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INDIAN JOURNAL OF ANESTHESIA AND ANALGESIA

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Editorial

COVID 19: Effect on Clinical Research

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Various factors have imposed tremendous impact on research during COVID 19 epidemic and clinical trials have taken a back foot. Clinical research was always challenging but conducting clinical trials during pandemic is particularly difficult especially when we are dealing with a novel virus. There is very little information about the disease and there is no reliable therapeutic information available. We're learning new things about it every day. There is an urgent desire to try or experiment new treatment regimens with or without their proven benefit. But trying an empirical therapy might not be the best approach. Therapeutic agents must be analyzed carefully in terms oftheir clinical outcomes and risk reward ratio. The current situation necessitates the critical need for therapeutic COVID 19 treatment along with clinical research to establish its safety in various groups like pregnant females, geriatric age group and children. Various ongoing research projects are also presently constrained because of redirection of resources and limitations in terms of in-person visits. So we need to look at the issues that arise during clinical trials in a pandemic. How they are tackled and how various other aspects like patient safety and ethics are dealt with?

We have seen an increased workload during the pandemic in terms of a large number of patients being diagnosed and admitted in hospital or Intensive Care Units (ICU). ICU's are currently running at expanded capacity. Several new ICU's are created to cater to increased patient input. Frontline Health care workers are working under the constant stress of getting exposed to the virus and fears regarding infection transmission to fellow staff, facing issues like fatigue and burnout. Some healthcare workers providing bedside care feel that it is impossible to deliver optimal patient care and do meaningful research simultaneously. The major challenge is maintaining standards of clinical care in current scenario. Developing a vaccine or selecting newer drugs rapidly in mid-outbreak isethically tricky and difficult. On the other hand, there is a concern aboutthe delay in the implementation of effective therapies if we await the results of Randomized Control Trials."We can expect dramatic effects on clinical trials (on going or new) during pandemic because of various factors such as travel limitations, active quarantine of patient and staff members, study closures because of redirection of resources and interruptions in the supply of products required for investigations".[1]

Other challenges include precise recording of the detailed impact of drug on the patient, detailed information about patient outcomes and adverse effects during pandemic. The clinicians are already overwhelmed because of increased number of patients getting infected daily. The patient variables needs to be recorded in an organized and methodicalway such as presence or absence of the virus, viral titres, antigen tests, haematological investigations, oxygen level measurement, requirement of oxygen or non-invasive ventilation/ventilator use etc. Randomisation may not be possible. Also it is ethically not possible to have a placebo group. At present various clinical trials are being conducted to measure therapeutic outcomes. Information about therapeutic benefits can be gained very rapidly owing to large number of patients affected with COVID 19. As a measure to overcome challenges and regional variations, World Health Organization (WHO) launched an international clinical trial called Solidarity, so that various clinical centres from different countries could participate. The main aim was to find an effective treatment for COVID 19. Trial compares options against standard of care, to assess their relative effectiveness. Several regimens: like the antimalarial drug such as Hydroxychloroquine; an antiviral drug example Remdesivir; and anti-HIV drugs, Lopinavir, Ritonavir, with or without the immune-system modulator interferon-beta-1a were part of trial.[2] WHO has cautioned physicians and medical associations against recommending or administering these unproven treatments until there is sufficient evidence?

'US Food and Drug Administration also have given recommendations for conducting clinical trials. The top most priority is participant's safety. It is essential to maintain compliance with good clinical practice, andminimize the anticipated risks that jeopardise trial integrity during the COVID-19 pandemic.'[3] One way to achieve this is by identifying the activities that place study participants at increased risk of COVID-19 due to study specific procedures. Trials should achieve timely recruitment, proper adherence to protocol-specified procedures along with ensuring participant's safety, high retention of participants, and proper statistical analyses to avoid undue loss of statistical power and increased risk of bias due to missing data.[3]

Various factors influence clinical trials. Patient-related issues include compliance with an intense study protocols and limitations of frequent visits to hospital because of lockdown in certain areas or movement restrictions to contain epidemic. Well organised infrastructure and management is required if there is involvement of multiple departments in clinical trial (i.e. need for radiological images and biopsy reports). Rapid administrative response, reorganisation of hospital management, and medical spaces and staff is required to prioritize COVID-19–infected patients. Cooperation and interdependence among various specialities is required to follow protocol procedures. There are increased safety concerns for participants in case they require some protocol-specific procedures for studies without violatingthe study protocol. Since this is a novel virus, more refinement of staff roles and study specific training of investigators may be required in clinical trials.[4]

The need of the hour is to develop new approaches like telehealth, home based testing. Innovating new ideas like courier pickup and delivery of samples. Participants can be followed up telephonically or by email or by requesting them to update data on electronic health portals.

Clinically, daily we are updating information about patient management and prognostic factors to recognize and treat high risk patients early in the course of the disease. Frontline workers are working hard to treat patients, identify certain markers that will help us improve clinical outcomes and educating and spreading knowledge. Hopefully very soon, various therapeutic trials will get completed and we get results about clinically effective therapeutic agents. As investigators and clinicians, there is an innate desire to find a cure that is effective in saving millions of patients and brings this pandemic to an end. We have learnt many lessons from past epidemics and we are utilising our previous knowledge to control COVID 19. Various measures like hand hygiene, social distancing and wearing a mask, temperature screening etc. have helped us slow down the spread of virus. With mutual support and encouragement we can move forward and focus on our goals to make clinical research better. The bright side is that we are evolving and making new innovations to advance our clinical research.

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Comparative Evaluation of Intrathecal Administration of Preservative free Levobupivacaine Alone and with Clonidine in Different Doses in Patients Undergoing Infraumbilical Surgeries

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Abstract

Introduction: This study was done to look for the onset of effect and hemodynamic alterations with levobupivacaine in spinal anesthesia and to compare the effect of clonidine on onset and duration of levobupivacaine when given intrathecally in two different doses. Adverse effects and complications associated with the use of above drugs were also studied.

Material and Methods: 75ASA I-II patients with age group 18-60 years undergoing infraumbilical surgeries were randomized to one of the three groups. Patients in Group 1 (L) received 15 mg (3.0 ml of 0.5%) preservative free levobupivacaine with 0.4 ml normal saline. Patients in group 2 (LC1) received 15 mg (3.0 ml of 0.5%) levobupivacaine with clonidine 30 µg (0.2 ml) and 0.2 ml normal saline. Group 3 (LC2) received 15 mg (3.0 ml of 0.5%) levobupivacaine with clonidine 60 µg (0.4 ml). Onset and duration of sensory and motor block, maximum sensory level achieved, sedation levels, hemodynamic parameters and adverse effects were recorded.

Results: Clonidine significantly shortened the onset of sensory and motor block and prolonged the time to two segment regression and regression of motor block to modified Bromage 0. In addition group LC2 had higher sedation scores. There was higher incidence of hypotension, bradycardia and respiratory depression in group LC2.

Conclusion: Intrathecal Clonidine in a dose of 30 µg significantly prolongs the anesthetic effects of intrathecal levobupivacaine without significant side effects. So, 30 µg is the preferred dose of clonidine over 60 µg, when used as an adjuvant to levobupivacaine in spinal anesthesia.

Keywords: Clonidine; levobupivacaine; Intrathecal; Spinal anesthesia.

Introduction

The most common and safe Anesthesia for infraumbilical surgeries is spinal Anesthesia because of its rapid onset, superior blockade, less failure rates and cost effectiveness.[1,2] Levobupivacaine is an amide local anesthetic that is the *S* (–) isomer of the racemic bupivacaine.[3,4] Levobupivacaine has been recently introduced in clinical practice because of its lower toxic effects as compared to bupivacaine.[5,6] Various adjuvants have been used with the local anesthetics to improve the block characteristics. Intrathecal clonidine produces dose

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dependent analgesia and prolongs the duration of intrathecally administered local anesthetics and has potent antinociceptive properties.[7,8] In the present study clonidine is used in combination with levobupivacaine in spinal Anesthesia.

Material and Methods

The study was conducted in ASA I-II patients with age group 18-60 years undergoing infraumbilical surgical procedures. Informed consent was obtained from the patients and approval was taken from the ethical committee of Indira Gandhi Medical College, Shimla. Exclusion criteria was patient with history of allergy to amide local anesthetics or clonidine, bleeding or coagulation abnormalities, peripheral neuropathy, raised intracranial pressure, demyelinating central nervous disorders, local sepsis, spinal deformities, uncooperative and unwillingness of the patient. Patients were randomly divided into three groups of 25 patients each. After routine premedication and nil per oral protocols patients were taken in the operation theatre and standard monitors were attached. Spinal Anesthesia was given to all the patients in L_3-L_4 interspace with 26 gauge quincke needle. All the patients received 3.4 ml of drug intrathecally. Patients in group 1 (L) received 15 mg (3.0 ml of 0.5%) preservative free levobupivacaine with 0.4 ml normal saline. Patients in group 2 (LC1) received 15 mg (3.0 ml of 0.5%) levobupivacaine with clonidine 30 µg (0.2 ml) and 0.2 ml normal saline. Group 3 (LC2) received 15 mg (3.0 ml of 0.5%) levobupivacaine with clonidine 60 µg (0.4 ml). The onset of sensory block was assessed from the time of injecting drug into subarachnoid space till complete analgesia at the level of T_{10}. Level of sensory block was checked bilaterally by pin prick method with 23- gauge hypodermic blunt needle and dermatomal level was tested every 2 minutes until the highest level was stabilized for four consecutive tests. Maximum level achieved was noted. After that sensory level assessement was done every 10 minutes till there was two segment regression of the block. The onset of motor block was assessed every 2 minutes till complete motor block achieved as per Modified Bromage Scale (1- total motor block, 2- patient can only move his/her feet, 3- patient can move his/her knees, 4- patient can lift his/her leg but cannot hold the position, 5- No hip function, patient can lift and hold his/her leg for 10 seconds, 6- No motor block).

Blood pressure (systolic blood pressure, diastolic blood pressure, mean arterial pressure), heart rate and peripheral oxygen saturation (SpO_2) were measured every 3 minutes for first 30 minutes, then every 5 minutes for next 30 minutes and every 10 minutes for next 1 hour. Vitals of all the patients were monitored for 2 hours after giving spinal Anesthesia. Oxygen was given by a face mask if the pulse oximeter reading decreased below 90%. Duration of sensory block was taken as the time from the onset of the sensory block to the time taken for two segment regression of the block from the maximum sensory block level. The duration of motor block was taken as the time from complete motor block (modified bromage 1) to time when lower limb can be moved freely (modified bromage 6). The degree of sedation was measured with a four point verbal rating scale (1- no sedation, 2-light sedation, 3-somnolence, 4-deep sedation). Hypotension (mean blood pressure recording less than 20% of baseline) if any, was treated with the help of intravenous fluid bolus and incremental doses of vasopressor agent mephentermine 6 mg intravenous. If bradycardia (heart rate less than 50 beats per minute) occured, it was treated with injection atropine 0.6 mg intravenous. Respiratory depression (if RR <8 breath/min or SpO_2 <90%) was treated with oxygen supplementation. Nausea, vomiting, shivering or any other side effects were followed up post operatively for 24 hours and treated upon. Postoperative pain was assessed with the help of visual analogue scale (VAS). For post operative pain (VAS >4) injection tramadol 100 mg i.v. was given as rescue analgesia and then can be repeated four hourly if needed (maximum daily dose 400 mg/day). Analysis of the data between groups was performed using one way analysis of variance test (ANOVA test), student t-test and chi-square test (whichever was applicable). $P<0.05$ was considered statistically significant.

Results

All the three groups were comparable in age, weight and sex distribution (Table 1). The baseline parameters (heart rate, blood pressure, SpO_2) were found to be comparable and the differences were statistically insignificant (p-value >0.05).

The onset of sensory as well as motor block was faster in the group LC1 and LC2 and this difference was found to be statistically significant (p-value 0.01) (Table 2). Maximum level of sensory block achieved was noted in each group. The difference of maximum level of sensory block was highly significant between the groups (p-value <0.05). The difference of the time for two segment regression from highest sensory level was highly significant (p-value 0.00) (Table 2).

The onset of motor block was also faster in group LC2 as compared to LC1 and L and the difference was significant (p-value 0.02) (Table 2). Difference of the mean duration of motor block in group L, LC1 and LC2 was highly significant statistically (p-value 0.00) (Table 2).

100% patients in group L had sedation score 1. 44% patients in group LC1 had sedation score 3. 32% patients in group LC2 developed deep sedation and had sedation score 4. The difference of the sedation scores was highly significant between the groups (p-value 0.00).

None of the patient in any of the three groups experienced nausea, vomiting or shivering. None of the patient in group L and LC1 experienced bradycardia. 24% patients in group LC2 experienced bradycardia. The difference was highly significant (p-value 0.001). 12% patients in group L, 56% patients in group LC1 and 68% patients in group LC2 developed hypotension. The difference was highly significant (p-value 0.00) (Table 3). 8% patients in group LC1 and 52% patients in group LC2 developed respiratory depression and was treated with oxygen supplementation. None of the patients in group L had respiratory depression. p-value was 0.000 which was highly significant (Table 3).

Doses of intravenous mephentermine given for treatment of hypotension was more in group LC2 as compared to L and LC1 (p-valve 0.04). Doses of intravenous atropine given for treatment of bradycardia was also more in group LC2 as compared to L and LC1 with p-valve of 0.01.

Table 1: Demographic Data

Parameter		Group L	Group LC1	Group LC2	p-value
Age (years)	Mean ±S.D.	45.44±13.79	42.20±14.68	49.60±17.56	0.46
Weight(Kg)	Mean ±S.D.	59.64±9.29	62.44±8.13	59.48±7.58	0.24
Sex	Male	21	18	20	0.573
	Female	4	7	5	

Table 2: Anesthetic characteristics of spinal block

Parameter	L	LC1	LC2	p
Onset of sensory block (in minutes)	3.72±0.84	3.64±0.90	2.96±0.97	0.01*
Time to achieve maximum sensory level (in minutes)	10.60±2.16	11.64±1.99	10.48±3.73	0.14
Maximum level of sensory block achieved	T_6 (T_5-T_8)	T_5 (T_4-T_6)	T_4 (T_3- T_6)	0.00**
Time for two segment regression (in minutes)	145.56±11.47	216.04±14.69	229.96±19.09	0.00**
Onset of motor block(minutes)	4.84±1.41	4.68±1.40	3.88±1.71	0.02*
Duration of motor block (minutes)	226.52±29.83	335.88±42.73	422.24±58.86	0.00**
Sedation scores	1	2 (1-3)	3 (2-4).	0.00**

Table 3: Assessment of side effects

Parameter	Group L		Group LC1		Group LC2		P
	Number	%age	Number	%age	Number	%age	
Nausea	0	0	0	0	0	0	NS
Bradycardia	0	0	0	0	6	24	0.001**
Hypotension	3	12	14	56	17	68	0.00**
Shivering	0	0	0	0	0	0	NS
Respiratory depression	0	0	2	8	13	52	0.00**

Discussion

Spinal Anesthesia provides adequate surgical Anesthesia and prolonged post-operative pain relief. It also blunts autonomic, somatic and endocrine responses to surgical stimulus.[1] Levobupivacaine has similar pharmacodynamic properties to racemic bupivacaine but has a documented reduced central nervous system and cardiovascular toxicity.[9,10] In the study conducted by Onur O et al.,[9] in which different doses of intrathecal levobupivacaine (7.5 mg, 10 mg, 12.5 mg and 15 mg) were used they found that 15 mg would be an ideal dose for lower limb orthopaedic surgeries. Since this dose of 15 mg provides an adequate sensory and motor block for lower limb orthopaedic surgical procedures, we selected 15 mg of levobupivacaine. It has also been found that 3 ml of 0.5% plain levobupivacaine (15 mg) has a density of 1.00419 at 37°C, (that is the body temperature) and behaves like an isobaric drug even at this temperature.[11] Hence it may be an ideal drug for lower limb orthopaedic surgeries and being an isobaric drug, it can produce a longer duration of sensory block.[12,13]

Levobupivacaine has been introduced recently in India in 2012 and is available as 0.5% isobaric 4 ml ampoules for intrathecal use. Not many studies have been done regarding its intrathecal route of administration in India. A study was required to know its efficiency for spinal Anesthesia. It is known that a single injection of levobupivacaine will not produce a prolonged duration of post-operative analgesia. Hence addition of a drug which can prolong the analgesic effect of levobupivacaine will be required.[14] Various adjuvants like opioids, benzodiazepines, neostigmine and alpha-2 agonists have been used to prolong the duration of spinal analgesia. Each of these adjuvants has their own side effects like opioids producing respiratory depression, nausea, vomiting, and pruritus[15] etc; neostigmine producing hypertension and tachycardia[16]; benzodiazepines like midazolam producing excessive sedation.[17] Clonidine is a partial alpha-2 agonist which is used as an analgesic supplement through epidural and intrathecal routes along with local anesthetics.[18,19] It is known to increase both sensory and motor block of local anesthetics.[20] The analgesic effect following its intrathecal administration is mediated spinally through activation of post synaptic alpha-2 receptors in the substantia gelatinosa of spinal cord.[20,21] The rationale behind intrathecal administration of clonidine is to achieve a high drug concentration in the vicinity of alpha-2 adrenoreceptors in the spinal cord and it works by blocking the conduction of C and A delta fibres, increases potassium conductance in isolated neurons in vitro and intensifies conduction block of local anesthetics.[22,23] When Clonidine is combined with bupivacaine for spinal Anesthesia, it has been found to prolong post operative analgesia.[24] Clonidine in the dose of 1 µg/kg body weight along with bupivacaine has been found to prolong the post operative analgesia but has produced significant perioperative hypotension and bradycardia.[25] Various studies have used smaller doses of intrathecal clonidine with bupivacaine and have obtained varying results. There are many conflicting reports regarding the smaller doses of intrathecal clonidine (15 µg – 45 µg) as supplement to local anesthetic agents. It has been found to produce prolongation of post operative analgesia with minimal cardiovascular complications.[26,27]

Not many studies have used clonidine along with the local anesthetic levobupivacaine in spinal Anesthesia for infraumbilical surgeries. Hence a study was undertaken to find out the effectiveness of isobaric 0.5% levobupivacaine in subarachnoid block in infraumbilical surgeries and also to find out the effect of different doses of clonidine as an adjuvant to levobupivacaine.

Conclusion

Clonidine shortens the time of onset and prolongs the duration of sensory and motor block. 30 µg clonidine is an attractive alternative as an adjuvant to spinal levobupivacaine in surgical procedures especially in those that need quite long time with minimal side effects and excellent quality of spinal analgesia.

Conflicts of interest: There are no conflicts of interest.

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Comparison of Intravenous Lignocaine and Dexmedetomidine for Attenuation of Hemodynamic Stress Response to Laryngoscopy and Endotracheal Intubation

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Abstract

Objectives: To compare the safety and efficacy of lignocaine versus dexmedetomidine in attenuation of cardiovascular response to laryngoscopy. *Study design*: Randomized controlled trial. Sixtypatients of ASA I & II category posted for elective surgery under general Anesthesia were enrolled in the study. Patients were randomly divided into two Groups: Group L(Lignocaine) and Group D (Dexmedetomidine) with 30 patients in each group.

Materials and Methods: Group L received 1.5 mg/kg of lignocaine intravenous (IV) and Group D received 1 mcg/kg of dexmedetomidine as IV infusion. Thiopentone was given until eyelash reflex was lost, and intubation was facilitated with succinylcholine. Anesthesia was maintained with 33:66 oxygen, nitrous oxide, and titrated doses of inhalation agents and vecuronium was given. Hemodynamic parameters were recorded as baseline vitals, at preinduction, after induction, during intubation, 1 min, 3 mins, 5 mins, and 10 mins after intubation.

SPSS version 16 was used for analysis.

Results: All the demographic variables were well matched between groups. There was a statistically significant difference ($p < 0.001$) between dexmedetomidine and lignocaine in parameters like heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure at all time intervals after tracheal intubation, with dexmedetomidine being the most effective. Sedation scores were more with dexmedetomidine.No adverse effects were noticed in patients of both groups.

Conclusion: Dexmedetomidine attenuates the hemodynamic stress response to laryngoscopy and intubation more effectively when compared with lignocaine 1.5 mg/kg IV, without any adverse effects.

Keywords: Lignocaine, Dexmedetomidine, Laryngoscopy, Intubation, Hemodynamic stress response.

Introduction

The introduction of general anesthetics into clinical practice lead to the development of modern surgery and spawned the speciality of anesthesiology. Airway management and patient safety is the most important aspect of patient management in general Anesthesia. Endotracheal intubation protects airway, delivers anesthetic gases and protects against aspiration.[1,2] During intubation, stimulation of laryngeal and tracheal tissues causes catecholamine discharge which results in a increase in heart rate and systemic arterial pressure.[3,4] Control of heart rate and blood pressure response

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to intubation is essential in preventing the adverse cardiovascular events, because rate pressure product acts as an indicator of oxygen demand by the heart.[5] There are a wide array of drugs such as opioids, beta blockers, calcium channel blockers, nitroglycerine, alpha agonist, lidocaine which blunts this response.[6-13] Dexmedetomidine is a highly selective centrally acting α_2 agonist, more selective and potent than clonidine ($\alpha_2 : \alpha_1$, 1620:1 for dexmedetomidine, 220:1 for clonidine) Lidocaine is one of the cheapest and easily available drug for attenuation of hemodynamic response.[14,15] On this background, we compared the safety and efficacy of lignocaine versus dexmedetomidine in attenuating the cardiovascular response to laryngoscopy and intubation.

Materials and Methods

It was a randomised controlled study, conducted after approval from institution ethical committee and obtaining valid written informed consent from the patients. Sixty patients, aged 18-60 years, weighing between 40 and 75 kg, belonging to ASA grade I and II undergoing elective surgeries under general Anesthesia were subjected in the study. Patient's refusal, known allergic to study drug and with comorbidities like hypertension, cardiac, renal, cerebral, hepatic, cerebral disease, obese patients, anticipated difficult airway, and in whom intubation attempts lasted longer than 15 second were excluded.

Patients were randomised using a computer generated randomization and divided into Groups L (Lignocaine) and group D (Dexmedetomidine) with 30 patients in each group. All patients received preoperative night sedation with T. Alprazolam 0.5 mg P.O and T. Ranitidine 150 mg P.O at bed time on the previous night. After shifting the patient to operating table, baseline parameters such as heart rate, blood pressure, SpO_2, respiratory rate were recorded.

Group L received 100 ml of normal saline over a period of 10 mins and completed 10 mins before induction and 1.5 mg/kg of lignocaine was administered IV 3 min before intubation. Group D received dexmedetomidine 1 mcg/kg diluted in 100 ml of normal saline IV over a period of 10 min, and completed 10 mins before induction.

All patients were premedicated with Inj. Glycopyrolate 10 mcg/kg intramuscularly, 20 mins before induction, Inj. Midazolam 0.04 mg/kg and Inj.Fentanyl 2 µg/kg intravenously 5 minutes before induction. Patients were preoxygenated with 100% oxygen for 3 minutes. Level of sedation was assessed using Ramsay sedation score before induction of Anesthesia in both the groups. All patients were induced with Inj.Thiopentone 2.5% solution intravenously till loss of eyelash reflex occurred. Endotracheal intubation was facilitated with Succinylcholine 2 mg/kg given IV 1 min prior to laryngoscopy and intubation. Laryngoscopy was performed using Macintosh laryngoscope, trachea intubated with appropriate size endotracheal tube, confirmed with bilateral equal air entry and tube was fixed and secured. Anesthesia was maintained with Oxygen and Nitrous oxide in the ratio of 33:66, with titrated doses of volatile anesthetics and inj. vecuronium. At the end of surgery, all anesthetic agents were stopped 100% oxygen was given, reversed with inj.neostigmine 50 mcg/kg and inj.glycopyrrolate 8 mcg/kg and extubated after adequate neuromuscular efforts.

Hemodynamic parameters were recorded at baseline, preinduction, after induction, during intubation, 1 min, 3 mins, 5 mins, and 10 mins after intubation.

At the end of study, the data were compiled and subjected to statistical analysis using students paired "t" test and Fisher's exact test. SPSS version 16 was used for analysis. A statistical value of ($p < 0.001$) was considered significant.

Results

Both the groups were comparable with respect to demographic variables (Age, Height, Weight)

Table 1: Patient demographics

	Dexmedetomidine		Lignocaine		p value
	Mean	SD	Mean	SD	
Age	31.03	12.53	32.20	11.90	0.713
Weight	55.60	7.73	54.40	8.50	0.591
Height	159.93	5.70877	159.23	5.82549	0.672

Table 2: Gender

Gender	Group				p value
	Dexmedetomidine		Lignocaine		
Male	14	46.70	15	50.00	0.999
Female	16	53.30	15	50.00	
Total	30	100.00	30	100.00	

Table 3: Mallampatti Grading

MPG	Group				p value
	Dexmedetomidine		Lignocaine		
I	18	60.00	16	53.30	0.999
II	12	40.00	14	46.70	
Total	30	100.00	30	100.00	

Table 4: ASA Grading

ASA	Group				p value
	Dexmedetomidine		Lignocaine		
I	20	66.70	14	46.70	0.192
II	10	33.30	16	53.30	
Total	30	100.00	30	100.00	

Table 5: Duration of Laryngoscopy(seconds)

Dexmedetomidine		Lignocaine		p value
Mean	SD	Mean	SD	
13.90	0.90	14.30	0.80	0.109

Table 6: Induction Dose of Thiopentone (milligram)

Dexmedetomidine		Lignocaine		p value
Mean	SD	Mean	SD	
199.1	24.1	253.1	19.2	<0.0001

Table 7: Comparison of Side Effects

Side Effect	Group B	Group R
Nausea/Vomiting/Bradycardia/ Hypotension/Apnea	Nil	Nil

Hemodynamics

On comparing, the changes in heart rate between Group L and Group D is statistically significant at the time of induction and until 10 minutes after intubation (p <0.001) (Fig. 1).

The changes in systolic pressurein both the groups is statistically significant at the time of induction and until 10 minutes after intubation (p <0.001) (Fig. 2).

The difference in mean diastolic blood pressure between both the groups is statistically significant at the time of intubation and 1 minute, 3 minutes post intubation (Fig. 3).

The difference in mean arterial blood pressure between both the groups is statistically significant at intubation, 1 min, 3 min p <0.001), 5 min (p <0.001) and 10 min p <0.001) post intubation (Fig. 4).

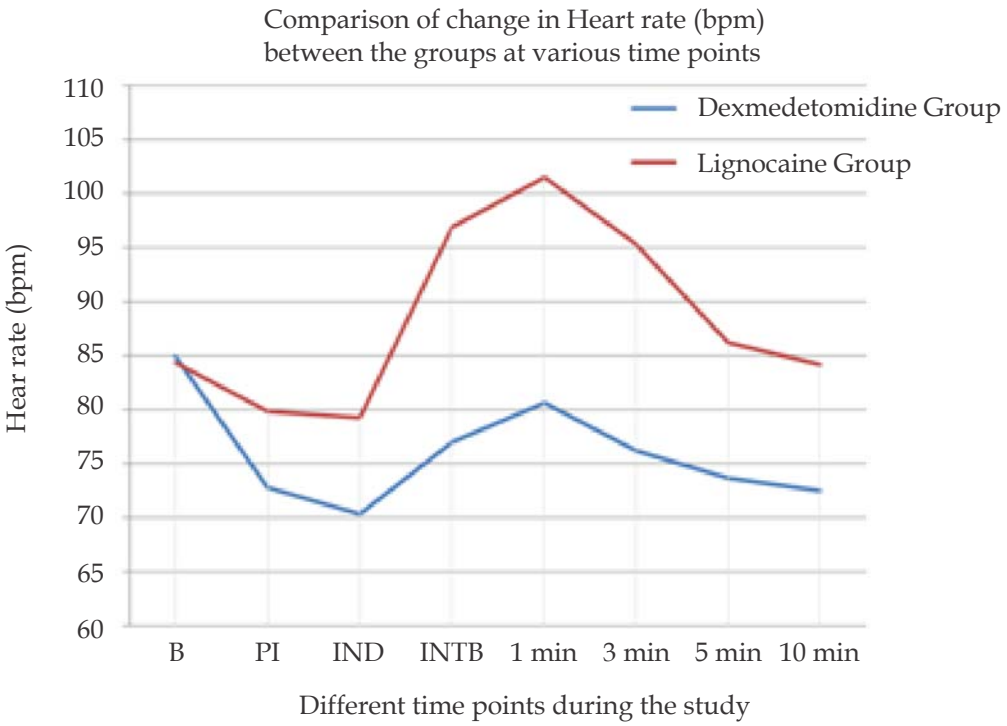

Fig. 1: Comparison of Heart rate in both groups.

B= Baseline; PI= Pre-induction; IND= Induction; INTB= During intubation; 1 min, 3 min, 5 min & 10 min represents readings after 1, 3, 5 and 10 minutes of intubation.

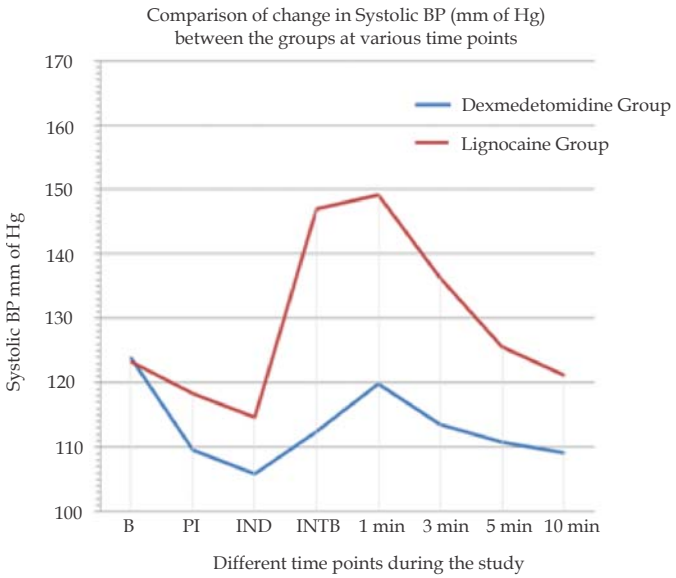

Fig. 2: Comparison of Systolic blood pressure in both groups.

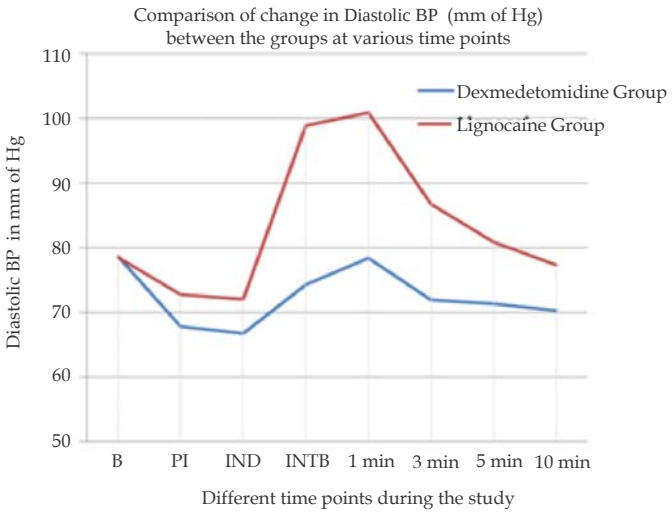

Fig. 3: Comparison of Diastolic blood pressure in both groups.

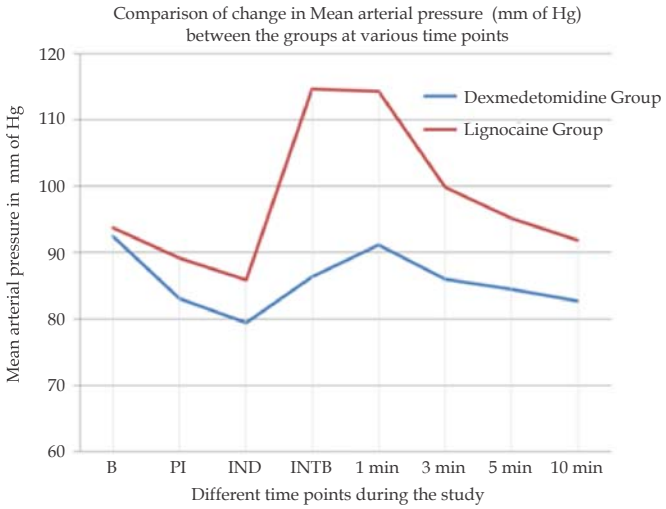

Fig. 4: Comparison of Mean arterial pressure in both groups.

Discussion

Hemodynamic response to laryngoscopy and endotracheal intubation was described by Reid and Brace in 1940.[16] The series of physiological changes following laryngoscopy and intubation occurs as a result of release of catecholamines and considered as the most critical event during general Anesthesia.[17] The response is transient occurring 30 seconds after intubation, peaks at 1 minute and lasting for less than 10 minutes. Usually these changes are transient and well coped by healthy individuals, but can be detrimental in cardiac and cerebrovascular patients.[5] This pressor response may predispose to development of pulmonary edema, acute ventricular failure, dysrrhythmias, intraoperative MI and cerebrovascular accident.[18,19] Various studies had been conducted to find an effective method to attenuate this pressor response. In our study, we had done comparative analysis between lignocaine and dexmedetomidine which drug attenuated the stress response better.

In our study, lignocaine 1.5 mg/kg IV given 3 min before intubation. Various studies[20-22] concluded that this dose is sufficient to debilitate the pressor response to intubation.

Dexmedetomidine used in our study was 1 mcg/kg diluted in 100 ml NS given over 10 min Various studies[23-25] proved that 0.5-1 mcg/kg of dexmedetomidine was sufficient to attenuate the hemodynamic response.

All patients in Group L had sedation score 2 and most of the patients in Group D had score of 3. Many authors[26,27] have reported that dexmedetomidine infusion produces sedation which are arousable to oral commands are in accordance with our study.

Scheinin et al.[28], L. keniya et al.[29], concluded that dexmedetomidine infusion given IV preinduction decreased the dose of thiopentone for induction of Anesthesia which was similar to our study.

Following infusion of dexmedetomidine, there was 14.25% reduction heart rate compared to Group L 5.33% and 16% reduction of mean arterial pressure in Group D compared to 4.9% in Group L which was statistically significant. Sukhminderjit Singh Bajwa et al.[30], Ozkose et al.[31], Aho et al.[32], Ferdi Menda et al.[33] concluded from their studies that dexmedetomidine (1 mcg/kg) attenuates the hemodynamic response significantly as of our study.

Miller CD et al., Wilson IG et al. reported that lignocaine fails to attenuate hemodynamic response significantly and our results are in accordance them.

None of the patients in our study developed hypotension, bradycardia, apnea.

Conclusion

From the present study, we conclude that dexmedetomidine 1 mcg/kg IV as infusion for 10 minutes attenuates the hemodynamic stress responseto laryngoscopy and intubation more effectively when compared with lignocaine 1.5 mg/kg IV, without any adverse effects.

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Comparison of Hemodynamic Response in Direct and Video Laryngoscopy in Hypertensive Patients

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Abstract

Introduction: Direct laryngoscopy & endotracheal intubation induces cardiovascular stress response which in turn causes tachycardia & hypertension. This is particularly harmful in hypertensive patients. In this study we compared the hemodynamic response in direct & video laryngoscopy in hypertensive patients.

Materials and Methods: In this study 98 controlled hypertensive patients ASA physical status 1 & 2 scheduled for elective surgery under general anesthesia requiring endotracheal intubation. Patients were divided in to 2 groups with 49 patients in each group. Group A: underwent endotracheal intubation with direct laryngoscopy. Group B: video laryngoscopy was used for the patients in this group. Both groups were assessed for Hemodynamic responses during laryngoscopy & intubation.

Statistical analysis: This was done using mean, standard deviation, ANOVA for repeated measures followed by Bonferroni test and 't' test.

Result: Video laryngoscopy showed less variations in hemodynamic responses compared to direct laryngoscopy, whereas time taken for video laryngoscopy was longer than that for direct laryngoscopy.

Conclusion: Video laryngoscopy is better than direct laryngoscopy to reduce stress responses during endotracheal intubation.

Keywords: Direct laryngoscopy; Video laryngoscopy; Hemodynamic response; Hypertension

Introduction

Endotracheal intubation is an integral part of anesthetic management and critical care of patient & has been practiced following its description by Rawbo them and Magil in 1921. Reild and Brace first described hemodynamic response to laryngoscopy and tracheal intubation. Adverse responses in the cardiovascular, respiratory and other physiological systems can be provoked due to noxious stimuli produced by laryngoscopy and intubation. This response can be transient, variable, unpredictable. Tachycardia and hypertension can result in myocardial ischemia and is undesirable and hence should be avoided.[1] The magnitude of hemodynamic response increases with the force and duration of laryngoscopy[1] and can be worsened by prolonged intubation time.[4,6] It begins 30 seconds after laryngoscopy and intubation and lasts for less than 10 minutes. Tracheal intubation approaches that minimize oro-pharyngo-laryngeal stimulation will attenuate this response. These changes may be well tolerated in healthy individuals. But in

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patients with hypertension, arrhythmias, coronary artery disease, it may prove fatal.

Recommendations for attenuating these responses are manifold and the techniques used should minimize these responses to the patients that are at risk.

The hemodynamic responses during laryngoscopy and endotracheal intubation may vary by premedication, social habits, preoperative medications, narcotic, and neuromuscular blocker doses and speed of anesthetic agent administration.[5]

Several drugs have been used to blunt these responses.[8,9] Certain drugs like Lidocaine, Esmolol, Fentanyl, Clonidine etc have been used to prevent pressor responses.[5]

Newer airway devices also play a major role is reducing pressor response to laryngoscopy and intubation. Video laryngoscopes provide better laryngeal view[7] as they do not require alignment of the oral, pharyngeal and laryngeal axis for visualization of glottis and tracheal intubation and cause minimal oropharyngolaryngeal stimulation and hence potentially attenuate the pressor response.

Recent publications have reported the superiority of video-laryngoscopy over direct laryngoscopy with respect to obtaining the glottic view, less associated local airway trauma, and maintaining oxygen desaturation when used for intubation of obese patients.[10–3] However, other studies report an increased intubation time and higher intubation failure rates with video laryngoscopy when compared to direct laryngoscopy.[16,17]

Materials and Methods

Following approval of institutional ethics committee and obtaining Informed and written consent, the study was conducted by department of anesthesiology, Father Muller Medical college and hospital, Mangalore. 98 patients of the age group above 18 yrs belonging to American association of anesthesiologist (ASA) class 1 and 2 posted for elective cases under e anesthesia were taken up for the study.

Patients unwilling or with Patients with blood pressure of >140/80, BMI >30kg/m^2, craniofacial abnormalities, chronic kidney disease, diabetes mellitus, ischemic heart disease, thyroid abnormalities were excluded from the study.

Thorough pre-anesthetic evaluation, routine investigations carried out and the patient was informed regarding the nature and purpose of the study.

The ease of intubation will be assessed based on the intubation difficulty scale

Parameter	Score
Number of attempts >1	N_1
Number of operators >1	N_2
Number of alternative techniques	N_3
Cormack-Lehane (CL) Grade 1	N_4
Lifting force required	
Normal	$N_5 = 0$
Increased	$N_5 = 1$
Laryngeal pressure	
Not applied	$N_6 = 0$
Applied	$N_6 = 1$
Vocal cord mobility	
Abduction	$N_7 = 0$
Abduction	$N_7 = 1$
Total IDS = Sum of scores	$N_1 = N_7$

Intubation difficulty scale (IDS) score (22)

Patient was explained about the NPO guidelines. Premedicated with Tab. Diazepam 5 mg and Tab. Pantoprazole 40 mg orally the night and asked to continue their antihypertensive medications at 6:00 am orally with sips of water on the day of the surgery.

On arrival to the operating room, all essential monitors connected and baseline heart rate, blood pressure, mean arterial blood pressure, oxygen saturation recorded. Large bore IV cannula (18G) secured and started on IV ringer lactate.

General anesthesia technique is standardized to all patients. Patients were divided into 2 groups: Group A and B. All patients were premedicated with Inj glycopyrrolate 0.2 mg/kg and Inj fentanyl 2 mcg/kg. Pre-oxygenated for 3-5 minutes, induced with Inj Propofol 2 mg/kg and paralyzed with Inj succinylcholine 2 mg/kg.

Group A intubated with Macintosh laryngoscope and Group B using video laryngoscope and with appropriate size cuffed oral endotracheal tube. After confirmation of tube position, cuff inflated, tube fixed and connected to ventilator. Anesthesia will be maintained with 33% oxygen, 66% nitrous oxide and isoflurane 0.6% on controlled ventilation. Vecuronium bromide will be used as maintenance with 0.1 mg/kg and top-ups 0.02 mg/kg.

Following parameters will be recorded before and after intubation

1. Heart rate
2. Mean arterial blood pressure
3. Oxygen saturation
4. End tidal carbon di-oxide

5. Laryngoscopic view/ease
6. Time taken for intubation

Result

Fig. 1 shows comparison of the Age between the two groups which shows that Age is higher in Direct laryngoscopy group with a t value of 0.494 and is statistically non significant with a p value of 0.623.

Table 2: Comparison of the Mean BP After intubation between the two groups shows that Mean BP After is higher in Direct laryngoscopy group with a t value of 7.26 and is statistically significant with a p value of <0.001.

Fig. 2 Comparison of the Mean BP after and before intubation and difference between the two groups shows that Mean BP after-before difference is higher in Direct laryngoscopy group with a t value of 25.965 and is statistically significant with a p value of <0.001.

Table 2: Comparison of the HR After intubation between the two groups shows that HR After is higher in Direct laryngoscopy group with a t value of 7.109 and is statistically significant with a p value of <0.001.

Fig. 3 Comparison of the HR after-before difference between the two groups shows that HR after-before difference is higher in Direct laryngoscopy group with a t value of 20.588 and is statistically significant with a p value of <0.001.

Comparison of the $EtCO_2$ After between the two groups shows that $EtCO_2$ After is higher in Direct laryngoscopy group with a t value of 6.997 and is statistically significant with a p value of <0.001.

Fig. 4 Comparison of the $EtCO_2$ after-before difference between the two groups shows that $EtCO_2$ after-before difference is higher in Video laryngoscopy group with a t value of -4.373 and is statistically significant with a p value of <0.001.

Table 2: Comparison of the Time taken between the two groups shows that Time taken is higher in Video laryngoscopy group with a t value of -6.133 and is statistically significant with a p value of <0.001.

Table 1:

	Group	N	Mean	Std. Deviation	t	df	P Value
Age	Direct laryngoscopy	49	49.140	8.629	0.494	96	0.623
	Video laryngoscopy	49	48.220	9.758			
Mean BP Before	Direct laryngoscopy	49	97.060	10.327	-9.617	96	<0.001
	Video laryngoscopy	49	115.040	8.039			
Mean BP After	Direct laryngoscopy	49	108.470	10.454	7.26	96	<0.001
	Video laryngoscopy	49	92.800	10.912			
Mean BP after - before difference	Direct laryngoscopy	49	11.410	5.184	25.97	96	<0.001
	Video laryngoscopy	49	-22.240	7.446			
HR Before	Direct laryngoscopy	49	76.350	6.437	-3.011	86.993	0.003
	Video laryngoscopy	49	81.100	8.987			
HR After	Direct laryngoscopy	49	85.940	7.625	7.109	96	<0.001
	Video laryngoscopy	49	74.960	7.665			
HR after -before difference	Direct laryngoscopy	49	9.590	4.378	20.59	96	<0.001
	Video laryngoscopy	49	-6.140	3.075			
$EtCO_2$ Before	Direct laryngoscopy	49	27.760	4.544	10.39	85.373	<0.001
	Video laryngoscopy	49	19.550	3.143			
$EtCO_2$ After	Direct laryngoscopy	49	32.160	4.165	6.997	96	<0.001
	Video laryngoscopy	49	26.690	3.548			
$EtCO_2$ after-before difference	Direct laryngoscopy	49	4.410	2.992	-4.373	95.591	<0.001
	Video laryngoscopy	49	7.140	3.195			
Time taken	Direct laryngoscopy	49	15.940	2.933	-6.133	96	<0.001
	Video laryngoscopy	49	19.960	3.529			

Table 2: Another pattern of the table

	Direct laryngoscopy(n=49) Mean ± sd	Video laryngoscopy(n=49) Mean ± sd	t	P Value
Age	49.14±8.63	48.22±9.76	0.494	0.623
Mean BP Before	97.06±10.33	115.04±8.04	-9.617	<0.001
Mean BP After	108.47±10.45	92.8±10.91	7.26	<0.001
Mean BP after - before difference	11.41±5.18	-22.24±7.45	25.965	<0.001
HR Before	76.35±6.44	81.1±8.99	-3.011	0.003
HR After	85.94±7.63	74.96±7.67	7.109	<0.001
HR after -before difference	9.59±4.38	-6.14±3.08	20.588	<0.001
$EtCO_2$ Before	27.76±4.54	19.55±3.14	10.394	<0.001
$EtCO_2$ After	32.16±4.17	26.69±3.55	6.997	<0.001
$EtCO_2$ after-before difference	4.41±2.99	7.14±3.2	-4.373	<0.001
Time taken	15.94±2.93	19.96±3.53	-6.133	<0.001

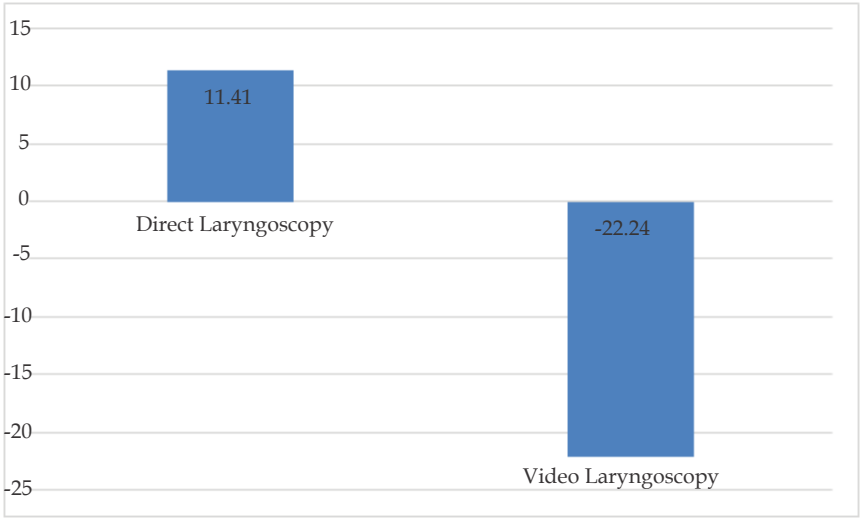


Fig. 1: Mean BP after-before difference

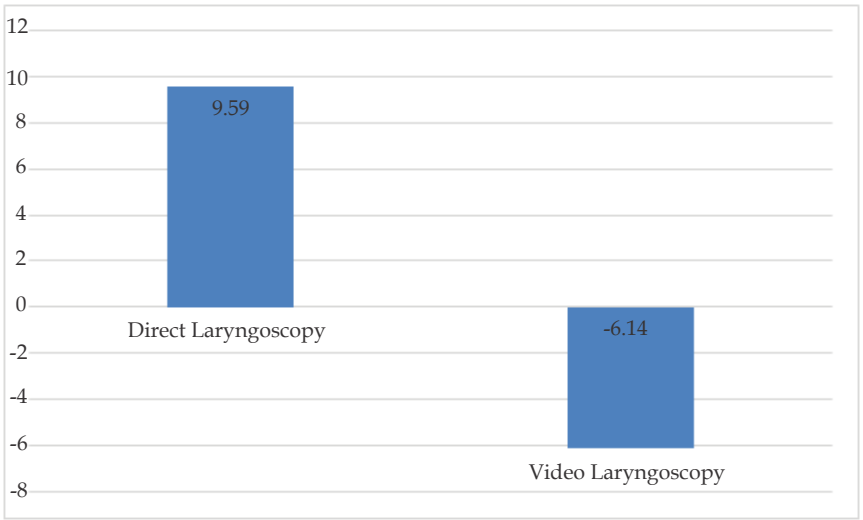


Fig. 2: HR after-before difference

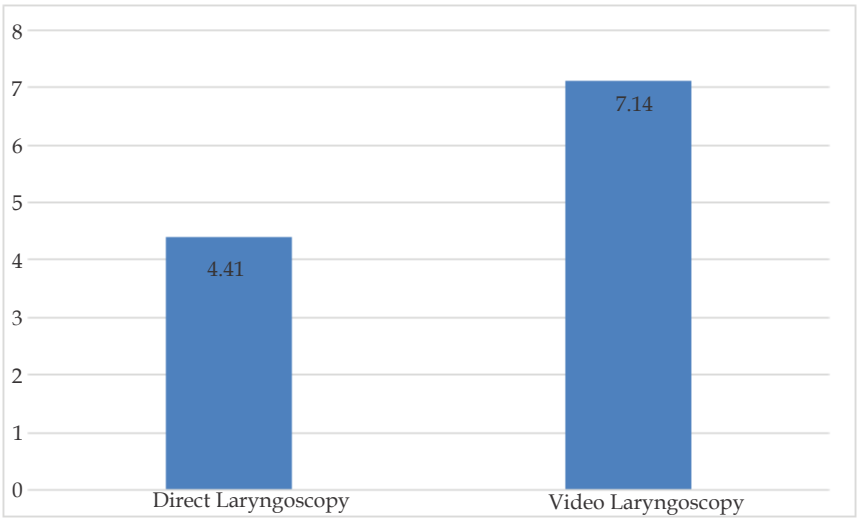


Fig. 3: $EtCO_2$ after-before difference

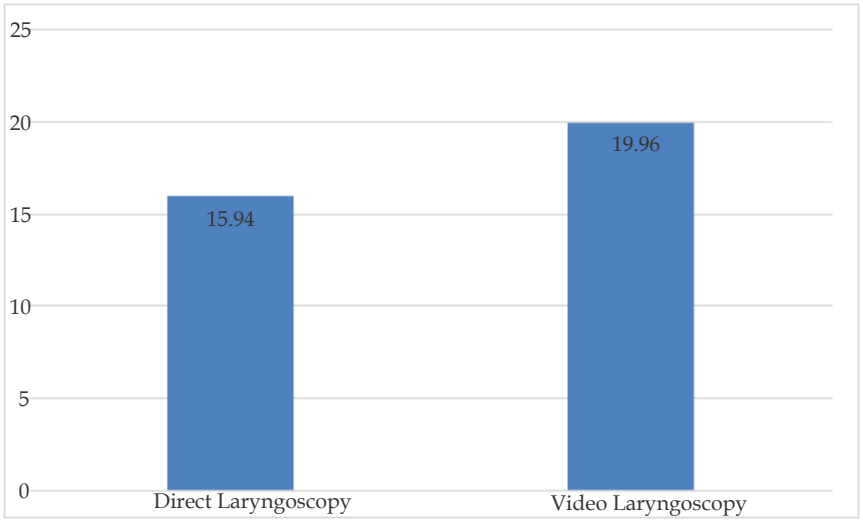


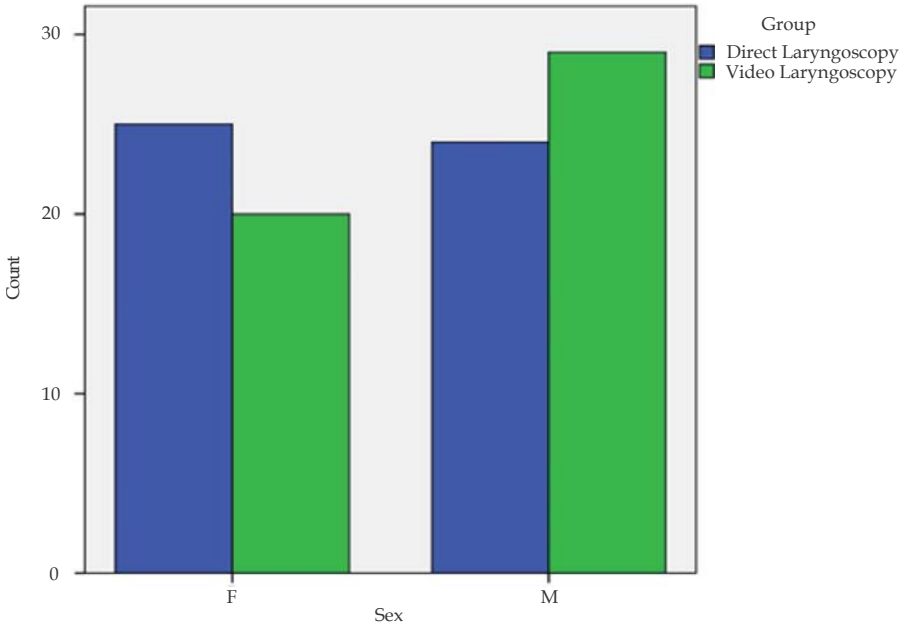
Fig. 4: Time taken for intubation

Chi square test for comparison of the categorical variables

Sex * Group

Crosstab					
			Group		Total
			Direct laryngoscopy	Video laryngoscopy	
Sex	F	Count	25	20	45
		% within Group	51.0%	40.8%	45.9%
	M	Count	24	29	53
		% within Group	49.0%	59.2%	54.1%
Total		Count	49	49	98
		% within Group	100.0%	100.0%	100.0%

Chi-Square Tests			
	Value	df	P value (<0.05 is significant)
Pearson Chi-Square	1.027	1	.311



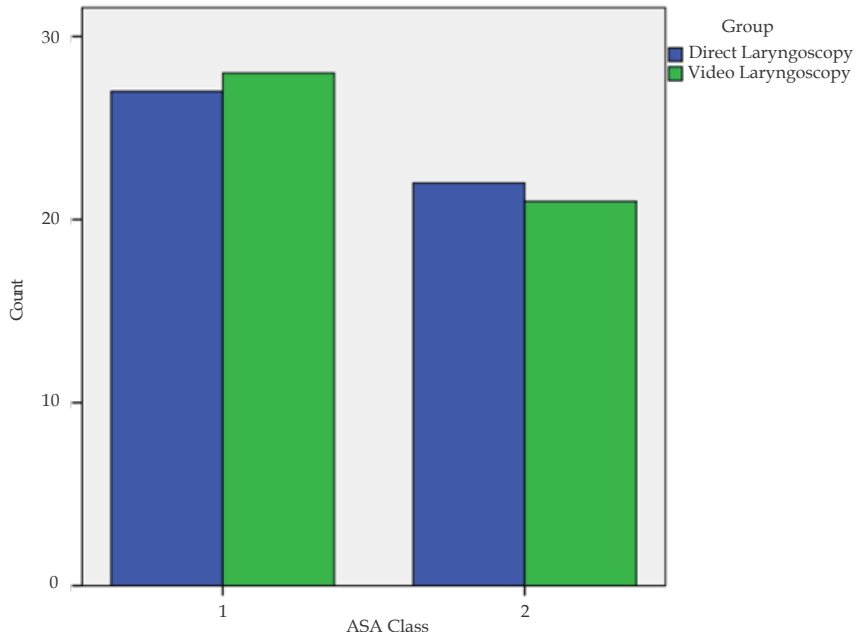
ASA class:

Crosstab

			Group		Total
			Direct laryngoscopy	Video laryngoscopy	
ASA Class	1	Count	27	28	55
		% within Group	55.1%	57.1%	56.1%
	2	Count	22	21	43
		% within Group	44.9%	42.9%	43.9%
Total		Count	49	49	98
		% within Group	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	P value (<0.05 is significant)
Pearson Chi-Square	.041	1	.839



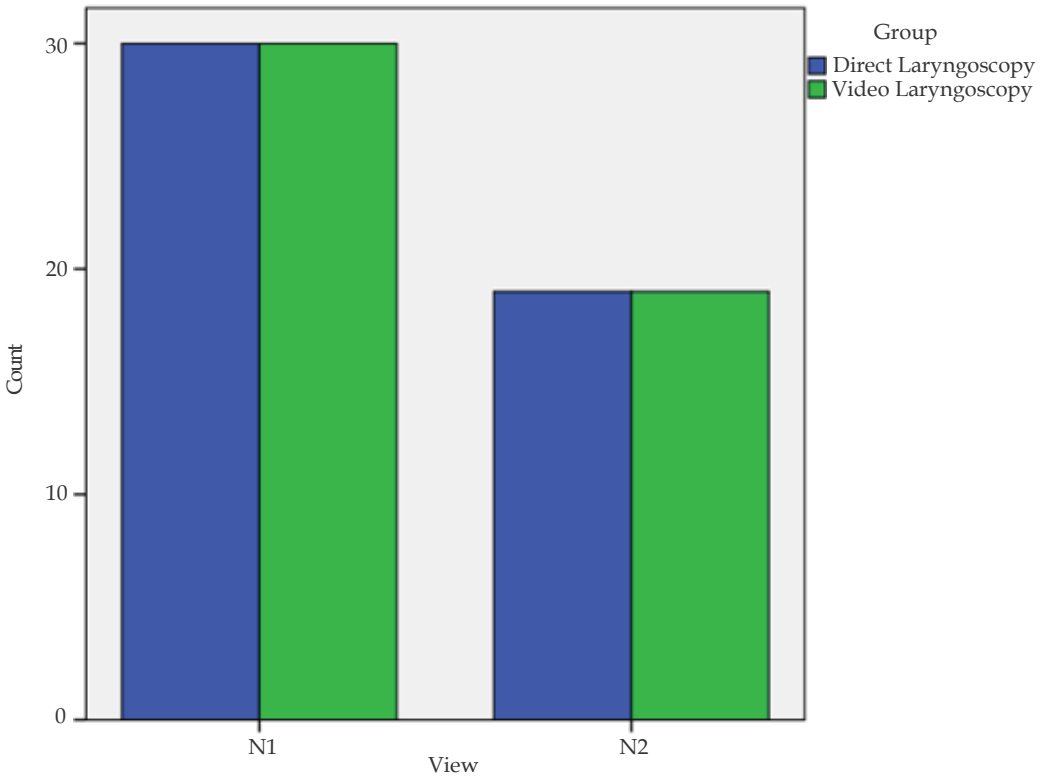
Laryngoscopic view:

Crosstab

			Group		Total
			Direct laryngoscopy	Video laryngoscopy	
View	N1	Count	30	30	60
		% within Group	61.2%	61.2%	61.2%
	N2	Count	19	19	38
		% within Group	38.8%	38.8%	38.8%
Total		Count	49	49	98
		% within Group	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	P value (<0.05 is significant)
Pearson Chi-Square	<0.001	1	1.000



Sum of ASA class and Laryngoscopic view

			Group					
			Direct laryngoscopy		Video laryngoscopy			
		N	Count	Column N %	Count	Column N %	Chi square	P value
Sex	F	45	25	51.00%	20	40.80%	1.027	0.311
	M	53	24	49.00%	29	59.20%		
ASA Class	1	55	27	55.10%	28	57.10%	0.041	0.839
	2	43	22	44.90%	21	42.90%		
View	N1	60	30	61.20%	30	61.20%	0	1
	N2	38	19	38.80%	19	38.80%		

On comparison of Direct laryngoscopy and Video laryngoscopy groups in relation to the parameter Sex, there are 45F and 53M numbers each category. The number of F is higher in Direct laryngoscopy group with a percentage of 51. The number of M category is higher in Video laryngoscopy group with a percentage of 59.2. This comparison is statistically not significant with a p value of 0.311.

On comparison of Direct laryngoscopy and Video laryngoscopy groups in relation to the parameter ASA Class, there are 55 1 and 43 2 numbers each category. The number of 1 is higher in Video laryngoscopy group with a percentage of 55.1. The number of 2 category is higher in Direct laryngoscopy group with a percentage of 44.9. This comparison is statistically not significant with a p value of 0.839.

Discussion

Laryngoscopy & endotracheal intubation results in sympathetic stimulation that leads to hypertension & tachycardia.[1] Heart rate is an important determinant of myocardial oxygen demand & tachycardia is a risk factor for development of perioperative myocardial ischemia & infarction.[2] Hypertension increases the peri-operative cardiac risk. Hence the need to attenuate sympathetic response to laryngoscopy & endotracheal intubation is important.[14,15] Direct laryngoscopy involves stretching the oropharyngeal tissues in an attempt to straighten the angle between the mouth & glottis opening & this stretch triggers a stress response.[5] As tracheal intubation is unavoidable for surgical procedures, sympathetic stimulation is reduced by minimizing the stretching of tissues in the laryngo-pharynx.

Various anesthetic agents, adjuvants & analgesics have been used to blunt the level of stimulation & stress response to the manipulation & stimulation of airway during laryngoscopy & intubation. Fentanyl, beta adrenergic receptor blockers, lignocaine have been used.[5,8,9]

Newer airway devices have also been used to facilitate either laryngoscopy & intubation to avoid major sympathetic stimulation or to aid difficult intubation. Video laryngoscope, McCoy laryngoscope are a few newer devices us for laryngoscopy to reduce the stress response. The upward lifting force required to expose the glottis during laryngoscopy is much less during video laryngoscopy when compared to a direct laryngoscopy & that results in less traction applied to soft tissues. Therefore it might be associated with less sympathetic stimulation.

It is usually recommended that elective surgery should be postponed in cases of severe hypertension (diastolic BP >115 mmHg, systolic BP >200 mmHg) until BP is less than 150/90 mmHg. It is seen that peri-operative hemodynamic fluctuations occur less frequently in treated hypertensive patients than in untreated hypertensive patients & hemodynamic fluctuations increase morbidity. It has been suggested that rapid correction of BP or prevention of increase in HR may be all that is required.

This study compared the hemodynamic responses during video laryngoscopy & direct laryngoscopy. All intubations were done by a single anesthesiologist experienced in both devices. This would eliminate any possible bias regarding device application. The study revealed that hemodynamic changes – (mean arterial blood pressure, heart rate) are less significant during tracheal intubation with video laryngoscopy than direct laryngoscopy. However, the time taken is higher in video laryngoscopy with a significant p value of <0.001. However, there is little evidence of association between a preoperative BP less than 140/90 mmHg & peri-operative cardiac risk. Our results demonstrated better hemodynamic stability following oral endotracheal intubation using video laryngoscopy than during direct laryngoscopy.

We conclude that endotracheal intubation is associated with less significant hemodynamic changes with video laryngoscopy than in direct laryngoscopy.

Studies done by Ali Reza Pournajafian, Mohammed Reza Ghodraty, Seyed Hamid Reza Faiz on Comparison Glidescope video laryngoscope & Macintosh laryngoscope regarding hemodynamic responses during orotracheal intubation showed no changes in heart rate but significant changes were seen with blood pressure & mean arterial pressure.

As per a study done by R.L.J.G. Massen, B.M.A. Pieters, B. Maathuis on Endotracheal intubation using Videolaryngoscopy causes less cardiovascular response compared to classic direct laryngoscopy in cardiac patient showed changes in heart rate & blood pressure.

Conclusion

According to the study we conducted, we conclude that video laryngoscopy is better than direct laryngoscopy.

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Original Research Article

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A Comparative Evaluation of the Characteristics of Recovery from Anesthesia with Isoflurane and Halothane in Day-Care Surgery

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Abstract

Background: The ideal anesthetic should produce a rapid and smooth onset of action, intra-operative amnesia and analgesia, good surgical conditions and a short recovery period without side-effects.

Objective: To evaluate recovery from Anesthesia with Isoflurane and Halothane in Day care surgery

Design: This was a hospital based Retro prospective Study

Duration: One Year January 2019 to December 2019

Setting: Department of Surgery, Owaisi Hospital & Research Centre

Participants: 60 Patients undergoing day care surgeries

Methods: This study was conducted in sixty patients (thirty patients in Group-I and thirty patients in Group-II). Glyucopyrrolate 0.2 mg i.v was given. Patient was induced with 1% propofol 2 mg/kg; slowly i.e. every 4 ml in 10 seconds until the eyelash reflex was obtunded. On abolition of eyelash reflex patient was maintained on spontaneous ventilation by using Magill's circuit with N20 6 Lts; 02 3 Ltrs. and Isoflurane 1.5% in Group-I or Halothane 1.5% in group-II patients.

Results: The early and intermediate recovery is faster with isoflurane than with halothane. The discharge times are also earlier with isoflurane than with halothane.

Conclusion: Isoflurane is a useful and better anesthetic even halothane and offers a clear advantage when used for maintenance of Anesthesia for operations of short duration performed on a day-care basis.

Keywords: Isoflurane; Halothane; Anesthesia; Propfol; Glyucopyrrolate.

Introduction

The practice of performing surgery under general anesthesia in an outpatient setting is certainly not new. Nicoll operated on several thousand children during the early 1900's and Waters described an out-patient anesthesia clinic in 1919.[1] There has been a dramatic increase in the demand for outpatient surgery over the last 20 years. For example, the American Hospital Association reported a 77% increase in out-patient procedures between 1979 and 1983, while inpatient procedures declined by 8%.[2] Although gynecological surgery is still the most common type of procedure, nearly all surgical sub-specialties are contributing to the increased surgery performed on an out-

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patient basis. Most of published studies relate to comparison of halothane or isoflurane to sevoflurane, desflurane and enflurane in pediatric surgeries done[3–8], dentistry and oral surgeries[9] or in animals.[10,11] It is estimated that 40-60% of all surgical procedures could be performed in out-patient surgery centers. General anesthesia is the most widely used anesthesia technique for ambulatory surgery. The same basic equipment as for inpatient anesthesia is required for delivery of anesthetic drug, monitoring and resuscitation.

Isoflurane is a widely used major anesthetic agent with rapid onset of action and rapid dispersal. Isoflurane is a halogenated anesthetic, similar in structure and activity to halothane, desflurane, enflurane and sevofurane. Isoflurane is typically given in inhaled concentrations of 0.5% to 3% in oxygen. Because of its pungent odor and somewhat slow onset of action, isoflurane is typically used to maintain anesthesia after induction with other agents such as nitrous oxide, fentanyl and propofol.

Halothane is rather more soluble in blood than the newer agents, although in most circumstances the greater solubility of halothane is of little clinical significance. The relative instability of the halothane molecule compared with enflurane and isoflurane has complications in terms of the potential to cause organ toxicity related to the products of metabolism. Because halothane is relatively inexpensive it continues to be used in developing countries.

The rapid elimination of anesthetic gases allows a fast recovery and early discharge of the patient. A similar spectrum of pharmacological activity is produced by the three commonly used volatile agents – halothane, isoflurane and enflurane.

Materials and Methods

Place of Study: Department of Surgery, Owaisi Hospital & Research Centre, Hyderabad

Type of Study: Hospital based retro prospective study

Sample Collection: Sample size: 60 patients

Sampling Methods: Consecutive Sampling

Inclusion Criteria: Patients age ranging from 18 to 55 years and weighing between 35 to 75 kgs for minor surgical procedures of duration varying from 5 minutes to 35 minutes were chosen for the study.

Exclusion Criteria: Patients who were less than 18 years of age or more than 55 years of age and major surgical procedures were excluded from our study

Statistical Analysis: Data were presented in the form of statistical Tables and charts. SPSS software version 20 was used for statistical analysis.

Ethical Approval: Approval was taken from the Institutional Ethics Committee prior to commencement of the study.

