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Original Research Paper

Anaesthesiology

A RANDOMISED PROSPECTIVE DOUBLE-BLIND STUDY OF COMPARISON OF EFFICACY OF INTRATHECAL ISOBARIC ROPIVACAINE (0.75%)15 MG WITH FENTANYL (25 MCG) AND HYPERBARIC BUPIVACAINE (0.5%)10 MG WITH FENTANYL (25 MCG) FOR SPINAL ANAESTHESIA FOR LOWER ABDOMINAL AND LOWER LIMB SURGERIES

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ABSTRACT

BACKGROUND Spinal anaesthesia (SA) is a widely used regional anaesthesia technique, with bupivacaine being a common choice. However, bupivacaine is associated with potential cardiovascular toxicity, especially in cases of accidental intravenous injection. Ropivacaine, an S-enantiomer derivative of bupivacaine, has been introduced as a safer alternative. This study aims to compare the clinical efficacy of isobaric ropivacaine and hyperbaric bupivacaine in spinal anaesthesia for lower abdominal and lower limb surgeries. **METHODS** A prospective, randomized, double-blind study was conducted on 126 patients undergoing lower abdominal and lower limb surgeries. Patients were randomly assigned to two groups: Group A received (isobaric ropivacaine 0.75% 15 mg with 25 mcg fentanyl) and Group B received (hyperbaric bupivacaine 0.5% 10 mg with 25 mcg fentanyl) for spinal anaesthesia. Sensory and motor blockade onset, duration was recorded, and statistical analysis was performed using SPSS 16 software. **RESULTS** The mean onset of sensory blockade was significantly faster in Group B (5.26 ± 0.936 minutes) compared to Group A (6.20 ± 0.969 minutes), with a P-value of 0.000. There was no significant difference in the duration of sensory blockade between the groups (Group A: 191.44 ± 3.34 minutes; Group B: 191.16 ± 3.50 minutes). The onset of motor blockade was significantly quicker in Group B (9.79 ± 1.69 minutes) compared to Group A (13.20 ± 2.42 minutes), with a P-value of 0.000. Group B also had a significantly longer duration for Grade III motor blockade (157.37 ± 3.44 minutes vs. 102.32 ± 4.92 minutes) and total motor blockade (189.90 ± 4.56 minutes vs. 120.92 ± 4.85 minutes), both with P-values of 0.000. **CONCLUSION** Both ropivacaine and bupivacaine were effective for spinal anaesthesia, with ropivacaine offering a faster onset of sensory and motor blockade but a shorter duration of motor blockade. Bupivacaine provided a longer motor blockade duration. The choice between these drugs should be based on the specific needs of the surgery, with ropivacaine being preferable for quicker recovery and bupivacaine for longer-lasting motor effects.

KEYWORDS :

INTRODUCTION

Central neuraxial blockade is probably the most widely used form of regional anesthesia today. A number of clinical studies suggest that spinal anesthesia may be superior to general or epidural anesthesia for certain patients and for certain surgical procedures. The endocrine- metabolic response to surgery appears to be blunted when spinal anesthesia is employed compared to the response during general anesthesia.

Bupivacaine, an anilide compound, a most widely used drug for spinal anesthesia presently, having longer duration of action and associated with few adverse cardiac effects and prolonged duration of sensory and motor blockade so there is a need to overcome these problems.

However, with time, a number of deaths from cardiac arrest were reported in association with regional anesthesia using bupivacaine mostly caused by accidental intravenous injection of these long-acting local anesthetics.

It was noted in 1977 that the propyl derivative of the pipecoloxylidides was less toxic than the butyl derivative (bupivacaine). Further work revealed that the nerve blocking properties of the R and S enantiomers were similar but that the S-enantiomer was less cardiotoxic. Thus, the S enantiomer of the propyl derivative (Ropivacaine) was chosen for further development.

