ORIGINAL RESEARCH PAPER
Volume - 13 | Issue - 07 | July - 2024 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

COMPARISON OF 0.75% HYPERBARIC ROPIVACAINE AND 0.5% HYPERBARIC BUPIVACAINE FOR SPINAL ANAESTHESIA IN ELECTIVE INFRA UMBILICAL SURGERY

Anaesthesiology

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ABSTRACT

Introduction- Ropivacaine, a newer amino - amide local anaesthetic agent similar to Bupivacaine in chemical structure, which is 30-40% less potent than Bupivacaine. Intrathecal Ropivacaine was found to be safe, having shorter duration of action than Bupivacaine and significant sensory motor differentiation. Objectives- To compare the onset and duration of sensory and motor blockade, duration of post-operative analgesia and the hemodynamic changes during spinal anaesthesia between 0.75% hyperbaric Ropivacaine and 0.5% hyperbaric Bupivacaine. **Material and Methods-** Total of 60 patients of age ranges between 18 and 60 years of either sex, ASA Grade 1 and 2, undergoing elective infra-umbilical surgeries were divided into Group-R and Group-B receiving intrathecal 0.75% hyperbaric Ropivacaine 3ml and 0.5% hyperbaric Bupivacaine 3ml respectively. The efficacy in terms of onset and duration of sensory block, motor block and duration of analgesia were assessed along with the heart rate, blood pressure at regular intervals during first hour of perioperative period. Results- Group-B and Group-R show statistically significant differences in the onset of sensory block, sensory block regression, onset of motor block, motor block regression, and duration of analgesia in both groups ($p<0.05$). Haemodynamic parameters (HR, SBP, DBP and MAP) were comparable in both groups except at intervals of 10, 15, 20, and 25min where Bupivacaine group having lower HR and SBP at 60min. interval. **Conclusion-** Hyperbaric Ropivacaine 0.75% can be used as a possible alternative to routinely used 0.5% hyperbaric Bupivacaine for spinal anaesthesia in infra-umbilical surgeries and day care surgeries as it provides greater sensory motor differential blockade with a shorter duration of motor block and adequate duration of sensory block for the surgery with minimal intraoperative and postoperative side effects and stable hemodynamic throughout the surgery.

KEYWORDS

Hyperbaric Ropivacaine, Hyperbaric Bupivacaine, Spinal Anaesthesia, infra-umbilical surgeries

1. Introduction

Spinal anaesthesia is considered as a preferred technique for infra umbilical surgeries. This technique is frequently used for infra umbilical surgeries due to its rapid onset, dense neural block, reduced morbidity and mortality in comparison to general anaesthesia. Spinal anaesthesia was first described by August Bier in 1899[1]. Cocaine was the first drug which was used for spinal anaesthesia but had many side effects like peripheral vasoconstriction, cardiac and central nervous system excitability and addiction[2]. Later Lignocaine became the preferred drug but because of side effects like transient neurological symptoms reported with 5% Lignocaine heavy and it was withdrawn from clinical uses[3]. Subsequently Bupivacaine became the most common drug used for spinal anaesthesia.

Some patients in which Bupivacaine was used reported life threatening cardiotoxicity like arrhythmias, which were refractory to treatment. This leads to the search of newer and safer local anaesthetic agents. An important feature related to cardiotoxicity due to Bupivacaine, is the stereospecificity of Bupivacaine. The 'S' isomer of Bupivacaine have lesser cardiotoxic potential compared to the 'R' form[4].Due to these side effects, Ropivacaine, a newer amino- amide local anaesthetic was discovered which is similar to Bupivacaine in chemical structure and 30-40% less potent than Bupivacaine[5]. Primary studies evaluated the safety and efficacy of hyperbaric Ropivacaine for spinal anaesthesia. Intrathecal hyperbaric Ropivacaine was found to be safer and having a shorter duration of action than Bupivacaine and lesser incidence of cardiotoxicity symptoms than Bupivacaine. Recently new preparation of hyperbaric Ropivacaine have become available in India. In this comparative study, we are comparing the clinical efficacy and safety of 0.75% Ropivacaine with hyperbaric 0.5% Bupivacaine to evaluate the suitability of Ropivacaine as an alternative to Bupivacaine for intermediate duration of surgeries and for day care surgeries under spinal anaesthesia. The primary objective of this study was to compare the onset and duration of sensory and motor blockade in spinal anaesthesia between 0.75% hyperbaric Ropivacaine and 0.5% hyperbaric Bupivacaine. We also compared the duration of analgesia and hemodynamic parameters in spinal anaesthesia between 0.75% hyperbaric Ropivacaine and 0.5% hyperbaric Bupivacaine.

2. Materials and Methods

After obtaining approval from Institutional Ethical Committee this comparative study was carried out in Tertiary care hospital among patients posted for elective infraumbilical surgery under spinal anaesthesia.