A clinical study was carried out in ASA Group-I and Group-II patients to compare the recovery characteristics in day care surgery after the anesthesia with Isoflurane in Group-I and halothane in Group-II patients. This study was conducted in sixty patients (thirty patients in Group-I and thirty patients in Group-II) after taking institutional approval for day-care surgery and patients were chosen from Owaisi group of hospitals. Selected patients were in the age group of 15 years to 60 years, and weight ranging from 35 kg to 75 kg. Pre-anesthetic check-up conducted to obtain a detailed history and complete clinical examination was done. Routine investigations like complete blood picture, random blood sugar, blood grouping and Rh typing were done. These patients were instructed to fast for a period of 12 hours before the procedure. An informed consent was taken from all the patients. Patients for minor surgical procedures of duration varying from 5 minutes to 35 minutes were chosen for the study. The selected groups of patients were explained in detail about the anesthesia procedure and various tests to be performed in postoperative period.

Glyucopyrrolate 0.2 mg i.v was given. Patient was induced with 1% propofol 2 mg/kg; slowly i.e. every 4 ml in 10 seconds until the eyelash reflex was obtunded. On abolition of eyelash reflex patient was maintained on spontaneous ventilation by using Magill's circuit with N_20 6 Lts; 0_2 3 Ltrs. and Isoflurane 1.5% in Group-I or Halothane 1.5% in Group-II patients.

The early-recovery was tested by asking the patient every one minute till he opens his eyes on command and gives his name, date of birth or date of marriage. The intermediate recovery was tested every 15 minutes by the following psychomotor tests:

- Choice reaction time
- Perceptive Accuracy test
- Finger tapping test
- Peg board test
- Card sorting test
- Trigger dot test

Observations and Results

Sixty patients of ASA Grade I and II including thirty patients in Group-I (Isoflurane group) and thirty patients in Group-II (Halothane group), whose age ranged between 18 to 55 years and weight ranged between 35 to 75 kg were selected for the study.

Table 1: AGE and SEX distribution

Sex	Group - I		Group - II	
	No. of cases	Percentage	No. of cases	Percentage
Male	19	63	17	57
Female	11	37	13	13
Total	30	100	30	100
Age in years	**Group - I**		**Group - II**	
	No. of cases	Percentage	No. of cases	Percentage
16 – 25	10	33	9	30
26 – 35	8	27	9	30
36 – 45	7	23	7	23
46 – 55	5	17	5	17
Range	16 – 55 years		16 – 55 years	
Mean	33.8		34.2	

P value = 0.89 (p>0.05) is insignificant

Males were predominant in both Isoflurane and Halothane group and majority of the patients undertaken belonged to the age group of 16–25 years in both the groups.

Table 2: Recovery in both Isoflurane and Halothane group

	Opening eyes on command	Giving date of birth
Group-I Isoflurane	4 min 42 sec.	5 min 42 sec.
Group-II Halothane	9 min 30 sec.	10 min 30 sec.

P value = 0.00 (p>0.05) significant.

There is a significant difference between the two groups. The Isoflurane group responded earlier than halothane group.

Patients of both groups could not perform these tests at 15 minutes but could perform at 30 minutes and average values of the results of psychomotor tests are as follows:

There is a significant difference between the two groups in the performance of Psychomotor tests at 30 minutes.

The isoflurane group performed better than halothane in all the Psychomotor tests done at half-an-hour after the termination of anesthetic.

The recovery in both the groups was also assessed by observing the ability to sit and stand unsupported at the intervals of every half-an-hour after the termination of anesthetic.

There was significant difference between the two groups in the abilities to sit at 30 minutes and to stand at 120 minutes. The higher percentage of patient was able to sit at 30 min and stand at 120 min with Isoflurane than with Halothane. At 120 min the number of cases that were ready for discharge from recovery room were more in the Isoflurane group than in the halothane group. At 180 min all the cases in both the groups were able to stand and walk without support.

Table 3: Psychomotor test in both Isoflurane and halothane group

Test	Isoflurane Group-I	Halothane Group-II	P - Value	Difference
1. Choice Reaction time	6.7 sec.	9.4 sec.	0.00	Significant
2. Perceptive Accuracy Test	98%	88%	0.00	Significant
3. FTT Score No.	46	40	0.00	Significant
4. Peg Board Test	96%	84%	0.00	Significant
5. Card sorting Test	98%	89%	0.00	Significant
6. Trigger dot Test	97%	93%	0.00	Significant

The results were as follows:

Table 4: Ability to sit up and stand unsupported across the Isoflurane and Halothane group

	Isoflurane Group-I	Halothane Group-II	P - Value	Difference
Ability to sit up	Percentage of patients	Percentage of patients		
At 30 min.	87	67	0.06	Significant
At 30-60 min	13	33		
Ability to standunsupported				
At 60-120 min.	83	60	0.04	Significant
At 120-180 min	17	40		

Discussion

Recent changes in medical system have resulted in a significant increase of ambulatory surgical procedures. Therefore, a safe and short postoperative recovery period and especially the full recovery of complex psychological function after general anesthesia has become increasingly important. In the present study between Isoflurane and halothane, we investigated the comparative profile of recovery including emergence time, psychomotor recovery, ability to sit and stand unsupported.

The only difference in both the groups is using isoflurane in one group and halothane in the other. Thus we have avoided narcotic analgesics and anti sialogognes such as atropine that cross blood brain barrier which may interfere with the recovery patterns. We found significant difference in average response time between both groups with average response time being more early in isoflurane group compared to halothane group. Our findings are similar to those done by Wren al[12] which found that recovery from isoflurane was much faster.

The results of the psychomotor tests to assess the intermediate recovery also showed the significant difference between the two groups. The performance at half an hour in psychomotor tests such as choice reaction time (P value = 0.00). Perceptive Accuracy Test (P value = 0.00), Finger Tapping Test (P value = 0.00), Peg board Test (P value = 0.00), Card Sorting Test (P value = 0.00) and Trigger – dot test was better with isoflurane than with halothane.A study conducted by Bhandarker et al.[13] (2006) also found that psychomotor recovery was quicker with is of lurane than with halothane.

There was difference between the two groups in the ability to sit at 30 min (P value = 0.06) and the ability to stand at two hours (P value = 0.04). Thus more number of patients in isoflurane group than in halothane group were able to sit at half-hour and stand at two hours. Thus the intermediate recovery was also found to be faster with isoflurane than with halothane, which were similar to study by Bhandarker et al.[13]

Thus the discharge times were found to be earlier with isoflurane than with halothane. The discharge times of 180 min with isoflurane in our results are comparable to the discharge times with isoflurane in Ekberg[14] and Lenmarken's[15] "study of comparison between desflurane and isoflurane for day care arthroscopy – 1996", journal of anesthesia which gives the discharges times with isoflurane in 92% of their study cases as around 180 min and in 100% of cases around 240 min.

The postoperative complications such as nausea, vomiting and pain were not present with either isoflurane or halothane which correlate with study done by Bhatia et al.[16] but the discharge times with isoflurane are earlier than with halothane.

Conclusions

In the above study of short duration day care surgical procedures where anesthesia is maintained with either isoflurane or halothane after standardized pre-medication. It is found that the recovery times are faster with isoflurane anesthesia than with halothane anesthesia. The postoperative complications such as nausea, vomiting and pain were not present with either isoflurane or halothane but the discharge times with isoflurane are earlier than with halothane. In conclusion it can be said that isoflurane is a useful and better anesthetic ever halothane and offers a clear advantage when used for maintenance of anesthesia for operations of short duration performed on a day-care basis.

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Comparison of Dexmedetomidine Propofol with Fentanyl Propofol for Laryngeal Mask Airway Insertion in General Anesthesia Patients Undergoing Elective Surgeries

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Abstract

Context: LMA secures airway better than face mask and also causes less hemodynamic stress than endotracheal tube insertion. We have done a study on, comparison of dexmedetomidine-propofol with fentanyl-propofol for laryngeal mask airway insertion.

Aims: To compare efficacy of Dexmedetomidine–Propofol and Fentanyl–Propofol for LMA insertion in terms of ease of intubation using Muzi and colleagues scoring system; compare the hemodynamic responses to LMA insertion.

Settings and Design: Prospective randomized double blind study

Methods and Material: After obtaining institutional ethical committee approval, 110 ASA I and II patients were included. Group A patients were preoxygenated for 3 min, dexmedetomidine 1 mcg/kg over 2 min. 30 sec later propofol 2 mg/kg was given for induction, Group B patients were preoxygenated for 3 min, fentanyl 1 mcg/kg given over 2 min. 30 sec later propofol 2 mg/kg was given for induction. Parameters observed include HR, SBP, DBP, MAP, SpO_2 and RR before insertion of LMA and after insertion of LMA.

Statistical analysis used: SPSS (version 18.0) to analyze data (version 18.0), and Sigma-Stat 12.0 is used to decide sample size.

Results: Dexmedetomidine group had better LMA insertion conditions like better jaw mobility, lesser incidence of cough and fewer incidence of breath holding spells. Moreover, reduction of hemodynamic parameters like SBP, DBP and MAP was more with fentanyl group than dexmedetomidine group.

Conclusions: From our study we conclude that dexmedetomidine caused less respiratory depression and more stable hemodynamic conditions, compared to fentanyl. Thus we feel that dexmedetomidine can be used as an alternative to fentanyl with an advantage for LMA insertions in short surgical procedures.

Keywords: Dexmedetomidine; Hemodynamic responses; Laryngeal Mask Airway; Propofol.

Introduction

laryngeal mask airway (lma), one of the extra glottis airways (ega), was invented by dr. archie brain in 1981. but, it was available commercially only after 1988 in united kingdom and 1991 in united states. with the introduction of lma classic (clma) there was wide spread recognition and it had major impact on anesthesia practice and airway management.[1]

LMA secures airway better than face mask and also causes less hemodynamic stress than

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endotracheal tube insertion. LMA is contraindicated in patients with risk of pulmonary aspiration, if peak inspiratory pressure is >20 cm of H_2O. American society of Anesthesiologists (ASA), in their difficult airway algorithm recommend the insertion of LMA when ventilation or intubation is difficult.[2]

During intubation of endotracheal tube with direct laryngoscopy, there are hemodynamic changes seen in the patient. Hemodynamic changes are in the form of transient increase in the arterial pressure and heart rate. These changes are due to mechanical stimulation of sympathetic system in the upper airway. Moreover, most episodes of myocardial ischaemia are seen with intubation response are mainly due to tachycardia. Hence, the use of LMA, a supraglottic airway device has advantage of not having intubation response that is associated with endotracheal tube insertion.[3]

Intubation response can be avoided with LMA insertion and there are less chances of myocardial ischaemia.[4] It is probably that stimulation of the trachea by a tracheal tube has a significant role in causing cardiovascular responses to tracheal intubation.[5] Moreover, there are several advantages of LMA over endotracheal tube placement. Apart from being benefit to the patients with cardiovascular disease, there is also less change in intraocular pressure and provides benefit to patients with glaucoma. Also lower incidence of cough at the time of emergence may benefit patients after Ent or open eye surgery, where, excessive straining is harmful. Lower incidence of sore throat and change in voice has benefits for professional voice users as well.[6]

One of the major advantage of using LMA is that it requires lighter plane of anesthesia when compared to endotracheal tube insertion.[7] Coming to the type of anesthesia, inhalational anesthesia is more efficient than intravenous anesthesia, but, requires more time.[8] Amongst intravenous anesthesia, propofol was chosen over thiopentone. With propofol, passage of LMA is smoother as it suppresses the upper airway reflexes and also it has got shorter half-life than thiopentone.

But, propofol itself does not possess any analgesic property. Also, the high dose of propofol for LMA insertion itself can cause apnoea. Therefore, adjuvants are used along with propofol to decrease its requirement. There are some studies that report that fentanyl reduces the 50% or median effective concentration (EC50) of propofol used for various noxious stimuli. But, fentanyl combined with propofol also has a depressive effect on hemodynamics.[9]

Dexmedetomidine, on the other hand, is a pharmacologically active dextromer of medetomidine and is a selective alpha-2 receptor agonist activity. It has sedative and analgesic activity without causing post operative respiratory depression.[10] Also, dexmedetomidine is said to be a good anesthetic adjuvant that decreases the requirement of propofol and maintains stable hemodynamics intraoperatively.

Therefore, we have done a study on, comparison of dexmedetomidine-propofol with fentanyl-propofol for laryngeal mask airway insertion, in patients posted for elective surgeries under general anesthesia.

Aims

To compare the combination of dexmedetomidine – propofol and fentanyl – propofol for conditions of LMA insertion in short elective surgeries under general anesthesia.

Objectives

To compare efficacy of dexmedetomidine – propofol and fentanyl – propofol for LMA insertion in terms of ease of intubation using MUZI and colleagues scoring system; to compare the hemodynamic responses to LMA insertion with in terms of heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and saturation.

Materials and Methods

For our study entitled, 110 patients admitted for elective surgeries posted under general anesthesia during the duration of march 2015 to June 2016.

Inclusion criteria: All elective patients belonging to age group 18-60 years with adequate mouth opening and ASA Grade I, II undergoing operative procedure undergoing general anesthesia.

Exclusion criteria: Patient's refusal; full stomach patients; patients undergoing emergency surgeries; smokers; patients undergoing oral surgeries.

Sampling procedure

A prospective randomized double blind study was planned. After obtaining approval from the ethical committee and taking informed consent, the patients who meet the inclusion criteria were taken for the study. They were randomly allocated into two groups.

Group A patients were preoxygenated for 3 min, dexmedetomidine 1 mcg/kg diluted in 10 ml normal saline was given over 2 min. 30 sec later propofol 2 mg/kg was given for induction without neuromuscular blocking agents.

Group B patients were preoxygenated for 3 min, fentanyl 1 mcg/kg diluted in 10 ml normal saline was given over 2 min. 30 sec later propofol 2 mg/kg was given for induction without neuromuscular blocking agents.

Anesthesia was maintained with 50% nitrous oxide and isoflurane with oxygen. To decrease pain due to propofol injection, 20 mg of lignocaine was added to 100 mg of propofol. It is a double blind study and the anesthesiologist was not aware of the inducing agent and theadjuvant used. He was called to insert the LMA after giving the inducing agent and adjuvant.

Parameters observed: heart rate, non-invasive blood pressure, oxygen saturation and respiratory rate before insertion of LMA and 30 sec, 1 min, 3 min, 5 min, 10 min and 15 min after insertion of LMA. Response of the patient to LMA insertion like coughing, gagging or any movement was noted. To assess the tolerance of LMA insertion we followed the scoring system modified by MUZI and colleagues.

Scoring system to assess jaw mobility

1. Fully relaxed; 2. Mild resistance; 3. Tight, but opens; 4. Closed

Scoring system to grade coughing or movement

1. None; 2. One or two coughs; 3. Two or more coughs; 4. Bucking or movement

Others: spontaneous ventilation; breath holding; expiratory stridor; lacrimation

In each category scores less than two (<2) was considered optimum for LMA insertion

Statistical analysis

SPSS (version 18.0) to analyze data (version 18.0), and Sigma-Stat 12.0 is used to decide sample size. Statistical analyses were performed using the Chi-square test and Fisher's exact test for categorical data and One-Way ANOVA for continuous data. A p value of < 0.05 was considered significant.

Study design: a prospective, randomized double blind study with 110 patients, randomized into two groups, 55 in group A (dexmedetomidine) and 55 in group B (fentanyl) were taken to study the hemodynamic responses and conditions for laryngeal mask airway insertion.

Results

The mean age subject in the study was 35.2±11.7 years and in Group B was 38.7±15.1 years. There was no significant difference in mean age between two groups. In the study majority of subjects in both group a and Group B were females. 81.8% in Group A and 70.9% in Group B. There was no significant difference in gender between two groups. Mean weight of subjects in Group A was 57.2±5.1 kgs and in Group B was 59.3±8.4 kgs. There was no significant difference in mean weight between two groups.

Table 1: Heart rate comparison between two groups

	Group				P value
	Group A		Group B		
	Mean	SD	Mean	SD	
Pre LMA	77.0	10.3	80.8	10.0	0.051
30 sec	73.0	9.8	75.0	9.4	0.280
1 min	67.8	7.2	72.3	9.2	0.006*
3 min	66.4	6.6	69.8	9.0	0.025*
5 min	68.7	9.7	68.6	8.8	0.975
10 min	68.5	9.7	67.9	9.0	0.745
15 min	68.5	9.6	67.6	9.1	0.626

In the study there was significant difference in mean heart rate between two groups at 1 min and 3 min. Mean HR was lower in group a than group B. No significant difference was observed between two groups at other intervals.

Table 2: SBPcomparison between two groups

	Group				P value
	Group A		Group B		
	Mean	SD	Mean	SD	
Pre LMA	122.7	9.5	125.3	9.0	0.146
30 sec	118.0	9.2	117.1	9.4	0.623
1 min	115.2	9.1	113.3	8.5	0.273
3 min	112.5	9.2	109.7	8.2	0.099
5 min	111.1	9.4	106.4	7.0	0.004*
10 min	110.6	9.5	104.3	6.7	<0.001*
15 min	110.4	9.4	103.8	6.7	<0.001*

In the study there was significant difference in mean SBP between two groups was observed from 5 min and persisted till 15 min intervals. At other intervals there was no significant difference in mean SBP between two groups.

Table 3: DBP comparison between two groups

	Group				P value
	Group A		Group B		
	Mean	SD	Mean	SD	
Pre LMA	68.4	6.3	70.6	7.3	0.091
30 sec	64.7	6.0	64.3	5.6	0.718
1 min	62.9	5.9	62.1	5.4	0.482
3 min	61.2	5.8	59.9	5.2	0.200
5 min	60.4	5.8	58.0	5.1	0.024*
10 min	60.0	5.7	57.1	5.0	0.005*
15 min	60.0	5.7	56.9	5.1	0.003*

In the study there was significant difference in mean DBP between two groups was observed from 5 min and persisted till 15 min intervals. At other intervals there was no significant difference in mean DBP between two groups. Table 4: MAP comparison between two groups.

Table 4: MAP comparison between two groups

	Group				P value
	Group A		Group B		
	Mean	SD	Mean	SD	
Pre LMA	86.3	6.9	88.6	7.3	0.085
30 sec	82.4	6.6	81.8	6.2	0.645
1 min	80.0	6.5	79.1	5.8	0.404
3 min	78.0	6.4	75.7	7.4	0.080
5 min	77.1	6.5	74.2	5.5	0.016*
10 min	76.6	6.5	72.9	5.2	0.001*
15 min	76.5	6.4	72.8	5.4	0.001*

In the study there was significant difference in mean MAP between two groups was observed from 5 min and persisted till 15 min intervals. At other intervals there was no significant difference in mean MAP between two groups.

In the study there was no significant difference in Mean SpO_2 between two groups at all the intervals.

In the study there was no significant difference in mean respiratory rate between two groups at all the intervals.

In Group A 70.9% had fully relaxed jaw, 25.5% had mild resistance and in 3.6% jaw was tight and opens. In Group B 61.8% had fully relaxed jaw, 36.4% had mild resistance and in 1.8% jaw was tight and opens. There was no significant difference in jaw mobility between two groups (Table 5).

In Group A 49.1% had no cough, 50.9% had one or two coughs and in 0% had two or more coughs. In Group B 56.4% had no cough, 41.8% one or two coughs and 1.8% had two or more coughs. There was no significant difference in cough between two groups (Table 6).

In Group A 72.7% had spontaneous ventilation, 27.3% had breath holding spells. In Group B 76.4% had spontaneous ventilation, 47.3% had breath holding and 1.8% had expiratory stridor. There was significant difference in breath holding spells between two groups.

In Group A, 14.5% of them were inserted on second attempt and 3.6% in Group B were inserted on second attempt. This difference was statistically significant.

Table 5: Jaw mobility comparison between two groups

		Group				P value
		Group A		Group B		
		Count	%	Count	%	
Fully Relaxed	0	16	29.1%	21	38.2%	0.313
	1	39	70.9%	34	61.8%	
Mild Resistance	0	41	74.5%	35	63.6%	0.216
	1	14	25.5%	20	36.4%	
Tight but Opens	0	53	96.4%	54	98.2%	0.558
	1	2	3.6%	1	1.8%	
Closed	0	55	100.0%	55	100.0%	–

Table 6: Cough comparison between two groups

		Group				P value
		Group A		Group B		
		Count	%	Count	%	
None	0	28	50.9%	24	43.6%	0.445
	1	27	49.1%	31	56.4%	
One or Two Coughs	0	27	49.1%	32	58.2%	0.339
	1	28	50.9%	23	41.8%	
Two or More Coughs	0	55	100.0%	54	98.2%	0.315
	1	0	0.0%	1	1.8%	
Bucking or Movement	0	55	100.0%	55	100.0%	–

Discussion

Laryngeal mask airway insertion, like insertion of any other airway device, requires certain prerequisites. If these prerequisites are fulfilled, there will be smooth insertion and correct positioning of LMA. The factors that affect the insertion and positioning of LMA are jaw relaxation, mouth opening, episodes of coughing or movement during insertion and the depth of anesthesia. If all these parameters are satisfactory, then there will be minimal hemodynamic stress response, which is required for LMA insertion.

Amongst intravenous anesthesia, propofol was chosen over thiopentone. With propofol, passage of lLMA is smoother as it suppresses the upper airway reflexes and also it has got shorter half-life than thiopentone.[7]

But, propofol itself does not possess any analgesic property. Also, the high dose of propofol for LMA insertion itself can cause apnoea. Therefore, adjuvants are used along with propofol to decrease its requirement. There are some studies that report that fentanyl reduces the 50% or median effective concentration (EC_{50}) of propofol used for various noxious stimuli. But, fentanyl combined with propofol also has a depressive effect on hemodynamics.[9]

Dexmedetomidine, on the other hand, is a pharmacologically active dextromer of medetomidine and has a selective alpha-2 receptor agonist activity. It has sedative and analgesic activity without causing postoperative respiratory depression.[10] also, dexmedetomidine is said to be a good anesthetic adjuvant that decreases the requirement of propofol and maintains stable hemodynamics intraoperatively. Thereby, we chose propofol as an intravenous anesthetic agent and we compared two adjuvants fentanyl and dexmedetomidine.

In our study, both the groups were comparable with respect to age, sex, weight and ASA physical status grading. Ismails et al. (2007) compared the effect of different age groups on hemodynamic response to LMA insertion. They divided 90 patients into 3 groups of 30 each. Group y (young) 18-25 years, group m (middle) 40-45 years and Group E (elderly) 65-80 years. To all the three groups they administered midazolam 7.5 mg orally one hour before induction, preoperatively. Then they were induced with propofol in the dose of 2 mg/kg and LMA was inserted. Here middle aged group had the greatest arterial pressure and heart rate changes, but when compared to the baseline, the change was very minimal. But our study didnot show any age related hemodynamic changes on LMA insertion.[11]

In our study, propofol was chosen as an intravenous anesthetic agent. But, the dose of propofol that was needed to be administered was decided from the previous study done by Blake et al. they had used four doses of propofol for LMA insertion. 1.0 mg/kg, 1.5 mg/kg, 2 mg/kg and 2.5 mg/kg IV propofol for LMA insertion. They evaluated that a dose of 1.5 mg/kg iv propofol was not optimum for LMA insertion. Hence we considered using 2 mg/kg iv propofol for LMA insertion. But as explained earlier, if propofol was used alone without adjuvants, we would have required more amount of propofol and that would have caused cardio-respiratory depression.[12]

In a study, Lawrence and colleagues (1997) assessed the perioperative hemodynamic stability and anesthetic requirements in patients administered with single dose of 2 mcg/kg intravenous dexmedetomidine as a pre-induction dose. It was seen that the requirement of intraoperative anesthetics, intubation response, extubation response, requirement of post-operative analgesics and post-operative antiemetic's was reduced in patients receiving dexmedetomidine.[13]

Moreover, HSUYW et al. (2004) investigated the respiratory effect of dexmedetomidine and remifentanil. They assessed the respiratory response of the 6 healthy volunteers using a step wise target-controlled infusion of dexmedetomidine, remifentanil and a pseudo natural sleep session. The patients receiving dexmedetomidine, had respiratory pattern that mimics the natural sleep. Also, the patients receiving dexmedetomidine, did not have respiratory depression, decreased apnoea/hypopnea index and had natural sleep pattern.[14]

Wong CM et al. (2007) chose 21 male and 54 female healthy female patients to study the optimal dose and duration of fentanyl required along with propofol for insertion of LMA. Here they administered fentanyl in the dose of placebo, 0.5, 1.0, 1.5 and 2.0 mcg/kg. Propofol was given in the dose of 2 mg/kg. After 90 seconds of induction, LMA was inserted. Around 95% of the patients required fentanyl above the clinical dose and 65% of the patients required fentanyl in the dose of 1 mcg/kg. And 90 seconds was optimum duration after induction for LMA insertion. Therefore, in our study we used fentanyl in the dose of 1 mcg/kg.[15]

Also, Uzumcugil F et al. (2008) studied the effects of dexmedetomidine administered with propofol and fentanyl administered with propofol

for laryngeal mask airway insertion in 52 patients. Group F received fentanyl in the dose of 1 mcg/kg with 1.5 mg/kg of propofol. Group D received dexmedetomidine in the dose of 1 mcg/kg with 1.5 mg/kg of propofol. They didnot use any neruromuscular blocking agents. After 90 seconds of induction, first attempt of LMA insertion was attempted. 50% nitrous oxide and sevoflurane in oxygen was used for maintenance of anesthesia. They observed jaw mobility, cough and other events like spontaneous ventilation, breath holding, expiratory stridor and lacrimation. The episodes of apnoea, reduction in systolic and mean blood pressure was more in fentanyl group than the dexmedetomidine group.[16]

When compared to this study, even in our study, dexmedetomidine group had better LMA insertion conditions like better jaw mobility, lesser incidence of cough and fewer incidence of breath holding spells. In Group A 72.7% had spontaneous ventilation, 27.3% had breath holding spells. In Group B 76.4% had spontaneous ventilation, 47.3% had breath holding and 1.8% had expiratory stridor. There was significant difference in breath holding spells between two groups.

Moreover, reduction of hemodynamic parameters was more with fentanyl group than dexmedetomidine group. This difference was statistically significant.

Conclusion from our study we conclude that dexmedetomidine caused less respiratory depression and more stable hemodynamic conditions, compared to fentanyl. Thus we feel that dexmedetomidine can be used as an alternative to fentanyl with an advantage, for LMA insertions in short surgical procedures.

Key Messages

Response to laryngoscopy and intubation which is not necessary because transient rise in the Heart rate and Blood pressures can be detrimental in undiagnosed hypertensives or Ischemic Heart disease patients. Laryngeal mask airway can be the choice which can be introduced with intravenous anesthetics along with opiods or alpha 2 adrenergic agents which produce sedation and analgesia and have an additive effect with propofol induction and with reduced airway manipulation and responses.

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A Clinical Comparative Study of Dexmedetomidine and Buprenorphine as an Adjuvant to 0.5% Bupivacaine for Ultrasound Guided Supraclavicular Brachial Plexus Block

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Abstract

Background and Aims: We compared the block characteristics between dexmedetomidine versus buprenorphine as an adjuvant to bupivacaine in ultrasound guided supraclavicular brachial plexus block. Duration of sensory and motor block along with duration of analgesia were the primary endpoints.

Materials and Methods: A comparative two group randomized clinical study was designed in which sixty ASA 1 and ASA 2 patients who were scheduled for elective upper limb surgeries under ultrasound guided supraclavicular brachial plexus block were randomly divided into two equal groups. Group D (n=30), received 24 ml 0.5% bupivacaine + 1 ml (50 µg) dexmedetomidine and Group B (n=30), received 24 ml 0.5% bupivacaine + 1 ml (100 µg) buprenorphine. Duration of sensory, motor blockade and analgesia were assessed along with onset of sensory and motor blockade, sedation, and side effects among the two groups.

Results: Duration of sensory and motor block in Group D (588.7±38.2 & 481.7±16.8) was longer than Group B (395.7±15.5 & 334.3±23.8; p <0.001). Duration of analgesia in Group D (805.7±54.1) was longer than Group B (579.0±41.4). There was no significant difference among the groups with respect to onset of sensory and motor blockade. Bradycardia was observed in one patient in Group D and vomiting was seen in two patients in Group B, no other adverse effects were observed.

Conclusion: Dexmedetomidine prolongs the duration of sensory and motor blockade and duration of analgesia as compared with buprenorphine when used as an adjuvant to bupivacaine in supraclavicular brachial plexus block, with no adverse side effects.

Keywords: Dexmedetomidine; Buprenorphine; Brachial plexus block; Ultrasound.

Introduction

Supraclavicular brachial plexus block provides Anesthesia for surgeries around the elbow, forearm and hand.[1,2] It also provides analgesia in the postoperative period, shortens the patient recovery time and avoids the undesirable side effects of general Anesthesia. Using ultrasound helps in better delineation of the anatomical structures, hence avoids complications. It also reduces the number of needle passes required to produce a more effective analgesic block after surgery despite the low volume of local anesthetic used.[3,4]

Various adjuvants like opioids and non opioid agents along with local anesthetics have been used in brachial plexus block to achieve quick, dense and prolonged block with better postoperative

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pain relief.[5] Dexmedetomidine is a highly selective alpha-2 adrenoreceptor agonist.[6] In various studies, use of dexmedetomidine as an adjuvant to local anesthetic in regional blocks has shown to prolong the duration of block and postoperative analgesia.[7-9]

Buprenorphine is a highly potent semisynthetic agonist–antagonist opioid. Some studies have concluded that buprenorphine added to bupivacaine in brachial plexus block provide a longer period of postoperative analgesia than other opioid variants.[10,11]

This study compares the effect of dexmedetomidine and buprenorphine added to bupivacaine in ultrasound guided supraclavicular brachial plexus block. The primary outcome was to compare the duration of the sensory and motor blockade, and duration of analgesia. Secondary outcomes included time to onset of sensory and motor blockade, sedation score, complications and side effects.

Material and Methods

After the approval of hospital ethical committee, patients were explained about the procedure and drugs. Informed written consent was taken from all the patients. Sample size calculation was done based on outcome variable on motor block for a two randomized groups with minimum mean difference of 12 and standard deviation of 20.3 (derived from previous literature), 90% statistical power and at 5% level of significance, the sample size of 60 (30 in each group), was adequate for a randomized two group clinical study.

A comparative two group randomized clinical study carried out on 60 ASA grade 1 and 2 patients of either sex, aged 18-60 years, posted for upper limb orthopaedic surgeries under ultrasound guided brachial plexus block. Patients were allocated into two groups of 30 patients each by systematic random sampling. The groups were, Group D: bupivacaine 0.5% 24 ml + dexmedetomidine 50g in 1 ml of normal saline and Group B: bupivacaine 0.5% 24 ml + buprenorphine 100g in 1 ml of normal saline. Exclusion criteria were patient refusal for block, history of significant neurological, cardiovascular, psychiatric, neuromuscular, pulmonary or hepatorenal disease. Patients on anti-coagulants, bleeding disorders, local infection at injection site, known hypersensitivity to local anesthetic drugs, uncontrolled diabetes mellitus, pregnant women were also excluded.

On the day of surgery, standard monitoring including non invasive blood pressure, pulse oximetry and ECG were attached to the patient. Intravenous access was obtained in the limb opposite to that undergoing surgery with a 18G bore IV cannula. Baseline systolic blood pressure and diastolic blood pressure, heart rate, SpO_2 were recorded at interval of every 5 minutes for the first 30 minutes and every 30 minutes thereafter. Patients were put in supine position with head turned away from the site to be blocked. Arm to be anesthetised was adducted and extended towards the ipsilateral knee as far as possible. Under strict aseptic precautions supraclavicular area was painted and draped. The brachial plexus was scanned using high frequency (8-14 MHz) linear ultrasound probe. After local infiltration of skin, a 22G, 5 cm short bevelled echogenic needle was inserted in line with the ultrasound beam till the tip of the needle was positioned near the brachial plexus which showed a bunch of grapes appearance on ultrasound. After negative aspiration of blood, 25 ml of respective drug was injected depending on whetherthe patient was allotted to either Group B or Group D.

The onset of sensory blockade was defined as time taken from the completion of injection of drug till the patient did not feel the pin prick. Sensory block was assessed by pin prick with 23G hypodermic needle in skin dermatomes C5-T1 once in every 2 min for initial 30 min and then after every 30 min till patient regained normal sensations. Sensory block was graded into three: Grade 0- Normal response to pin prick. Grade 1- Analgesia, dull sensation felt. Grade 2- Anesthesia, no sensation felt.[12] Duration of sensory blockade was defined as time taken from the onset of sensory blockade till the patient feels pin prick.

Onset of motor blockade was defined as the time taken from the injection of the drug till the patient develops loss of movement in ipsilateral upper limb. Quality of motor block was assessed at the same interval and graded using modified Bromage scale for upper extremities.[12] Duration of motor blockade was defined as time taken from the onset of the motor blockade till complete recovery of motor function of the hand and forearm.

Sedation was assessed to the patients after administration of drugs every 30 min in first two hours then every 2 hours till 6 hours postoperative using modified Ramsay sedation scale.[13] Pain was assessed using Visual analog scale (VAS 0-10; 0= no pain, 10= worst pain imaginable), every hourly postoperatively. At VAS score of 4, rescue analgesia (inj. diclofenac sodium 75 mg I.M.) was given. Duration of analgesia was the time between

complete sensory block to the time of first rescue analgesia. All patients were observed for any side effects like nausea, vomiting, bradycardia, respiratory depression, hypotension, pruritis and urinary retention.

Statistical analysis

The data was analyzed by SPSS version 18.0 (Statistical Package for Social Sciences) software and Microsoft word and Excel were used to generate graphs and tables. Demographic and hemodynamic data were subjected to student's T-test and for statistical analysis of onset time and duration of sensory, motor blockade, and duration of analgesia, unpaired T-Test was applied. P value <0.05 was considered as statistically significant and P <0.001 as highly significant. Chi-square/ Fischer's exact test were used to analyze any adverse effects.

Results

There were no significant difference in between the two groups for age, gender, body weight, and duration of surgery in the two groups (Table 1). The onset time of sensory and motor block was found to be comparable in both the groups (Table 2). The duration of sensory and motor blockade was significantly longer in Group D as compared to Group B (Table 2). Duration of analgesia (time for rescue analgesia) was significantly longer in Group D than Group B (Table 2).

The hemodynamic parameters (HR, BP and MAP) were comparable in both the groups with no statistical significance. One patient in Group D had bradycardia, treated with inj atropine 0.6 mg IV. Two patients in Group B had vomiting. There were no other side effects such as pneumothorax, Horner's syndrome, phrenic nerve palsy or respiratory depression in any of the patients.

Modified RSS for Group D was 2/6 (13 patients), for Group B it was 1/6 (6 patients) (Table 3). Most of the patients (41.7%) were cooperative, oriented and tranquil alert. 23.3% patients were anxious, agitated or restless. 35% patients were responding only to commands.

Table 1: Demographic data

Patient characteristics	Group D	Group B
Age in years	41.1±11.8	37.8±10.3
Weight in KG	71.4±9.1	74.5±8.7
Gender (M/F)	20/10	23/7
Duration of surgery (DOS)	94.7±14.8	96.0±19.0

Table 2: Sensory and motor block onset, duration of blockade and analgesia.

	Group D (n=30)	Group B	P value
Onset time (min) of sensory block (mean ± SD)	4.7 ± 1.4	5.2 ± 1.6	0.189
Onset time (min) of motor block (mean ± SD)	8.5 ± 1.4	9.2 ± 1.5	0.073
Duration (min) of Sensory block (mean ± SD)	588.7 ± 38.2	395.7 ± 15.5	<0.001
Duration (min)of motor block (mean ± SD)	481.7 ± 16.8	334.3 ± 23.8	<0.001
Duration(min) of Analgesia (mean ± SD)	805.7 ± 54.1	579.0 ± 41.4	<0.001

Table 3: Ramsay Sedation scale distribution in two groups of patients studied

Sedation	Group D	Group B	Total
1	8(26.7%)	6(20%)	14(23.3%)
2	13(43.3%)	12(40%)	25(41.7%)
3	9(30%)	12(40%)	21(35%)
4	0(0%)	0(0%)	0(0%)
5	0(0%)	0(0%)	0(0%)
6	0(0%)	0(0%)	0(0%)
Total	30(100%)	30(100%)	60(100%)

Discussion

Brachial plexus nerve block has been used as ideal alternative to general Anesthesia. The advantages of brachial plexus block includes better intraoperative and postoperative analgesia, minimal anesthetic exposure, reduced need of systemic analgesia and early discharge.[14] Usage of ultrasound helps in delineating the anatomical structures and locating the brachial plexus. It improves the quality of the block and reduces the failure rate when compared with paraesthesia technique and electrical nerve stimulus technique.[15,16]

Local anesthetics alone for supraclavicular brachial plexus block provides good operative conditions but have a shorter duration of postoperative analgesia. Hence various drugs such as opioids, alpha2 receptor agonists, dexamethasone, midazolam, magnesium sulphate etc were used as adjuvant with local anesthetics in brachial plexus block to achieve quick, dense, prolonged block and duration of analgesia postoperatively.[17–20] In this randomised comparative clinical study, we compared dexmedetomidine and buprenorphine as an adjuvant to bupivacaine in ultrasound guided supraclavicular brachial plexus block.

Swami et al. concluded that dexmedetomidine when added to bupivacaine 0.25% in supraclavicular brachial plexus block increased the duration of sensory and motor blockade and also the duration of analgesia which is similar to our study.[12] Dexmedetomidine as an adjuvant for nerve blocks have shown that the duration of analgesia is prolonged due to hyperpolarisation activated cation current flow ($I_h$current).[21]

Esmaoglu et al. added dexmedetomidine to levobupivacaine for axillary brachial plexus block showed that it shortens the onset time of both sensory and motor block, prolongs the duration of block and the duration of postoperative analgesia.[8] However in our study we found that onset of sensory and motor blockade was faster with Group D as compared with Group B, but it was statistically not significant. The duration of sensory, motor blockade and analgesia in Group D was longer than Group B, and it was statistically significant.

Viel and colleagues conducted comparision study for post operative pain relief in brachial plexus block with buprenorphine and morphine.They concluded that buprenorphine in supraclavicular brachial plexus block produces significantly longer analgesia than morphine after upper limb surgeries.[22] Trivedi V, Shah J, conducted a comparative study between buprenorphine versus butorphanol in supraclavicular brachial plexus block and concluded that buprenorphine produces prolonged sensory, motor blockade and duration of analgesia than butorphanol.[23]

In our study we have compared dexmedetomidine 50g versus buprenorphine 100g as an adjuvant to 0.5% bupivacaine via ultrasound guided supraclavicular brachial plexus block. Group D (dexmedetomidine) had prolonged duration of sensory and motor blockade, and duration of analgesia compared to Group B (buprenorphine). Sedation after block was assessed using the sedation score described by Ramsay. The results of our study were similar to that obtained by Agarwal S et al., where dexmedetomidine was added to bupivacaine and sedation was assessed using modified Ramsay sedation score. They observed that patients who received dexmedetomodine had higher sedation score.[24] One patient had bradycardia in Group D and two patients in Group B had vomiting. No other side effects were observed in any group. None of the patients in Group D required sedation intra operatively and they were comfortable throughout the surgery with arousable sedative effect.

Conclusion

We conclude that dexmedetomidine prolongs the duration of sensory and motor blockade and duration of analgesia as compared with buprenorphine when used as an adjuvant to bupivacaine in ultrasound guided supraclavicular brachial plexus block.

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Original Research Article

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Antiemetic Efficacy of Dexamethasone in Prevention of Postoperative Nausea and Vomiting after Laparoscopic Surgery

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Abstract

Background: Efficient prevention and management of postoperative nausea and vomiting [PONV] continues to be a concern that needs to be addressed.

Objective: The aim of this study is to evaluate the effectiveness of the single dose dexamethasone [I.V. 8 mg] in preventing post operative nausea and vomiting in patients undergoing laparoscopic surgery under general anesthesia.

Design: This was a hospital based Retro prospective Study.

Duration: One Year December 2019 to November 2019.

Setting: Department of Surgery, Owaisi Hospital and Research Centre.

Participants: 50 patients undergoing laparoscopic surgery.

Materials and Methods: A randomized, placebo-controlled study was conducted on 50 patients undergoing elective laparoscopic surgery under general anesthesia. The patients were allocated randomly to one of the two groups Group A - Dexamethasone I.V 8 mg, Group B - I.V saline The anesthetic was standardized. The patients were premedicated with glycopyrrolate 0.2 mg i.v., ranitidine 50 mg i.v., midazolam 0.05 mg/kg and fentanyl 1.5 mg/kg i.v. Vomiting was treated with metoclopromide 10 mg i.v. repeated if necessary.

Results: The total incidence of nausea and vomiting was 28% in the dexamethasone group compared with 68% in the saline group. Dexamethasone is shown to be more effective in reducing nausea than vomiting.

Conclusion: Prophylactic administration of single dose of dexamethasone 8 mg, IV resulted in prevention of post operative nausea and vomiting. Dexamethasone is more useful either alone or in combination with other antiemetics in prevention and treatment of postoperative nausea and vomiting, especially when it is severe andfrequent.

Keywords: Dexamethasone; Post operative Nausea and Vomitting [PONV]; Saline; Anesthesia; Metroclopromide.

Introduction

Postoperative nausea with or without vomiting is probably the most common complication of surgery performed under general anesthesia. Patients undergoing laparoscopic surgeries are particularly at risk of experiencing postoperative nausea and vomiting. In the absence of any antiemetic

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prophylaxis, the incidence of postoperative nausea and vomiting after laparoscopic surgery can range from 40%-75%.[1]

Postoperative nausea and vomiting is one of the important factors that determine the length of stay after day care surgery. Most of the currently used antiemetic drugs [for example: antihistaminics, anticholinergics and dopamine receptor antagonists] possess clinically significant side effects such as sedation, adrenergic blockade, dry mouth, dysphoria, restlessness, and extra pyramidal symptoms.[2]

The quest for more effective antiemetic drugs without the potential for side effects has led to the idea that the combination of drugs currently used in the treatment of nausea and vomiting in patients receiving chemotherapy could be a solution to control postoperative nausea and vomiting where it is severe and frequent.[3]

Dexamethasone is one such drug which has been used successfully since 1981 for the treatment of nausea and vomiting in patients receiving chemotherapy either alone or in combination with other antiemetics. The abundant research in the oncology literature demonstrates its efficacy with minimal adverse effects.

Investigations of perioperative use of dexamethasone are surprisingly uncommon. Recently dexamethasone has also been reported to be effective in reducing the incidence of postoperative nausea and vomiting in pediatric patients undergoing strabismus repair, tonsillectomy, and adenoidectomy and in women undergoing major gynaecological surgery.[4] As dexamethasone has an antiemetic effect in various situations, we thought that it may also be effective in the prevention of emesis after laparoscopic surgery. Therefore we have planned to evaluate the antiemetic effect of intravenous dexamethasone in the prevention of nausea and vomiting after laparoscopic surgery in adult patients.

Materials and Methods

Place of Study: Department of Surgery, Owaisi Hospital and Research Centre, Hyderabad.

Type of Study: Hospital based retro prospective study.

Sample Collection: Sample size: 50 Patients.

Sampling Methods: Consecutive Sampling.

Inclusion Criteria: Patients aged between 20–60 years, Patients belonging to ASA I and II, Patients undergoing elective laparoscopic surgery under general anesthesia.

Exclusion Criteria: Patients with a history of motion sickness, Patients who had received antiemetics within 24 hrs prior to surgery. Patients with clinically significant cardiovascular, pulmonary, renal, hepatic, neurological or endocrine abnormalities.

Statistical Methods: Data were presented in the form of statistical Tables and charts. SPSS software version 20 was used for statistical analysis.

Ethical Approval: Approval was taken from the Institutional Ethics Committee prior to commencement of the study.

A randomized, placebo-controlled study was conducted on 50 patients undergoing elective laparoscopic surgery under general anesthesia at Owaisi Hospital and Research Centre. The patients were allocated randomly to one of the two groups Group A - Dexamethasone I.V 8 mg, Group B - I.V saline.

The anesthetic was standardized. The patients are premedicated with glycopyrrolate 0.2 mg i.v., ranitidine 50 mg i.v., midazolam 0.05 mg/kg and fentanyl 1.5 mg/kg i.v.

At the end of surgery, glycopyrrolate 0.5 mg i.v and neostigmine 2.5 mg i.v were administered for reversal of neuro muscular block, and the patient was extubated. After surgery, patients were observed for 24 hrs. Post operative analgesia was provided by injdiclofenac sodium 1.5 mg/kg every 8th hourly. Throughout the 24 hrs period, vital signs such as pulse rate, blood pressure and respiratory rate were monitored every 4th hourly except during sleep. The incidence of nausea or vomiting was also recorded every 4th hourly for 24 hours, except during sleep.

Vomiting was treated with metoclopromide 10 mg i.v. repeated if necessary.

Observations and Results

A total of 50 patients were taken for study, 25 of them received placebo (normal saline) while the other 25 received dexamethasone.

Table 1: Patient Characteristics (mean or number and range)

	Placebo Group	Dexamethasone Group
N.	25	25
Age (yrs)	32.56 (20-60)	32.68 (20-60)
Weight (kgs)	54.08 (46-72)	54.16 (44-70)
Sex (M/F)	8/17	11/14
Duration of anesthesia (min)	101.2 (75-135)	97.92 (65-150)
Duration of surgery (min)	86.68 (60-120)	82.20 (60-120)
Duration of CO_2 Insufflations (min)	75.56 (50-105)	72.40 (50-110)

The mean duration of anesthesia for placebo group was 75–135 min (mean min) and for dexamethasone group it was 65–150 (mean 97.92 min).

The mean duration of surgery for placebo group was 86.68 min (range 60–120 min) and for dexamthasone group it was 82.20 min (range 60–130 min).

The mean duration of carbondioxide insufflation for placebo group was 75.56 min (range 50-105 min) and for dexamethasome group it was 72.40 min (range 50-110 min).

Table 2: Incidence of Nausea from 0-4 hr, 4-8 hr and 8-24 hr after Recovery from Anesthesia

Assessment Period	Placebo Group	Dexamethasone group
0 - 4 hr	9 (36%)	4 (16%)
4 - 8 hr	11 (44%)	4 (16%)
8 - 24 hr	4 (16%)	3 (12%)

During 0-4 hr of observation 36% (9 out of 25) of patients had nausea and 12% (3 out of 25) of patients had vomiting in placebo group. Whereas in the study group only 16% (4 out of 25) of patients had nausea and 8% (2 out of 25) of patients had vomiting.

During 4-8 hrs of observation period 44% (11 out of 25) of patients had nausea and 24% (6 out of 25) of patients had vomiting in placebo group. Whereas in the study group only 16% (4 out of 25) of patients had nausea and 8% (2 out of 25) had vomiting.

During 8-24 hrs of observation period 16% (4 out of 25) of patients had nausea and 16% (4 out of 25) had vomiting in placebo group. In study group only 12% of patients (3 out of 25) had nausea and 4% of patients (1 out of 25) had vomiting.

Table 3: Number of Episodes of Vomiting in First 24 Hour Post Operative Period

No. of episodes	Placebo group	Dexamethasone group
0	15 (60%)	22 (88%)
1	6 (24%)	1 (4%)
2	3 (12%)	2 (8%)
>2	1 (4%)	0
Total	25	25

The number of emetic episodes in both the groups were as shown in Table 4. In placebo group 24% (6 out of 25) had one emetic episode each and 12% (3 out of 25) had two emetic episodes each. Only one patient in placebo group had more than 2 emetic episodes. In dexamethasone group, one patient vomited once and two patients had two emetic episodes each.

In placebo group 4 out of 25 patients received rescue antiemetic, whereas in study group it is 2 out of 25 patients.

Discussion

Nausea and vomiting following general anesthesia has been a distressing problem for patients. Sometimes it may be the only distressing long lasting memory of patient's experience regarding general anesthesia. It increases the recovery time, intensity of nursing care and patient morbidity.[5,6] Even though laparoscopy avoids prolonged exposure and manipulation of intestines and decreases the need for peritoneal incision and trauma when compared to laparotomy, the incidence of postoperative nausea and vomiting is higher after laparoscopy than that after laparotomy probably because of various other reasons like gas insufflations, diaphragmatic irritation etc. Postoperative nausea and vomiting is one of the main complaints after laparoscopy (in 40 to 75% of patients) and the most important factor determining the length of stay after ambulatory anesthesia. But multiple postoperative benefits which include less trauma, less pain, less pulmonary dysfunction, quicker recovery and shorter hospital stay made laparoscopy as standard and accepted procedure for many surgical problems.

In this study all the patients underwent laparoscopic surgery, a type of surgery associated with the highest incidence of postoperative nausea and vomiting, under general anesthesia. Duration ofanesthesia, surgery and carbondioxide insufflation were similar in both groups. In addition, after random allocation, age and sex distribution in both groups was similar. Analgesia for postoperative pain was standardized and pain scores were similar in both the groups. Therefore we believe that differences in the incidence of postoperative nausea and vomiting were attributed to the study drugs.

In this study the prophylactic administration of dexamethasone significantly, reduced the incidence of nausea and vomiting after laparoscopic surgery.

The total incidence of nausea and vomiting was 28% in the dexamethasone group compared with 68% in the saline group. Dexamethasone is shown to be more effective in reducing nausea than vomiting.

These findings are in accordance with recent studies that showed dexamethasone can be effective in preventing PONV in adults and children. Compared with other preventive medications, dexamethasone has equal or even better efficacy

in reducing the incidence of PONV and has the advantages of low cost and longer effectiveness as well.[7-11]

Adverse effects related to single dose of dexamethasone are extremely rare. Usually the adverse effect of dexamethasone depends on duration and dose. Less than 24 hours of dexamethasone therapy is considered safe and almost without adverse effects.

Conclusions

We conclude that prophylactic administration of single dose dexamethasone (8 mg i.v), when given just before induction, significantly reduced the incidence of nausea and vomiting after laparoscopic surgery. If our results are confirmed in larger studies, dexamethasone will be more useful either alone or in combination with other antiemetics in prevention and treatment of postoperative nausea and vomiting, especially when it is severe and frequent.

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Original Research Article

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Comparison of Intrathecal 0.75% Ropivacaine-Fentanyl and 0.5% Bupivacaine-Fentanyl in Equipotent Doses for Lower Abdominal and Lower Limb Surgeries Under Spinal Anesthesia

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Abstract

An observational & comparative study was designed to compare the efficacy, safety of Ropivacaine-Fentanyl versus Bupivacaine-Fentanyl intra-thecally for lower abdominal and lower limb surgeries not exceeding 2 hours.

70 patients of either gender with ASA I & II aged between 18 to 55 years were randomized into two groups, n = 35 each. Group R received 3 ml of (0.75%) Ropivacaine+ Fentanyl 25 µg (0.5 ml) and Group B received 3 ml of (0.5%) Bupivacaine+ Fentanyl 25 µg (0.5 ml). Spinal anesthesia procedure was standardized. Hemodynamic parameters, onset and duration of sensory & motor blockade, level achieved, duration of analgesia, regression and side effects were checked.

Onset and Regression of sensory blockade in ropivacaine group was faster with a P <0.001 which was statistically significant. Onset of motor blockade was rapid in both the groups, but duration of motor blockade was significantly shorter in ropivacaine group. Ropivacaine group were recorded with excellent analgesia and stable hemodynamics with no side effects.

From the present study we concluded that with addition of fentanyl to local anesthetics there is prolongation of analgesic effect. The hemodynamic parameters and SpO_2 are comparable in both the groups. Postoperative analgesic consumption is less in both groups. When bupivacaine-fentanyl combination was introduced intra-thecally, they produced a significantly longer duration of analgesia. Their sensory block and motor block were also longer than ropivacaine-fentanyl combination. Shorter duration of motor block with ropivacaine allows for early ambulation, voiding and physiotherapy, therefore it is preferred in day care surgeries.

Keywords: Duration of Analgesia; Fentanyl; Intrathecal Ropivacaine; Intrathecal Bupivacaine; Motor Block; Sensory Block.

Introduction

Karl August Bier introduced spinal anesthesia in clinical practice, in 1898.[1,2] It provides sensory and motor block, both of which are must for surgical work. Hyperbaric lignocaine (50 mg/ml) and Bupivacaine were commonly used in past for but were associated with many adverse events, hence their use has declined with development of newer agents.[3] This made researcher look for newer and safer local anesthetic agents.[4]

Ropivacaine, an amino-amide local anesthetic (LA) agent is a relatively newer agent whose chemical structure is nearly similar to bupivacaine. Incidence of transient neurological symptoms

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(TNS) is low compared to lignocaine. The duration of motor block is shorter than bupivacaine, allow rapid mobilization.[5] Currently Ropivacaine's isobaric preparations are only available commercially; hyperbaric solutions are prepared freshly by adding 50% glucose.[6]

Postoperative analgesia can be prolonged with the use of various intrathecal adjuvants. We have used fentanyl with local anesthetic which offers advantages of synergistic analgesic effect. This enhances analgesia that is required for surgery and this is attained even with the subtherapeutic doses of local anesthetic. With this adequate analgesia is attained with a dose of LA that is otherwise an inadequate dose for producing analgesic effect.[7]

Aims of Study

The main aim of the study was to compare equipotent doses of 0.75% Ropivacaine (3 ml) with 0.5% Bupivacaine (3 ml), when both the local anesthetist agents are combined with Fentanyl 25 µg (0.5 ml) for spinal anesthesia in patients posted for lower abdominal and lower limb surgery.

Objectives of Study

Objectives of the study were to compare the time of onset of sensory as well as motor block, the duration of sensory as well as motor block, the highest level of sensory block, the analgesic duration in both the groups, the vital parameters (heart rate; systolic, diastolic and mean blood pressure) and the occurrence of side effects (Nausea, Hypotension, Pruritus, Vomiting, Bradycardia, Rigor, Respiratory Depression) if any in either of the two groups and evaluate the safety of the two drugs.

Materials and Methods

We planned to conduct a observational study which was comparative in nature. The study was conducted in the Dhiraj General Hospital, Piparia. We enrolled seventy patients that met inclusion criteria and none of the exclusion criterias. The study was conducted as per local as well as global ethical norms as well as local regulatory guidelines. Data was collected to study and compare the effect of equipotent doses of 0.5% Bupivacaine (3 ml) and 0.75% Ropivacaine (3 ml) that were administered along with Fentanyl 25 µg for spinal anesthesia in patients that underwent lower abdominal and lower limb surgeries.

Patients of either sex aged between 18 and 55 years, scheduled for abdomen or lower limb surgeries not exceeding more than 2 hours with American Society of Anesthesiologists Grade l & ll (ASA I & II) were included in study. Patient of ASA III or IV, with coagulopathy, spine deformity, any skin infections at site of injection of LA, allergy to LA and patients that did not want to participate in the study were excluded from the study.

Sample Size of seventy (70) patients was included for data analysis.

Once enrolled, the participant underwent a detailed pre-anesthetic check-up with regards to patients demographics, vitals, systemic examination, and investigations.

The study population of 70 patients was randomly allocated to either of the two groups mentioned below, on the day of the surgery using Chit method:

Study Groups

Group B - 0.5% Bupivacaine (3ml) + Fentanyl 25 µg (0.5 ml)

Group R- 0.75% Ropivacaine (3 ml) + Fentanyl 25 µg (0.5 ml)

Procedure for study drug administration:

On arrival of patient in the operation theatre Standard monitoring, ECG, Non-Invasive blood pressure and SpO_2 were applied and all the baseline vitals were noted. An 18G intravenous cannula was secured in preloading with Ringer lactate at the rate of 10 ml/kg was started. Premedication inj. Glycopyrrolate 0.2 mg and inj. Ondansetron 4 mg given intravenously. Penetration with 23 gauge Quinke's spinal needle at L4-L5 interspace and either of the study drug was administered. Following this, patient was made to lie down in supine position.

Sensory block was assessed with Pin prick using hypodermic needle. Onset of sensory block (difference in the time from intrathecal injection of drug to the time taken to achieve T10 segment level block), highest level of sensory blockade, two level regression time, total duration of sensory block (time period from onset of block to the sensory block regressed by two segment from T10) were recorded.

Assessment was done at 2 min, 5 min and at 5 min interval thereafter until 2 consecutive levels of sensory block were identical (i.e. fixation of the level) after which assessment was done every 30 mins.

Motor block was assessed using modified Bromage scale. Time of onset of the motor block (time when modified Bromage scale 3 was attained

post intrathecal administration of the drug), Duration of motor blockade (time period between modified Bromage scale 3 to modified Bromage scale 0).

It was assessed 5 min, 10 min, 15 min, than every 15 minutes upto 120 minutes and than 30 minute intervals until the motor block had regressed completely.

Pulse rate and Systolic, Diastolic and mean blood pressure were recorded before giving spinal anesthesia, after spinal anesthesia, at 5 min, 10 min, 15 min, 30 min, and after that every 15 min till the end of the surgery.

A ≥20% decrease in systolic arterial pressure (SAP) or decrease in mean arterial pressure (MAP) below 60 mmHg indicated significant hypotension. These were managed using injection mephentermine 6 mg in increments intravenously along intravenous fluid replacement. Significant bradycardia (HR <60 beats/min) was treated with inj. atropine sulphate 0.6 mg intravenously.

Duration of surgery was noted, and duration of spinal anesthesia was recorded. Analgesic requirement was recorded for each patient. Side-effects and complications, if present, were recorded and treated.

Statistical Analysis

Data were analyzed using SPSS software version 18.0. *'f' test and 't' test* were applied for comparison of continuous data. *'Chi' test* was applied for comparison of nominal data. '*p*' value of 0.05 was considered as statistically significant. (Confidence interval of 95% was taken into account).

Results

The distribution of patients with respect to age, height, weight was statistically not significant in both the groups. (Table 1): Graph 1: Mean age, height and weight of patients in both the groups.

Mean time to onset of motor block was greater in Group B (7.91±0.70 minutes) compared to group Group R (5.86±0.69 minutes): Graph 2

Average duration of motor block was greater in Group B (193.71±18.48 minutes) compared to Group R (121.71±15.81 minutes): Graph 2

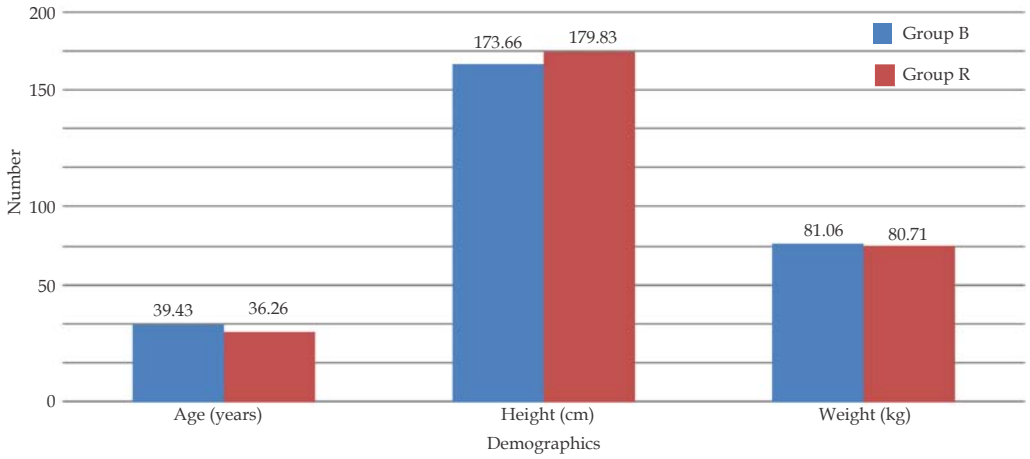
Mean time to onset of sensory block was higher in Group B (7.16±0.74 minutes) compared to Group R (5.40±0.76 minutes): Graph 3

Mean duration of sensory block higher in Group B (217.71±20.59 minutes) compared to Group R (137.43±19.26 minutes): Graph 3

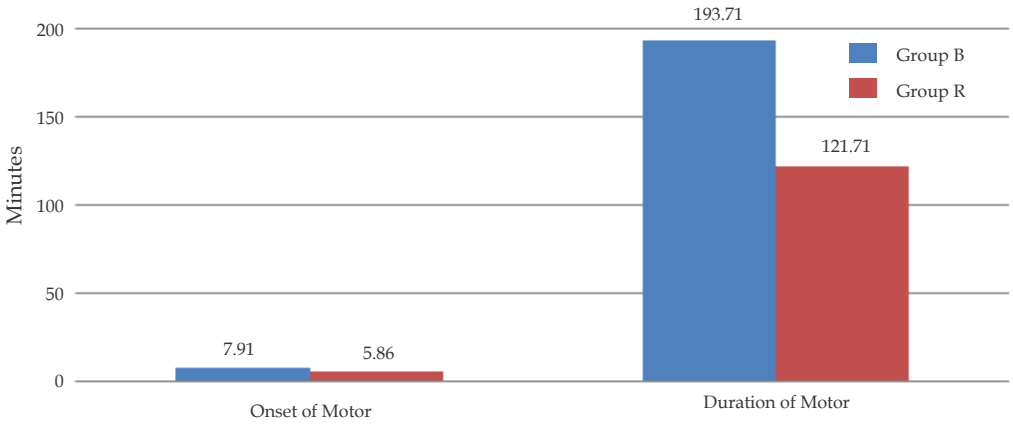
Duration of analgesia in the Group B was higher (427.43±44.28 minutes) compared to Group R (305.43±28.63 minutes): Graph 3

There was statistically no significant difference in pulse rate; systolic, diastolic and mean blood pressure between to groups: Graph 4

Intraoperatively, 8 patients in Group B and 5 patients in Group R developed hypotension while 2 patients in Group B and 3 patients in Group R developed bradycardia. Overall the safety profile was comparable. None of the patients in any of the groups had any post-operative complications.



Graph 1:



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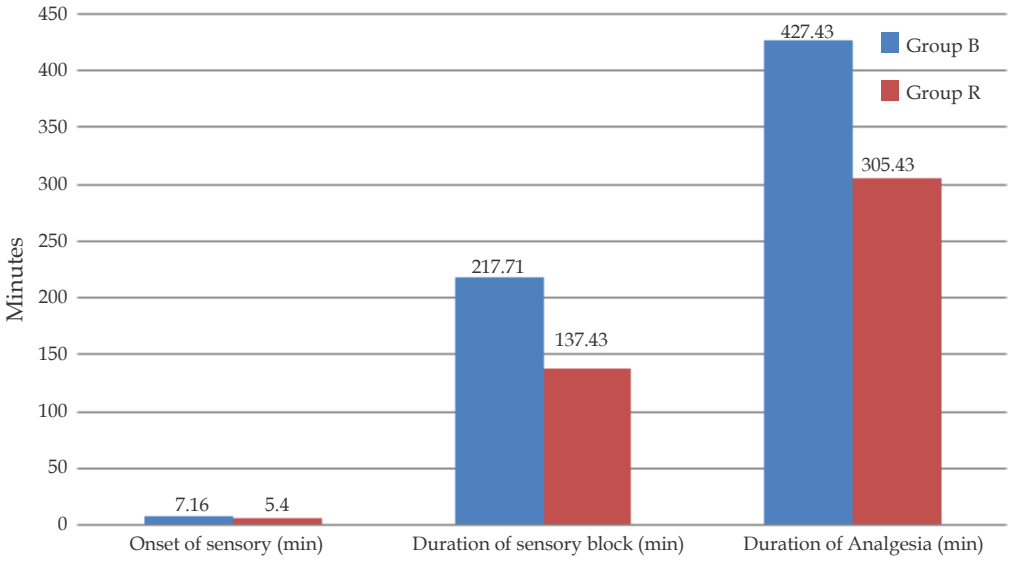
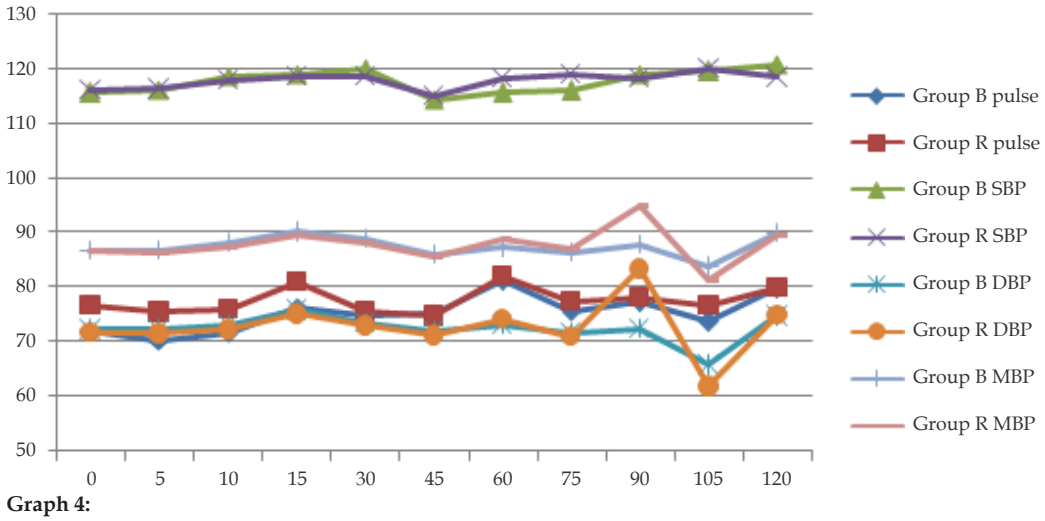


Graph 3



Graph 4:

Discussion

In surgeries below umbilicus, the local anesthetic drug given in subarachnoid space in small incremental doses is ideal as it provides sensory and motor block that is complete, rapid and deep with advantage of rapid recovery and minimal side-effects. Various agents, especially opioids, are added to prolong the intraoperative and postoperative analgesia. This allows for use of lower doses of both the drugs and thereby helps avoid unwanted side effects of large doses.

In our study there was no difference observed in demographic data (Age, Weight, Gender distribution, American Society of Anesthesiologists status) of both the group. Thus both the groups were comparable in terms of demographics and there was no statistically significant difference between the two groups. (p>0.05). Lee YY, et al. (2005), Koltka K et al. (2009), Layek A, et al. (2015) in their studies also did not find any significant difference between the two groups in demographic data considering age, weight, gender of the patient and ASA status.[9,10,12]

In our study, we added Fentanyl 25 μg (0.5 ml) with 0.5% Bupivacaine (3 ml) in Group R and Fentanyl 25 μg (0.5 ml) with 0.75% Ropivacaine (3 ml) in Group B. The literature suggest that fentanyl in the doses from 10-25 mcg is safe and provides prolonged analgesia without having any impact on motor block. Hence in our study we had combined a dose of 25 μg of fentanyl with bupivacaine and ropivacaine.[14-16]

In our study, we observed the mean onset of sensory block was delayed in Group B (7.16± 0.74) as compared to Group R (5.40± 0.76 min) (p value <0.01) which was statistically highly significant, however, the duration of sensory block was longer in Group B (217.71±20.59 minutes) as compared to Group R (137.43±19.26 minutes) which was also statistically highly significant. (p<0.01). Koltka K et al. (2009) observed that mean time onset of sensory blockade was 10±4.5 minutes in Group B and 9±4.0 minutes in Group R. The duration of sensory block was 185±40 minutes and 160±40 minutes in Group B and Group R respectively.

