Comparative Study of Hyperbaric Bupivacaine and Isobaric Ropivacaine for Lower Limb Surgery under Spinal Anesthesia

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ABSTRACT

Introduction: Subarachnoid block is commonly employed technique for lower abdominal and lower limb procedures. Bupivacaine and ropivacaine are commonly used local anesthetics for subarachnoid block. The aim of this study is to compare the efficacy and safety of isobaric Ropivacaine over hyperbaric Bupivacaine.

Methods: This was a prospective comparative study for a duration of six months. 60 ASA grade I-II adult patients between 16-60 years undergoing lower limb surgery under spinal anesthesia were randomized into two groups. Group I including patients who received 15 mg of hyperbaric bupivacaine 0.5% and group II including patients who received 22.5 mg of isobaric ropivacaine 0.75%. The onset and duration of sensory and motor block and hemodynamics including heart rate (HR), non invasive mean arterial blood pressure (MAP) and respiratory depression were recorded. Data were entered in Microsoft excel and statistical analysis was done by chi square test and T test using SPSS (version 23.0).

Results: Both the groups were demographically statistically insignificant. Successful block was attained in all patients in both groups. The sensory onset and motor onset were significantly delayed in the Ropivacaine Group compared to the Bupivacaine Group P<0.001. There was no significant difference in the hemodynamics (heart rate and mean arterial pressure).

Conclusions: Though isobaric ropivacaine provided lesser degree of sensory and motor block with delayed onset compared to hyperbaric bupivacaine, it can effectively and safely used in subarachnoid block in lower limb surgeries without any major hemodynamic changes and adverse effects.

Keywords: hyperbaric bupivacaine; ropivacaine; spinal anesthesia.

INTRODUCTION

Bupivacaine is largely used for spinal anesthesia, mainly as hyperbaric solution.¹ Ropivacaine is one of the amide local anesthetic group with a chemical structure close to bupivacaine but with a better safety profile because it has the advantage of being less cardiotoxic with lower propensity for motor block and can be used as an alternative to bupivacaine.² The objective of the study was to compare isobaric ropivacaine with hyperbaric bupivacaine used for spinal anesthesia in lower limb surgery in terms of efficacy, safety, hemodynamic changes and adverse effect.

METHODS

This was a randomized prospective comparative study. conducted at Nobel Medical College
Teaching Hospital, Birtanagar for the duration of six months. The study included sixty ASA grade I and II adult patients of both genders between 16-60 years of age undergoing lower limb surgery under subarachnoid block. Ethical approval was obtained from the institutional review committee and written consent was taken from all the participants. All patients were randomly selected and were divided into two groups (I and II) each comprising 30 patients. Group I (n=30) received an intrathecal injection of 3ml of 0.5% hyperbaric bupivacaine (15mg) while Group II (n=30) received an intrathecal injection of 3 ml of 0.75% isobaric ropivacaine (22.5mg).

Exclusion criteria included patient refusal to participate in the study, ASA grade III-V, Uncooperative patient, documented hypersensitivity to any of the study drugs, patients on anticoagulant or Antiplatelet therapy or with bleeding diathesis or coagulopathy, infection at the puncture site, patients with h/o cardiac, renal, hepatic and respiratory failure. All the patients were prepared preoperatively as per the institutional protocol of preoperative assessment and preparation. Standard hemodynamic monitoring was done for all the patient during intraoperative and postoperative period. With the computer generated randomization the either hyperbaric bupivacaine or isobaric ropivacaine was chosen for spinal anesthesia. Under all aseptic precautions, lumbar puncture was performed with 25 G Quincke’s needle by using a midline approach at L3-L4 interspace in sitting position.

**Technique of anesthesia:** Pre-operatively an intravenous line were secured with an 18G intravenous cannula & preloading with Ringer Lactate solution at the rate of 10ml/kg over half an hou was done before the initiation of subarachnoid block. After shifting the patient to operation table, a baseline blood pressure, pulse rate, respiratory rate and arterial oxygen saturation were recorded before anesthesia. After confirmation of clear CSF, the study drug was injected at the rate of 0.2 ml/sec and the patient was placed supine.

**Assessment of Sensory Blockade:** The efficacy of the block was assessed in terms of onset and duration of sensory and motor block. Onset of sensory block was assessed by loss of cold sensation with a cotton swab soaked in rectified spirit and was assessed every 2 minutes till the level adequate sensory loss was achieved. Onset of sensory blockade was defined as the time taken from injecting the study drug into the subarachnoid space. The duration of sensory block was measured from the onset of sensory block till the first analgesic dose or verbal complaint of pain.

**Assessment of Motor blockade:** Assessment of Motor block in the lower limb was done following sensory block assessment until normal motor function had been attained. Assessment was done using modified Bromage scale (0 = no motor block, 1 = can flex knee, move foot but cannot raise leg, 2 = can move foot only, 3 = cannot move foot or knee) Onset of maximal motor blockade was defined as time taken from injecting the study drug into the subarachnoid space until Bromage 3 score was obtained. Duration of motor blockade was taken as the time from injecting the study drug into the subarachnoid space till the patient had attained slight motor recovery to < Bromage 3. Motor blockade was assessed every min versus minutes.

