.0	
20 min	76.0 ± 17.4	66.3 ± 8.7	
25 min	81.0 ± 14.1	65.5 ± 10.1	= 0.001
30 min	79.7 ± 13.5	66.3 ± 9.8	
45 min	78.6 ± 13.0	66.3 ± 9.2	
60 min	73.5 ± 14.4	64.4 ± 8.9	
75 min	73.0 ± 15.6	63.3 ± 9.2	
90 min	76.3 ± 12.7	66.0 ± 8.6	

min = minutes, p<0.05 is considered statistically significant, values are expressed as Mean ± SD.

Heart rate was significantly less in group LN patients starting from baseline value and at all the time points as compared to group LS and same trend was observed till the last measured time point (Figure 2). There was no statistically significant difference in SBP and DBP (Figure 3).

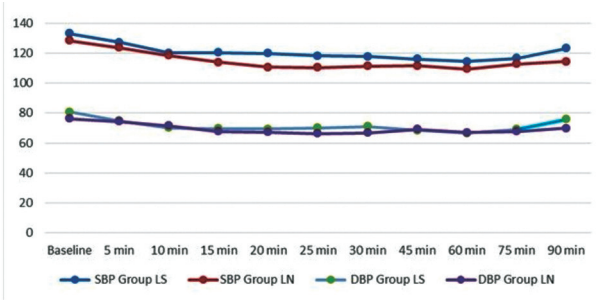

Fig. 3: Blood pressure trends in both groups.

For Figure 3 Blood pressure trends in both groups Systolic Blood Pressure (SBP in mmHg).

Time	Group LS (n = 23)	Group LN (n = 24)	P
Baseline	133.1 ± 10.8	128.3 ± 14.5	
5 min	127.3 ± 13.1	123.7 ± 13.7	
10 min	120.0 ± 14.0	118.5 ± 14.5	
15 min	120.3 ± 12.0	114.0 ± 13.4	
20 min	119.8 ± 11.3	110.7 ± 14.0	
25 min	118.2 ± 14.0	110.4 ± 12.4	0.061
30 min	117.7 ± 12.7	111.3 ± 11.8	
45 min	116.2 ± 12.7	111.7 ± 10.2	
60 min	114.5 ± 12.0	109.4 ± 10.2	
75 min	116.5 ± 10.0	112.7 ± 8.8	
90 min	123.2 ± 14.7	114.4 ± 9.2	

min = minutes p< 0.05 is considered statistically significant, values are expressed as Mean ± SD

Diastolic Blood Pressure (DBP in mmHg)

Time	Group LS (n = 23)	Group LN (n = 24)	P
Baseline	80.9 ± 8.7	76.4 ± 8.7	
5 min	74.9 ± 10.7	74.4 ± 10.3	
10 min	70.1 ± 13.8	71.5 ± 10.8	
15 min	69.7 ± 11.7	67.8 ± 9.1	
20 min	69.3 ± 9.7	67.2 ± 9.4	
25 min	70.1 ± 12.0	66.3 ± 9.8	0.433
30 min	71.1 ± 12.4	66.8 ± 11.1	
45 min	68.4 ± 10.0	69.2 ± 9.4	
60 min	66.6 ± 10.3	67.0 ± 8.4	
75 min	69.2 ± 7.6	67.7 ± 9.2	
90 min	75.9 ± 15.5	69.8 ± 8.3	

min = minutes

p< 0.05 is considered statistically significant,values are expressed as Mean ± SD

Respiratory rate was within normal range and comparable in both groups. (Figure 4) (P=0.318)

All the patients in group LS and LN had a sedation score of 0 or 1. None of the patients had sedation score ≥ 2. The degree of sedation was comparable in both the groups at 5, 10 and 90 min.

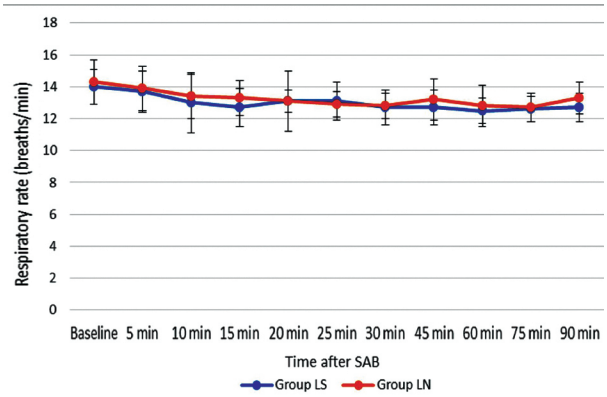

Fig. 4: Respiratory rate trends in both groups.

For figure 4 Respiratory rate trends in both groups.

Time	Group LS (n = 23)	Group LN (n = 24)	P
Baseline	14.0 ± 1.1	14.3 ± 1.4	
5 min	13.7 ± 1.3	13.9 ± 1.4	
10 min	13.0 ± 1.9	13.4 ± 1.4	
15 min	12.7 ± 1.2	13.3 ± 1.1	
20 min	13.1 ± 1.9	13.1 ± 0.7	0.318
25 min	13.1 ± 1.2	12.9 ± 0.8	
30 min	12.7 ± 1.1	12.8 ± 0.8	
45 min	12.7 ± 1.1	13.2 ± 1.3	
60 min	12.5 ± 0.8	12.8 ± 1.3	
75 min	12.6 ± 0.8	12.7 ± 0.9	
90 min	12.7 ± 0.9	13.3 ± 1.0	

min = minutes

p< 0.05 is considered statistically significant, values are expressed as Mean ± SD.

However at all-time points from 15 min to 75 min, more number of patients in group LN had a sedation score of 1 compared to group LS and a statistically significant difference was seen. (Table 4)

Hypotension was seen in two patients in group LS and one patient in group LN. Bradycardia was seen in six patients in group LS compared to none in group LN. There was no incidence of pruritus, headache, dizziness, nausea, vomiting or any other side effects. (Table 5)

Discussion

'Intrathecal nalbuphine' has been used in many studies as an adjuvant to hyperbaric bupivacaine in dose ranging from 0.2 to 2.4 mg. Also, many studies have been conducted in past by using levobupivacaine through subarachnoid route in dose ranging from 8-15 mg. But there are only

limited number of studies which have analysed the effect of addition of nalbuphine to levobupivacaine via subarachnoid route. Hence this study was planned to find out the effect of addition of 1 mg nalbuphine to 12.5 mg isobaric levobupivacaine for the conduct of inguinal hernia surgeries under subarachnoid block.

The major findings of our study were that the duration of effective analgesia and the time of regression of sensory block to T12 dermatome were not prolonged with the addition of nalbuphine to levobupivacaine. Patients in the nalbuphine group had minimal sedation and were easily arousable on verbal commands (score 1). The quality of sensory and motor block and frequency of side-effects were also not affected by the addition of nalbuphine.

There were three cases of failed subarachnoid block (two in group LS and one in group LN), where the sensory block remained below T10 level. However, in all the other patients, the duration of sensory block provided by 12.5 mg levobupivacaine was sufficient to conduct the surgery in both the groups. Previous studies have also found a similar dose of levobupivacaine to be sufficient for the conduct of TURP procedures under subarachnoid block.[7]

In our study the time of onset of block to T10 was 5.30 ± 2.34 min in control group and 5.41 ± 2.07 min in nalbuphine group (P= 0.774). Previous study[13] has reported the median time of onset of levobupivacaine alone to be 3 min, which is early as compared to our study. This difference may be attributed to the different definition adopted by them for the onset.They defined the onset of block to be at the level of T12, which is a lower dermatome than T10, defined in our study. In the study by Vanna et al[7], the onset of block was 10.4 ± 4.3 min which is delayed as compared to our finding. This difference may be due to the lower volume of the intrathecal drug used in their study (2.5 ml) compared to 3 ml in our study. In our study, addition of nalbuphine to levobupivacaine had no effect on the time of onset of SAB.In most of the previous studies, 'intrathecal nalbuphine had' no effect on the time of onset of hyperbaric bupivacaine.[14,15]

The median maximum block height of T6 [T6-T8] was attained in both the groups. Other studies have also reported similar block height with levobupivacaine.[13,16] However, in the study by 'Vanna et al'[7], the median maximum block height was T9, with a very large variation ranging from T4-T10. This may be due to isobaric nature of drug. In our study, the interquartile range of block height was between T6-T8. However, in three patients sensory block height was lower than T10 and hence these patients were excluded from the analysis as defined in the protocol.

Studies have shown that use of isobaric local anaesthetic by subarachnoid route has been associated with a greater variability in spread of block and a less predictable spread, so the block height achieved may be low, being inadequate for surgery or high leading to side effects.[17,18] Mukherjee et al[19] studied nalbuphine in dose of 0.2 mg, 0.4 mg and 0.8 mg as adjuvant to 12.5 mg of 0.5% bupivacaine versus 0.5 ml normal saline plus 12.5 mg of 0.5% bupivacaine and found the maximum block height as T6 in all the groups.This finding was similar to our study as the addition of nalbuphine did not affect the maximum block height attained by using local anaesthetic alone.

In the studies by Mantouvalou et al[20] and Jindal et al[21] the time to two segment regression was found to be 65 ± 11 min and 69.8 ± 6.61 min respectively. These observations are very close to our findings where the time to two segment regression was 61.09 ± 28.88 min in control group. Longer time to two segment regression with levobupivacaine have however been reported in the study by Hoda et al[2], Vanna et al[7] and Sinha et al[22] (129.68 ± 15.54, 101.0 ± 54.3, 111.77 ± 6.03 respectively).We did not find any prolongation in time to two segment regression with addition of nalbuphine (54.58 ± 19.33 min). Our findings are in contrast to those of Sinha et al[22] who reported an increase in the time to two segment regression with 0.4 mg nalbuphine (111.77 ± 6.03 min with plain levobupivacaine versus 175.03 ± 7.93 min with levobupivacaine plus nalbuphine).

In our study, the time of regression of block to T12 was 161.09 ± 40.50 min in group LS while it was 167.50 ± 50.17 min in group LN and was comparable. None of the studies with levobupivacaine-nalbuphine combination have reported regression time to T12 level. However, the study by Shraddha et al[23] found that addition of nalbuphine to intrathecal bupivacaine prolonged the time of regression of block to S1.

In our study, duration of effective analgesia was 177.39 ± 43.53 min in group LS and 183.75 ± 56.69 min in group LN and there was no significant prolongation with addition of nalbuphine. The finding of Sinha et al[22] is contradictory to our result as in their study,the duration of effective analgesia was 168.47 ± 6.49 min with plain levobupivacaine and 316.13 ± 15.62 min with levobupivacaine-nalbuphine combination.

A median motor block grade 3 Modified Bromage Scale i.e. complete motor block was obtained in both the groups by 15 min and was present till the end of surgery. So the operating conditions were reported as good by most of the surgeons.

Though in our study, there was a statistically significant difference seen in the heart rate between the two groups, this was because the mean baseline heart rate was less in nalbuphine group. The same trend was continued till the last measured time point. The difference in baseline cannot be attributed to our study drug and therefore it was purely by chance. All other haemodynamic parameters like systolic blood pressure, diastolic blood pressure and mean arterial blood pressure were comparable in both groups at all the time points. So, the addition of nalbuphine to levobupivacaine did not alter the haemodynamic parameters. Similar to our study, Sinha et al[22] reported comparable hemodynamics with levobupivacaine with or without addition of nalbuphine.

In our study, there was no evidence of respiratory depression with the addition of nalbuphine. Similar findings were also reported by Rehab et al[24] and Sinha et al[22] Nalbuphine exhibits ceiling effect on respiratory depression. This is because respiratory depression is μ receptor mediated and nalbuphine is μ antagonist.[25]

In our study, all the patients had a sedation score of 0 or 1. None of the patients had sedation score ≥ 2. At all the time points from 15 min to 75 min, more number of patients in nalbuphine group had a sedation score of 1 compared to control group. Sedation was minimal as per University of Michigan Sedation Scale and these patients were easily arousable with verbal commands. Similar to our study, Jyothi et al[25] and Shakooh et al[26] also reported occurrence of sedation with addition of nalbuphine. The patients undergoing surgery under subarachnoid block are aware of their surroundings, and it becomes necessary to sedate them. Intrathecal nalbuphine provides light sedation, thus reducing the need for any additional sedative drug. However, none of the patients had deeper levels of sedation as seen with the μ-agonists. The incidence of hypotension, bradycardia, pruritus, dizziness, headache, nausea, vomiting or any other side effect was not increased due to the addition of nalbuphine to levobupivacaine.

This was one of the few studies which compared the block characteristics of intrathecal levobupivacaine with or without nalbuphine in a uniform group of patients undergoing similar type of surgery, i.e. inguinal hernia surgeries. So the degree of pain, the extent of tissue handling during the surgery was similar among the patients, thus removing the element of bias due to these factors. However, the study has a few limitations. The detailed motor block parameters like onset, time to peak motor blockade and duration of motor blockade and time to home readiness were not studied.

From the above observations, we conclude that 12.5 mg levobupivacaine with or without nalbuphine is sufficient to conduct inguinal hernia surgery. Intrathecal nalbuphine in a dose of 1 mg when added to 12.5 mg levobupivacaine provided similar sensory and motor block characteristics as 12.5 mg levobupivacaine alone with minimal sedation and without any increase in the incidence of side effects.We recommend that further studies using higher dose of nalbuphine as adjuvant to levobupivacaine via subarachnoid route should be conducted to assess its analgesic efficacy for providing postoperative analgesia.

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Original Article

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Comparison of Baska Mask and Conventional Endotracheal Tube in Airway Management during Laparoscopic Cholecystectomy: A Randomized Clinical Study

Karthik G.S[1], Sudheer R[2], Priyanka D[3], S. Rangalakshmi[4], Sameera Halima[5], Supriya R[6]

Author's Affiliation: [1,2]Professor, [4]Professor and HOD, [3,5,6]Junior Resident, Department of Anesthesiology, Rajarajeswari Medical College and Hospital, Bangalore, Karnataka 560074, India.

