Section: Anaesthesia

Original Research Article

COMPARATIVE EFFICACY OF INTRATHECAL HYPERBARIC ROPIVACAINE (0.75%) VERSUS HYPERBARIC BUPIVACAINE (0.5%) IN LOWER ABDOMINAL AND LIMB SURGICAL PROCEDURES

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ABSTRACT

Background: Spinal anaesthesia has become popular because of the simplicity of the procedure, profound sensory analgesia, adequate muscle relaxation, less operative blood loss and minimal pre-operative preparation. Relatively newer local anaesthetic amide Ropivacaine have gained popularity due to their lower cardiotoxicity and neurotoxicity. Present study was done with an aim to compare the effects of intra thecal hyperbaric Ropivacaine and Bupivacaine in regards to onset, regression, duration of sensory & motor blockade.

Materials and Methods: 102 patients of ASA I to ASA III physical status undergoing elective lower abdominal and lower limb surgery under spinal anaesthesia were recruited and randomized based on computer generated randomized control table. Group R received 3ml 0.75% hyperbaric Ropivacaine (n=51) and Group B received 3ml 0.5% hyperbaric Bupivacaine (n=51) intrathecally. Onset and regression of sensory & motor blockade along with its level were monitored intraoperatively. Haemodynamic variation and presence of side effects were noted. Total duration of blockade and time to receive first rescue analgesia was noted postoperatively.

Results: Present study demonstrated that Group R had slower sensory onset (R= 5.2 ± 0.65) vs B= 4.3 ± 1.1) mins and took more time for sensory blockade to reach T10 level (R = 6.0 ± 0.86) vs (B= 5.0 ± 0.22) mins & mean time taken for sensory blockade to reach peak level in Group R was also longer (R= 7.78 ± 0.33 vs B = 6.53 ± 0.78) mins (P<0.001). The time taken for onset of motor blockade i.e to attain a modified bromage scale of 1 was longer (R= 6.0 ± 0.78 vs B= 5.0± 0.67) mins and modified bromage scale 3 was comparable in group R and group B (R = 8.0 ± 0.67 vs B= 7.0 ± 0.77) mins (P<0.001) respectively. There was a significant mean difference in systolic and diastolic blood pressure and heart rate at 2min, 5 min, 10 min, 15 min, 20 min, 25min and 30 min between two group R and group B (P <0.05).

Conclusion: Hyperbaric Ropivacaine had a slower onset of sensory, motor blockade, with early regression. It is more cardiostable with lesser side effects and shorter duration of analgesia. It provides patient and surgeon satisfaction comparable to bupivacaine, and hence ropivacaine is better option in short duration surgery.

Keywords: Hyperbaric Bupivacaine, hyperbaric Ropivacaine, Lower Limb Surgeries, Spinal anaesthesia.

INTRODUCTION

Pain is considered to be the fifth vital sign and is an important variable in assessing the post-operative morbidity in the patients. Perioperative pain relief is an essential component of balanced anaesthesia. Spinal anaesthesia (Subarachnoid block) is the most commonly used regional anaesthesia technique

today for lower abdominal and lower limb surgery.[1]

Local anaesthetic agents like bupivacaine, levobupivacaine, and ropivacaine are extensively used in neuraxial nesthesia. Bupivacaine is most widely used agent and provides adequate anaesthesia and analgesia for intermediate to long duration surgeries.[2] But it has been associated with potentially fatal cardiotoxicity, especially with accidental intravascular administration. So, in this aspect, bupivacaine is less safe than other long-acting local anaesthetics like ropivacaine.[3] Due to its high lipid solubility and protein bonding nature, bupivacaine is associated with central nervous system (CNS) toxicity as well. The potential for CNS toxicity can be further exacerbated by hypercarbia, hypercapnia, systemic acidosis. The recognition of acute life-threatening cardiotoxicity of bupivacaine led to the search for a local anaesthetic agent comparable with bupivacaine but with lower cardiotoxicity, resulting in development of a relatively new amide.