In our study, the mean time to onset of motor block was shorter in Group R (5.86±0.69 minutes) as compared to Group B (7.91±0.70 mins) which was statistically highly significant (p<0.01). The mean duration of motor block was longer in Group B (193.71±18.48 minutes) as compared to Group R (121.71±15.81 minutes) which was statistically highly significant (p<0.01). The result of the following studies are comparable to our study: Koltka K et al. (2009) observed that mean time onset of motor blockade was comparable in both the groups. However, the duration of motor block was 182±46 minutes was significantly longer in Group B as compared to Group R 139±39.[10] Jagtap S et al. (2014) observed that mean onset time of motor blockade was 6.02±2.1 minutes in Group B and 6±3.6 minutes in Group R. The duration of motor block was 242.8±47.06 minutes and 268±49.9 minutes in Group B and Group R respectively.[11] This was in constrast to our study that onset of motor block in Group R is delayed or equivalent as compared to Group B.

In our study, the mean duration of analgesia was prolonged in Group B (427.43 ± 44.28 min) as compared to group R (305.43 ± 28.63 minutes) which was statistically highly significant (p<0.0001). This is comparable to the studies done by Jatap S et al. and Saran et al.

Study by Varun S et al. was in contrast to our study in onset of analgesia that in Group R is delayed or equivalent as compared to Group B. We observed that there was no statistically significant change in mean pulse rate, systolic blood pressure as well as diastolic blood pressure in both groups intraoperatively and postoperatively in the present study. (p>0.05).[8] Jagtap S et al. (2014), Layek A et al. (2015), Padmanabhan K. R. et al. (2016) also did not observe change in mean vital parameter.[11-13]

In our study, intraoperatively, 8 patients in Group B and 5 patients in Group R developed hypotension while 2 patients in Group B and 3 patients in Group R developed bradycardia. None of the patient developed postoperative nausea, vomiting, rigors or hypotension. Overall the safety profile was comparable. Koltka K et al. (2009) observed bradycardia in 8% patients in bupivacaine group and 12% patients in ropivacaine group.[10] It was concluded by Jagtap S et al. (2014) that bradycardia occurs in 3.3% population in both the groups. Similarly, there was hypotension in 3.3% patients in ropivacaine group and 10% patients in bupivacaine group.[11] On the contrary, Layek A et al. (2015) did not observe any incidence of bradycardia or hypotension.[12]

Conclusion

Bupivacaine-fentanyl combination produces a longer duration of analgesia, sensory block and motor block than ropivacaine-fentanyl combination. Shorter duration of motor block with ropivacaine allows for early ambulation, voiding and physiotherapy therefore it is preferred in day care surgeries with shorter hospital stay.

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Evaluation of Predictors for Difficult Laryngoscopy and Intubation in Pediatric Population

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Abstract

Background: Airway management is very essential in medical speciality, difficulty in airway access can lead to hypoxic brain damage, cardiac arrest and even death or morbidity. A difficult airway in pediatric airway examination can be stressful condition for all involved. Hence in order to avoid the morbidity and mortality it is essential to evaluate airway in preoperative examination and identify potentially difficult airway. In order to find the predictors of difficult airway we conducted a study in 200 patients with age limit of 3-6 years scheduled for elective surgeries under general anesthesia. We studied the following tests: Interincisor distance (IID), MMC (Modified Mallampati classification), Thyromental distance (TMD) and CLG (Cormack Lehane Grade). We correlated EVL (easy visualization of larynx) CLG I, IIa, IIb and DVL (difficult visualization) CLG III, IV with above parameters. It was observed that there was no such difference in EVL and DVL with IID, MMC and TMD. While MMC-I showed statistically significant difference between EVL and DVL. Sensitivity of TMD was 84.69% and specificity was 98.5%. with MMC.

Conclusion: Thyromental distance was good predictor for difficult laryngoscopy and intubation.

Keywords: Pediatric population; Difficult airway predictors.

Introduction

The training of airway examination is emphasized in anesthesia practice and when visualization of anatomic structures of the airway becomes difficult; more scientific approach of its evaluation and management becomes necessary[1] unexpected difficulty with intubation is an important cause of morbidity and mortality. One of the reason for anesthesia related cardiac arrest, death and brain injury in healthy children is due to difficulty in airway management.[2,3] In order to avoid complications there are multiple tests for prediction of difficult airway which can be used preoperatively.

The skills of airway management are important in every medical speciality. Respiratory events like inadequate ventilation, oesophageal intubation and difficult tracheal intubation are common in clinical practice of anesthesiology.[4]

Difficult airway in pediatric patient can be a stressful situation.[5] Examination of airway in pediatric population using predefined parameters during pre anesthetic checkup may help us to recognize difficult airway.[6]

Anatomic differences are observed according to age, most of the studies are carried out in adults, as pediatric patients are uncooperative and lack of observation in airway examination, may indicate

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the need of more studies in pediatric airway assessment.[7]

Although forecasting and predicting is tough, in view of complications, considerable amount of focus has been given to predict difficult intubation in patients.

Preoperative airway assessment in pediatric age group is an essential parameter to anticipate difficult airway and intubation, in order to avoid complication.[8] Until now there has not been a single unique observation to predict a difficult airway.

Aim was to evaluate predictors for difficult laryngoscopy and intubation in pediatric population. Following parameters were studied: Inter Incisor Distance (IID), Modified Mallampati classification (MMC), Thyromental Distance (TMD) and Cormack Lehane Grade during Laryngoscopy (CLG).

Material and Methods

An observational cross sectional study was conducted, after taking approval of ethical committee, in ASAI/II/III pediatric patient of either sex between 3-6 years scheduled to undergo elective surgery under general anesthesia. We included children between 3-6 years of age belonging to ASA-I,II,III. Children with congenital upper airway malformations, swelling in head and neck regions, scars around oral cavity and neck, mentally challenged and obese children were excluded. Informed consent was taken from parents/guardians of the children. A detailed preoperative history especially with reference to airway was recorded. Standard airway examination including:

- Interincisor Distance: Distance between upper and lower teeth in centimeters(cms)
- Modified Mallampati Class: seen after opening of mouth and protrusion of tongue.
- Thyromental Distance: Distance from mentum to thyroid cartilage (cms)
- Cormack Lehane Grading noted after laryngoscopy

The patient was taken in the operation theater after standard protocol of pre medication. Monitors were attached & IV line secured. Patients were premedicated prior to surgery. Patient taken into operation theater and injection Ondensatron 2 mg and injection Fentanyl (1.5 mcg/kg) given. Patient was preoxygentated with 100% oxygen for 3 to 4 mins. Under effect of Succinylcholine 2 mg/kg, patient was ventilated with 100% oxygen and laryngoscopy was performed and Cormack Lehane Grade was noted. Patient was intubated using an uncuffed Endotracheal Tube (ETT) appropriate for age, by senior anesthesiologist. Noninvasive blood pressure, ECG, temperature and SpO_2 were monitored throughout the procedure. Anesthesia was maintained as per requirement of surgery following which patient was reversed and extubated and then shifted to postoperative room.

The entire data is statistically analyzed using Statistical Package for Social Sciences (SPSS ver 21.0, IBM Corporation, USA) for MS Windows.

Obeservation and Results

Table 1: Distribution of cases according to Cormack Lehane Grading

Cormack Lehane Grading	No. of cases	% of cases
I	120	60.0
IIA	61	30.5
IIB	15	7.5
III	4	2.0
Total	200	100.0

Table 2: Distribution of cases according to difficulty level.

Visualization score	Status	No. of cases	% of cases
I to IIB	Easy	196	98.0
III	Difficult	4	2.0
Total	–	100	100.0

Table 3: Distribution of mean age according to Cormack Lehane Grading.

	Cormack Lehane Grade				P-value
	Easy (n=196)		Difficult (n=4)		
	Mean	SD	Mean	SD	
Age (years)	4.41	1.15	3.50	1.00	0.116^{NS}

P-values by independent sample t test. P-value <0.05 is considered to be statistically significant. NS-Statistically non-significant.

Table 4: The sex distribution of cases studied according to visualization difficulty score.

	Visualization Difficulty Score				P-value
	Easy (n=196)		Difficult (n=4)		
Sex	n	%	n	%	
Male	132	67.3	1	25.0	0.110^{NS}
Female	64	32.7	3	75.0	
Total	196	100.0	4	100.0	

P-values by Chi-Square test (Fisher's exact probability test). P-value <0.05 is considered to be statistically significant. NS-Statistically non-significant.

Table 5: Distribution of means of various bed side parameters inter-incisor distance (IID) and thyromental distance (TMD) according to Cormack Lehane Grade

	Cormack Lehane Grade				P-value
	Easy (n=196)		Difficult (n=4)		
Parameters	Mean	SD	Mean	SD	
IID (cm)	3.19	0.40	3.32	0.54	0.513^{NS}
TMD (cm)	4.66	0.52	4.50	0.67	0.535^{NS}

P-values by independent sample t test. P-value <0.05 is considered to be statistically significant. NS-Statistically non-significant.

Table 6: The distribution of modified Mallampati class among the cases studied according to Cormack Lehne Grade

	Cormack Lehane Grade				P-value
	Easy (n=196)		Difficult (n=4)		
Mallampati class	n	%	n	%	
I	168	85.7	3	75.0	0.003**
II	25	12.8	0	0.0	
III	3	1.5	1	25.0	
Total	196	100.0	4	100.0	

P-values by Chi-Square test (Fisher's exact probability test). P-value <0.05 is considered to be statistically significant. **P-value<0.01.

Table 7: Distribution of area under the ROC curves (AUC) for all bed side parameters studied inter-incisor distance (IID) and thyromental distance (TMD) for the prediction of difficult Visualization score.

Parameter	Optimal Cut-Off Based on ROC	AUC ± SE	95% CI of AUC	P-value
IID (cm)	3.05 cm	0.447±0.168	0.118–0.776	0.717^{NS}
TMD (cm)	4.05 cm	0.595±0.170	0.261–0.929	0.516^{NS}
Modified Mallampati Class	II	0.570±0.164	0.249–0.890	0.634^{NS}

NS - P-value>0.05 (Statistically non-significant). Reference value = 0.500. SE – Standard Error.

Table 7 shows the result of receiver operating characteristics (ROC) curve analysis in predicting the difficult visualization. The distribution of area under the curve (AUC) did not differ significantly for IID, TMD and modified mallampati class (MMC) for the prediction of difficult Visualization score from the reference value of 0.500 (P-value >0.05 for all). Based on the ROC analysis, the optimal cut-offs of IID, TMD and MMC measurements for the prediction of difficult Visualization score is 3.05 cm, 4.05 cm and II respectively with area under the curves being 0.447, 0.595 and 0.570 respectively.

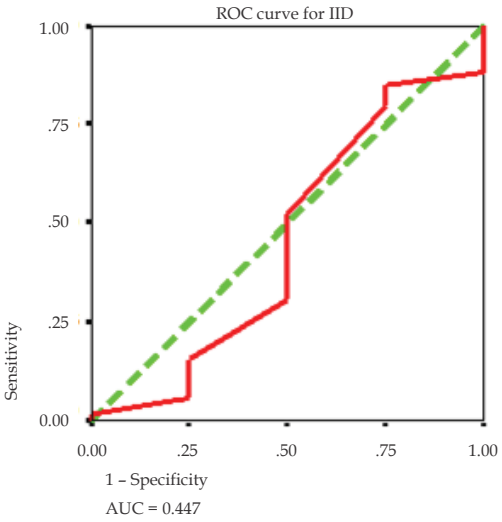

Fig. 7.1: Receiver operating characteristic (ROC) analysis for IID. Dotted line is a reference line

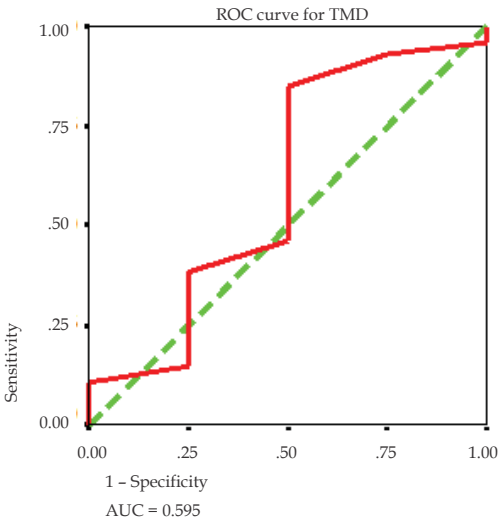

Fig. 7.2: Receiver operating characteristic (ROC) analysis for thyromental distance (TMD), dotted line is a reference line.

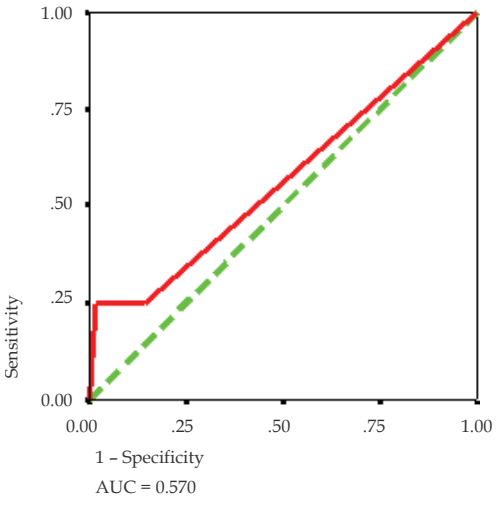

Fig. 7.3: Receiver operating characteristic (ROC) analysis for Modified mallampati score, dotted line is a reference line.

Table 8: The distribution of measures of diagnostic efficacy measures of various bed side parameters [Sensitivity and Specificity] for the prediction Cormack Lehane Grade.

Parameters (Cut-off)	Sensitivity (%)	Specificity (%)
IID (cm) (>3.05 cm)	52.04	50.00
TMD (cm) (<4.05 cm)	84.69	50.00
MMC (>II)	25.00	98.50

There was no statistically significant correlation between Modified Cormack Lehane Grading and other parameters except Modified Mallampati Class which differs significantly between easy and difficult visualization groups (p-value <0.01).

Discussion

The airway management remains an important challenge for anesthesiologist and proper preoperative assessment enables us to take appropriate measures during difficult intubation. We conducted the study in 200 patients of both the sexes, the age between 3-6 years and ASA Grade I,II,III. We observed Interincisor distance (IID), Modified Mallampati Class (MMC), Thyromental distance(TMD) and Cormack Lehane group(CLG).

In our study age, sex and ASA distribution was statistically insignificant. In CLG distribution of grades was as follows: 60% of cases- GradeI, 38% Grade IIA/IIB, 2% grade III. None of the patient had grade IV. EVL was seen in 98% of the cases and DVL in 2%.

The bedside tests IID and TMD were not statistically significant with easy and difficult visualisation in our observation. Similarly NB Rafique[1] observed that mean TMD did not differ between EVL and DVL in our observation. While Krobbuaban et al. stated the IID was not a predictor of difficult laryngoscopy and visualisation, but he also said that ratio of height to TMD had higher sensitivity and the study was conducted in adults which cannot be correlated with pediatric population.

The MMC distribution in our study was observed to be statistically significant. In Class I of MMC, EVL was in 168 cases while DVL was seen in 3 cases. While Class III had 3 cases of EVL and 1 case of DVL. But Lundstrom H[2] showed a good relation between Modified Mallampati Class and Cormack Lehane Grade in his study of pediatric age group, which is contradicting our study.

When specificity and sensitivity were studied with IID, TMD, MMC. TMD was more sensitive with 84.69% while MMC was more specific with 98.5%. Similarly Shiga et al.[3] suggested that the most useful bedside test for prediction was found to be combination of the Mallampati classification and Thyromental distance. Frek et al.[4] also stated that when Thyromental distance and Modified Mallampati Class were combined they have greater sensitivity and specificity which is similar to our study, but when used alone they were poor predictors. In contrast, the combination of MMT and TMD was not an adequate predictor of a difficult intubation in a study by Koh et al.[5]

The study by Bhavdip P et al.[6] stated that MMC alone is not a good predictor of difficult intubation in adults, when TMD and SMD were added to MMC for preoperative assessment prediction was improved. This is not good test in children because of continous growth and increasing height.

We considered sensitivity the most important parameter as our target was to identify more number of difficult intubation cases to avoid the potentially serious outcome of unanticipated difficult tracheal intubation. There are no routine tests to assess airway preoperatively in pediatric population and are several limitations as the incidence of difficult airway in pediatric population is very rare, unless there is a dysmorphic feature. The sample size of study population is very small so we could not reach a conclusion with above said tests.

Summary and Conclusion

The present study was conducted in 200 patients between 3-6 years age, of ASA Grade I, II and III undergoing elective surgeries. Preoperatively all the patients were assessed for IID, TMD and MMC. After standard induction protocol, laryngoscopy was performed under effect of muscle relaxant and laryngoscopic view was assessed by Cormack Lehane Grading. Later preoperative assessment of above mention parameters were compared with EVL and DVL of larynx with Cormack Lehane's grading. Sensitivity of TMD was 84.69% and Specificity of MMC was 98.5%. Following observations:

1. Thyromental Distance is a good predictor for difficult laryngoscopy and intubation in pediatric age group.
2. Multiple bed side parameters when combined together have better results than when used alone.

Ongoing future researches will be required to determine the algorithm for prediction of difficult airway in pediatric population. The anesthesiologist must be prepared with multiple predefined practical plans for unanticipated difficult airway management in children.

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Efficacy of Dexmedetomidine in Supraclavicular Brachial Plexus Block with 0.5% Ropivacaine hydrochloride

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Abstract

In the present study, 100 patients of ASA Grade I and II between age group of 20-65 years of weight range 40-70 kg were included. These 100 patients were divided into 2 equal groups of 50 patients each according to the drugs administered for brachial plexus block. Group A control group received 30 ml of Ropivacaine 0.5% with 0.5 ml of normal saline and Group B patients received 30 ml Ropivacaine 0.5% with Dexmedetomidine 50 µgm 0.5 ml for brachial plexus block. Intravenous infusion line was set up and all patients were monitored throughout intraoperative period and observed for changes in pulse rate, blood pressure, respiration and any untoward effects.

It was observed that, the onset of motor and sensory block was significantly quicker in Group B (study group) as compared to Group A (control group). The duration of motor blockade and sensory blockade was significantly longer in Group B patients as compared to Group A patients. The quality of sensory blockade was excellent in Group B patients and satisfactory in Group A patients. The duration of postoperative analgesia was significantly more prolonged in Group B patients as compared to Group A patients. There were no significant changes in mean pulse rate and mean arterial pressure at various time intervals in both groups during intraoperative and postoperative period. There were no dreadful complications in any patients during intraoperative and postoperative period in both groups.

Keywords: Dexmedetomidine; Supraclavicular; 0.5% Ropivacaine hydrochloride.

Introduction

Many times peripheral nerve blocks provide ideal operative conditions and desired prolonged postoperative analgesia without any significant systemic side effects. These techniques offer an excellent alternative for patients with compromised hemodynamic status or where general anesthesia is relatively at greater risk.

Most of the upper limb orthopaedic and plastic reconstructive surgeries are being performed under regional blocks. Brachial plexus block provide adequate intraoperative anesthesia, prevents untoward side effects of endotracheal anesthesia, preserves mental functions and provides better intraoperative profile, uneventful recovery and effective postoperative analgesia.

Brachial plexus is usually approached by interscalene, supraclavicular, infraclavicular and axillary routes. Supraclavicular approach is associated with a rapid onset of action, easy technique and higher success rate. The first supraclavicular brachial plexus block was performed by Kulenkampff in 1920. Ultrasound

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guided brachial plexus block is safest in recent era.[22,45,33,9,10]

Lignocaine hydrochloride had been common local anesthetic agent, now almost not in practice due to its side effects of central neuraxial complications. Bupivacaine hydrochloride being most commonly accepted local anesthetic agent for regional techniques of anesthesia Bupivacaine has prolonged duration of action combined with its high quality sensory block relative to motor block. Some cardiac toxicity compelled for better choice of local anesthetic agent. Levo Bupivacaine was also tried in between for some years[3,8,9,15,48]. Ropivacaine hydrochloride is newer local anesthetic with longer duration of action, with many similarities with Bupivacaine, wider safety margin and with less cardio-toxicity.[41,33,27,40]

Various adjuvants have been tried with local anesthetic agents to potentiate the action, to prolong the duration of action in view of reducing the side effects of each other. Adrenaline, Neostigmine, Ketamine, opioids, clonidine and new one Dexmedetomidine.[3,5,8,13,29,27] These are commonly used adjuvants along with local anesthetic agents.

Dexmedetomidine, a pharmacologically active dextroisomer of medetomide is a sedative α_2 adreno-receptor agonist used as an adjuvant during regional and local anesthesia techniques. It has an α_2 and α_1 selectivity ratio which is eight times more potent than clonidine.[9,10] It has shorter half life of 2-3 hours as compared to 12-14 hours of clonidine[11]. It has desired sedative action without respiratory depression. It has potent analgesia sparing effect, reducing the opioid requirement perioperatively.[15,20,38,42,11]

The present study was undertaken to evaluate the efficacy of Dexmedetomidine when given along with Ropivacaine in supraclavicular brachial plexus block in respect to onset of sensory and motor block, duration of motor and sensory block, quality of block, total duration of postoperative analgesia, hemodynamic stability and intra and postoperative complications.

Material and Methods

In the present study, 100 patients of either sex with age range of 20-65 years, weighing 40-70 kg of ASA grade I and II posted for upper limb surgeries were selected. The patients with neuromuscular disorders, coagulopathy, extremes of age, pregnancy, etc were excluded from the study. These 100 patients were divided into 2 equal groups of 50 patients each. Group A patients received Ropivacaine 0.5% 30 ml with 0.5 ml normal saline and group B received Ropivacaine 0.5% 30 ml with Dexmedetomidine 50 µgm in 0.5 ml for brachial plexus block. All patients were preanesthetically evaluated for fitness of anesthesia and necessary investigations were carried out. After college ethical committee approval, informed valid consent was obtained from every patient.

After securing intravenous infusion line on opposite side of block, all standard monitoring devices were attached. Under all aseptic precautions, after cleaning and draping, supraclavicular brachial plexus block was instituted and mixture of Ropivacaine was infiltrated by fan like in supraclavicular region. All the patients were monitored throughout the procedure for development of any complications related to technique of block or drugs administered. Intraoperatively the changes in pulse arte blood pressure, oxygen saturation were recorded at regular interval intraoperatively as well up to 12-18 hours postoperatively.

In all patients, the onset motor block, onset of sensory block, duration of motor and sensory block, quality of sensory block, muscle relaxation, total duration of surgery, duration of postoperative analgesia, intraoperatively changes in mean pulse rate, mean arterial pressure were monitored and noted. All patients were observed for intraoperative and postoperative complications. All observations were statistically evaluated for its significance.

Observations

Out of 100 patients, there were about 75-76% male patients and 24-25% female patients in both groups. Mean age range was 35.88±10.74 years in Group B and 35.78±9.47 years in group a patients. The weight range was 57.0±6.11 kg in Group B and 56.24±5.22 kg in Group B patients. These patients were posted for various operative procedures as shown in Table 1.

Table 1: Showing various operative procedures

	Group A		Group B	
Diagnosis	**Number**	**Percentage**	**Number**	**Percentage**
# Both bones	23	46%	25	50%
# Galezzi	13	26%	14	28%
# Radius	8	16%	6	12%
# Ulna	4	8%	3	6%
P/O/C # Radius	2	4%	2	4%
Total	50	100%	50	100%

There were maximum number of patients having # both bones in both groups followed by # Galezzi, # radius and # ulna.

These patients were posted for following operative procedures as shown in Table 2.

Table 2: Showing Operative Procedures

Operative procedures	Group A	Group B
C & IF with nailing	27	25
Implant Removal	2	2
ORIF plating	21	20
Total	50	50

Mean onset of sensory was assessed by pin prick test at each minute after the completion of block in dermal areas of median nerve, ulnar, radial and musculo-cutaneous nerves. It was assessed as 0 – normal sensation, 1 as loss of sensation (analgesia) and 2s loss of touch sensation (anesthesia). Mean onset of sensory block was noted as shown in Table 3.

Table 3: Showing Mean Onset of Sensory Block

	Group B	Group A
Onset of Sensory block in minutes	16.47 ± 3.0	10.12 ± 2.83
	t = 10.788, p <0.002 HS	

The mean onset of sensory block was 10.12±2.83 minutes in Group A patients and 16.42±3.0 minutes in Group B patients. The onset of sensory block was significantly quicker in Group B as compared to Group A patients.

The mean onset of motor block was noted as the time from administration of drug to time required for complete motor block (Grade II) where motor block was assessed as 0 – normal motor functions, 1 – ability to move only fingers and 2 – inability to move elbow joint. It was as shown in Table 4.

Table 4: Showing Mean Onset of Motor Block

	Group A	Group B
Onset of Motor block in minutes	23.22 ± 2.54	17.14 ± 3.49
	t = - 9.962, p < 0.001 HS	

The mean onset of motor block was 23.22±2.54 minutes in group A and 17.14±3.49 minutes in Group B patients. The mean onset of motor block was significantly quicker in Group B patients as compared to Group A patients.

Mean duration sensory block was noted as the time from administration of drug to time required to complete resolution of local anesthetic drug action. It was as shown in Table 5.

Table 5: Showing Mean Duration of Sensory Block

	Group A	Group B
Mean Duration of Sensory Block in minutes	531.5 ± 37.45	700.8 ± 20.39
	t = - 28.077, p < 0.001 HS	

Mean duration of sensory block was 700.8 ± 20.39 minutes in Group B patients as compared to 531.5 ± 37.45 minutes in Group A patients. The duration of sensory block was significantly longer in Group B patients as compared to Group A patients.

Mean duration of motor block was assessed as the time from administration of drug to time required for complete recovery of motor function. It was noted as shown in Table 6.

Table 6: Showing Mean Duration of Motor Block

	Group A	Group B
Mean Duration of Motor Block in minutes	441.8 ± 40.04	612.1 ± 14.95
	t = - 28.178, p < 0.001 HS	

Mean duration of motor block was 441.8 ± 40.04 minutes in group A and 612.1 ± 14.95 minutes in group B patients. The mean duration of motor block was significantly more in group B patients as compared to group A patients.

The mean duration of sensory block was significantly more in both groups as compared to mean duration of motor block. Thus in group B there is prolonged duration of postoperative analgesia than group B patients.

Mean duration of operative procedure was noted as the time from surgical incision to time taken up to skin closure, It was as shown in Table 7.

Table 7: Showing Mean Duration of Operative Procedure

	Group A	Group B
Mean Duration of Operative procedure in minutes	105.8 ± 18.93	105.9 ± 17.22
	t = - 0.228, p < 0.05 NS	

Mean duration of operative procedure was approximately identical in both groups and there was no statistical significant difference.

The quality of supraclavicular plexus block was assessed and noted in both groups. Quality of block was assessed as 0 – complete failure, 1 – unsatisfactory block and 2 – satisfactory block. It was as shown in Table 8.

Table 8: Showing Quality of Block

	Group A	Group B
Quality of Block	1.91 ± 0.3	1.96 ± 0.2
	t = - 28.178, p < 0.001 HS	

The quality of block was satisfactory in both groups and failure of block patients were not included in the study. So the findings were not statistically significant.

The adequacy of the block or postoperative analgesia was assessed with visual analogue scale

(0-10) in both groups. 0 – No pain, 2 – annoying (mild pain), 4 – uncomfortable (moderate pain), 6 – dreadful (severe pain), 8 – horrible (very severe pain) and 10 – agonizing (not able to perform surgery.

Table 9: Showing Visual analogue scale

	Group A	Group B
Mean Duration of Motor Block in minutes	2.68 ± 0.47	2.7 ± 0.46
	t = - 0.214, p < 0.05 HS	

Most of the patients were having either no pain or very mild pain in both groups. The findings were not statistically significant.

In all patients, mean pulse rate was monitored and was noted as preoperative, every 5-10 minutes up to 30 minutes, at 15, 30 ad 60 minutes intervals intraoperatively and postoperatively for 6 hours. Throughout intraoperative period, mean pulse rate was almost stable in both groups at various time intervals.

In both groups, mean arterial pressure at above time intervals during intraoperative postoperative period was noted. There was no statistically significant difference in mean arterial pressure at various time intervals intraoperatively as well as postoperatively in both groups. Thus hemodynamic stability was noted in both groups intraoperative and postoperative period. Respiratory rate and arterial oxygen saturation were maintained in both group patients throughout intra and postoperative period.

There were no any intraoperative or postoperative complications during administration of block or drugs administered in any patients.

Discussion

Supraclavicular brachial plexus block is being accepted regional anesthesia technique for upper limb orthopaedic or general surgery operative procedures in recent era.[12,21,47,44,33] For regional anesthesia Lignocaine hydrochloride, Bupivacaine hydrochloride, levoBupivacaine and now Ropivacaine are usually preferred. Lignocaine hydrochloride being blamed for transient neurotoxicity and bupivacaine having cardiotoxicity[6] hence not in common practice. Ropivacaine with less cardiovascular and neurotoxicity as compared to Lignocaine and bupivacaine is being tried in regional anesthesia techniques.[7,6,16] Ropivacaine is less potent than bupivacaine and levobupivacaine at lower doses. Ropivacaine 0.75% has significantly faster sensory and motor onset of action than 0.5% bupivacaine.[8,16,26,30,20] In 0.5% concentration in dose of 30 ml has less toxicity and efficient early sensory and motor onset of action in various regional blocks.[2,3]

McGlade et al.[107], Casali et al.[108], Riazi et al.[109] have tried Ropivacaine 0.5% for brachial plexus block in their studies. As like these authors we have also used 0.5% Ropivacaine for brachial plexus block. For improved quality of block and prolonged postoperative analgesia was obtained by adding various pharmacological agents to local anesthetic solutions noted by Damin B Murphy, Colin J L, M C Cartery and Vincient W S (2000).[22,23,46,37,33] They emphasized the efficacy of adding analgesic adjuvants as opioids, clonidine neostigmine, Tramadol to brachial plexus block. They noted that analgesic benefits of opioids adjuvants remain equivocal. Dexmedetomidine acts as a selective α_2 adrenoreceptor agonist. There is increased ratio or α_2 and α_1 activity of 1620:1 with Dexmedetomidine as compared to 220:1 with clonidine. In dose of 1 μgm/kg it is equipotent and beneficial[97] Brummet [20,21,22] showed that Dexmedetomidine prolonged the duration of nerve block when added to Ropivacaine in dose dependent manner. Obayhand et al. (2000)[11], Marhofer et al. (2012)[48], Rancourt et al. (2012)[11] many other authors have used Dexmedetomidine 0.5-1 μgm/kg as adjuvant to local anesthetic agent Bupivacaine, Levo Bupivacaine or Ropivacaine in regional blocks. Many of these authors have observed early onset of action (sensory and motor) and prolonged duration of analgesia and complete sensory and motor blocks in their studies. As compared to these authors, we have also noted significantly quicker onset of sensory and motor blockade in Dexmedetomidine group as compared to plane group in brachial plexus block. Our observations coincide with Esmaoglu et al.[2], Ohayag et al.[11], K Kaygusuz et al.[10], A S Ammare et al.[49], Sandhya Agrewal[4,2], A P Singh[14], etc. There were similar findings as quicker onset of sensory and motor block.

In the present study, the duration of sensory blockade was 700±20.39 minutes in study group and 531.50±37.45 minutes in plane group. There was stastically significant prolonged duration of sensory block in study group as compared to control or plane group. The duration of motor blockade was also significantly longer in study group as compared to control group. These observations were similar to the observations of many above authors in their respective studies. As like Rachana Gandhi et al.[10] we have noted prolonged duration of sensory and motor blockade. It was on the basis that larger fibers require higher concentration

of local anesthetic agents than small fibers. The minimum effective concentration of local anesthetic required for large motor fibers was greater than small sensory fibers.[35,42,44] So motor functions return before pain perception and duration of motor block was shorter than sensory block.[20,43,37] It is particularly beneficial in lower extremity blocks for day care surgery so that early ambulation and early discharge of the patient from hospital.

There were minimum changes in hemodynamic parameters as mean pulse rate, mean arterial pressure at various time intervals intraoperatively as well as postoperatively in both groups. Thus Dexmedetomidine with local anesthetic is safe adjuvant for hemodynamic stability during regional anesthesia techniques. With higher concentration of drugs, there may be decrease in heart rate and mean arterial pressure which may be seen secondary to systemic absorption of Dexmedetomidine.[9–11] Presynaptic activation of α_2 adreno-receptors in central nervous system inhibits release of norepinephrine, terminating prolongation of pain signals and their postsynaptic activation. Para Sympathetic activity reduces heart rate and blood pressure. Transient hypertensive response may be encountered with dose of 1-4 µgm/kg attributed to initial stimulation of β_2 receptors in vascular smooth muscles. Bradycardia is a reflex response to transient response ad it persists subsequently due to central sympathetic inhibition.[49,39] Baroreceptor reflex and heart rate response to presser agents is well preserved with Dexmedetomidine, which is responsible for hemodynamic stability.[21,19,28]

There was prolonged and satisfactory duration of postoperative analgesia in both groups and it was more study in study group as compared to control group. The quality of sensory and motor blockade was comparable in both groups and these were in accordance with above many authors. There were no dreadful intraoperative as well as postoperative complications related to the drugs or technique of anesthesia in both groups.

Summary

In the present study, 100 patients of ASA grade I and II between age group of 20-65 years of weight range 40-70 kg were included. All patients were preanesthetically evaluated and investigated for fitness of anesthesia. These 100 patients were divided into 2 equal groups of 50 patients each according to the drugs administered for brachial plexus block. Group A control group received 30 ml of Ropivacaine 0.5% with 0.5 ml of normal saline and group B patients received 30 ml Ropivacaine 0.5% with Dexmedetomidine 50 µgm 0.5 ml for brachial plexus block. Under all aseptic precautions supraclavicular brachial block by infiltrating the drug was administered according to group allocated. All emergency drugs and trolley was kept ready. Intravenous infusion line was set up and all patients were monitored throughout intraoperative period and observed for changes in pulse rate, blood pressure, respiration and any untoward effects.

After the completion of block, onset of sensory and motor block, duration of sensory and motor block, duration of surgery, quality of sensory block, and total duration of analgesia was noted in all patients of both groups. Intraoperative and postoperative complications related to the technique of anesthesia and drugs were observed in both groups.

It was observed that, the onset of motor and sensory block was significantly quicker in group B (study group) as compared to group A (control group). The duration of motor blockade and sensory blockade was significantly longer in group B patients as compared to group A patients. The quality of sensory blockade was excellent in group B patients and satisfactory in group A patients. The duration of postoperative analgesia was significantly more prolonged in group B patients as compared to group A patients. There were no significant changes in mean pulse rate and mean arterial pressure at various time intervals in both groups during intraoperative and postoperative period. There were no dreadful complications in any patients during intraoperative and postoperative period in both groups.

Conclusions

Supraclavicular brachial plexus block is accepted technique of anesthesia for upper limb orthopaedic or general surgery operative procedures. Ropivacaine hydrochloride 0.5% in dose of 25-30 ml is better alternative for brachial plexus block as replacement for 0.5% Bupivacaine hydrochloride. Addition of adjuvants Dexmedetomidine (50-100 µgm) along with Ropivacaine for brachial plexus block improves the quality of block and significantly prolongs the duration of postoperative analgesia. Ropivacaine 0.5% with Dexmedetomidine 50 µgm provides early onset of sensory and motor block, better quality of sensory block, prolonged duration of intraoperative duration of motor and sensory blockade and also prolongs the duration of postoperative analgesia without significant changes in hemodynamic parameters. There are

less chances of intraoperative and postoperative dreadful complications.

Hence addition of Dexmedetomidine with local anesthetic agent satisfies all the requirements of regional block particularly brachial plexus block in indicated patients. It can be safely administered in regular practice of anesthesia.

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Comparative Study of Isobaric Ropivacaine (0.75%) and Isobaric Ropivacaine (0.75%) with Adjuvants Clonidine and Dexmedetomidine Administered Intrathecally in Adult Patients Undergoing Lower Limb Surgeries

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Abstract

Spinal anesthesia is unparalleled in the way a small dose of local anesthetic, virtually devoid of systemic pharmacologic effect, can produce profound surgical anesthesia. The quality and duration of analgesia is improved when a local anesthetic is combined with alpha 2 adrenergic agonist. Here we evaluate the clinical effects of the adjuvants, α2 agonists-dexmedetomidine 5 mcg and clonidine 15 mcg in conjunction with intrathecal isobaric ropivacaine 0.75% for lower limb surgeries and assessing 1. The onset and duration of sensory block 2. The onset and duration of motor block 3. The duration of analgesia 4. Hemodynamic changes.

Material and Methods: Prospective study was done on patients undergoing lower limb surgeries under neuraxial block were split into three equivalent groups. Group RR: subjects received 3 ml of isobaric Ropivacaine 0.75% with sterile water 0.1 ml (total=3.1 ml), Group RC: subjects 3 ml isobaric Ropivacaine 0.75% with clonidine 15 mcg (total=3.1 ml), Group RD: subjects 3 ml isobaric Ropivacaine 0.75% with dexmedetomidine 5 mcg (total=3.1 ml).

Result: Statistical analysis shows significant difference in onset, duration of sensory and motor block and duration of analgesia among three Groups, Group RD, RC and RR. The time of onset of sensory, motor block was earlier and duration of sensory, motor block was longer and duration of analgesia (time to requirement of first rescue analgesic) prolonged in Group RD as compared to Group RC and Group RR.

Conclusion: Dexmedetomidine with isobaric ropivacaine 0.75% produces more rapid onset of sensory and motor block, prolonged duration of sensory and motor block and longer duration of analgesia than clonidine with isobaric ropivacaine 0.75% and isobaric ropivacaine 0.75% alone intrathecally.

Keywords: Ropivacaine; Clonidine; Dexmedetomidine; Sensory blockade; Motor blockade; Local anesthetic.

Introduction

Spinal anesthesia is a customary regional anesthetic technique, having a decent safety-efficacy profile in lower limb surgeries. There have been time and again efforts to improve its efficacy and utility even for longer duration surgeries. Ropivacaine, a amide local anesthetic, is considered to have a better tolerability profile for neuro-cardiovascular tissues and has been signaled as an alternative to bupivacaine. Hyperbaric ropivacaine though produces a more consistent nerve block than isobaric preparation, unavailability of commercial hyperbaric preparations have invited investigations on addition of adjuvant to isobaric ropivacaine to overcome its drawbacks.

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The alpha agonists like clonidine, dexmedetomidine and ephedrine, are assuming greater importance as anesthetic adjuvants to local anesthetics and opioids. Dexmedetomidine and clonidine owing to their alpha-2 adrenergic agonistic action has a synergistic effect on local anesthetics. They act by binding to pre synaptic C - fibers and postsynaptic dorsal horn neurons. Their analgesic action is a result of depression on the release of C - fiber neurotransmitters and hyper polarization of postsynaptic dorsal horn neurons. The prolongation of sensory effect of local anesthetics may result from synergism between local anesthetic and α2-adrenoceptor agonist, whereas the prolongation of the motor block may result from the attachment of α2-adrenoceptor agonists to motor neurons in the dorsal horn. Clonidine is a well established adjuvant to intrathecal local anesthetics. Dexmedetomidine has been used as adjuvant to spinal anesthetics in doses ranging from 3 to 10 µg in humans without any evidence of neurologic deficits after 2-week follow-up.

Materials and Methods

This study was conducted in Sri Venkateshwaraa Medical College Hospital and Research Centre after approval of the medical college ethical board and informed written consent was taken from all patients. A double blinded randomized clinical study was performed on ninety male and female adults patients (ASA-1&2), posted for upper limb surgeries during the period of December 2017 to January 2019. The randomization was made by envelope technique which was sealed one. Analysis of statistics was done with software SPSS V(23) and Anova was used to compare the means between Groups and p-value less than 0.05 was considered statistically significant. Prospective study by blinding both study performer and patients was done and patients undergoing elective lower limb surgeries were randomly divided into three equal Groups and each Group consisting of 30 subjects, *Group RR:* subjects received 3 ml of isobaric Ropivacaine 0.75% with sterile water 0.1 ml (total=3.1ml), *Group RC:* subjects 3 ml isobaric Ropivacaine 0.75% with clonidine 15 mcg (total=3.1 ml), *Group RD:* subjects 3 ml isobaric Ropivacaine 0.75% with dexmedetomidine 5 mcg (total=3.1 ml). Following parameters including 1.The onset and duration of sensory block 2. The onset and duration of motor block 3. The duration of analgesia 4. Hemodynamic changes (Pulse rate, SBP, DBP, RR, SpO_2) between three Groups were recorded.

Result

Statistical analysis shows significant difference in onset of S&M blockade (Table 1), high significance in duration of S&M blockade between RR, RC and RD groups (p=0.000) (Table 2). High Statistical significance was seen in analgesia duration (P=0.000) and duration till requirement of first rescue analgesia (p=0.0001) among RR, RC and RD groups (Table 3) this values are shown in tables below. No significant difference in HR, SBP, DBP (p>0.05) among three groups.

Table 1: Onset of sensory and motor block in three groups (Minutes)

Onset	Group (RR)	Group (RC)	Group (RD)	p-value
S- Block	7.58± 0.85 min	5.15± 0.99 min	3.56 ± 1.01 min	p-value=0.000
M- Block	11.23±1.79 min	8.07±1.18 min	3.56 ±1.10 min	p-value=0.000

S- sensory, M- motor

Table 2: Sensory and motor block duration in three groups

Duration	Group (RR)	Group (RC)	Group (RD)	p-value
S- Block	123.03±8.96 min	186± 12.27 min	219.53±16.34 min	p-value =0.000
M- Block	111.63±8.96 min	163.57±9.95 min	197.17±17.28 min	p-value =0.000

Table 3: Duration of analgesia and Rescue analgesia among three groups

Duration	Group (RR)	Group (RC)	Group (RD)	p-value
Duration of Analgesia	220.60± 7.16 min	330.23±13.95 min	364.80±15.37 min	p-value = 0.000
Time of Rescue Analgesia	220.60± 7.16 min	330.23±13.95 min	364.80±15.37 min	p-value = 0.000

Discussion

Spinal anesthesia is a customary regional anesthetic technique, having a decent safety-efficacy profile in lower limb surgeries. There have been time and again efforts to improve its efficacy and utility even for longer duration surgeries. Ropivacaine, a amide local anesthetic, is considered to have a better tolerability profile for neuro cardiovascular tissues and has been signalled as an alternative to bupivacaine.[10,11] Hyperbaric ropivacaine though produces a more consistent nerve block than isobaric preparation, unavailability of commercial hyperbaric preparations have invited investigations on addition of adjuvant to isobaric ropivacaine 0.75% to overcome its drawbacks. The alpha agonists like clonidine, dexmedetomidine and ephedrine, are assuming greater importance as anesthetic adjuvants to local anesthetics and opioids.[9] Dexmedetomidine and clonidine owing to their alpha-2 adrenergic agonistic action has a synergistic effect on local anesthetics.[12] Duration of S and M blockade was significantly extended in study done by Kujur S et al. 2012[1], Kanazi GE et al. in 2006[2], Gupta R et al. in 2011[3], Singh AK et al. in 2015[4], Al-Mustafa MM et al. in 2008[5], Ravipati P et al. in 2017.[6]

Dexmedetomidine is the recent drug which acts on α2-adrenergic receptors in the dorsal horn of the spinal cord to produce analgesic effects[7], Clonidine is a partial α2- adrenergic agonist used intrathecally, with a well established record of efficacy and safety. Dexmedetomidine action is mainly through the alpha 2 receptor which is adrenergic in nature.[8] The selectivity to this receptor is very high and acts as agonist. The activity at alpha 1 receptor and alpha 2 receptor is 1:220 times for clonidine and 1:1620 times for dexmedetomidine.

In our current study the time of onset of sensory, motor block was earlier and duration of sensory, motor block was longer and duration of analgesia (time to requirement of first rescue analgesic) prolonged in Group RD as compared to Group RC and Group RR. Among Group RC and Group RR, Group RC had earlier onset of sensory, motor block and longer duration of sensory, motor block and prolonged duration of analgesia. Among Group RC and Group RD, Group RD had earlier onset of sensory, motor block and longer duration of sensory, motor block and prolonged duration of analgesia.

Conclusion

Dexmedetomidine with isobaric ropivacaine 0.75% produces more rapid onset of sensory and motor block, prolonged duration of sensory and motor block and longer duration of analgesia than clonidine with isobaric ropivacaine 0.75% and isobaric ropivacaine 0.75% alone intrathecally. Both dexmedetomidine 5 mcg or Clonidine 15 mcg did not produces any significant hemodynamic instability or sedation. Hence we conclude that dexmedetomidine 5 mcg with isobaric ropivacine 0.75% is better a adjuvant than clonidine 15 mcg with isobaric ropivacine 0.75% and isobaric ropivacaine 0.75% alone intrathecally.

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A Prospective Study of the Impact of Hot Climate on Polytrauma Patients

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Abstract

Background: Climatic change is the biggest global health threat of the 21st century. It is widely recognized that extreme climatic conditions during summer months may constitute public health threat. Elderly persons, children & patients with chronic medical problems or poor physical reserves are particularly susceptible to heat related illness. Trauma is the overall leading cause of death in younger age group. Persons who are working outside in the fields are exposed to direct atmospheric heat via radiations from sun. The industrial workers get exposed to industrial pollution and high humidity levels which interfere with evaporation.

Aims and Objectives: We aimed to compare the incidence of complications and hospital stay in polytrauma patients during hot climate with comfortable temperature.

Material and Methods: A prospective study was undertaken to study the impact of hot climate on 100 polytrauma patients of age 20-70 yrs of either sex with moderate trauma (Trauma index score >8). Patients were grouped on the basis of peak outdoor temperature. Group I included the polytrauma patients when peak outdoor temperature ranged between 20-29°C (comfortable zone) and Group II included the polytrauma patients when peak outdoor temperature was >40°C. Fifty patients were enrolled in each group. To reduce the bias, inclusion and exclusion criterion were defined. Meteorological factors, patient characteristics, surgical procedures undertaken and other related data were noted.

Results: There was no statistically significant difference in relation to duration of hospital stay and complications among both groups. Mean duration of hospital stays (days) was 15.11±5.78 in group I and 17.14±7.61 in group II with p-value of 0.161. In group I, only 19 patients (38%) whereas in group II, 22(44%) patients had complications (p-value 0.271).

Conclusion: We did not find any statistically significant difference on hot climate as compared to comfortable temperature in 100 polytrauma adult patients. Four patients died during study period, one in group I and three in group II. All patients who died were high risk as per Shoe Maker's Risk Score and ASA physical status.

Keywords: Polytrauma; Peak outdoor temperature; Complications.

Introduction

It is widely recognized that extreme hot climatic conditions during summer months may constitute a public health hazard.[1] Heat related illness may range from trivial heat injury to life threatening emergencies.[2] Future climate scenarios suggest the higher global mean temperatures could lead to marked changes in the frequency of temperature extremes. Climate change is the biggest global health threat of the 21st century.[3] Ambient mean temperature is increasing globally by 0.07°C per decade.[4] As there is gradual global warming, the

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threat of intermittent heat wave on human life is increasing day by day. Epidemiological studies of mortality during summer in England, Belgium, USA, France, Czech, Spain and many other countries reported similar higher mortality during hot climate.[5–10]

Body temperature is regulated through a dynamic balance between heat production and heat loss. The regulatory mechanisms fail to work above the body temperature of 40°C or below 35°C resulting in multiorgan injury.[11] It has been reported that heat waves occurring in the spring or early summer often resulted in more deaths than heat waves occurring later in the summer.[12,13]

Epidemiological studies of heat related morbidity and mortality during heat wave suggest that elderly and young children are more vulnerable.[14] In our previous study conducted on elderly population during hot weathr found that hot and humid weather adversely affects the outcome in terms of prolonged hospital stay and complication rate in elderly surgical patients (>60 years).[2] Persons who are working outside in the fields are exposed to direct atmospheric heat via radiations from sun. The industrial workers get exposed to industrial pollution and high humidity levels which interfere with evaporation.

Although a lot of research have been carried out to evaluate effect of hot climatic conditions and its correlation with other medical conditions on morbidity and mortality yet only a few have been considered in trauma patients. Thus, we designed study to evaluate the impact of hot climatic conditions on perioperative complications and hospital stay in polytrauma patients during hot climatic conditions (peak outdoor temperature ≥40°C) and comfortable outdoor temperature (20°C-29°C).

Materials and Methods

This study was conducted in the Department of Anesthesiology and Resuscitation in a tertiary care hospital after approval from the institutional ethics committee. Informed consent was taken from all the patients. A Total of 100 polytrauma patients were enrolled, aged 20-70 yrs of either gender with moderate trauma (Trauma index score>8) belonging to ASA grade I-IV undergoing or not undergoing any surgical procedures under Anesthesia irrespective of patient's characteristic and socio-economic status, divided into two groups of 50 patients each. Patients were grouped on the basis of peak outdoor temperature.

Group I – 50 Polytrauma patients when peak outdoor temperature ranging between 20-29°C.

Group II - 50 Polytrauma patients when peak outdoor temperature ranging >40°C.

Daily data was collected from meteorological department, Punjab Agricultural University to enrol patients. We considered peak ambient temperature at the time of hospital admission as our reference point. To minimize the bias due to medical problems and adaptation of body in the air conditionedenvironment, the exclusion criterion was designed as follows:

- Patients who were reported after 24 hours of hospital admission, minor trauma (trauma index score <8), living in regular air-conditioned atmosphere (more than 18 hours per day).
- Patients suffering from hyperthyroidism, hypothyroidism and malignant hyperthermia, taking drugs interfering with temperature regulation -β blockers, anticholinergics, phenothiazines or other neuroleptic drugs.

Environmental record

Peak outdoor temperature, relative humidity and evaporation index was noted from Meteorological Department, Punjab Agricultural University, Ludhiana. Indoor temperature was noted in wards, where the patients were admitted. Humidex or heat index are the commonly used indices to study the effects of temperature and relative humidity. Heat index was derived from the above noted value with the formula given below:

Heat Index (HI)[9] or apparent temperature (AI)=

$-42.379 + 2.04901523\ (Tf) + 10.14333127\ (RH) - 0.22475541\ (Tf)\ (RH) - (6.83783 \times 10^{-3})\ (Tf^2) - ((5.481717 \times 10^{-2})\ (RH^2) + ((1.22874 \times 10^{-3})\ (Tf^2)\ (RH) + ((8.5282 \times 10^{-4})\ (Tf)\ (RH^2)) - ((1.99 \times 10^{-6})\ (Tf^2)\ (RH^2)$

Tf = Temperature in Fahrenheit

RH = Relative humidity

All patients included in the study were assessed clinically for symptoms and signs of heat related illness, past history of medical problems, injury details, economical status and drug intake history including alternative medicine. Socioeconomic status of patient was assessed using Kuppuswamy's socioeconomic status scale.[15] Patient's risk stratification was done on basis of ASA physical status[16], trauma index score[17] and Shoemaker's risk criteria.[18] If patient was undergoing surgery, then nature of surgery, operative procedure, duration, blood loss or any other adverse event was also recorded. Routine

investigations such as (hemoglobin, total leukocyte count, platelet count, packed cell volume, bleeding time, clotting time, prothrombin index, activated partial thromboplastin time, urine routine, random blood sugar, blood urea, serum creatinine, serum sodium, serum potassium, serum chloride, LFT, creatine phosphokinase and serum procalcitonin if done, chest X-rays etc) electrocardiogram were recorded. Any complications, sign of septicaemia (as evident from fever, increased WBC count or culture report), organ dysfunction during hospital stay were recorded along with the date and time of the episode. Outcome of patients was evaluated and compared in the form of incidence of complications, duration of hospital stays. Morbidity and clinical outcome variables were correlated with various risk factors and compared among both groups.

Statistical analysis

All the observations were noted in the proforma and analysed using student test, z-test & chi-square test for statistical significance. Stepwise multivariate regression analysis was used to compare the risk factors for morbidity.

Results

One hundred patients were enrolled in study with 50 in each weather. Patients in both groups were comparable with regards to their demographic characteristics, socioeconomic status, risk stratification based on ASA physical status,Shoe Maker's Risk Score (Table 1). Average age among groups I and II was 38.18±13.37 and 37.86±11.16 respectively. There were more males (92%) in both groups belonging to middle socioeconomic class II & III (76% in group I and 64% in group II, Fig. 1). Most of patients in both groups belonged to ASA classes I & II (Fig. 2). In group I, there were 7 patients in class IV, 5 patients in class V and none in class I. In group II, there were 11 patients in class IV, 7 in class V and none in class I.

In our study most of patients suffered from moderate degree of trauma (TIS 7-15) 86% group 1 and 78% in group II with mean trauma index score of 12.42±2.70 and 13.76±3.09 in group I and group II respectively with p-value 0.023 (Fig. 3). 7 patients in group I and 11 patients in group II had higher Trauma Index Score of 16-25. Patients mostly belonged to low risk shoemaker's score. Most of patients underwent surgery in both groups (92% in group I and 96% in group II). There was statistically significant difference in peak temperature, relative humidity and heat index among both groups (Table 2, Fig. 4). In group I, mean peak temperature was 26.05±2.71°C. Whereasin group II, it was 40.94±1.53°C (p-value 0.000). Mean relative humidity (%) in group I was 87.92±13.13 as compared to 46.34±10.68 in group II (p-value 0.000). Mean heat index in group II was 131.40±9.23 as compared to 83.38±11.35 in group I (p-value 0.000) There was no statistically significant difference in haematological and biochemical parameters in both groups. 76% patients in group I received blood transfusion compared to 68% in group II with p-value of 0.373.

No statistical difference was found among both groups in relation to hospital stay. Mean duration of hospital stays (days) was found to be 15.11 ±5.78 in group I and 17.14±7.61 in group II with p-value 0.161(Fig. 5). We found that 44% patients had complications in group II as compared to 38% patients in group I with p-value of 0.271 (Fig. 6). It was further seen that there were more complications related to infection (12%) and acute renal failure (10%) in group II as compared to group I, 6% and 4% respectively. The incidence of tachycardia and hypotension was comparable in both groups. In group I, 6% patients and in group II, 4% suffered from respiratory distress. In group II, one patient had liver dysfunction.

There was no statistically significant difference in complications among both groups in relation to ASA status, socioeconomic status and trauma index score (Fig. 7,8,9). But patients belonging to lower, lower middle and upper lower socioeconomic classes (classes III, IV&V) were found to have higher complications.

Both groups were comparable in relation to mortality rate (2% in group I and 6% in group II with p-value of 0.162, Table 3) In group II, one patient had pulmonary embolism and one had myocardial infarction. Two other patients, one in each group died because of cardiorespiratory arrest related to high risk stratification in relation to poor ASA physical status and high trauma index score.

Multiple logistic regression analysis was used to compare patients on the basis of age, gender, different heat variables, trauma index score and other surgical risk factors. Trauma Index Score and blood transfusions were found to be the risk factor for predicting perioperative complications with p-value of 0.001 (Table 4)

Table 1: Comparison of demographic parameters and risk score among two groups

Parameters	Group I	Group II	p-value
Age	38.18+-13.37	37.86+- 11.16	0.897
Male	46(92)	46(92)	NS
Female	4(8)	4(8)	NS
ASA I and II	37(74)	36(72)	0.732
Trauma index score	12.42+- 2.70	13.76+-3.09	0.023
Trauma index score 7-15	43(86)	39(78)	
Trauma index score 16-25	7(14)	11(22)	
Shoe Makers Risk Criteria Low Risk	47(94)	47(94)	NA
Shoe Makers Risk Criteria High Risk	3(6)	3(6)	NA

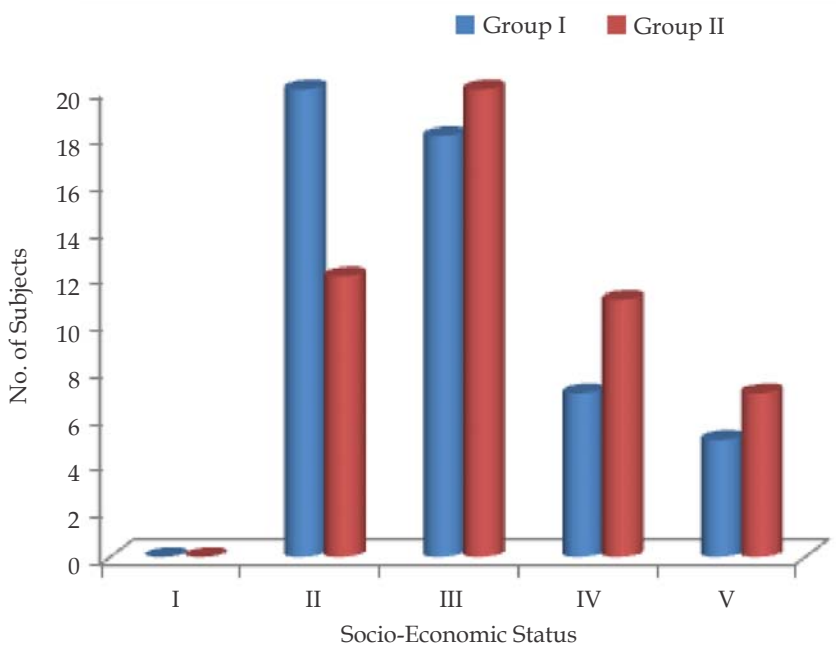

Fig. 1: Distribution of Subjects According to Socio-Economic Status

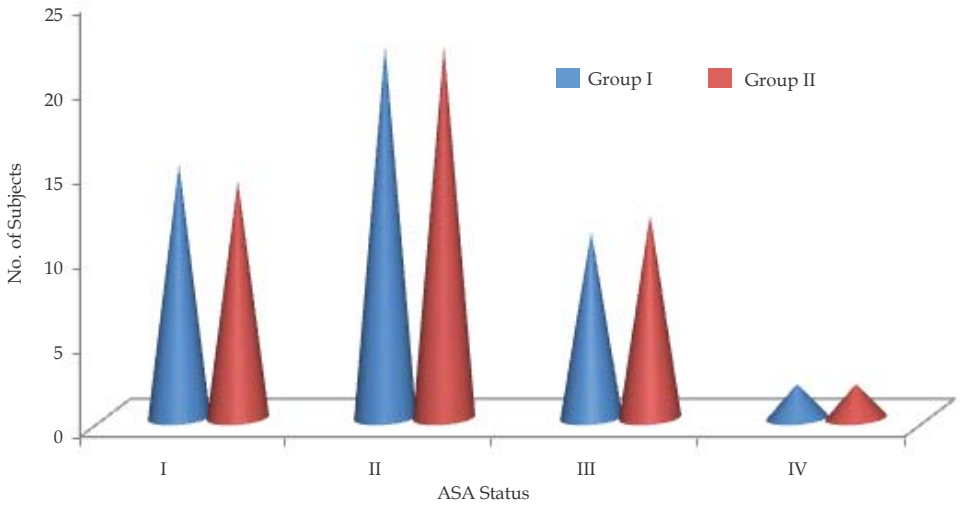

Fig. 2: Comparison of Subjects According to ASA Status

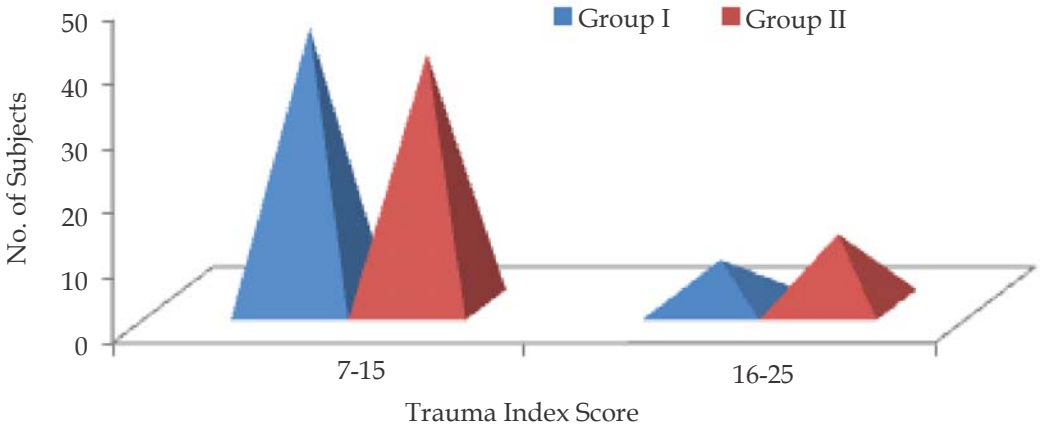

Fig. 3: Comparison of Subjects According Totrauma Index Score

Table 2: Comparison of Different Heat Variables

Heat Variables	Group-I	Group-II	p-value
Peak Temperature(°C)	26.05±2.71	40.94±1.53	0.000
Relative Humidity (%)	87.92±13.13	46.34±10.68	0.000
Heat Index	83.38±11.35	131.40±9.23	0.000

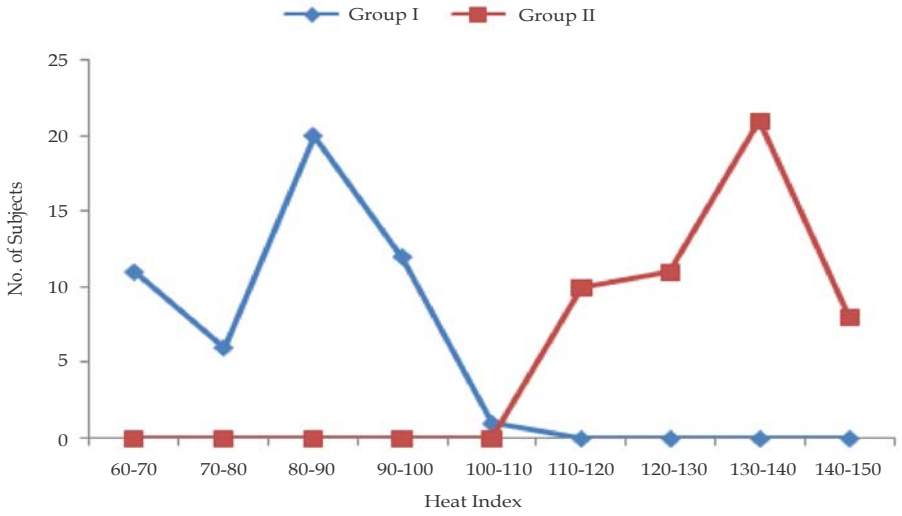

Fig. 4: Distribution of Subjects According to Heat Index

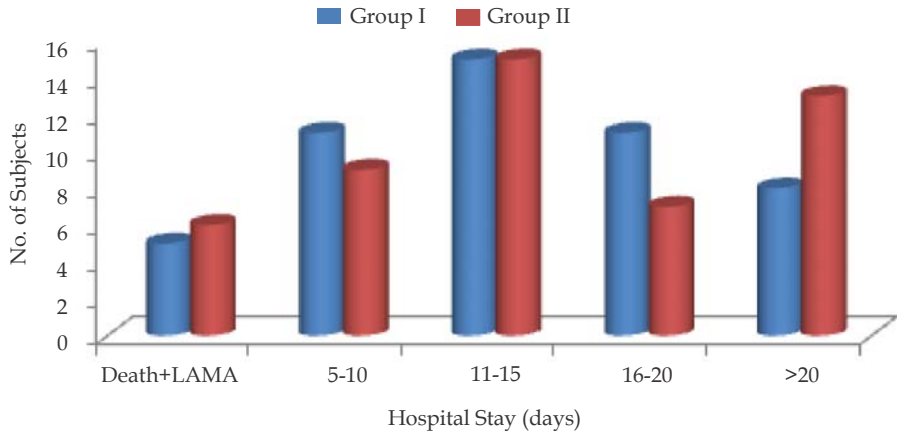

Fig. 5: Comparison of Subjects According to Duration of Hospital Stay (Days)

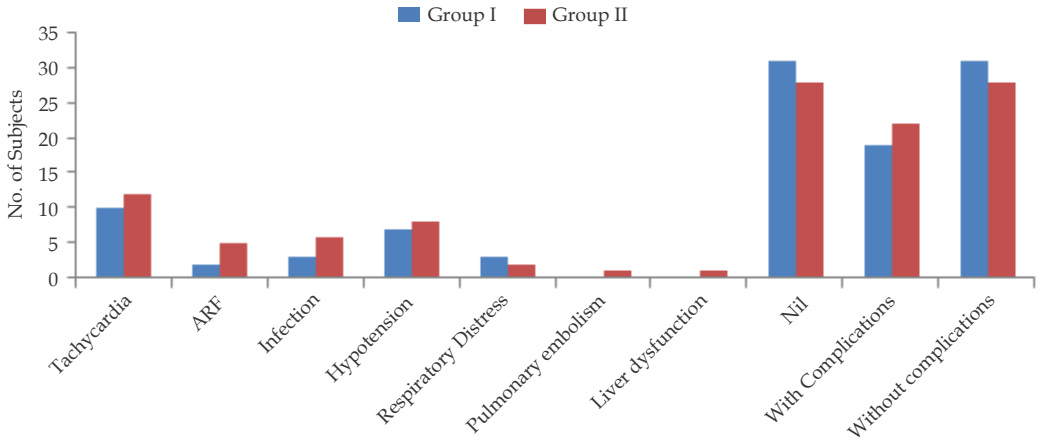

Fig. 6: Comparison of Subjects According to Complications among both Groups

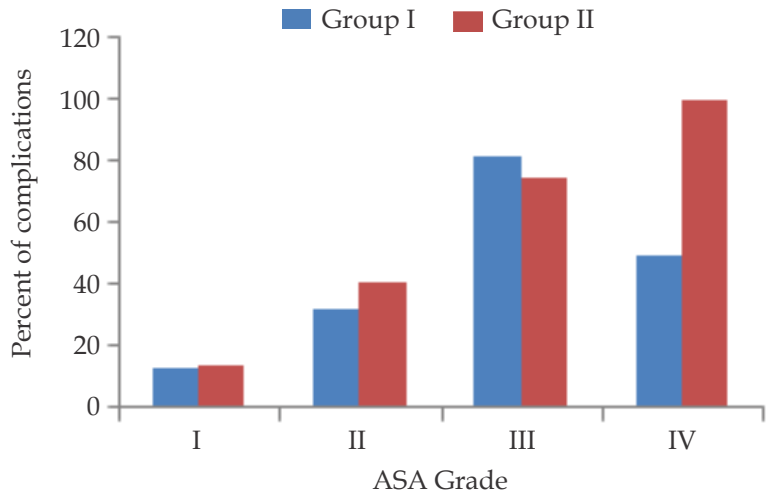

Fig. 7: Complications in Relation to ASA Status among both Groups

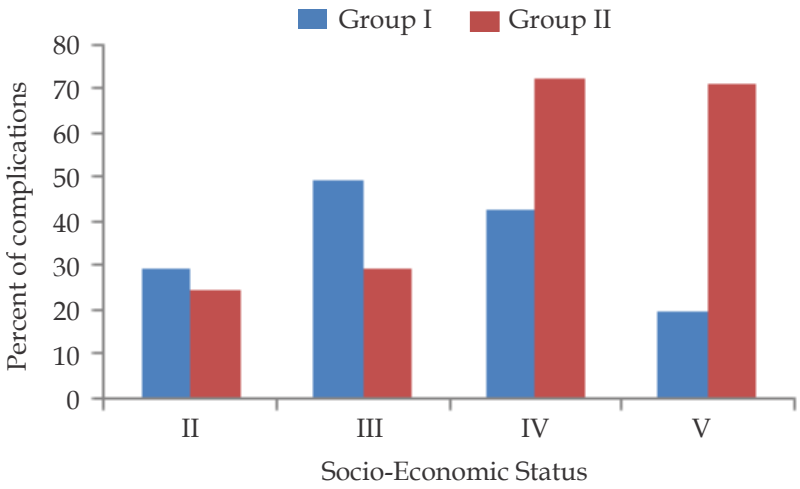

Fig. 8: Complications in Relation to Socio-Economic Status among both Groups

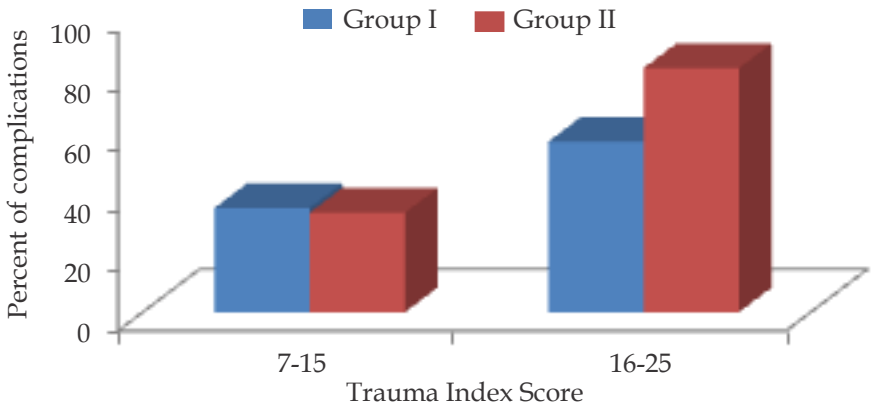

Fig. 9: Complications in Relation to Trauma Index Score among both Groups

Table 3: Details of Patients who Died During Hospital Stay

	Group I	Group II		
Mortality Rate	**2%**		**6%**	
Age	55 yrs	45	65	46
Sex	M	M	F	M
S.E Status	III	IV	IV	II
Peak Temp.	27	40	42	42.6
Peak Relative Humidity	94	55	41	45
Heat Index	88.2	137.3	129.9	138.9
Underwent Surgery(+/-)	+	+	+	+
ASA	III	IV	III	III
Trauma Index Score	17	14	11	18
Shoe Maker's Risk	HR	HR	LR	HR
p-value		0.162		

Table 4: Factors Predicting Complications: Multiple Logistic Regression Analysis

Variable	Ist Run Equaton		Final Run Equation	
	B	p-value	B	p-value
Constant	-13.089	0.054	-4.944	0.000
Age (years)	-0.019	0.415		
Sex: M=2; F=1	0.310	0.783		
Peak Temperature	0.271	0.323		
Peak Relative Humidity	0.059	0.194		
Heat Index	-0.041	0.409		
Trauma Index Score	0.308	0.004	0.298	0.001
Duration of Procedure	-0.220	0.372		
Transfusion Yes=1, No=0	2.503	.000	2.209	0.000

Discussion

Global warming is emerging as a threat to the survival of human beings in the coming future. There are a number of epidemiological surveys to address the heat wave and heat wave-related morbidity and mortality.[6,18] In a study by Nakai S et al., the authors observed that heat-related deaths were more prone to occur during the day, with peak daily temperatures of >38°C, and the incidence of these deaths showed an exponential dependence on the number of hot days. In the last decade, numerous epidemiological studies related to heat wave appeared in the literature from Italy,[1,19] USA,[20–22] Japan[23] France,[24] Belgium[6] and many other countries.