Ropivacaine, structurally resembling bupivacaine, with a propyl group on the piperidine nitrogen atom of the molecule is a relatively new amino-amide anesthetic agent, similar in chemical structure to bupivacaine has been recently launched in India, for clinical evaluation having various advantages like early onset and shorter duration of action and having lesser cardio toxicity as compared to bupivacaine. The drug ropivacaine, relieves the psychological distress of being immobile for a longer period of time after lower abdominal surgeries.

The objective of our study is to investigate the clinical efficacy of isobaric ropivacaine compared with hyperbaric bupivacaine for spinal anesthesia in lower abdominal and lower limb surgeries.

STUDY SITE AND SOURCE OF DATA

This study was conducted at MGM Medical college Hospital, Navi Mumbai in coordination with Impulse hospital Ahmednagar on patients undergoing lower abdominal and lower limb surgeries under regional anesthesia.

STUDY POPULATION

All patients with ASA I and II requiring spinal anesthesia for lower abdominal and lower limb surgeries, satisfying inclusion and exclusion criteria of the study.

STUDY DESIGN

This is a prospective randomized double-blind study of 126 cases with 63 cases in each group. After obtaining approval from ethics committee and informed consent from patients who fulfill the inclusion criteria, cases will be divided randomly into two groups as, Group A(n=63): Will receive isobaric Ropivacaine (0.75%)15mg with 25mcg Fentanyl intrathecally.

Group B(n=63): Will receive hyperbaric Bupivacaine (0.5%)10mg with 25mcg Fentanyl intrathecally.

INCLUSION CRITERIA

Patients with ASA grade I & II
Patient of age above 18 years to 70 years
Patient of either gender with valid, informed and written consent

EXCLUSION CRITERIA

Patient refusal
Patients allergic to local anesthetic drugs

METHOD

Injection midazolam 1mg and injection ondansetron 4mg is given as premedication intravenously. After taking the patient to the operation theatre, good intravenous access is confirmed, full non-invasive monitoring is applied including pulse oximeter, electrocardiography and sphygmomanometer. Baseline heart rate(HR), blood pressure(BP) & oxygen saturation(SpO2) are recorded. Preloading is done with Ringer Lactate solution 10 ml per kg of body weight. Oxygen at 4 liter per minute with Hudson's mask is supplemented.

The patient is positioned in the lateral decubitus. Under all aseptic precautionary measures L3-L4 space is palpated and local infiltration done with 2ml of 2% Lignocaine. Sub arachnoid space is reached with 25 G Quincke's spinal needle in a midline or para median approach and confirmed by negative aspiration of blood and free flow of CSF. The study drug is prepared & loaded in a sterile syringe by another person & handed over to the anesthesiologist who is unaware of which drug is given. Then study drug is injected into sub-arachnoid space of the patient. The patient is immediately made to supine position after spinal injection of drug. Operating table is kept horizontal throughout the procedure. Pulse rate and Blood pressure is recorded at 3,5, 7,10,12,15,20,30,45,60,90,120,150 and 180 minutes. Criteria for tachycardia, bradycardia, hypotension and hypertension are any increase or decrease of more than 30% from the base line, but treatment is given only when blood pressure falls more than 30% from base line or systolic BP <90mmHg which ever happens early, and bradycardia is treated when heart rate is <50beats / minute. Incidence of nausea or vomiting if any is noted and treated accordingly.

The onset of sensory blockade is determined by loss of pin prick at T10 level. The peak level of sensory block is determined by loss of pin prick above T10 by checking every minute till level is fixed. Motor block is assessed with Modified Bromage Scale (0=no motor block, 1=inability to raise extended legs, 2= inability to flex knees and 3= inability to flex ankle joints) at timed intervals after injecting drug to know the onset and duration of motor blockade. Onset of motor blockade was determined by inability to raise the extended leg. The assessment is continued till complete regression of sensory and motor block. During regression duration of grade 3 motor block is noted by ability to move ankle joint and total duration is noted by ability to raise the leg. Duration of sensory block is noted by feeling of pin prick at S1 level.