Abstract

Background: Baska mask has been chosen to secure airway for surgeries under general anesthesia in view of its adaptability during positive pressure ventilation as it moulds accordingly.

Aims: Our aim was to compare BASKA mask with Endotracheal tube primarily for hemodynamic changes, and also ease of insertion in terms of number of attempts and time taken for insertion, airway trauma, intraoperative and postoperative laryngopharyngeal morbidity (LPM) occurring in patients undergoing laparoscopic cholecystectomies under general Anesthesia.

Methods: A hospital based prospective, randomised comparative clinical study involving60 ASA I and II patients undergoing laparoscopic surgeries under general Anesthesia were randomly divided into 2 groups of 30 each (n=30), either using BASKA mask or ETT. Hemodynamic changes in both the groups were compared, along with number of attempts and time for insertion and laryngopharyngeal morbidities.

Results: Hemodynamic fluctuations are less in patients who received Baska mask for their airway management than with endotracheal tube insertion. The number of attempts of insertion and time duration of insertion of Baska Mask (Mean ±SD=13.50±5.49) for airway management were less and with negligible postoperative laryngopharyngeal comorbidities when compared with endotracheal intubation in adult patients undergoing elective laparoscopic cholecystectomy under general anaesthesia with positive pressure ventilation.

Conclusion: Baska Mask with its unique anatomy and features is a good alternative to endotracheal tube for airway management in elective laparoscopic cholecystectomies under general anaesthesia with positive pressure ventilation in terms of negligible hemodynamic changes, less number of attempts and reduced mean time duration of insertion, and less laryngopharyngeal morbidities.

Key words: BASKA Mask; Endotracheal Tube; Hemodynamic Response; Laparoscopic Cholecystectomy.

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Corresponding Author: Priyanka D, Junior Resident, Department of Anesthesiology, Rajarajeswari Medical College and Hospital, Bangalore, Karnataka, 560074, India.
E-mail: dvhavshampgowda@gmail.com

Introduction

Till date, airway management for laparoscopic cholecystectomies under General Anesthesia, the gold standard technique was endotracheal intubation. But it involves rigid laryngoscopy which may damage tissues, increased risk of heamodynamic response like tachycardia, hypertension, arrhythmias which may lead to myocardial damage, laryngo-pharyngeal morbidities like sore throat, dysphagia, dysphonia and dysarthria, hence it requires better alternative.[1]

Supraglottic airway devices with gastric drainage ports are being used.[2] Supraglottic airway device also has special part to play in difficult airway algorithm for both anticipated and unanticipated difficult airway.[3] Newly designed second generation supraglottic airway devices Like Baska mask have cuff with high sealing pressure and allow to drain the gastric contents through a gastric drain tube.[4]

Methods

A prospective randomised comparative clinical study was conducted after taking approval from ethical committee at Rajarajeswari medical college and hospital. This study involved 60 patients with age ranging from 18-40yr and BMI ranging 25-35, belonging to ASA I and II undergoing elective laparoscopic cholecystectomy surgeries. All relevant investigations and workup were done keeping in view of patients co-morbidities if any. Consent was obtained for the procedure after explaining to patients in their own understandable language.

Patients were randomised into two groups as group B and E. The sample size was calculated as per the previous study conducted by Kara D et.al., considering a mean second generation supraglottic airway device insertion time of about 10-12 seconds with the power (1-β) of 80% and an alpha error (α) of 5%, 30 patients in each group were selected for our study. This was done with the help of computer generated code where group B involvedstudy population who received Baska Mask insertion and the other group receivedEndotracheal intubation for their airway management.[8]

Patients with Mouth opening (interincissor gap) of <2.5cm, Cervical spine pathology, Risk of aspiration of gastric contents (history of gastroesophageal reflux disease, hiatus hernia, uncontrolled diabetes mellitus and gross obesity, Pregnant woman), difficult intubation based on history of difficult airway, thyromental distance <6.5cm, modified Mallampatti grading III/IV, smokers who are not well optimised, and patients who refused for the study were not considered.

Patients scheduled for surgery were kept nil per oral for 6 hours before surgery. Tablet pantoprozole 40mg was given orally in the previous night half an hour before food and tablet alprazolam 0.5mg was given a night prior to surgery to allay anxiety and apprehension. An intravenous line was secured and intravenous injection of pantoprazole 40mg and metoclopromide 10mg were given on the morning of surgery.

Anaesthesia machine and other apparatus were checked along with cylinders and volatile anaesthetics. All drugs about to be administered were loaded and labelled. After shifting the patient inside the operation theatre, all standard ASA monitors were attached. The baseline readings of heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation were recorded. All patients were pre oxygenated with 100% oxygen for 3-5 minutes. At the same time patients were premedicated with injection Midazolam 0.02mg/kg, injection Glycopyrrolate 0.005mg/kg and injection fentanyl (for analgesia)1-2mcg/kg. Patients were induced with injection propofol 2-2.5mg/kg till the loss of verbal commands, injection veccurronium 0.08-0.1mg/kg was given for neuromuscular blockade after ensuring adequate ventilation.

After induction and adequate muscular paralysis, Group B patients received appropriate size Baska Mask insertion after lubricating the dorsal surface of it and Group E patients had direct laryngoscopy and endotracheal intubation with appropriate sized well lubricated endotracheal tube along with adequate cuff pressure monitoring to prevent trauma.

The number of attempts of insertion and time interval from holding the airway device to confirmation of correct placement of airway by checking bilateral air entry on auscultation was recorded as intubation time. If Baska Mask was not able to insert or ventilate through it properly, two more attempts were tried. It was considered as “easy insertion”, if insertion was successful with first attempt of insertion and “difficult insertion” if inserted with resistance or inserted during 2nd attempt. If third attempt was unsuccessful to establish an airway then it was considered as failed attempt and airway was managed with tracheal intubation under direct laryngoscopy with endotracheal tube.

Once the airway was secured, we maintained the anaesthesia under controlled ventilation with oxygen, nitrous oxide, isoflurane and intermittent doses of injection vecurronium 0.01mg/kg as and when required for muscular paralysis.

Hemodynamic parameters like heart rate, mean arterial blood pressure, oxygen saturation were recorded before intubation, at the time of insertion, at 10 seconds, 1,3,5 minutes intervals after insertion, after achieving pneumoperitoneum and during removal of devices along with end tidal carbon dioxide ($ETCO_2$) monitoring.

When the surgery was completed, residual muscular paralysis was reversed with injection of mixture of injection glycopyrrolate 0.01mg/kg and inj neostigmine 0.05mg/kg. When the patient was fully awake with adequate respiration, with normal hemodynamics, thorough suctioning was done and then airway device was removed or extubated.

Post extubation-coughing, laryngospasm or bronchospasm, blood stain on the airway device, oral injuries, regurgitation or aspiration were noted. Postoperative sore throat, dysphagia, dysphonia were asked and noted in both the groups.

The collected data were entered and tabulated in Microsoft Excel and were subjected to analysis using Statistical software namely SPSS 22.0, and R environment ver.3.2.2. Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters.

A t-test is a statistical test that is used to compare the means of two groups. Chi-square/Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis. Fisher Exact test was used when cell samples are very small. P value: 0.05<P<0.10 suggestive of significant, 0.01<P ≤0.05 suggests moderately significant, P≤0.01 suggests strongly significant.

Results

60 patients were enrolled for the study as per the study protocol mentioned above. There were no dropout of patients in any of the groups. Both the groups B and E were comparable with respect to age (Table1, Graph 1), sex distribution (Table 2, Graph 2), BMI in kg/mt2 (Table 3, Graph 3), ASA grading (Table 4, Graph 4) and mallampatti grading (table 5, Graph 5).

Table 1: Age distribution of patients studied.

Age in Years	Group B	Group E	Total
21-30	60	43.3	51.7
31-40	40	56.7	48.3
Total	100	100	100
Mean ± SD	29.73±5.11	31.13±5.34	30.43±5.23

Samples are age matched with P=0.304, student t test.

Graph 1: Graphical representation of Age distribution of patients studied between groups.

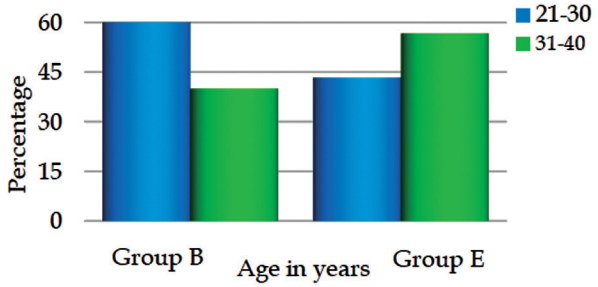


Table 2: Gender distribution of patients studied.

Gender	Group B	Group E	Total
Female	50	53.3	51.7
Male	50	46.7	48.3
Total	100	100	100

Samples are gender matched with P=0.796, student t test.

Graph 2: Graphical representation of Gender distribution of patients between groups.

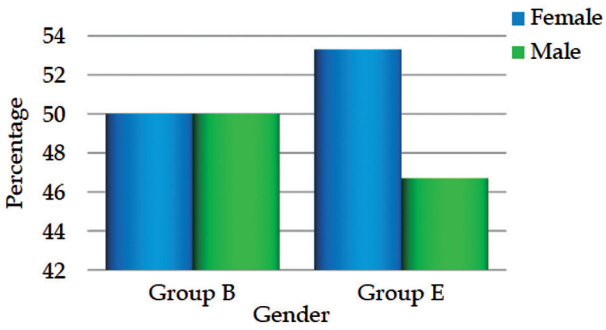


Table 3: Comparison of BMI in kg/mt²

BMI (kg/m²)	Group B	Group E	Total
<18.5	1(3.3%)	0(0%)	1(1.7%)
18.5-25	17(56.7%)	18(60%)	35(58.3%)
25-30	12(40%)	12(40%)	24(40%)
>30	0(0%)	0(0%)	0(0%)
Total	30(100%)	30(100%)	60(100%)

P=1.000 which is Not Significant, Fisher Exact Test was used

Graph 3: Graphical representation of BMI (kg/m^2) distribution in two groups of patients studied.

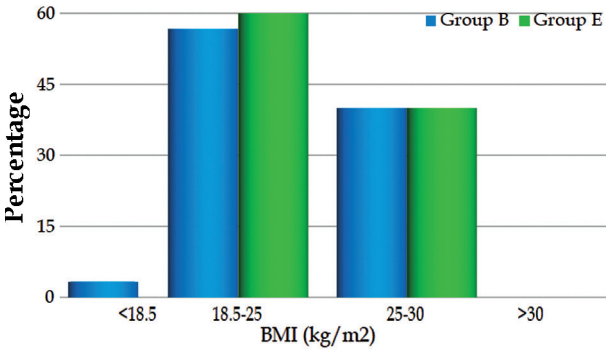


Table 4: ASA Grade – distribution in two groups of patients studied.

ASA Grade	Group B	Group E	Total
I	22(73.3%)	16(53.3%)	38(63.3%)
II	8(26.7%)	14(46.7%)	22(36.7%)
Total	30(100%)	30(100%)	60(100%)

P=0.108, Not Significant, Chi-Square Test was used.

Graph 4: Graphical representation of ASA Grade–distribution in two groups of patients studied.

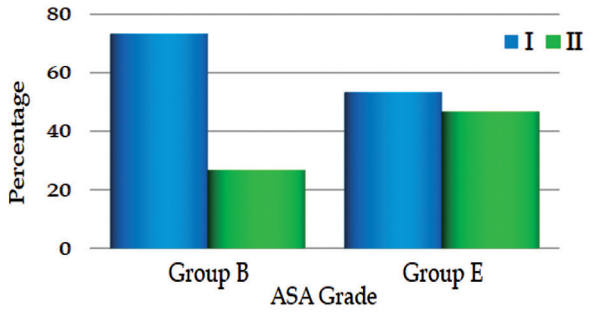


Table 5: MPG distribution in two groups of patients studied.

MPG	Group B	Group E	Total
I	11(36.7%)	14(46.7%)	25(41.7%)
II	19(63.3%)	16(53.3%)	35(58.3%)
Total	30(100%)	30(100%)	60(100%)

P=0.432 which is Not significant, Chi-Square test was used.

Graph 5: Graphical representation of MPG distribution in two groups of patients studied.

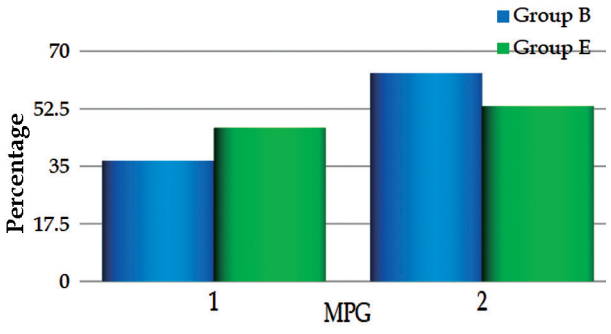


Table 6: Heart rate (bpm)- A Comparison in two groups of patients studied.

Heart rate (bpm)	Group B	Group E	Total	P value
Pre induction	84.53±9.32	81.40±7.33	82.96±8.46	0.153
10sec after insertion	92.80±13.27	106.33±10.11	99.57±13.54	<0.001**
1minute after insertion	88.93±11.7	106.00±12.76	97.47±14.88	<0.001**
3minute after insertion	83.73±10.66	90.00±10.56	86.87±10.99	0.026*
5minute after insertion	80.53±9.69	84.63±8.57	82.58±9.31	0.088+
At Pneumo-peritoneum	85.27±10.42	84.80±10.33	85.03±10.29	0.862
At Extubation	97.13±7.32	108.50±9.47	102.82±10.16	<0.001**

Student T test was used.