Ropivacaine is the 99.5% chiral pure S (–) enantiomer of propivacaine, and is a long- acting amide local anaesthetic agent. Ropivacaine is almost similar to bupivacaine in chemical structure except it has a propyl group on the piperidine nitrogen atom compared to bupivacaine, which has a butyl group. The length of the carbon side chain on the tertiary nitrogen atom is shorter in Ropivacaine than that of bupivacaine. The short length of the carbon chain makes Ropivacaine less lipid soluble which influences the potency of the compound.[4,5]

Due to low lipid solubility, it penetrates myelin sheath less. It inhibits sodium as well as potassium ions through the channel as a result it inhibits the creation and transmission of impulse.

Ropivacaine blocks nerve fibres involved in pain transmission (A and C fibres) to a greater degree than those controlling motor function (Aβ fibres) it therefore has been found to induce less intense motor blockade than bupivacaine. Ropivacaine is a welltolerated regional anaesthetic effective for surgical anaesthesia as well as the relief of postoperative and labour pain.[6-8]

Ropivacaine therefore fits the characteristics of an ideal spinal anaesthetic agent in day care setting that includes a rapid onset of a reliable block providing adequate surgical anaesthesia of appropriate duration, rapid recovery of sensory and motor block with minimal side effects.

Aim of the present study was to compare intrathecal Hyperbaric Ropivacaine (0.75%) and Hyperbaric Bupivacaine (0.5%) for spinal anaesthesia and analgesia in lower abdominal and lower limb surgeries.

MATERIALS AND METHODS

The present study was carried out at Sterling hospital, Ahmedabad in which 102 patients of ASA grade I to ASA III. All patients were divided into two groups of 51 patients each and alternatively received 3ml total volume of the study drug intrathecally: 102 adult ASA grade I-III patients undergoing elective lower abdomen and lower limb surgery under spinal anaesthesia and willing to participate were taken as sample size. The sample size was determined by convenience sampling using "Sample Size Calculation – The Survey System".

Ethical approval was taken from the institutional ethical committee and written informed consent was taken from all the participants.

Inclusion Criteria

1. Patients ASA I-III Physical status.
2. Age 18-80 years.
3. Undergoing elective lower abdominal and lower limb surgery (arthoscopy, lower limb ortho surgeries, gynaecological procedure, hernia surgeries, perineal surgery).

Exclusion Criteria

1. Patient's refusal.
2. History of allergy to local anesthetic.
3. Infection at the site of injection.
4. Presence of bleeding disorder/ coagulopathy.
5. Severe hypotension.
6. Severe Mitral stenosis or Aortic stenosis.
7. Raised intracranial tension.

Any other contraindications to spinal anaesthesia

102 patients were divided into two groups, Group R: Ropivacaine 0.75 % (hyperbaric) 3ml. and Group B: Bupivacaine 0.5 % (hyperbaric) 3ml. Pre-operatively Patients were kept NBM 8 hours prior to surgery. Intravenous access was established and intravenous fluid (Inj. Ringer lactate / Inj. Normal saline) 10-15 ml/kg/hr was started 30 min prior to surgery. Baseline vital parameters were recorded. Inj. Ondansetron 0.08mg/kg was administered 30 mins prior to surgery.

After the patient was shifted in the operating room, Electrocardiogram, Pulse oximetery, Non-invasive blood pressure monitors were attached for monitoring purpose. Spinal anaesthesia was administered in sitting position after preparing the insertion area with antiseptic and infiltrating the area with local anaesthetic solution in L3-L4 space with 23 gauge Quincke type of spinal needle. The local anaesthetic study drug was administered after confirmation of free flow of CSF at the speed of 0.2ml/second. Group B was administered 3ml of Bupivacaine 0.5% Hyperbaric (15mg) and Group R was administered 3ml of Ropivacaine 0.75% hyperbaric (22.5mg). The patient was placed supine after injecting the drug. Intraoperative patient was given Inj. Ringer lactate/ Inj. Normal saline 10ml/kg/hr. Sensory block was assessed by loss of pin prick sensation using a short bevelled end of a 24 gauge needle every 1min till 10 mins after administration of intrathecal injection followed by every 20 mins up to regression of 2 levels. Further It was assessed every 30 mins up to 4 hours or till the sensory effect weaned off.