Sixty patients of either sex, age between 18-60years, belonging to ASA grade I and II with no contraindication for central neuraxial block, were randomly divided into two group by chit in box method. Group B patient received 3ml of 0.5% hyperbaric Bupivacaine intrathecally while Group R patient received 3ml of 0.75% hyperbaric Ropivacaine. A thorough pre anaesthetic evaluation was done and advised for overnight fasting. In the preoperative area standard monitors (NIBP, ECG, heart rate and oxygen saturation) were attached and baseline heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure and oxygen saturation were noted. A wide bore 18 Gauge intravenous cannula was inserted in non dominant hand and co-loaded with Ringer lactate solution 15ml/kg dose. Spinal anaesthesia was performed at level of L3-L4 interspace in sitting position using 25G Quinckie needle under strict aseptic precautions. Once the intrathecal space was confirmed by free flow of cerebrospinal fluid, 3ml of appropriate study as per allocated group was administered. All patient were immediately placed in trendelenburg position following the injection. Time of block was noted from the time of injecting the drug.

The level of sensory block was tested every minute by pin prick method till T6 dermatome reached and the time of onset of sensory block was taken as the time taken for block to reach T6 dermatome. The regression of sensory block was checked after 60minutes at regular 15minute intervals till the block regress to S2 dermatome. Motor block was assessed by by Modified Bromage scale. Motor onset time was taken to reach modified bromage score=4 and the total duration of motor block was taken as time for regression of motor block to Modified Bromage score=1. Haemodynamic parameters were also recorded at 2minute, 5minute and every 5minute for 1st hour of surgery. Duration of analgesia was measured from time of intra thecal drug administration to the administration of rescue analgesic (Injection tramadol !00mg IV) Adverse effects like nausea vomiting and shivering were also recorded.

Statistical Analysis

Sample Size at 90% Power:

Sample size was calculated on the basis of variation in duration of sensory block time in the study groups using the formula,

$$n = k\frac{\left(z_\alpha + z_\beta\right)^2\left(\sigma_1^2 + \sigma_2^2\right)}{d^2}$$

Where σ_1 = 9.00, The SD of duration of sensory block time in the first group

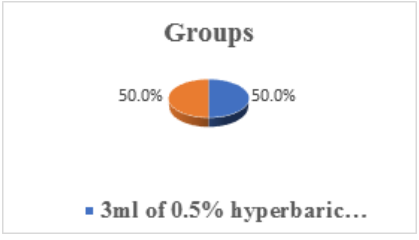
σ_2 = 10.217, The SD of duration of sensory block time in the second group[6].

d = min (σ_1, σ_2), the minimum difference considered to be clinically significant

k = 1.0 the design effect
type I error α = 5% corresponding to 95% confidence level
type II error β = 10% for detecting results with 90% power of study
n = 30 cases in each group

Observation and results

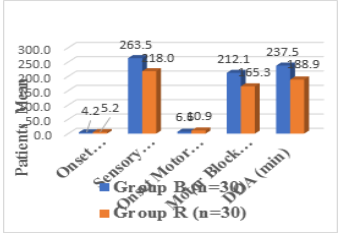
Fig. 1 : Distribution of the studied cases based on groups



There were 60 patients in the study and divided equally into two groups of 30 each: Group B and Group R. Group B received 3ml of 0.5% hyperbaric Bupivacaine, and Group R received 3ml of 0.75% hyperbaric Ropivacaine.

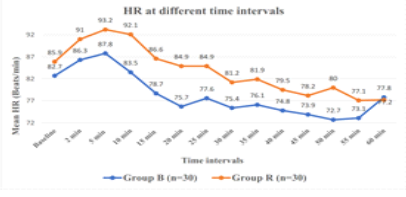
The average age of patients in Group B was 41.2 years, while the average age of patients in Group R was 37.7 years. The majority of patients in both groups were male (83.3% in Group B and 73.3% in Group R). Approximately 60% of patients in both groups had an ASA Grade of I. The average BMI of patients in Group B was 23.9 kg/m2, while the average BMI of patients in Group R was 23.4 kg/m2. There was no statistically significant difference in the mean age, gender distribution, ASA grade, or BMI between Group B and Group R (p>0.05).

Fig.2 Sensory and motor block characteristics



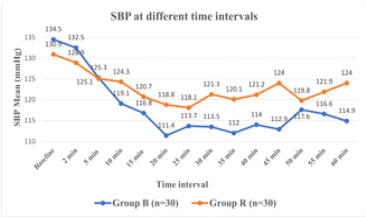
Group B and Group R show statistically significant differences in the Onset of sensory block, Sensory block regression, Onset of motor block, Motor block regression, and DOA (Duration of Analgesia) in both groups (p<0.05).