Intraoperatively any side effects related with the drugs and procedure were noted and treated accordingly. Patients were followed up on post operative days 1 and 5 regarding possible side effects. Hemodynamic parameters before and after the spinal anesthesia were also compared between the two groups. Subsequent readings of blood pressure, pulse rate, arterial oxygen
saturation and respiratory rate were taken every 2 minutes for 10 minutes and every 5 minutes till the end of surgery and then every 15 minutes in post anesthesia care unit (PACU). If surgery was prolonged, then the anesthesia was supplemented with general anesthesia.

All the parameters were recorded in the proforma. Data were entered in Microsoft excel and statistically analysed by SPSS (version 23.0). Categorical data were presented as percentage and frequency while continuous data were presented as mean and standard deviation. Chi Square test and Student T test was used for statistical analysis. P value <0.05 was considered as significant.

RESULTS

No significant statistical differences were observed between both groups with respect to age, gender, weight, height, repetition of gender word and ASA score.

Table 1. Demographic data(mean ±SD)

<table>
<thead>
<tr>
<th>Demographic characteristics</th>
<th>Bupivacaine group (n=30)</th>
<th>Ropivacaine group (n=30)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>40.63 ± 10.12</td>
<td>41.73 ± 10.45</td>
<td>0.68</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>14/16</td>
<td>19/11</td>
<td>0.19</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>160 ± 9.05</td>
<td>159.4 ± 10.13</td>
<td>0.77</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>61.83 ± 7.94</td>
<td>62.33 ± 7.12</td>
<td>0.8</td>
</tr>
<tr>
<td>ASA I/ASAII</td>
<td>21/9</td>
<td>23/7</td>
<td>0.56</td>
</tr>
<tr>
<td>BMI</td>
<td>24.12 ± 2.5</td>
<td>24.56 ± 2.25</td>
<td>0.47</td>
</tr>
</tbody>
</table>

Preoperative baseline Heart rate, systolic and diastolic blood pressure and mean arterial pressure were comparable in both the groups.

Hemodynamic changes: The changes in heart rate and mean arterial pressure of the groups after injection of anesthetic solution are shown in figure 1 and 2 below. There was decrease in the heart rate and mean arterial pressure (MAP) within 4 to 15 minutes after the injection of local anesthetic solution, which are comparable in both groups, and were not clinically and statistically significant.

Figure 1. Heart rate trend in two groups

![](image-url)
Acceptable levels of sensory block were obtained in all patients before surgery. The sensory onset time to T10 dermatome was significantly shorter in the bupivacaine group (7.5±1.67min) compared with ropivacaine (10.10±1.76min) with P < 0.001. The duration of sensory block were significantly shorter in the ropivacaine group (145.83±13.46min) compared to ropivacaine group (163.33±9.58min) with P<0.001. Acceptable degrees of motor block were obtained in all patients before surgery. The onset time to Bromage 3 was significantly shorter in the bupivacaine group (8.57 ± 1.406 min) than in the ropivacaine group (13.33 ± 1.86 min) with P <0.001. The total duration of motor block was significantly shorter in the ropivacaine group (128.57 ± 5.77 min) than in the bupivacaine group (143.67 ± 9.37 min) with P <0.001.

Table 2. Sensory and Motor onset time and duration in Bupivacaine and Ropivacaine group

<table>
<thead>
<tr>
<th></th>
<th>Bupivacaine Group</th>
<th>Ropivacaine Group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensory onset time</td>
<td>7.50± 1.676</td>
<td>10.10± 1.768</td>
<td>0.000</td>
</tr>
<tr>
<td>Sensory Duration</td>
<td>163.33± 9.589</td>
<td>145.83± 13.460</td>
<td>0.000</td>
</tr>
<tr>
<td>Motor onset time</td>
<td>8.57± 1.406</td>
<td>13.33± 1.863</td>
<td>0.000</td>
</tr>
<tr>
<td>Motor Duration</td>
<td>143.67± 9.371</td>
<td>128.57± 5.776</td>
<td>0.000</td>
</tr>
</tbody>
</table>

In regards to side effects, hypotention was noted in 3(10%) of patients in bupivacaine group and 2(6.6%) patients in ropivacaine group, Bradycardia was noted in 5(16.6%) patient in bupivacine group and 1(3.3%) patients in ropivacaine group. Nausea was noted in 4(13.3%) patients in bupivacaine group and 2(6.6%) patients in ropivacaine group, and high spinal was noted in 2(6.6%) of patients in bupivacaine group and 1(3.3%) of patients in ropivacaine group There was no clinical or statistical significance in the incidence of side effects in both groups.