Following parameters were assessed for sensory block: Onset of Sensory Block, Time taken for sensory blockade to reach T10 level, Time taken for sensory blockade to reach peak level, two segment regression time and Total duration of sensory block.
Motor block was assessed every one minute for the first 10 minutes followed by every 20 minutes till the sensory level regressed by 2 levels using Modified bromage scale. Following parameters were assessed for motor block: Onset of motor block, Time taken for motor blockade to reach Modified bromage scale B3, Time taken for motor blockade to recede to B1 level and Duration of motor block.
Baseline Heart rate and Blood pressure were recorded before administration of the drug. The values were recorded at 2, 5 10, 15 ,20,25, 30min and every 15 min till 120 min followed by every 30 mins until discharge from the recovery room and up to 240 mins. Patient was also monitored for other side effects intraoperatively like shivering, nausea, vomiting, respiratory distress and the same was documented. Post Operatively Patient‟s VAS score was monitored every 30 mins for the first 2 hours followed by one hourly for the next 8 hours. The time for request for first rescue analgesia was noted from the time of administration of spinal anaesthesia to complain of pain.

Statistical Analysis

Data was entered on excel sheet. Statistical analysis was performed using Statistical Programme for Social Sciences (SPSS) 20 for Windows system. For continuous range mean and standard deviation has been calculated and for categorical variables proportion and percentage has been calculated. Continuous data were analysed using independent 't' test and categorical data were analysed using Chi-square test. A 'P' value of <0.05 was regarded as statistically significant.

RESULTS

The observed difference between both groups was not statistically significant with regards to age (P>0.05). [Table 1]
The observed difference was not statistically significant. (P>0.05). [Table 2]
The mean time taken for onset of sensory block in group R was 5.2 ± 0.65 minutes while in group B was 4.3 ± 1.1 minutes, the mean time taken for sensory block reach to T10 level in group R was 6 ± 0.86 minutes while in group B was 5 ± 0.22 minutes, the mean time taken to peak sensory block in group R was 7.78 ± 0.33 minutes while in group B was 6.53 ± 0.78 minutes, the mean time taken by sensory block to regress by 2 level in group R was 110 ±7.8 minutes while in group B was 130 ± 8.6 minutes and the mean duration of sensory block in group R was 150 ± 23.67 minutes while in group B was 160 ± 45.2 minutes. The above observed differences were statistically significant between both groups. (p<0.05). [Table 3]
There was statistically significant difference found in mean HR, Systolic Blood Pressure, Diastolic Blood Pressure at 2, 5, 10, 15, 20, 25, 30 minutes between group R and group B.(P<0.05). [Table 4]
The mean time to first rescue analgesia in group R was 170 ± 5.66 minutes while in group B was 190 ± 4.55 minutes. The observed difference was statistically significant. (P<0.05). [Table 5]
Quality of anaesthesia as judged by the Patients in terms "GOOD" & "SATISFACTORY". In both, Group R an Group B there was no complain of intraoperative pain and no patient in either of the two groups required intraoperative intravenous analgesic/sedative. The patient of Group R gave 84.3% and 86.3% % of Group B gave good opinion regarding quality of block respectively. [Table 6]
The incidence of hypotension in group B was more than group R and the difference was significant statistically. (p<0.05) The incidence of Bradycardia, nausea and shivering between group R and group B was statistically not significant. (p>0.05) There were no cases of retention of urine in both groups.

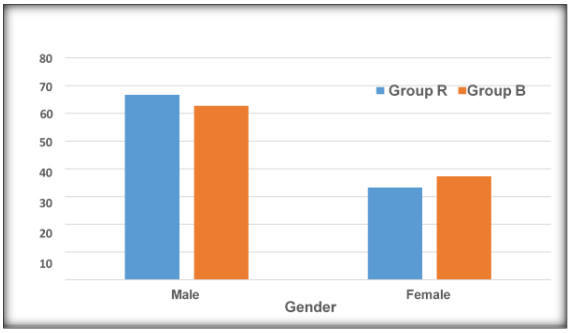

Figure 1: Gender Distribution

The gender distribution in both group patients was statistically not significant. (P>0.05).