Fig. 2: Heart Rate at different time intervals



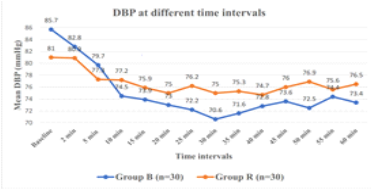
There was a statistically significant difference in HR between Group B and Group R at 10, 15, 20, and 25 min., with Group B having a lower HR (p<0.05).

Fig. 3: Systolic Blood Pressure at different time intervals



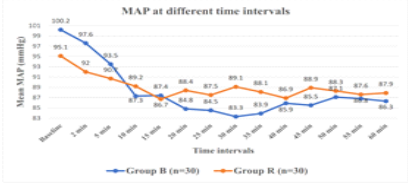
At most time intervals, there are statistically no significant differences in SBP between Group B and Group R (p>0.05). However, at 60 minutes, Group R shows a statistically significant higher SBP than Group B (p<0.05).

Fig 4: Diastolic Blood Pressure at different time intervals



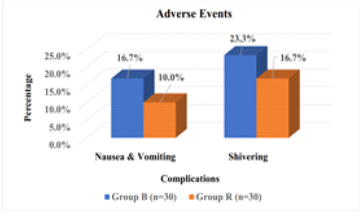
For all time intervals (baseline to 60 min), there are statistically no significant differences in DBP between the two groups (p>0.05).

Fig 5: Mean Arterial Pressure at different time intervals



For all time intervals (2 min to 60 min), there were statistically insignificant differences in MAP between the two groups(p>0.05).

Fig 6: Adverse Effects



For nausea and vomiting, Group B exhibited a slightly higher occurrence at 16.7% compared to 10.0% in Group R. However, the observed difference was statistically not significant (p>0.05). Similarly, for shivering, the incidence in Group B was 23.3%, while in Group R, it was 16.7%. The difference was statistically not significant between the two groups (p>0.05).

4. Discussion

Ropivacaine, a relatively newer amino-amide local anaesthetic agent is a pure form of the S enantiomer of propyl derivative of pipecoloxylidide. It has low lipid solubility than Bupivacaine which may cause this drug to penetrate large myelinated A fibres more slowly so block sensory nerve fibres more readily than motor fibres. However intrathecal use of Ropivacaine was limited because hyperbaric Ropivacaine was not available commercially earlier and hyperbaric solution provide more reliable spinal anaesthesia compare to isobaric solution.

In our study, there were 60 patients divided equally into two groups: Group B and Group R. Group B received 3ml of 0.5% hyperbaric Bupivacaine, and Group R received 3ml of 0.75% hyperbaric

Ropivacaine. The average age of patients in Group B was 41.2 years, while the average age of patients in Group R was 37.7 years. The majority of patients in both groups were male (83.3% in Group B and 73.3% in Group R). Approximately 60% of patients in both groups were ASA Grade I. The average BMI of patients in Group B was 23.9 kg/m2, while the average BMI of patients in Group R was 23.4 kg/m2. There was no statistically significant difference in the mean age, gender distribution, ASA grade, or BMI between Group B and Group R ($p>0.05$). Regmi et al [7], reported that no significant statistical differences were observed between both groups with respect to age, gender, weight, height, and ASA score. Latwal BS et al [8] reported that demographic profile such as age, gender, ASA grade and BMI does not show any statistical differences between both groups ($p>0.05$).

In our study, Group B and Group R show statistically significant differences in the onset of sensory block, in both groups ($p<0.05$). The time of onset of sensory block in group B was (4.2+/-0.76 min) and group R was (5.2+/-1.4 min) which was approximately one minute faster in group B. Similar findings were stated by Chatterjee et al [6], in their study using 3ml of 0.5% hyperbaric Bupivacaine and 3ml of 0.75% hyperbaric Ropivacaine and they noted that the time of onset of sensory block was delayed in the Ropivacaine group and faster in the Bupivacaine group. Ruparel R et al [9], in their study using 3ml of 0.75% isobaric Ropivacaine and 3ml of 0.5% hyperbaric Bupivacaine, also reported that sensory onset in Ropivacaine group was significantly delayed than in Bupivacaine group with a p value of 0.04 ($p<0.05$).

In our study the duration of sensory block regression was significantly prolonged in group B (263.5+/-19.6 min) than group R (218.0+/-19.2min), $p<0.001$. Duration of sensory block was approximately 45 min longer in Bupivacaine group than Ropivacaine group. Similar result was reported by Dar FA et al [10], in their study using 3ml of 0.5% hyperbaric Bupivacaine and 3ml of 0.5% hyperbaric Ropivacaine. They reported that the mean duration of sensory block was significantly shorter with Ropivacaine group (160 ± 12.9 min) than with Bupivacaine group (260 ± 16.1 min; $P < 0.001$). Kulkarni KR et al [11], in their study used 3ml of 0.5% hyperbaric Bupivacaine and 3ml of 0.5% hyperbaric Ropivacaine, also reported the mean duration of sensory block was shorter in Group R than in Group B ($P = 0.028$, $P < 0.05$).