Graph 6: Graphical representation of Heart rate (bpm)- A Comparison in two groups of patients studied.

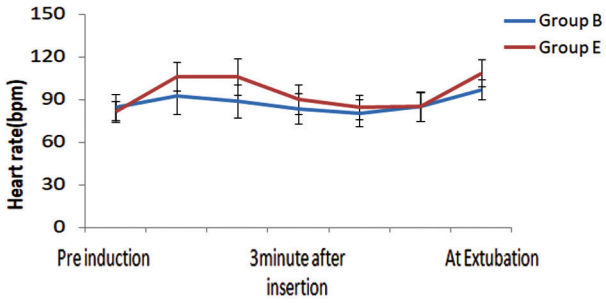


Table 7: MAP (mm Hg)- A Comparison in two groups of patients studied.

MAP (mm Hg)	Group B	Group E	Total	P value
Pre induction	84.37±7.46	82.63±4.78	83.50±6.27	0.289
10sec after insertion	87.10±7.93	102.47±9.14	94.78±11.49	<0.001**
1minute after insertion	85.10±7.31	102.37±8.74	93.73±11.81	<0.001**
3minute after insertion	80.30±6.8	86.70±10.74	83.50±9.48	0.008**
5minute after insertion	79.37±7.48	80.93±9.95	80.15±8.76	0.493
At Pneumo-peritoneum	87.90±9.35	83.17±10.67	85.53±10.23	0.073+
At Extubation	92.83±8.20	101.27±11.71	97.05±10.88	0.002**

Pre-induction heart rate mean values in group B and group E were 84.53 and 81.40 respectively and we obtained a p value of 0.153 which shows that pre induction heart rate were matched. Where the mean heart rate at 10 seconds after insertion, 1

minute after insertion and at extubation in group B were 92.80, 88.93 and 97.13 respectively, the mean heart rate at 10 second, 1 minute after insertion and at extubation in group E were 106.33, 106.00 and 108.50 respectively.

Graph 7: Graphical representation of MAP (mm Hg)-A Comparison in two groups of patients studied.

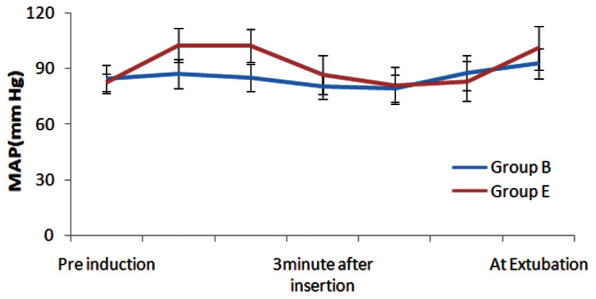
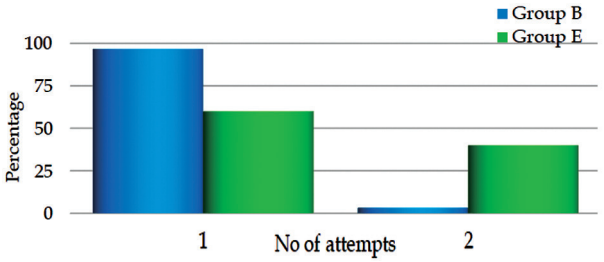


Table 8: No. of Attempts- distribution in two groups of patients studied.

No. of Attempts	Group B	Group E	Total
1	29(96.7%)	18(60.0%)	47(78.3%)
2	1(3.3%)	12(40.0%)	13(21.7%)
Total	30(100%)	30(100%)	60(100%)

P<0.001** which is statistically Significant, Fisher Exact Test was used.

Graph 8: Graphical representation of No. of Attempts-distribution in two groups of patients studied.



We obtained a p value of <0.001 at the time mentioned above and it showed mean heart rate at 10 sec, one minute after insertion and at extubation in group E was high with statistical significance when compared with that of group B. At 3 minutes after insertion, mean heart rate in group E was significantly high with a p value of <0.05 when compared with group B (Table 6, Graph 6).

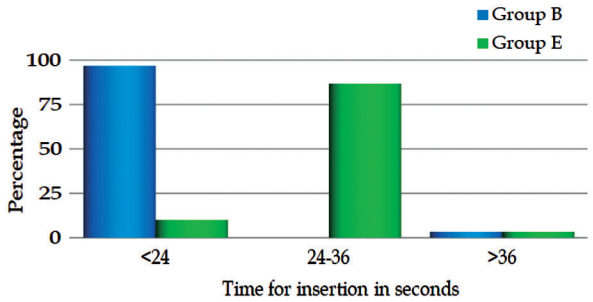
Pre-induction mean MAP(mmHg) value in group B and group E were 84.37 and 87.10 respectively and we derived a p value of 0.289 which shows that pre-induction mean MAP(mmHg) values were matched. The mean MAP(mmHg) at 10 seconds after insertion, 1 minute after insertion in group B were 87.10 and 85.10 respectively as when compared with mean MAP(mmHg) at 10 seconds, 1 minute after insertion in group E which were 102.47 and 102.37 respectively, p value of <0.001 was obtained at the time mentioned above. This shows that mean MAP(mmHg) at 10sec, one minute after insertion in group E was high which was statistically significant when compared with group B. At 3 minutes after insertion mean MAP(mmHg) in group E was significantly high with a p value of 0.026 when compared with group B. At extubation, the p value for MAP was 0.002 which was also statistically significant (p value<0.05) (Table 7, Graph 7).

Table 9: Time to secure airway in seconds- distribution in two groups of patients studied.

Time for insertion in seconds	Group B	Group E	Total
<24	29(96.7%)	3(10%)	32(53.3%)
24-36	0(0%)	26(86.7%)	26(43.3%)
>36	1(3.3%)	1(3.3%)	2(3.3%)
Total	30(100%)	30(100%)	60(100%)
Mean ±SD	13.50±5.49	28.53±3.82	21.01±8.91

P<0.001** which is statistically Significant, Student t test was used.

Graph 9: Graphical representation of Time to secure airway in seconds- distribution in two groups of patients studied.



In group B, 96.7% of patients airway was secured with Baska Mask at first attempt where remaining 3.3% of patients airway secured with Baska Mask in second attempt. In group E, 60.0% of patients airway was secured with endotracheal tube in first attempt where remaining 40.0% of patients airway secured with endotracheal tube in second attempt. Both groups were compared using Chi-Square test and obtained a p value of 0.001 which was statistically significant (Table 8, Graph 8).

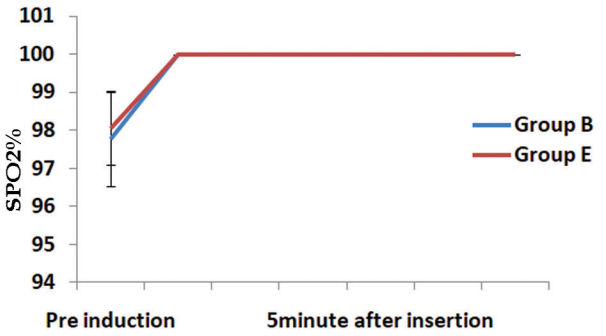
In group B patients, the mean time taken for insertion of Baska Mask was 13.50seconds and the mean time taken to secure endotracheal tube among group E patients is 28.53seconds. The time taken to secure airway in seconds between two groups were compared using Student t test and obtained a p value <0.001 which was statistically significant (Table 9, Graph 9).

Table 10: SpO_2% A Comparison in two groups of patients studied.

SpO_2%	Group B	Group E	Total	P value
Pre induction	97.77±1.25	98.06±0.98	97.91±1.12	0.315
10sec after insertion	100.00±0.00	100.00±0.00	100.00±0.00	-
1minute after insertion	100.00±0.00	100.00±0.00	100.00±0.00	-
3minute after insertion	100.00±0.00	100.00±0.00	100.00±0.00	-
5minute after insertion	100.00±0.00	100.00±0.00	100.00±0.00	-
At Pneumo-peritoneum	100.00±0.00	100.00±0.00	100.00±0.00	-
At Extubation	100.00±0.00	100.00±0.00	100.00±0.00	-

Student T test used, p values are not significant.

Graph 10: Graphical representation of SpO_2% Comparison in two groups of patients studied.



In group B and group E, SpO_2 was compared using student T test and we obtained the result stating that both groups were comparable and maintained saturation throughout the procedure (Table 10, Graph 10).

Table 11: ETCO2 (mmhg)- A Comparison in two groups of patients studied.

$ETCO_2$	Group B	Group E	Total	P value
10 sec after insertion	35.20±3.39	36.53±12.02	35.87±8.78	0.561
1minute after insertion	34.40±2.40	33.37±2.59	33.88±2.53	0.115
3minute after insertion	34.30±2.10	33.83±1.90	34.07±2.00	0.370
5minute after insertion	33.90±2.16	34.07±2.10	33.98±2.11	0.763
At Pneumo-peritoneum	36.80±2.94	36.63±2.33	36.72±2.63	0.809
At Extubation	37.03±2.57	37.57±2.42	37.80±2.59	0.120

Student T test was used to obtain p values which are not significant.

Graph 11: Graphical representation of $ETCO_2$ (mmhg) Comparison in two groups of patients studied.

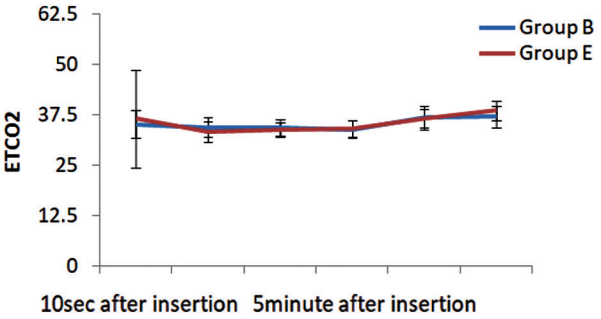


Table 12: Comparison of complications At removal of airway device between groups of patients studied.

At Removal	Group B (n=30)	Group E (n=30)	Total (n=60)	P value
Coughing	1(3.3%)	11(36.7%)	12(20%)	0.001**
Blood staining of device	0(0%)	4(13.3%)	4(6.7%)	0.112
Trauma to lip, teeth, tongue	0(0%)	1(3.3%)	1(1.7%)	1.000

Chi-square test was used.

Graph 12: Graphical representation of Comparison of complications at removal of airway device between groups of patients studied.

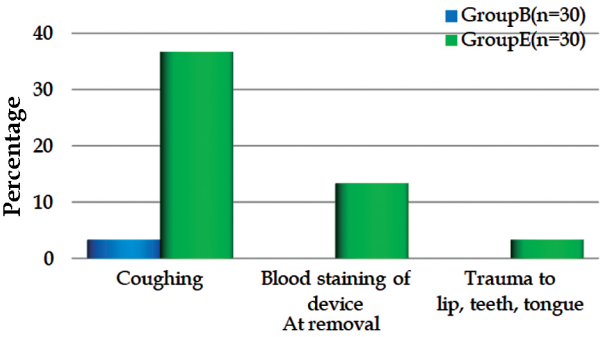


Table 13: Comparison of postoperative complications of airway device between groups of patients studied.

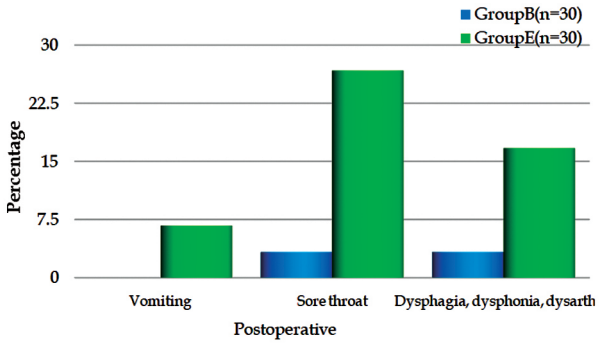
Postoperative	Group B (n=30)	Group E (n=30)	Total (n=60)	P value
Vomiting	0(0%)	1(3.3%)	1(1.7%)	0.192
Sore throat	1(3.3%)	8(26.7%)	9(15%)	0.026*
Dysphagia, dysphonia, dysarthria	1(3.3%)	2(6.7%)	3(5)	0.195

Chi-square test was used.

In group B and group E, $ETCO_2$ (mmhg) was compared and found that both groups were comparable and maintained saturation throughout procedure. p value obtained was 0.561, 0.115, 0.370, 0.763, 0.809, 0.120 when $ETCO_2$ was compared between two groups at 10sec after insertion, 1

minute after insertion, 3 minute after insertion, 5minute after insertion, at pneumoperitoneum, at extubation respectively which were statistically not significant (p value >0.05)(Table 11, Graph 11).

Graph 13: Graphical representation of Comparison of postoperative complications of airway device between groups of patients studied.



Only 3.3% of Group B patients developed coughing after removal of Baska Mask whereas 36.7% of group E patients developed coughing at removal of endotracheal tube which was statistically significant (pvalue<0.001). This shows that the incidence of cough while removal of airway device was more in group E when compared to group B.

The number of patients in whom blood staining was observed among both the groups was almost less and statistically insignificant (p value 0.112).

The incidence of trauma to lip, teeth, tongue when observed between both the groups was found statistically not significant (Table 12, Graph 12). (p value 1.000)

When incidence of postoperative vomiting between these two groups were compared, 1 patient in group E had one episode of vomiting. No patients in group B had vomiting. But statistically the inference was insignificant (p value was 0.192).