Temperature, humidity, wind, evaporation and sunshine are the important climatic elements of environment which directly influences body's comfort and well-being.[25] Body produces heat as a result of cellular metabolism and also gains heat from the environment if the ambient temperature is higher than body temperature. Maintenance of

body temperature is very complex. Evaporation is a primary way of heat loss when the environmental temperature is higher than that of the body.[24] Active sympathetic cutaneous vasodilatation increases the blood flow in the skin up to 8 L/min. In order to facilitate heat dissipation, there occurs reduced visceral perfusion, particularly in the intestine and kidneys as blood gets shunted from the central circulation to skin and muscles.[24]

As long as evaporation can remove the secreted moisture, it has a cooling effect but this process is restricted, resulting in uneasiness, discomfort and profuse sweating develops. Continuous active evaporation without adequate water intake poses a risk of dehydration and heat-related illness.[24]

Public health outcomes of hot weather and heat waves depends upon the level of exposure (frequency, severity and duration), population sensitivity as well as the ability to adapt to hot weather.[22] Furthermore, most deaths were reported either in children (<4 years) or (>70 years). Heat wave is prolonged period of excessively hot weather, which may or may not be accompanied by high humidity. It is one of the major causes of weather-related deaths. Heat wave as recommended by the glossary of meteorology is defined as: A period of abnormally and uncomfortably hot and usually humid weather. More realistically, the comfort criteria for any one region are dependent upon the normal conditions of that region.

Both groups were comparable on the basis of their demographic profile i.e. age and socioeconomic status. There were higher number of male patients 92% among both the groups in our study belonged to middle socioeconomic status scale.

Risk stratification was done on the basis of ASA physical status of the patient, trauma index score to compare the degree of trauma and shoemaker's surgical risk score. Both the groups were comparable on the basis of all these factors. Most of patients in our study suffered from moderate degree of trauma (TIS 7-15). 86% group 1 and 78% in group II with mean trauma index score of 12.42±2.70 and 13.76±3.09 in group I and group II respectively with p-value 0.023. Most of patients were belonged to ASA II among both groups. Patients mostly belonged to low risk shoemaker's score. Most of patients underwent surgery in both groups. Gautam et al. found more complications in patients with poor reserves through ASA status and Shoemaker's criteria in their study. Moreover, these patients had more complications when temperature and other heat variables were unfavourable. However, the power of study was low as sample size was small.[2] In our study group there were more young patients with a smaller number of high-risk patients. Hematological and Biochemical parameters were not statistically significant among both groups.

We found that 44% patients had complications in group II as compared to 38% patients in group I with p-value of 0.271. It was further seen that there were more complications related to infection (12%) and Acute Renal Failure (10%) in group II as compared to group I 6% and 4% respectively. Probably, high temperature and humidity led to dehydration compromising splanchnic circulation leading to translocation of bacteria from gut.[24] It may be high humidity and sweat resulting in infectious pockets in skin folds and leading to infections from breached skin due to trauma and intravascular catheters. However, we did not study the pattern and epidemiology of infections in our study. Semenza documented a higher incidence of acute renal failure during heat wave.[26] In group I, 6% patients and in group II 4% suffered from respiratory distress. In group II, one patient had liver dysfunction.

On further subgrouping, according to socioeconomic status as per Table (12), patients belonging to poor socioeconomic status (class IV and class V) in group II had higher complications than in group I. It corroborates the findings of McGeehin et al.,[7] Kuan-che Lu et al.[11] and Reid et al.[27] that poor socioeconomic status groups are more prone to side effects of hot weather despite their adaptation due to prolonged heat exposure. Lu KC and Wang reported that as heat loss is proportional to square of wind velocity, lower socioeconomic status populations are at a higher risk of heat related illnesses.[11] They also have poor air conditioning facility which is another risk factor for development of heat related diseases.[28] We did not record the exact demographics i.e. housing, type of urbanization etc.

No statistical difference was found among both group in relation to hospital stay. The mean duration of hospital stays (days) was found to be 15.11±5.78 in group I and 17.14±7.61 in group II. However in the previous study by our authors; Gautam et al, in elderly surgical patients there was prolonged duration of hospital stay in hot climate.[2] Probably the patients in our study tolerated heat stress better being young trauma victims.

Four (8%) patients in group I and three (6%) in group II were lost during follow up as they left hospital against medical advice. The mortality rate was 2% in group I and 6% in group II. In group II, one patient had pulmonary embolism, other had

myocardial infarction. Two other patients, one in each group died because of cardiorespiratory arrest related to high risk stratification in relation to poor ASA physical status, high trauma index score. There was difficulty to attribute mortality in relation to heat related illness in these patients. However, High-risk patients with poor cardiorespiratory reserve are at a greater risk of complications. Inglis et al. also found seasonal variations in cardiac failure patients in the Australian population in the summer season.[29] Also, body's ability of thermoregulation is impeded when too much blood is diverted from vital organs to skin surface on exposure to high temperature, putting increased stress on vital organs like heart and lungs.[28]

On multivariate regression analysis comparing age, gender, various heat variables and trauma index score, it was found that trauma index score is an important risk factor for the development of periopearative complications. Trauma patients often have little or no unused reserves in cardiopulmonary function. Bhattacharya et al. (2001) studied significant positive relationship between maximum daily temperature and trauma admissions.[24] Patients who died, were high risk as per Shoe Maker's Risk Score and ASA physical status.

Our study is novel of its kind, because there is paucity of literature to compare. However, if we see the physiological adaptation of hot weather,[11,24] it becomes a supportive evidence that patients who have compromised cardiorespiratory reserves have higher rate of morbidity and thus would have poor surgical outcome in hot and humid weather.

Our study corroborates some of the findings of a previous study by Gautam et al., where authors found significantly higher number of perioperative complications and increased duration of hospital stay in high risk patients during hot weather. The difference probably lies in our study from previous results of Gautam et al., that in our study patients were young and in earlier published study patients were elderly having compromised cardiorespiratory reserves.

In our region, the change in weather is gradual as compared to the coastal regions. Whenever temperature is high, the evaporation index also goes up to counteract the effect of humidity, so there is better adaptation and acclimatization to climate. On the basis of results in our study, this aspect needs to be further explored by better study designs in a larger sample of population. We also recommend that prior to elective surgery patients should be stabilized in air-conditioned environment for some time for better outcome if possible.

Being a pioneer work, there were many limitations of our study. The major one being sample size was small to find out the relationship of complications with various variables and intragroup comparison. The patients were young, with an average age of 36-38 years with low Shoemakers risk criteria and surgical risk factors among both groups were not similar. Risk stratification variation in relation to ASA physical status, trauma index score needs to be adjusted to minimize the bias. Although both the groups were comparable but bias due to Trauma Index Score could not be ruled out. We did not include the vulnerable group categorically, except the age group. There is enough literature analysis on heat vulnerability factors.[6,31] Heat vulnerability varies spatially, on local, regional, national and international scales. Even within the same city, in addition to the regional difference in heat vulnerability, a higher vulnerability had been seen within the downtown areas of all cities compared with the suburban areas, regardless of the city's overall vulnerability. Our study design lacks control in the same period of year with acclimatization in air-conditioned weather for some time.

Conclusion

It is well known that extreme hot climate adversely affects the health and high risk patients. We studied the impact of hot weather on young polytrauma patients. But we did not find any statistically significant difference in the complications, hospital stay and mortality among both groups i.e hot climate and comfortable temperature. Four patients who died during study were high risk as per Shoe Maker's Risk Score and ASA physical status. One patient belonged to group I and three patients belonged to group II. Thus, hot and humid weather has minimal impact on morbidity on young trauma patients. However, high risk surgical patients may be at added risk in hot climate.

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Support: Nil

Conflicts of interest: Nil

Permissions: Nil

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Questionnaire to Assess the Knowledge, Attitude and Acceptance of Epidural Labor Analgesia among Paramedical Staff

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Abstract

Context: Labor pain is characterized by regular, painful uterine contractions that increase in frequency and intensity in three stages of labor. Women's experience of pain during labor greatly varies from feeling of little pain to extremely distressing pain. Therefore, we have conducted a questionnaire based study in the primary caregivers like paramedical staff to assess their knowledge about labor pain and the methods to counteract like labor analgesia.

Aims: To check awareness about labour analgesia and anesthesia among paramedical staff and To provide the knowledge regarding labour analgesia.

Settings and Design: Questionnaire based study

Methods and Material: After obtaining institutional ethical committee approval, this study is conducted between January - February 2020 among the paramedical staff. The members included were belonging to age group 20-45 years.

Statistical analysis used: Data entered to Microsoft Excel and presented in %.

Results: Out of the total population, only 7.5% had the awareness about labour analgesia and 92.5% didn't have awareness about labour analgesia. Out of 15 members have who had knowledge about labour analgesia, 12 members gained this through doctors and 03 members through their friends or relatives.

Conclusions: Our study revealed that most of the paramedical staff still have that fear of labour pains and still suffer from the agony of labor pains due to lack of awareness, or knowledge about availability of labor analgesia service.

Keywords: Analgesia; Epidural; labour; Questionnaire.

Introduction

The pain of child birth is the most severe pain, that the women will have in their lifetime. Labor pain is characterized by regular, painful uterine contractions that increase in frequency and intensity in three stages of labor. Pain originates from different sites in each stage of the labor, which is a physiological phenomenon and its evolution is associated with ischemia of the uterus during contraction, effacement, dilation of cervix, stretching of the vagina, perineum, and compression of pelvic structures.[1]

Women's experience of pain during labor greatly varies from feeling of little pain to extremely distressing pain. Since pain relief in labor has always been surrounded with myths and controversies,

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providing effective and safe analgesia during labor have remained an ongoing challenge.

Many pharmacological and non-pharmacological treatments have been developed to alleviate labor pain. The effectiveness of the methods varies, but epidural analgesia remains the safest. It is the widely used analgesia that provides almost complete labor pain relief (90%) with a favorable birth experience.[2]

In developed countries, analgesia is widely utilized for pain relief and they also focused on choice of methods and complication, but in developing countries the issue concentrates on awareness, acceptability, and availability.

Therefore, we have conducted a questionnaire based study in the primary caregivers like paramedical staff to assess their knowledge about labor pain and the methods to counteract like labor analgesia. If at all they do not have the idea about labor analgesia, we will try to give a basic knowledge and will see their response whether they are ready to spread this knowledge among the patients who still suffer labor pain and also if necessary whether they are ready adopt for themselves.

Aims and Objectives

1. To check awareness about labour analgesia and anesthesia among paramedical staff.
2. To provide the knowledge regarding labour analgesia.

Materials and Methods

After obtaining institutional ethical committee approval, this study is conducted between January - February 2020 among the paramedical staff. The members included were belonging to age group 20-45 years.

Data was collected using a structured, pretested, and self-administered questionnaire prepared by adapting from different studies.

The questionnaire had four essential components related to obstetric analgesia utilization in labor pain management. The care providers were requested to complete the questionnaire following informed consent.

Results

Table 1: Age distribution among paramedical staff

Age (in years)	Number of Patients	Percentage (%)
20-25	92	46
26-30	46	23
30-35	40	20
35-45	22	11

Out of 200 staff, 46% were between 20-25 years, 23% of 26-30 years, 20% of 30-35 years, 11% of 35-45 years of age.

Table 2: Previous deliveries among the paramedical staff

Previous Deliveries	Number of Patients	Percentage (%)
Vaginal	73	36.5
Assisted	5	2.5
Operative	47	23.5
Nil	75	37.5

Out of 200 paramedical staff, 125 staff members had undergone previous deliveries and 75 staff members were unmarried. Out of 125 members, 36.5% had undergone vaginal deliveries, 23.5% had undergone cesarean section.

Table 3: Knowledge about the nature of labour pain and attitude of the labour pain

Knowledge About the Labour Pain	Number of Patients	Percentage (%)
Experienced Labour Pain Before?	125	62.5
Pain Free	No	–
Painful		
Mild	–	–
Moderate	20	10
Severe	140	70
Intolerable	40	20
Should Labour Pain Be Relieved		
Yes	185	92.5
No	–	–
No Opinion	15	7.5

62.5% of the population had experienced labour pain before. 70% of the total population had knowledge about labour pain and explains as severe pain, were as 20% of the total say it as intolerable. 92.5% of the population were in favorer the opinion that labour pain has to be relieved. Most the members does not know who provides the labour analgesia.

Table 4: Awareness regarding labour analgesia

Awareness	Number of Patients	Percentage (%)
Yes	15	7.5
No	185	92.5
Source of Information?		
Doctors	12	80
Friends and Relatives	3	20

Out of the total population, only 7.5% had the awareness about labour analgesia and 92.5% didn't have awareness about labour analgesia. Out of

15 members have who had knowledge about labour analgesia, 12 members gained this through doctors and 03 members through their friends or relatives.

Discussion

The modern era of childbirth analgesia began in 1847 when Dr J Y Simpson administered ether to a woman in childbirth, and Queen Victoria was given chloroform by John Snow (1853) for the birth of her eight child Prince Leopold and this did much to popularize the use of pain relief in labour.

Many pharmacological and non-pharmacological treatments have been developed to alleviate labor pain. Among the methods, systemic opioids, non-opioids, epidural analgesia, combined spinal-epidural analgesia, inhalation agents, pudendal block, transcutaneous electrical nerve stimulation, massage, acupuncture, water immersion, yoga, music therapy, biofeedback, continuous support, positioning, ambulation, hypnosis, and breathing technique are used to manage labor pain.[3]

Neuraxial analgesia into obstetric practice was introduced at the end of the 19th century, an year after August Bier, a German surgeon, described six lower extremity operations rendered painless by means of "cocainisation of the spinal cord". Cleland in the year 1949 introduced the technique of epidural analgesia using a Tuohy needle with epidural catheter.[4]

The effectiveness of these methods varies, but epidural analgesia remains the safest. It is the widely used analgesia that provides almost complete labor pain relief (90%) with a favorable birth experience.

The aim of pain relief in labor is to make an emotionally satisfying experience where a woman is delivering a healthy baby with as little distress, pain, and exhaustion as possible and with minimal risk to both mother and fetus. "Delivery of the infant into the arms of a conscious and pain-free mother is one of the most exciting and rewarding moments in medicine".[5]

In developed countries, analgesia is widely utilized for pain relief and they also focused on choice of methods and complication, but in developing countries the issue concentrates on awareness, acceptability, and availability.

On the other hand, the major factors that affect the utilization of obstetric analgesia in developing countries by caregivers are unavailability of drugs, health care delivery systems, knowledge, and religion. Of these, knowledge, attitudes, and skills of the health care provider to offer labor analgesia are main factors. Moreover, misconceptions of long-term backache, harm to baby, breastfeeding problem, increased cesarean section, slow labor progress, and permanent medical problems for the mother and newborn are some of the factors that affect utilization of labor analgesia. [6]

Therefore, we have conducted a questionnaire based study in the primary caregivers like paramedical staff to assess their knowledge about labor pain and the methods to counteract like labor analgesia. If at all they do not have the idea about labor analgesia, we will try to give a basic knowledge and will see their response whether they are ready to spread this knowledge among the patients who still suffer labor pain and also if necessary whether they are ready adopt for themselves.

Conclusion

Our study revealed that most of the paramedical staff still have that fear of labour pains and still suffer from the agony of labor pains due to lack of awareness, or knowledge about availability of labor analgesia service. Not only the antenatal women, paramedical staff needs to be educated regarding physiology of labor, labor pain and pain relief and available options for labor pain relief.

Therefore in collaboration with anesthesia and obstetrics department, the awareness programs about labour pain and labour analgesia have to be conducted.

Key Messages

The pain experienced during labour is very distressing and knowledge about pain relief that can be obtained is lacking among parturients, lay people and Health care providers. Proper education and avilabilty of knowledge of labour analgesia can bring about lot of changed and acceptability of labour analgesia.

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Support: Nil

Conflicts of interest: Nil

Permissions: Nil

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Comparative Study of Preprocedural Anxiety in Patients Undergoing Interventional Pain Management in Prone Position Under Monitored Anesthesia Care: First Timer vs Experienced

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Abstract

Background and Objective: The prevalence of preoperative anxiety has varied widely, from 11% to 80%, depending on the methods used to assess it. Patients with increased anxiety may carry greater risk of experiencing pain and complications during noxious medical procedures and interventional pain management. Aim of our study is to compare anxiety and expected pain before procedure and pain experienced during procedure in first timer patients and experienced patients undergoing interventional pain management.

Material and Methods: The 400 participating patients were divided into two groups. Group 1 (First timer) and Group 2 (Experienced). Pre-procedural anxiety and expected procedural pain were assessed 1 hr before procedure. After half an hour post procedure, patient was given same Proforma for scoring of experienced procedural pain. Data was analyzed by using SPSS 20.0 (SPSS Inc., Chicago, IL, USA). Mann Whitney U test and Wilcoxon Signed Rank test were used for statistical analysis.

Results: Preoperative anxiety is significantly higher in first timer patients than that in experienced patients. [Median- first timer patients = 8 (7-8), experienced patient = 4(3-5)], (P value= <0.001). Expected pain before procedure is seen higher in first timer patient than that in experienced patients. [Median- first timer patients=8(7-8), experienced patients=4(3-5)], (P value <0.001). Procedure pain experienced by first timer patients is significantly higher than that in experienced patients. [Median- first timer patients=6(5-7), experienced patients= 4(3-4)], (P value <0.001).

Conclusion: We concluded that lower level of anxiety in experienced group was associated with lower level of preprocedural expected pain and pain experienced during procedure. While in first timer, higher level of preprocedural anxiety was associated with higher level of preprocedural expected pain and pain experienced during procedure.

Keywords: Pain management; Anxiety; Anesthesia; Prone position.

Introduction

Preoperative anxiety is described as an unpleasant state of tension that is secondary to a patient being concerned about a disease, hospitalization, incapacitation, anesthesia, surgery or his or her anticipation of postoperative pain.[1-2] In clinical studies, the prevalence of preoperative anxiety has varied widely, from 11% to 80%, depending on the methods used to assess it.[3-5] Risk factors for preoperative anxiety include, female gender, high

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trait anxiety, negative future perception, history of cancer and smoking, previous psychiatric disorders, moderate to intense depressive symptoms and, higher educational level etc.

Patients with increased anxiety may carry greater risk of experiencing pain and complications during noxious medical procedures and interventional pain management. Moreover, anxiety has been correlated with increased pain, nausea and vomiting in the postoperative period, prolonged recovery and increased risk for infection.[6] It also intensifies pain during trigger point injection.[7] Thus; specifically targeting anxiety maybe beneficial in the control of pain during interventional pain management. Aim of our study is to compare anxiety in first timer patients and experienced patients undergoing interventional pain management, and to compare expected pain before procedure and pain experienced during procedure in first timer patients and experienced patiets.

Material and Methods

After obtaining institutional ethics committee approval and written informed consent, 400 patients undergoing interventional pain management enrolled in this prospective observational study. The participating patients were divided into two groups. Group 1 (First timer), consists of patients, who were undergoing interventional pain management for the first time. Group 2 (Experienced), consists of patients, who had experience of interventional pain management in past and come for repeat intervention. On the morning of procedure, pre-procedural anxiety and expected procedural pain were assessed 1 hr before procedure with the help of predesigned Proforma on zero to ten scale. After procedure, patient was shifted to post operative ward and after half an hour patient was given same Proforma for scoring of experienced procedural pain. Data was analyzed by using SPSS 20.0 (SPSS Inc., Chicago, IL, USA). Mann Whitney U test and Wilcoxon Signed Rank test were used for statistical analysis. Descriptive study in the form of mean, standard deviation was done. Multiple comparisons between two groups were done with independent t test.

Observations and Result

Statistically significant difference was not present among both the groups in terms of gender, age and weight.

Table 1: Pre-operative anxiety (anxiety pre-op), pre-operative expected pain (pain_pre-op), real pain experienced by patients intra-operative recorded in post-operative period (pain_post-op):

Patient's groups	Anxiety_ preop Median (Interquartile range)	Pain_ preop Median (Interquartile range)	Pain_ postop Median (Interquartile range)
Experienced (n=236)	4 (3-5)	4 (3-5)	4 (3-4)
First Timer (n=164)	8 (7-8)	8 (7-8)	6 (5-7)
Total	6 (4-7)	5 (4-7)	4 (3-6)
p value	<0.001	<0.001	<0.001
Mann Whitney U test used			

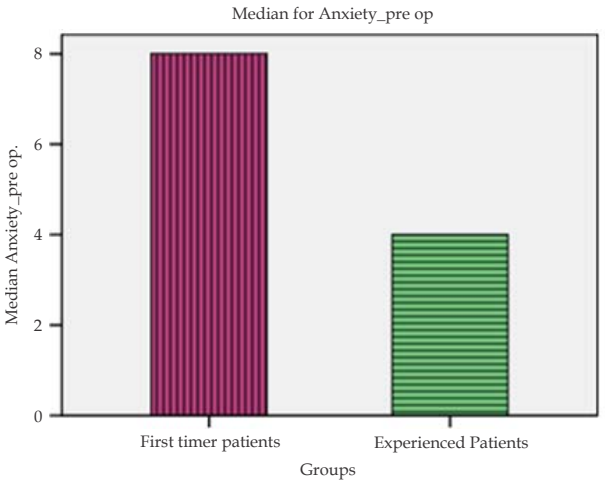

Fig. 1: Median anxiety in two groups:

There is significant difference in pre-operative anxiety in two groups. Anxiety is significantly higher in first timer patients than that in experienced patients. [Median- first timer patients = 8 (7-8), experienced patient = 4(3-5)], (P value= <0.001).

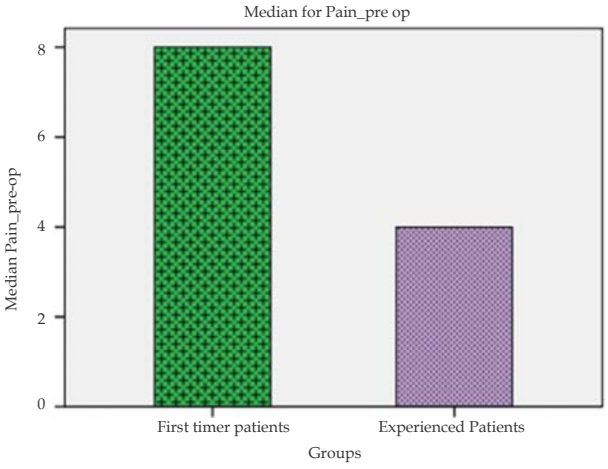

Fig. 2: Median pain _ pre-op in two groups:

There is significant difference in pre-operative expected pain in two groups Expected pain before procedure is seen higher in first timer patient than

that in experienced patients. [Median- first timer patients=8(7-8), experienced patients=4(3-5)], (P value < 0.001).

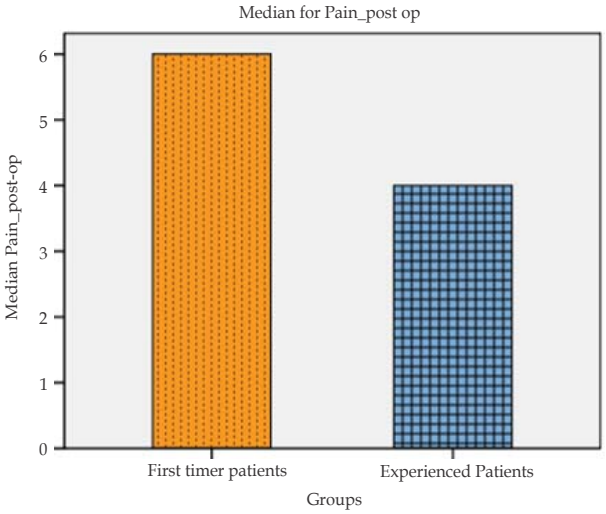

Fig. 4: Median pain _ post-op in two groups:

There is significant difference in procedural pain experienced in two groups. Procedure pain experienced by first timer patients is significantly higher than that in experienced patients. [Median-first timer patients=6(5-7), experienced patients= 4(3-4)], (P value <0.001)

Table 5: Comparison of pain_preop and pain post-op in two groups:

Patients Groups	Pain_preop	Pain_postop	p value
Experienced (n=236)	4 (3-5)	4 (3-4)	<0.001
First timer (n=164)	8 (7-8)	6 (5-7)	<0.001
Total	6 (4-7)	5 (4-7)	<0.001
Wilcoxon Signed Rankes test used			

There is significant difference between pain-preop and pain_postop in first timer group (p<0.001) as well as in experienced group (p<0.001).

Table 6: Relation between anxiety (pre-op) and education levels in two groups:

Education level	Median anxiety in two groups	
	First timer	Experienced
Illiterate	9	7
Primary education	8	6
High school	7	5
Intermediate	6	4
Graduation	5	3
Post-graduation	4	2
Above post graduation	3	1

Anxiety seems to be higher in patients with low education level in both group and decreases as the level of education increases.

Discussion

In this study, there was higher level of preprocedural anxiety, expected pain before procedure and pain experienced during procedure in first timer group, in comparison to the experiencd group. Higher level of preprocedural anxiety is associated with higher level of pain perception as seen in first timer group.

It is also observed that in first timer group median value of preprocedural expected pain was is higher than median value of pain experienced during procedure. In experienced group, median values of preprocedural expected pain and pain experienced during procedure were same i.e. Four; but distribution of preprocedural expected pain was in the range of (Two to Nine) which is higher in comparison to distribution of pain experienced during procedure (One to Eight) (P <0.001).

Lower level of pain experienced during procedure might be because of several factors such as proper counseling of patients before start of procedure, precise anesthetic care, adequate analgesia technique, and fluoroscopic guided procedure technique and operator's expertise. Education level also had impact on preprocedural anxiety level of patients of both groups. Higher level of education was associated with lower level of anxiety in first timer group as well as in experienced group.

Similar studies in the past like Eralp Baser et al.[8] investigated effect of pre-procedural state-trait anxiety on pain perception and discomfort in women undergoing colposcopy for cervical cytological abnormalities. Study showed that women, who had a high level of state anxiety and with fewer past gynecological examinations were more likely to experience pain and discomfort during colposcopy. Duman et al.[9] evaluated pain and anxiety levels related to diagnostic punch biopsy in dermatology out patients. Study showed that Pain scores of patients with severe anxiety were higher than that of patients with moderate and no anxiety. Impact of pre-procedural anxiety levels on pain perception in patients undergoing office hysteroscopy was investigated by M.K. Kokanali et al.[10] Study results showed that pain perception during the procedure is higher in patients with higher preprocedural anxiety. In our study too, higher level of preprocedural anxiety was associated with higher level of pain perception. L Ebirim et al.[11] investigated factors responsible for pre-operative anxiety in elective surgical patients. Study result showed that only previous surgical treatment was associated with significantly lower levels of preoperative anxiety. Effect of anxiety and waiting time on patients' tolerance of upper endoscopy

on out-patients who underwent endoscopy was studied by Pontone et al.[12] It was concluded that higher levels of preprocedural anxiety was associated with a higher level of pain perception. Fathi M, Alavi SM, Joudi M et al.[13] investigated preoperative anxiety and its predisposing factors in a group of adult patients who were candidate for any kind of heart surgery. Result of this study showed that Widowed or divorced female patients were more prone to experiencing higher stages of anxiety. More over Higher income rates and better social support may decrease anxiety level. In our study too, patients with higher education level show lower level of preoperative anxiety. Tokmak et al.[14] investigated effect of pre-procedure anxiety levels on post-procedure pain scores in women undergoing hysterosalpingography. He concluded that there was a positive correlation between anxiety scores and post-procedure pain scores. In a Study by Yilmaz et al.[15], effect of Pre-Procedure Anxiety on Pain Perception during first session of Shock Wave Lithotripsy was investigated. Their Study showed that the increased anxiety level made the procedure more painful.

In our study, patients undergoing interventional pain management were included. Depending up on their previous exposure history they were divided into two groups (Fist timer group/experienced group), so that effect of previous experience could be detected. More over in both groups pain scoring before and after procedure were noted. This was done to find out difference in patient's expectation for procedural pain and real pain experienced during procedure, later was amazingly low might be because of several factor including expert hands.

Limitations

We did not study effect of socio-economic status and waiting time before procedure on preprocedural anxiety, preprocedural expected pain and pain experienced during procedure. We also did not study effect of any anxiolytic drug on preprocedural anxiety. Further study is needed in this field.

Conclusions

Based on above study we concluded that previous experience of procedure significantly reduces preprocedural anxiety in patients undergoing interventional pain management while the patients undergoing interventional pain management for the first time shows high level of anxiety. Lower level of anxiety in experienced group was associated with lower level of preprocedural expected pain and pain experienced during procedure. While higher level of preprocedural anxiety in first timer was associated with higher level of preprocedural expected pain and pain experienced during procedure. Education level also has impact on pre-procedural anxiety. Patients having higher level of education showed lower level pre-procedural anxiety in patients of both groups.

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The Effect of Endotracheal Tube Cuff Pressure Control on Postoperative Sore Throat in Faciomaxillary Surgeries

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Abstract

Background: Sore throat is a common problem following general anesthesia and intubation. It has been found to correlate with increased endotracheal tube (ETT) cuff pressure. In this study, we assessed the incidence and severity of sore throat in patients who had their ETT cuff pressure monitored and compared them with patients in whom the adequacy of cuff inflation was assessed only by clinical methods.

Material and Methods: Forty-eight ASA I and II patients in the age group of 18-60 years, posted for faciomaxillary surgeries were randomly divided into two groups. In Group 1, the adequacy of inflation of ETT cuff was checked by palpating the sternal notch and auscultating with a stethoscope to rule out leak. In Group 2, ETT cuff pressure was adjusted to 25 cm H_2O using a cuff manometer. Postoperatively, sore throat was assessed using a 10 point scale at 1 hour, 6 hours and 24 hours of surgery.

Results: There was no statistically significant difference in the incidence of sore throat between the groups. The sore throat scores recorded after one hour of surgery were significantly higher in Group 1 compared to Group 2 (median score 4 in Group 1 vs 2 in Group 2, P=0.008). There was no statistically significant difference in the sore throat scores recorded after 6 and 24 hours of surgery in both the groups.

Conclusion: Endotracheal tube cuff pressure has to be routinely monitored and kept in the optimal range of 20-30 cm H_2O to minimize postoperative complications like sore throat.

Keywords: General anesthesia; Cuff pressure; Faciomaxillary surgeries; Sore throat.

Introduction

Sore throat is a common complaint following general anesthesia with endotracheal intubation. The incidence of sore throat after intubation varies from 30% to 55%.[1] The use of cuffed endotracheal tubes protects from aspiration of gastic contents. Inadequate inflation of cuff can cause aspiration while overinflation can cause complications like ischemia, granulation, ulceration and stenosis of trachea[2,3] and these conditions can present as cough, sore throat and blood streaked expectoration. Postoperative sore throat has been found to correlate with increased cuff pressure.[3] The acceptable cuff pressure has been found to be 20-30 cm of H_2O.[4]

Clinically, the adequacy of cuff inflation is determined by gradually inflating the cuff to a sealing pressure until no leak is heard at the mouth and also by palpating the sternal notch for gurgling noise. The bell of the sthethoscope could also be used to auscultate at the sternal notch for presence of harsh breath sounds around the endotracheal tube (ETT). As a more objective method, a cuff manometer could be used to determine the cuff pressure and thereby the adequacy of cuff inflation.[5]

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In this study, sore throat was evaluated post operatively in one group of patients who had their ETT cuff inflation checked by clinical methods and compared with another group who had their cuff pressures checked by a cuff manometer, following faciomaxillary surgeries.

Material and Methods

A prospective randomized controlled trial was undertaken in Saveetha university, Kanchipuram district, Tamilnadu. Patients in the age group of 18-60 years, who belonged to ASA status I and II and posted for faciomaxillary surgeries were included in the study. Informed consent was obtained from all patients and institutional ethics committee clearance was obtained before starting the study. Pregnant ladies, patients with ASA status III and above and patients with oral cancer were excluded from the study. A total of 48 patients were chosen based on the inclusion and exclusion criteria at the power of 90. The patients were randomly divided in to two groups using computer generated random numbers. In Group 1, ETT cuff inflation was checked by clinical methods while in Group 2, cuff pressure was adjusted with a cuff manometer (Portex). One day before surgery, the patients were explained how to rate the severity of postoperative sore throat (POST) by using a 10 point score:[6]

0 = no sore throat,

1–3 = mild sore throat (complains of sore throat only on asking),

4–7 = moderate sore throat (complains of sore throat on his/her own),

8–10 = severe sore throat (change of voice or hoarseness, associated with throat pain).

After shifting the patients in to the operating room, an 18G intravenous cannula was placed for administration of fluids. Standard monitors like electrocardiogram (ECG), non invasive blood pressure (NIBP), pulse oximetry (SpO_2) and capnography ($ETCO_2$) were connected. Anesthesia was induced with intravenous fentanyl 2 mcg/Kg, propofol 2 mg/Kg and vecuronium 0.1 mg/Kg. Direct laryngoscopy was done and nasal intubation was performed with an appropriate sized Polyvinyl chloride nasal RAE endotracheal tube (7.5 mm in males, 7.0 mm in females). In Group 1, after endotracheal intubation, cuff was gradually inflated in one ml increments until there was no palpable air leak in the sternal notch and no leak was audible on auscultation with the bell of a stethoscope. In Group 2, after intubation, ETT cuff was inflated in one ml increments until the cuff manometer showed a reading of 25 cm H_2O. After securing the airway, a throat pack was kept in all patients. Anesthesia was maintained with 1 MAC sevoflurane in air- oxygen mixture and intermittent intravenous boluses of vecuronium and fentanyl. Nitrous oxide was avoided in both the groups. The duration of surgery was recorded. At the end of surgery, throat pack was removed. Patients were reversed with neostigmine 0.05 mg/Kg and glycopyrrolate 0.01 mg/Kg and trachea was extubated. Postoperatively, the patients were questioned about the presence of sore throat at 1, 6 and 24 hours after surgery and appropriate scores were recorded.

Statistical Analysis

The parametric data like age, height, weight and duration of surgery were expressed as mean and standard deviation and analyzed using student t test. The sex distribution and incidence of sore throat were compared using Chi square test. The sore throat scores after 1, 6 and 24 hours in the groups were expressed as median and interquartile range and analyzed using Mann Whitney test. P value < 0.05 was considered statistically significant.

Results

The two groups were comparable in terms of age, sex, height and weight. There was no significant difference in the duration of surgery between the two groups (P>0.05, Tables 1 & 2). Two patients in Group 1 and one patient in Group 2 did not complain of any sore throat while all other patients had some degree of sore throat. There was no statistically significant difference in the incidence of sore throat between the groups (Table 3). The sore throat scores recorded after one hour of surgery were significantly higher in Group 1 compared to Group 2 (median score 4 in Group 1 vs 2 in Group 2, P=0.008). There was no statistically significant difference in the sore throat scores recorded after 6 and 24 hours of surgery in both the groups (Table 4).

Table 1: Demographic data and duration of surgery

Parameters	Group	N	Mean	Std deviation	P value
Age (years)	1	24	39.95	9.58	0.538
	2	24	38.25	9.5	
Height (cm)	1	24	162.12	7.69	0.943
	2	24	161.95	8.31	
Weight (Kg)	1	24	71.79	9.57	0.793
	2	24	71	11.12	

Duration of Surgery (minutes)	1	24	120.83	47.54	0.759
	2	24	117.08	35.56	

Table 2: Sex distribution

Group	Sex	N	Percentage	P value
1	Males	14	58.3	0.562
	Females	10	41.7	
2	Males	12	50	
	Females	12	50	

Table 3: Incidence of Sore Throat

	Group 1 (N=24)	Group 2 (N=24)	P value
No. of patients with Sore throat	22	23	0.547
Percentage	91.66	95.83	

Table 4: Comparison of Sore Throat Scores

	Group	N	Median	Interquartile range	P value
ST 1 hr	1	24	4.0	2.00-5.75	0.008
	2	24	2.0	1.00-4.00	
ST 6 hrs	1	24	2.0	1.25-4.00	0.117
	2	24	2.0	1.00-2.00	
ST 24 hrs	1	24	0.0	0.00-1.00	0.511
	2	24	0.0	0.00-1.00	

ST- Sore throat

Discussion

Sore throat is a common complaint following general anesthesia and endotracheal intubation. High volume- low pressure cuffs can exert high pressure on the tracheal mucosa if overinflated and can contribute to postoperative sore throat.[7] When the ETT cuff pressure exceeds 30 mmHg, blood flow to the trachea decreases significantly and at pressures of 50 mm Hg and above, ischemic injury to the tracheal mucosa occurs.[8]

In our study, the incidence of sore throat was comparable in both the groups. However we found that the sore throat scores after one hour of surgery were significantly higher in the group in which the ETT cuff pressures were adjusted by clinical methods, reflecting a higher degree of severity of symptoms in Group 1. At 6 and 24 hours, the sore throat scores were comparable. Our findings were partly similar to the observations made by Liu[9] et al. who found that the incidence and severity of sore throat was higher in patients in whom cuff pressure was not monitored compared to patients in whom cuff pressure was monitored.

In a study conducted by Borhazowal[5] et al., the authors reported that the cuff pressures and incidence of sore throat were significantly higher in the group in which cuff leak was checked by palpation compared to the group in which auscultation method was used. This again shows the drawback associated with one of the clinical methods of cuff inflation.

In our study, we performed nasotracheal intubation in all patients and placed a throat pack in all of them. Pharyngeal packing has been found to be associated with sore throat in some studies.[10] This could have contributed to the comparable incidence of sore throat in both the groups in our study.

In a study conducted by Sengupta[3] et al., the authors measured cuff pressures one hour after inflating the ETT cuff by clinical methods. They reported that 50% of patients had cuff pressures measuring 30 cm H_2O and above while 27% had values in excess of 40 cm H_2O. In our study, we did not measure the cuff pressures in Group 1 but the increased severity of sore throat in the first hour could have been due to increased cuff pressure. The reduction in severity of sore throat at later hours could have been due to natural healing.

Limitations

We could have measured the cuff pressures at the end of surgery in Group 1 to see how effective the cuff inflation method was. We could have also done a bronchoscopic examination in all patients to assess tracheal mucosal damage.

Conclusion

We advocate the routine use of cuff manometer to maintain the endotrachaeal cuff pressures in the recommended range of 20-30 cm H_2O to minimize postoperative sore throat and ensure better patient satisfaction.

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Original Research Article

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Intravenous Versus Epidural Dexmeditomidine: Comparison of Effect on Prolongation of Analgesia after Subarachnoid Block with Bupivacaine in lower limb Surgery

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Abstract

Introduction: Subarachnoid block is the most common technique amongst regional anesthesia for lower abdomen and lower limb surgeries. Dexmedetomidine, a new highly selective α2-agonist, is under evaluation as a neuraxial adjuvant as it provides stable hemodynamic conditions, good quality of intraoperative and prolonged postoperative analgesia with minimal side effects. In this study we want to compare efficacy of Epidural Dexmeditomidine with Intravenous Dexmeditomidine in subarachnoid block with Inj. Bupivacaine.

Aims and objectives: Primary objective of this study is to compare the duration of post-operative analgesia of IV Dexmeditomidine with epidural Dexmeditomidine in subarachnoid block given for lower limb surgeries. Our secondary objective is to compare the onset of sensory blockade, onset of motor blockade, sedation Score and any complications like bradycardia, hypotension in both groups.

Methodology: Sixty patients posted for lower limb surgeries were included in this study. In Group I Inj Dexmeditomidine 0.5 ug/kg diluted in 100 ml NS was given as infusion over 15 minutes and Group E received, 100 ml NS as infusion over 15 minutes. Epidural space was identified with Tuohy needle by LOR resistance and 10 ml NS was given epidurally in Group I and 0.5 ug/kg of Inj dexmedetomidine in 9.5 ml of NS was given epidurally in Group E. Subarachnoid block was given by 25G spinal needle in L3-L4 space in sitting position using all aseptic precautions in both the groups with 3.5 ml 0.5% hyperbaric Bupivacaine. Onset of sensory and motor blockade, pulse rate, MAP, sedation score, time for two segment regression and the time when patients request first analgesic were noted and analysed.

Result: The mean time of onset of sensory blockade and mean time of onset of motor blockade were comparable between the groups, in Group I onset of sensory blockade was 7.27±2.75 min while in Group E 8.17±2.03 min with P >0.05 while onset of motor blockade was 11.33±3.45 min in Group I and 12.03±2.07 min in Group E with p >0.05. The time taken for two-segment regression was significantly earlier in Group I 157.5 ±22.35 min than in Group E 171.03±13.01 min. with P <0.006. The mean duration of post-operative analgesia was significantly longer in Group E 447.33±41.78 while in Group I 425.5±27.16 min with P <0.02. The mean of RSS (Ramsay sedation score) in Group I was 3±0.12 and in Group E was 2±0.24, the difference was clinically significant with P = 0.036.

Conclusion: Administration of Epidural Dexmeditomidine 0.5 ug/kg leads to prolongation of sensory blockade after intrathecal Bupivacaine and prolongs postoperative analgesia than Intravenous Dexmeditomidine.

Keywords: Dexmeditomidine; Intravenous; Epidural; Subarachnoid.

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Introduction

Subarachnoid block is the most common technique amongst regional anesthesia for lower abdomen and lower limb surgeries. Intense anesthesia, good muscle relaxation, less bleeding, good cardiovascular stability, early ambulation, less chances of post-operative respiratory infection and embolization and postoperative analgesia are the advantages of Subarachnoid block. With use of only LA, there is limited post-operative analgesia, so different additives are used along with LA. Dexmedetomidine, a new highly selective α2-agonist, is under evaluation as a neuraxial adjuvant as it provides stable hemodynamic conditions, good quality of intraoperative and prolonged postoperative analgesia with minimal side effects.[1] The unique analgesic properties have encouraged anesthesiologists to use it perineurally. Previous studies have declared that dexmedetomidine potentiates local anesthetic effect when administered by neuraxial route. We carried out a study with an aim to compare the duration of post-operative analgesia in patients receiving intravenous dexmedetomidine with epidural dexmedetomidine in patients operated under subarachnoid block for lower limb surgery.

Objectives

Primary objective of this study is to compare the duration of postoperative analgesia of IV Dexmeditomidine with epidural Dexmeditomidine in subarachnoid block given for lower limb surgeries. Our secondary objective is to compare the onset of sensory blockade, onset of motor blockade, sedation Score and any complications like bradycardia, hypotension in both groups.

Methodology

It is a prospective, randomized, double blind, comparative study conducted in Government Medical College, Aurangabad. The study was carried out in 60 ASA Gr I and II patients posted for elective lower limb surgeries. Patients were randomly allocated into 2 groups. After detail preoperative evaluation, consent and confirming the NBM status, patients were posted for the surgery. All patients were monitored with continuous ECG, Pulse oximetry, Non-invasive blood pressure. IV line was secured with angiocath no 18G and 0.9% NS 500 ml infusion was given. In Group I Inj Dexmeditomidine 0.5 ug/kg diluted in 100 ml NS was given as infusion over 15 minutes and Group E received, 100 ml NS as infusion over 15 minutes. Epidural space was identified with Tuhoy needle by LOR resistance and 10 ml NS was given epidurally in Group I and 0.5 ug/kg of inj dexmedetomidine in 9.5ml of NS was given epidurally in Group E. Subarachnoid block was given by 25G spinal needle in L3-L4 space in sitting position using all aseptic precautions in both the groups with 3.5 ml o.5% hyperbaric Bupivacaine.

Immediately after completion of the injection patients were made to lie supine hemodynamic monitoring was done at 5 min interval. Oxygen was administered via face mask (at 4l/min). The onset time of sensory blockade at T10 dermatome was considered as the time of onset of analgesia. Sensory testing was assessed by loss of pinprick sensation to 23G hypodermic needle. Onset of motor blockade was noted and assessed by Modified Bromage criteria. Sedation was assessed by Modified Ramsay Score. NIBP, PR, SpO_2 and continuous ECG were monitored till the end of surgery and thereafter at every 15 min in the 1st post-operative hour followed by every half hourly for next 3 hours. The time when patient requests first analgesic dose was noted and it was considered as duration of postoperative analgesia.

Sedation was assessed by Modified Ramsay Score.

1-anxious and agitated

2-alert and wide awake

3-arousable to verbal command

4-arousable to gentle tactile stimulation

5-arousable to vigorous shaking 6-unarousable.

Observations and Results

In our study, the demographic profile of the patients of both the groups are comparable with no significant difference. The age distribution of patients between both the groups are comparable with Mean age in group I was 41.37 years and in group E was 42 years with P = 0.741. The groups are comparable as per height with mean height of the patients in Group I was 165.87 cms and in Group E 166.33 cms with P = 0.298, the difference is insignificant. The mean weight of the patients in Group I was 61.86±19.19 kg and 59.79±18.38 kg in Group E, (P = 0.0744), the difference is insignificant.

The mean time of onset of sensory blockade and mean time of onset of motor blockade were comparable between the groups, in Group I onset of sensory blockade was 7.27±2.75 min while in Group E 8.17±2.03 min with P >0.05 while onset of motor blockade was 11.33±3.45 min in Group I and 12.03±2.07 min in Group E with p >0.05.

The mean time of onset of sensory blockade were comparable between the groups, P >0.05 Fig. 1.

The mean time of onset of motor blockade were comparable between the groups, P >0.05 Fig. 2.

The time taken for two-segment regression was significantly earlier in Group I 157.5±22.35 min than in Group E 171.03±13.01 min. with P <0.006. The mean duration of post-operative analgesia was significantly longer in Group E 447.33±41.78 while in Group I 425.5±27.16 min with P <0.02.

The time taken for two-segment regression was earlier in Grp I, P <0.006 Fig. 3.

The mean duration of post-operative analgesia was significantly longer in Grp E, P <0.02 Fig. 4.

The mean of RSS (Ramsay sedation score) in Group I was 3±0.12 and in Group E was 2±0.24, the difference was clinically significant with P = 0.036. Thus, suggesting the sedation due to dexmedetomidine was more than in the intravenous group than in the epidural group.

Repeated measures ANOVA (Green house-Geisser) was used to compare pulse rate (PR) at 17 time points for two different routes namely Intravenous and Epidural. The pulse rate between these two groups was not found to be statistically significant (F=0.705, df = 4.8, p=0.6153). Similarly the same test was applied to compare the mean arterial pressure (MAP) at same 17 different time points. This too was not found to be statistically significant. (F=2.247, df=4.8, p=0.52.)

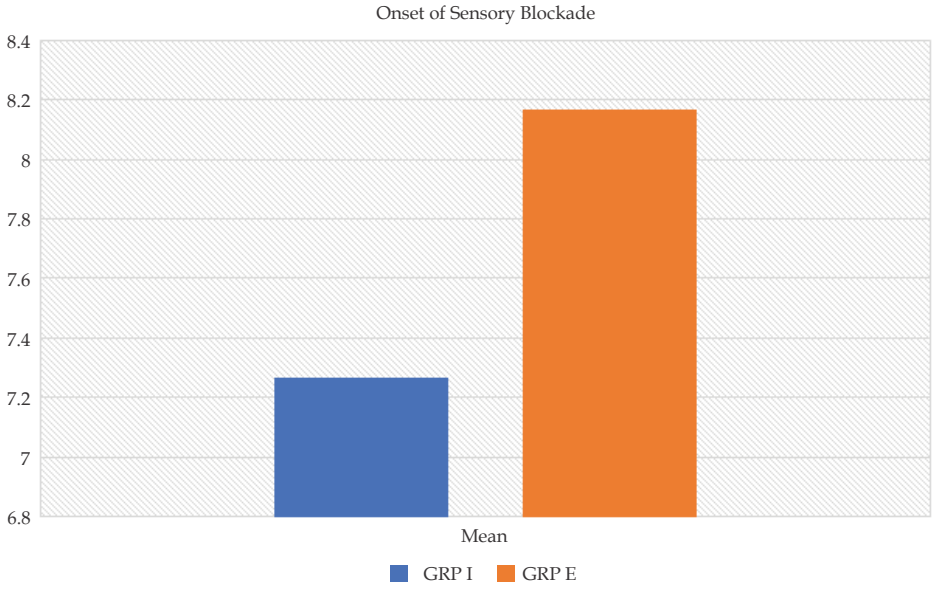

Fig. 1:

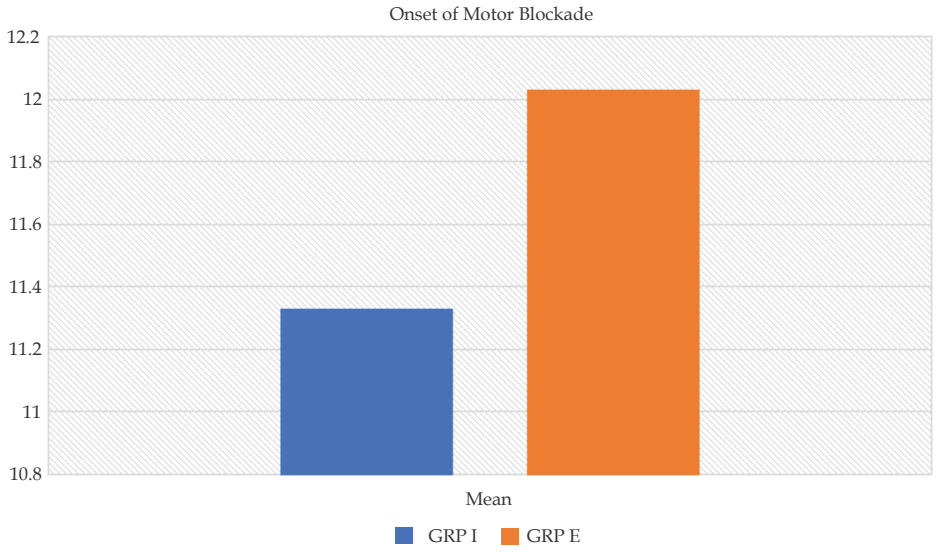

Fig. 2:

Fig. 3:

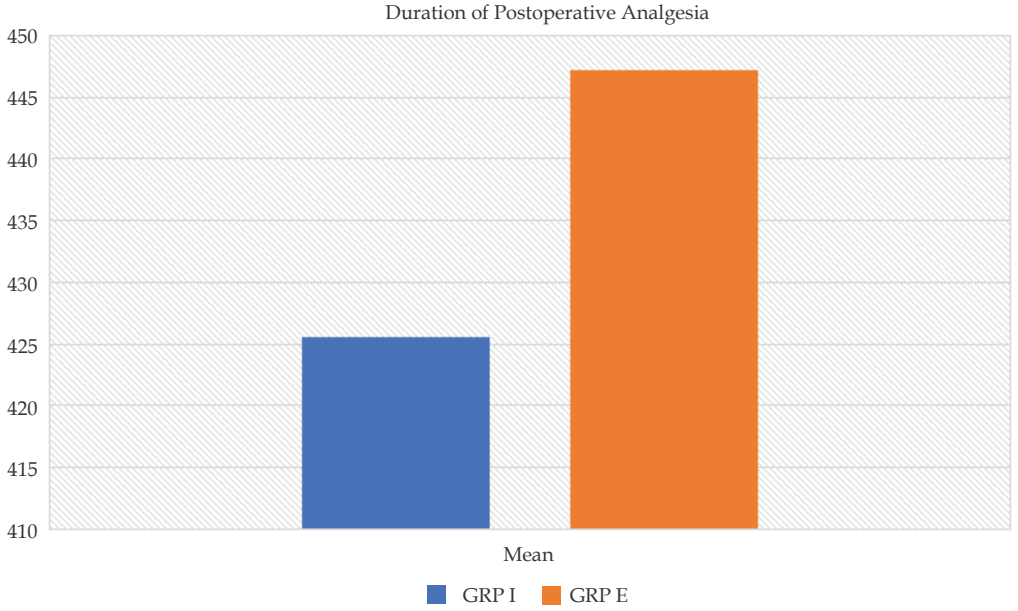

Fig. 4:

Discussion

This study was conducted to evaluate and compare the effect of epidural Dexmedetomidine with Intravenous Dexmedetomidine for potentiating perioperative analgesia in spinal anesthesia with Bupivacaine in patients undergoing elective lower-limb surgery. The mean time of onset of sensory and motor blockade was comparable in both groups while we found that two segment regression and time of first request of analgesic in group E was significantly prolonged than in group I which indicates epidural Dexmeditomidine prolongs duration of sensory blockade more than Intravenous Dexmeditomidine. Similar fiondings were noted In the study conducted by SI Shaikh and et al.,[4] who compared epidural dexmedetomidine (1.5 µg/kg) or clonidine (2 µg/kg) in 10 ml normal saline along with 0.5% isobaric levobupivacaine 15 mg (3 ml) and found that mean time taken for rescue analgesia in Group A (Clonidine) was 363.73 min and that of Group B (Dexmeditomidine) was 456.87 min.

In literature we found comparative study of IV verses Intrathecal Dexmeditomidine but we didn't find any study comparing Intravenous verses Epidural Dexmeditomidine. Ahmed

M.S. Hamed, Sahar M. Talaat[2] reported that durations of sensory and motor blockade and postoperative analgesia were significantly longer in the IT group. Annamalai A, Singh S, Singh A, Mahrous DE[3] compared effect of IV saline with IV Dexmeditomidine 10 minutes prior to spinal anesthesia and IV Dexmeditomidine 10 minutes after spinal anesthesia and concluded that Intravenous dexmedetomidine prolonged spinal bupivacaine sensory blockade in both the groups. Our findings were comparable with these studies which indicates that intravenous or Epidural administration of Dexmeditomidine prolongs postoperstive analgesia but it is more with Epidural administration.

Epidural administrations of α2 agonists lead to anxiolysis, sedation, analgesia, and hypnosis.[4,5] The anesthetic and the analgesic requirement get reduced because of their analgesic properties and augmentation of local anesthetic effects as they cause hyperpolarization of nerve tissues by altering transmembrane potential and ion conductance at locus coeruleus in the brainstem.[4] Dexmedetomidine may exert its effect on sensory and motor block through the supraspinal, spinal, and peripheral action.[6] It acts on both presynaptic and postsynaptic sympathetic nerve terminal and central nervous system, thereby decreasing the sympathetic outflow and norepinephrine release causing sedative, antianxiety, analgesic, sympatholytic, and hemodynamic effects.[7] Even with the evidence of both the supraspinal and peripheral sites of action of dexmedetomidine, the spinal mechanism may be mainly responsible for the analgesic effects.[4,8,9] Epidural dexmedetomidine has greater selectivity for α-2 receptors with greater lipid solubility which might be the reason for early onset of sensory and motor blockade. Reduction of the systemic absorption of the local anesthetic caused by local vasoconstrictor subtypes mediated by the C2 in smooth muscle and venous epidural plexus might be responsible for prolongation of analgesia. All these factors might be responsible for prolonged analgesia we found in epidural Dexmeditomidine group than in Intravenous group.

Intravenous dexmedetomidine may also augment the effect of the intrathecal block. Although the mechanism remains unclear, the supraspinal direct analgesic and the vasoconstrictive effect of dexmedetomidine are likely to be involved. Neurons in the locus coeruleus are connected to the noradrenergic nuclei in the brain stem. The activity of noradrenergic neurons is decreased by agonists acting at α2-adrenergic receptors in the locus coeruleus cell bodies, and therefore exerts a descending inhibitory effect on nociception in the spinal cord.[6,10]

Administration of dexmedetomidine intravenously reduces the release of norepinephrine and inhibits sympathetic activity, thus resulting in decreasing heart rate and blood pressure.[10] As we infuse Dexmeditomidine over a period of 15 min and 500 ml of Normal Saline before administration of spinal anesthesia we didn't observe significant bradycardia or hypotension in both groups.[6] Bradycardia during spinal anesthesia is believed to be secondary to decreased venous return and from the blockade of sympathetic stimulation to the heart that arise from the first four thoracic spinal segments.[11] The hypnotic and supraspinal analgesic effects of dexmedetomidine are mediated by the hyperpolarization of noradrenergic neurons, which suppresses neuronal firing in the locus coeruleus along with inhibition of norepinephrine release and activity in the descending medullospinal noradrenergic pathway. We didn't observed sedation or respiratory depression in both groups.

So we could say that epidural Dexmeditomidine is a better option for providing prolonged analgesia than Intravenous Dexmeditomidine.

Conclusion

Epidural Dexmeditomidine 0.5 microgram/kg leads to prolongation of sensory blockade after intrathecal Bupivacaine and also prolongs postoperative analgesia than Intravenous Dexmeditomidine. Also it provides good cardiovascular stability without sedation and respiratory depression. We can conclude that Epidural Dexmeditomidine prolongs sensory blockade significantly than Intravenous Dexmeditomidine.

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Original Research Article

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Adductor Canal Block: A Prospective Case Series Report in Unilateral Total Knee Arthroplasty

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Abstract

Introduction: Total knee arthroplasty is associated with moderate to severe pain and effective analgesia is essential to facilitate post operative recovery. This non randomised case series examined the analgesic effect of adductor canal block as a central tool in an integrated multi modal analgesia.

Material and Methods: We used adductor block to manage postoperative pain in 43 patients presenting to our service for unilateral primary total knee arthroplasty. We recorded pain scores, opioid usage and any adverse side effect.

Result: Pain control was generally satisfactory. Very few patients required fentanyl infusion as a rescue analgesia. Vomiting was reported but other side effects such as hypotension, itching, fall etc were unremarkable.

Conclusion: Adductor block was practical, safe and effective method of analgesia for pain relief in patients who have undergone unilateral total knee replacement.

Keywords: Adductor canal block, Analgesia, Total knee arthroplasty.

Introduction

Total knee arthroplasty (TKA) is associated with relatively severe pain and difficult to manage. It has been demonstrated that about 60% of patients have severe pain and 30% of patients have moderate pain post TKA.[1] The pain after TKA does not only impose restriction on early mobilization but also increase the rate of immobility related complications such as deep vein thrombosis. Effective analgesia post TKA is of extreme importance to the postoperative patients, which can improve the patient's satisfaction. To relieve the pain and improve the effect of TKA, the most common analgesic methods are patient controlled intravenous analgesia(PCIA), epidural analgesia, femoral nerve block(FNB).[2,3]

However, PCIA needs a large amount of opioids and is relevant to more adverse events than FNB, and patients who receive epidural analgesia had a higher rate of hypotension and urinary retention.[4] FNB may weaken the strength of quadriceps and increase the incidence of falling.[5,6] TKA patients who fell were more likely to go on to suffer additional major cardiac, pulmonary, thromboembolic and other organ-systems complications with higher 30 day mortality compared with TKA patients who did not fall.[3]

With the advent and development of ultrasonography, the adductor canal as an aponeurotic structure in the middle third of the thigh can be seen clearly. Through this new technology, adductor canal block (ACB) can be successfully implemented and thus can be performed to the knee surgery to relieve pain. This method selectively

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blocks the sensory nerve but does not block the motor neuron. So this can relieve pain, meanwhile it does not weaken the strength of quadriceps and adductor, thus reducing the incidence of fall.[7]

Material and Methods

Ethical approval of this study was unnecessary because it was a review of existing literature and did not involve any handling of individual patient data. The study was carried out at Sant Parmanand Hospital, New Delhi. Our institute is a tertiary referral centre providing care for all major orthopaedic surgery with an active joint arthroplasty programme. Patients scheduled for TKA with spinal anesthesia between May 2016 to May 2017 were included. Eligible participants were patients scheduled for primary TKA with spinal anesthesia aged between 45 years and 80 years with an American society of anesthesiologist physical status classification of 1 to 3. Exclusion criteria were inability to cooperate, inability to speak Hindi or English, allergy to any drug used in the study, alcohol or drug abuse, daily intake of strong opioids, rheumatoid arthritis and if the spinal anesthesia had resolved before conducting the block.

Premedication consisted of 0.25 mg Alprazolam and Panmid DSR given 2 hrs preoperatively. Spinal anesthesia was induced with 2 to 2.5 ml of 0.5% hyperbaric bupivacaine at the L3/4, L4/5 or L2/3 interspace. Sedation and intraoperative fluid therapy were administered at the discretion of anesthesiologist. All patients received a femoral tourniquet perioperatively. At the conclusion of surgery all patients received periarticular injection of

1 Bupivacaine 0.5% 20 ml

2 Amikacin 0.5 gm 01 ml

3 Clonidine 75 mcg 0.5 ml

4 Adrenaline 0.5 mg 0.5 ml

5 Saline 78 ml

ACB was performed in the Post Anesthesia Care unit, immediately postoperative. For the ACB we performed an ultrasound survey at the medial part of the thigh, halfway between anterior superior iliac spine and the medial part of patella. In a short axis view, we identified the femoral artery underneath the Sartorius muscle with the vein just inferior and the saphenous nerve just lateral to the artery. The needle was introduced in-plane and 2-3 ml of saline was used to ensure correct placement of the needlein the vicinity of saphenous nerve in the adductor canal. The catheter was than introduced and advanced 1 to 2 cm beyond the tip of the needle. The correct spread of bupivacaine bolus injection in a semi-circular form around the artery was observed. 8 ml of 0.5% bupivacaine as a bolus dose was administered via the adductor canal catheter. Thereafter 8 ml of 0.25% bupivacaine was administered through the adductor canal catheter at 8 hour interval. This dose was repeated earlier if the patient complained of pain. Fentanyl infusion was started as a rescue analgesia if the pain persisted. In addition the patient also received injection Paracetamol, 1 gm iv thrice daily and injection Flexilor, 8 mg iv twice daily.

Measurements

Pain assessment: All patients in the study had their pain scores assessed initially at 4 hours and then every 8 hrs by the anesthesiologist. Pain was assessed using VAS, a numerical rating scale from 0-10 (with 0 representing no pain and 10 representing the worst possible pain) at 4 hours, 12 hours, 24 hours and 36 hours. Zero time was taken from first adductor top up immediately after the insertion of adductor canal catheter.

Opioid usage: Fentanyl infusion was used as a rescue analgesia if the patient had VAS score 4 or more.

Adverse events: All patients were closely attended to by the nursing close supervision by the anesthesiologist for any adverse event like vomiting, itching, hypotension, fall. Patients were encouraged to report any such adverse event immediately.