STATISTICAL ANALYSIS

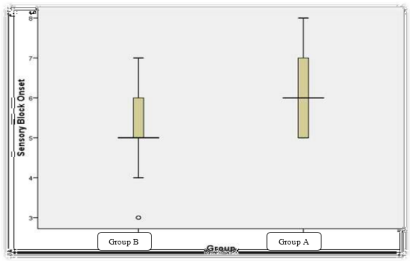
The data obtained was entered into Microsoft Excel spreadsheet and analyzed by using SPSS 16 software. Appropriate tests like unpaired t test (for comparison of mean between two groups) & Chi square test (for comparison of proportions between two groups) were used as per data. The p values less than 0.05 were taken as significant.RESULTS

TABLE 1: COMPARISON OF ONSET AND DURATION OF SENSORY AND MOTOR BLOCKADE BETWEEN TWO GROUPS

Group		N	Mean	Std. Deviation	P value	Significance
SB Onset	Group A	63	6.20	0.969	0.000	Significant
	Group B	63	5.26	0.936		
SB Duration	Group A	63	191.44	3.34	0.640	Not signific
	Group B	63	191.16	3.50		
MB Onset	Group A	63	13.20	2.42	0.000	Significant
	Group B	63	9.79	1.69		
MB Grade III Duration	Group A	63	102.32	4.92	0.000	Significant
	Group B	63	157.37	3.44		
MB Total Duration	Group A	63	120.92	4.85	0.000	Significant
	Group B	63	189.90	4.56		

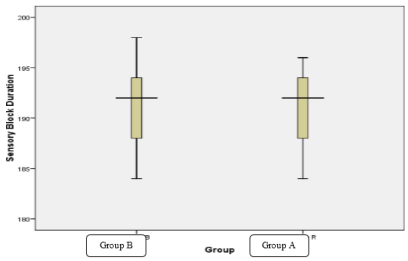
(Unpaired t test) (P<0.05 – Significant)

GRAPH 1 :COMPARISON OF MEAN ONSET TIME FOR SENSORY BLOCKADE BETWEEN TWO GROUPS

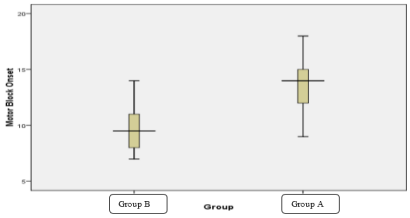


In this study the mean onset time in Group B was 5.26 minutes which was significantly low as compared to 6.20 minutes in Group A.

GRAPH 2: COMPARISON OF DURATION OF SENSORY BLOCKADE BETWEEN TWO GROUPS



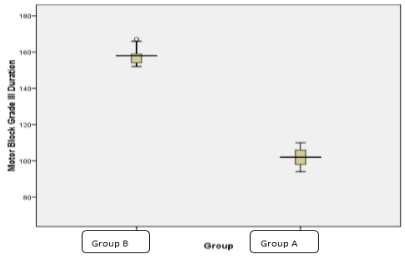
In this study the mean time duration of sensory blockade of Group B was 191.16 minutes and in group A was 191.44 which was comparable in both groups without any significant difference.



GRAPH 3: COMPARISON OF MEAN ONSET TIME FOR MOTOR BLOCKADE BETWEEN TWO GROUPS

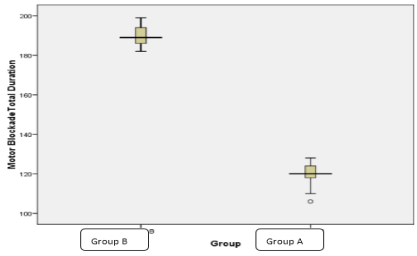
In this study the mean onset time of motor blockade was 9.79 minutes in Group B which was significantly low as compared to 13.20 minutes in Group A.

GRAPH 4: COMPARISON OF MEAN MAXIMUM GRADE ACHIEVED FOR MOTOR BLOCKADE BETWEEN TWO GROUPS



In this study the mean time to achieve Grade III motor block was 102.32 minutes in Group A which was significantly low as compared 157.37 minutes Group B.