The incidence of postoperative sore throat in group E (26.7%) was more when compared with group B (3.3%) (p value of 0.026). One patient in group B (3.3%) and two patients in group E (6.7%) had incidence of postoperative dysphagia, dysphonia, dysarthria but was statistically not significant (Table 13, Graph 13). (p-value of 0.195)

Discussion

Dr Kanag Baska (Australian Anaesthetist) and Dr Meena Baska (retired GeneralMedical Practitioner) were the people who designed SGAD named Baska Mask. It consists of

1. *Cuff:* thin membranous, variable pressure, self sealing and recoiling cuff, non inflatable.
2. *Sump area:* is aninbuilt cushion device which provides internal cricoid pressure to maintain communication between sump area and upper end of oesophagus for the clearance of gastric fluids efficiently via two tubes which is located alongside the airway.
3. *Airway Tube:* is oval shaped which matches the shape of mouth and prevents rotation within pharynx and it has bite block throughout length to prevent kinking. While removal, if the mask is bitten/ the main airway opening gets blocked by tongue, then the two tubes alongside the airway allow air entry and maintains oxygenation.
4. *Shape and Design:* single molding without any joints except a 22mm connector inserted at top end. Shape and flexibility improvises ease of insertion, without head/neck extension.
5. *Tab:* makes intubation easier and faster by pulling the Tab and prevents insertion of finger for insertion or positioning of Baska Mask.
6. *Suction elbow*: accessible for suction port connection on one port, second port with dual role one as suction port and as free airflow access point. Nowadays in elective surgeries under general anaesthesia, Supraglottic airway devices are found to be good alternative to endotracheal intubation. Among numerate Supraglottic airway devices, Baska Mask is the new generation Supraglottic airway device which is designed in such a way to increase the ease of insertion and reduce hemodynamic complications which will be developed in relation to other airway devices insertion.[5]

Supraglottic airway devices offer an excellent non invasive option for maintenance of airway instead of endotracheal intubation. They are now mostly useful in emergency situations where in rapid access to airway is provided. These include ease of insertion even with limited training in emergency situations.

Other advantages include rapidity, low post operative complications and reduced autonomic imbalance during insertion. The advanced innovations of Supraglottic airway devices improve the safety of patients in terms of efficacious ventilation. Baska mask can also be used for short gynaecological procedures such as dilatation and curettage, hysteroscopy and tubal ligation. This short surgical procedures can be done using monitored anaesthesia care using propofol itself. In

such scenarios Baska mask helps in early recovery as suggested by Anurag Garg et.al.[6]

In another study Alexiev et.al identified unique advantages when they used baska mask during surgeries. They opined that non inflatable cuff of Baska mask leads to a good airway seal with integrated bite block and also has a good conduit to aspirate the pharyngeal contents, there by minimising the risk of aspiration. The overall success rate was 100% with minimal complication rates. They compared Baska Mask insertion with I Gel insertion and concluded that Baska Mask gave a superior airway seal and acceptable interoperation $ETCO_2$ values when compared to I Gel.[7]

Our study also correlated with a study conducted by Duygu Kara et.al who also postulated that postoperative hoarseness and dysphagia were less common in patients where Baska Mask was used though it requires a longer insertion time. They also opined that there is gradual improvement in Baska Mask seal against the glottis over the first 2-3 minutes, which might be due to the mobility of membranous mask, making it more adaptable to the shape of laryngeal outlet over time.[8] Hemodynamic changes were also minimal after insertion of Baska mask.

As per the article published by William Donaldson et.al., the second generation Supraglottic airway device does not cause any complication during and after insertion with very minimal adverse effects such as hoarseness, sore throat and swallowing difficulties. Though there is still a lack of high quality evidence associated with the use of second generation Supraglottic airway devices but still it is clinically very useful for all types of surgeries with lower incidence of hemodynamic complications, complications where these observations are also noted by us.[9]

According to Tom Van Zundert et.al. (Journal of Obstetric anaesthesia and critical care), they also found in their study that Baska Mask can be used successfully during anaesthesia for a large variety of surgical interventions. They did not demonstrate any significant leak around the cuff. They also confirmed that on fiberoptic evaluations of the anatomical position of the Baska Mask, that a perfect or a near perfect position of the vocal cords could be obtained. Accordingly we also did not demonstrate any significant leak around the cuff.[10]

A study conducted by J.M.Bellina et.al. where in comparison was made in between Baska mask and LMA Supreme. Where in they concluded that both devices were similar regarding intraoperative and postoperative events. According to them, Baska Mask is a good device for patients undergoing laparoscopic cholecystectomy under general anaesthesia, which provided an enough seal pressure to perform positive pressure ventilation. They found no differences when relating to incidence of hemodynamic changes, postoperative sore throat, dysphagia and hoarseness between the two groups.[11]

Though some authors found that Baska Mask required more number of insertion attempts and took longer time for insertion. AL Ravahi et.al., concluded that Baska mask has faster time of insertion when compared to Proseal LMA. Accordingly we also took minimum attempts for insertion of Baska Mask.[12]

Hemodynamic Changes

Heart rate, mean arterial pressure, oxygen saturation, end tidal carbon dioxide has been compared between group B and group E. The comparison of hemodynamic changes between the two groups in our study was our primary objective. We found that there is less increase in heart rate (88.93±11.7, 83.73±10.66, 80.53±9.69bpm) (Table 5), mean arterial pressure (87.10±7.93, 85.10±7.31, 80.30±6.8mmHg) (Table 6) at 10seconds, 1, 3minutes after insertion respectively and with faster recovery to baseline values in group of patients who received Baska Mask when compared with group of patients who recieved endotracheal intubation. The oxygen saturation and end tidal carbon dioxide was also maintained within normal limits throughout the procedure.

This can be compared with the study conducted by Ranjana Khetarpal et.al., Rajan Kumar et.al., who came up with statistically significant rise in heart rate, mean arterial pressure in group of patients with endotracheal intubation when compared with group of patients who received Baska Mask in adults undergoing elective non laparoscopic surgeries under general anaesthesia. This also proves accordingly that Baska Mask has a favourable profile when compared to endotracheal intubation.[13]

Ease of Insertion

In our study, 96.7% of patients of group B, airway was secured with Baska Mask at first attempt with mean time of insertion of 13.50±5.49 seconds when compared with group E, 60% of patients airway was secured with endotracheal intubation at first attempt with mean time of insertion of

28.53±3.82 seconds.(Table 7 and table 8) Which can be comparable with the results of study done by Anil Kumar et.al., who found 94% success rate on first attempt insertion of Baska Mask to secure the airway in executive surgeries under general anaesthesia with mean insertion time of 10.21 seconds.[14]

The number of attempts of insertion and mean duration of insertion is less in patients who received Baska Mask when compared with endotracheal intubation because of ease of insertion and less technical expertisation with steep learning curve.

Complications

Intraoperative: In our study, none of our cases had any intraoperative complications like airway leak, gastric insufflation, regurgitation or aspiration in both the groups of patients who received Baska Mask and endotracheal intubation. Airway was well secured in both the groups.

At removal: At removal of device, in our study we found that the incidence of cough while removal of airway device is more in group E (36.7%) when compared with group B patients (3.3%). The incidence of blood staining of device in group E (13.3%) is more when compared with group B (0%). The incidence of trauma to lip, teeth, tongue in group E (3.3%) was more when compared with group B (0%).

Postoperative: Postoperatively in our study, the incidence of vomiting in group E(3.3%) was more when compared with group B(0%). The incidence of postoperative sore throat in group E (26.7%) was more when compared with group B (3.3%).The incidence of postoperative dysphagia, dysphonia, dysarthria in group E (6.7%) is more when compared with group B(3.3%).

When compared with the study conducted by Ranjana Khetarpal et.al., and Rajan Kumar et.al., we also found that postoperative cough, vomiting, sore throat more common in patients who received endotracheal intubation when compared with group of patients who received Baska Mask for airway management in elective surgeries under general anaesthesia, which was in accordance with our study.[13]

Although there are few limitations in our study, Baska mask has emerged as widely used SGAD due to its better seal and negligible adverse effects with a superior safety profile when compared to ETT. Further studies may be warranted with larger samples to validate these observations including its use in morbidly obese patients and in various clinical situations as there were very less human clinical trials.

Conclusion

Our study shows that less hemodynamic fluctuations in patients who received Baska mask for airway management when compared with patients who received endotracheal intubation for their airway management. We also concluded that number of attempts of insertion along with mean time duration of insertion of airway device is less in group of patients who received Baska Mask with less postoperative laryngopharyngeal comorbidities when compared with group of patients who recieved endotracheal intubation for airway management.

We finally conclude that Baska Mask can be considered as an alternative airway to endotracheal intubation for elective laparoscopic cholecystectomy surgeries under general anaesthesia with positive pressure ventilation in adult patients.

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Review Article

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Impact of Ultrasonography on Choice of General Anesthesia and Regional Anesthesia in Adult & Pediatric Upper Limb Surgeries

Kopparapu Sai Charan Sateesh[1], D K Sinha[2]

Author's Affiliation: [1]Graded Specialist, [2]Senior Adviser, Department of anaesthesiology, Military Hospital Secunderabad 500015, Telangana, India.

Abstract

Brachial plexus is a complex bundle of nerves, extending from the neck to the axilla, which supplies both motor and sensory fibres to the upper extremity. So clear understanding of anatomy and distribution of nerves is effective for regional anaesthesia.

The introduction of ultrasound guidance techniques not only reduces the possible risk of pneumothorax but also allows a faster onset time of the block, with a reduction of the volume of local anaesthetic mixture,that has to be injected for a successful peripheral nerve blocks Also detects vascular structures and pleura, needle tip control, and monitoring of distribution of local anaesthetic (LA).

After obtaining the approval of institutional ethical committee of hospital, a retrospective review of anaesthesia register from January 2015 until January 2020 (60 months) was done.

All the adult patients who underwent upper limb surgeries underwent peripheral nerve stimulator guided injections for supraclavicular brachial block and paediatric patients under axillary block by landmark technique from January 2015 to July 2017, will be allocated to Pre-US group and after availability of portable ultrasonography as Post-US with ultrasonography being available since July 2017 and outcome will be recorded.

As it is a retrospective study, all possible data will be included and analysed. As it is a retrospective study, nothing could be excluded.So comparision for 30 months of pre ultrasound and 30 months of post ultrasound period.

Conclusions: In adults ultra sound increased 26 % rise in no of surgeries under regional anaesthesia which is quite significant.The reduction in mean effective volume(MEV) in adults was about 51% by the application of ultrasound. In children, there was a definitive rise of 60 % increase in no of cases under Axillary approach of brachial block and 43% reduction in the mean effective volume(MEV).

Key words: Ultrasonography; Supraclavicular nerve block; Axillary nerve blocks; Peripheral nerve stimulator; General Anaesthesia; Mean Effective Volume.

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Corresponding Author: D K Sinha, Senior Adviser, Department of Anaesthesiology, Military Hospital, Secunderabad 500015, Telangana, India
E-mail: deependraksinha@gmail.com

Introduction

Brachial plexus is a complex bundle of nerves, extending from the neck to the axilla, which supplies both motor and sensory fibres to the upper extremity. So clear understanding of anatomy and distribution of nerves is effective for regional anaesthesia.

Anatomy of Supra Clavicular Brachial plexus

The brachial plexus provides somatic motor and sensory innervation to the upper extremity, including the scapular region. As the brachial plexus travels through the posterior triangle of the neck into the axilla, arm, forearm, and hand, it contains various named regions based on how the plexus is formed.

Ventral rami from spinal nerves C5 to T1, form roots of the brachial plexus, with C5 and C6 roots forming the superior, C7 root continuing as the middle trunkand the C8 and T1 roots forming the inferior trunk.Each of the trunks of the brachial plexus continues as an anterior and posterior division to form lateral, posterior, and medial cords.

The 3 cords (lateral, posterior and medial) are formed from the anterior and posterior divisions, and they are named based on their relationship to the parts of the axillary artery. The 3 posterior divisions converge to form the posterior cord. While the anterior divisions from the superior trunk and the middle trunk join to form the lateral cord. The medial cord is formed as a continuation of the anterior division from the inferior trunk.

The result of this "mixing" of nerve fibers is that the lateral cord contains components of C5, C6, and C7, the medial cord with contribution from C8 and T1, and the posterior cord carrying fibers from all levels of the brachial plexus (C5 to T1). The final subdivision of the brachial plexus consists of five terminal branches containing different contributions from the C5-T1 spinal levels[1]

The 5 terminal branches of the brachial plexus are the musculocutaneous, median, ulnar, axillary, and radial nerves.

(a) The musculocutaneous nerve (C5-C7) is formed by the lateral cord and provides motor innervation to the muscles of the anterior compartment of the arm: biceps brachii, coracobrachialis, and brachialis muscles. Also provides cutaneous innervation to the lateral upper forearm.

(b) The median nerve (C6-T1) is formed by medial and lateral cords. It provides the majority of motor supply to muscles in the anterior forearm as well as the thenar compartment in the palmar hand. The nerve also provides cutaneous innervation to the lateral 3 1/2 fingers of the palmar hand.

(c) The ulnar nerve is completely formed by the medial cord. In the anterior forearm, the ulnar nerve innervates the medial half of the flexor digitorum profundus muscle and the flexor carpi ulnaris muscle. It branches into a superficial branch and a deep branch in the hand.

(d) The two terminal branches that originate from the posterior cord are the axillary nerve and radial nerve. The axillary nerve supplies deltoid and teres minor muscles. The radial nerve provides motor innervation to all muscles in the posterior arm and forearm. The radial nerve divides into the superficial and the deep branch of the radial nerve.

At the level of the supraclavicular fossa, the plexus is most condensely arranged and enclosed in perineurium which makes it a target for local anesthetic deposition. The supraclavicular approach of the brachial plexus has a high success.