Statistical Analysis

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Age	41	53.00	82.00	66.5122	6.74211
Valid N (listwise)	41				

		Frequency	Percent
Valid	Male	14	31.8
	Female	30	68.2
	Total	44	100.0

Descriptive					
	Sex			Statistic	Std. Error
Age	Male	Mean		70.0000	2.09978
		95% Confidence Interval for Mean	Lower Bound	65.3784	
			Upper Bound	74.6216	
		5% Trimmed Mean		69.8889	
		Median		67.0000	
		Variance		52.909	
		Std. Deviation		7.27386	
		Minimum		60.00	
		Maximum		82.00	
		Range		22.00	
		Interquartile Range		14.00	
		Skewness		.617	.637
		Kurtosis		-.979	1.232
	Female	Mean		65.0690	1.12619
		95% Confidence Interval for Mean	Lower Bound	62.7621	
			Upper Bound	67.3759	
		5% Trimmed Mean		65.1877	
		Median		65.0000	
		Variance		36.781	
		Std. Deviation		6.06472	
		Minimum		53.00	
		Maximum		75.00	
		Range		22.00	
		Interquartile Range		8.50	
		Skewness		-.288	.434
		Kurtosis		-.623	.845

Item Statistics			
	Mean	Std. Deviation	N
V4	2.05	.899	43
V12	1.65	.613	43
V24	1.35	.482	43
V36	1.21	.412	43
V48	1.12	.324	43

Reliability Statistics	
Cronbach's Alpha	N of Items
0.734	5

Cronbach's alpha	Internal consistency
$\alpha \geq 0.9$	Excellent
$0.9 > \alpha \geq 0.8$	Good
$0.8 > \alpha \geq 0.7$	Acceptable
$0.7 > \alpha \geq 0.6$	Questionable
$0.6 > \alpha \geq 0.5$	Poor
$0.5 > \alpha$	Unacceptable

Rescue					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		41	93.2	93.2	93.2
	Fenta in	3	6.8	6.8	100.0
	Total	44	100.0	100.0	

Descriptives

VAS

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
1	43	2.05	.899	.137	1.77	2.32	1	5
2	44	1.66	.608	.092	1.47	1.84	1	3
3	44	1.36	.487	.073	1.22	1.51	1	2
4	44	1.20	.408	.062	1.08	1.33	1	2
5	44	1.11	.321	.048	1.02	1.21	1	2
Total	219	1.47	.666	.045	1.39	1.56	1	5

Anova

VAS

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	25.046	4	6.261	18.723	.000
Within Groups	71.566	214	.334		
Total	96.612	218			

Multiple Comparisons

Dependent Variable: VAS

	(I) Vas_Code	(J) Vas_Code	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
LSDl4e l;f	1	2	.387*	.124	.002	.14	.63
		3	.683*	.124	.000	.44	.93
		4	.842*	.124	.000	.60	1.09
		5	.933*	.124	.000	.69	1.18
	2	1	-.387*	.124	.002	-.63	-.14
		3	.295*	.123	.017	.05	.54
		4	.455*	.123	.000	.21	.70
		5	.545*	.123	.000	.30	.79
	3	1	-.683*	.124	.000	-.93	-.44
		2	-.295*	.123	.017	-.54	-.05
		4	.159	.123	.198	-.08	.40
		5	.250*	.123	.044	.01	.49
	4	1	-.842*	.124	.000	-1.09	-.60
		2	-.455*	.123	.000	-.70	-.21
		3	-.159	.123	.198	-.40	.08
		5	.091	.123	.462	-.15	.33
	5	1	-.933*	.124	.000	-1.18	-.69
		2	-.545*	.123	.000	-.79	-.30
		3	-.250*	.123	.044	-.49	-.01
		4	-.091	.123	.462	-.33	.15

Multiple Comparisons							
Dependent Variable: VAS							
	(I) Vas_Code	(J) Vas_Code	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Bonferroni	1	2	.387*	.124	.020	.04	.74
		3	.683*	.124	.000	.33	1.03
		4	.842*	.124	.000	.49	1.19
		5	.933*	.124	.000	.58	1.28
	2	1	-.387*	.124	.020	-.74	-.04
		3	.295	.123	.174	-.05	.65
		4	.455*	.123	.003	.10	.80
		5	.545*	.123	.000	.20	.90
	3	1	-.683*	.124	.000	-1.03	-.33
		2	-.295	.123	.174	-.65	.05
		4	.159	.123	1.000	-.19	.51
		5	.250	.123	.438	-.10	.60
	4	1	-.842*	.124	.000	-1.19	-.49
		2	-.455*	.123	.003	-.80	-.10
		3	-.159	.123	1.000	-.51	.19
		5	.091	.123	1.000	-.26	.44
	5	1	-.933*	.124	.000	-1.28	-.58
		2	-.545*	.123	.000	-.90	-.20
		3	-.250	.123	.438	-.60	.10
		4	-.091	.123	1.000	-.44	.26

*. The mean difference is significant at the 0.05 level.

Results

The mean pain scores for subjects with ACB (n=43) was 2.05 after 4 hours, 1.65 after 12 hours, 1.35 after 24 hours, 1.21 after 36 hours and 1.12 after 48 hours. This result demonstrates that adductor canal block provides adequate postoperative pain relief in unilateral total knee arthroplasty patients.

Discussion

The adductor canal is a musculoaponeurotic space in the thigh, extending from the apex of the femoral triangle to the adductor hiatus, between the vastus medialis muscle anterolaterally and the adductor longus and adductor magnus muscles posteromedially. It is roofed in the entire length by the vastoadductor membrane.[8–10] It contains several nerve branches that supply sensory innervations to the knee, including consistently the saphenous nerve (which innervates the infrapatellar skin and anterior knee capsule) and a distal branch of the motor nerve to the vastus medialis (which provides sensory innervation to the superomedial aspect of the knee and knee capsule.[11] In addition other small sensory nerves involved in analgesia of the knee course frequently, although not consistently, through this space. The adductor canal is therefore an attractive location to provide sensory innervations to the knee with potential limited effect on motor function.

Adductor canal block (ACB) is a relatively new alternative for post-TKA pain management. Regional anesthesia is deposited within an adductor canal that can be easily visualized at the middle third of the thigh with use of ultrasonography. Consequently, ACB can be performed with a high success rate. Anatomical study of adductor canal showed that an adductor canal contained multiple afferent sensory nerves (e.g. saphenous nerve, medial femoral cutaneous, and medial retinacular nerve etc.) but only a single efferent motor nerve (vastus medialis of the quadriceps muscle) that potentially affected motor function.[8–10] Therefore, ACB may have a minimal effect on quadriceps muscle strength, but provides a comparable level of pain relief and early mobilization.

All blocks were performed postoperatively under spinal anesthesia. This was done due to 2 reasons:

1. To avoid entrapment of the catheter between the nerve and the tourniquet.

2. To avoid dislodging of the catheter during surgery.

The local anesthetic were administered as repeated boluses through a catheter to ensure spread of local anesthetics throughout the aponeurotic canal. This is because adequate adductor canal block blocks more than just the saphenous nerve in the adductor canal. In addition to the saphenous nerve, the adductor canal also contains the nerve to vastus medialis, the medial femoral cutaneous nerve, the medial retinacular nerve and finally the articular branches from the obturator nerve, which enters the distal part of the canal.

The dose administered was 8 ml injected into the adductor canal. The volume was kept low because increasing the volume caused the drug to spread proximally to the anterior and posterior divisions of the femoral nerve outside the canal thereby increasing the risk of motor blockade.

We used integrated multimodal analgesic protocols, as defined by the American Society of Anesthesiologist practise guidelines on perioperative pain management, use two or more analgesic modalities with different mechanism of actions to provide superior analgesia and limit side effects and adverse events.[12] Regional analgesic technique is usually at the centre of these multi modal protocols in a background of NSAIDS and low dose opioids. There is anascent but growing case being made in the contemporary literature to support ACB as the most appropriate regional analgesic technique to be the core of multimodal analgesic protocol for TKA due to its decreased potential for quadriceps weakness.[13,14]

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Effect of Platelet Rich Plasma in Knee Osteoarthritis

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Abstract

Back ground and Aims: This study aims to evaluate the effectiveness of intra-articular injection of platelet rich plasma (PRP)in reducing pain and improving physical function, in osteoarthritis.

Method: Prospective longitudinal study comprising of 100 patient& divided into 3groups according to Kallgren & Lawrence grading of osteoarthritis of knee and followed up for period of 1 year (january18 to October 19). All patients were treated with intraarticular PRP injection (C-arm guided) in affected knee at 4weeks apart. VAS (Visual analog scale), KOOS (knee injury osteoarthritis outcome score) used for clinical evaluation. Data analyzed using SPSS software 22.0.

Result: Outcome were almost similar for grade 1&2 though intensity of pain showed significant improvement even in grade3($p<0.05$). on the basis of VAS SCORE Highly significant improvement in pain in Grade1 and Grade2 osteoarthritis having p value<0.0001 and significant improvement in Grade3 osteoarthritis having p value=0.003(<0.05). On the basis of KOOS SCORE all the parameter like pain symptom, functional daily activity, sport & recreational activity and quality of life highly significant improve in Grade1&2 pvalue<0.0001 and for Grade3 significant improvement in all parameter having p value<0.05.

Conclusion: PRP injection is a cost effective, reliable, minimal invasive, no side effect, good efficacy & used in less equipped setting. And showed clinical as well as functional improvement in VAS score and KOOS score. It is highly significant for grade 1 and 2 and significant for grade 3 osteoarthritis.

Keyword: Platelet rich plasma (PRP); Knee injury & osteoarthritis outcome score (KOOS); Visual analogue scale.

Introduction

Osteoarthritis is the leading cause of disability in human.[1] Knee osteoarthritis account for more than 80% disease burden comparative to other medical condition[2.] India is likely to notice an endemic of osteoarthritis in 2013 Osteoarthritis in India affect over 15 million Indian each year with prevalence of 22 to 39% and this prevalence increased drastically with age after 50 years.[3]

The term osteoarthritis defined as an idiopathic slowly progressive disease of diarthrodial (synovial) joints mainly occurring late in life and characterized pathologically by focal degeneration of articular cartilage, subchondral bone thickening

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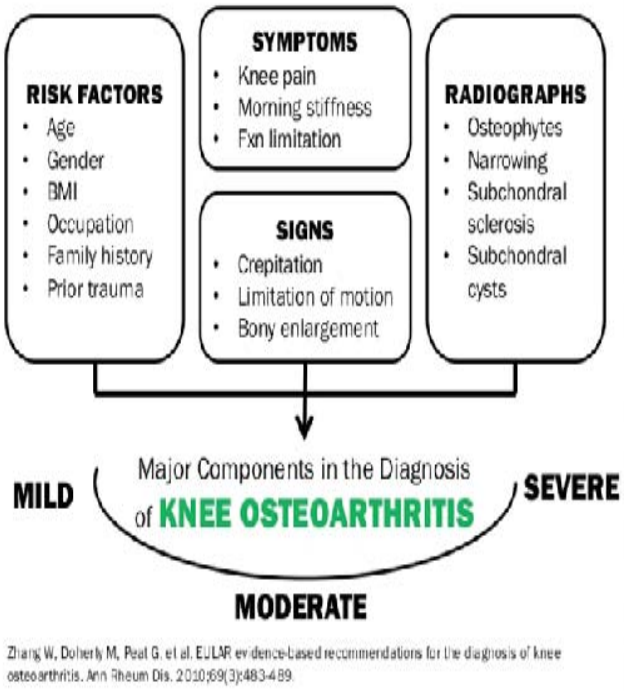
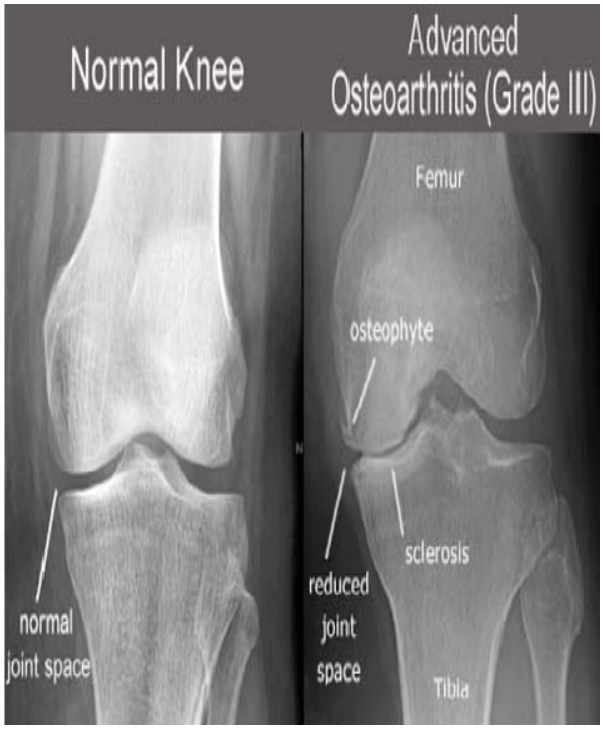




(sclerosis), marginal osteochondral outgrowth (osteophytes), and joint deformity.[4]

There are various predisposing factor & sign-symptom are.[5]

Management Non Pharmacological

Education like life style modifiaction , behavioural-intervention, weight loss,and physiotherapy like quadriceps strengthening.[6]

Pharmacological-Symptom Modifying Drugs:

Acetaminophen is recommended as first line therapy for osteoarthritis in addition to non-pharmacological therapy.[7]

Salicylate and NSAIDS for those who do not obtain adequate pain relief with paracetamol.[7]COX-2inhibitors like celecoxib, etoricoxib, valdecoxib for pain mangement and with better gastrointestinal tolerability, but having some cardiovascular general side effect.

Tramadol is good for pain, stiffness, physical function, in patient with chronic pain.[8]

Intraarticular corticosteroid injection most effective in patient with inflammation, effusion or both .[9]

Symptomatic slow acting drug for osteoarthritis/ structure modifying oa drug-Hyaluronic acid (hyalgan and synvisc) are viscosupplementation use in OA knee & Diacerein and its active metabolite has capability to inhibit IL-1β.

Operative Method- Includes 1- Joint debridement. 2- Realignment osteotomy 3- Joint replacement 4-Arthodesis.

Platelet Rich Plasma For Treatment of Knee Degenration And Osteoarthritis

There are number of side effect after using the pharmacological drug in Osteoarthritis (gastric irritability, cardiovascular problems etc.) For operative management for osteoarthritis , it needs highly skilled and experienced surgeons and they are not cost effective.

Recently platelet rich plasma has been proposed as a useful modality in treatment of osteoarthritis knee joint which is cost effective and having less side effects comparative to existing treatment. Platelet rich plasma is autologous blood derived product Principally composed of a high concentration of Platelet. Platelet rich plasma therapy provides delivery of a highly concentrated cocktails of growth factors to accelerate healing.

Broadly platelet concentration are of 4 types:-[10]

Pure prp

Leukocyte rich prp .

Pure platelet rich fibrin (prf)..

Leukocyte rich prf

Platelets contain three types of granules –

Lysosomal granules,

Dense granules

Alpha granule

Alpha Granules-having GFs, like Platelet derived growth factor (PDGF),transforming growth factor(TGF-β), Platelet derived epidermal growth factor{PDEGF), Vascular endothelial growth factor(VEGF), Insulin-like growth factor(IGF-1) and epidermal growth factor(EGF); also contain cytokine and chemokines, which involved in stimulating chemotaxis, cell proliferation and maturation, modulating inflammatory molecules and maturation.

Dense Granules- Store ADP, ATP, calcium ions, histamine, serotonin and dopamine, which are also play a complex role in tissue modulation and regeneration.

Plasma itself help in healing mechanism of connective tissues and also contributing to the platelet stimulus in tissue regeneration.[11,12]

Aims and Objective

The aim is to evaluate the effectiveness of platelet rich plasma in reducing pain.

Objective is to assess the improving physical function in osteoarthritis knee.

Material and Methods

This study had been conducted in the Department of Anesthesiology critical care and pain medicine, GSVM Medical college & Associated Hospitals, Kanpur.

Study Group :

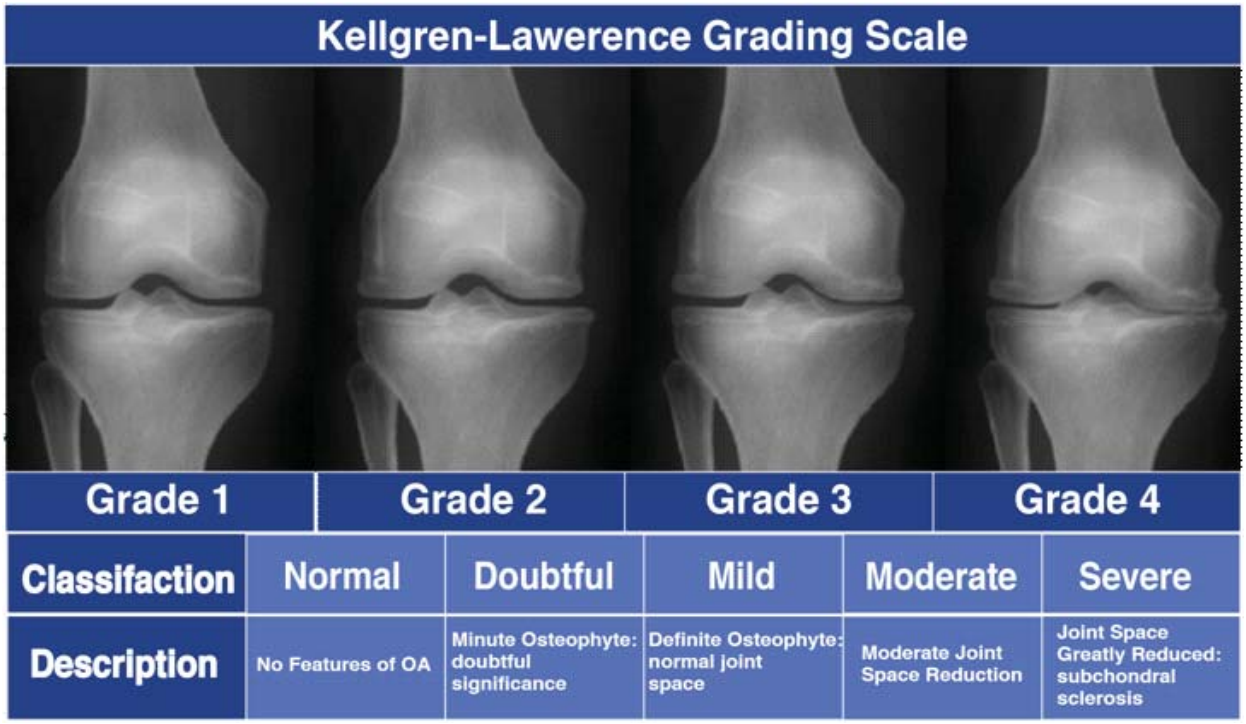
The study included patient of knee osteoarthritis admitted through Pain OPD of this Institution.

Study Design : Prospective Study, Single Arm, Open Label, to evaluate efficacy and safety of PRP technique in Knee Osteoarthritis

Study Duration : 1 year, January 2018 to October 2019.

Sample Size:- 100 Patient of OA Knee

Statistical Analysis : Analysis of data was done using the SPSS software 22.0 . The results were expressed as mean ± SD. Ap value of 0.05 or less



is considered significant. A paired t test, Non parametric paired t test was used for comparison of the data. ANOVA (Analysis of variance) is used.

Inclusion criteria:

Unilateral / bilateral osteoarthritis knee patient of Grade 1 , 2 & 3 on basis of Kellgren –Lawrence classification.

Age more than 35 years

pain and swelling more than 4 months

Exclusion Criteria:

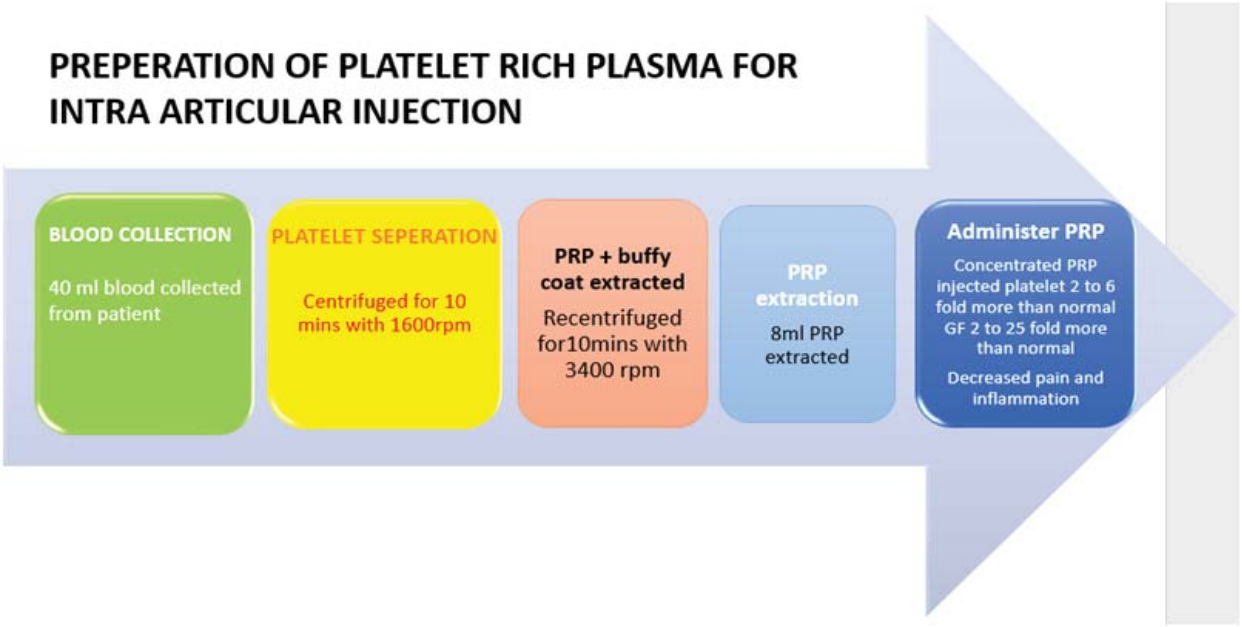
Age more than 70 years

Grade 4 osteoarthritis knee.

3. disease like diabetes, rheumatoid arthritis,

hematological disease, severe cardiovascular diseases, infections, immunodepression, patients therapy with anticoagulants or anti-platelet aggregants

Preparation of platelet rich plasma and intra articular injection A 40ml venous blood sample drawn from patient itself under aseptic conditions in a 50ml syringe with 4ml CPD-A as anticoagulant for every knee treated. Then, 2 centrifuge twice the first at 1600 rpm for 10 minutes to separate



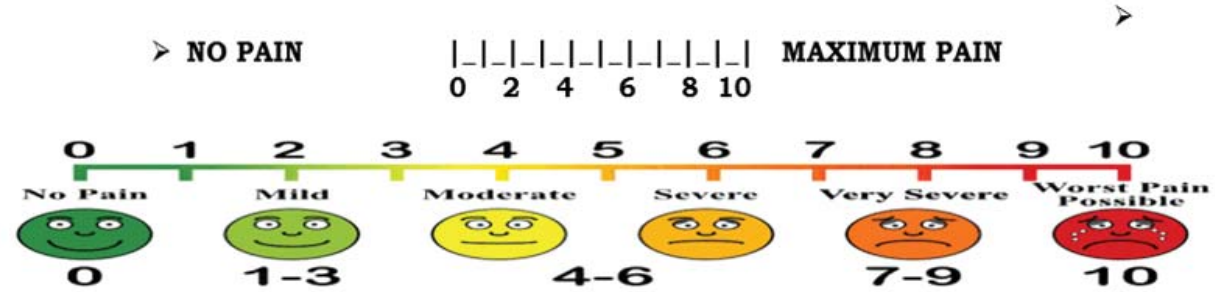
erythrocytes and a second at 3400 rpm for 10 minutes to separate concentrate platelets produced a unit (08ml) of PRP . The unit of PRP was divided into 2 small units of 2ml and 6ml.

2ml was sent to the laboratory for analysis of platelet concentration and microbiological assessment. After getting the quality analysis of PRP. The remaining 6 ml PRP was injected in the knee[18]. Followed by two similar injection cycle of PRP at a interval of 4 weeks.

After the injection, patients were sent home with instructions to restrict the use of leg for at-least 24 hours and to use cold therapy/ice on affected area to relieve pain. During this period of 72 hours, the use of non-steroidal medication was forbidden, however, if patient complain for pain we prescribe Paracetamol for pain management. patients were advised life style modifications, Physical therapies like Quadriceps strengthening exercises.

We assess the effect of platelet rich plasma

➢ **VISUAL ANALOGUE SCALE**



on pain and functional activity of patient by using VAS Score and KOOS Score at 1,4,6 & 12 month from1st day after intraarticular injection.

Visual Analogue Scale

Pain was further graded as –

0 – (VAS 0) comfortable

1 – (VAS 1-3) Mild Pain

2 – (VAS 4-6) Moderate pain

3 – (VAS 7 – 10) Severe pain

Knee Injury and Osteoarthritis Outcome Score (KOOS)[17]

The Knee Injury and Osteoarthritis Outcome Score (KOOS) is a questionnaire and it contain five item: pain, symptoms, activities of daily living, sport and recreation function, and knee-related quality of life and. all items have five possible answer options scored from 0 (No problems) to 4 (Extreme problems).

Interpretation of scores

Scores are 0–100 scale,and zero represent extreme knee problems and 100 represent no knee problems. Scores between 0 and 100 represent the percentage of total possible score achieved.

Results

First we enrolled 150 patient 40 patient are exclude because 30 patient not meeting inclusion criteria 8 refused , 2 respond to conservative treatment. 10 patient lost to follow up. Hence, the wanalysis done on 100 patients.

Table 1: Distribution o f patients of osteoarthritis according to gender

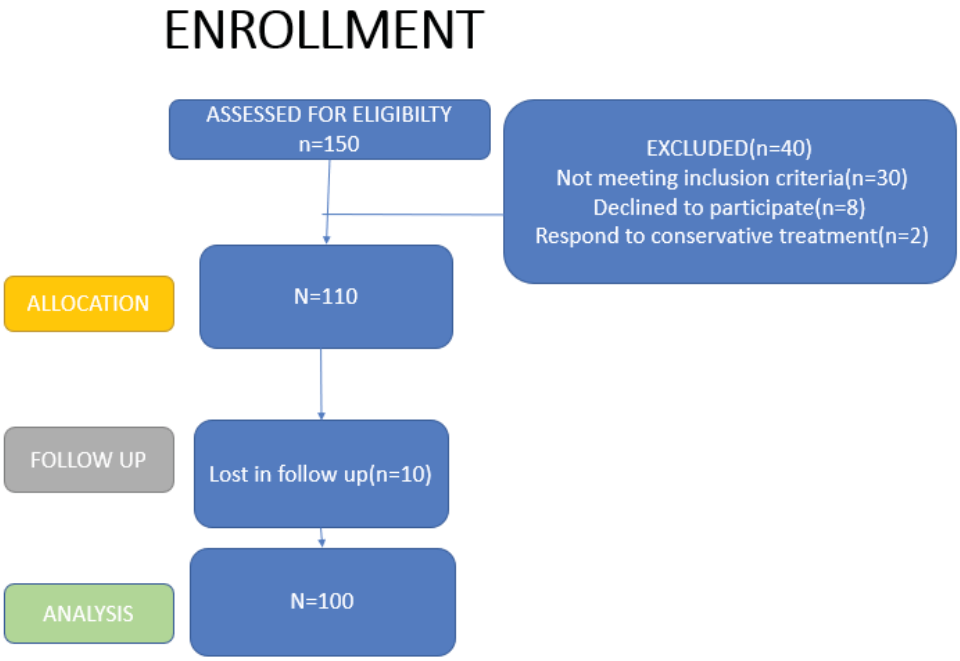
Sex	No. of patients	%age
No. of males	55	55%
No. of females	45	45%

In our study there is 55% are male and 45% are female

Table 2: Age distribution of different grades of osteoarthritis in study subjects

Age distribution	No. of grade I Osteoarthritis		No. of grade II Osteoarthritis		No. of Grades III osteoarthritis	
	No.	%	No.	%	No.	%
35 – 44	9	9	1	1	0	0
45 – 54	16	16	9	9	0	0
55 – 64	5	5	33	33	2	2
65 – 75	0	0	11	11	14	14

Most of the patient are of 55 – 64 years of age having grade 2 osteoarthritis of total study subject. in 35 – 44 years of age maximum patients of grade



1 osteoarthritis in 45 – 54 years of age maximum patients of grade 1 osteoarthritis while in 65 – 75 years of age 14 patients of grade 3 osteoarthritis and 11 patients are grade 2 osteoarthritis means severity increases with age.

Table 3: Comparison of VAS Score to study subjects before and after PRP administration

Determinant	PRE PRP		Post PRP	
VAS Score	Mean	SD	Mean	SD
	7.34	±.88	3.22	1.80±

P value< 0.0001

In our study mean pre injection VAS score is 7.34 ± 0.88 and it improved to score of 3.22 ± 1.80 at 12 months of follow up.

	Pre-PRP		**Post-PRP**		**P value**
	Mean	**± S.D.**	**Mean**	**± S.D.**	
Grade 1	6.8	±0.653	2.4	± 0.84	<0.0001
Grade 2	7.3	± 0.86	2.57	±0.80	<0.0001
Grade 3	7.8	± 0.85	6.8	± 1.01	=0.0029

In our study patient having grade 1, grade 2, grade 3 all are improved but grade 1 and grade 2 much better improved that grade 3.

In grade 1 and grade 2 osteoarthritis there has been very highly significant improvement in KOOS score while there has been highly significant improvement in a KOOS score in grade.[3]

Discussion

Platelet Rich Plasma has emerged as noble technique cost effective, reliable, good efficacy least side effect and can be used in less equipped setting in the treatment of osteoarthritis. Platelet rich plasma point to having a two to eight fold increase in platelet concentration and one to twenty five fold growth factor concentration of that of blood. PRP is an autologous blood derive product has been used as a treatment and has shown to have promising result in terms of clinical function. As per Laudy *et* al,[14] the level of evidence regarding this association is not strong and needs further corroboration specially in different environmental and clinical situation as well as different other alternative treatment option.

There were two major consideration while planning the study First is whether intra-articular use of platelet rich plasma is feasible without complication Second weather platelet rich plasma provide a clinical/functional improvement in patient with osteoarthritis knee.

For this purpose, a total of 100 patients of with unilateral or bilateral osteoarthritis underwent of PRP interventions and were subsequently followed up upto 12 month for symptomatic relief. Age of patient ranged from 35 to 70 years with a mean of 57.68 ± 8.77 years. Filardo *et* al[15] too in their series reported the mean age of patient as 56.5year which is close to the mean age of present study. In present male female ratio is 55 and 45%.In different clinical study evaluating the role of platelet rich plasma the gender ratio has shown a variability. Wang-Saegusa *et al.*[16] *in their study had 41.8%women ,.* **as observed in present study. But in another Indian study** Patel,Sandeep *et al.*[18] **reported70.7% of their study population is women.**

In our study we aimed to show the efficacy of PRP application in reducing pain &improving physical function in OA Knee and find that PRP application improved pain and clinical outcomes. PRP enhance synthesis of type 2 collagen and chondrocyte by stimulating the proliferation of chondrocytes and pluripotent mesenchymal.

In present study, majority of cases had bilateral disease (54%).and majority of patient is Grade 2 (54%) followed by Grade 1 (30%), and Grade 3 (16%) respectively. Compared to this . Filardo, KON *et al*[15] in there study reported 57.9% patient in KL grade1-3 and remaining 42.1% in KL grade 4.In Spakova T *et al*[17] study total of 120 patient were included which include Grade1, Grade2, Grade3 osteoarthritis patient.

Vas Score At Follow Up-

In our study over all VAS score after PRP decreased from 7.34±0.88 to 3.22±1.8 at 12 months of follow up. very highly significant improvement in VAS Score in Grade 1 and Grade 2 Osteoarthritis pvalue <0.0001 while there is significant improvement in Grade 3 osteoarthritis with pvalue of 0.0029. Sampson S et al[19] conducted a study in which mean VAS score during moving decreased from 4.5 to 2.5 at 12 month of follow up. Sandeep *et al* [18] conducted a study in which the VAS score decreased from 4.54 to2.16 at 52 week followup. which is close to our study.

Koos Score Assesment

In our study KOOS Score there had been significant improvement in all 5 components p value in all cases had been less then 0.0001. there has been highly significant improvement in avg. KOOS Score in Grade 1 Grade 2 osteoarthritis and for grade 3 significant improvement, In Grade 3 osteoarthritis KOOS score for pain is .0041, for symptom 0.0065 and for functional daily activity

is0.033 and for sports and recreational activity is 0.012 and for quality of life is 0.0004 which is significant but on other side for grade 1 and 2 is <.0001 which is very highly significant. with max improvement is in quality of life. Alberto Gobbi *et al* [20] conducted a study in which KOOS scoring showed significant improvement in all components at 12 months of follow up So on the basis of VAS SCORE AND KOOS SCORE we can say that PRP is effective for Grade 1,2 and 3 but most effective for grade 1 and 2

No serious complication was noted in any case.

Conclusion

The Platelet Rich Plasma showed clinical improvement in VAS score and KOOS score. It is highly significant for grade 1 and 2 and significant for grade 3 osteoarthritis. Thus The findings of study conclude that PRP is cost effective, reliable, good efficacy ,having no side effect &used in less equipped setting and useful in improving the symptoms and functions of patients knee joint.

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Original Research Article

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Comparison of Conventional Central Venous Pressure with Peripheral Venous Pressure and External Jugular Venous Pressure in Patients with Sepsis

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Abstract

Context: Central venous pressures along with other dynamic and static variables are used to guide fluid therapy in patients with sepsis admitted to ICU. However, insertion of central venous catheter is associated with serious complications. We, therefore measured external jugular venous pressure (EJVP), peripheral venous pressure (PVP) and correlated with central venous pressure (CVP) measured by conventional technique and thus technical difficulty and complications can be avoided.

Aims: To evaluate the correlation between conventional CVP with EJVP and PVP values in patients with sepsis.

Settings and Design: Prospective observational study.

Methods and Material: Study done on 54 patients admitted with sepsis requiring fluid resuscitation. CVP, EJVP and PVP measurements were taken using a water column manometer in cm H_2O. All the three venous pressures were repeated 3 times following every fluid challenge of 250 ml.

Statistical analysis used: Pearson's correlation and Bland–Altman's analysis.

Results: The observations were analyzed by dividing the patients into 2 groups on the basis of CVP measurements

Group A (CVP ≤ 10)

Mean difference between CVP with PVP and EJVP is >2 cm H_2O and p value is insignificant.

Group B (CVP >10)

Mean difference between CVP with PVP and EJVP is <2 cm H_2O and p value ($p<0.001$) is strongly significant.

Conclusions: The present study concludes that, there is definite correlation between CVP, EJVP and PVP in a given patient. Further concludes the difference between CVP and EJVP/PVP was minimum (<2 cm H_2O) when the CVP was >10 cm H_2O.

Keywords: Central venous pressure; External jugular venous pressure; Peripheral venous pressure; Sepsis.

Introduction

According to Surviving Sepsis Campaign 2016 guidelines, central venous pressures along with other dynamic and static variables are used to guide fluid therapy in patients with sepsis admitted to critical care unit.[1] However, insertion of central venous catheter is associated with serious complications such as venous air embolism, pneumothorax, carotid artery puncture, arrhythmias, perforation

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of right atrium, cardiac tamponade and catheter related blood stream infection.[2] Unlike central venous cannulation, patients with vasofix inserted into external jugular vein and peripheral vein are less likely to encounter any serious complications.

Till date, only few studies are done to show the association between central venous pressure and peripheral venous pressure.[3–5] Peripheral venous pressure monitoring is an easy procedure and also can be used as reserve to central venous pressure in governing fluid volume status among critically ill patients.[6]

At present, in most of resource limited ICU's still rely on conventional central venous pressure monitoring using water column manometer for managing fluid resuscitation in septic patients.[7]

Materials and Methods

Main objectives of the study includes to measure CVP, EJVP and PVP and to evaluate the correlation between conventional CVP with PVP and EJVP in patients with sepsis.

This is a prospective observational study conducted on 54 patients with sepsis requiring fluid resuscitation received to tertiary care hospital, ICU from January 2018 to May 2019 after obtaining clearance from institutional ethical clearance.

Patients of above 18 years of age with sepsis admitted in ICU requiring fluid resuscitation were included and exclusion criteria includes patients with h/o cardiovascular disease, coagulopathy, inability to cannulate central/peripheral vein and infection at the site of cannulation.

Study was started after obtaining written informed consent taken from patient or next of kin. Necessary investigations like complete blood count, bleeding time and clotting time were done in all patients prior to cannulation to rule out coagulopathy. Under strict aseptic precautions, each of the PVP, EJVP and CVP was measured simultaneously using water column manometer. Initially 10 observations were done under supervision before start of study. Peripheral venous pressure was measured from 16G or 18G vasofix sited in right/left cubital fossa, external jugular venous pressure measured from 16 or 18G vasofix sited in right/left external jugular vein and central venous pressure measured from 16G distal port of 7 French triple lumen central venous catheter of 15 cm length sited in right/left internal jugular vein/subclavian vein. Water column manometers were connected to all the three catheters and zeroed at mid–axillary line corresponding to sternal angle. The zero point was identified on the manometer that corresponds to the patient's right atrium.[2,10] Zero reference point for venous pressures in the thorax in a point on the external thorax where the fourth intercostal space intersects the mid-axillary line (the line midway between the anterior and posterior axillary folds). When the patient is in supine position, this point (phlebostatic axis) corresponds to the location of the right and left atrium Recordings of the measurements that corresponds with the lower meniscus of the normal saline was taken as reading for CVP, PVP and EJVP. The measurement is expressed in cmH_2O. If the patient is on mechanical ventilation, we subtracted the PEEP value above 5 cmH_2O from the actual measurement of CVP value. Before fluid challenge peripheral venous pressure, external jugular venous pressure and central venous pressure are measured in all patients admitted with sepsis. All the three venous pressures were repeated 3 times following every fluid challenge of 200 ml.

Following insertion of central line, patient was subjected for chest x-ray to rule out pneumothorax. After check x-ray, we also checked the catheter tip position. Catheter tip position should ideally above the level of carina. This is the joining of the right and left innominate veins with the superior vena cava (SVC). If the catheter tip is too high in position, those values are associated with inaccurate values of CVP measured, hence such values were not considered in our study. If the patient develops any arrhythmias 12 lead ECG would be recorded and arrhythmias will be analyzed. If there is doubtful of catheter related blood stream infection after 48 hours of following central venous cannulation, two blood cultures will be done. One sample taken from central line and another from peripheral site. Peripheral venous catheters were changed every 72 hours or earlier when the signs of phlebitis noticed according to institutional practice.

Statistical analysis

Statistical analysis was done using SPSS Version 22 software. Sample size was estimated based on correlation co–efficient between central venous pressure and peripheral venous pressure from the study by Kumar et al. at the baseline with 90% power, 99% C.I and Type 1 Error 1%. Calculated sample size of 53 was obtained.[3]

Correlation co-efficient was used to study the relation between continuous variables. p value <0. 05 will be considered as statistically significant. In the present study, descriptive and inferential statistical analysis has been carried out. Continuous

measurements results are presented on Mean±SD (Min-Max) and results on categorical measurements are presented in Number (%) Assessment of significance is at 5% level of significance Pearson correlation co-efficient ranging between -1 to 1, -1 being the perfect negative correlation, 0 is the no correlation and 1 means perfect Positive correlation. The Bland–Altman method derives the mean difference between two methods of reading (the 'bias'), and 95% limits of agreement as the mean difference (2 SD) [or more precisely (1.96 SD)]. The better agreement is when there is small range between these two limits. 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)

Results

Study was done on 54 patients, all of the study subjects were analyzed. Out of which 43 patients were male and 13 patients were female. In each patient 12 observations were made. Hence for a total of 54 patients 648 observations were made. The observations were analyzed by dividing the patients into 2 groups on the basis of CVP measurements.

Group A is patients with CVP ≤10 and Group B is patients with CVP >10. Out of 648 observations, 396 observations belonged to Group A and 252 observations under Group B.

In Group A

Total mean CVP was 7.88 cmH_2O, mean EJVP was 10.83 cmH_2O and mean PVP was 11.17 cmH_2O.

CVP and EJVP -mean difference was 3.9, r=0.386, p=0.192

CVP and PVP -mean difference was 4.3, r=0.137, p= 0.174

In Group A (CVP ≤10) mean difference between CVP with PVP and EJVP is >2 cmH_2O and p value is insignificant.

In Group B

Overall mean CVP was 11.90 cmH_2O, mean EJVP was 12.58 cmH_2O, and mean PVP was 13.52 cmH_2O.

CVP and EJVP-mean difference was 1.3, r=0.685, p<0.001

CVP and PVP –mean difference is 1.8, r=0.785, p<0.001

In Group B (CVP >10) mean difference between CVP with PVP and EJVP is <2 cmH_2O and p value (p<0.001) is strongly significant and comparable.

To evaluate the degree of agreement, Bland and Altman plots were done between CVP - EJVP and CVP –PVP with 95% limits of agreement as the mean difference (1.96SD).

We didn't appreciate any difference with regards to CVP measurements or technical difficulty with

Table 1: Distribution of CVP at baseline in patients studied

	No. of patients	%
<=10 (Group A)	33	61.1
>10 (Group B)	21	38.9
Total	54	100.0

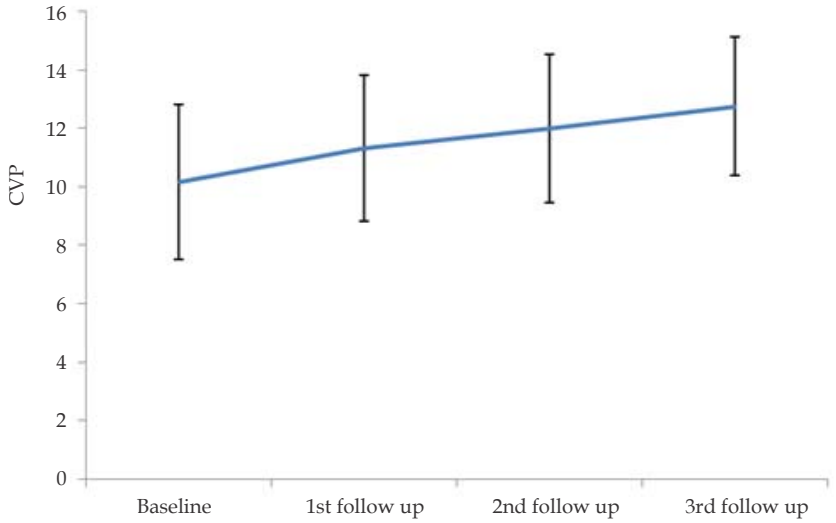

Fig. 1: Line diagram of CVP assessment among patients studied

the procedure regardless of the site (IJV/subclavain) or side of central venous catheterization (right side/left side). Out of 54 patients, 29 patients were on mechanical ventilation.

Among 54 patients, 2 patients developed phlebitis at the peripheral cannula site after 2 days, one patient had accidental subclavian arterial puncture and another patient developed hematoma while inserting right sided IJV due to carotid artery puncture which was subsided by giving local compression.

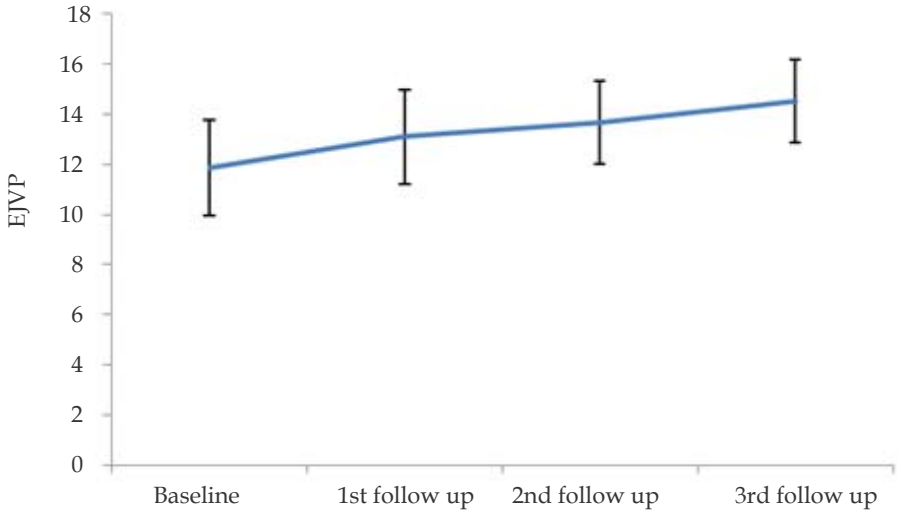

Fig. 2: Line diagram of EJVP assessment among patients studied

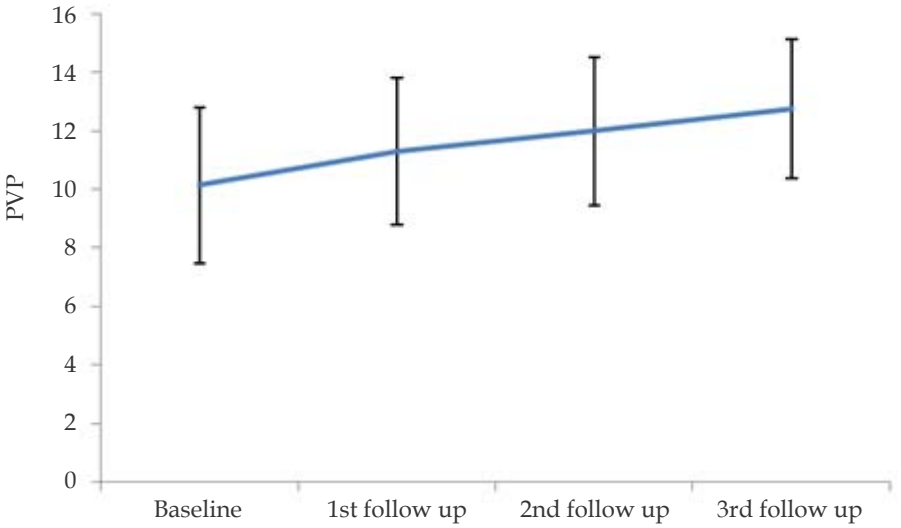

Fig. 3: Line diagram of PVP assessment among patients studied

Table 2: Bland altmnan plot statistics of CVP and EJVP

CVP vs EJVP	Baseline	1st follow-up	2nd follow up	3rd follow up
No of Patients	54	54	54	54
Mean Difference	1.68	1.76	2.33	1.74
SD-diff	1.97	1.85	2.18	1.89
Mean diff-1.96SD	-5.5	-5.4	-6.6	-5.5
Mean Diff+1.96SD	2.2	1.9	1.9	2.0
T value	6.287	6.979	7.863	6.749
P value	<0.001**	<0.001**	<0.001**	<0.001**
95% CI	1.14-2.22	1.25-2.26	1.73-2.93	1.22-2.26

Table 3: Bland altmnan plot statistics of CVP and PVP

CVP vs PVP	Baseline	1st follow-up	2nd follow up	3rd follow up
No of Patients	54	54	54	54
Mean Difference	2.37	2.40	12.50	2.20
SD-diff	1.67	2.07	2.09	2.08
Mean diff-1.96SD	-5.7	-6.5	-7.30	-6.30
Mean Diff+1.96SD	0.9	1.7	1.40	1.90
T value	10.403	8.510	43.762	7.76
P value	<0.001**	<0.001**	<0.001**	<0.001**
95% CI	1.91-2.82	1.84-2.97	11.93-13.07	1.63-2.77
Total	120			

Table 4: Correlation between CVP and PVP, CVP and EJVP in Group A and GROUP B

Pair	EJVP		Difference of CVP & EJVP	PVP		Difference of CVP & PVP
	r value	p value		r value	p value	
CVP ≤ 10						
• At baseline	0.504	<0.001**	2.67±1.71	0.137	0.448	3.12±1.49
• At 1st follow up	0.072	0.750	3.14±1.83	0.000	1.000	3.83±1.84
• At 2nd follow up	0.386	0.192	5.08±1.89	0.093	0.763	5.31±1.97
• At 3rd follow up	0.681	0.043*	4.78±1.56	0.179	0.644	5.22±1.86
CVP >10						
• At baseline	0.831	<0.001**	1.00±0.71	0.791	<0.001**	1.48±0.81
• At 1st follow up	0.685	<0.001**	1.19±0.74	0.801	<0.001**	1.75±1.29
• At 2nd follow up	0.646	<0.001**	1.75±1.01	0.709	<0.001**	2.41±1.43
• At 3rd follow up	0.637	<0.001**	1.40±0.96	0.732	<0.001**	1.78±1.33

Discussion

In hemodynamically unstable septic patients, it is important to optimize cardiac output and tissue oxygenation. Fluids remain the main line of treatment in patients with septic shock. Not all patients are fluid responsive i.e. respond to fluid challenge by increasing stroke volume and cardiac output.

Both inadequate fluid and excessive fluid administration would result in increasing morbidity and death in critically ill patients. Therefore accurate predictors of fluid responsiveness are essential for managing patients in septic shock.

For accurate prediction of fluid responsiveness, we need to monitor other dynamic variables/ parameters of fluid responsiveness such as systolic pressure variation, pulse pressure variation, stroke volume variation or echocardiographic measurement of stroke volume/cardiac output of left ventricle function or IVC (compressibility/ distensibility index) variation during respiration for fluid challenge which requires continuous arterial pressure monitoring, USG with cardiac probe and needs proficiency in using echocardiography.[8]

Cardiac output and pulmonary artery occlusion pressure can also be measured. As the procedure is more invasive and many complications associated with pulmonary artery catheterization, the procedure is not recommended for routine use.[9]

But in resource limited hospital, it would not be feasible to monitor the above mentioned parameters and would rely on CVP monitoring for guiding i.v fluids in septic patients. Therefore CVP still remains most routinely used parameter in guiding septic patients for fluid resuscitation.

Main advantage of CVP is easy to measure, minimal instruments are required and it is cheap. Main drawback of measuring CVP to guide fluid resuscitation is its inability to predict a response to fluid challenge, even when the CVP is within acceptable range of 8-12 cmH_2O.[10] Rather than isolated CVP value, trend of CVP measurement over time/change in response to fluid challenge may provide more reliable information regarding intravascular volume status.

As capillary blood flow depends on the gradient between mean arterial pressure(MAP) and central venous pressure(CVP), high CVP result in reduced capillary and organ blood flow. Infusing i.v fluids beyond CVP of 18 cmH_2O would worsen cardiac function and impair venous return and capillary blood flow. Hence CVP would guide the clinician in optimizing fluid administration in a given patient.

Studies proven that a patient who is hypovoluemic with good LV function would increase CVP not more than 2 mmhg and the CVP would return to baseline within 10 minutes and improvement of blood pressure for a fluid challenge of 200 ml suggest the patient is fluid responsiveness.

Major obstacle for CVP measurement is the requirement for appropriate location of central line placement. Nonetheless insertion of central line catheter is associated with serious complications such as venous air embolism, pneumothorax, cardiac tamponade, arrhythmias, carotid artery puncture, perforation of right atrium, and CLABSI. Less invasive alternatives to the traditional measurement for assessing intravascular volume status have been described which includes measuring PVP and EJVP.

At present, most of the resource limited ICU's still rely on CVP monitoring using water column manometer for managing fluid resuscitation with sepsis patients. In our study we measured EJVP, PVP and correlated pressures with CVP measured by conventional technique.[11]

Kumar et al. in 2015 studied on 50 critically ill patients on mechanical ventilation. Measurements were done between CVP and PVP using a water column manometer. The study arrived at a judgment of positive correlation between CVP and PVP with r=0.038, p=0.004 and Bland –Altman analysis showed 95% Limits of agreement to be -3.180 -11.350, whereas in patients with CVP>10 cmH_2O, the correlation was better with PVP r=0.766, p<0.0001 and Bland-Altman analysis showed 95%Limits of agreement to be 95% LOA to be -1.254-5.540[3]

Munis et al. concluded that the trends of PVP were parallel to the trends of CVP and that their relationship was independent of the patients. Between CVP and PVP, Analysis of variance indicated a significant relationship with p <0.001 with Pearson coefficient of 0.82.[6]

Leonard et al. concluded that EJVP was an acceptable estimate of CVP with mean difference of –0.3 mmhg in supine position and also concluded that though agreement was poor in lateral position but was stronger for trend rather than absolute values.[12]

Abdullah et al. did a prospective study which showed that EJVP and CVP recordings were parallel and also showed strong correlation with mean difference of <2 mmhg.[13]

In our study, we observed the patients in Group A (CVP ≤ 10) mean difference between CVP with PVP and EJVP was >2 cmH_2O and p value was insignificant and in Group B (CVP >10) mean difference between CVP with PVP and EJVP was <2 cmH_2O and p value (p<0.001) was strongly significant and comparable. This showed that PVP and EJVP strongly correlate with CVP at higher baseline CVP than at a lower baseline CVP.

Limitations of the study

This is an observational study with limited study population studied in limited duration. CVP is static parameter and hence cannot accurately predict volume responsiveness in a patient with septic shock and ultrasound guided central venous catheterization will definitely reduce complications associated with catheterization.

Strengths of the study

Study was conducted in rural setup, where monitoring dynamic indices for assessing fluid responsiveness is not feasible, CVP/EJVP/PVP will be surrogate marker for assessing fluid responsiveness in septic patient.

Conclusion

The present study concludes that, there is definite correlation between CVP, EJVP and PVP in a given patient. Further concludes the difference between CVP and EJVP/PVP was minimum (<2cmH_2O) when the CVP was >10 cmH_2O.

Key Messages

PVP and EJVP measurements can be used to predict central venous pressure as an easier surrogate measurement for the assessment for guidance of fluid therapy in patient with sepsis.

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Permissions: Nil

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Original Research Article

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Comparison of Efficacy of Dexamethasone and Clonidine as an Adjuvant in Supraclavicular Brachial Plexus Block Using 0.5% Bupivacaine in Upper Limb Surgeries

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Abstract

Background and Objectives: Dexamethasone, a synthetic corticosteroid has been found to prolong local anesthetic block duration. Clonidine, an Alpha-2-receptor agonist, has been used as an additive to local anesthetics for various regional anesthetic techniques. We compared Dexamethasone and Clonidine as an adjuvant to local anesthetic agent in supraclavicular brachial plexus block with respect to onset of sensory and motor block and duration of post-operative analgesia.

Methodology: A prospective, randomized, controlled, double blind study carried out at Bangalore Medical College and Research Institute, Bengaluru. ASA I and II patients aged 18 to 60 years of either sex were included in the study. We compared the anesthetic and analgesic effects of adding dexamethasone and clonidine to 30 ml 0.5% Bupivacaine and injecting into brachial plexus sheath in 60 patients undergoing upper extremity surgeries. Patients were randomized into 2 groups of 30 each. Group D received Dexamethasone 8 mg and Group C received clonidine 75 mcg as an adjuvant to 0.5% bupivacaine.

Results: There was a significant difference in onset of sensory and motor blockade and postoperative analgesia between two groups. Mean onset of sensory block and motor block was 5.9±0.8 minutes and 8.4±0.9 minutes in dexamethasone group and 8.7±0.9 minutes and 11.7±1.5 minutes in clonidine group. Mean duration of postoperative analgesia was 7.3±0.7 hours in dexamethasone group and 5.9±0.5 hours in clonidine group. There was significant difference in mean HR, SBP and DBP between two groups from 0 min to 12 hours. Mean heart rate, SBP and DBP was higher in dexamethasone group at all intervals compared to clonidine group.

Conclusion: Our study demonstrates that, dexamethasone provides faster onset of sensory block and motor block, longer duration of post-operative analgesia, less number of rescue analgesics in post-operative 12 hours with cost-effectiveness. Hence, dexamethasone can be an alternative to clonidine in brachia plexus block.

Keywords: Supraclavicular brachial plexus block; Dexamethasone; Clonidine; Bupivacaine

Introduction

Peripheral nerve blockade is now a well-accepted concept for comprehensive anesthesia care. From the operative suite, the role of peripheral nerve blockade was expanded for management of postoperative pain and chronic pain.

The recent emergence of pain management and the advantage of regional over general anesthesia in case of emergent surgeries and the increasing importance of outpatient (ambulatory) surgery in anesthesia practice demand a subspecialty peripheral nerve block. Supraclavicular brachial plexus block is the preferred regional anesthesia for

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upper limb surgeries. Here, the brachial plexus is presented most compactly at the proximal division or at the trunk level that provides most reliable anesthesia for upper limb surgeries by anesthetising the middle and lower plexus over 80% of the times (median, radial and ulnar).

After synthesis of Lignocaine 1943 Lofgren's systematic study of a whole range of compounds (Lofgren 1948), so laying the foundation for all subsequent studies of local anesthetic drugs. From these studies have come derivatives of lignocaine such as Local anesthetic administered as regional nerve blocks are utilized in providing postoperative pain relief in many surgical procedures by blocking signal traffic to the dorsal horn. Certain drugs may be used as adjuncts to local anesthetics to lower the dose of each agent and enhance analgesic efficacy while reducing the incidence of adverse reaction. Drugs like neostigmine, opioids, hyaluronidase, midazolam etc.[1-3] have been added to local anesthetics in order to modify the block. Nowadays different drugs have been used as adjuvant with local anesthetics in brachial plexus block to achieve quick, dense and prolonged block. Use of adjuvants to local anestheics is demonstrated to prolong the duration of analgesia in peripheral nerve blocks. Dexamethasone, a synthetic corticosteroid has been found to prolong local anesthetic block duration in animal and human studies. Similarly, several studies have demonstrated analgesic effects of Clonidine, an alpha agonist, in local, spinal and epidural anesthesia when combined with local anesthetic like bupivacaine. This observation that Clonidine has analgesic effects at spinal level has stimulated research to examine analgesic effects in the periphery. It has direct localaction on the nerve itself and facilitation of local anesthetic action. Also, Clonidine seems to provide analgesic benefit without major adverse effects.

The aim of this study is to compare the peripheral action of dexamethasone and clonidine with 0.5% bupivacaine solution to prolong the block with adequate anesthesia in brachial plexus.

Anatomy of Brachial Plexus[4,5,6]

Knowledge of formation of brachial plexus and its ultimate cutaneous and muscular distribution is absolutely essential to the intelligent and effective use of brachial plexus anesthesia for upper limb surgeries. Close familiarity with the vascular, muscular and fascial relationships of the plexus is equally essential to the mastery of various techniques, for it is these perineural structures which serve as the landmark by which needle may accurately locate the plexus percutaneously.

In its course from intervertebral foramina to the upper arm, the fibres are composed consecutively of roots, trunks, divisions, cords and terminal nerves.

Formation of Brachial Plexus

Brachial plexus is formed by the union of ventral rami of lower fourcervical nerves (C5,6,7,8) and first thoracic nerve (Tl) with frequentcontributions from C4 or T2. When contribution from C4 is large and from T2 is lacking, the plexus appears to have a more cephaloid position and is termed "Prefixed".

When contribution from T2 is large and from C4 is lacking, the plexus appears to have a caudal position and is termed "postfixed". Usually prefixed or postfixed positions are associated with the presence either of a cervical rib or of an anamolous 1st rib.

Roots

Represent the anterior primary divisions of lower four cervical and first thoracic nerves. They emerge from the intervertebral foramina and fuse above the first rib to form the trunks.

Trunk

The roots combine above the first rib to form the three trunks of the plexus. C5 and C6 unite at the lateral border of the scalenus medius and form the "Upper trunk", C8 and Tl unite behind the scalenus anterior to form "lower trunk" and C7 continues as a sole contributor to the "middle trunk".

Divisions

As the trunks pass over the first rib and under the clavicle, each one of them divides into anterior and posterior divisions.

Cords

The fibres, as they emerge from under the clavicle, recombine to form three cords. The "lateral cord" is formed by anterior divisions of upper and middle trunks, lateral to the axillary artery. The anterior division of lower trunk descend medial to the axillary artery forming the "medial cord". The posterior divisions of all three trunks unite to form the "posterior cord", at first above and then behind the axillary artery.

The medial and lateral cords give rise to nerves that supply the flexor surface of upper extremity, while nerves arising from the posterior cord supply extensor surface.

Major Terminal Nerves

Each of these cords gives off a branch that contributes to or become one of the major nerves to the upper extremity and then terminates as a major nerve. The lateral and median cords give off lateral and medial heads of the medial nerve and continue as major terminal nerves, the lateral cord terminating as musculocutaneous nerve and medial cord as ulnar nerve. Posterior cord gives off, axillary nerve as its major branch and then continues as the radial nerve.

In summary, conveniently it can be considered that brachial plexus begins with five nerves (C5-T1) and terminates in five nerves (Musculocutaneous, radial, axillary, median and ulnar nerves) with its intermediate portions displaying in sets of three, that is, three main trunks which divide into 2 sets of three, which reunite and give rise to three cords. These three cords give off three lateral branches before becoming the major terminal branches of brachial plexus.

Pharmacology of Bupivacaine[7–10]

Local AnestheticDrugs

Local anesthetics are drugs that produce reversible conduction blockade of impulse along central and peripheral nerve pathways after regional anesthesia. With progressive increases in concentrations of local anesthetics the transmission of autonomic, somatic sensory and somatic motor impulses are interrupted producing autonomic nervous system blockade, sensory anesthesia, and skeletal muscle paralysis in the area innervated by the affected nerve. Removal of the local anesthetic is followed by spontaneous and complete return of nerve conductions, with no evidence of structural damage to nerve fibres.

Local anesthetics have similar configuration. They have one aromatic lipophilic part (Benzene ring) and one hydrophilic part (quaternary ring) connected by an intermediate ring either ester (-COO-) or an amide (-NHCO-).

Bupivacaine

Source: Bupivacaine, a synthetic drug, was prepared by A.F. Ekenstam in 1957.

Chemistry: The molecular weight of the chloride salt is 325 and that of the base form is 288. It has a melting point of 258°C. Solutions containing epinephrine have a pH of about 3.5.

The chemical name is l-n-butyl-DL-piperidine-2 carboxylic acid-2,6 dimethylamilide hydrochloride.

The molecular formula is C18N2OH28HCl.

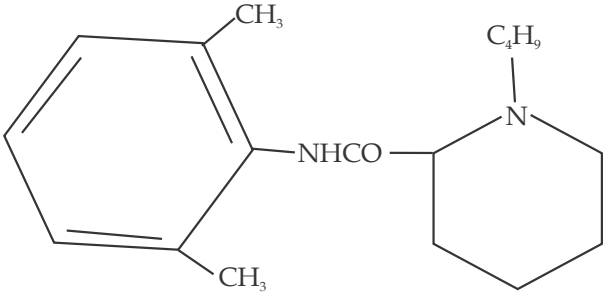

Fig. 1: Chemical Structure of Bupivacaine

Physiochemical properties

Solubility: The base is sparingly soluble, but the hydrochloride is readily soluble in water.

Stability and sterilization: Bupivacaine is highly stable and can withstand repeated autoclaving.

pH of saturated solution: 5.2

Specific gravity: 1.021 at 37°C

Melting point: 247-258°C

Anesthetic properties

Potency

Bupivacaine is approximately three to four times more potent than Lidocaine. The duration of action for local anesthesia is two to three times longer than Lidocaine.

Anesthetic index

Bupivacaine's anesthetic index is 3.0 to 4.0.

Mechanism of action

It is similar to that of any other local anesthetics. The primary action of local anesthetics is on the cell membrane of the axon, on which it produces electrical stabilization. The large transient increase in permeability to sodium ions necessary for propagation of the impulse is prevented. Thus the resting membrane potential is maintained and depolarization in response to stimulation is inhibited.

The mechanism by which local anesthetics block sodium conductance is as follows:

a) Local anesthetics in the cationic form act on the receptors within the sodium channels, on the cell membrane and block it. The local anesthetic can reach the sodium channel either via the lipophilic pathway directly across the lipid membrane, or via the axoplasmic opening. This mechanism

accounts for 90% of the nerve blocking effects of amide local anesthetics.

b) The second mechanism of action is by membrane expansion. This is a nonspecific action in contrast to the more specific drug receptor interaction.

***Dexamethasone*[11–14]**

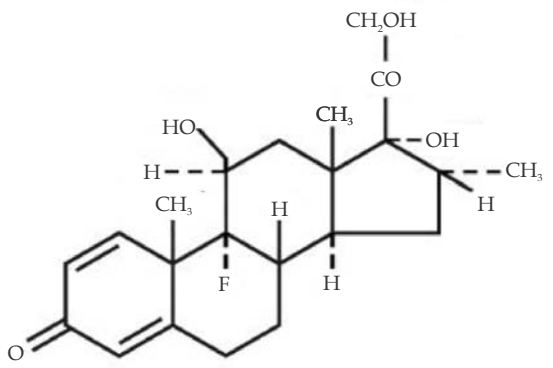

Fig. 2: Chemical Structure of Dexamethasone.

Dexamethasone is a water soluble ester, in the form of dexamethasone sodium phosphate. It has an oral, intramuscular or intravenous preparation. It acts rapidly and attain high concentration in tissue fluids. Dexamethasone is mainly metabolized in the liver by hepatic microsomal enzymes. The t 1/2 of dexamethasone in greater than 36 hrs, its action starts within 30 minute of injection and action persists even after the drug disappears from the circulation.

***Clonidine*[15–19]**

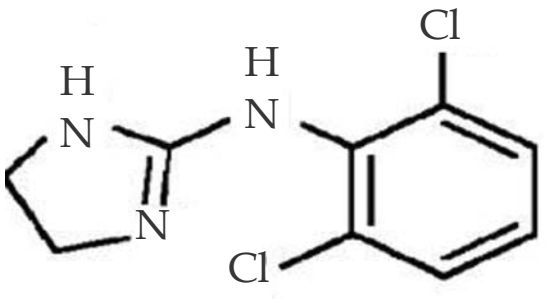

Fig. 3: Chemical Structure of Clonidine.

Clonidine hydrochloride, an imidazoline derivative was originally developed as a nasal decongestant and vasoconstrictor. Its hypotensive and bradycardia effects were first appreciated in 1962. It is a centrally acting adrenergic agonist that lowers blood pressure by decreasing basal sympathetic nervous system activity. It was introduced first in Europe in 1966 and subsequently in the U.S. for use as an antihypertensive agent.

Clonidine hydrochloride is an imidazoline derivative and exists as a mesomeric compound. The chemical name is 2-(2,6-dichlorophenylamino)-2-imidazoline hydrochloride. The following is the structural formula: C9H9C12N3HCl.

The molecular weight of Clonidine is 266.56. Clonidine hydrochloride is an odourless, bitter, white, crystalline substance soluble in water and alcohol.

Objectives of the Study

The objectives of this study are to compare the effects of dexamethasone and clonidine as an adjuvant to 30 ml of 0.5% bupivacaine used for Supraclavicular approach to brachial plexus block with respect to

- Onset time of sensory block
- Onset time of motor block
- Duration of postoperative analgesia
- Monitoring of hemodynamic parameters.

Methodology

Preoperative Preparation

The study protocol was approved by the hospital ethical committee. All patients were visited and evaluated thoroughly on the day prior to surgery along with laboratory investigations. The anesthetic procedure to be undertaken including development of paraesthesia was explained to the patients and an attempt was made to alleviate the anxiety of the patient. A written informed consent was obtained. Pre-anesthetic preparation of patient included a period of overnight fasting. All patients received oral diazepam 10 mg night before surgery. A meticulous airway assessment was also carried out. Routine laboratory examinations were conducted including complete haemogram, urine analysis and whenever appropriate blood sugar, ECG and chest X-ray.

Materials and Methodology

Seventy five patients aged between 18 and 60 years of physical status ASA 1 and 2 undergoing upper limb surgeries lasting more than 30 minutes were included in the study. The study was carried out at Victoria Hospital and Bowring and Lady Curzon Hospitals attached to Bangalore Medical College and Research Institute. The patients mainly included those undergoing orthopedic, plastic and reconstructive surgeries.

Inclusion Criteria

Patients between age group 18 and 60 years, under the physical status ASA 1 and ASA 2 scheduled for upper limb surgeries were included after obtaining ethical clearance from the institution and informed written consent from the patients.

Exclusion Criteria

Patients with history of hypersensitivity reactions to local anesthetics, bleeding disorders, pregnant and lactating women, peripheral neuropathies and patients who refused to participate in the study.

Method of Collection of Data

After obtaining informed written consent from patients, patients will be randomly divided into 2 groups, dexamethasone group (Group D, n=30) and Clonidine group (Group C, n=30) in a double blind fashion.In the pre-operative room, an intra-venous line is secured with 18G cannula on the normal arm. Baseline: E.C.G [Electrocardiogram], NIBP [Noninvasive blood pressure] and SpO_2 [Oxygen saturation] recorded. The patients were premedicated with Inj. Ranitidine 50 mg i.v. stat and Inj.

Ondansetron 4 mg i.v. stat, 30 minutes before Surgery. The Anesthetist performing the procedure was blinded to the study group and patients were selected by random chit selection method. Supra-clavicular Brachial Plexus block was performed after eliciting paresthesia and 32 ml of anesthetic solution was given after bloodless aspiration. The onset of sensory block was assessed with pin prick method. Assessment of motor block done by Modified Bromage Scale.

All necessary equipments and drugs needed for administration of general anesthesia and for emergency resuscitation were kept ready in order to manage failure of block or toxic reactions occurring during procedure.