In our study the duration of onset of motor block in group B (6.6+/-2.3 min) was significantly shorter than group R (10.9+/-3.9 min), $p<0.001$. Onset of motor block was approximately 4minute faster in group B than group R. Ghimire and Gyawali [12] in their study used 3ml of 0.5% hyperbaric Bupivacaine and 3ml of 0.5% hyperbaric Ropivacaine also noted that onset of maximum motor block was significantly faster in Bupivacaine than Ropivacaine group. Chari VRR et al [13], also reported that the onset of motor block was significantly delayed in Ropivacaine group than Bupivacaine group, $p<0.001$.

In our study we found that the duration of motor block regression was significantly longer in group B (212.1+/-21.5min) than group R (165.3+/-26.6min), $p <0.001$. Duration of motor block was approximately 57min lesser in Ropivacaine group possibly due to its lesser affinity to large myelinated motor fibres than Bupivacaine. Latwal BS et al [8], in their study also reported that duration of motor block was significantly longer in Bupivacaine group than Ropivacaine group , ($p<0.001$). Garaniya RR et al [14], in their study also reported that duration of motor block was significantly less in group R than group B, ($p<0.0001$).

In our study we found that the duration of analgesia was significantly prolonged in group B (237.5+/-46 min) than group R (188.9+/-25.2min); $p<0.001$. Duration of analgesia was 50min shorter in group R than group B. Chatterjee et al [6], in their study noted that the time for first rescue analgesic was significantly earlier in Ropivacaine group in comparison to Bupivacaine group; ($P<0.001$). Ruparel R et al [9], in their study also noted that there was significant longer duration of analgesia in Bupivacaine group than Ropivacaine group; ($p<0.001$).

In our study, there was statistical differences in HR between the two groups ($p>0.05$) at 10, 15, 20, and 25 min., with Group B having a lower HR ($p<0.05$) possibly due to lesser lipophilicity and stereo selective properties of Ropivacaine leads too lesser cardio depressant effects[5]. Adhikari et al [15], in their study noticed significant difference in mean pulse rate at 5, 15 and 90min interval between two groups. At these intervals pulse rate was significantly lower in the Bupivacaine group. They also reported that incidence of bradycardia was higher in Bupivacaine group.

In our study, most time intervals show there were no statistical differences in SBP between Group B and Group R; ($p>0.05$). However, at 60 minutes, Group R shows a statistically significant difference between both groups ($p<0.05$). This difference was possibly due to absence of R enantiomer in Ropivacaine which results in more hemodynamic stability in comparison to Bupivacaine[5]. For most time intervals (baseline to 60 min), there are no statistical significant differences in DBP between the two groups ($p>0.05$). In our study, MAP was comparable in both groups at all intervals ($p>0.05$). Adhikari et al [23], in their study reported insignificant difference in systolic blood pressure and diastolic blood pressure between two groups except at 10minute interval at which systolic as well as diastolic blood pressure was significantly lower in Bupivacaine group. In our study we did not find such changes at any intervals. Mean arterial blood pressure was comparable in both groups. They also reported that incidence of hypotension was numerically higher in Bupivacaine group. Garaniya RR et al [14], in their study reported that intraoperative hemodynamic parameters were stable in both groups, but in Bupivacaine groups more patients had episodes of hypotension compare to patients in Ropivacaine groups during 10 to 30 minutes after induction.

In our study, Group B exhibited a slightly higher incidence of nausea and vomiting at 16.7% compared to 10.0% in Group R. However, the observed difference was not statistically significant ($p>0.05$). Similarly, for shivering, the incidence in Group B was 23.3%, while in Group R, it was 16.7%. The difference was not statistically significant between the two groups ($p>0.05$). Oraon P et al [16] reported that the incidence of nausea and vomiting was comparable between groups. Shivering was comparable in both the groups. Subba S et al [17] reported that the incidence of side effects like hypotension and bradycardia were comparable in both groups. Shivering was observed more in the Bupivacaine group and one patient had vomiting in the Ropivacaine group.

5. Conclusion

Hyperbaric Ropivacaine 0.75% can be used as a possible alternative to routinely used 0.5% hyperbaric bupivacaine for spinal anaesthesia in infra-umbilical surgeries and day care surgeries as it provides greater sensory motor differential blockade with a shorter duration of motor block and adequate duration of sensory block for the surgery with minimal intraoperative and postoperative side effects and stable hemodynamic throughout the surgery.

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