However, the proximity of the pleura, most anaesthesiologists have been troubling to perform this supraclavicular approach. The introduction of ultrasound guidance techniques not only reduces the possible risk of pneumothorax[2] but also allows a faster onset time of the block[3], with a reduction of the volume of local anaesthetic mixture[4]that has to be injected for a successful block. This makes the supraclavicular approach a valuable alternative and is named as spinal anaesthesia ofupperlimb.[5]

In recent years, the use of ultrasound in the application of peripheral nerve blocks has facilitated nerve localization, detection of the boundaries of vascular structures and pleura, visual control of the needle tip, and monitoring of distribution of the injected volume of a local anaesthetic (LA).[6]

Furthermore, the success rate of the block increased, and the complication risk, block performance time, number of needle insertions, and LA volume were reduced. Performing a block under ultrasound guidance effectively requires hand-eye coordination, neural anatomy, USG , and skill.[7]

Anatomy of axillary approach of brachial plexus

In the apex of the axilla, the three plexus cords (lateral, medial, and posterior) divide into further branches. Axillary, musculocutaneous branches leaves the plexus and median, ulnar, and radial nerves accompany the blood vessels through the axilla where the blocks are performed. In the axilla, the median and musculocutaneous nerves

lie superior to the artery, whereas the ulnar and radial nerves lie inferior to it. So the disposition of nerves around the axillary artery gives a confident approach to axillary group of brachial plexus.

Axillaryblock offers several advantages over the supraclavicular technique of brachial plexus block and has no serious disadvantages. The principal advantage of the axillary approach is the complete avoidance of the complication of pneumothorax, while offering at least an equal chance of successful block.

When bilateral blocks are to be performed, the axillary technique is particularly suitable as it avoids the doubled risk of inducing pneumothorax and phrenic nerve paralysis which exists if the supra clavicular method is used.[8] Complications include Vascular Puncture, Intravascular LA Injection, Hematoma, LA Toxicity.

It is generally observed that supraclavicular injection with the aid of peripheral nerve stimulator for brachial block need large volumes of local anaesthetic mixture to achieve complete block.

So it is our goal to assess for the change in amount of local anaesthetic volume that is administered to supraclavicular blocks in adult and axillary block in paediatric patients. Also to observe any change in the cases operated under regional or general anaesthesia.

Materials and Methods

After obtaining the approval of institutional ethical committee of hospital,aretrospective review of anaesthesia register from January 2015 untilJanuary 2020(60 months) was done.

All the adult patients who underwent upper limb surgeriesunderwent peripheral nerve stimulator guided injections for supraclavicular brachial block and paediatric patients under axillary blockby landmark technique from January 2015 to July 2017, will be allocated to Pre-US group and after availability of portable ultrasonography as Post-US with ultrasonography being available since July 2017 and outcome will be recorded.

All data pertaining to age, sex(graph-1), weight,height(table-1)(table-2) ASA grading, local anaesthetic volume, cases converted to General anaesthesia after incomplete blockade,duration of surgery were collected for analysis.

Inclusion criteria

As it is a retrospective study, all possible data will be included and analysed.

Exclusion Criteria

As it is a retrospective study, nothing could be excluded. So comparision for 30 months of pre ultrasound and 30 months of post ultrasound period.

- Pre block preparation

All the patients will be prepared in block room, vascular access will be established on the opposite site of surgery. Patients were attached with the electrocardiogram,Non invasive blood pressure, Pulse oximetry monitoring.Intravenous fluid with a crystalloid is started. After all aseptic precautions, all blocks were performed using a linear ultrasound probe. After antiseptic preparation, all blocks were performed using a linear ultrasound probe with Musculo skeletal templateand 100 mm 21G Stimuplex needle (B. Braun).

- Peripheral Nerve Stimulator (PNS) guided technique:Pre US group

All the blocks before the portable ultrasound (Pre -US) group, were guided by visual twitching of muscle groups with 0.5 mA current by a nerve stimulator and intraneural injection is avoided by visible contractions at 0.3 mA current . after nerve location LA mixture with 0.5% bupivacaine and 2% lignocaine mixture was administered as the LA solution with gentle aspiration after every 3 ml aliquots.

- Ultrasonography guided technique: Post US group

In adults patients, lateral, medial, and posterior cords of the brachial plexus were located around the subclavian artery in supra clavicular area. In-plane technique with ultrasound probe to visualise the needle and the drug distribution hydrodissecting the cords and surrounding the artery. The LA mixture was injected into the neural bundle around the subclavian artery.

Patients were transferred to the operation room after achieving adequate blockade. In cases of inadequate analgesia, intravenous analgesic agent or general anesthesia was administered.

Block failure was defined as sensation of pain, requirement for intravenousanalgesics, administration of general anesthesia during surgery. Pneumothorax, vascular puncture, LA toxicity, respiratory distress, and Horner syndrome were recorded as complications.[8]

Paediatric Axillary Approach of Brachial Block

In paediatric patients posted for upperlimb surgeries after securing the intravenous access

in the paediatric ward and shifted to OT with mother by side. Parents are counselled of parent separation anxiety and paediatric patients are sedated with inj. ketamine 0.25 mg/kg and inj. midazolam 0.5 mg and children were separated fromparents and shifted to OT. Later in the OT patients were attached with necessary ECG, Pulse oximetry,oxygen administration if necessary and respiratory monitoring.

- Land Mark Technique Of Axillary Artery: Pre US Group

Children were given ipsilateral axillary block of the arm to get operated. patients are given the axillary blocks with palpation of axillary artery after 90oabduction of arm. Necessary top up dose of 5-10 mg ketamine or 10 mg propofol while needle is introduced.

- Ultra-Sonography Guided Technique: Post US Group

Out of plane technique with ultra sound probe was used to visualise the needle and spread of local anaesthetic mixture around the axillary artery in the axilla. Block is performed with 2% lignocaine and 0.5% bupivacaine mixture and assessed for adequacy of blockade.

Pain relief was evident while the child allowed for removal of cast dressing and preparing the limb for surgery. Ifchild is found to be anxious and restless then sedation was given with intravenous propofol.If extremely agitated and non-cooperative then general anaesthesia was administered before proceeding with the surgery.

Statistical Analysis

Patient Characteristics

Table 1 : Adults Sex, Age & Weight Distribution.

Adults	Pre Us	Post Us	P Value
Male (%)	172(76%)	181(72%)	0.192
Female (%)	52(24%)	72(28%)	
Ages(Years)M±SD	43.73±8.17	44.47±8.50	0.330
Weight(Kg) M±Sd	52.47±6.14	53.5±6.27	0.070+

Graph 1:

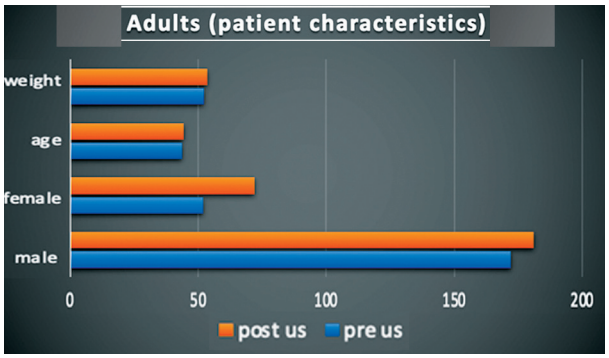


Table 2: Paediatrics : Sex, Age & Weight Distribution.

Adults	Pre Us	Post Us	P Value
Male (%)	78(87%)	80(85%)	0.618
Female (%)	11(13%)	14(15%)	
Ages(Years)M±SD	8.25 ±1.96	8.41 ± 2.44	0.630
Weight(Kg) M±Sd	16.78±3.25	17.18± 4.32	0.480

Graph 2 :

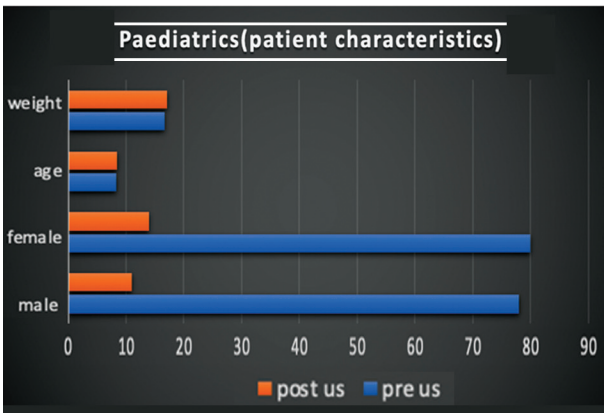


Table 3: Duration of Surgery.

Adults	Duration of Surgery in mins	P Value
Pre us	82.1±22.02	0.410
Post us	79.67±19.34	

*p>0.05 statistically not significant.

Graph 3: Duration of Surgery.

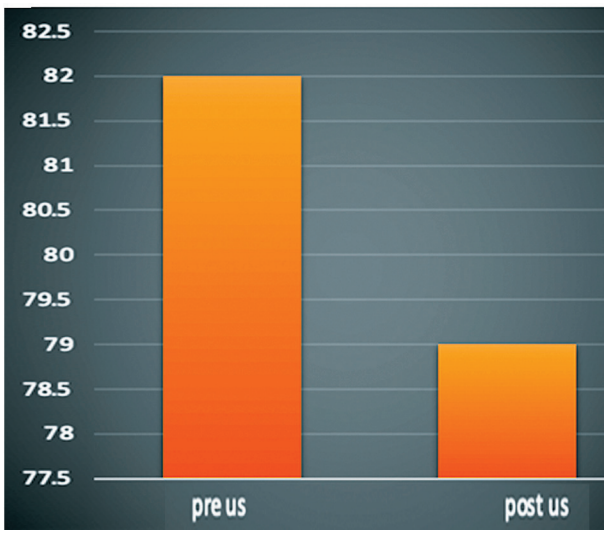


Table 4: Paediatrics Duration of Surgery.

Pediatrics Groups	Duration of Surgery in mins	P Value
Pre us	54.82 ± 10.59	0.010*
Post us	50.45 ± 12.18	

Graph 4:

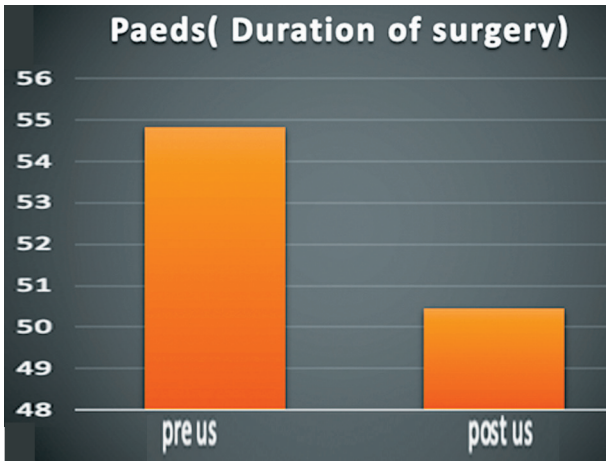


Table 5: Adults Year wise no of cases.

	Year	Adults	
		GA	RA
Pre us	2015	25	32
	2016	32	42
	2017	10	83
Post us	2018	07	105
	2019	02	84
	2020	01	54

Graph 5:

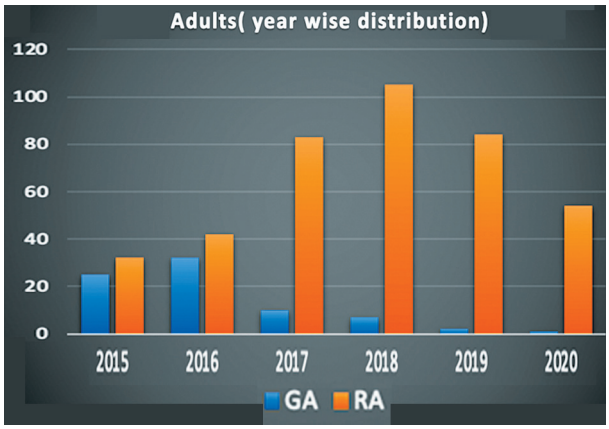


Table 6: Year wise no of cases: Paediatrics.

	Year	Paediatric	
		GA	**RA**
Pre us	2015	19	04
	2016	25	06
	2017	27	08
Post us	2018	11	30
	2019	08	26
	2020	00	19

Graph 6:

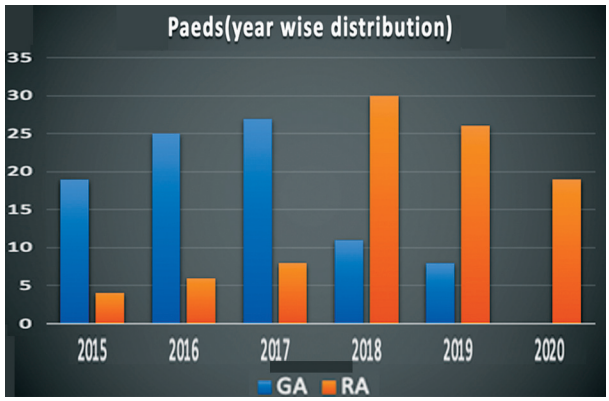


Table 7: Comparision of cases in GA vs RA in adults under supraclavicular block.

	Adults		P value
Groups	**GA**	**RA**	
Pre us	67(30%)	157(70%)	
Post us	10(4%)	243(96%)	<0.001**
P value	X^2=59.100; P<0.001**		

Graph 7:

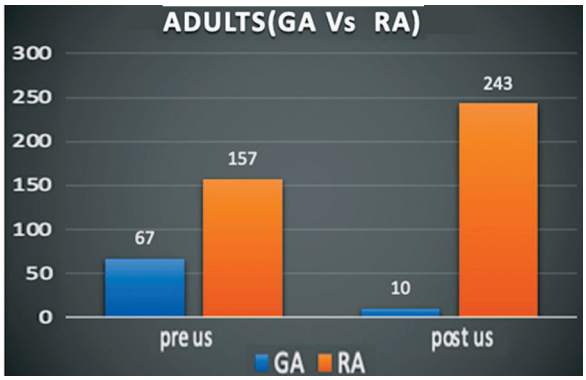


Table 8 : Comparision of cases in GA vs RA in paediatric pts under axillary block.