Procedure

Intravenous access was obtained in the limb opposite to that undergoing surgery with 18G cannula. Standard monitors like ECG monitoring, Pulse oximeter, Non-invasive blood pressure were connected and monitored in all the patients. The patient was placed in a supine position with the head turned away from the side to be blocked. The arm to be anesthetized should be adducted, and the hand should be extended along the side towards the ipsilateral knee as far as possible. Using classic technique approach, the midpoint of the clavicle was identified and marked. The posterior border of the sternocleidomastoid was palpated easily when the patient raised the head slightly. Palpating the belly of the anterior scalene muscle moving towards interscalene groove with the fingers, a mark was made at approximately 1.5 to 2.0 cm posterior to the midpoint of the clavicle. By palpating the subclavian artery at this site, landmark was confirmed.

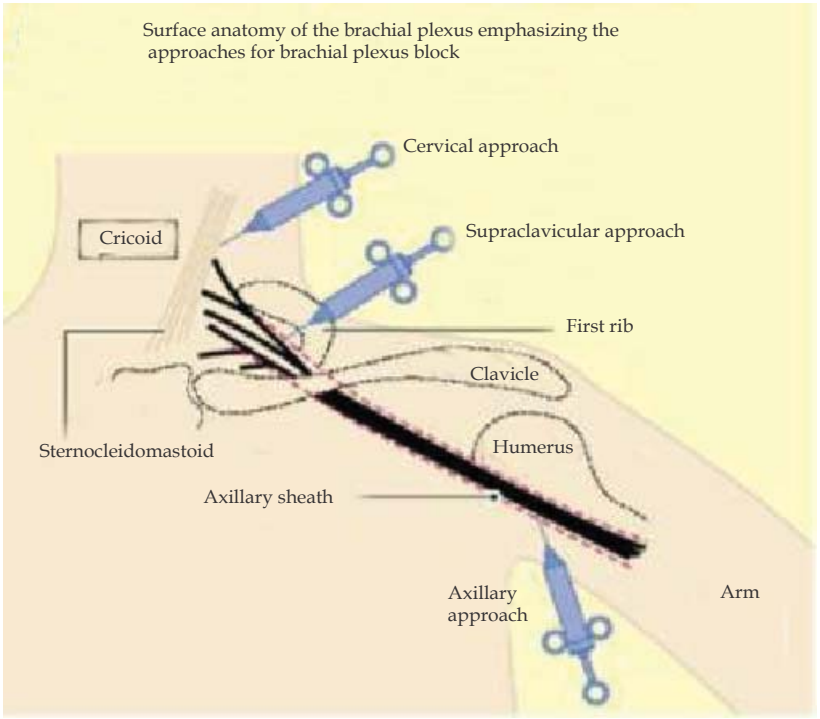

Fig. 4: Surface Anatomy of Brachial Plexus

After appropriate preparation and injection of a skin wheal, 22-gauge needle was inserted at the point of entry above the midpoint of clavicle in the backward-inward-downward direction (BID). Although the direction of needle was towards the first rib, it was not always necessary to touch the rib. Paresthesia in the forearm or hand was elicited. After negative aspiration for air or blood, appropriate drugs were injected. Group D received 30 ml of 0.5% Bupivacaine and 2 ml of 8 mg dexamethasone. Group C received 30 ml of 0.5% Bupivacaine and Clonidine 75 µg. The effects of the anesthetic agents on the following parameters were observed:

1. The onset time of sensory blockade, defined as time between injection and total abolition of temperature sensation, was evaluated in 4 nerve areas (median, ulnar, radial and musculocutaneous) at every 5 minutes until 30 minutes after the injection. The block was judged to have failed if anesthesia was not present in 2 or more peripheral nerve distributions and such patients were excluded from the study.
2. The onset time of motor blockade was determined according to modified Bromage scale 6 ranging from Grade 0 (normal motor function) to Grade 2 (complete motor block with inability to move the fingers). Following tests were done to see different nerve function: Thumb abduction for the radial nerve, thumb adduction for the ulnar nerve, thumb opposition for the median nerve and flexion of elbow for the musculocutaneous nerve.
3. The duration of analgesia, defined as the time between onset of action and onset of pain, was the time when patients received the first dose of analgesic.
4. During surgery, pulse, arterial blood pressure and peripheral oxygen saturation were monitored. Symptoms such as nausea, vomiting, drowsiness and other adverse effects/complications were also monitored.

Ramsay Sedation Scale[20]

1	Anxious and agitated, restless
2	Co-operative, oriented, tranquil
3	Responsive to verbal commands, drowsy
4	Asleep, responsive to light stimulation (loud noise, tapping)
5	Asleep, slow response to stimulation no response to stimulation

Statistical analysis

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. Chi-square test was used as test of significance for qualitative data.

Continuous data was represented as mean and standard deviation. Independent t-test or man whitney U test was used as test of significance to identify the mean difference between two quantitative variables. Graphical representation of data: MS Excel and MS word was used to obtain various types of graphs such as bar diagram and Line diagram. p value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Statistical software: MS Excel**,** SPSS version 22 **(**IBM SPSS Statistics, Somers NY, USA) was used to analyze data.

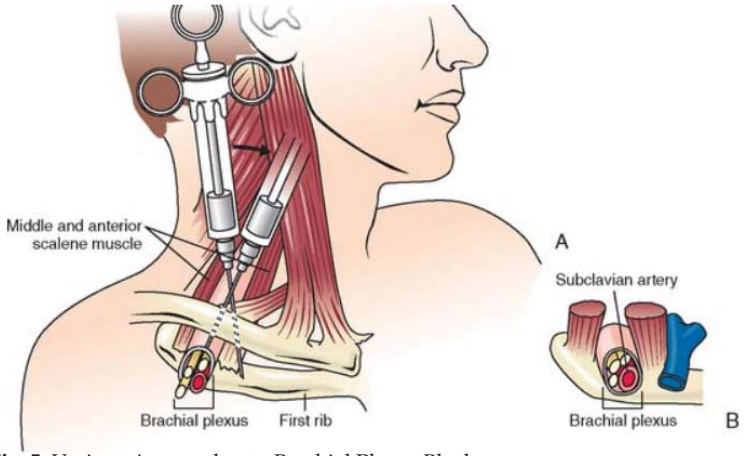

Fig. 5: Various Approaches to Brachial Plexus Block
A. Supraclavicular Block
B. The Three Trunks are Compactly Arranged at the Level of the First Rib.

Results

Table 2: Age distribution comparison between two groups

		Group			
		Group D		Group C	
		Count	%	Count	%
Age	<30 years	5	16.7%	3	10.0%
	31 to 40 years	9	30.0%	12	40.0%
	41 to 50 years	10	33.3%	9	30.0%
	>50 years	6	20.0%	6	20.0%

χ^2 =0.981, df =3, p = 0.806

In Group D, majority were in the age group 41 to 50 years (33.3%). In Group C, majority were in the age group 31 to 40 years (40%). There was no significant difference in age distribution between two groups.

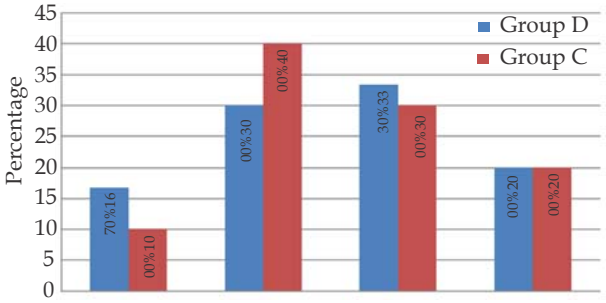

Fig. 6: Diagram showing Age distribution comparison between two groups

Table 3: ASA Grade comparison between two groups

		Group			
		Group D		Group C	
		Count	%	Count	%
ASA Grade	1	21	70.0%	20	66.7%
	2	9	30.0%	10	33.3%

χ^2 =0.077, df =1, p = 0.781

In Group D, 70% had ASA grade 1 and 30% had ASA grade 2. In Group C, 66.7% had ASA grade 1 and 33.3% had ASA grade 2. There was no significant difference in ASA grade between two groups.

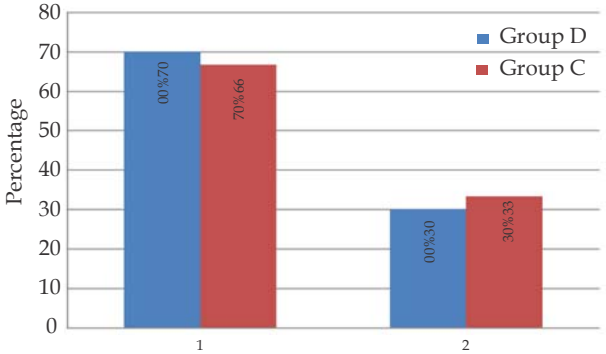

Fig. 7: Bar diagram showing ASA Grade comparison between two groups

Table 4: Duration of surgery comparison between two groups

	Group				P value
	Group D		Group C		
	Mean	SD	Mean	SD	
Duration of Surgery	85.2	20.4	101.7	28.0	0.022*

Mean duration of surgery in Group D was 85.2 ±20.4 min and in Group C was 101.7±28.0 min. There was significant difference in mean duration of surgery between two groups.

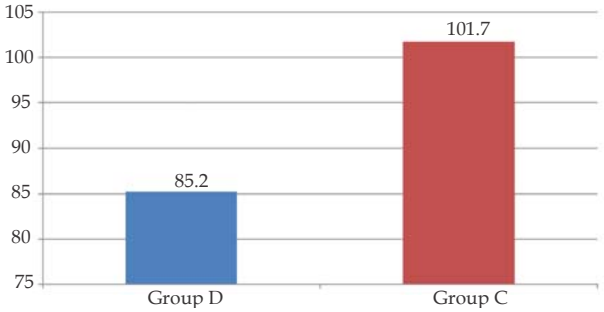

Fig. 8: Bar diagram showing Duration of surgery comparison between two groups

Table 5: Onset of Sensory Block comparison between two groups

	Group				P value
	Group D		Group C		
	Mean	SD	Mean	SD	
Onset of Sensory Block	5.9	0.8	8.7	0.9	<0.001*

Mean Onset of Sensory Block in Group D was 5.9 ±0.8 min and in Group C was 8.7±0.9 min. There was significant difference in mean Onset of Sensory Block between two groups.

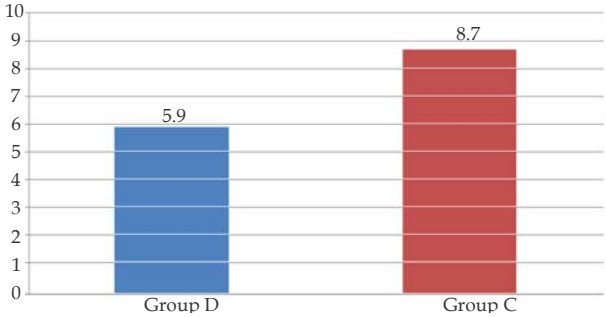

Fig. 9: Bar diagram showing On set of Sensory Block comparison between two groups

Table 6: Onset of Motor Block comparison between two groups

	Group				P value
	Group D		Group C		
	Mean	SD	Mean	SD	
Onset of Motor Block	8.4	0.9	11.7	1.5	<0.001*

Mean Onset of Motor Block in Group D was 8.4 ±0.9 min and in Group C was 11.7±1.5 min. There was significant difference in mean Onset of Motor Block between two groups.

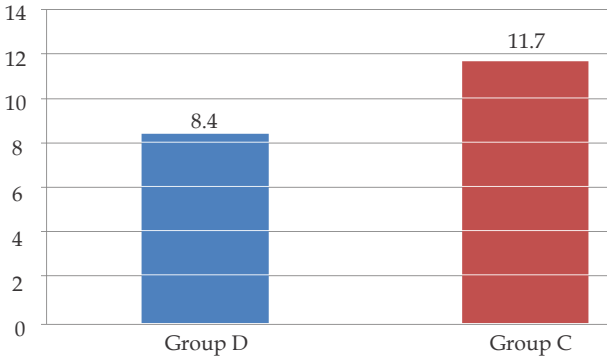

Fig. 10: Bar diagram showing On set of Motor Block comparison between two groups

Table 7: Duration of Postoperative Analgesia comparison between two groups

	Group				P value
	Group D		Group C		
	Mean	SD	Mean	SD	
Duration of Postoperative Analgesia	7.3	0.7	5.9	0.5	<0.001*

Mean Duration of Postoperative Analgesia in Group D was 7.3±0.7 min and in Group C was 5.9±0.5 min. There was significant difference in mean Duration of Postoperative Analgesia between two groups.

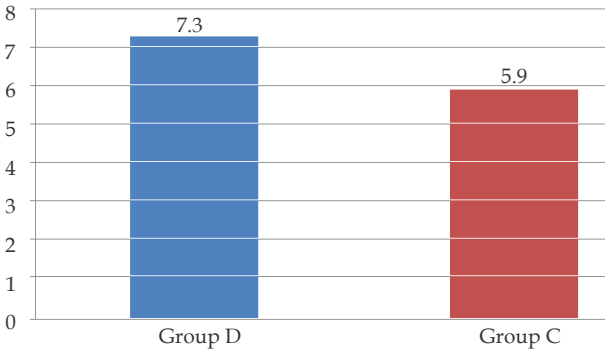

Fig. 11: Bar diagram showing Duration of Postoperative Analgesia comparison between two groups

Table 8: No of Rescue Analgesia comparison between two groups

		Group			
		Group D		Group C	
		Count	%	Count	%
No of Rescue Analgesia	0	24	80.0%	0	0.0%
	1	6	20.0%	25	83.3%
	2	0	0.0%	5	16.7%

χ^2 =40.64, df =2, p < 0.001*

In Group D, 80% required 0 doses of Rescue Analgesia and 20% required 1 dose of Rescue Analgesia. In Group C, 83.3% required 1 dose of Rescue Analgesia and 16.7% required 2 doses of Rescue Analgesia. There was significant difference in no of Rescue Analgesia needed between two groups.

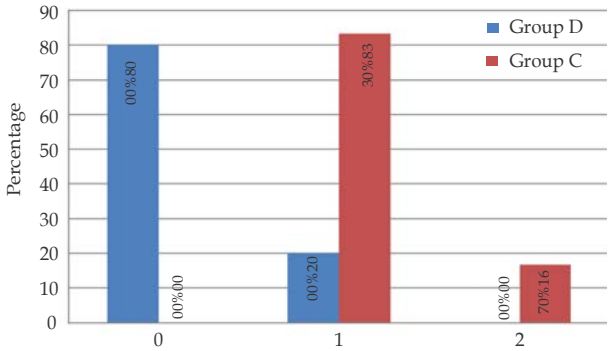

Fig. 12: Bar diagram showing No of Rescue Analgesia comparison between two groups

Table 9: Ramsay Sedation Score comparison between two groups

	Group						P value
	Group D			Group C			
	Mean	SD	Median	Mean	SD	Median	
0 min	0.07	.25	0	1.00	0.00	1	<0.001*
5 min	0.13	0.35	0	1.00	0.00	1	<0.001*
15 min	0.10	0.31	0	1.13	0.35	1	<0.001*
30 min	0.13	0.35	0	1.17	0.38	1	<0.001*
60 min	0.00	0.00	0	1.67	0.71	2	<0.001*
2 hr	0.00	0.00	0	1.47	0.57	1	<0.001*
6 hr	0.00	0.00	0	1.13	0.35	1	<0.001*
12 hr	0.00	0.00	0	0.73	0.45	1	<0.001*

In the study there was significant difference in Mean Ramsay sedation scores between two groups from 0 min to 12 hrs.

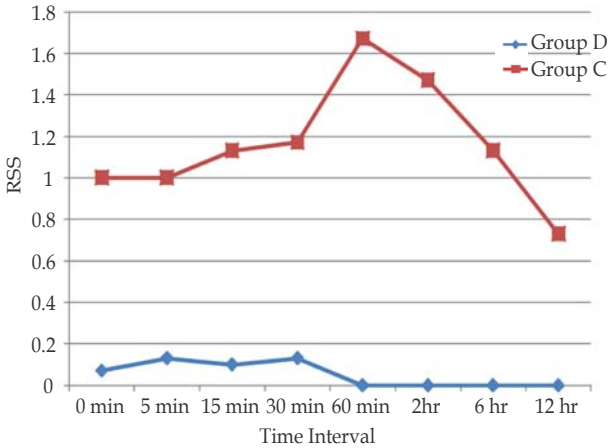

Fig. 13: Line diagram showing Ramsay Sedation Score comparison between two groups

Table 10: Heart rate comparison between two groups at different intervals of follow up

HR	Group				P value
	Group D		Group C		
	Mean	SD	Mean	SD	
0 min	97.4	10.5	80.9	9.1	<0.001*
5 min	95.2	10.3	80.8	8.5	<0.001*
15 min	91.6	18.8	77.2	13.2	<0.001*
30 min	93.8	10.4	76.9	6.7	<0.001*
60 min	91.9	8.6	76.1	7.3	<0.001*
2 hr	91.4	9.1	75.7	7.3	<0.001*
6 hr	93.0	9.3	78.4	6.2	<0.001*
12 hr	93.1	9.2	81.4	6.7	<0.001*

In the study there was significant difference in mean HR between two groups from 0 Min to 12 hrs. Mean HR at all the intervals was higher in Group D than in Group C.

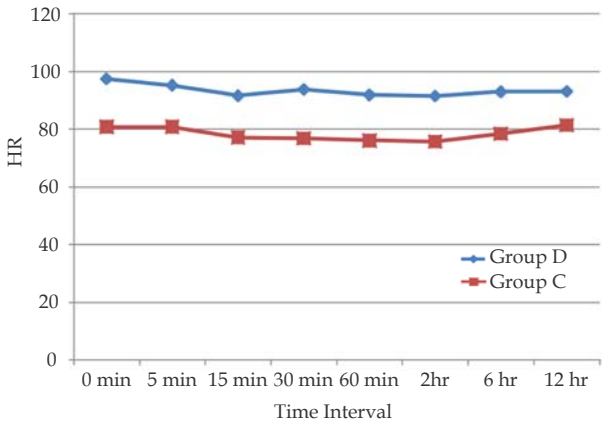

Fig. 14: Line diagram showing Heart rate comparison between two groups at different intervals of follow up

Table 11: SBP comparison between two groups at different intervals of follow up

SBP	Group				P value
	Group D		Group C		
	Mean	SD	Mean	SD	
0 min	135.2	12.7	126.0	9.9	0.003*
5 min	130.7	11.7	122.4	9.4	0.003*
15 min	129.4	10.4	120.9	9.1	0.001*
30 min	129.2	9.7	119.8	8.0	<0.001*
60 min	128.4	10.4	119.8	6.9	<0.001*
2 hr	128.2	9.8	117.7	7.5	<0.001*
6 hr	127.3	9.1	117.7	7.4	<0.001*
12 hr	126.1	10.2	117.7	8.8	0.001*

In the study there was significant difference in mean SBP between two groups from 0 Min to 12 hr. Mean SBP at all the intervals was higher in Group D than in Group C.

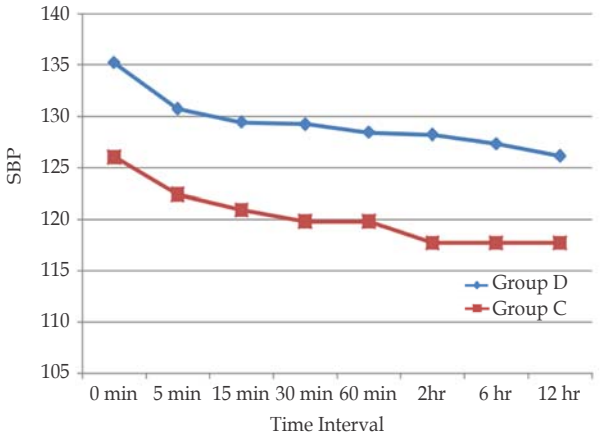

Fig. 15: Line diagram showing SBP comparison between two groups at different intervals of followup

Table 12: DBP comparison between two groups at different intervals of followup

DBP	Group				P value
	Group D		Group C		
	Mean	SD	Mean	SD	
0 min	73.17	7.50	62.37	6.14	<0.001*
5 min	70.63	7.90	59.87	4.45	<0.001*
15 min	71.93	7.19	57.80	3.58	<0.001*
30 min	70.57	7.38	58.13	3.88	<0.001*
60 min	70.00	6.93	58.17	2.90	<0.001*
2 hr	69.73	5.90	57.40	2.92	<0.001*
6 hr	69.00	6.53	57.83	2.44	<0.001*
12 hr	69.37	6.41	61.60	2.65	<0.001*

In the study there was significant difference in mean DBP between two groups from 0 min to 12 hr. Mean DBP at all the intervals was higher in Group D than in Group C.

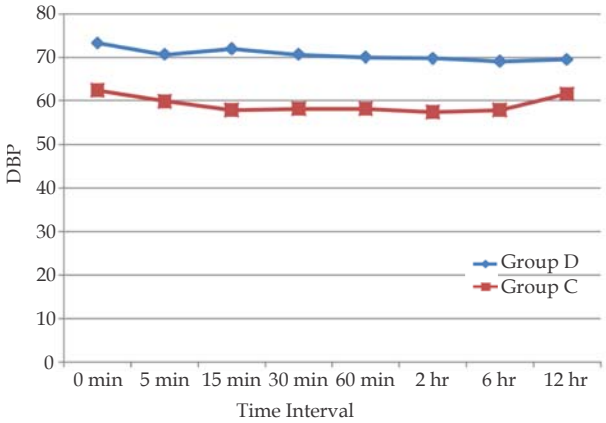

Fig. 16: Line diagram showing DBP comparison between two groups at different intervals of followup

Table 13: SpO_2 comparison between two groups at different intervals of follow up

SpO_2	Group				P value
	Group D		Group C		
	Mean	SD	Mean	SD	
0 min	99.2	0.4	98.4	0.8	<0.001*
5 min	98.8	0.4	98.0	0.5	<0.001*
15 min	98.9	0.7	98.6	0.6	0.069
30 min	99.2	0.9	98.8	0.5	0.034*
60 min	99.8	0.4	98.7	0.6	<0.001*
2 hr	98.9	0.6	98.3	0.5	<0.001*
6 hr	99.1	0.8	98.9	0.4	0.247
12 hr	98.7	0.5	98.2	0.6	0.001*

In the study there was significant difference in mean SpO_2 between two groups from 0 min to 12 hr except at 15 min and 6 hr. Mean SpO_2 at all the intervals was higher in Group D than in Group C.

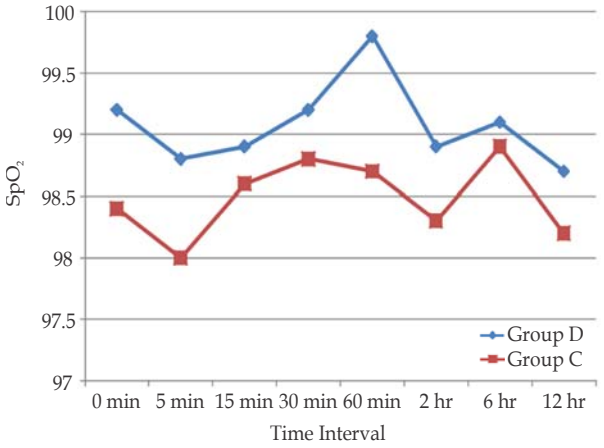

Fig. 17: Line diagram showing SpO_2 comparison between two groups at different intervals of followup

Table 14: RR Comparison between two groups at different intervals of follow up

RR	Group				P value
	Group D		Group C		
	Mean	SD	Mean	SD	
0 min	15.9	1.8	14.2	1.2	<0.001*
5 min	15.4	1.1	13.4	1.7	<0.001*
15 min	15.0	2.4	13.1	1.1	<0.001*
30 min	16.3	1.6	13.1	1.1	<0.001*
60 min	15.2	1.0	13.2	1.0	<0.001*
2 hr	16.2	1.6	14.6	1.2	<0.001*
6 hr	16.1	1.7	14.5	.9	<0.001*
12 hr	15.0	1.7	15.0	1.3	1.000

In the study there was significant difference in mean RR between two groups from 0 Min to 12 hr except at 12 hr. Mean RR at all the intervals was higher in Group D than in Group C.

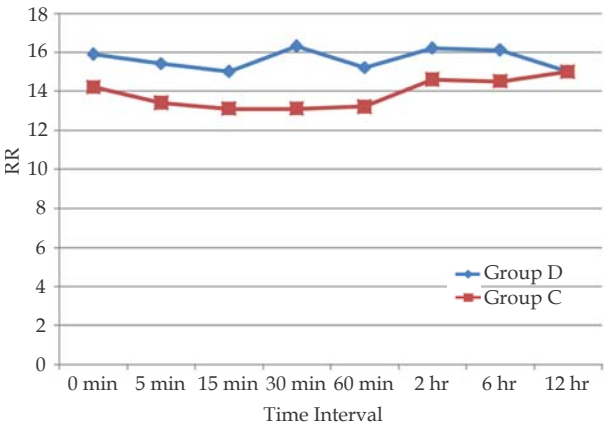

Fig. 18: Line diagram showing RR comparison between two groups at different intervals of follow up

Discussion

A variety of receptors mediate anti-nociception on peripheral sensory axons. The peripheral administration of appropriate drugs (adjuncts) may have good anesthetic condition, analgesic benefit and reduce systemic adverse effects. In an attempt to improve peri-operative analgesia, a variety of adjuncts such as opiods, verapamil, neostigmine, tramadol and alpha-2 agonist like clonidine have been administered concomitantly with local anesthetics into the brachial plexus sheath. The aim of this study was to compare the additional anesthetic and analgesic effects of dexamethasone and clonidine (alpha-2 adrenoreceptor), after administration into brachial plexus sheath along with bupivacaine. The study was a prospective, randomized study carried out at Bangalore Medical College and Research Institute, Bangalore. Sixty ASA-1 and ASA-2 patients undergoing elective upper limb surgery were divided into 2 groups of 30 each[group D and group C]. Group D received brachial plexus block with 30 ml 0.5% bupivacaine and dexamethasone 8 mg, group C received brachial plexus block with 30 ml 0.5% bupivacaine and clonidine 75 mcg.

Parameters observed include onset of sensory blockade, onset of motor blockade, duration of analgesia, hemodynamic monitoring, Ramsay sedation scale, side effects and requirement of rescue analgesia in 12 hr post-operatively. In our study both the groups were comparable with respect to age and gender.

In our study, we observed that onset of sensory block was earlier in Group D [dexamethasone group] having a mean value of 5.9±0.8 min in comparison with group C [clonidine group] having a mean value of 8.7±0.9 min, which is statistically significant (p <0.001) and onset of motor block was

earlier in Group D [dexamethasone group] having a mean value [8.4±0.9 min] in comparison with Group C having mean value of [11.7±1.5 min], which is statistically significant (p <0.001). Sensory blockade was assessed using pin prick method and motor blockade was assessed using modified bromage scale.

The mean time from onset of block to request of analgesia is taken as total duration of analgesia. Postoperative analgesia was 7.3±0.7 hr in group D and 5.9±0.5 hr in group C, which is statistically significant with p <0.001. In our study, the mean numbers of rescue analgesia dosed were lesser in dexamethasone group i.e. 80%(24) required zero doses of rescue analgesia and 20%(6) required 1 dose of rescue analgesia. In Clonidine group it was 83.3%(25) required 1 dose of rescue analgesia and 16.7%(5) required 2 doses of rescue analgesia which was statistically significant p <0.001**.**

In our study, intra-operatively no patient had bradycardia, there was significant difference in mean heart rate between two groups from 0 to 12 hr. Mean heart rate at all intervals was higher in group D than in group C with p <0.001. There was significant difference in mean systolic blood pressure and mean diastolic pressure between two groups from 0 min to 12 hr, at all intervals mean systolic blood pressure and mean diastolic blood pressure was higher in group D than in group C. In our study, there was significant difference in respiratory rate between two groups from 0 min to 12 hr except at 12 hr in which there was significant depression in respiratory rate in clonidine group (p<0.001) when compared to dexamethasone group. No patient of any group complained of respiratory difficulty. We did not find any appropriate study to compare change in respiratory rate.

Ramsay sedation scale was compared between 2 groups. In Group D, all patients were awake and alert and had sedation score of 1. In Group C, sedation corresponding to score 2 was observed in some patients. Statistical analysis of sedation score by independent t test showed that the difference in sedation score was significant (P <0.001). The sedation in Group C and Group D patients were desirable, without any need for airway assistance. We did not find any appropriate study to compare change in Ramsay sedation scale.

Conclusion

To conclude, our study demonstrates that, dexamethasone can be an alternative to clonidine when administered with 0.5% bupivacaine as an adjuvant for supraclavicular brachial plexus block in upper limb surgeries. Dexamethasone provides:

- Faster onset of sensory block.
- Faster onset of motor block.
- Longer duration of post-operative analgesia.
- Less number of rescue analgesics in postoperative 12hr.
- Cost-effectivness.

Limitations

- Did not perform ultrasound-guided blocks because of unavailability at the time of our study which would have helped us to lower the volume of local anesthetic.
- An ideal scale for assessment of quality of block achieved.
- Small sample size in each group might have limited the true clinical significance of our comparison.

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Evaluation of Effect of Adding Dextrose to Levobupivacaine, Compared to Levobupivacaine Plain in Subarachnoid Block for Lower Limb and Lower Abdominal Surgeries

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Abstract

Context: The search of a drug which can give the perfect balance of sensory and motor block with minimal side effects has always missed researchers. We have conducted a study to study the efficacy of adding dextrose to levobupivacaine and try to find an alternate to the routinely used bupivacaine.

Aims: Evaluation of effect of adding dextrose to levobupivacaine, compared to levobupivacaine plain in terms of onset and duration of sensory and Motor blockade; Quality of analgesia.(VAS score).

Settings and Design: Open Labelled Study

Methods and Material: 140 patients admitted for elective surgeries, during the period of January 2017 to December 2017. Group L: Hyperbaric Levobupivacaine with 150 mg dextrose.(0.3 ml of 50% dextrose), volume is 3.3 ml; Group p: Plain levo Bupivacaine. (volume is 3.3 ml).

Statistical analysis used: Student t test (two tailed, independent),. Chi-square/Fisher Exact test.

Results: In Group II Time to two segmentsensory level regression was significantly more (188.89±22.32) compared to Group I (118.96±33.69); duration of analgesia and motor block was also more. VAS scores in Group II were less compared to Group I. Rescue doses required in Group II were less compared to Group I.

Conclusions: Addition of dextrose have proved to be effective in quick onset of sensory, motor blockade and longer duration of blockade and prolonged two segment regression time with no adverse side effects.

Keywords: Dextrose; Levobupivacaine; Sub arachnoid Block.

Introduction

Intrathecal medications with the perfect balance of sensory and motor block with minimal side effects is always missed by researchers.

Due to its long duration of action, racemic bupivacaine is used for the regional, intrathecal, and epidural block by most anesthetists. Myocardial depression and even cardiac arrest can occur after accidental intravascular injection, resuscitation has been found to be difficult and may be unsuccessful. This led to the search for a local anesthetic agent with lower cardiotoxicity.[1]

Ropivacaine, registered for use in 1996, introduced in India in 2009, is produced as pure

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"S" enantiomer with lower lipid solubility, easier reversibility after inadvertent intravascular injection, significant reduction in central nervous system toxicity, lesser motor block and greater differentiation of sensory and motor block. Motor blockade of 0.75% ropivacaine was comparable to 0.5% bupivacaine.[2]

MLAD estimates for intrathecal ropivacaine, levobupivacaine, and bupivacaine in the first stage of spontaneous labor in nulliparous women is bupivacaine > levobupivacaine > ropivacaine.[3]

Therefore we have conducted a study to evaluate the efficacy of levobupivacine in the lower limb and lower abdominal surgeries and in try to find an alternate to the routinely used bupivacaine in our setup.

Objectives

Evaluation of effect of adding dextrose to levobupivacaine, compared to levobupivacaine plain in terms of time of onset of sensory blockade and Motor blockade as per Bromage scale; the height of sensory blockade, total duration of sensory blockade and motor blockade; two segment sensory regression time and Quality of analgesia. (VAS score). Number of Rescue analgesia doses for 24 hours and Incidence of adverse effects will be noted.

Materials and Methods:

Open Labelled Study

Selection of patients – Randomized table in computer

Source of Data

140 patients admitted for elective surgeries, to be done under spinal anesthesia during the period of January 2017 to December 2017.

Method of Collection of Data

Inclusion criteria: Patients belonging either gender, ASA grade I and II; Age 18-60 yr; Weight- more than 45 kg; Height- more than 150cm

Exclusion criteria: Patients suffering from cardiac Arrhythmias, heart blocks, bradycardia; Patients with known allergy to test drug; Patients with gross spinal abnormality, localised skin sepsis, hemorrhagic diathesis, neurological involvement/ diseases; Patients with head injury, raised intra cranial pressure; Patients who are hemodynamically unstable.

Sampling Procedure

After obtaining informed consent, patients will be randomly divided into two groups. Randomization will be done by computer generated table.

Group L: Hyperbaric Levobupivacaine with 150 mg dextrose. (0.3 ml of 50% dextrose), volume is 3.3 ml; Group p: Plain levo Bupivacaine. (volume is 3.3 ml)

All patients were examined a day before surgery. All were kept fasting overnight after 10:00 pm and received tab. Ranitidine 150 mg orally and tab. Alprazolam 0.5 mg orally as premedication at night before surgery and at 6:00 am with sips of water on the day of surgery. All patients were preloaded with 15 ml/kg ringer lactate solution after securing IV access with 18G cannula. In the operation theatre pulse rate, blood pressure, ECG and SpO_2 were monitored.

Under all aseptic precautions, left lateral position, 25G quincke spinal needle used for spinal block at L3-L4 interspace, midline approach and patient put to supine position. Patients in group L received 3 ml of 0.5% hyperbaric Levobupivacaine with 0.3 ml of 150 mg dextrose. Patients in group P received 3.3 ml of Plain levo Bupivacaine. The time of intrathecal injection is considered as 0 and the following parameters were observed.

Parameters observed

1. Time of onset of sensory blockade.
2. The height of sensory blockade.
3. Motor blockade as per Bromage scale.
4. Total duration of sensory blockade & motor blockade.
5. Quality of analgesia.(VAS score)
6. Two segment sensory regression time.
7. Need for rescue analgesia when patient complains of pain. (if VAS is >4, rescue analgesia Inj Tramadol; 50 mg was given and Number of doses given within 24 hrs was noted.
8. Incidence of adverse effects was noted.

Vitals recorded every 2 min for 10 min and then every 10 min throughout the intra operative period and also at the completion of surgery. The vital signs recorded at time 0, 2 min, 5 min and then every 10 min for first hour and half hourly till the end of surgery.

Rescue analgesia: is defined as analgesia given when patient complains of pain (VAS >4).

Quality of analgesia was assessed by visual analogue scale.

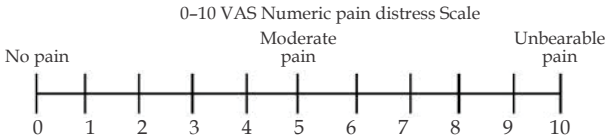
Visual analogue scale for pain:

0 No pain

1-3 Mild pain

4-6 Moderate pain

7-10 Severe pain



Motor blockade will be assessed using Bromage scale

Bromage scale: Grade Definition

0 Full flexion of knee and feet.

1 Inability to raise extended leg; able to move knee and feet.

2 Inability to raise extended leg and move knee; able to move feet.

3 Complete block of lower limb

Statistical Methods: Statistical analysis

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. 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.

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.

Results

Samples are age matched with P=0.505 and gender matched with P=0.567. Onset of sensory block was significantly fast in group II, less than 2 minutes in 33.3% compared to group I, 18.1%. maximum level of sensory block achieved, T6 was 45.8% in group II compared to 30.6% in Group I patients. After 6 minutes there was a significant drop in heart rate in Group II compared to Group I. Hemodynamics was stable in both groups.

In Group II Time to two segment regression of sensory level was significantly more (188.89±22.32) compared to Group I (118.96±33.69); total duration of analgesia and motor block was also more.

Table 2: VAS score when patient complaints of pain distribution in two groups of patients studied

VAS score when patient complaints of pain	Group I	Group II	Total
1	6(8.3%)	10(13.9%)	16(11.1%)
2	24(33.3%)	30(41.7%)	54(37.5%)
3	34(47.2%)	22(30.6%)	56(38.9%)
4	8(11.1%)	10(13.9%)	18(12.5%)
Total	72(100%)	72(100%)	144(100%)
Mean ± SD	2.61±0.80	2.44±0.90	2.53±0.85

P=0.242

VAS scores in Group II were less compared to Group I.

Table 3: Number of rescue analgesia doses given during 24 hours

Number of rescue analgesia doses given during 24 hours	Group I	Group II	Total
0	0(0%)	32(44.4%)	32(22.2%)
1	14(19.4%)	15(20.8%)	29(20.1%)
2	44(61.1%)	25(34.7%)	69(47.9%)
3	14(19.4%)	0(0%)	14(9.7%)
Total	72(100%)	72(100%)	144(100%)
Mean ± SD	2.00±0.63	0.90±0.89	1.45±0.94

P<0.001**

Table 1: Comparison of study variables according to two groups of patients studied

Variables	Group I	Group II	Total	P value
Time to two segment regression of sensory level (mins)	118.96±33.69	188.89±22.32	153.92±45.19	<0.001**
Total duration of analgesia (mins)	191.88±40.86	261.67±31.31	226.77±50.42	<0.001**
Time for complete motor recovery (mins)	175.14±39.79	302.65±32.72	238.9±73.56	<0.001**

Rescue doses required in Group II were less compared to Group I.

Discussion

Levobupivacaine is the S(–) enantiomer of racemic bupivacaine. The cardiotoxicity of levobupivacaine is less than that of racemic bupivacaine, due to the lower affinity of the S(–) isomer than the R(+) isomer for the inactivated state of the cardiac sodium channel. In view of this potential decrease in cardiotoxicity, levobupivacaine appears to be an attractive alternative to racemic bupivacaine.[1]

The volume of distribution and overall clearance of levobupivacaine was significantly lower than that of dextrobupivacaine (Burm et al. 1994).[4] Pharmacokinetics of the unbound fraction of levobupivacaine accounts for its less toxicity. Because of its increased protein-binding affinity, unbound fraction of levobupivacaine was significantly lower than that of unbound dextrobupivacaine.[5] The higher clearance of the unbound levobupivacaine explains the shorter elimination half-life of levobupivacaine. An increase in postoperative levels of alpha-1-glycoprotein (Dauphin et al. 1997) binds large amounts of levobupivacaine. [6]

Levobupivacaine has a safety margin of 1.3, which means toxic effects are not seen until the concentration rises by 30%. The concentration necessary to produce cardiac and neurotoxicity is higher for levobupivacaine than for racemic bupivacaine.[7]

Subarachnoid block with Levobupivacaine has similar sensory and motor characteristics and recovery like bupivacaine. Onset of sensory and motor block is hastened with hyperbaric levobupivacaine as compared to isobaric levobupivacaine. 15 mg of levobupivacaine provides an adequate sensory and motor block lasting for approximately 6.5h. Minimum effective local anesthetic dose of levobupivacaine as recommended by an up- and-down sequential design study is 11.7 mg.[7]

The quality of anesthesia, sensory and motor block characteristics and hemodynamics in patients requiring a higher level of spinal block for lower abdominal approach after either hyperbaric or isobaric levobupivacaine are of particular interest. Generally we use the hyperbaric form of local anesthetics for intra-abdominal surgery but the manufactured hyperbaric form of levobupivacaine is not available so it was interesting to know whether it is worth making it hyperbaric.[8]

According to Sananslip V et al., hyperbaric solution had a faster onset of sensory and motor block and reached T4 sensory levels, sufficient for the planned surgical procedures, faster, and more reliably than with isobaric. Nine patients (90%) in the hyperbaric group underwent surgery completely without additional anesthesia compared with four (40%) in the isobaric group.[8]

Sen et al. study says hyperbaric levobupivacaine had a faster onset of sensory and motor block and had a shorter duration of sensory and motor block than did the isobaric form, except for 2-segment regression time, which were similar in both groups.[9]

According to Mcloed GA et al., the density of local Anesthetics decreases with increasing temperature and increases in a linear fashion with the addition of dextrose. Levobupivacaine 5 mg ml±1 has a significantly higher density compared with bupivacaine 5 mg ml±1 and ropivacaine 5 mg ml±1 at 23 and 37°C both with and without dextrose. Levobupivacaine 7.5 mg ml±1 is an isobaric solution within all patient groups at 37°C.[10]

Glucose was usually used to increase the density of anesthetic solution, which can be great benefit to cycle fluctuations inhibition in clinical anesthesia. Hyperbaric local anesthetics made with glucose produce effectiveness in controlling the level of anesthesia.[11]

Difference in density between cerebrospinal fluid (CSF) and local Anesthetic is an important factor in determining the distribution of the solution. Local anesthesia density reduces with increased temperature and increases with an increase in glucose concentration.

But some studies that have reported that neurotoxicity occurred after intrathecal administration of local anesthetic mixed with glucose compared with intrathecal injection 5% lidocaine alone, the rats with 5% lidocaine with 10% glucose had induced more severe sensory impairment and morphologic damage.[11]

In our study we have compared the effects of plain levobupivacaine (0.5% 3.3 ml, 5 mg per ml) and addition of dextrose (0.3 ml 150 mg) to levobupivacaine (0.5% 3 ml 5 mg per ml). When compared to above studies, addition of dextrose have proved to be effective in faster onset of sensory and motor blockade and longer duration of blockade and prolonged two segment regression time with no adverse side effects.

In view of reducing the side effects caused by the use of dextrose, we use lesser dose that is 0.3 ml 50 mg per 0.1 ml when compared to Hyperbaric

Bupivacaine which we use daily has 80 mg per ml dextrose in it.

Conclusion

Addition of dextrose have proved to be effective in faster onset of sensory and motor blockade and longer duration of blockade and prolonged two segment regression time with no adverse side effects.

Key Messages

Levobupivacaine has less toxicity effects compared to bupivacaine and is available in plain form which is used in short surgeries and the block may not be extended with changing the position of patient as with Heavy bupivacaine. We have added dextrose to make it heavy and the beneficial effects are studied here.

Prior publication: Nil

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Changes in Hemodynamic Parameters in Patients Undergoing TURP and TURBT Due to Additive Intrathecal Clonidine

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Abstract

Introduction: Clonidine has been used by anesthesiologists as an anesthetic adjunct to provide increased perioperative cardiovascular and sympathoadrenal stability, to enhance general and regional anesthesia, as well as sedation and analgesia.

Materials and Method: This randomized prospective double blind study conducted at MIOT hospitals, Chennai, from October 2014 – December 2015, evaluated the effective dose of clonidine with 10 mg of 0.5% heavy bupivacaine in 80 patients posted for these surgeries and also to find the effect of various doses of clonidine on various subarachnoid block characteristics. Patients of either physical status ASA 1 or ASA 2 admitted for elective TURP and TURBT.

Results: There were statistically significant differences in the heart rate between the groups from 30 min onwards but none of the patients in any group needed atropine to treat bradycardia (ie., heart rate did not fall below 60 beats per minute). There was a significant fall in MAP (mean arterial pressure) at 10-20 minutes in all the 4 groups following the subarachnoid block. The mean dose of ephedrine given was 10 mg in group NS, 10 mg in group BC25, 15 mg in group BC35 which was significant.

Conclusion: Addition of 35 mcg of clonidine to bupivacaine when compared to 25 mcg/15 mcg clonidine significantly prolongs the duration of analgesia without affecting the onset and maximum level achieved of sensory block.

Keywords: Hemodynamic parameters, intrathecal clonidine,TURP, TURBT.

Introduction

Clonidine was synthesized in 1962 as nasal decongestant, and marketed as antihypertensive in 1972. Bloor and Flacke in 1982 demonstrated in mongrel dogs that intravenous clonidine 5 and 20 μg/kg decreased halothane MAC by 42% and 48% respectively.[1] Since then, clonidine has been used by Anesthesiologists as an anesthetic adjunct to provide increased perioperative cardiovascular and sympathoadrenal stability, to enhance general and regional anesthesia, as well as sedation and analgesia.[2,3]

Transurethral resection of the prostate (TURP) are largely restricted to the geriatric population. They have a high incidence of anesthesia-related complications, especially hypotension increasing the risk of ischemia to various vital organs.[4] Bupivacaine, most commonly used the drug for subarachnoid block produces hypotension and bradycardia.[5] High doses of bupivacaine may lead to myocardial depression, heart blocks and dysrhythmias. The addition of certain adjuvants can counter balance these side effects of the subarachnoid block with bupivacaine. There

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are a number of studies on the use of intrathecal clonidine or fentanyl with bupivacaine in various lower abdominal surgeries.[6–8]

Materials and Method

This randomized prospective double blind study conducted at MIOT hospitals, Chennai, from October 2014 – December 2015, evaluated the effective dose of clonidine with 10 mg of 0.5% heavy bupivacaine in 80 patients posted for these surgeries and also to find the effect of various doses of clonidine on various subarachnoid block characteristics. Patients of either physical status ASA 1 or ASA 2 admitted for elective TURP and TURBT.

Formula used for the sample size n:

$n = (Z\alpha_{/2} + Z\beta)^2 * 2 * \sigma^2 / d^2$,

where Zα /2 is the critical value of the Normal distribution at α/2 (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Zβ is the critical value of the Normal distribution at β (e.g. for a power of 80%, β is 0.2 and the critical value is 0.84), σ2 is the population variance, and d is the difference you would like to detect.

Patients of ASA physical status 1 and 2, were included in the study. while the patients of ASA physical status 3 and above, allergic to any of the study drugs, undergoing treatment with α2 agonists, patients refusing for the trial, coming with emergency bladder outlet obstruction, Patients with Absolute contraindication for spinal anesthesia-Raised ICT, Bleeding disorders, and Infection at the site, Neurological deficit were excluded from the study.

After institutional ethics committee approval and informed consent 80 patients were included in the study. Patients were randomized to one of the four groups according to a computer generated randomization list:

- Group BN: 10 mg (2 ml) 0.5% hyperbaric bupivacaine + normal saline (0.24 ml)
- Group BC15: 10 mg (2 ml) 0.5% hyperbaric bupivacaine + 15 µg clonidine (diluted with normal saline to 0.24 ml).
- Group BC25: 10 mg (2 ml) 0.5% hyperbaric bupivacaine + 25 µg clonidine (diluted with normal saline to 0.24 ml).
- Group BC35: 10 mg (2 ml) 0.5% hyperbaric bupivacaine + 35 µg clonidine

Routine preanesthetic check was done and advice regarding medications for associated disease was given. Each patient was advised to fast after 10 pm and diazepam [5-10 mg] given orally night before surgery and 2 hrs before surgery.

In the operating room standard monitors such as Electrocardiogram (ECG) Pulse oximeter (SpO_2) Noninvasive blood pressure (NIBP) were connected and the basal pulse rate and Blood Pressure were recorded.

Subarachnoid block was performed under aseptic conditions with patient in sitting position. All patients [i.e; patients in group BN BC15 BC25 BC35] received 2 ml bupivacaine(+additive normal saline/clonidine) intrathecally over 1 minute after ensuring free flow of cerebro spinal fluid (CSF). The patient was then positioned supine and the level of sensory and motor blockade were assessed. The cephalad spread of anesthesia and the degree of motor block was assessed every 5 min. The level of sensory block was assessed by pin prick using 25G needle. The onset of motor blockade noted as the time taken for loss of knee reflex. [Modified bromage score 3]. The maximum height of the blockade was determined by the sensory level achieved at 20 min.

Heart rates (HR), MAP, SpO_2 were monitored continuously and noted every 5 min. Bradycardia defined as heart rate <60 beats per minute (bpm) and was treated with IV atropine. Fall of Mean arterial pressure i.e., MAP <60 Millimeters of mercury (mm of hg) was treated with rapid infusion of IV fluids (normal saline/ringer lactate) at 10 ml/kg and IV ephedrine (3-6 mg boluses). All patients received oxygen by facemask at the rate of 6 L/min.

All patients were observed intraoperatively for any complaints of pain, discomfort, restlessness or for other symptoms or TURP syndrome. All patients were monitored in PACU after the Surgery for a period of 24 hr.

The severity of postoperative pain was assessed using 10 point visual analog scales every 30 min by postoperative ward nurses who were blinded to the study. Time for 1st analgesic requirement noted. Duration of pain relief = time from intrathecal injection to first analgesic request. Rescue analgesia (injection Diclofenac 1.5 mg/kg upto maximum of 75 mg) was administered when VAS score was ≥4 and when the patient complained of pain.

Any symptom of TURP Syndrome like restlessness was noted. Time for catheter sensation was noted. Urinary retention was defined as inability to void spontaneously by 8 hr postoperatively. Adverse effects were noted finally

Results

The mean age of patients(+SD) in group BN was 44.95+15.34 years compared to 47.15+15.15 years in group BC15, 45.10+14.46 years in group BC25 and 43.20+16.67 years in group BC35. The difference in age between the groups was not significant. The gender distribution was comparable between the groups.

The distribution of patients according to ASA physical status between the groups was also comparable. 7 patients in group BN, 7 patients in group BC15, 11 patients in group BC25 and 8 patients in group BC35 belonged to ASA physical status 2 and mainly had controlled essential hypertension.

The mean weight in kilograms of patients in group BN was 77.50±15 as compared to 72.50±8 in group BC15, 75.85±11.47 in group BC25 and 72.05±9.19 in group BC35. The difference in weight between the groups was not significant.

The duration of surgery between the 4 groups was of mean duration of 42.60±5.67 min in group BN, 46±6.58 mins in group BC15, 46.85±7 mins in group BC25 and 52±7.17 mins in group BC35 (Table and Fig. 1).

Heart Rate

The heart rate (mean+SD) was compared between the 4 groups. The baseline heart rate per minute was 82.95+7.17 in group BN, 86.80+5.83 in group BC15, 85.70+5.95 in group BC25 and 83.50+5.37 in group BC35 which was comparable. There was fall in the heart rate from baseline in all the groups. There were statistically significant differences in the heart rate between the groups from 30 min onwards but none of the patients in any group needed atropine to treat bradycardia (ie., heart rate did not fall below 60 beats per minute). (Table and Fig. 2).

Mean Arterial Pressure (MAP)

The mean MAP(mean arterial pressure) of all the 4 groups was compared the baseline MAP was 84.25±3.11 in group BN, 86.45±4.28 in group BC15. 85.7±5.54 in group BC25, 88.95±8.32 in group BC35 and were all comparable. There was a significant fall in MAP at 10-20 minutes in all the 4 groups following the subarachnoid block.

All the groups had a fall in the mean arterial pressure to less than 20% of the baseline after the subarachnoid block. The difference was statistically significant between the groups NS and BC35 (P=0.000). It was not statistically significant between the groups BC15 and BC25 and between BC25 and BC35.

On comparison of the MAP trends within each group a significant fall in MAP was observed starting from 5-10 min following administration of subarachnoid block. Subgroup analysis was done to determine the significant between the groups. A highly significant difference in MAP was observed between the group NS AND BC35 (P=0.000). There

Table 1: Demographic data

Parameters	Group BN	Group BC15	Group BC25	Group BC35	P Value
Age	44.95±15.34	47.15±15.15	45.10±14.46	43.20±16.67	NS
Gender (M/F)	2/10	2/10	2/10	2/10	NS
ASA (1/2)	13/7	13/7	9/11	12/8	NS
Weight	77.50±15	72.50±8	75.85±11.47	72.05±9.19	NS
Surgical duration (min)	42.60±5.67	46±6.58	46.85±7	52±7.17	0.000

P value<0.05 significant, NS: not significant.

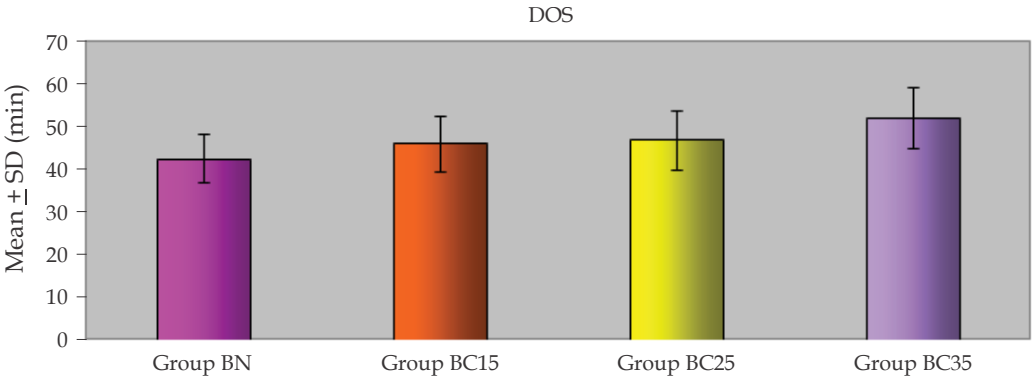

Fig. 1:

were no significant differences in MAP between BC15 and BC25 and between BC25 and BC35 groups. The mean arterial pressure (mean±SD) is shown in the Table 7 and displayed graphically in (Table and Fig. 3).

Ephedrine Requirement

3 Patients in group NS, 3 Patients in group BC25 and 2 patients in group BC 35 had a MAP <60 mm hg and received intravenous ephedrine boluses.

Table 2: Heart Rate

HR(min)	Group BN	Group BC15	Group BC25	Group BC35	P Value
0	82.96±7.17	86.8±5.83	85.7±5.95	83.5±5.37	0.162
5	84.7±9.14	85.2±6.05	84.6±5.64	82.15±5.78	0.495
10	83.9±11.08	84.4±5.67	83.6±6.17	80.45±6.12	0.350
15	80.45±9.85	82.55±6.6	83.05±5.84	78.7±5.4	0.202
20	81.65±12.51	80.95±6.57	81.65±5.91	78.05±5.88	0.458
25	81.05±11.58	79.6±6.36	80.45±5.6	80±5	0.488
30	82.1±9.41	79.7±6.35	79.75±6.66	75.55±6.27	0.046
35	81.15±9.37	79.2±6.31	79.2±6.37	75.4±7.14	0.106
40	81.53±9.53	79.39±7.08	77.75±6.73	74.45±6.21	0.035
45	82.25±10.41	80.69±6.48	78.13±6.83	74.28±6.23	0.027
50	79.6±8.32	80±6.48	75.4±7.74	73.75±6.37	0.121
55	84.5±13.43	80.57±6.65	78.8±4.32	75.25±6.6	0.208
60			82±1.73	75.5±4.5	0.042

P Value <0.05 significant, NS – Not significant.

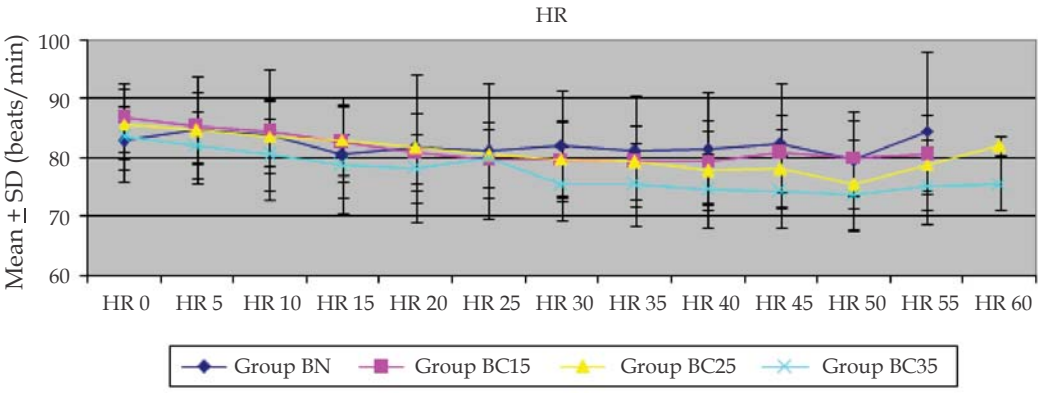

Fig. 2:

Table 3: Mean Arterial Pressure

MAP	Group BN	Group BC15	Group BC25	Group BC35	P Value
0	84.25±3.11	86.45±4.28	85.7±5.54	88.95±8.38	0.075
5	74.65±9.01	83.8±4.21	83.85±5.43	86±7.72	0.000
10	72.9±8.65	82.16±4.71	82±5.52	83.8±7.42	0.000
15	71.15±7.47	80.55±4.62	79.95±5.32	81.4±7.15	0.000
20	69.4±6.2	78.55±5.03	77.95±5.21	79±7.06	0.000
25	68.3±5.24	77.25±4.54	75.95±5.2	77.1±6.91	0.000
30	68.85±4.45	76.6±4.76	74.3±5.01	75.1±6.95	0.000
35	65.15±4.46	78.45±5.13	74.9±4.52	76.1±7.54	0.000
40	68.41±4.62	81.21±4.79	77.6±4.5	78±7.21	0.000
45	71.23±4.4	82.15±3.53	79.44±4.77	79.44±5.97	0.000
50	74.33±2.16	83.4±3.53	81.75±5.1	81.67±5.59	0.004
55	78±2.82	83±2.3	83±5.93	85.13±6.4	0.390
60			81.67±5.77	84±7	0.679

P Value <0.05 significant, NS – Not significant.

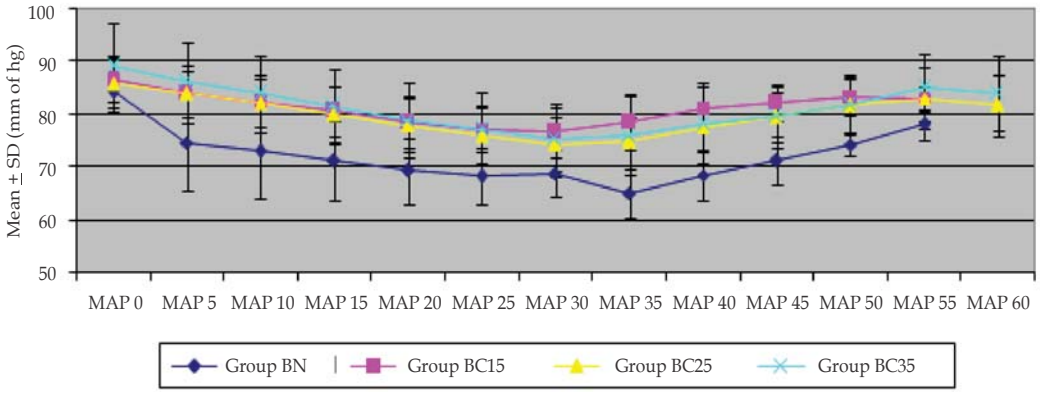

Fig. 3:

Table 4: Ephedrine Requirements

Parameter	MEAN±SD		
	BN	BC25	BC35
Ephedrine(mg)	10±1.73	10±1.73	15±0.00
No of patients	3	3	2

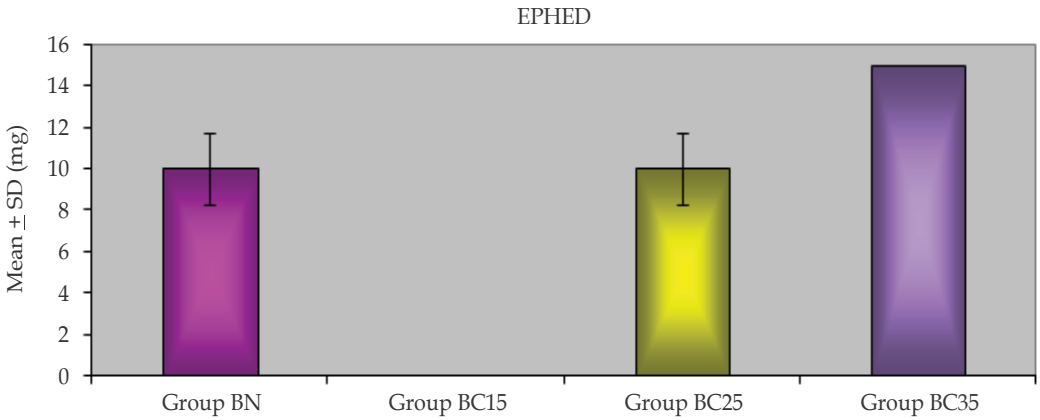

Fig. 4:

The mean dose of ephedrine given was 10 mg in group NS, 10 mg in group BC25, 15 mg in group BC35 which was significant.

Subgroup analysis showed a significant difference in ephedrine requirement between groups NS and BC35, BC25 and BC35 (Table and Fig. 4).

Oxygen Saturation

The oxygen saturation (SpO_2) (Mean±SD) was compared between the 4 groups. The baseline SpO_2 was 99.95±0.22 in group BN, 100±0.00 in group BC15,100±0.00 in group BC25, and 99.95±0.22 in group BC35 which were comparable.

All patients received oxygen by face mask at 6L/min. There was no significant change in SpO_2 (mean±SD) between the groups during the procedure.

Discussion

The addition of clonidine to intrathecal bupivacaine prolongs the duration of motor block by 30-50%.[9] The mechanism is due to the alpha 2 adrenoreceptor induced hyperpolarisation of motor neurons in the ventral horn of spinal cord.[10] However these studies have used higher doses of local anesthetics (15 mg) along with higher doses of clonidine (75 mcg) for patients undergoing lower limb and lower abdominal surgeries.[9]

The most common adverse effects noted with the use of intrathecal clonidine are hypotension and bradycardia. Maximal incidence of hypotension was seen with doses more than 75 mcgs of clonidine.[11] Alpha2 adrenergic agonists like clondine produce sympatholysis and decreased blood pressure by their action on brainstem nuclei and on sympathetic preganglionic neurons

in the spinal cord. This effect overrides the direct vasoconstriction that would have resulted from their action on adrenergic receptors in the peripheral vasculature.[12] The hypotensive effect produced by clonidine can last upto 2 hr. Different criteria have been used for defining hypotension following intrathecal administration of clonidine with bupivacaine. Some studies have defined significant hypotension as a 20% to 30% fall in systolic blood pressure (SBP), while others have used criteria such as SBP <90 mm of hg. Or fall in MAP more than 20% of the base line value. We also defined hypotension as SBP<90 mm of hg or fall in MAP more than 20% of baseline value. The difference was statistically significant between the groups NS and BC35 (P=0.000). It was not statistically significant between the groups BC15 and BC25 and between BC25 and BC35.

Patients in group BC35 had severe fall in blood pressure (MAP<60 mm of hg) and received more number of intravenous ephedrine boluses to increase the blood pressure. Subgroup analysis showed a significant difference in ephedrine requirement between groups NS and BC35. The amount of hypotension and the required dosage of ephedrine was more in patients receiving 35 mcg of clonidine compared to control group.

Most of the studies have reported a significant fall in blood pressure when 150 mcg clonidine was added to the local anesthetic for patients undergoing lowerlimb orthopedic and abdominal surgeries. In contrast, when clonidine is added to a low dose of bupivacaine it results in a greater decrease in mean arterial pressure than that observed with bupivacaine alone. In this study 10 mg of hyperbaric bupivacaine was used in patients of all groups with various doses of clonidine. Addition of 35 mcg clonidine to hyperbaric bupivacaine resulted in hypotension in patients who were hypertensive and on multidrug therapy.

Kothari and coworkers observed an increased incidence of hypotension in those who received 12.5 mg of 0.5% hyperbaric bupivacaine (72%) compared to 8 mg (57%) or 10 mg (35%) of 0.5% hyperbaric bupivacaine with 50 mcg clonidine.[13] In conclusion increasing the dose of bupivacaine increases the incidence of hypotension significantly. In this study the dose of bupivacaine remained the same (10 mg) in all the four groups but varying doses of clonidine were used. There were more episodes of significant hypotension in patients whom 35 mcg clonidine was used than in other groups.

Heart rate in this study was found decreased in all the 4 groups. However, the change was comparable between groups. This might be because of the use of low doses of clonidine along with low dose of hyperbaric bupivaciane in all the patients. None of the patients in any group required atropine to treat bradycardia which was defined as heart rate below 60 beats per minute.

Satish Dhasmana and coworkers found that with the addition of clonidine, there was a decrease in the heart rate from the baseline in their study on effects of addition of fentanyl or clonidine to intrathecal ropivacaine in patients undergoing anorectal surgeries.[14]

In a study in patients undergoing cesarean section Kothari and coworkers observed an increased incidence in bradycardia (22.85%) in patients who received a higher dose of hyperbaric bupivacaine (12.5 mg) as compared to who received lower doses of bupivacaine (8 mg) with 50 mcg clonidine (7.14%).[13] There was no difference in bradycardia between patients who received 50 mcg clonidine with 8 mg (7.14%) or 10 mg of 0.5% hyperbaric bupivacaine (14.28%). They explained that use of higher doses of bupivacaine (12.5 mg) resulted in higher level of block and contributed to bradycardia.

In contrast we found a lower incidence of bradycardia in this study. This could be due to use of low doses of clonidine as well as bupivacaine in this study. In this study there was no difference in the oxygen saturation between the four groups at any time during the procedure. None of the patients in any group had nausea, vomiting or pruritis.[15] This is similar to the effects observed in other studies.

Conclusion

There is good evidence from literature that clonidine has an antinociceptive effect at spinalcord and brainstem level. This is borne out in our study which concludes that addition of 35 mcg of clonidine to bupivacaine when compared to 25 mcg/15 mcg clonidine significantly prolongs the duration of analgesia without affecting the onset and maximum level achieved of sensory block.

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A Comparative Study of Laryngoscopic View and Intubation Response using Macintosh, McCoy and AirTraq Laryngoscopes in Adults Undergoing Elective Surgeries

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Abstract

Context: Laryngoscopes are most commonly used for endotracheal intubation. It plays an important role in securing airway in emergency conditions and in administration of general anesthesia. They range from simple rigid scopes with a light bulb to complex fiber optic video devices.

Objectives: The purpose of the study was tocompare laryngoscopy and intubating conditions in three groups of patients using Macintosh, McCoy and Airtraq laryngoscope:Visualisation of pharyngeal structures and larynx as per Modified Cormack and Lehane grading; Hemodynamics; Adverse effects, if any.

Settings and Design: Randomised prospective comparative study.

Methods and Material: after obtaining ethical committee approval, 90 adult patients of either sex, aged between 18 to 60 years, of physical status ASA Grade I and Grade II undergoing elective surgeries under general anesthesia after obtaining written informed consent were included. Divided into 3 groups of 30 each and randomly allocated. Group I -Patients intubated with Macintosh laryngoscope (n-30); Group II - Patients intubated with Airtraq optical laryngoscope (n-30); Group III -Patients intubated with McCoy laryngoscope (n-30).

The laryngoscopy view obtained was compared according to Cormack and Lehane grading. The change in systolic, diastolic, mean arterial pressure, pulse rate and SpO_2 will be recorded at pre-induction, pre-intubation and post intubation at 1, 3 and 5 minutes.

Statistical analysis used: The demographic data was analysed using descriptive statistics and expressed as mean ± standard deviation. Categorical data was analyzed by chi square test. P value of 0.05 or less was considered statistically significant.

Results: Airtraq laryngoscope improved the Cormack and Lehane glottic view compared with the McCoy and Macintosh laryngoscopes. The maximum change in HR was 24% in the Macintosh, 2.27% in the Airtraq and 11.9% in the McCoy group, and increase mean arterial pressure was 20.63% in the Macintosh, 4.37% in the Airtraq and 7.37% in the McCoy group. This difference between the three groups was significant ($P < 0.0001$).

Conclusions: From the present study, it is concluded that Airtraq optical laryngoscope provides a better glottic exposure and triggers minimal hemodynamic response to laryngoscopy and intubation when compared to Macintosh and McCoy.