Table 1: Mean age of patients of „Ropivacaine" and „Bupivacaine" group [N=102]

Age (in year)	R Group (n=51)	B Group (n=51)	P value*
Mean ± SD	43.0 ± 12.6	44.9 ± 12.4	0.43

* - Student unpaired „t" Test

Table 2: Mean duration of surgery" in patients of Ropivacaine and Bupivacaine group [N=102]

Mean duration of surgery (in min)	R Group (n=51)	B Group (n=51)	P value*
Mean ± SD	90.55 ± 4.65	86.67 ± 6.78	0.31

Table 3: Sensory Characteristics

Sensory Characteristics	R Group (n=51)	B Group (n=51)	P value*
Time taken for onset of sensory block (in min)	5.2 ± 0.65	4.3 ± 1.1	**0.001***
Time taken for sensory block reach to T10 (in min)	6.0 ± 0.86	5.0 ± 0.22	**0.03***
Time taken to peak sensory block (in min)	7.78 ± 0.33	6.53 ± 0.78	**0.0001***
Time taken by sensory block to regress by 2 level (in min)	110.0 ± 7.8	130.0 ± 8.6	**0.0001***
Mean duration of sensory block (in min)	150.0 ± 23.67	160.0 ± 45.2	**0.0001**

Table 4: Motor Characteristics

Motor Characteristics	R Group (n=51)	B Group (n=51)	P value*
Time taken for onset of motor block (in min)	6.0 ± 0.78	5.0 ± 0.67	**0.002**
Time taken for motor block to reach bromage score 3 (in min)	8.0 ± 0.67	7.0 ± 0.77	0.19
Time taken by motor block to recede to bromage score 1 (in min)	108 ± 5.66	122 ± 6.77	**0.001**
Mean duration of motor block (in min)	130 ± 30.55	150 ± 23.58	**0.0001**

Table 5: Mean time to first rescue analgesia in patients of Ropivacaine and Bupivacaine group [N=102]

Mean time to first rescue analgesia (in min)	R Group (n=51)	B Group (n=51)	P value*
Mean ± SD	170 ± 5.66	190 ± 4.55	**0.0001**

Student unpaired t‟ Test

Table 6: Quality of block judge by patient among „Ropivacaine‟ and „Bupivacaine‟ group [N=102]

Quality	R Group (n=51)		B Group (n=51)	
	N	%	N	%
Good	43	84.3	44	86.3
Satisfactory	8	15.7	7	13.7

* Chi-square Test

DISCUSSION

Till today spinal anaesthesia is the most versatile block available and being used for various surgeries on the lower half of the body. The advantages of spinal anaesthesia include simplicity, ease of performance, good muscle relaxation, postoperative analgesia, blunting of autonomic, somatic, endocrine response and prevention of complications like deep vein thrombosis.

Present study was conducted in Department of Anaesthesiology, Sterling hospital, Ahmedabad to compare ropivacaine and bupivacaine in terms of sensory and motor blockade characteristics, side effects and surgeon's and patients satisfaction, in terms of surgical anaesthesia. We conducted a study of 102 patients of ASA Grade I-III between age group of 18 to 80 years, scheduled for lower abdominal and lower limb surgery. Kuthiala G et al,[9] showed that Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres, resulting in a relatively reduced motor blockade. Thus, ropivacaine has a greater degree of motor sensory differentiation, which could be useful when motor blockade is undesirable. The reduced lipophilicity is also associated with decreased potential for central nervous system toxicity and cardiotoxicity.