	Pediatrics		P value
Groups	**GA**	**RA**	
Pre us	71(80%)	18(20%)	
Post us	19(20%)	75(80%)	<0.001**
P value	X^2=64.9; P<0.001**		

Graph 8:

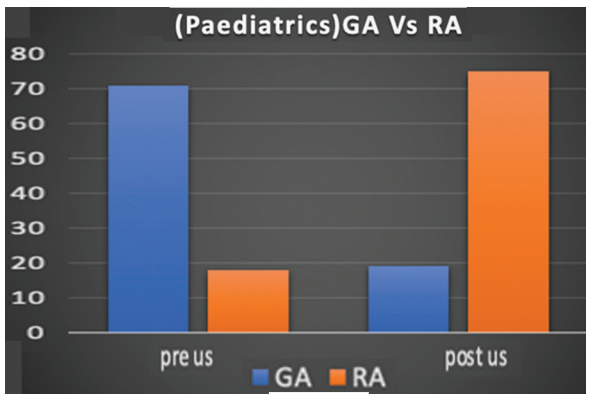


Table 9: Volume of local anesthesia mixture: (adults).

	Adults	
Groups	**Volume of LA in ml**	**P***
Pre us	28.56 ± 3.41	53% reduction in vol
Post us	13.89 ± 1.35	

* Moderately significant (P value:0.01<P ≤ 0.05)

Graph 9:

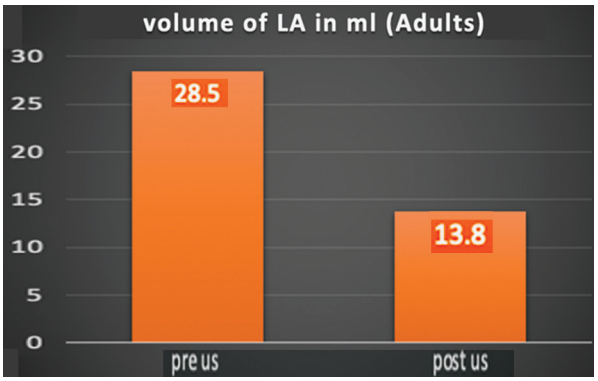
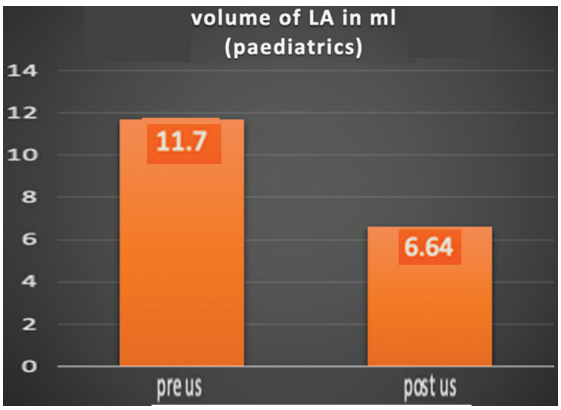


Table 10 : Volume of local anesthesia mixture: (Paediatrics).

	Adults	
Groups	**Volume of LA in ml**	**P***
Pre us	11.77 ± 1.8	43% reduction in vol
Post us	6.64 ± 0.90	

* Moderately significant (P value:0.01<P ≤ 0.05)

Graph 10:



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. The following assumptions on data is made.

Assumptions: 1. Dependent variables should be normally distributed, 2. Samples drawn from the population should be random, Cases of the samples should be independent

Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Leven`s test for homogeneity of variance has been performed to assess the homogeneity of variance. A t-test is a statistical test that is used to compare the means of two groups. It is often used in hypothesis testing to determine whether a process or treatment actually has an effect on the population of interest, or whether two groups are different from one anotherwith the null hypothesis (H0) is that the true difference between these group means is zero and the alternate hypothesis (Ha) is that the true difference is different from zero.

Chi-square/Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis. Fisher Exact test used when cell samples are very small.

Significant figures

+ Suggestive significance (P value: 0.05<P<0.10)

* Moderately significant (P value:0.01<P ≤ 0.05)

** Strongly significant (P value : P ≤ 0.01)

Statistical Software: The Statistical software namely SPSS 22.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

Discussion

In our retrospective analysis, statistical analysis of the in adult groups (table-1) reveals to be similar with 76 % male to 24% female patients (graph-1) in pre Ultra sound group and 72% male to 28% females in post ultra sound. Both the groups were similar with respect to age and weight in all aspects. (table-1)

Analysis of the paediatric set of cases(table-2), with respect to patient characteristics showed to be also similar with 87 % male to 13% female patients in pre US group, 85% male to 15 % female patients in post ultra sound group(graph-2). Also age distribution in groups was found to be 8 years approximately (table-2). Weight distribution in both the groups were similar too. (table-2) Duration of surgery in our study means time from achieving administering anaesthesia in RA or in cases of General anaesthesia till completion of surgery including post-operative dressings.

In adult groups, the duration of surgery in both groups were comparable around 82 minutes in

pre ultrasound and 79 minutes in post ultrasound groups (table-3)(graph-3). Also in cases posted for paediatric patients posted for upperlimb surgeries under axillary blocks and duration of surgery in the groups was similar with 54 minutes in pre ultrasound and 50 minutes in post ultra sound group (table-4) (graph-4).

Then after examining our records for no of cases operated under general anaesthesia and regional anaesthesia. It was found that a total of 224 cases were operated before ultrasound availability in the department. Out of which 67 cases were performed under general anaesthesia that is 30% of cases in the Pre US group and i.e 157(70%) cases under supra clavicular brachial plexus block(table-5).

Whereas in the post US group,total of 253 cases were operated after the availability of USG in the department. There were only 10 cases i.e. 4% of total cases under general anaesthesia. Whereas 243 cases i.e. about 96% of total cases under USG guided supra clavicular approach for brachial plexus blocks was a significant increase in no of cases under regional anaesthesia.So there was a 26 % rise in no of surgeries (graph-7) under regional anaesthesia which is quite significant (table-7).

In paediatric subset, pre US group with 80% of cases were operated under general anesthesia and 20 % under axillary approach of brachial block with minimal conscious sedation. In post US group, 20% of cases under General anaesthesia, with a definitive rise of 60 % increase(graph-8) in no of cases(table-8) under Axillary approach of brachial block.

The success of complete blockade of brachial block is ensured by ultrasound guidance which helps in hydrodissection of the nerves and surrounds the brachial plexus interrupting the nerve transmission of various modalities of sensations and motor blockade to provide the surgeon with an immobile operative field.

On analysis of the volume of local anesthetic been used in adults for supraclavicular block in pre US group was found to be 28.5 ml as average value of the group to achieve a complete block(table-9). However on many occasions associated with sparing of few areas on the arm,tourniquet pain that has to be supplemented with short acting analgesic by opioids etc.

Whereas in the post US group the volume of local anesthetic mixture is reduced to 13.9 ml. The very precise and accurate visualisation of the nerve bundle with the aid of ultrasound waves makes the injection of the drug mixture in the nerve sheath. The reduction in mean effective volume(MEV) in our study was near about 51% (graph-9) by the application of ultrasound (table-9).

In the paediatric subset, with axillary block the mean effective volume in the pre US group by landmark technique of axillary artery was 11.7 ml (table-10). While in the post US group of children, the average volume of local anaesthetic was found to be 6.6 ml which ensured complete analgesia and benefited to have a cooperative child in the surgery.The application of ultrasound has resulted in 43% reduction (graph-10) in the mean effective volume(table-10)for performing surgeries under regional anaesthesia.

In both the group adults local anaestheticmixture administeredfor supraclavicular brachial block was 2% lignocaine and 0.5% bupivacaine not exceeding the toxic doses according the body weight and 10 ml of normal saline to help in spreading of the mixture around the nerve bundle.

In paediatric group the local anaesthetic mixture administered in both the groups for axillary approach of brachial block was 2% lignocaine and 0.5% bupivacaine not exceeding the toxic doses according the body weight.

Limitations of study

- Our study couldnot reveal the data about the intra operative satisfaction of the patient.
- It did not reveal the side effects and consequences intraoperatively and post operatively in both the procedures.
- Our study is insufficient, with regard to duration of post-operative analgesia in the adult and paediatric patients.
- It could not study the duration of hospital stay post operatively.
- It couldnot study the cost benefits conferred to the hospital.

Conclusions

- In adults ultra sound increased 26 % rise(graph-7) in no of surgeries (table-7) under regional anaesthesia which is quite significant.
- The reduction in mean effective volume(MEV) in adults was near about 51%(table-9) by the application of ultrasound(graph-9).
- In children, there was a definitive rise of 60 %(graph-8) increase in no of cases(table-8) under Axillary approach of brachial block by ultrasonography.
- Also, 43% reduction(graph-10) in the mean

effective volume(MEV) (table-10)in children for performing surgeries under regional anaesthesia.

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Case Report

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Anaesthetic Management of a Patient with Failing Modified Fontan, Morbid Obesity, Atrial Flutter and OSA posted for RFA-A Case Report

Snigdha Paddalwar[1], Jaswant Singh Sumal[2]

Author's Affiliation: [1,2]Consultant Pediatric, Cardiac Anaesthesia, Glenfield Hospital, University Hospitals of Leicester, Leicester, UK.

Abstract

The Classic Fontan has been abandoned these days due to occurrence of rapid and incessant complications. Presence of complications like, morbid obesity, obstructive apnoea, chronic atrial flutter, elevated Fontan pressures as seen in our patient, increases the risk of Anaesthesia manifold times. We report a case of 32 year old male patient with failing modified Fontan and aforementioned complications, posted for radiofrequency ablation under general Anaesthesia.

Key words: Failing Fontan Circulation; Remifenanil; Morbid obesity.

Key Messages: Anaesthetic management of patients with failing modified Fontan and its associated complications needs long standing experience , thorough understanding and proper selection of anaesthetic drugs to conduct a case safely without causing fatal acute decompensation.

Introduction

The Fontan procedure, first done in 1968, is a well-established surgical treatment for single ventricle congenital cardiac defects.[1] Several modifications have been made over the past decades, in particular, the atrial- pulmonary anastomosis has been replaced with a total cava-pulmonary artery anastomosis.[2] This has significantly improved prognosis and patient survival, with a lower occurrence of arrhythmias, delaying the onset of cardiac failure,as compared to patients with "classic Fontan"(atriopulmonary connections).[3-4]

Classic Fontan is totally abandoned these days hence its rare to encounter adult patients with this type of repair. Fontan circulation and its failing component implies highly complex physiologic and multiorgan considerations requiring a meticulous planning and execution of Anaesthesia in order to maintain homeostasis and avoid fatal complications and acute decompensation. Factors like morbid obesity, OSA, loss of A-V synchrony, rising pressure in Fontan Circuit can pose significant threat to life. Therefore managing this case perioperatively is a unique and rare challenge an anaesthesiologist would come around.

We present here Anaesthetic management of a case of failing Classic Fontan complicated with morbid obesity, chronic atrial flutter, Diabetes Mellitus type 2 and Obstructive sleep apnoea syndrome, posted for Radiofrequency ablation.

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Corresponding Author: Snigdha Paddalwar, Consultant Pediatric, Cardiac Anaesthesia, Glenfield Hospital, University Hospitals of Leicester, Leicester, UK.

E-mail: spdrsnigdha96@gmail.com

Case History

A 32 year old male patient, weighing 132.6 kgs, BMI of 45, s/p Modified Fontan operation, had unbalanced AV canal defect, hypoplastic(rudimentary) right ventricle, severe Pulmonary stenosis. He had undergone staged surgeries on a single ventricle pathway and had a long history of atrial flutter with multiple interventions including DC cardioversions and RFA. Now presented with recurrentpalpitations, severe breathlessness NYHA-3, MET less than 4, orthopnoea, desaturations to mid 80s and persistent cyanosis. His latest catheter data correlated with failing Fontan, pressure in Fontan circuit 20mm Hg, high TPG, moderate ventricular dysfunction, moderate AV valve regurgitation, massively dilated IVC, RSVC and Coronary sinus draining into hugely dilated right atrium draining into Main pulmonary artery. Dilated Fontan circuit had stasis and energy losses. Had history of acute decompensation after RFA in the past and now was on sotalol, warfarin and lisinopril.Lab data wise had polycythemia and elevated hepatic enzymes.

He had severe anxiety disorder particularly needle phobia and refused for sedation in spite of counselling for benefits of maintaining spontaneous breathing, hence, we planned GA for him. We anticipated difficult intubation and mask ventilation.

On the day of procedure, no oral premedication was given in view of his sleep apnoea. Monitors were connected and 18G IV cannula secured. Preinduction fluid 500mls Hartmann solution given. Anaesthetic induction done with Remifentanil infusion on TCI with effect site target of 2ng/ml initially later increased to 4ng/ml for intubation, supplemented with Inj Midazolam 2mg, Inj Propofol 100mg and Inj Atracurium 100mg. Intubation was done in single attempt with McCoy blade followed by arterial and central line. Hehad mild hypotension and bradycardia, BP was in low 80s and heart rate low 50s after induction drugs, which was countered with another 500mls of volume, Inj Phenylephrine boluses and Inj Glycopyrollate. Thereafter his hemodynamics stabilized to acceptable values. He was Ventilated on volume control, peak airwaypressures limited to 20, PEEP of 6, RR to maintain $ETCO_2$ less than 40mmHg. We could not monitor his SVV, PPV or cardiac output due to his atrial flutter rhythm.