Keywords: Airtraq laryngoscope; Intubation response; Laryngoscopy; Macintosh laryngoscope; McCoy laryngoscope.

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Introduction

In General Anesthesia, Laryngoscopy and endotracheal intubation plays a crucial role. Facilitation of tracheal intubation under vision is done using Direct laryngoscopy.[1] "Sniffing position" where there is flexion at the lower cervical spine and extension at the atlanto-occipital joint is achieved, by aligning the axes of the oral cavity, pharynx and larynx.

Laryngoscopes are used for purpose of inserting an endotracheal tube into the endobronchial tree. They range from simple rigid scopes with a light bulb to complex fibre optic video devices.[2]

Macintosh laryngoscope is a type of rigid direct laryngoscope which is most commonly used in day to day practice.

The McCoy blade is a modification of the Macintosh blade (with a hinged tip) which blade decreases the amount of forces exerted during laryngoscopy and endotracheal intubation. Thus, the exaggerated reflex hemodynamic response becomes clinically insignificant.[3]

The Airtraq optical laryngoscope is a type of rigid indirect laryngoscope. It contains a lateral channel used for passage of endotracheal tube, which has a built in antifog system and a low temperature light.[4] Without the alignment of oral, pharyngeal and laryngeal axis, Airtraq allows the visualization of vocal cords.[5]

The process of laryngoscopy is known to have profound cardiovascular effects and stimulation of supraglottic region by laryngoscopic blade with tracheal tube placement is the major cause of the sympathoadrenal response and cuff inflation, causing little additional stimulation.[6,7] Following laryngoscopy the pressor response leads to complications like myocardial ischemia, cardiac failure, intracranial hemorrhage and increase in intracranial pressure.[8,9]

Objectives

Comparative assessment laryngoscopy and intubating conditions in three groups of patients using Macintosh, McCoy and Airtraq laryngoscope: Visualisation of pharyngeal structures and larynx as per Modified Cormack and Lehane grading in all three groups; Hemodynamics in all three groups; Adverse effects in all the three groups, if any.

Materials and Methods

Ninety (90) patients in the age group of 18-60 years undergoing elective surgery under General Anesthesia were included. The duration of study was December 2013 to May 2015.

Ethical clearance was obtained from Institutional Ethics, patients posted for various elective surgeries requiring general Anesthesia were recruited in our study after taking written informed consent. All the patients were explained regarding the study and objectives.

Ninety (90) patients scheduled for different elective surgeries under General Anesthesia were randomly allocated to one of the three groups of 30 patients each group.

Group I: Patients intubated with Macintosh laryngoscope (n-30)

Group II: Patients intubated with Airtraq optical laryngoscope (n-30)

Group III: Patients intubated with McCoy laryngoscope (n-30)

Inclusion criteria: ASA grade I and II; Age group 18-60 years; Mallampati class I or II.

Exclusion criteria: Patients with uncontrolled hypertension and cardiac disease.; Patients allergic to any of the general Anesthetics; Obese patients; Patients with inter incisor distance less than 3 cm; Patients recognised as difficult laryngoscopy and intubation during pre Anesthetic checkup.

All patients were examined a day prior to surgery. A systemic examination was done to rule out any conditions mentioned in the exclusion criteria. The hemodynamic variables, heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure are recorded preoperatively and airway assessment was done. All the routine investigations were done.

All patients were kept Nil Per Oral (NPO) for 8 hr prior to the surgery. Pre-medication includes Tab. Ranitidine 150 mg and Tab. Alprazolam 0.5 mg at night previous today before surgery. Patients were repeated with Tab. Ranitidine at 6:00 am on the day of surgery.

In this study, English Macintosh size 3 blade, Airtraq optical laryngoscope size 3 and McCoy laryngoscope size 3 were used. Psychological assurance given to the patient in operation theatre and intravenous line was started.

The following monitors were connected before induction: Pulse oximeter; Non invasive blood pressure monitor; ECG monitor; $EtCO_2$.

Patients were premedicated with glycopyrrolate 0.2 mg, fentanyl 2 ug/kg and Injection Xylocard 1.5 mg/kg body weight. Then patient was

preoxygenated with mask for 3 minutes with 100% oxygen and preinduction heart rate, noninvasive blood pressure, SpO_2 and ECG monitoring were recorded.

General Anesthesia was standardized by using Injection propofol 2 mg/kg for induction and Inj. Suxamethonium 2 mg/kg for muscle relaxation before intubation. The heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, oxygen saturation (SpO_2) and ECG was noted just prior to laryngoscopy.

Patients in group A and group C were put into "sniffing position" and intubated with Macintosh and McCoy laryngoscope respectively. Patients in group B were put in neutral position and intubated with Airtraq laryngoscope.

The laryngoscopy view obtained was compared according to Modified Cormack and Lehane grading as follows.

Grade 1: Most of the glottis is visible

Grade 2: Only posterior extremity of glottis visible

2a-partial view of the vocal cords

2b-only the arytenoids and the epiglottis seen

Grade 3: No part of glottis visible only epiglottis visible

3a–epiglottis can be lifted from the posterior pharyngeal wall

3b–epiglottis cannot be lifted.

Grade 4: Not even epiglottis visible

The endotracheal tube was connected to Bain's circuit. Position of the tube was confirmed by $EtCO_2$ and auscultation. The endotracheal tube was secured and controlled ventilation was instituted. General Anesthesia was maintained with 66% N_2O, 33% O_2 and isoflurane 0.4%. Intravenous vecuronium bromide, 0.1 mg/kg loading dose and 0.02 mg/kg as maintenance dose was used as neuromuscular blocking agent.

Study parameters were assessed. Noninvasive blood pressure, pulse rate and SpO_2 was recorded at preinduction, preintubation and post intubation at 1, 3 and 5 minutes. Any arrhythmias and complications during intubation like local injuries, bleeding, regurgitation, laryngospasm and fall in SpO_2 was noted.

Neuromuscular blockade was reversed with Inj. neostigmine 0.05 $mgkg^{-1}$ and Inj. Glycopyrrolate 0.01 $mgkg^{-1}$ both IV after ensuring adequate recovery from neuromuscular blockade. Oral cavity and throat were suctioned thoroughly prior to extubation.

Statistical analysis

The demographic data was analysed using descriptive statistics and expressed as mean ± standard deviation. Categorical data was analyzed by chi square test. P value of 0.05 or less was considered statistically significant.

Result

Ninety (90) patients in ASA grade I and II of either sex aged between 18 years to 65 years with Mallampatti Class I and II posted for elective surgery under general Anesthesia were selected for the study. The study was conducted to evaluate the efficacy of laryngoscopy on Cormack Lehane grade and hemodynamic response to endotracheal intubation between Airtraq optical laryngoscope, McCoy laryngoscope and Macintosh laryngoscope.

In our study, the mean age of the patients was 39.37±13.43 years in Group I, 35.67±12.1 3 years in Group II and 40.10±13.98 years in Group III. The difference in age groups between the two groups were statistically insignificant (p= 0.383).

There were 11 males and 19 females in Group I, 9 males and 21 females in Group II and 10 males and 20 females in Group III. The differences in the sex distribution between the two groups were statistically insignificant (p=0.861).

The mean weight of patients in Group I was 58.40±6.97 kg, Group II was 60.93±6.69kg and Group III was 59.03±8.98. The differences in mean weight between the three groups were statistically insignificant (p = 0.411).

The mean height of patients in Group I was 157.43±7.71 cm, Group II was 158.77±7.04 cm and Group III was 159.13±7.24 cm. The differences in mean height between the two groups were statistically insignificant (p = 0.642).

The mean BMI of patients in Group I was 23.68±3.26 kg/m^2, Group II was 24.21±2.29 kg/m^2 and Group III 23.28 ± 3.04 kg/m^2. The differences in mean BMI between the two groups were statistically insignificant (p = 0.463).

The differences in the Cormack and Lehane grading between the group I and II and between the group II and III were statistically significant (p = 0.001).

Table 1: Cormack and Lehane grading by groups

CLG	Group I		Group II		Group III	
	No	%	No	%	No	%
I	20	66.7	30	100.0	21	70.0
II	10	33.3	0	0.0	9	30.0
Total	30	100.0	30	100.0	30	100.0

P=0.002

Group I-Group II: P=0.001**

Group I-Group III: P=0.781

Group II-Group III: P=0.001**

Table 2: Mean heart rate (bpm) prior to intubation and after intubation

Heart Rate (bpm)	Group I	Group II	Group III	Overall P value	Pair-Wise Significance		
					Group I-Group II	Group I-Group III	Group II-Group III
Baseline	82.07±7.62	84.07±10.64	87.10±7.79	0.089+	0.654	0.074	0.379
0 min	81.53±7.53	85.33±10.79	85.03±7.83	0.186	0.225	0.281	0.991
1 min	105.53±6.93	87.60±10.57	96.93±7.95	<0.001**	<0.001**	0.001**	<0.001**
3 min	97.93±6.49	89.67±9.58	90.53±8.00	<0.001**	<0.001**	0.002**	0.910
5 min	92.43±8.65	92.67±10.30	87.70±7.78	0.059+	0.994	0.108	0.087+

The increase in mean heart rate after intubation was more with Macintosh laryngoscope compared to Airtraq optical laryngoscope and McCoy laryngoscope.

Table 3: Mean systolic blood pressure (mmHg) prior to intubation and after intubation

SBP (mm Hg)	Group I	Group II	Group III	Overall P value	Pair-Wise Significance		
					Group I-Group II	Group I-Group III	Group II-Group III
Baseline	120.60±10.53	123.27±9.77	122.23±9.38	0.577	0.552	0.799	0.914
0 min	122.23±10.53	121.67±10.02	120.37±9.44	0.761	0.974	0.751	0.870
1 min	148.70±10.03	128.03±10.24	130.50±8.77	<0.001**	<0.001**	<0.001**	0.589
3 min	136.73±9.47	125.37±10.14	124.40±9.63	<0.001**	<0.001**	<0.001**	0.922
5 min	110.27±20.82	115.60±9.24	117.87±10.72	0.121	0.334	0.112	0.818

The increase in systolic blood pressure after intubation was more with Macintosh laryngoscope compared to Airtraq optical laryngoscope and McCoy laryngoscope.

Table 4: Mean diastolic blood pressure (mmHg) prior to intubation and after intubation

DBP (mm Hg)	Group I	Group II	Group III	Overall P value	Pair-Wise Significance		
					Group I-Group II	Group I-Group III	Group II-Group III
Baseline	71.90±15.03	79.00±8.15	77.20±6.43	0.029*	0.029	0.132	0.787
0 min	76.17±7.09	77.27±8.39	76.03±6.39	0.775	0.831	0.997	0.792
1 min	93.43±6.04	80.40±8.58	86.63±6.14	<0.001**	<0.001**	0.001**	0.003**
3 min	87.73±6.65	79.40±8.54	81.17±6.46	<0.001**	<0.001**	0.002**	0.617
5 min	73.30±7.34	75.17±8.09	73.87±6.24	0.596	0.582	0.951	0.768

The increase in diastolic blood pressure after intubation was more with Macintosh laryngoscope compared to Airtraq optical laryngoscope and McCoy laryngoscope.

Table 5: Mean arterial pressure (mmHg) prior to intubation and after intubation

MAP (mm Hg)	Group I	Group II	Group III	Overall P value	Pair-Wise Significance		
					Group I-Group II	Group I-Group III	Group II-Group III
Baseline	90.13±7.23	93.77±8.31	92.13±5.53	0.147	0.124	0.523	0.648
0 min	90.97±7.19	91.77±8.41	90.80±5.56	0.855	0.902	0.996	0.860
1 min	111.60±6.32	95.97±8.60	98.17±19.17	<0.001**	<0.001**	<0.001**	0.780
3 min	103.90±6.41	94.77±8.61	95.53±5.37	<0.001**	<0.001**	<0.001**	0.904
5 min	86.77±6.65	88.73±8.03	88.53±5.77	0.479	0.512	0.582	0.993

The increase in arterial pressure after intubation was more with Macintosh laryngoscope compared to Airtraq optical laryngoscope and McCoy laryngoscope.

Discussion

Securing the airway is a vital step in administrating General Anesthesia. Airway is secured through endotracheal intubation. Direct laryngoscopy is used to facilitate tracheal intubation under vision. Successful direct laryngoscopy depends on achieving a line of sight from the maxillary teeth to the larynx. To aid the process of intubation, laryngoscopes ranging from simple rigid laryngoscope to complex fiber optic video devices have been developed and studied.

Tracheal intubation is a crucial skill in Anesthetic practice. It needs direct laryngoscopy to view the vocal cords for insertion of the tube. Both laryngoscopy and passage of a tracheal tube are noxious stimuli that can incite adverse events in the respiratory, cardiovascular and other physiologic systems.[1] Direct laryngoscopy and intubation are noxious stimuli that can provoke adverse responses in the cardiovascular system like tachycardia and hypertension. The hemodynamic changes was first described by Reid and Brace. The magnitude of the response is greater with increasing force and duration of laryngoscopy. Transitory hypertension and tachycardia are probably of no consequences in healthy individuals. Both may be hazardous to those with hypertension, myocardial insufficiency and cerebrovascular disease.

Thus the laryngoscopes should facilitate good laryngoscopic view of the vocal cords to ease the process of intubation while triggering minimal stress response. The Macintosh blade is one of the most popular blades. The tongue has a gentle curve that extends to the tip. In cross section, the tongue, web, and flange form a reverse Z. Numerous modifications have been suggested.

The McCoy laryngoscope is a modified Mackintosh laryngoscope, which has a hinged tip controlled by a lever on the handle. It is designed to elevate the epiglottis with its hinged tip. This unique design has two advantages compared with the Macintosh laryngoscope. First, using the McCoy laryngoscope results in less force being applied during laryngoscopy and the stress response to laryngoscopy is reduced. Secondly, difficult laryngeal visualization may be improved by lifting the epiglottis. Especially in patients with the neck fixed in the neutral position, this laryngoscope can improve the laryngeal view.

The Airtraq is a new intubation device that has been developed to facilitate tracheal intubation inpatients with normal or difficult airways As a result of the exaggerated curvature of the blade and an internal arrangement of optical components, a view of the glottis is provided without alignment of the oral, pharyngeal and tracheal axes.

The blade of the Airtraq consists of two side by side channels. One channel acts as a conduit through which an endotracheal tube (ETT) can be passed, while the other channel contains a series of lenses, prisms and mirrors that transfers the image from the illuminated tip to a proximal view finder, giving a high quality wide-angle view of the glottis.

In our study, the efficacy of laryngoscopy on Cormack Lehane grade and hemodynamic response to endotracheal intubation between English Macintosh laryngoscope, McCoy laryngoscope and Airtraq optical laryngoscope were studied.

A total of Ninety (90) patients between the age group of 18-60 years were included in the study. The study population was randomly divided into three groups with 30 patients in each group.

The mean age in Group I (Macintosh) was 39.37 ±13.43 years, Group II (Airtraq) was 35.67±12.13 years and Group III (McCoy). The differences in the mean age between the three groups were statistically insignificant.

There were 11 males and 19 females in Group I, 9 males and 21 females in Group II and 10 males and 20 females in Group III. The differences in the sex distribution between the two groups were statistically insignificant (p=0.861).

The mean weight of patients in Group I was 58.40±6.97kg, Group II was 60.93±6.69kg and Group III was 59.03±8.98kg. The differences in mean weight between the three groups were statistically insignificant(p = 0.411).

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The mean BMI of patients in Group I was 23.68±3.26 kg/m^2, Group II was 24.21 2.29 kg/m^2 and Group III 23.28±3.04 kg/m^2. The differences in mean BMI between the two groups were statistically insignificant (p = 0.463).

Thus patients in all three the groups were comparable with respect to age, sex, weight, height and BMI.

Laryngoscopic view

The laryngoscopic view was compared according to Modified Cormack and Lehane grading. The Cormack and Lehane grading system, although originally designed to compare glottic views at direct laryngoscopy, provided a useful comparison of the direct and indirect laryngoscopic views achieved in this study.

So in the present study the visualization of larynx according to Cormack and Lehane grading was better with Airtraq optical laryngoscope compared with Macintosh laryngoscope and McCoy laryngoscope which was statistically highly significant.

Maharaj et al. compared the Airtraq with the Macintosh laryngoscope in patients deemed at low risk for difficult intubation in a randomized, controlled clinical trial and found that Airtraq laryngoscope provided a better laryngoscopic view when compared to Macintosh laryngoscope.[10]

Lopez-Negrete et al. compared the AirTraq and Macintosh views and assessed whether predictor of intubation difficulty are useful when the AirTraq laryngoscope is used and found that Airtraq laryngoscope provided a better laryngeal view when compared to Macintosh laryngoscope.[11]

Ranieri D et al. compared intubation conditions produced by the Macintosh and Airtraq laryngoscopes when used in obese patients in the ramped position and concluded that the Airtraq laryngoscope provided an improved vocal cord view as assessed by the Cormack and Lehane score when compared with the Macintosh laryngoscope.[12]

These results are similar and comparable to the present study.

Hemodynamic response to laryngoscopy and intubation

Hemodynamic response to laryngoscopy and intubation include tachycardia, hypertension and dysrhythmias. In healthy patients these responses are generally well tolerated but in patients with limited coronary or myocardial reserve these changes can be detrimental.

Airtraq laryngoscope resulted in less alteration in heart rate following laryngoscopy when compared to Macintosh and McCoy laryngoscope.

The increase in systolic blood pressure after intubation between the three groups was statistically highly significant. The increase in systolic blood pressure was more with Macintosh laryngoscope when compared to McCoy and Airtraq laryngoscope.

The increase in diastolic blood pressure after intubation between the three groups was statistically highly significant. The increase in diastolic blood pressure after intubation was more with Macintosh laryngoscope compared to McCoy and Airtraq laryngoscope.

The increase in mean arterial pressure after intubation between the three groups was statistically highly significant. The increase in mean arterial pressure after intubation was more with Macintosh laryngoscope compared to McCoy and Airtraq laryngoscope.

Maharaj et al. compared the Airtraq with the Macintosh laryngoscope in patients deemed at low risk for difficult intubation in a randomized, controlled clinical trial and demonstrated that Airtraq resulted in less alterations in heart rate.[10]

Maharaj et al. compared the ease of intubation using the Airtraq with the Macintosh laryngoscope, in patients at increased risk for difficult tracheal intubation, in a randomized controlled clinical trial and found that Airtraq reduced the degree of hemodynamic stimulation when compared to the Macintosh laryngoscope.

McCoy et al. compared Macintosh and McCoy laryngoscope and concluded that the stress response to laryngoscopy was less marked with the use of the McCoy blade and is it probably due to a reduction in the force necessary to obtain a clear view of the larynx.[13]

Padmaja Durga et al. compared tracheal intubation using Airtraq and McCoy laryngoscope

in presence of a rigid cervical collar simulating cervical immobilisation for traumatic cervical spine injury cases and concluded that Airtraq improved the ease of intubation significantly when compared to McCoy blade.[14]

Gabbott compared the ease of intubation using the Macintosh laryngoscope and McCoy laryngoscopes in people with rigid cervical collar and concluded that McCoy laryngoscope significantly improves the view at laryngoscopy in the patient whose neck is immobilized in a rigid cervical collar.[15]

Mehtab A Haidry et al. compared the hemodynamic responses to tracheal intubation with Macintosh and McCoy laryngoscopes and concluded that hemodynamic changes was lesser in magnitude and of shorter duration with McCoy laryngoscope.[16]

These results are similar to our study. The process of laryngoscopy is known to have profound cardiovascular effects. This includes pressor response and tachycardia along with an increase in catecholamine concentration, mainly nor-epinephrine. The major cause of the sympathoadrenal response is believed to rise from stimulation of supraglottic region by laryngoscopic blade with tracheal tube placement and cuff inflation contributing little additional stimulation. The magnitude of response is greater with increasing force and duration of laryngoscopy.

In the present study, Airtraq optical laryngoscope resulted in lesser alterations in the heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure when compared to Macintosh laryngoscope. This can be attributed to the fact that Airtraq provides a view of the glottis without the need to align the oral, pharyngeal and tracheal axes, and therefore requires less force to be applied during laryngoscopy.

Strength and Limitation

Strength of our study is all the health care providers with proper training can use Airtraq during both elective and emergency intubation. Airtraq has better laryngoscopic view with minimal hemodynamic response during laryngoscopes and intubation.

Limitation of our study is that Airtraq is costly and also all health care providers need adequate training in usage of the scope for laryngoscopy and intubation. When not used properly it may lead to difficult intubation.

Conclusion

From the present study, it is concluded that

1. Airtraq optical laryngoscope provides a better glottis exposure when compared to Macintosh and McCoy laryngoscopes.
2. Airtraq optical laryngoscope triggers minimal hemodynamic response to laryngoscopy and intubation when compared to Macintosh and McCoy laryngoscope and this can be attributed to the reduction in lifting force necessary to obtain a clear view of the glottis.

Key Messages

Students are trained with classical Macintosh blade and Miller blade in the initial period, once they understand the technique and when the novice becomes a master in routine case management; other gadgets are introduced for their appreciation in accessing difficult airway. When trained properly these gadgets can ease the access of instrumenting and intubation the difficult airway.

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Support: Nil

Conflicts of interest: Nil

Permissions: Nil

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Original Research Article

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Comparative Evaluation of Dexmedetomidine and Fentanyl as Adjuvants to Ropivacaine for Epidural Anesthesia in Lower Limb Orthopaedic Surgeries

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Abstract

Background: Epidural anesthesia is the most commonly used technique for providing not only peri-operative surgical anesthesia but also post-op analgesia in lower abdominal and limb surgeries. The addition of an adjuvant not only increases the effectiveness of a local anesthetic by prolonging and intensifying the sensory blockade but also causes reduction in dose of local anesthetic agent. In comparison to bupivacaine, ropivacaine is known to have lesser cardiotoxicity and motor blockade, with similar pain relief at equivalent analgesic doses. Fentanyl is partial agonist on μ opioid receptor. Mainly acting on the substantia gelatinosa of the dorsal horn of spinal cord. Dexmedetomidine is a selective a -2 agonist which provides sedation, anxiolysis, hypnosis, analgesia and sympatholysis. To evaluate dexmedetomidine and fentanyl as adjuvant for epidural local Anesthetics, for lower limb orthopedic surgeries in term of: Comparative evaluation of sensory and moter blockadge in relation of onset, duration and intensity Duration of postoperative analgesia Hemodynamics parameter.

Materials and Methods: 100 patients of either sex with ASA grade I and II, 21 to 50 yrs old, posted for elective lower limb orthopedic surgeries were randomly selected and divided into 2 groups of 50 each, Group RD- given 15 ml of 0.75% Ropivacaine along with Dexmedetomidine 1 μg/kg, Group RF- given 15 ml of 0.75% Ropivacaine along with fentanyl 1 μg/kg. After taking all aseptic precautions, 18 G epidural catheter was placed in space L3-L4 with the help of Touhy Epidural needle with use of LOR technique and fixed at 15 cm marking. Each patient was observed for, onset of sensory and Motor block, Height and Intensity of Motor Block Duration of post operative analgesia and Level of sedation.

Result: In comparison to addition of fentanyl as 1 microgram/kg (Group RF), addition of dexmedetomidine as 1 microgram/kg in 15 ml of 0.75 percent Ropivacaine (RD Group) for epidural anesthesia has early onset of sensory and motor block ($p < 0.001$), lesser time for achieving complete motor block ($P<0.001$) prolong duration of motor block and postoperative analgesia ($P<0.001$). Bradycardia and hypotension were found more in Group RD and nausea and vomiting were found more in Group RF but these findings in both the groups were statistically not significant. *Conclusion*: Addition of dexmedetomedine 1 μg/kg to ropivacaine, as comparison to addition of fentanyl, for epidural anesthesia has early onset of sensory and prolong duration of motor block and postoperative analgesia, without an increased incidence of side effects.

Keywords: Epidural set 18G; Ropivacain 0.75%; inj. Fentanyle; inj Dexmedetomedine.

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Introduction

Epidural anesthesia is the most commonly used technique for providing not only peri-operative surgical anesthesia but also post-op analgesia in lower abdominal and limb surgeries. ***Fidel Pages***[1] described a lumbar epidural in abdominal surgery in 1921. ***Achile Dogliotti***[2] described the loss of resistance technique to locate epidural space in 1931. The next important event in the history of regional anesthesia was the adaptation of Tuohy's catheter technique(1945) developed for continuous spinal anesthesia to lumbar epidural anesthesia by ***Curbello***[3] in 1949. The addition of an adjuvant not only increases the effectiveness of a local anesthetic by prolonging and intensifying the sensory blockade but also causes reduction in dose of local anesthetic agent. In comparison to bupivacaine, ropivacaine is known to have lesser cardiotoxicity and motor blockade, with similar pain relief at equivalent analgesic doses. Fentanyl is partial agonist on μ opioid receptor. Epidural fentanyl has been widely used as analgesic adjuvant mainly acting on the substantia gelatinosa of the dorsal horn of spinal cord. Dexmedetomidine is a selective *a* -2 agonist which provides sedation, anxiolysis, hypnosis, analgesia and sympatholysis.

Material and Methods

After prior permission of hospital ethical committee the present study was conducted in the department of Anesthesiology and critical care Medicine, MLB Medical College Jhansi on patients admitted for lower limb orthopaedic surgery.

Selection of Cases

100 Patients undergoing lower limb orthopaedic surgery of both genders, age ranging from 21 to 50 years and belonging to American Society Of Anesthesiologist (ASA) grade 1or 2 were screened and included in the study. A thorough preAnesthetic check up was done including the detailed history and physical examination. Airway examination was done In all patients.

Exclusion Criteria

- Patients refusal
- Diabetes mellitus
- Cardiac disease
- Hypertensive patients on β blockers
- Chronic obstructive respiratory disease
- Coagulation abnormalities
- Spinal deformities
- And patients allergic to amide type of local anesthetics were excluded from the study.

Informed and written consent was obtained from all patients. The patient was kept fasting as required for surgery. Procedure was explained to the patient. No medication preoperatively and divided into 2 groups of 50 each:

- Group RD- given 15 ml of 0.75% Ropivacaine along with Dexmedetomidine 1 μg/kg
- Group RF- given 15 ml of 0.75% Ropivacaine along with fentanyl 1 μg/kg

Drug preparation: Dexmedetomidine available as 100 mcg/ml so 0.5 ml was made to 2 ml by adding 1.5 ml NS in 2 ml syringe. Fentanyl 50 mcg/ml, 1 ml (50 mcg) made to 2 ml by adding 1.0 ml NS in 2 ml of syringe

Randomization 100 coded slip were prepared and placed in a plastic box and divided into two different groups and were kept inside a plastic box.

Multipara monitor- with HR, BP, SpO_2 and ECG recording

Epidural Tuohy Needle was used and it is 18G, 3 or 3.5 inch long (10 cm), blunt bevel with gentle curve of 15-30 degree at the tip.

Epidural catheter: Placing a catheter into the epidural space allows for delivery of study drug. Typically, a 19- or 20-gauge catheter is introduced through 18-gauge epidural needle. Catheter has marking up to 20 cm, every marking with 1 cm apart. Marking guides insertion length of epicat.

Lignocaine(2%): For skin infiltration at site of epidural needle insertion.

Dexmedetomidine: Available as 100 μg/ml in 0.5 ml, 1 ml and 2 ml ampoule.

Fentanyl: Available as 50 μg/ml in 2 ml ampoule.

Ropivacaine(0.75%): Available in 20 ml ampoule.

Anesthetic Technique

After shifting the patient to OT the procedure was explained to him again. Then multipara monitor was attached and reading of all vitals- HR, SBP, DBP, MAP, SpO_2 were marked as baseline values. Then 18G of IV canula was inserted into a peripheral vein and patient was hydrated with 10 ml/kg body weight of ringer's Lactate solution. The patient was placed in sitting position with straight leg on the OT table. The assistant maintain the patient in a vertical plain while flexing the patient neck and arms over the pillow to open up the lumber vertebral space. Under all Aseptic precautions, part was prepared, painted

& draped. At lumber space, L3-L4, 3 ml of 2% lignocaine is injected subcutaneously and a small skin wheal was formed. After interval of around 2 min, 18G epidural needle was taken & inserted through the skin, then LOR plastic syringe filled with 2 ml of air was attached. Then needle is further preceded through supraspinous ligament, pointing in a slightly cephaled direction then into the interspinous ligament, which is encountered at a depth of 2-3 cm. Then needle was advanced, millimeter by millimeter, with either continuous or rapidly repeating attempts. As the tips of needle just enter the epidural space there is a sudden loss of resistance and piston of syringe is easy pushed. Syringe was removed and catheter was introduced gently via the needle into the epidural space. The catheter has markings showing the distance from its tip and should be advanced to 15 cm through hub of the needle to ensure that sufficient length of the catheter has entered the epidural space. Then after needle was removed carefully. Epidural catheter was secured and patient placed in supine position. Test dose 3 ml of 0.75% ropivacaine with was administered into epidural space. After 15 min of test dose, the study drug was given via epidural catheter.

Result

A total 100 Patients undergoing lower limb orthopedic surgeries of both genders age ranging from 21 to 50 years belonging to American Society of Anesthesiologist (ASA) grade 1 or 2 were be screened out for the purpose of study

Each patient was observed for Demographic parameter, anthropometric parameter and duration of surgical time which was comparable in both group and statistically insignificant (P >0.05).

Difference in heart rate, systolic and diastolic blood pressure, mean arterial pressure, and SpO_2 of both groups was statistically insignificant (p value >0.05).

Table 1: Onset time of sensory block in min (at T10)

	Group RD	Group RF
Number of subjects	50	50
Minimum time (min)	8	10
Maximum time (min)	11	15
Mean (min)	9.22	11.30
Standard Deviation	0.86	1.12
Statistical significance	t= 11.62 p<0.001	

Table 1 shows that time to achieve sensory level at T10 was found to be significantly less (p<0.001) in Group RD (9.22±0.86 min) as compared to Group RF (11.30±1.12 min).

Table 2: Time of Onset of moter block (time taken to achieved Bromage motor scale 1)

	Group RD	Group RF
Number of subjects	50	50
Minimum time (min)	8	11
Maximum time (min)	12	15
Mean (min)	10.02	13.36
Standard Deviation	1.11	1.17
Statistical significance	P<0.001	

Tab 2 shows that significantly (p <0.001) early onset of motor block with Group RD was (10.02 min) as compared to Group RF (13.36 min).

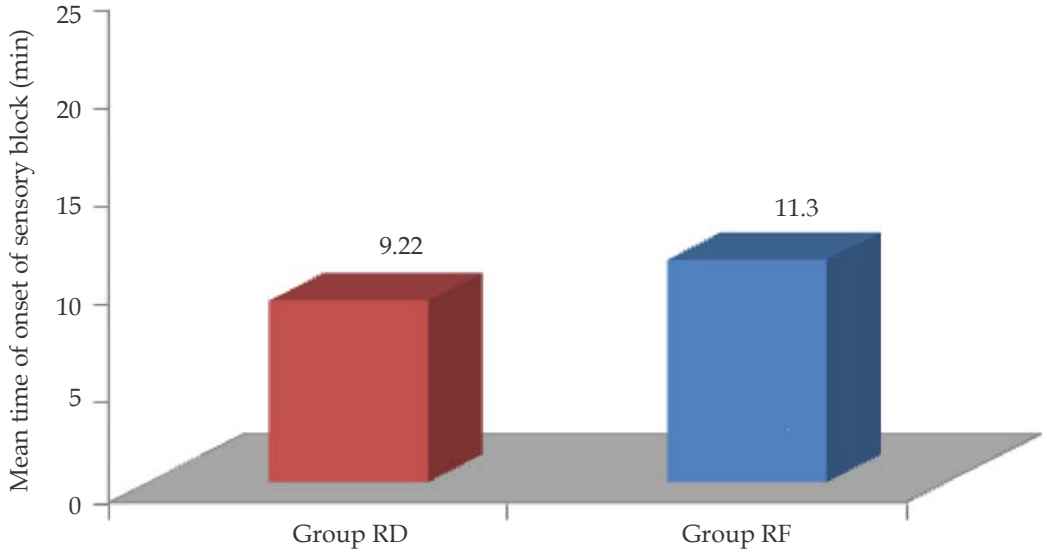


Fig. 1:

Table 3: Height of Block Achieved by Study Population

Sensory level	Group RD		Group RF	
	Number	Percent	Number	Percent
T4	6	12.0	–	0.00
T5	16	32.00	4	8.00
T6	24	48.00	33	66.00
T7	2	4.00	12	24.00
T8	2	4.00	1	2.00
Median level of block	T5		T6	

p value < 0.001

Table 3 shows that sensory level of T6, T7, and T8 was achieved significantly higher proportion ($p<0.001$) in subjects Group RF (92%) as compared to Group RD (56%) but block of T4 and T5 level was more higher proportion in group RD (46%) as compared to 8% in RF group. median level of block was T5 in RD as compared to T6 in Group RF.

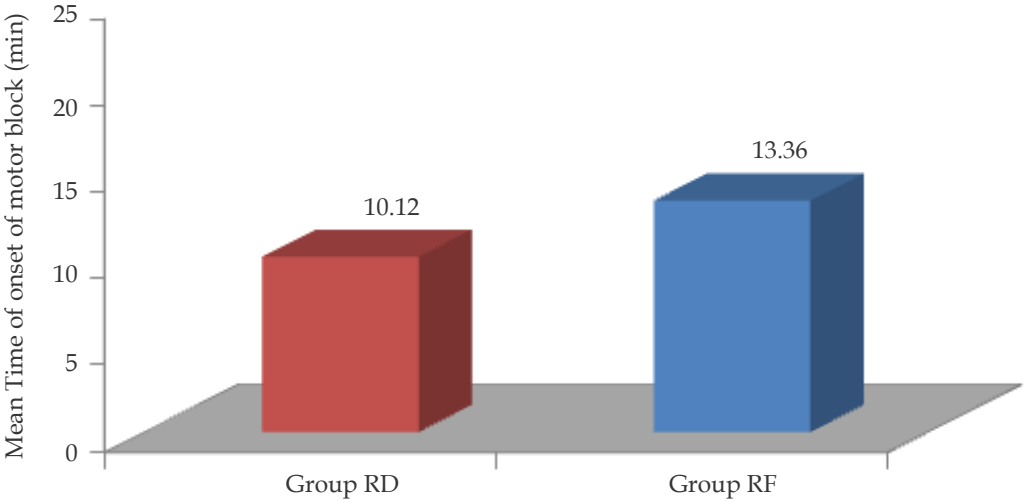


Fig. 2:

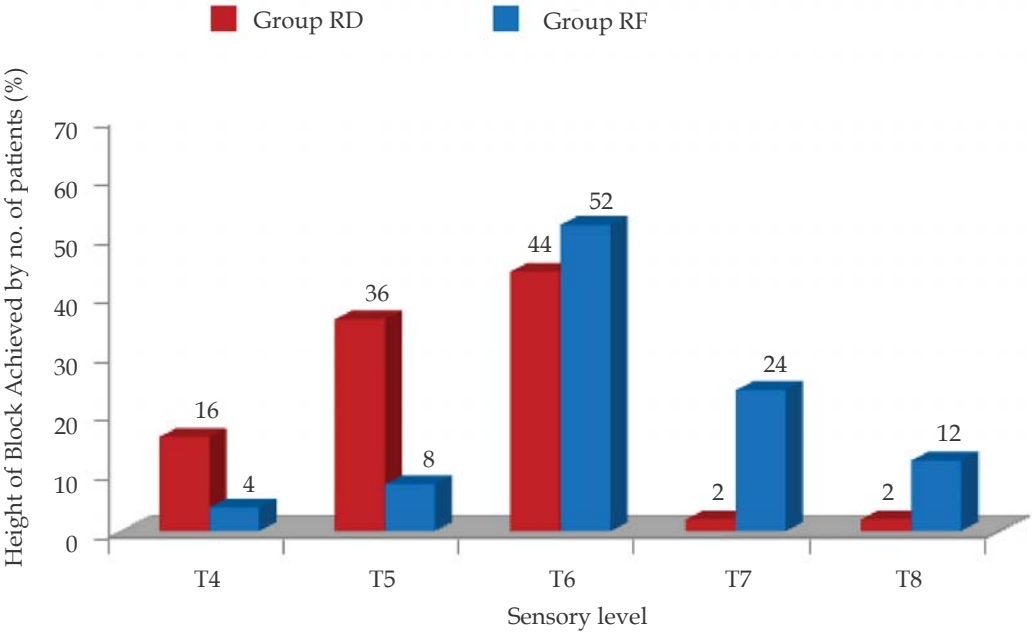


Fig. 3:

Table 4: Time to Achieve the Complete Motor Block (Min)

	Group RD	Group RF
Number of subjects	50	50
Minimum time (min)	14	20
Maximum time (min)	19	25
Mean (min)	17.9	24.00
Standard Deviation	1.82	0.94
Statistical significance	p<0.001	

Table 4 shows that time to achieve complete motor block in Group RD was 17.9+1.82 minutes and in Group RF it was found to be 24.00+0.94 minutes. Complete motor block was achieved in significantly lower (p <0.001) time by Group RD subjects as compared to Group RF subjects.

Table 5: Duration of motor block (min)

	Group RD	Group RF
Number of subjects	50	50
Minimum time (min)	210	175
Maximum time (min)	260	209
Mean (min)	231.88	189.7
Standard Deviation	10.46	9.24
Statistical significance	p value < 0.001	

Table 5 shows that duration of motor block in Group RD was 231.88±10.46 minutes and in Group RF it was found to be 189.7±9.24 minutes. Duration of motor block was significantly higher (p <0.001) in Group RD subjects as compared to Group RF subjects.

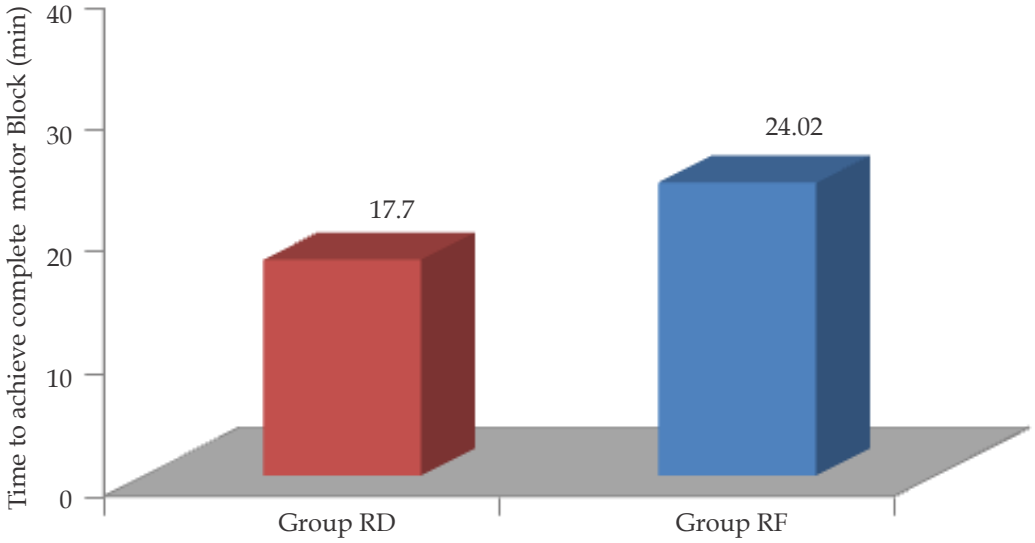


Fig. 4:

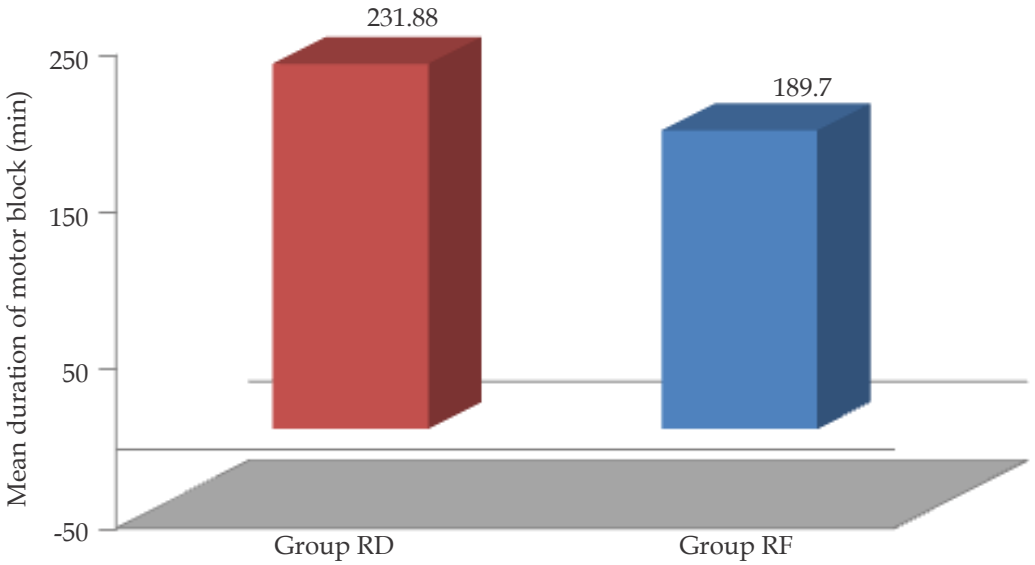


Fig. 5:

Table 6: Duration of Analgesia (minutes)

	Group RD	Group RF
Number of subjects	50	50
Minimum time (min)	340	240
Maximum time (min)	430	300
Mean (min)	382	272.50
Standard Deviation	20.84	20.14
Statistical significance	p<0.001	

Table 6 shows that duration of analgesia was significantly higher (p <0.001) in Group RD (382+20.84 minutes) as compared to Group RF (272.50+20.14 minutes).

Table 7: Side effects in Study Population

	Group RD		Group RF		Statistical significance
Side Effects	**No.**	**%**	**No.**	**%**	**p value**
Nausea/vomiting	8	16.00	11	22.00	0.181
Respiratory distress	0	0	0	0	–
Hypotension	4	8.0	3	6.0	0.695
Bradycardia	8	16	2	4.0	0.346
Urinary Retention	5	10.0	3	6.0	0.249

Table 7 shows that Nausea and vomiting was found to be in higher proportion of subjects from Group RF as compared to Group RD but this difference was statistically not significant (p >0.05). Hypotension, bradycardia were found in higher proportion of Group RD subjects as compared to Group RF, this was also statistically insignificant (p value >0.005). Urinary retention was also found in both group but which was insignificant.

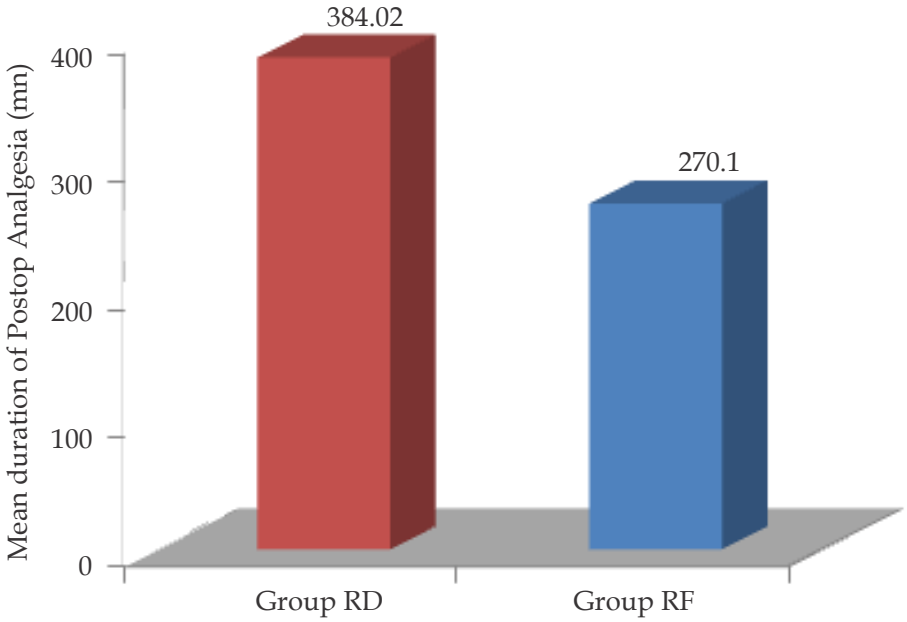


Fig. 6:

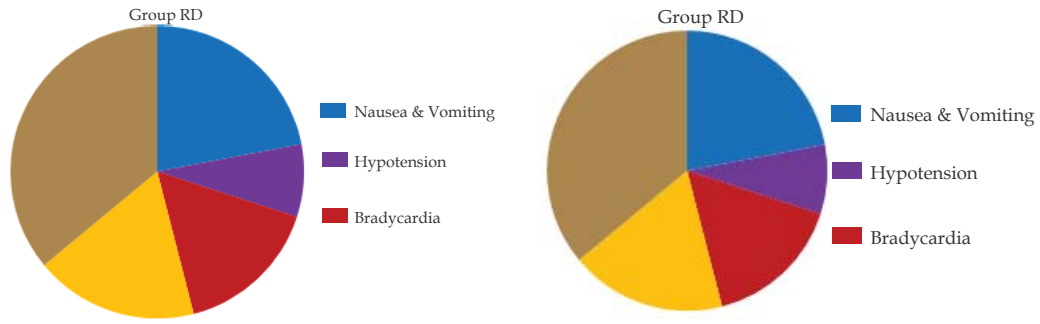
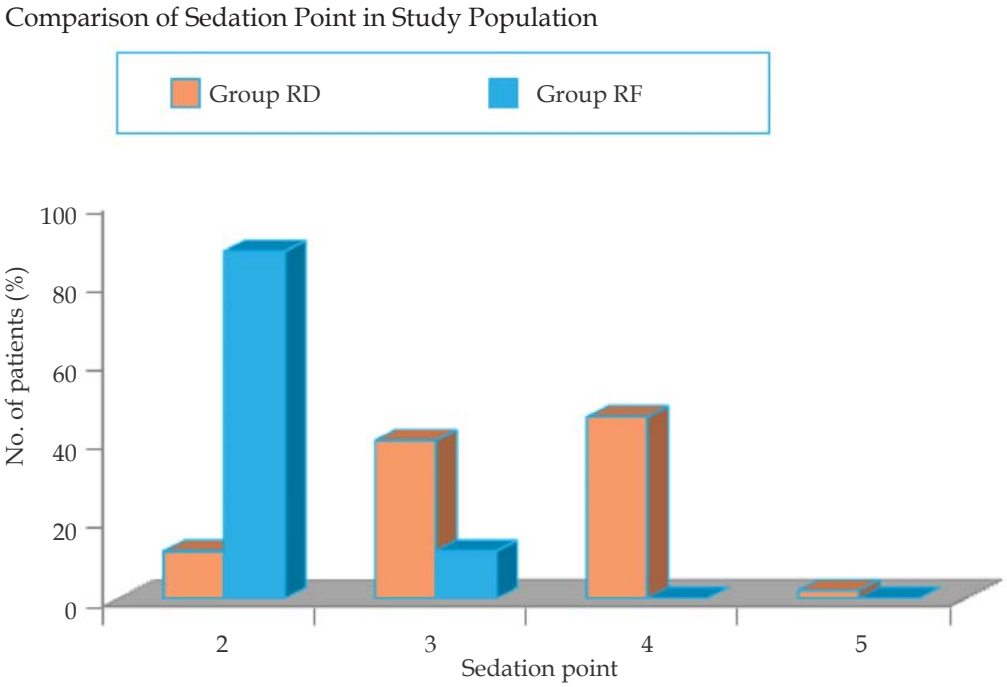


Fig. 7:



Sedation point 2 was found in significantly higher proportion of subjects from Group RF (80%) as compared to Group RD (16%). None of the subjects from Group RF reported Sedation point 4, 5.

In Group RD sedation score was 3&4 in most of case (84%) i.e. better sedation score was found in Group RD. Sedation score 5 was also non reported in group RD.

Discussion

The present study was designed to compare the effects of adding dexmedetomidine or Fentanyl as adjuvants to Ropivacaine in Epidural Anesthesia.

Anesthesiologist are specialized clinicians to treat pain by adopting various techniques and drugs. Pain is a very unpleasant and distressful condition to the patient. If not treated it may result into various physiological changes, including rise in heart rate, blood pressure, restricted physical activity and sleepless nights.

The use of lumbar epidural analgesia provides superior analgesia. It decreases the requirements of other Anesthetic agents intraoperativly and in post operative period it decreases the requirement of other systemic analgesic. Ropivacaine in comparison to bupivacaine, it has a wider margin of safety, less motor blockade, less cardiovascular or neurological toxicity.

Dexmedetomidine used in spinal, epidural, caudal, oral and intraarticular routes to provide analgesia was used in the current study. Maroof M et al.[4] (2004) were found that Dexmedetomidine has the following physiological properties: Sedation, analgesia, it reduces the stress response to the surgery by reducing plasma catecholamine concentration, and prevents shivering via α2 adrenoceptors in the central nervous system. Scheinin M, Pihlavisto et al.[5] (2000): The analgesic effect of the α2 agonists is a complex issue. They can induce analgesia by acting at three different sites: in the brain and brainstem, spinal cord and in peripheral tissues. α2-adrenergic and opioidergic systems have common effector mechanisms in the locus coeruleus, representing a supraspinal site of action. In the spinal cord, their analgesic effect is related to activation of the descending medullospinal noradrenergic pathways or to the reduction of spinal sympathetic outflow at presynaptic ganglionic sites. Moreover, there is also significant interaction between opioids and α2 agonists at the spinal cord level (Arian SR et al.[6] 1998).

The antihypertensive effect of dexmedetomidine results from stimulation of α2 inhibitory neurones in the medullary vasomotor center. Bradycardia is caused by an increase in vagal tone resulting from central stimulation of parasympathetic outflow, as well as a reduced sympathetic drive (Talke P, Chen R, et al. 2000).[7] Dexmedetomidine has unique sedative properties caused by hyperpolarization of excitable cells in the locus coeruleus (Berridge CW et al. 2003).[8] It produces a unique form of sedation, in which patients become responsive as well as

calm and cooperative when aroused, and then back to sleep when not stimulated. Confusion, cited as a common problem for other traditional sedatives. (Martin E, Ramsay G et al.).[9]

On analysis of the demographic profile the age and weight were comparable in both the groups. Age wise distribution of subjects in both the groups did not show any statistically significant difference (p=0.216). Weight of study subject in both the groups did not show any statistically significant difference (p=0.979). Duration of surgery was also comparable in both group.

Onset time of sensory block (at T10) was found to be significantly lower (p <0.001) in Group RD (9.22±0.86 min) as compared to Group RF (11.30±1.12 min). Sukhminder Jit Singh Bajwa et al.[10] Addition of dexmedetomidine to ropivacaine as an adjuvant resulted in an earlier onset (8.52±2.36 min) of sensory analgesia at T10 as compared to the addition of clonidine (9.72±3.44 min) comparison (P <0.05). Time of onset of motor block with Group RD was (10.02±1.02 min) as compared to fentanyl (13.36±1.17 min). Bhawna Rastogi, Kumkum Gupta et al.[11] (2013) found that epidural administration of 15 mL of 1% ropivacaine plus 100 µg fentanyl has onset times of motor block up to Bromage scale 1 and 2 were significantly more rapid in the Fentanyl group (11.9 +/- 4.6 and 24.4 +/- 5.9 min). Maximum height of sensory block is T6 (60%) as compared to Group RD (48%). More height of block was achieved in RD group, In Group RF median level of block was T6 as compared to T5 in Group RD.

Sukhminder Jit Singh Bajwa et al.[10] (2011): Dexmedetomidine with ropivacaine provided a higher dermatomal spread (mean level of block is T5 to T6). Sukhminder Jit Singh et al.[12] (Saudi J Anesth Year: 2011): used 0.75% Ropivacaine 15 ml + fentanyl (1 µg/kg) and of 0.75% Ropivacaine 15 ml +dexmedetomidine (1 µg/kg) found maximum sensory block achieved T4 to T6 in dexmedetomidine group as T5 to T7 in fentanyl group. Sarabjit Kaur et al.[13] (Saudi J Anesth Year: 2014): found that Epidural Dexmedetomidine (1 µg/kg) as an adjuvant to Ropivacaine 0.75% 15 ml is associated with T5 level of block. Time to Achieve the Complete Motor Block in Group RD was 17.9+1.82 minutes and in Group RF it was found to be 24.00+0.94 minutes. Complete motor block was achieved in significantly lower (p<0.001) time by Group RD subjects as compared to Group RF subjects. Manjunath Thimmappa et al.[14] (2014) were compare epidural ropivacaine 0.75% alone and Ropivacaine 0.75% with alpha 2 agonists and found that Mean time to complete motor blockade in Group Ropivacaine was 21.37±2.13 min, group RC was 16.47±1.38 min and in Group RD was 15.77±1.25 min.

Duration of analgesia was significantly higher (p <0.001) in Group RD (382.02+20.84 minutes) as compared to Group RF (272.50+20.18 minutes). Bang EC et al.[15] Onset of labor epidural analgesia with ropivacaine and a varying dose of fentanyl ware randomly assigned 0, 50, 75, or 100 µg with 0.2% ropivacaine 12 ml. The onset of analgesia (mean±SD) was shortened with an increasing dose of fentanyl (14.3±5.4, 14.2±6.5, 12.1±5.1, and 8.7±3.8 min with fentanyl 0, 50, 75, or 100 µg, respectively, P=0.001). The duration of analgesia was prolonged with an increasing dose of fentanyl (87.4±20.8, 112.3±19.5, 140.8±18.8, and 143.6±18.6 min with fentanyl 0, 50, 75, or 100 µg, respectively, P <0.001. The addition of increasing doses of fentanyl to 0.2% ropivacaine contributed to shortened onset as well as prolonged duration of labor epidural analgesia and improved patient satisfaction.

Sukhminder Jit Singh Bajwa et al.[12] (2011) also reveals statistically significant post-operative block characteristics among the two groups. The time for rescue analgesia was comparatively shorter (242.16±23.86) in the patients who were administered fentanyl as compared to dexmedetomidine group who experienced prolonged pain free period (366.62±24.42) (P=0.012). The superior block characteristics by the addition of dexmedetomidine were clearly evident from the lesser dose consumption (76.82±14.28) of ropivacaine for postoperative analgesia for the next 24 hours (P=0.026)

Salgado PF at et.[16] Epidural dexmedetomidine prolonged sensory and motor block duration time (p <0.05) and postoperative analgesia (p <0.05), and also resulted in a more intense motor block, l (p <0.05). Postoperative analgesia was prolonged significantly in RD group followed by the patient receiving fentanyl.

Nausea and vomiting was found to be in higher proportion of subjects from Group RF as compared to Group RD but this difference was statistically not significant (p >0.05).

None of the subjects from either of the groups had suffered with respiratory distress i.e. SpO_2 <90%. Hypotension, bradycardia and were found in higher proportion of Group RD subjects as compared to Group RF, but this difference was statistically non-significant. Dexmedetomidine produced significantly profound sedation (sedation score 4, 3 and 2 in 50%, 34% and 16% patients

respectively) as compared to mild sedation in Fentanyl group (sedation score 2 and 3 in 80% and 20% patients respectively).

Sedation score was highly significant with administration of dexmedetomidine.

Conclusions

Addition of dexmedetomedine 1 µg/kg to ropivacaine, as comparison to addition of fentanyl, for epidural anesthesia has early onset of sensory and motor block, prolong duration of motor block and postoperative analgesia, without an increased incidence of side effects. Therefore, it was concluded that dexmedetomidine is better as an adjuvant to ropivacaine than fentanyl for epidural anesthesia because of intense analgesia, better quality of motor block and prolong post op analgesia, along with higher sedation scores and insignificant side effects.

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Original Research Article

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Comparison of Dexmedetomidine and Fentanyl as Adjuvants to Hyperbaric Bupivacaine 0.5% in Gynaecological Surgery.

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Abstract

Background: Regional anesthesia is the preferred technique for most of lower abdominal and lower limb surgeries as it allows the patient to remain awake and minimizes or completely avoids the problem associated with airway management. Hyperbaric bupivacaine 0.5% is extensively used for spinal anesthesia. Fentanyl is a synthetic lipophilic opioid commonly used for postoperative analgesia.

Aim: The aim of the study is to compare the following factors in two groups i.e. Hyperbaric bupivacaine 0.5% and 5 mcg Dexmedetomidine and Hyperbaric bupivacaine 0.5% and 25 mcg Fentanyl when given intrathecally.

Materials and Methods: This randomized controlled trial was designed to evaluate the onset and duration of sensory and motor block as well as operative analgesia and adverse effects of Dexmedetomidine vs Fentanyl given intrathecally with heavy 0.5% Bupivacaine for spinal anesthesia in patients scheduled for Total Abdominal hysterectomy patients receiving 5 mcg of Dexmedetomidine and 25 mcg of Fentanyl with 3 ml of Bupivacaine intrathecally.

Results: The addition of Dexmedetomidine significantly prolonged the duration of sensory and motor block, significantly prolonged the time for demand analgesia and had no effect on the onset of sensory or motor block when compared with fentanyl. The incidence of side effects was limited to the occurrence of Hypotension, Bradycardia, vomiting in the groups that received Dexmedetomidine intrathecally. The incidence of pruritus were more in the groups that received fentanyl intrathecally. The addition of Dexmedetomidine intrathecally had similar effect on sedation when compared to fentanyl.

Keywords: Dexmedetomidine; Hyperbaric bupivacaine; Fentanyl; intrathecally.

Introduction

Regional anesthesia is a safe, effective and economical technique for pain relief with an added advantage of extension of long post-operative analgesia. Lower limb surgeries may be performed under local, regional (spinal or epidural) or general anesthesia, spinal block is still a first choice, because of its rapid onset, high quality of blockade, lack of catheter related infection, less failure rate and also cost effective, but the duration of block and postoperative analgesia is limited.

In recent years, usage of intrathecal adjuvants[1] has gained much popularity with the benefit of prolonging the duration of blockade, better success

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rate, patient satisfaction, decreased resource utilization compared with general anesthesia and faster recovery. Adequate pain management accelerates functional recovery, facilitates rehabilitation and enables the patients to quick return to their normal activity. The quality of the spinal anesthesia has been reported to be improved by the addition of opioids and other drugs [such as vasoconstrictors, clonidine, neostigmine, ketamine and midazolam. Intrathecal dexmedetomidine is associated with prolonged motor and sensory block, hemodynamic stability, and reduced demand for rescue analgesics in 24h as compared to fentanyl.[2] Therefore, the present study performed to compare Fentanyl and Dexmedetomidine in their efficacy as adjuvants to sub arachnoid block.

Material and Methods

Patients who fulfil the inclusion criteria and undergo elective surgery in Sultan Bazar Maternity Hospital, Koti, Hyderabad and Modern Government Maternity Hospital, Petlaburz, Hyderabad.

Inclusion criteria

Patients aged between 30–60 years belonging to ASA class I & II without any co-morbid disease, admitted for elective TAH.

Exclusion criteria

Patients with co-morbid conditions, Allergy to local Anesthetics, Patients belonging to ASA class III, IV and V posted for emergency surgeries. Patients having absolute contraindication for spinal anesthesia like raised intracranial pressure, severe hypovolaemia, bleeding diathesis and local infection.

After approval from the ethical committee of our Hospital, 100 ASA I and II patients scheduled for total abdominal hysterectomy surgeries under spinal anesthesia were chosen for the study. Pre-anesthetic check up was done one day prior to the surgery. Patients were evaluated for any systemic diseases and laboratory investigations recorded. The procedure of SAB was explained to the patients and written consent was obtained. The patients were educated about the use of visual analogue scale.

Preparation of patients included period of overnight fasting. Patients were premedicated with Tab. Rantac 150 mg and Tab. Alprazolam 0.5 mg H.S. Boyles anesthesia machine was checked. Appropriate size endotracheal tubes, working laryngoscope with medium and large size blades, stylet and working suction apparatus were kept ready before the procedure. Emergency drug tray consisting of atropine, adrenaline, mephenteramine, ephedrine, dopamine were kept ready.

Procedure

Patients shifted to OR table, base vitals were recorded. IV access was obtained on the forearm with No 18G IV cannula and all patients were preloaded with 15 ml/Kg, Ringer's Lactate, 15 mins before the surgery. Patients were randomly allocated into groups. Under strict asepsis, using 23 G Quincke spinal needle, lumbar puncture was performed at L3-L4 space.

Group D received 3 ml, 0.5% hyperbaric bupivacaine+5 mcg Dexmedetomidine (0.1 ml)+0.4 ml Normal Saline (Total vol 0.5 ml).

Group F received 3 ml, 0.5% hyperbaricbupivacaine+25 mcg Fentanyl (Total vol 0.5 ml).

Intraoperatively pulse rate, non-invasive blood pressure, electrocardiogram, SpO_2 was recorded, every 2 minutes for the first 10 minutes, every 10 minutes for the next 50 minutes and every 15 minutes till the end of surgery.

Time of onset of T10 sensory block and peak sensory block was noted using pin prick method, time of onset of bromage 3 motor block was noted.

Motor block was assessed with Modified Bromage scale Bromage 0 - the patient is able to move the hip, knee and ankle Bromage 1 - the patient is unable to move the hip but is able to move the knee and ankle Bromage 2 - the patie nt is unable to move the hip and knee but able to move the ankle Bromage 3 - the patient is unable to move the hip, knee and ankle.

Modified Ramsay sedation scale was used for intraoperative sedation 1 = agitated, restless 2 = cooperative, tranquil 3 = responds to verbal commands while sleeping, 4 = brisk response to glabellar tap or loud noise while sleeping 5 = sluggish response to glabellar tap or loud noise while sleeping 6 = no response to glabellar tap or loud noise while sleeping.

Hypotension (>20% fall of baseline blood pressure) was treated with bolus dose of 6 mg Mephentermine i.v. Bradycardia (pulse rate <50 bpm), was treated with 0.6 mg atropine i.v. Incidence of respiratory depression defined as respiratory rate less than 9/min and SpO_2 less than 90% on room air, was noted. Side effects if any were noted. Post operatively regression of the sensory block and the motor blockade to reach modified

Bromage 0 was noted Pain was assessed using "Visual Analogue Scale" advocated by Revill and Robinson in 1976. It is linear scale, consists of 10 cm line anchored at one end Visual analogue scale by a label such as "No pain" and other end by "Worst pain imaginable". Patient simply marks the line to indicate the pain intensity. Supplemental analgesia was given for visual analogue score of more than 6. Time of supplemental analgesia was noted.

Visual analogue scale was used to assess post-operative pain. 0 = no pain, 10 = severe pain.

Statistical Methods: Descriptive statistical 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. 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. Chi-square/Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

A Comparative two group randomized clinical study with 100 patients with 50 patients in Group F (Fentanyl) and 50 patients in Group D (Dexmedetomidine) is undertaken to study the changes in hemodynamics and side effects. Statistical analysis was done by applying Chi-square test, Anova test and students 't' test to analyse the data, p value was determined. P >0.05 is not significant P <0.05 is significant P <0.001 is highly significant.

Results

ASA Grading in both groups: Both groups were similar in respect of ASA grade. [p >0.05] which is not statistically significant.

Table 1: Demographic distribution in present study

Parameters	Group D	Group F	'P' Value
Age [years]			
Mean	50.08	51.64	0.314
S.D	6.26	6.60	
Height [cm]			
Mean	156.1	157.5	0.261
S.D	5.83	6.54	
Weight [kg]			
Mean	58.94	61.72	0.100
S.D	8.82	7.91	

Demographic data: The two groups were comparable with respect to their age, height and weight. There was no statistically significant difference among two groups in demographic aspects.

Shows distribution of pulse rate at various intervals between two groups and p value is statistically significant at 5 min, 10 min, 15 min, 20 min, 30 min, 75 min and 90 min (Fig. 1).

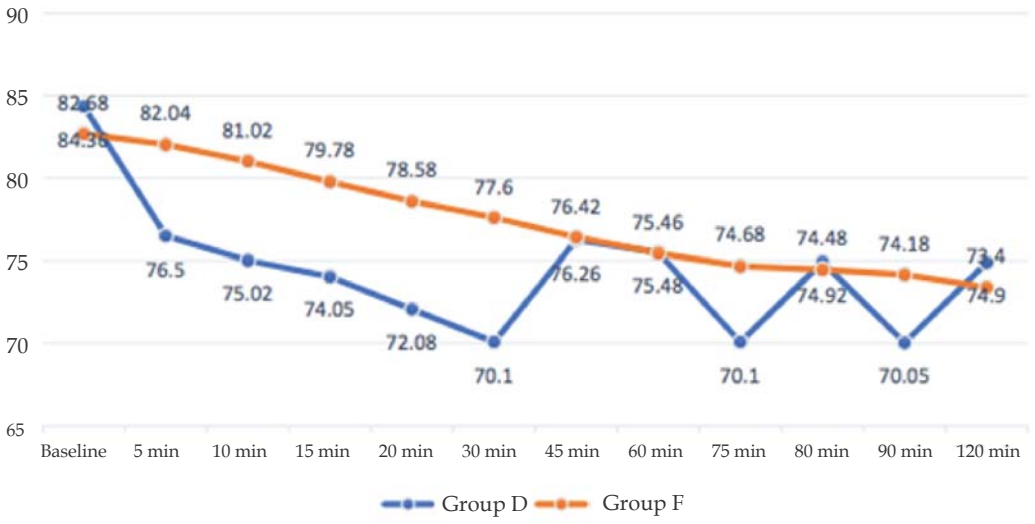

Fig. 1: Comparison of heart rate between two groups at various intervals

Shows the distribution of SBP at various interval between the two groups and p value is statistically significant at 5 min, 10 min, 15 min, 20 min, 45 min and 120 min (Fig. 2).

Shows the distribution of DBP at various interval between the two groups and p value is statistically significant and at 5 min, 10 min, 15 min, 20 min, 30 min, 75 min and 90 (Fig. 3).

Table 2: Sensory and motor block in mins by groups

	Group D	Group F	'P' Value
Onset of sensory block [T10]			
Mean	2.62	2.79	0.146
S.D	0.56	0.59	
Time to reach t6 in mins			
Mean	11.72	11.47	0.314
S.D	1.23	1.23	
Onset to Bromage 3 (min)			
Mean	10.59	10.38	0.31
S.D	1.00	1.08	
Time for 2 segment regression of sensory block from the highest sensory level (min)			
Mean	125.18	89.3	< 0.0001
S.D	4.29	5.44	
Regression of motor blockade to bromage 0 (min) by groups			
Mean	361.79	178.46	<0.0001
S.D	6.95	7.59	

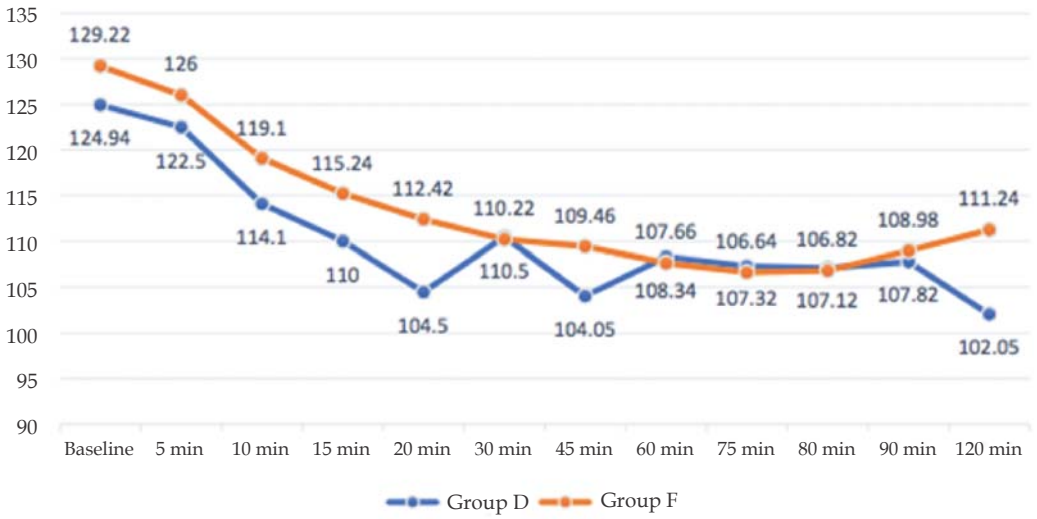

Fig. 2: Comparison of systolic blood pressure between two groups at various intervals.