GRAPH 5: COMPARISON OF MEAN DURATION FOR MOTOR BLOCKADE BETWEEN TWO GROUPS



In this study the meantime duration for motor block was 120.92 minutes in Group A which was significantly low as compared 189.90 minutes Group B.

DISCUSSION

Central neuraxial blockade has been a preferred alternative in the provision of surgical anesthesia and post-operative analgesia in the last few decades. With increasing awareness of the potential benefits of regional anesthesia, there has been a resurgence of interest in the role of central neuraxial blockade in anesthesiology. Developments in multimodal analgesia, newer local anesthetics and adjuvant drugs, have opened up a plethora of possibilities and offer the potential for greater patient benefit from subarachnoid blocks in the future. Ropivacaine is the pures (-) enantiomer of propivacaine, and is a long-acting amide local anesthetic agent, eliciting nerve block via reversible inhibition of sodium influx in nerve fibers.

The present study intends to compare efficacy of intrathecal ropivacaine with fentanyl and bupivacaine

with fentanyl for spinal anesthesia for lower abdominal and lower limb surgeries.

In our study Onset of sensory blockade was determined by loss of pinprick sensation at T10 level. Mean onset time in group A was found to be 6.20 ± 0.969 minutes while it was 5.26 ± 0.936 minutes in group B. The difference was significant and we conclude that onset of sensory blockade was earlier in Group B compared to Group A.

Time duration of sensory blockade was 191.44 ± 3.34 minutes in Group A and 191.16 ± 3.50 minutes in Group B, the difference was not found to be statistically significant.

In our study the onset time of motor blockade was 9.79 ± 1.69 minutes in group B which was less than 13.20 ± 2.42 minutes in group A, this difference was found to be statistically significant. The time duration of maximum grade (grade III) of motor blockade using the modified Bromage scale was significantly higher in group B(157.37 ± 3.632)minutes than in group A (102.32 ± 4.92)minutes.

In our study there was a statistically significant difference in the duration of motor blockade between the two groups. The duration of motor blockade in Group B was189.90 ±

4.56 minutes which was significantly higher as compared to 120.92 ± 4.85 in Group A. Helena Kallio, Eljas .Veli Snall et al compared intrathecal plain solutions containing Ropivacaine 20 or 15 mg versus Bupivacaine 10 mg in lower limb surgeries. They found that Ropivacaine provides similar duration of sensory blockade and faster motor recovery as compared to Bupivacaine.

Michela Camorica , Giorgio Capogna et al studied the relative potencies for motor block after intrathecal Ropivacaine, Levobupivacaine, and Bupivacaine. They found that intrathecal ropivacaine and levobupivacaine are significantly less potent than bupivacaine, which may explain the lesser motor blocking effects of intrathecal ropivacaine and levobupivacaine.

B.Whiteside, D.Burke & J.A.Wildsmith et al compared ropivacaine 0.5% (in glucose 5%) with bupivacaine 0.5% (in glucose 8%) for spinal anaesthesia for elective surgery .They found that onset of sensory blockade was earlier with Bupivacaine as compared to Ropivacaine and equal doses of Ropivacaine and Bupivacaine produced sensory blockade of similar onset and duration.

CONCLUSION

Thus, from our study we can conclude the spinal anesthesia with intrathecal Ropivacaine 15 mg provides a faster motor recovery as compared with Bupivacaine 10 mg with almost equal duration of sensory blockade and therefore found to be more suitable for ambulatory lower abdominal and lower extremity surgeries of approximately two hours.

From our study we conclude that both Bupivacaine and Ropivacaine with 25 mcqs of fentanyl intrathecally, promote satisfactory anesthesia for lower abdominal and lower limb surgeries.The spinal anesthesia with intrathecal Ropivacaine 15 mg provides a faster motor recovery as compared with Bupivacaine 10 mg which is more suitable for ambulatory lower abdominal and lower extremity surgeries of approximately two hours.

LIMITATIONS

As our sample size is small, it is recommended for further studies in this context. No conflict of interest

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