Maintenance of Anaesthesia was done with Remifentanil @ 2ng/ml on TCI and Desflurane with a MAC of 0.7 to 0.8, no further boluses of muscle relaxant were given. BIS was maintained between 40-50.. His Fontan pressure was 20 to begin with and later increased to 24. Started on Phenylephrine infusion in low dose to support his pressure which maintained a pressure above 90 systolic. ABG showed normal values. He received a total of 2.5 litres of volume throughout the procedure. Urine output improved to 1ml/kg after first hour and later was increased to 1.5ml/kg.

Patient underwent procedure uneventfully which lasted for 4 hours. On conclusion his Anaesthetics were stopped, he was reversed and extubated in sitting position after he was fully awake. He was shifted to ward after 30mins. Post operative course was uneventful.

Discussion

The hallmark of the Fontan circulation is a sustained, abnormally elevated central venous pressure acting as driving force for pulmonary circulation in the absence of subpulmonary ventricle, combined with decreased cardiac output, especially during periods of increased demands, resulting in a cascade of physiologicalconsequences(5-6). Any alterations caused during Anaesthetic management can trip off the balance of such precariously maintained circulation.

In our patient the problem was compounded by extremely high pressures in Fontan circuit(sign of failing Fontan), morbid obesity, OSA and loss of AV Sequential synchrony, specially in a very high risk substrate of "classic Fontan" circuit.(9, 10,11,12) By contributing to alterations in pulmonary functionand increased systemic vascular resistance, overweight contributes rapidly to Fontan failureand physiological changes associated with OSA, hypercarbia, hypoxia, and hypoxic pulmonary vasoconstriction (HPV) worsens the PVR.[7]

Other Clinical hazards faced by these patients include progressive fatigue, heart failure, arrhythmias, and end-organ complications such as liver disease, plastic bronchitis, protein loosing enteropathy, desaturations, thromboembolic complications, multiple surgical and non surgical interventions, in addition to anxiety and concern about their condition and future.[13,14] Our patient had almost all the problems except plastic bronchitis and PLE.

Induction of general endotracheal anesthesia with administration of cardiac depressant medications and conversion to positive pressure ventilation often results in decreased contractility and decreased pulmonary blood flow secondary to increased mean airway pressure leading to acute decompensation.

Choosing Remifentanil and Desflurane kept his hemodynamics stable and led to full and quick recovery from GA.[8] Choice of drugs was of utmost importance to maintain his physiology.

Conclusion

Patients with Fontan,are in a state of chronic low cardiac output and elevated systemic venous pressure. Risks and challenges of anaesthesia are increased due to presence of various complications specially in a classic modified Fontan.

Therefore we believe that complete understanding of Fontan circuit, factors affecting flow through this circuit, effect of long term complications, current catheter data and most important is the experience to deal with this highly complex substrate of patients is the key to managing these patients successfully.

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Case Report

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Awake Retrograde Submental Intubation in a Patient with Pleomorphic Adenoma of Palate

V.N.V.Vaishnavi[1], S.Kiran kumar[2], K.Yugandhar[3]

Author's Affiliation: [1]Post Graduate, [2]Professor, [3]Assistant Professor, Department of Anaesthesiology, Mamata Medical College, Khammam 507002, Telangana, India.

Abstract

Retrograde intubation is one of many techniques that can be used in those cases where oral or nasal tracheal intubation may be extremely difficult or impossible. Retrograde intubation is a reliable and easily learned technique that offers an alternative to more invasive surgical solutions for securing the airway. Submental intubation provides intraoperative airway control, avoids use of oral and nasal route, with minimal complications. Submental intubation is an acceptable option, especially when long-term post-operative ventilation is not planned. We hereby report a case of a 55-year-old woman with a recurrent history of a pleomorphic adenoma of palate which required tumour excision under General Anaesthesia for which Awake Retrograde Submental Intubation was done.

Key words: Anaesthesia; Pleomorphic Adenoma; Palatal Tumour; Retrograde; Submental intubation.

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Case Report

Approximately 10% of Pleomorphic Adenomas occur in the minor salivary glands with the palate being the most common site. Pleomorphic adenomas account for the majority of palatal tumours; however, minor salivary gland tumours have a higher risk of malignancy compared to tumours of the major salivary glands, so appropriate diagnostic evaluation should be prompt.

We present a case of a 55-year-old woman with a recurrent history of a pleomorphic adenoma of palate since 23years which required tumour excision under General Anaesthesia. Patient presents with a history of swelling in the oral cavity with severe pain and difficulty in breathing on lying down since 2 months. In the Pre-Anaesthetic evaluation, there was no significant medical history and all routine and specific investigations were within normal limits. The airway examination revealed that the patient had mouth opening of 4cms (>two finger breadth), thyromental distance of 6cms (three finger breadth) and mallampati grading couldn't be elicited due the tumour mass in the oral cavity.

Awake Retrograde Submental intubation was planned and Tracheostomy kit was kept ready in case of an urgent need to secure the airway. The procedure was explained in detail to the patient

Corresponding Author: V.N.V.Vaishnavi, Post Graduate, Department of Anaesthesiology, Mamata Medical College, Khammam 507002, Telangana, India.
E-mail: smile.vyshu@gmail.com

and an informed consent was obtained both for the procedure and for an Emergency Tracheostomy.

Airway block was planned, airway preparation was done on the night before and 2hrs before surgery. On arrival to the pre OP room, Baseline monitoring was done. Under Aseptic conditions, Airway block was performed to block the internal branch of the superior laryngeal nerve and the recurrent laryngeal nerve.

Cricothyroid membrane puncture was then performed with 18G needle and a guide wire used in central venous cannulation was advanced cephalad through the needle, the larynx and out of the mouth; the Flexometallic endotracheal tube (ETT) was railroaded over the guide wire into the trachea. Bilateral Air Entry was checked and confirmed equal on both sides.

Induction was then done with Inj.Propofol 2mg/kg and paralysed with Inj.Vecuronium1mg/kg. A Throat pack was placed around the ET tube just above the level of vocal cords to prevent aspiration. A 1.5-cm skin crease incision was made in the left Submental region by the operating surgeon. Bluntdissection was performedto enter the oral cavity, and proper haemostasis was achieved. The pilot balloon of ET tube was directed towards and brought out of the Submental incision followed by the ET tube. The ETT cuff was inflated, and the breathing system was connected. After ensuring bilateral equal air entry, the ETT position was secured with skin sutures.

The 6hrs surgery proceeded uneventfully and maintenance was done with Vecuronium 0.2mg/kg and Isoflurane. The Emergency Cricothyroidotomy kit was kept ready before extubation in case of urgent airway control. After thorough oral suctioning, the ET tube was brought back to the oral cavity from the submental position and the submental incision was closed using two monofilament skin sutures, and sterile dressing was applied, now the throat pack was removed. The Neuro-muscular blockade was reversed with Inj. Neostigimine 0.05mg/kg + InjGlycopyrolate 0.5mg and was successfullyextubated after extubation criteria is met. The patient was transferred to the Post-Anesthesia care unit. The submental incision healed with good cosmetic appearance and without specific complications.

Conclusion

Henceforth, we conclude that management of nasopharyngeal/oral cavity tumours is one such challenge we all should be trained and emphasis should be on importance of Retrograde Intubation and Submental Intubation in such anticipated difficult airway.

Discussion

Difficult intubation is defined as inadequate visualization of the glottis and failed tracheal intubation as inability to insert a tracheal tube from the oropharynx into the trachea. The use of retrograde wire technique to assist in the management of difficult airway was first reported in 1981. Since then, modifications of this technique have included in the use of the fiberoptic bronchoscope to permit tracheal intubation under direct visual control.

This technique may be useful in trauma patients requiring cervical spine immobilization as well as in patients with facial trauma, tumours of oral cavity, trismus, ankylosis of the jaw and cervical spine, upper airway masses and bleeding. Flexible fiberoptic bronchoscope is the method of choice for coping with such difficult tracheal intubations. Although Retrograde Submental tracheal intubation has been described as a useful, safe, and effective airway management technique during maxillofacial surgery, especially to avoid a short-term tracheostomy and its attending morbidity. It's also better alternative in airway management in difficult airway conditions where there is no fiberoptic laryngoscope. Tracheostomy would have been an appropriate option to secure the airway under these circumstances if multistage reconstructive surgery was planned, with challenges of a difficult airway each time and significant risk of prolonged postoperative airway compromiseresulting from soft tissue edema.

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Anaesthetic Managemetnt of Surgical Resecton of A Giant Mediastinal Mass – A Case Report

Snigdha Paddalwar[1], Vaibhav Dhabe[2], Hiren Shah[3]

Author's Affiliation: [1]Consultant Pediatric, Cardiac Anaesthesia, Glenfield Hospital, University Hospitals of Leicester, Leicester, UK, [2]Consultant Pediatric, [3]Junior Consultant Pediatric, SRCC Children's Hospital, K-Khadey Marg, opposite Haji Ali, Mumbai, Maharashtra 400034, India.

Abstract

Giant mediastinal mass tumors have been associated with perioperative respiratory and circulatory life- threatening complications during induction of general anaesthesia and initiation of positive pressure ventilation leading to sudden cardiac arrest known as MMS, 'Mediastinal mass syndrome' (4, 5,6). A detailed meticulous preanaesthetic evaluation and a well thought out anaesthetic plan can avoid life-threatening events during management of these patients. We report a successful anaesthetic management of a 12 yrs old pediatric patient with a left sided giant mediastinal germ cell tumor, posted for complete surgical resection. We followed the guiding principles for anaesthetic management of such cases, maintaining propped up position, avoiding muscle relaxants, maintaining spontaneous breathing, keeping cardiac team and perfusion team ready to cannulate and institute CPB in case of sudden cardiorespiratory collapse, adapting to low volume ventilation and titrated and step wise induction of anaesthesia.

Key words: Mediastinal Mass Syndrome; Germ Cell Tumour; CPB.

Introduction

Giant mediastinal tumors like germ cell tumors are known to cause significant airway and great vessel compression.[1] It has been associated with perioperative respiratory and circulatory life-threatening complications during induction of general anaesthesia and initiation of positive pressure ventilation leading to sudden cardiac arrest known as MMS, 'Mediastinal mass syndrome.[4-6] A detailed meticulous preanaesthetic evaluation and a well thought out anaesthetic plan can avoid life-threatening events during management of these patients. Germ cell tumors (GCTs) are rare tumors thought to be derived from totipotential primitive germ cells that either mismigrate along the urogenital ridge during early embryogenesis or are distributed physiologically. GCTs show a wide diversity of benign or malignant characteristics.[2] Among extra gonadal GCTs, mediastinal germ cell tumors (MGCTs) in children are extremely rare and often form giant masses invading the surrounding vital organs and tissues.[3] We are reporting

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Corresponding Author: Snigdha Paddalwar, Consultant Pediatric, Cardiac Anaesthesia, Glenfield Hospital, University Hospitals of Leicester, Leicester, UK.

E-mail: spdrsnigdha96@gmail.com

anaesthetic management of a pediatric case with a giant mediastinal germ cell tumor for surgical resection without CPB support. This is the largest tumor ever reported for anaesthetic management, as per our search through the literature.

Case Report

A 12 yrs. old male patient, weighing 40kgs was referred to Anaesthetic OPD for Preanaesthetic evaluation with a diagnosis of a giant anterior mediastinal mass, a germ cell tumor. He had received 3 cycles of Bleomycin, Cisplatin and Etoposide and presented with complaints of breathlessness, which had increased rapidly over a period of 6 months from NYHA 2 to 4 at present, with MET of 4. He also complained ofleft sided chest pain, shoulder pain, fullness on left side of the chest, loss of appetite, weight and change of voice. He specifically complained of not being able to lie supine or in right lateral position, so he adapted left lateral and propped up position to sleep. He also had history of GCTS for which he was being treated with anticonvulsants after ruling out neurological causes with neuroimaging.

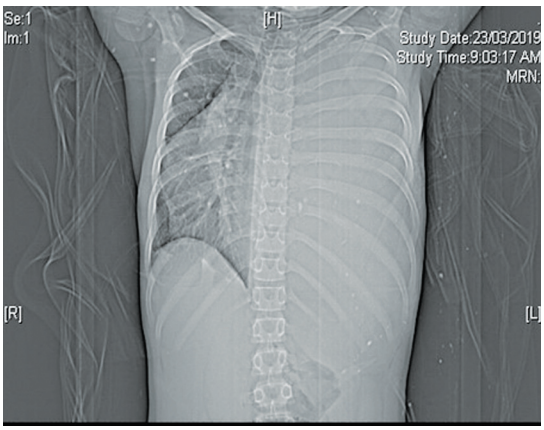

Fig. 1 X-Ray Chest: Massive tumor seen in left thorax, mediastinal shift to right with heart completely displaced into right hemithorax, tracheal deviation to the right, compression of left bronchus, left diaphragm displaced into abdomen, great vessels stretched.

His lab investigations were within normal limit. X-Ray chest (Fig.1) showed left thorax complete white out, left lung completely collapsed, significant mediastinal shift to right, tracheal deviation to right left hemi diaphragm displaced intothe abdomen. CTchest scan (Fig.2) confirmed findings of chest X-Ray with additional findings of complete obliteration of left bronchus (Fig.3,4) and left pulmonary artery completely plastered to the mass, other great vessels were compressed and encased in the mass; heart was shifted into right hemi thorax. (Fig.2,3,5) Trachea was shifted into right mediastinum. (Fig.1,2) The tumor size was 16*19*27cms.