Table 3. Adverse complication in Bupivacaine and Ropivacaine group

<table>
<thead>
<tr>
<th></th>
<th>Bupivacaine group (n=30)</th>
<th>Ropivacaine group (n=30)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypotension, n(%)</td>
<td>3 (10%)</td>
<td>2 (6.6%)</td>
<td>0.64</td>
</tr>
<tr>
<td>Bradycardia, n(%)</td>
<td>5 (16.6%)</td>
<td>1 (3.3%)</td>
<td>0.08</td>
</tr>
<tr>
<td>Nausea</td>
<td>4(13.3%)</td>
<td>2(6.6%)</td>
<td>0.12</td>
</tr>
<tr>
<td>High Spinal</td>
<td>2(6.6%)</td>
<td>1(3.3%)</td>
<td>0.53</td>
</tr>
</tbody>
</table>

**DISCUSSION**

In this study, we compared the effect of intrathecal ropivacaine and bupivacaine in patients undergoing lower limb surgery. Our results demonstrate a comparable hemodynamic changes, slower onset and
shorter duration of both sensory and motor blocks with 22.5 mg of isobaric ropivacaine compared with 15 mg of heavy bupivacaine. No clinical or statistical significance side effects were seen in both groups. These results show that isobaric ropivacaine 22.5 mg can be safely used in patient undergoing lower limb surgery. When identical doses of isobaric ropivacaine and bupivacaine were compared, ropivacaine was found to have almost similar efficacy but shorter duration of sensory and motor block. On using bupivacaine and ropivacaine in 1:1.5 dose ratio, the block characteristics were almost comparable with the two local anesthetics.

Lee Y. Ying et al, conducted a prospective, randomized, double blind trial of dose response study which gave a useful information to clinician to choose the optimal dose of spinal ropivacaine under different clinical situations. They concluded that the ED$_{50}$ and ED$_{95}$ for spinal ropivacaine of 50 minutes duration or less in lower limb surgery were 7.6 and 11.4 mg respectively. As our surgeries required more time, we choose a higher dose to cover the duration of the surgery. Chari VRR, et al. conducted a study comparing 3 ml of 0.75% isobaric injection ropivacaine and 3 ml of 0.5% hyperbaric injection bupivacaine for spinal analgesia in ASA score I-II patient scheduled for lower abdominal and lower limb surgeries and they concluded that intrathecal isobaric ropivacaine produced a longer sensory block (117.2 ± 12.5 min) when compared with bupivacaine (108.5 ± 10.61 min) (P – value <0.001) and shorter motor block (149.7 ± 8.60 min) with minimum hemodynamic affection compared to intrathecal hyperbaric bupivacaine. Singh S. et al. compared 12.5 mg of 0.5% intrathecal hyperbaric bupivacaine and 24 mg of 0.75% intrathecal isobaric ropivacaine in 46 parturients of ASA grade I-II scheduled for elective cesarean delivery and concluded that 0.75% isobaric ropivacaine provided clinically effective surgical anesthesia with shorter duration of both sensory and motor block without compromising neonatal outcome and can be used as safe alternative to bupivacaine. Rani C. Radhika, et al., conducted a randomized double blind trial and compared intrathecal administration of 3 ml of 0.5% hyperbaric bupivacaine and 3 ml of 0.5% isobaric ropivacaine in sixty patients of ASA grade I –II and they found that compared to hyperbaric bupivacaine, isobaric ropivacaine provided lesser grade of motor block with short duration of both motor and sensory blockade with less intraoperative hemodynamic complication and suggested that isobaric ropivacaine can be used for short duration orthopedic surgeries and early mobilization can be planned. Ruparel R. et al., compared 3 ml of intrathecal isobaric ropivacaine 0.75% with 3 ml of hyperbaric bupivacaine 0.5% in 100 patients of either sex, ASA grade I-II patients undergoing lower abdominal and lower limb surgeries and observed that isobaric ropivacaine provide adequate level of block for lower abdominal and lower limb surgeries with lesser duration of motor and sensory blockade with hemodyanamic stability. Prasad M. Sule and Shakuntala Basantwani, conducted a double blind prospective study of effect of intrathecal 3.5 ml of isobaric ropivacaine 0.75% and 3.5 ml of hyperbaric bupivacaine 0.5% for lower limb orthopedic surgeries and observed that compared to 0.5% hyperbaric bupivacaine, isobaric ropivacaine 0.75% had late onset of both sensory and motor blockade with shorter duration of analgesia and anesthesia with same quality of block.

**CONCLUSIONS**

Isobaric Ropivacaine 0.75% (study group I) provides lesser grade of motor blockade and shorter duration of both sensory and motor blockade for short duration orthopaedic surgeries where prolonged motor blockade is quite undesirable and early mobilization can be planned. Therefore 0.75% isobaric ropivacaine can be safely used in lower limb especially in cases where early ambulation is desired.

**CONFLICT OF INTEREST:** None
REFERENCES


11. Sule MP, Basantwani S. A double blind prospective study of effect of intrathecal ropivacaine 0.75% and bupivacaine 0.5% for lower limb orthopedic surgery in young patients. Int J Basic Clin Pharmacol. 2016;5(5).