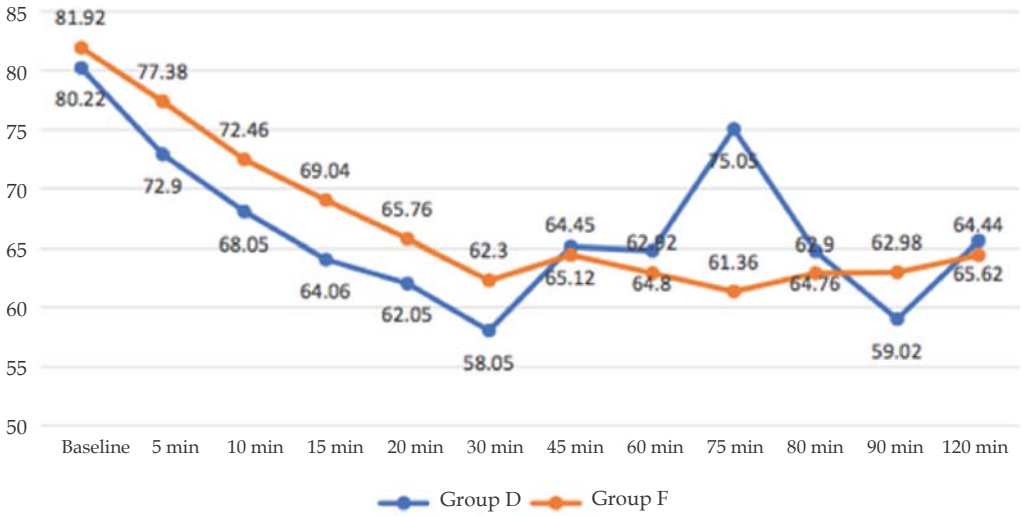

Fig. 3: Comparison of Diastolic blood pressure between two groups at various intervals

Sensory level of T10 was statistically no significant difference among two groups. Peak sensory level of T6 was no statistically significant difference among two groups. Time taken to achieve Bromage 3 from the time of SAB was statistically no significant difference among two groups.

The mean duration of return of motor block to Bromage scale zero [0] was in Group D 361.79±6.95 min and in Group F was 178.46±7.59 min. There was statistically significant difference among two groups in the mean duration of motor block p <0.05.

Table 3: Distribution of duration of analgesia (min) by groups

	Group D	Group F	'P' Value
Duration of analgesia (mins)			
Mean	246.00	165.84	<0.0001
S.D	5.03	2.33	
Time to reach highest sensory level by			
Mean	12.36	12.16	0.455
S.D	1.48	1.16	

The mean time for demand analgesia [defined as the time at which patient demands some mode of pain relief] was 246.00±5.03 min in Group D and was 165.84±2.33 min in Group F. There was statistically significant difference among two groups in the duration of time for demand analgesia p <0.05.

The highest level of sensory block was T4-T6 in both groups. The median of the onset of sensory block was T6 in both groups. T4 was 32% in Group F and 36% in Group D. T6 was 50% in Group F and 54% in Group D which was statistically not significant, p value >0.05.

Table 4: Distribution of cases by groups and side effects

Side Effects	Group D		Group F	
	No	%	No	%
Hypotension	11	22%	7	14%
Bradycardia	5	10%	2	4%
Pruritus	0	0%	3	6%
Vomiting	1	2%	1	2%
Rescue Analgesia	4	8%	6	12%

The incidence of Hypotension in Group D was 22% and in Group F was 14% which was statistically not significant p >0.05.

The incidence of Bradycardia in group D was 10% and in Group F was 4% and there was no statistically significant difference in both groups p >0.05.

The incidence of pruritus in Group D was zero and in Group F was 6%. p <0.05 which was statistically significant.

The incidence of vomiting in Group D was 2% & Group F was 2% which was statistically not significant p = 1.

Table 5: Distribution of cases by sedation score

Ramsay Score	Group	Mean	SD	P-Value
30 min	D	2.0000	0.00000	–
	F	2.0000	0.00000	
60 mins	D	2.0000	0.00000	–
	F	2.0000	0.00000	
90 mins	D	3.4000	0.49487	<0.001
	F	2.1600	0.37033	
120 mins	D	2.0000	0.00000	0.006
	F	2.1400	0.35051	
150 mins	D	2.0000	0.00000	–
	F	2.0000	0.00000	
180 mins	D	2.0000	0.00000	–
	F	2.0000	0.00000	

The incidence of sedation score 2 was 100% in both the groups at the end of 60 min, 150 min and 180 min and was statistically not significant p >0.05.

Table 6: Distribution of cases by VAS

VAS	Group	Mean	SD	P value
6 hr	D	0.0000	0.00000	<0.001
	F	3.5000	0.50508	
12 hr	D	3.5000	0.50508	<0.001
	F	5.9000	0.97416	
18 hr	D	5.5200	0.50467	<0.001
	F	7.2800	0.94847	
24 hr	D	3.6200	0.69664	<0.001
	F	7.2400	0.95959	

There was statistical difference between VAS score of both groups at the end of 6 hr, 12 hr, 18 hr, 24 hr. p value < 0.05

Discussion

Subarachnoid Block is a commonly used Anesthetic technique for lower abdominal surgeries. There has been a growing interest in the use of analgesic additives to spinal local Anesthetics. Alpha-2 agonist like Dexmedetomidine have been shown to prolong the duration of both sensory and motor blockade and to provide extended postoperative analgesia. In this study 5 mcg of Dexmedetomidine was added to 15 mg [3 ml] of 0.5% Hyperbaric Bupivacaine or 25 mcg of fentanyl added to 15mg [3 ml] of 0.5% Hyperbaric Bupivacaine and its efficacy as an adjuvant to subarachnoid Bupivacaine was studied in 100 patients undergoing elective Total Abdominal Hysterectomy.

The mean time to onset of sensory Block (T10 level) was 2.62±0.56 mins in Group D and 2.795 ±0.59 mins in Group F. In our study the addition of 5mcg of Dexmedetomidine to Hyperbaric Bupivacaine did not shorten the onset of sensory block [T10 level] when compared to the addition of 25 mcg of fentanyl to Hyperbaric Bupivacaine. The onset of sensory block [T10 level] was similar in both groups.

This correlated with the study Gupta et al.[3]who compared the effect of 5 mcg Dexmedetomidine and fentanyl 25 mcg on the onset and duration of sensory and motor block when added to 12.5 mg of Bupivacaine for lower abdominal surgeries and found no statistically significant difference between the two groups. Subhi M Al-Ghanem et al.[4] who compared the effect of 5 mcg Dexmedetomidine Vs fentanyl 25 mcg in intra operative analgesia and the duration of sensory & motor block when added to 10mg intrathecal plain Bupivacaine and observed that there is no statistically significant difference between the two groups as regards to the onset time of sensory block at T10 level.

Ibrahim F.A. Khalifa et al.[5]did a comparative study of adding intrathecal 5 mcg Dexmedetomidine and 5 mcg of sufentanil to 10 mg of heavy Bupivacaine found that there is no statistically significant difference in the onset of sensory block T10 level Group D = 5.5±3.7, where Group 57 = 6.2±1.3 p <0.69.

The median of the upper limit block was T6 in Group D and Group F. There was no statistically significant difference among the two groups in the maximum level of sensory Block. The addition of Dexmedetomidine to hyperbaric Bupivacaine did not increase the speed of sensory level when compared with 25 mcg of fentanyl to hyperbaric Bupivacaine.

Kanazi et al.[6] found that there is statistically no significant difference for the maximal sensory Block for 12 mg Bupivacaine 0.5% alone or combined 3 mcg of Dexmedetomidine or 30 mcg of clonidine [p = 0.3]. Mahmoud M. Al Mustafa et al.[4] found that addition of intrathecal Dexmedetomidine in increasing doses 5 mcg, 10 mcg of Dexmedetomidine with 12.5 mg of Spinal Bupivacaine increased the level of sensory block as the dose of Dexmedetomidine increases. Ibrahim F.A. Khalifa et al.[7]found that there is statistically no significant difference for the maximal sensory block when compared with 5 mcg of Dexmedetomidine and 5 mcg of sufentanil to 10 mg of heavy Bupivacaine.

The mean time to reach T6 level was 11.72±1.23 mins in Group D and 11.47±1.23 min in Group F. There is no statistically significant difference among the two groups. Subhi M. Al Ghanem et al.[8] who found that addition of 5 mcg of Dexmedetomidine and 25 mcg of fentanyl with 10 mg of isobaric Bupivacaine intrathecally had significant difference on the mean time to reach peak sensory level 19.34±2.87 in Group D and 18.39±2.46 in Group F (p = 0.12). Gupta et al.[2] also found that there was no difference between groups F and D in the time to reach peak sensory level of T6.

The mean time to achieve Bromage 3 score was 10.59±1.00 min in Group D and 10.38±1.08 min in Group F. The addition of 25 mcg fentanyl or 5 mcg Dexmedetomidine to 15 mg of Bupivacaine have no effect on the onset of motor block. Gupta et al.[3] who found that that there was no difference in the onset time to bromage 3 motor block. 11.2±1.3 in Group F and 11.6±1.8 in Group D. Ibrahim F. A. Khalifa et al.[7] found that there is statistically no significant difference with 5 mcg of Dexmedetomidine and 5 mcg of sufentanil to 10 mg of heavy Bupivacaine on the mean time to achieve bromage 3 score.

In our study the duration of analgesia was 246.00 ±5.03 min in Group D and 165.84±2.33 min in Group F. The addition of 5 mcg of Dexmedetomidine to Hyperbaric Bupivacaine significantly prolonged the duration of sensory block. Gupta et al.[3], who found that duration of analgesia was significantly longer in Group D as compared to Group F. Khan et al.[9], found a significant difference between two groups with respect to duration of sensory block. Group F 77.50 and Group D 129.50 Subhi M. Al-Ghanem et al.[8], found that the addition of 5 mcg of Dexmedetomidine to 10mg of isobaric Bupivacaine 274.83±73.4 significantly prolong the duration of sensory blockade while 25 mcg of fentanyl to 10 mg of isobaric Bupivacaine was 179.5±47.4. There was statistically significant difference among the two groups p <0.001. Kanazi et al.[6], found that the addition of 3 mcg of Dexmedetomidine to 12 mg of intrathecal Bupivacaine or 30 mcg of clonidine significantly prolonged the sensory block. Al Mustafa MM et al.[10] studied that there is a significant difference in the duration of sensory block among three groups who received spinal Bupivacaine 12.5 mg alone or combined with 5 mcg of Dexmedetomidine or with 10mcg of Dexmedetomidine. He concluded that Dexmedetomidine has a dose dependent effect on the onset and regression of sensory and motor block when used in Subarachnoid Block.

In our study the mean duration of motor block was 361.79±6.95 min in Group D and 178.46±7.59 min in Group F. Gupta et al.[3] found the regression of motor block to Bromage 0 was significantly slower with addition of Dexmedetomidine i.e. 149.3±18.2 in Group F and 421±21.0 in Group D.

Khan et al.[9] found that regression of motor block to Bromage 1 was significantly prolonged with Dexmedetomidine i.e. 187.0±6.87 in Group F and 377.25±11.32 in Group D.

Subhi M. Al-Ghanem et al.[8] found in their study that 5 mcg of Dexmedetomidine to 0.5% hyperbaric Bupivacaine prolonged effect of motor blockade that 25 mcg of fentanyl to 0.5% hyperbaric Bupivacaine intrathecally.

Kanazi et al.[8] observed that addition of 12 mg of Bupivacaine supplemented with dexmedetomidine and 12 mg of Bupivacaine with 30 mcg of clonidine intrathecally produces similar prolongation in the duration of motor block when compared 12 mg of Bupivacaine alone. [The prolongation of motor block produced by subarachnoid Hyperbaric Bupivacaine combined with 5 mcg of Dexmedetomidine results from binding these agonist to motor neurons in the dorsal horn of the spinal cord].

Mahmoud M. Al Mustafa et al.[10] found that Dexmedetomidine has a dose dependent effect on the duration of motor blockade when added to Bupivacaine. Ibrahim F.A Khalifa et al.[40] found that the addition of 5 mcg of Dexmedetomidine to 2 ml of heavy Bupivacaine and 5 mcg of sufentanil to 2 ml of heavy bupivacaine produces a significant difference in the duration of motor blockade.

In our study the mean Time to two segment regression was 125.18±4.29 in Group D and 89.3±5.44 min in Group F. The addition of 5 mcg of Dexmedetomidine to 0.5% Bupivacaine significantly prolonged the time to two segment regression. Gupta et al.[3] found that time to two segment regression was significantly slower with addition of intrathecal Dexmedetomidine as compared with Fentanyl i.e. 76±20.3 min in Group F and 120±22.2 min in Group D. Khan et al.[9] found that time to two segment regression was significantly slower in Group D as compared to Group F i.e. 77.50±7.42 in Group F and 129.50±9.07 in Group D.

In our study HR, SBP and DBP at all the above intervals were lower in group D than Group F. Difference of HR was statistically significant at all the above intervals except at before dural puncture, 45 min, 80 min, and 120 min after dural puncture. Difference of SBP was statistically significant at all the above intervals except at baseline, 30 min, 75 min, 80 min and 90 min after dural puncture. DBP did not show a statistically significant difference at baseline and 45 min, 80 min, 120 min after dural puncture. Khan et al.[9] who found that Heart rate to be lower in Group D than Group F except at before dural puncture, 35 min, 40 min, 120 min after dural puncture. SBP lower in Group D than Group F except at baseline, just after dural puncture and 5 min after dural puncture. DBP was lower in Group D than Group F except baseline, after dural puncture, 5 min, and 70 min after dural puncture.

In our study the incidence of Hypotension was 22% in Group D and 14% in Group F. Hypotension was mild to moderate in both groups which was not statistically significant ($p > 0.05$). Gupta et al.[3], found that Hypotension was more in Group D than Group F. But it was not statistically significant. Khan et al.[9] found that incidence of Hypotension was more in Group D than Group F. But this was not statistically significant. Kanazi et al.[6] studied that the addition of Dexmedetomidine or clonidine to Bupivacaine did not cause a significant decrease in the Blood pressure intraoperatively or postoperatively. Intrathecal local Anesthetics block the sympathetic outflow and reduce the blood pressure. The sympathetic block is usually near-maximal with the doses used for spinal anesthesia. The addition of a low dose of α2 agonist to a high dose of local Anesthetics does not further affect the near maximal sympatholysis.

Ibrahim FA Khalifa et al.[7] found that the addition of 5 mcg of Dexmedetomidine to spinal Bupivacaine and 5 mcg of sufentanil to spinal Bupivacaine did not produce a significant difference in the incidence of hypotension. Subhi M. Al-Ghanem et al.[8] found that hypotension was more in fentanyl group than in the Dexmedetomidine group but it did not reach a significant difference. Meanwhile, hypotension occurred 25-30 minutes after spinal injection in 2 patients in the Dexmedetomidine group and one patient in fentanyl group had mild episodes of Hypotension in PACU.

The incidence of bradycardia was 4% in Group F and 10% in Group D [$p < 0.301$]. There is no statistically significant difference among two groups. Khan et al.[9] found that bradycardia was higher in Dexmedetomidine group as compared to fentanyl group, yet the difference was not statistically significant. Ibrahim F.A. Khalifa et al.[40] found that there is statistically no significantly difference in the incidence of Bradycardia in both the groups with 5 mcg of sufentanil to 10 mg of 0.5% Bupivacaine and 5 mcg of Dexmedetomidine

to 10 mg of 0.5% Bupivacaine. Subhi M Al-Ghanem et al.[8] found that there is statistically no significant difference in the incidence of Bradycardia among two groups of 5 mcg of Dexmedetomidine to 10 mg of isobaric Bupivacaine and 25 mcg of fentanyl to 10mg of isobaric Bupivacaine intrathecally.

The incidence of pruritus was 0% in Group D and 6% in Group F. There is statistically significant difference among two groups. Ibrahim F.A. Khalifa et al.[7] found that there is significant difference in the incidence of pruritus in the sufentanil group. Subhi M. Al. Ghanem et al.[8] found that there is statistically significant difference in the incidence of pruritus. Pruritus after intrathecal fentanyl is reported to be 40-70% but if was only 13% in present study which can be explained by the fact that pruritus is a benign subjective symptom which is under reporting and usually needs to treatment. Bogra J. Srivastava P et al.[5] found there is statistically significant difference in the incidence of pruritus with 10 mg of fentanyl, 12.5 mg of fentanyl, added to hyperbaric Bupivacaine.

The incidence of vomiting was not statistically significant in both the groups. This correlated with the study Kanazi et al.[6] found that intrathecally administrated α2 agonist have a dose-dependent sedative effect. The doses of clonidine and dexmedetomidine selected in their study were at the lower end of the dosing spectrum. This explains the lack of sedative effects between the study groups B and C and the intraoperative anxiety one patient in Group D.

Conclusion

Intrathecal Dexmedetomidine supplementation of spinal block seems to be a good alternative to intrathecal Fentanyl since it produces prolonged sensory block and motor block. It is evident that this type of block may be more suitable for lower abdomen and lower extremities surgeries.

A drawback of Dexmedetomidine supplemented spinal block characteristics is the increase in the duration of motor block which may not suit short term surgical procedures or ambulatory surgery.

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Original Research Article

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Evaluation of Effectivenss of Intrathecal Bupivacaine with Adjuant Fentanyl and Clonidine in Patient Undergoing Lower Segment Caesarean Section: A Randomised Control Trial

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Abstract

Background and Objectives: Intrathecal opioids potentiate the analgesic property of local anesthetics. Among an alpha2 adrenergic agonist, Clonidine potentiates the effect of local anesthetics and allows decrease in required doses. Hence, this study was conducted to evaluate effectiveness of intrathecal bupivacaine with adjuvant fentanyl and clonidine in patient undergoing lower segment caesarean section.

Material and Method: 100 participants, aged 18 to 35 years, of ASA Physical status I and II, scheduled for lower segment caesarean section under subarachnoid block, were randomly divided into two groups (n=50 each); Group C (n=50) was given intrathecal inj. Bupivacaine 0.5% heavy 1.7 ml (8.5 mg)+ inj. Clonidine 0.2 ml (30 mcg)+inj. Normal saline 0.3 ml Total volume 2.2 ml and Group F (n=50) was given intrathecal inj. Bupivacaine 0.5% heavy 1.7 ml (8.5 mg) + inj. Fentanyl 0.5 ml (25 mcg) Total volume 2.2 ml. Degree of sensory and motor block, quality of intraoperative anesthesia, postoperative analgesia (VAS score), time of 1st rescue analgesia effective analgesia, hemodynamic variables and side effects were evaluated and compared. At VAS ≥4, rescue analgesic Inj. Diclofenac Sodium I.V. was given.

Results: The result of the present study shows that in group F there was significant reduction in the time for onset (1.20+0.36 min), peak of sensory blockade (1.99±0.59 min) and significant prolongation in the total duration of sensory blockade (240.40±53.45 min) extending into the postoperative period as compared to group C (2.02±0.45, 2.79±0.45 and 163±22.79 min respectively with p <0.0001, hence provided effective postoperative analgesia up to 12 hours. Complete analgesia lasted longer in group F for 11.46±1.9 hrs compared with group C for 10.96±1.9 min (p 0.19). The duration of effective analgesia was significantly prolonged in group F (14.78±2.03 min) as compared with group C (13.17±1.31 min), (p<0.0001)

Conclusion: In conclusion, addition of 25 µg Fentanyl as an adjuvant with 0.5% hyperbaric Bupivacaine, in subarachnoid block for lower segment caesarean section, has faster onset and prolongs sensory block and motor blockade; also improves postoperative analgesia with minimal side effects as compared to 30 µg clonidine.

Keywords: Subarachnoid Block; Fentanyl; Clonidine; hyperbaric Bupivacaine; Lower segment caesarean section.

Introduction

Alleviation of postsurgical pain is one of most fundamental goal in anesthesiology. Postoperative pain relief is not only desirable but also important for reduction of postoperative morbidity. Postoperative pain, apart from patients suffering, has many other adverse consequences like respiratory depression, circulatory disturbances and metabolic stress

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response.[1] Postoperative pain relief helps in early patient mobilization, reduction of respiratory complications, good patient's outcome, reduced morbidity and improved patient's satisfaction. And hence, its alleviation should be prime objective in anesthesia practice. Subarachnoid block being most versatile and commonly used regional block worldwide today, was introduced in 1885 by Leonard corning.[2] Most commonly used anesthetic technique for lower segment caesarian section.[2] Carl Koller's discovery of local anesthetic effects of cocaine in the 19th century heralded the birth of a new era in the field of Anesthesia. The first case of spinal Anesthesia using cocaine for surgical operation was performed by August Bier in 1898.3 In 1973, Pert and Snyder 4 identified the opiate receptors in CNS including spinal cord. Since the discovery of opioid receptors and the increase in spinal cord neuropharmacological knowledge as to transmission inhibition of nociceptive stimulation, there has been an increased interest in spinal drugs for Anesthesiology and pain relief. Advantage of simplicity of technique, rapid onset of action, reliability in producing uniform sensory and motor blockade, preservation of consciousness, thereby preventing the risk of aspiration, good postoperative analgesia, with minimal drug cost and side effects has made this method a viable alternative to general anesthesia for a variety of surgical procedure. Its main disadvantage related to its limited duration of action hence, lack of long lasting postoperative analgesia. To overcome this problem, administration of local anesthetics in combination with different adjuvants is an excellent technique which not only relieves postoperative pain but also refines the quality of sensory and motor blockade of subarachnoid block and hence, acts as synergistic to local anesthetics with lower local anesthetic requirement, decreased side effect and excellent postoperative analgesia. Growing interest in caesarean anesthesia, particularly in subarachnoid space, in the use of bupivacaine with adjuvant drugs in order to improve the quality of blockage and extend the duration of analgesia.[5] In addition, the use of adjuvants reduces the dose of bupivacaine with a lower incidence of side effects[5] and improves the quality of sensory and motor block and increased the duration of post-operative analgesia. The quality of the spinal anesthesia has been reported to be improved by the addition of opioids (such as morphine, fentanyl and sufentanil) and other drugs (such as dexmedetomidine, clonidine, magnesium sulfate (Mg), neostigmine, ketamine, and midazolam).[6,7] Among an alpha2 adrenergic agonist, Clonidine potentiates the effect of local anesthetics and allows decrease in required doses.[8] Clonidine is partial alpha2 adrenergic agonist used intrathecally with well-established efficacy and safety profile with effective prolongation of both motor and sensory blockade.[9,10] Fentanyl is a synthetic lipophilic opioid with a rapid onset of action and unlike morphine, has fewer tendencies to migrate rostrally to the fourth ventricle in sufficient concentration to cause delayed respiratory depression.[11-13] When administered with bupivacaine in subarachnoid block, fentanyl by virtue of its lipophilic property like rapid onset of action and recovery, prolonged duration, reduces the need for supplements during surgery and also prolongs the postoperative analgesia.[14,15] And there are limited studies available for comparison of adjuvant with subarachnoid bupivacaine in lower segment caesarean section, which prompted us to evaluate the safety and efficacy of fentanyl and clonidine as an adjuvant to bupivacaine in patients undergoing lower segment caesarean section.

Methodology

After approval from the Institutional Review Board [(IRB No.789/2018) & (CTRI registration no. CTRI/2019/01/023468)] and informed written consent from patients, this prospective, randomized, double blind controlled study was carried out in the Govt. Medical College and Sir. T. Hospital, Bhavnagar, Gujarat. 100 patient, aged 18-35 years of ASA physical status I and II scheduled for lower segment caesarean section surgery were enrolled in this study. All the patient were subjected to detailed pre-anesthetic evaluation with clinical history and systemic examination, routine investigations like haemogram, random blood sugar, renal profile were done as per patient clinical evaluation.

Inclusion Criteria

- Age of patient- 18 to 35 years
- Gender – female
- ASA Grade I or II
- Patient undergo lower segment caesarean section.

Exclusion Criteria

- Patient refusal
- Any contraindications to spinal Anesthesia.
- Patient suffering from any valvular heart disease.
- Allergy to local anesthetic or study drug.

- Neurological disorders
- History of bleeding disorder.
- Patient on anti-coagulant therapy

In the pre anesthetic preparation room, monitoring consisting of heart rate, non-invasive blood pressure, and peripheral oxygen saturation was established and baseline vital parameters were recorded. Each patient was inform in detail regarding nature and purpose of the study and was explained 0-10 point visual analogue scale (VAS) on sheet of paper where (0) labelled as (no pain) and (10) as (worst possible pain).

Sampling Method

Patients were randomly allocated to one of the two groups of 50 patient each by computer generated randomization. One member of the team opened the envelope and filled up the drug as per the group assigned.

- Group F (n=50) was given intrathecal inj. Bupivacaine 1.7 ml (8.5 mg) + inj. Fentanyl 0.5 ml (25 mcg)= Total volume 2.2 ml
- Group C (n=50) was given intrathecal inj. Bupivacaine 1.7 ml (8.5 mg)+ inj. Clonidine 0.2 ml (30 mcg)+inj. Normal saline 0.3 ml=Total volume 2.2 ml

Each participant was informed in detail regarding the nature, purpose of the study and explained 0-10 point Visual Analog Scale (VAS) on paper sheet where zero end marked as 'no pain' while the other end marked as 'worst possible pain'. Written informed consent was obtained after explaining the procedure to the participant. Participants with inadequate sensory and motor block, who required supplementation were excluded from the study. In pre-anesthesia preparation room,

- ➢ Baseline vital parameters [heart rate, blood pressure (systolic and diastolic), respiratory rate and oxygen saturation] were recorded.
- ➢ Intravenous access was secured using 18G venous catheter and the participants were premeditated with Inj. Ondansetron 0.08 mg/kg intravenously 15 minutes prior to procedure.
- ➢ Then the participants were shifted to Operation Theatre in the operation theater, Preloading was done with Inj. Ringer Lactate 10 ml/kg.
- ➢ All equipment's and drugs necessary for resuscitation and general Anesthesia were kept ready
- ➢ Under all aseptic and antiseptic precautions, with the participant placed in left lateral position, subarachnoid block was performed with 25G spinal needle in L3-L4 intervertebral space with midline approach and the drug was injected after obtaining free and clear flow of CSF, as per the group assigned
- ➢ Principle investigator who performed the sub arachnoid block and injected the solution in the sub arachnoid space was unaware of the content of the solution injected in the subarachnoid space. All participants were given supplemental oxygen by nasal prong at the flow rate of 3L/min.
- ➢ Immediately after the block, participant was turned supine. The time of injection was noted as time "0" and participants were assessed for sensory and motor characteristics of blockade as per the grading shown in the tables (Table A) at every 30 seconds interval till peak effect was achieved.
- ➢ The primary outcomes of this randomized, double-blind clinical trial will be evaluate the time to requirement of first rescue analgesia.
- ➢ The secondary outcomes included the assessment of sensory block onset time, onset of motor block, duration of blockade, hemodynamic variables, the incidence of hypotension, ephedrine requirements, bradycardia, hypoxemia (saturation of peripheral oxygen (SpO_2) < 90), and adverse events such as dizziness, and postoperative nausea and vomiting.
- ➢ Intra operatively, Pulse rate, respiratory rate, blood pressure and oxygen saturation monitoring was done at 2,5,10 minuts, 15 minuts, 20 minuts, 30 minutes thereafter throughout the surgery and postoperative 4 hours and 8 hours
- ➢ Any supplementation required for inadequate block or side effects like hemodynamic disturbances, nausea, vomiting, shivering, pruritus and respiratory depression were recorded and managed as mentioned below.
- ➢ Bradycardia – defined as fall in pulse rate below 60 bpm and treated with bolus inj. Atropine (0.02 mg/kg) intravenously.
- ➢ Hypotension – defined as decrease in systolic or diastolic blood pressure more than 30% of baseline value and treated with IV crystalloids (200 mL bolus) or inj. Mephentermine 5 mg IV as needed.

- Nausea and vomiting- Treated with Inj. Ondansetron 4 mg IV
- After the completion of surgery, participants were shifted to Post Anesthesia Care Unit and sensory and motor block were assessed at 30 minutes interval till regression of sensory and motor blockade. Thereafter participants were monitored at 4 hourly intervals for next 24 hours for complications and adverse events if any
- Time of analgesia request was noted in post-operative period. At the time of analgesia request, the participants were asked to point out the intensity of pain on 'Visual Analog Scale' (VAS) explained to the participant preoperatively. Rescue analgesia- Inj. Diclofenac Sodium (1.5 mg/kg) intravenous was given at VAS ≥ 4.
- The duration of complete analgesia - time from subarachnoid injection to first reports of pain (pain score greater than 0) and effective analgesia - time from subarachnoid injection to first dose of rescue analgesic were recorded.

Table B: Modified Bromage Scale for Motor Block Evaluation

- The pain was scored as:

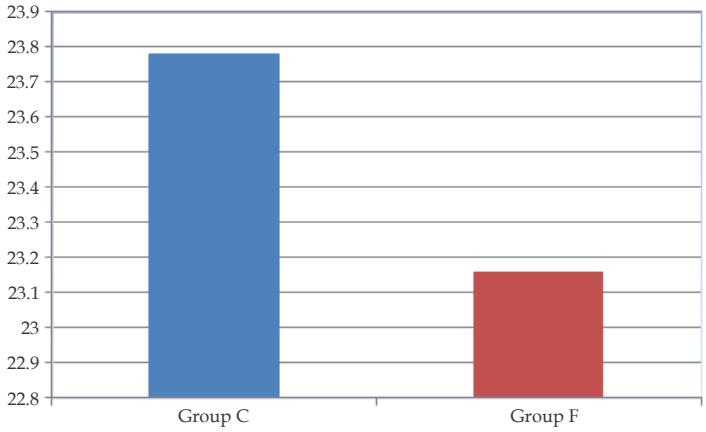
Grade 0	The patient is able to move the hip, knee and ankle
Grade 1	The patient is unable to move the hip, but is able to move the knee and ankle
Grade 2	The patient is unable to move the hip and knee but is able to move the ankle.
Grade 4	The patient is unable to move the hip, knee and ankle.

Observation and Results

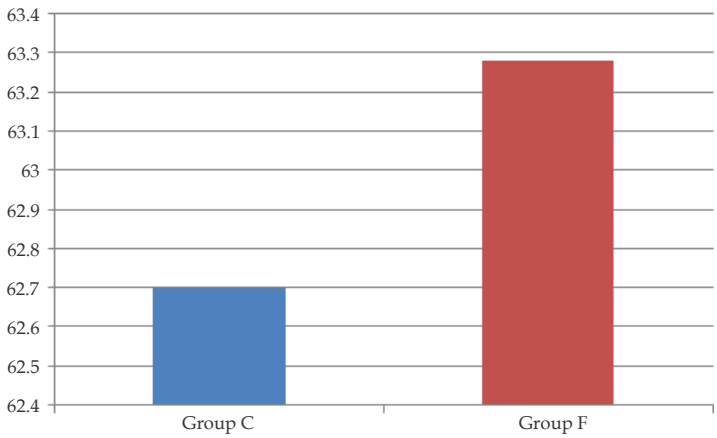
Demographic data

	Group C Mean±2SD (n=50)	Group F Mean±2SD (n=50)	P Value
Age (year)	23.78±2.61	23.16±2.77	0.25
Weight (kg)	62.7±3.66	63.28±4.34	0.47
Height (cm)	158.1±3.53	158.04±4.07	0.93

Demographic data in turns of age, sex, weight, height were comparable among both the groups.



Bar Diagram 1A: Distribution of participants with respect to age.



Bar Diagram 1B: Distribution of participants with respect toweight.

Sensory blockage

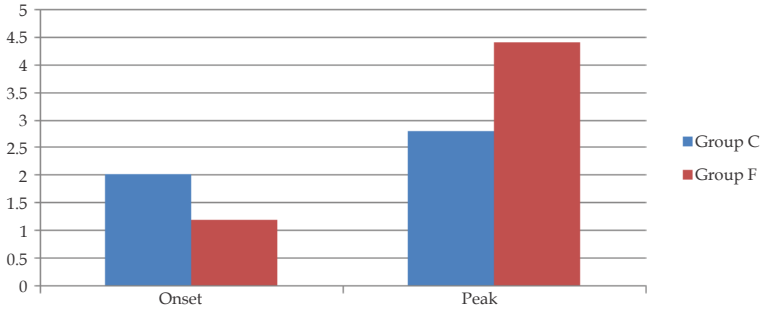
	Group C Mean±2SD	Group F Mean±2SD	P value
Onset (minutes)	2.02±0.45	1.20±0.36	<0.0001
Peak (minutes)	2.79±0.45	1.99±0.59	<0.0001
Duration (minutes)	163±22.79	240.40±53.45	<0.0001

The mean onset of sensory block in group C was 2.02±0.45 minutes and in group F was 1.20±0.36 minutes. There is statistically significant difference in mean time of onset and peak of sensory block in both the group. There was early onset and peak achieved in group F as Compared to group C. Duration of sensory block was prolonged in group F as compared to group C difference was statistically significant.

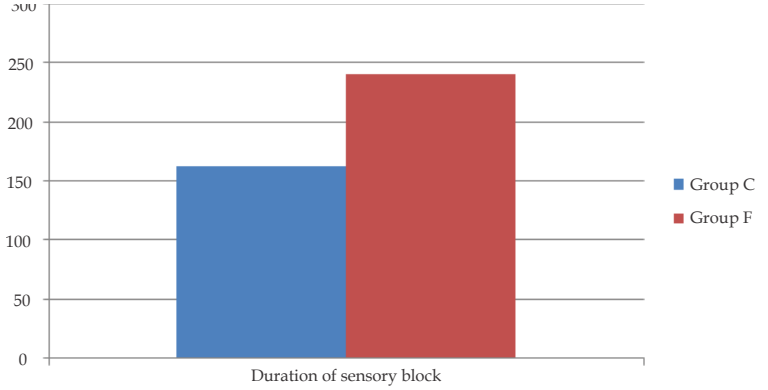
Motor block

	Group C Mean±2SD	Group F Mean±2SD	P value
Onset (minutes)	2.20±0.47	1.43±0.40	<0.0001
Peak (minutes)	2.87±0.61	2.22±0.62	<0.0001
Duration (minutes)	144.6±21.20	223±53.93	<0.0001

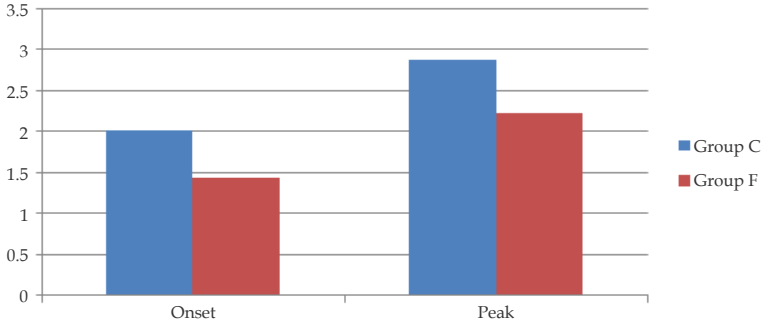
There were statistically significant difference in mean time of onset peak and duration of motor block in both the groups. There was faster onset and peak of motor block in group F as compared to group C. duration of motor block were longer significantly in group F as compared to group C.



Bar Diagram 2A: Onset and peak of sensory block



Bar Diagram 2B: Duration of sensory block



Bar Diagram 3A: Onset and peak of motor block

Heart rate

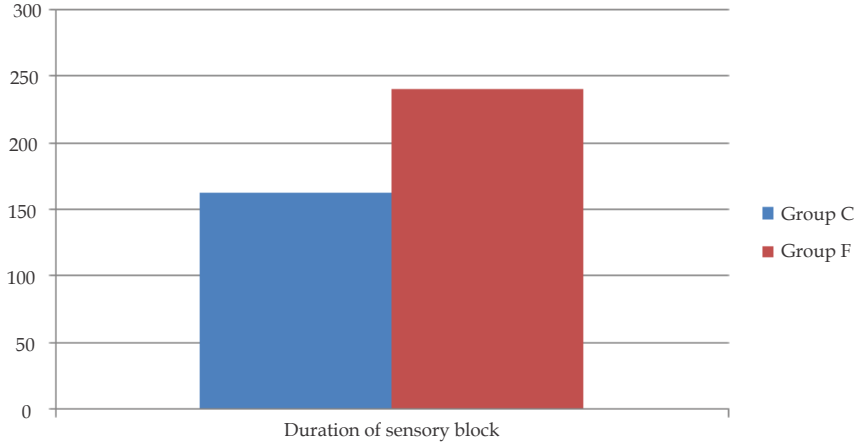
	Group C Mean±2SD	Group F Mean±2SD	P value
Base line	88.3±7.48	89.64±8.51	0.40
Before block	89.56±8.43	88.3±7.43	0.43
After block	87.66±9.78	91.32±10.34	0.07
1 min	91.32±10.34	89.8±10.71	0.47
3 min	88.14±10.8	85.52±10.8	0.91
5 min	88.14±10.8	85.52±10.8	0.23
10 min	87.2±11.08	83.6±10.07	0.08
15 min	86.1±10.84	82.3±10.11	0.07
20 min	86.1±10.22	80.54±9.9	0.006
30 min	86.6±10.62	78.36±9.6	<0.0001
45 min	86.54±10.62	78.36±9.6	<0.0001

There were statistically significant difference in fall in heart rate in group C as compared to group F. At 30 minutes and 45 minutes significant fall in heart rate in group C. Which was corrected by injection atropine 0.6 mg

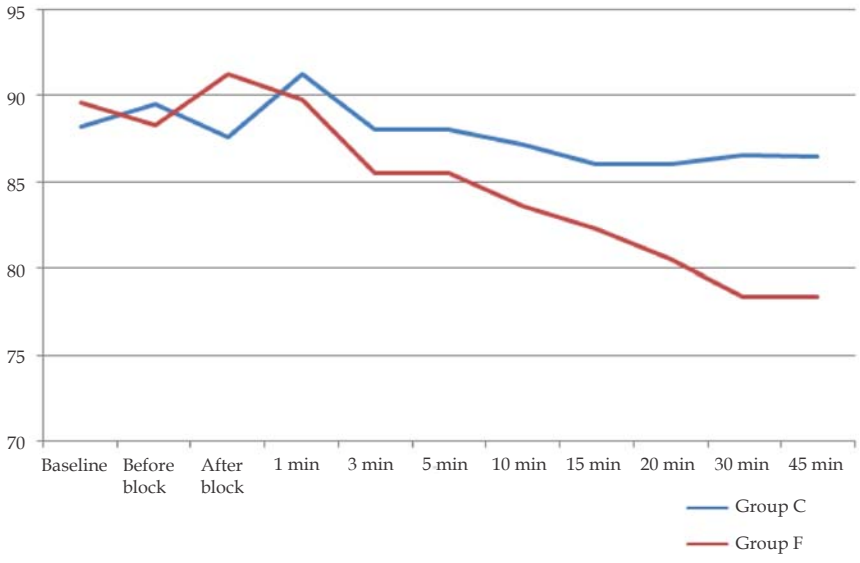
Arterial Blood Pressure

	Group C Mean±2SD	Group F Mean±2SD	P value
Base line	88.87±6.1	90.78±6.9	0.54
Before block	87.40±7.5	89.7±5.9	0.81
After block	85.30±6.2	87±5.3	0.51
1 min	84.20±5.53	85.95±5.4	0.72
3 min	82.40±4.8	84.82±5.05	0.20
5 min	74.67±12.85	81.5±7.3	<0.0001
10 min	89.06±10.5	76.68±12.5	<0.0001
15 min	75.38±10.70	77.54±7.67	0.0002
20 min	74.81±11.42	76.64±9.78	0.0077
30 min	73.24±11.37	76.46±10.32	0.0145
45 min	74.22±11.50	77.06±8.2	0.0001

There were statistically significant difference in fall in mean arterial blood pressure at 5, 10 and 15, 45 min after subarachnoid block in group C as compared to group F. Which was corrected by injection Mephentermine 5 mg i.v.



Bar Diagram 3B: Duration of motor block

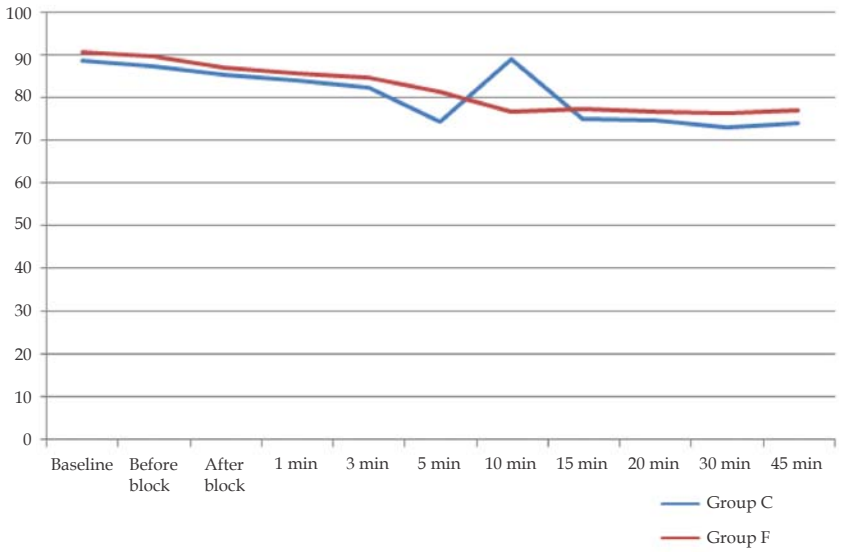


Bar Diagram 4: Heart rate

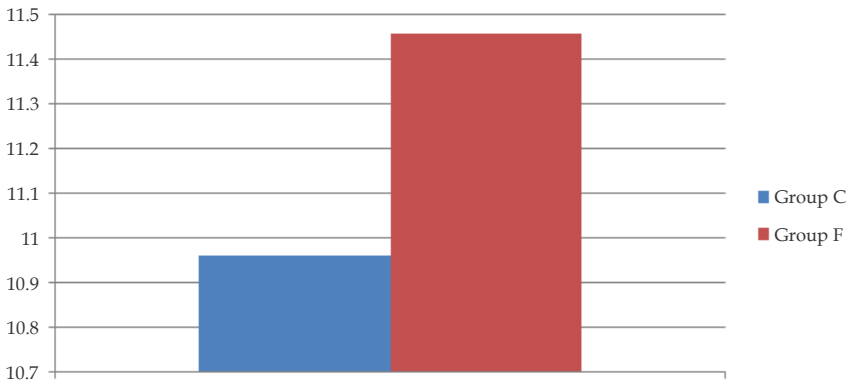
Duration of post-operative analgesia

	Group C Mean±2SD	Group F Mean±2SD	P value
Duration of Postoperative Analgesia	10.96±1.9	11.46±1.9	0.19

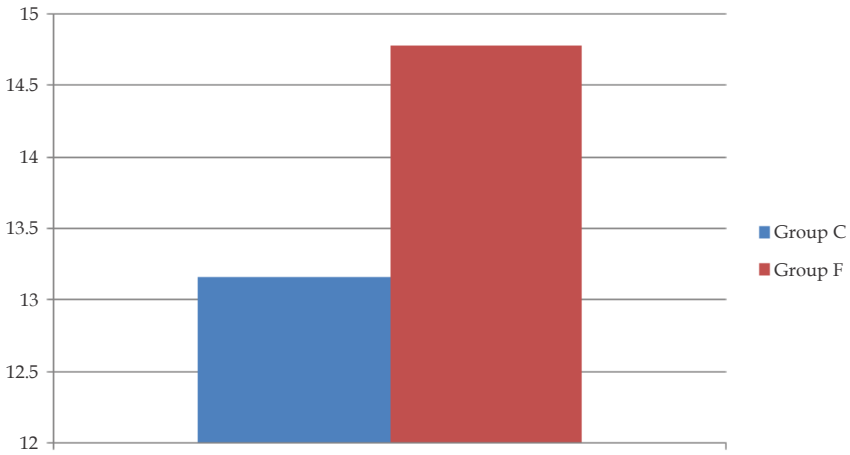
There is no statistically significant difference in duration of post-operative analgesia in both group. Duration of post-operative analgesia is prolong in group F as compare to group C but p value 0.19 is statistically insignificant.



Bar Diagram 5: Mean Arterial Blood Pressure



Bar Diagram 6: Duration of postoperative analgesia



Bar Diagram 7: Rescue Analgesia

Rescue Analgesia

	Group C Mean±2SD	Group F Mean±2SD	P value
Rescue Analgesia	13.17±1.31	14.78±2.03	0.0018

There was significant prolong postoperative analgesia in group F as compared to group C.

1st rescue analgesic requirement

Post Op Duration	Group C	Group F
10 Hours	01	03
12 Hours	21	03
14 Hours	25	21
16 Hours	03	15
18 Hours	00	06
20 Hours	00	01
24 Hours	00	00

Postoperative analgesic requirement in fentanyl group maximum around 18 hours in 6 patient. Postoperative analgesic requirement in clonidine group maximum around 14 hours in 25 patients.

Discussion

Both fentanyl and clonidine if used in low doses are safe and prolongs postoperative analgesia of intrathecal bupivacaine. Thorough literature search revealed paucity of studies directly comparing these two drugs for their efficacy and safety. Present study was designed to directly compare these two drugs. To compare the efficacy we used the duration of effective analgesia measured by time in hours for requirement of rescue analgesia. In consistency to results of several other studies.[53-58] We found both drugs to be effective as adjuvants to intrathecal bupivacaine prolonging the duration of analgesia.

Fentanyl citrate, a synthetic amine opioid from the class of pure μ opioid receptor agonist, is structurally related to the phenylpiperidine nucleus and 100 times more potent than morphine[59] as an analgesic in equivalent doses. Fentanyl is a very important drug in anesthetic practice because of its relatively shorter time to peak analgesic effect,[60] rapid termination of effect after small bolus doses, minimal direct depressant effects on the myocardium, and their ability to significantly reduce the dosing requirement for the volatile action.

Fentanyl was first introduced for widespread palliative use with the clinical introduction of the Duragesic patch in clinical practice in mid 1960s. Availability of fentanyl in a wide range of preparations like, intravenous, buccal tablets or patches, nasal sprays, inhalers, and active transdermal patches made it a recreational drug. Nowadays it is popularly used as an I.V. analgesic supplement, component of inhalational Anesthesia, balanced Anesthesia, neuroleptic analgesia and also a sole anesthetic in intensive care unit and in the management of severe pain states.

Morphine is a forerunner as an opioid adjuvant added to local anesthetic for spinal Anesthesia and causes delayed respiratory depression (>2 hours after administration) which is to some extent dose-related[61] and believed to be a result of the cephalad spread of opioids to the medulla within the cerebrospinal fluid (CSF), seen more commonly with hydrophilic opioids. Hence, the lipophilic drugs like fentanyl, sufentanil, remifentanil, alfentanil, methadone are more logical choice.

The safety of fentanyl regarding neurotoxicity has been demonstrated in animal studies and it has been proved safest among all opioids.[62,63] Yaksh et al.[64] in 1988, found that intrathecal administration of opioids can produce profound segmental analgesia without causing significant alteration of motor or sensory function or subjective effects.

Epidural use of fentanyl citrate for postoperative pain or labor analgesia has significant popularity. A combination of intrathecal opioids with local anesthetics permits reduction in the dosage of both components, minimizing the side effects of the local anesthetic (motor blockade) and the opioid (i.e. urinary retention, itching and delayed respiratory depression in the case of morphine). An important caveat to their spinal use is that, because of their rapid clearance, these agents at analgesic spinal doses can produce blood levels that are similar to those producing effects after systemic administration.[65,66]

The synergistic effect of opioid combined with local anesthetic can be explained by virtue of their different mechanism of action. Intrathecal opioids inhibit nociceptive afferent synaptic transmission via Aδ and C fibers by opening presynaptic K^+ channels to inhibit transmitter release and thus reduce calcium influx. There is also a direct postsynaptic effect with hyperpolarization and reduced neuronal activity evoked by glutamate.

Local anesthetic, bupivacaine, works primarily by causing blockade of voltage-gated Na^+ channels in the axonal membrane and, possibly, a further effect on presynaptic inhibition of Ca^{2+} channels. The results of our study are consistent with experimental evidence of synergistic interaction between spinal opioids and local anesthetics, which are characterized by enhanced somatic analgesia without effect on the degree or level of the local anesthetic induced sympathetic or motor blockade.[67-70]

Clonidine is an α2–agonist which block the conduction of Aδ and C fibers, thereby prolongs the action of local anesthetics. When used intrathecally, it activates the postsynaptic α2–receptors in Substantia gelatinosa of spinal cord and produces analgesia.[71,72] Analgesic properties of clonidine have been shown to depend on the activation of $\alpha 2$ receptors located in the dorsal horn. Presynaptic stimulation of $\alpha 2$ receptors inhibits neurotransmitter release and postsynaptic stimulation prevents neuronal transmission through hyperpolarization[73.s1] Bhure et al. demonstrated that addition of clonidine, fentanyl, and midazolam to bupivacaine significantly improves the onset and duration of sensory and motor block with relative hemodynamic stability, prolongs the duration of analgesia, and reduces the consumption of systemic analgesics in comparison to bupivacaine alone. They concluded that clonidine is an excellent additive to bupivacaine in spinal anesthesia and provides prolonged duration of analgesiawithout any deleterious effects on the mother and baby.[74 AE]

With this background, present study was carried out in the Dept. of Anesthesiology, Government medical college & Sir T General Hospital, Bhavnagar to evaluate the effects of fentanyl in subarachnoid block in patients undergoing lower segment caesarean section.

Morphine is a forerunner as an opioid adjuvant added to local anesthetic for spinal Anesthesia and causes delayed respiratory depression (>2 hours after administration) which is to some extent dose-related[61] and believed to be a result of the cephalad spread of opioids to the medulla within the cerebrospinal fluid (CSF), seen more commonly with hydrophilic opioids. Hence, the lipophilic drugs like fentanyl, sufentanil, remifentanil, alfentanil, methadone are more logical choice.

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With this background, present study was carried out in the Dept. of Anesthesiology, Government medical college & Sir T General Hospital Bhavnagar to evaluate the effects of fentanyl in subarachnoid block in patients undergoing lower segment caesarean section.

The result of our study shows that demographic data (age, weight, height, and duration of surgery) was comparable in both the groups ($p > 0.05$).

In our study, in group F significantly reduced the time for onset (1.43+0.40 min), peak of motor blockade (2.22±0.62 min) and significantly prolonged the total duration of motor blockade (223±53.93 min) extending into the postoperative period as compared to group C (2.02±0.45, 2.79±0.61 and 144.6±21.20 min respectively with p<0.0001).

In other study there were faster onset and prolong duration of both sensory and motor block in clonidine group as compare to fentanyl group but they used more than 30µg clonidine which was higher than taken in our study.[75-77]

Complete analgesia lasted longer in group F for 11.46±1.9 hr compared with group C for 10.96±1.9 min (p 0.19). The duration of effective analgesia was significantly prolonged in group F (14.78±2.03 min) as compared with group C (13.17 ±1.31 min), (p<0.0001).

To compare the efficacy we used the duration of effective analgesia measured by time in hours for requirement of rescue analgesia. In consistency to results of several other studies.[53-58] We found both drugs to be effective as adjuvants to intrathecal bupivacaine prolonging the duration of analgesia). The duration of effective analgesia was significantly prolonged in group F (14.78±2.03 min) as compared with group C (13.17±1.31 min), (p<0.0001).

Another study by Bathari et al. concluded that intrathecal fentanyl was superior to intrathecal clonidine in knee arthroscopy.[78] this is in agreement in our study.

Bhattacharjee et al. concluded from their study that perioperative analgesia for cesarean section was prolonged by the addition of 75 µg of clonidine and 25 µg fentanyl to bupivacaine. However, prolongation of postoperative analgesia was more with fentanyl compared to clonidine, and side effects such as nausea, vomiting, and Hypotension were more with clonidine.[79] This study is in agreement with our study.

Prolonged duration of analgesia due to fentanyl in our study was different to other studies.[80,81] In other study duration of analgesia was significantly higher in BC60 group (598.7±140.47 min) than in BF25 (417.75±108.76) group, (p<0.01). But in their study 2.0 ml of hyperbaric bupivacaine 0.5% with either 60 µg of clonidine (BC 60) or 25 µg of fentanyl (BF25) intrathecally. However intrathecal addition of 60 µg clonidine to bupivacaine provides longer duration of postoperative analgesia than 25 µg of fentanyl and is a preferred option when sedation is acceptable or required. Chhabra et al. in their study concluded that clonidine 60 µg has advantage over fentanyl and it prolonged the duration of the subarachnoid block and postoperative analgesia.[82]

Lavand'homme et al. showed higher incidence of hypotension and sedation with intrathecal clonidine 150 µg than clonidine 75 µg.[83] but its increase the duration of post-operative analgesia as compared to 25 µg fentanyl.

But in our study we used 30 µg clonidine and 25 µg of fentanyl so prolong analgesia in fentanyl group as compared to clonidine group. To minimize the side effects like bradycardia and hypotension due to high dose clonidine we take 30 µg clonidine.

Singh et al. evaluated the effect of addition of intrathecal clonidine to hyperbaric bupivacaine on postoperative pain after caesarean section and has shown that the duration of postoperative analgesia increases significantly on adding 75 µgclonidine to 2 ml of hyperbaric bupivacaine without any increase in maternal side effects. There was no effect on neonatal outcome.[84] Shidhaye et al. concluded that intrathecal addition of 25 µg fentanyl to bupivacaine provides good analgesia with less sedation and is a better option when sedation is not desirable. However, intrathecal addition of 60 µg clonidine to bupivacaine provides longer duration of postoperative analgesia than 25 µg of fentanyl and is a preferred option when sedation is acceptable.[85] In our study fentanyl group give prolong analgesia but dose of clonidine was 30 µg.

Based on the data found in Marzieh Beigom Khezri, 1, it was concluded that Administration of intrathecal clonidine 75 µg with bupivacaine prolonged intraoperative anesthesia and the time to first analgesic request after cesarean delivery compared to fentanyl and control groups. This is not in agreement in our study.

The result of the present study shows that in group F significantly reduced the time for onset (1.20+0.36 min), peak of sensory blockade (1.99 ± 0.59 min) and significantly prolonged the total duration of sensory blockade (240.40±53.45 min) extending into the postoperative period as compared to group C (2.02±0.45, 2.79±0.45 and 163±22.79 min respectively with p<0.0001), hence provided effective postoperative analgesia up to 12 hours.

In other study[75–77] there was faster onset, peak and prolong duration of sensory blockade in clonidine group as compared to fentanyl group. But they use higher dose of clonidine than our study.

However, Mahendru et al. in their study opined that intrathecal 30 µg clonidine is comparable to 25 µg fentanyl regarding sensory and motor block

characteristics which was not in agreement with our study.[11 AE]

There is statistically significant difference in fall in heart rate in group C as compared to group F, at 30 minutes and 45 minutes significant fall in heart rate in group C.

There is statistically significant difference in fall in mean arterial blood pressure at 5, 10 and 15, 45 min after subarachnoid block in group C as compared to group F. The finding in Marzieh Beigom Khezri,[86] which should be taken into account is that transient hypotension episodes and vasopressor requirementin clonidine group were significantly greater than fentanyl group a finding in agreement with our studies.

Side effects observed in our study were nausea, vomiting, hypotension, bradycardia and shivering. The total number of participants who experienced side effects were significantly less in group F. Twelve participants (24%) in the group C and three participants (6%) in the group F had hypotension in our study, requiring treatment with intravenous Inj. Mephentermine (5mg) in addition to crystalloid bolus.

Two participants (4%) in group C experienced nausea and vomiting as compared to group F, which was statistically not significant.

In present study, 25 µg fentanyl and 30 µg clonidine was used and no participant in either group experienced respiratory depression. Reuben SS et al.[87] and Varrasi G et al.[88] found that although no patient developed respiratory depression.

Late rostral spread with small dose intrathecal fentanyl is less and studied by Neil Roy et al.[89], Echevarria et al.[90], Singh H et al.[91], Dalhgren G et al.[92] and Olofsson et al.[93] and they concluded that 25 µg fentanyl is the safest dose. In our study no patient in fentanyl group developed respiratory depression.

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Review Article

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COVID 19 Severe Acute Respiratory tract infection and Pneumonia: Recommendations for Oxygen Therapy in a Resource Limited setting

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Abstract

This article reviews the WHO and CDC guidelines of oxygen therapy for COVID-19 infected patients keeping in view the resource limited constraints of a healthcare system.

Early recognition of patients with worsening respiratory function while on conventional oxygen therapies, such as simple face masks or masks with reservoir bags and referral to a tertiary care center for advanced oxygen therapy and mechanical ventilation is important to ensure the timely and safe escalation of respiratory support. Early optimisation of care and involvement of medical care Unit is suggested. In patients with COVID-19 there is the potential for a worsening of hypoxemia and an increased need for high flow oxygen and intensive care management so close monitoring is advised. The resource limitations are oxygen supply or availability of oxygen delivery devices, personal protective equipment for the staff, proper donning and doffing areas dedicated for suspected and confirmed covid positive patients. The idea of writing this review article was to ensure safe and economical management of these patients in a resource constrained setting using minimum possible measures.

In the mild and moderate stages of disease, normal oxygen supportive measures (facemask oxygen) could also be advantageous. Supplemental oxygen therapy is immediately needed for patients with respiratory distress, hypoxemia or shock with a target SpO_2 >94% as recommended by the WHO. Patients may still have increased work of breathing or hypoxemia even when oxygen is delivered via a mask with reservoir bag (flow rates of 10–15 L/min, which is usually the minimum flow required to take care of bag inflation; FiO_2 0.60–0.95).

Keywords: COVID-19 Severe Acute Respiratory Infection (SARI) and Pneumonia, oxygen therapy, resource limited setting.

Introduction

Corona virus disease (Covid-19) caused by Severe Acute Respiratory Syndrome-Corona Virus-2 (SARS-CoV-2), is a single-stranded ribonucleic acid (RNA) encapsulated corona virus and is highly contagious. Transmission is assumed to be predominantly by droplet spread (i.e. relatively large particles that settle in the air), aerosol generation and direct contact with the patient. There is still no specific antiviral treatment for COVID-19 infection, only supportive therapies including respiratory care and oxygen supplementation for affected patients, especially in more severe cases.

Suspect and confirm diagnosis of COVID-19 infection

Clinical diagnosis, antibody test or if available by laboratory (RT-PCR). Start infection prevention

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and control (IPC) measures.[1] Put a simple surgical face mask on the patient. This prevents spread of the virus to staff and other patients.

Consider IPC issues of staff personal protection equipment (PPE), medical equipment and COVID-19 hospital areas.[4]

Suspect pneumonia and confirm need for oxygen[2]

Any patient with fever or suspected respiratory infection, with one of the following signs: Respiratory rate >22 breaths/min; severe respiratory distress; altered mental status or SpO_2 ≤90% on room air.

Pediatric patients with cough or difficulty in breathing and a minimum of one among the following signs: central cyanosis or SpO_2 <90%; severe respiratory distress (e.g; stridor, grunting, chest indrawing).

In neonates signs of pneumonia with other classical symptoms: Inability to breast feed or drink, lethargy or unconsciousness or convulsions with other signs of pneumonia may be present: chest indrawing, faster breathing rate (in breaths/min): <2 months ≥60; 2–11 months ≥50;1–5 years ≥40.

Confirm hypoxia with pulse oximeter[2]

Oxygen therapy to be started if SpO_2 <90%. oxygen delivery device preferred: Nasal cannula (prongs) or nasal catheter or face mask.

Nasal prongs recommended for child <5 years. Simple face mask/hudson's mask is preferred over nasal prongs or any other type of oxygen face mask. This limits aerosol generation and therefore prevents viral load and spread to the medical staff and other patients.

Oxygen flow needs to be adjusted to target SpO_2 >90% adults & children. And if there are signs of multi-organ failure including shock or alteration of mental status SpO_2 >94% is recommended.

In pregnant patients as per the WHO guidelines target SpO_2 >92–95% in all the three trimisters.

If oxygen saturation of >90% cannot be achieved, or if SpO_2 <90% despite using the high concentration oxygen devices viz; non-rebreathing mask(NRM) at high flow of O_2(10-15 litres) or oxygen hood in pediatric patients (FiO_2 of 80-90%) suspect Acute Respiratory Distress Syndrome(ARDS). Consider nursing the patient in prone position in periodic intervals. This may improve the ventilation and oxygenation of the patients and avoid the need for mechanical ventilation.[3] If the oxygen saturation does not improve further, advanced oxygen therapy and mechanical ventilation may be required. If possible these patients should be shifted to ICU'S as soon as possible for management of intubation and ventilation as these are high aerosol generating procedures and would require proper PPE'S to be worn by the medical staff. Timely decision of enhancing the oxygen support while monitoring the blood gases and other vital parameters including urine output are paramount for the patient management.

Oxygen delivery devices[4]

Titrate O_2 flow with SpO_2.

Nasal prongs O_2 1 – 5 L/min → FiO_2 28%–40% child and adult

Nasopharyngeal catheter O_2 1 – 2 L/min → FiO_2 45%–60% infant and child

Oxygen face mask O_2 6 – 10 L/min → FiO_2 44%–60% child and adult

Venturi oxygen face mask O_2 4 – 15 L/min → Fi O_2 24%–60% (for Venturi O_2 flow rate FiO_2 device specific)

Oxygen face mask reservoir bag O_2 10–15 L/min → FiO_2 60%–95%

Caution

Aerosol generation with droplet spread using open high flow oxygen devices is responsible for most of the contamination and spread of corona virus infection. Simple surgical face mask over nasal prongs is preferable.

Humidification and nebulisation should be avoided as much as possible: Viral spread and equipment may be contaminated being one more aerosol generating procedure.

While HFNO (High frequency Nasal Oxygenation carries a small risk of aerosol generation, it is considered a recommended therapy for hypoxia associated with COVID-19, as long as the staff are wearing optimal PPE. The risk of airborne spread and transmission to the medical staff is considered low when optimal PPE's with and other infection control precautions including donning and doffing are done properly.

Resource limitations: Oxygen supply and availability of oxygen delivery devices.

Assessment of oxygen delivery devices and monitor oxygen supply.

Disinfection of oxygen delivery devices viz; nasal prongs, catheters and face masks.

Infection prevention and control (IPC) measures and policies as per the local protocol of the hospital for contaminated medical equipment.[5]

Oxygen supply[4]

Cylinders may not easily be refilled. Infection prevention and control (IPC) measures if cylinder is at the bedside.

If bulk supply of oxygen is not available then alternate methods may be devised and modified as per the local needs and demand.

Oxygen concentrators produce 4–10 L/min of O_2 and can serve as an important alternative to cylinders in a resource constrained setting.

Decontamination and Disinfection[5,6]

Cleaning of oxygen delivery devices or any surface of secretions and mucus. Disinfect with 70% (ethyl or isopropyl) alcohol or soak in 0.1% sodium hypochlorite solution (1000 ppm available chlorine) for 30 minutes.

Preparation of 0.1% sodium hypochlorite solution[4]

5% sodium hypochlorite contains 50,000 ppm available chlorine, and the dilution contains 1000 ppm. Household bleach to be diluted usually 5% = 5g sodium hypochlorite /100 ml 1:50 with tap water. One measure of bleach to be added to 49 measures of tap water.

Check the concentration of sodium hypochlorite on label (in g/100 ml) and dilute accordingly. For example: 2.5% sodium hypochlorite bleach contains 2.5g sodium hypochlorite /100 ml. add 24 measures tap water to 1 measure of bleach. 4.2% sodium hypochlorite bleach equals 4.2g sodium hypochlorite /100 ml. One measure of bleach is added to 41 measures of tap water. All the dilutions contain 1000 ppm available as chlorine.

A container of solution is to be prepared in a well ventilated place. Store covered, cool and shaded. Discard at 24 hours. Avoid direct contact with eyes and do not mix this solution with detergents.

Thoroughly rinse the oxygen delivery devices before reusing again.

Oxygen Therapy with Resource Limited Conditions

COVID-19 Severe Acute Respiratory Infection and Pneumonia

Key Points

Suspect and Confirm Diagnosis of COVID-19 infection

- Diagnose clinically or by laboratory test
- Simple surgical face mask to be used
- Start infection prevention and control (IPC) measures
- Consider personal protection (PPE) for the medical staff, disinfect medical equipment and designate a dedicated Covid-19 hospital area

Suspect Severe Pneumonia and Confirm Need for Oxygen

- Respiratory signs and symptoms
- Adult or adolescent SpO_2 ≤90%
- Child SpO_2 as per the age

Confirm Hypoxia Pulse Oximeter

- Start oxygen therapy if SpO_2 <90%
- Nasal cannula (prongs) or nasal catheter or face mask
- Nasal prongs for child < 5 years
- Adjust O_2 flow to target SpO_2 >90%
- Try prone position with pillow under the chest
- If SpO_2 not increasing or <90%-Advanced oxygen/Ventilatory support

Resource Limitations

- Availability of oxygen delivery devices and oxygen supply
- Assessment and monitoring of oxygen supply
- Consider disinfection of oxygen delivery devices

Decontamination and Disinfection

- Physical and mechanical cleaning of equipment
- 0.1% sodium hypochlorite solution to be used for 30 minutes

Caution

- Surgical face mask preferred over prongs for the risk of contamination.
- Risk of droplet spread with high flow O_2 from all devices
- Humidification and nebulisation to be avoided

Oxygen Delivery Devices

- Nasal prongs O_2 1–5 L/min
- Nasal catheter O_2 1–2 L/min (infant & child)
- Oxygen face mask O_2 6–10 L/min PPP
- Face mask reservoir bag O_2 10-15 L/min (Make sure reservoir bag inflates)
- Venturi oxygen face mask O_2 4–15 L/min (O_2 flow rate device specific)

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- Margins 2.5 cm from all four sides
- Title page contains all the desired information. Running title provided (not more than 50 characters)
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- Abstract provided: Structured abstract provided for an original article.
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Language and grammar

- Uniformly American English
- Abbreviations spelt out in full for the first time. Numerals from 1 to l0 spelt out
- Numerals at the beginning of the sentence spelt out

Tables and figures

- No repetition of data in tables and graphs and in text.
- Actual numbers from which graphs drawn, provided.
- Figures necessary and of good quality (color)
- Table and figure numbers in Arabic letters (not Roman).
- Labels pasted on back of the photographs (no names written)
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