The time taken for sensory blockade to reach T10 level was noted which was (6.0± 0.86) mins in group R and (5.0 ± 0.22) mins in group B. The mean time taken for sensory blockade to reach peak level in Group R was (7.78 ± 0.33) mins and in Group B was (6.53 ± 0.78) mins. (P<0.001) The mean time for sensory regression by two levels was (110 ± 7.8) mins in Group Rand (130 ± 8.6) mins in Group B (P<0.05). The duration of sensory blockade in Group was (150 ± 23.67) mins and in Group B was (160 ± 45.2) mins. (P<0.001) The findings mentioned above were statistically significant. Whiteside JB et al,[11] in 2003 conducted similar study by comparison of ropivacaine 0.5% (in glucose 5%) with bupivacaine 0.5% for spinal anaesthesia for elective surgery. The onset of pinprick analgesia at T10 was more rapid with bupivacaine (P<0.05), Median block height with time was slightly higher throughout in the Bupivacaine group and the maximum block height achieved was significantly higher (P<0.001). The total duration of sensory block was shorter with ropivacaine (P=0.0001). Vidyalakshmi et al,[10] in 2022 conducted a comparative study of hyperbaric ropivacaine and hyperbaric bupivacaine for spinal anesthesia. The sensory block onset time and time to peak sensory blockade was delayed in Ropivacaine group compared with Bupivacaine group and the difference found between two groups was statistically highly significant. P<0.05. Two segment regression was found to be early in Ropivacaine group.

The time for motor onset i.e to attain a bromage scale of 1 was (6.0 ± 0.78) mins in Group R and (5.0 ± 0.67) mins in group B. The time taken to attain bromage scale 3 in group R was (8.0 ± 0.67) mins and (7.0 ± 0.77) mins in Group B.(P>0.05). Whereas the time taken for motor blockade to regress to bromage scale 1 was shorter in group R which was (108 ± 5.66) mins and (122 ± 6.77) mins in group B(P<0.05). The study conducted by Dar FA et al,[12] in 2015 showed that the mean duration of motor block was also shorter in the ropivacaine group compared to bupivacaine group (P < 0.05). The study conducted by Tarkase A.S. et al,[13] 2020

showed the time for motorblock onset and the mean time of total duration motor block in Ropivacaine group was more than Bupivacaine group and difference between two groups was statistically significant($p<0.001$) The study conducted by Vidyalakshmi et al10 in 2022 showed the degree of motor blockade bromage grade 3 was efficiently larger in Group B than in Group R patients. ($p< 0.05$)

In our study the time of first rescue analgesia mean time to first rescue analgesia that is the time from drug administration till the time patient complained of pain (VAS score>3 at rest or >5 on movement) in Group R was 170 ± 5.66 mins and in Group B was 195.06 ± 12.24 mins. ($P<0.001$) The study conducted by Vidyalakshmi et al,[10] showed that bupivacaine had a longer duration of rescue analgesia as compared to ropivacaine.

In our study the Quality of anaesthesia as judged by the patient was good in 84.3% of group R and 86.3% % of Group B and the quality of anaesthesia as judged by the surgeon was good 86.3% in Group R and 88.2% in Group B. The study conducted by Leena Mahajan et al,[14] had similar results to our study which showed that : the quality of anesthesia was comparable between two groups.

In our study, systolic blood pressure and diastolic pressure, heart rate show significant difference between two R and B groups at 2,5,10,15,20,25,30minutes. ($p <0.05$) In bupivacaine group 15 (29.4%) patients, in ropivacaine group 8 (15.7%) patients required inj. Mephentermine for hypotension ($P <0.05$). Leena Mahajan et al,[14] showed that most common side effect in both the groups observed was hypotension and was proved to be statistically significant. Since the study was conducted in a single institute, care should be taken while inferring the result to the general population.

CONCLUSION

Hyperbaric ropivacaine (0.75%) is comparable to the readily available hyperbaric (0.5%) bupivacaine in terms of quality of block, but with a delayed onset of motor and sensory block, shorter and early recovery profile. It has good haemodynamic profile and lesser side effects , shorter time of rescue analgesia. It is suitable for short procedures where a rapid return of ambulatory function is desirable, such as in the day case setting, where its recovery profile could confer a distinct clinical advantage.

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