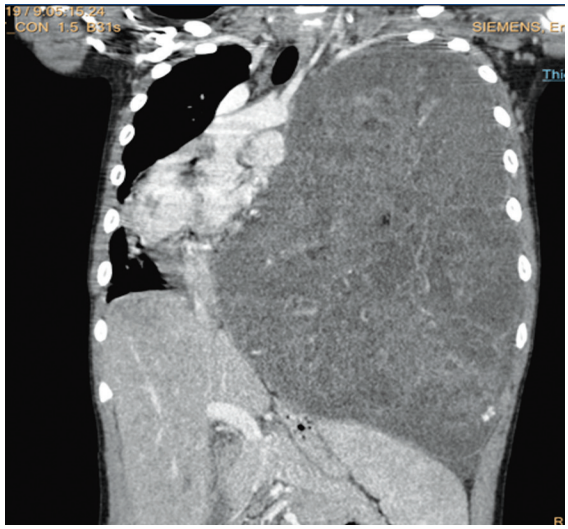

Fig. 2: CT scan images massive tumor occupying the left hemithorax and whole mediastinum, Heart displaced into right hemithorax, tracheal displacement and compression, left diaphragm flattened and displaced into abdomen.

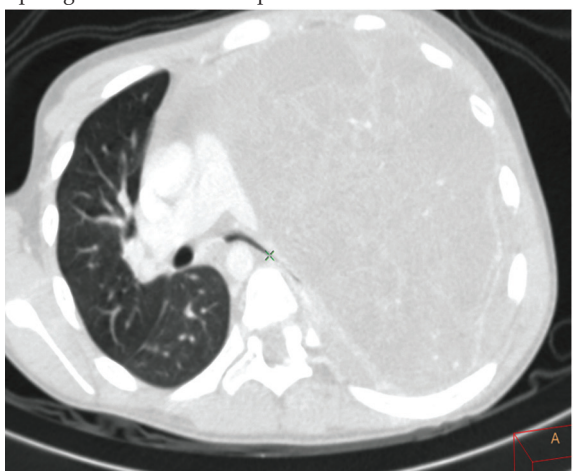

Fig. 3: Large heterogeneous mass 16cm*19cm*27cm, left lung completely collapsed, mild pleural effusion. Left bronchus and left pulmonary artery cut off.

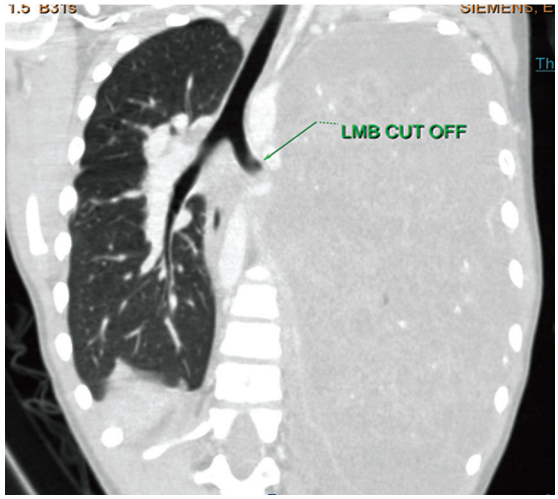

Fig. 4: Large mass with left bronchus cut off in sliced CT image, mild compression of right bronchus.

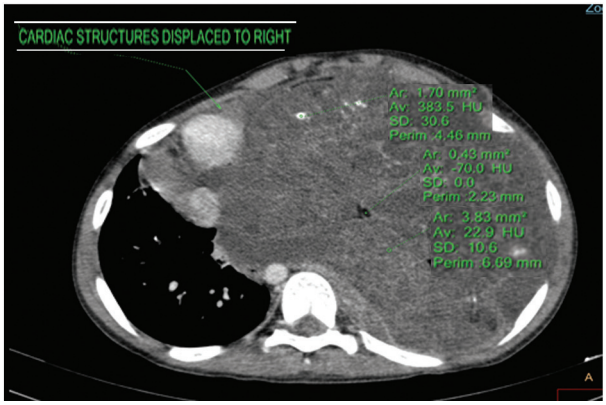

Fig. 5: cross sectional view of giant germ cell tumor, cardiac shadow seen in right hemithorax compressed between mass and the anterior chest wall.

After discussing with oncosurgical and cardiac surgical team we finalized a plan for Anaesthesia induction, airway intervention and back up strategy.

On the day of surgery after connecting him to all the essential monitors. We placed him in propped up position.We secured a 18G thoracic epidural catheter in T5-6 space followed by radial arterial line, central line in Rt IJV and 2 16 G IV cannulas in lower limb while patient was awake, under local anaesthetic. We had our CPB machine, perfusion team and cardiac team standby for induction of anesthesia, as these patients are very high risk for cardiac arrest during anaesthetic induction. We had a rigid bronchoscope as a stand by to stent the trachea if it all it collapses after induction. Our plan was to institute CPB for E-CPR with femoral access so we kept femoral triangle prepared and marked with USG. Before induction we gave him a volumebolus, followed by1micgm/kg of fentanyl and 2mg of midazolam as premedication and induced with SEVO and a small-titrateddose of Propofol maintaining spontaneous breathing.

We intubated him without a muscle relaxant in propped up and left lateral position, with conventional laryngoscope and SLT. Ventilation was achieved with 6ml/kg of tidal volume with peak airway pressure of 25 with a good $ETCO_2$ trace. He had hypotension, which responded to volume loading and few boluses of phenylephrine otherwise he tolerated induction well. As soon as surgeons were ready for sternotomy we positioned him supine. His ventilatory parameters improved slightly after sternotomy and we gave our first dose of muscle relaxant. We started with epidural infusion of Ropivacaine 0.1% with Baxter pump.

Excision of entire tumor was done in total, without CPBin 10 hours and he had significant blood loss approx. 950 ml, which was replaced with blood and blood products. Surgeon had to convert his incision to clamshell to gain access to difficult aspects of the tumor.Problems encountered Intraoperatively apart from excessive blood loss and long operative time was difficulty in maintaining hemodynamics and ventilation every time tumor was manipulated and mobilized. Any manipulation in tumor caused significant fall in blood pressure and extreme increase in airway pressures with inability to ventilate due to complete obstruction of airway and compression of heart into right thorax.

Each time we warned the surgeon to lift the tumor off the great vessels, heart and airway. Intraoperatively his hemodynamics were very labile as surgeon had to manipulate the tumor for fine detailed dissection to free all the important vascular and airway structures from the tumor and hence needed constant intervention. With meticulous coordination between surgeon and the anesthesiologist we could counter all the challenges and avoided CPB completely.

Towards the end we started a small dose of noradrenaline to keep up his MAP above 60. As tumor was removed from the thorax his heart moved into the mediastinum spontaneously and LPA looked full and free. His ventilation improved significantly with Pinsp pressure of 18, we could deliver a tidal volume of 10mls/kg. His tumor weighed 3.4kgs. He had received 3 units of PRBC, 2 units of FFP, 2 units of platelets 3.5 litres of crystalloid. His maximum lactates were 3.5 and hemoglobin 10.6gm%

Sternotomy was closed and he was then shifted to PICU with stable hemodynamics. His pain control was appropriate and urine output was 1ml/kg/hour. He got extubated after 3 days of ventilation

Patient was brought back to the operating room 2 times for sternal wound infection and thereafter he was extubated and discharged after 20 days of hospital stay.

Discussion

MMS is defined as acute right ventricular failure secondary to vascular compression after positive pressure ventilation in patients with a mediastinal mass.[4,5] Difficulty with ventilation and cardiac arrest in the course of anaesthesia for diagnostic or therapeutic procedures in patients with mediastinal mass is well described.[3,4] Some centers have reported an incidence in pediatric patients of 7–20% during anaesthesia and 18% in the postoperative period. Nevertheless, insufficient preoperative

preparations and inadequate perioperative management can promptly lead to life- threatening situations.[3] Therefore, careful diagnostic workup and detailed preoperative imaging is essential in all cases to assess the anatomy and exact relationship of the tumor with the surrounding vital mediastinal structures. In our case we did a detailed imaging analysis and studied the status of all great vessels and airway, in relation to the tumor, along with our surgical and the radiology team.

Our patient had all the clinical signs of significant tracheobronchial obstruction, which could have potentially worsened, with induction of general anaesthesiaand intermittent positive pressure ventilation (IPPV). Decreased chest wall tone and caudal displacement of the diaphragm leads to loss of the distending transmural pressure gradient. Anaesthesia induction in patients with anterior mediastinal mass will shrink the transverse diameter of the thorax owing to a decrease in the inspiratory muscle tone, cephalic displacement of the abdominal contents secondary to loss of the abdominal muscle tone and relaxation of bronchial smooth muscles, leading to a major airway collapse. In addition, the craniocaudal movement of the diaphragm will be lost, or significantly dimin- ished with the administration of neuromuscular blockers leading to sudden collapse of the airway.[6]

Hence, maintenance of spontaneous ventilation is critical to avoid precipitating complete obstruction in these patients. Awake intubation in propped up position or inhalational induction with maintenance of spontaneous ventilation is recommended depending on the degree of obstruction and the symptoms produced.[7,8] If there is any difficulty in ventilation because of obstruction at the level of the carina or the bronchus, a rigid bronchoscope should be inserted and ventilation maintained by connecting a Sanders injector or jet ventilator to the side port of the bronchoscope. In the presence of severe symptomatic obstruction, stenting could be performed to rescue the patient. As we had prepared in our case by securing all the lines in awake propped up left lateral position, maintaining spontaneous breathing during intubation avoiding muscle relaxants, keeping rigid bronchoscope by our side, secure large bore IV cannulas in lower limb and preparation for CPB

Predictors of perioperative complications concerning respiratory or circulatory collapse in patients with a mediastinal mass are CT findings of ≥50% tracheal compression or ≥130 cm3 mass volume, presence of pleural effusion or pericardial effusion, presence of superior vena cava compression, pulmonary artery compression on one side, atelectasis on the other side, peak expiratory flow rate ≤40% of the predicted value, and an obstructive or mixed pattern of pulmonary function test.[1,6] Our patient could not perform PFT due to severity of symptoms.

Based on all the investigations and clinical examination patient can be categorized as low risk and high risk for MMS. This risk stratification may guide the utilization of perioperative pre-emptive measures and precautions, like the safest form of anesthesia, the optimal positions for induction of anesthesia and surgery, the additional value of intraoperative (rigid) bronchoscopy and TEE, and the potential assistance of extracorporeal circulation (ECC). Furthermore, due to the possible involvement of the superior vena cava (SVC) in large mediastinal masses, large-bore venous access should be secured in the lower extremity (preferably the femoral vein) rather than the upper extremity in all patients, regardless of risk category.

The rescue modality when MMS occurs is ECC, providing an avenue for both oxygenation and circulatory support. Earlier reports have described "stand-by" ECC as a rescue measure[9-11] for intraoperative hemodynamic or respiratory deterioration. However, even with a primed ECC circuit and perfusionist present in the operating room, it will still take 5–20 minutes before emergency cannulation of the femoral vessels is performed and ECC is initiated[12]; an interval likely to result in significant neurological injury. Therefore, several authors have recommended femoral cannulation under local anesthetics and initiation of ECC before induction of anesthesia (6, 48) especially in patients with high risk of MMS and are deemed "uncertain" or "unsafe" according to the classification proposed by Erdös and Tzanova.(6, 48) But we were assured of dealing with any such complications by rescue position and then institution of CPB as our cardiac surgeons and perfusion team was in theatres during induction, well prepared with appropriate size cannulas and markings on the femoral vessels sited with USG.

We could successfully do this high-risk case without any complications as we had comprehensive and detailed preop preparation, involvement of multidisciplinary team, anticipation of problems and possible events and a plan to counter that. We could find a rescue position and maintained the same until sternotomy. Meticulous management of intraoperative hemodynamics, ventilation and fluid status, urine output helped us in optimum outcome. Maintaining optimum temperature

through out helped us in achieving hemostasis inspite of extensive surgical bed and high risk for bleeding.

Conclusion

Anaesthetic induction of patients with giant mediastinal masses can pose a significant challenge to an anaesthesiologist in view of high risk for cardiovascular collapse and respiratory compromise. Literature search has showed few cases with giant germ cell tumors and their anaesthetic management however ours is the largest mass ever reported. Our casereport highlights the strategy for successful management of such cases. Following are the keys to form a strategy to avoid unwarranted life threatening events. Assess the risk and degree of severity through a detailed history and physical examination. Preoperative imaging and echocardiogram to ascertain details of mediastinal mass and nearby compressed structures. Classify risk of developing media stinal mass syndrome.

Explore the best position for less dyspnea and greater comfort i.e rescue position, usually it is a propped up, prior to initiating general anaesthesia.[7,8]

Intubation should be done in the operating room with preoperative consultation by a multidisciplinary team involved in specialized Anaesthetics, intensivists and cardiothoracic surgeons and all present in the theatre during induction. Consider awake fibreoptic in certain situations, with rigid bronchoscope by the side.

Make a cardiopulmonary bypass or extracorporeal membrane oxygenator and perfusionist available, as the patient may need rescue cardiorespiratory support. Femoral venous cannulation or readiness to cannulate, should be arranged prior to anaesthesia induction in high-risk patients.

Avoid deep sedation and proceed with stepwise induction and titrated doses of anaesthetics. Inhalational anaesthesia can be a safe alternative and avoid muscle relaxants. Maintain spontaneous, low-tidal volume ventilation during intubation and after initiation of mechanical ventilation.

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Guidelines for Authors

Manuscripts must be prepared in accordance with "Uniform requirements for Manuscripts submitted to Biomedical Journal" developed by international committee of medical Journal Editors

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Standard journal article

[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.

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Article in supplement or special issue

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Corporate (collective) author

[4] American Academy of Periodontology. Sonic and ultrasonic scalers in periodontics. J Periodontol 2000; 71: 1792–801.

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Chapter in book

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Kidd EAM, editors. Dental caries: The disease and its clinical management. Oxford: Blackwell Munksgaard; 2003. pp 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/HSQ20.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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