Comparison of intrathecal isobaric ropivacaine with fentanyl and isobaric bupivacaine with fentanyl for spinal anesthesia for lower abdominal and lower limb surgery

Anita Saran, DA, DNB¹, Amrusha Raipure, MD², Ravindra Singh Chauhan, DNB³, Sukesh Bohra⁴, Sudip Bhargava, DA, DNB⁵

ABSTRACT

Introduction: Subarachnoid block is commonly used for lower limb and lower abdominal surgeries. This study compares the efficacy of intrathecal ropivacaine and bupivacaine with fentanyl for these surgeries.

Methodology: A prospective randomized controlled study was carried out on 100 randomly selected patients between 18-75 years, undergoing lower abdominal and lower limb surgeries under spinal anesthesia. Group R received plain ropivacaine (0.75%) 15 mg and Group B received plain bupivacaine (0.5%) 10 mg with 20 µg fentanyl each intrathecally. The upper and lower spread of sensory block was determined using loss of sensation to pin prick and motor block assessed with Modified Bromage Scale. Statistical analysis was performed using Student’s t-test for quantitative data and Chi-square test for qualitative data.

Results: The difference in age, height and weight was not statistically significant in the participants of the two groups. The gender distribution and ASA classification were comparable in two groups and there was no significant difference. The onset time of sensory block was 5.26 ± 0.986 vs. 6.24 ± 1.001 min in Group B and Group R respectively (p < 0.001). Duration of sensory blockade was not significantly different [191.38 ± 3.562 vs. 191.24 ± 3.414 min (p = 0.841)] in two groups. The onset of motor blockade was significantly rapid in Group B compared to Group R [9.72 ± 1.691 vs. 3.18 ± 2.569 min (p < 0.001)]. The mean duration of Grade III motor block was significantly low in Group R compared to Group B (102.04 min vs. 157.46 min), as was the mean duration for motor block (121.04 vs. 189.92 min) in Group R and Group B (p < 0.001).

Conclusion: Spinal anesthesia with intrathecal ropivacaine 15 mg provides faster motor recovery as compared with bupivacaine 10 mg, making it more suitable for ambulatory lower extremity and lower abdominal surgeries of short duration.

Key words: Ropivacaine; Bupivacaine; Fentanyl; Motor recovery; Ambulatory surgery.

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INTRODUCTION

Spinal anesthesia or subarachnoid block is a commonly used modality of central neuraxial blockade in lower limb orthopedic surgeries and lower abdominal surgeries. Bupivacaine has been the most widely used drug for spinal anesthesia. However, with time, a number of deaths from cardiac arrest were reported in association with regional anesthesia using bupivacaine. All appeared to be caused by accidental intravenous injection of these long acting local anesthetics, and the doses required to produce cardiotoxicity seemed to be close to the convulsant doses. These deaths and subsequent recommendations of the United States Food and Drug Administration (FDA) provided the impetus to develop a safer drug. It was possible that a less fat soluble drug than bupivacaine would be less cardiotoxic.\(^1\)

It was noted in 1977 that the propyl derivative of the piperidines was less toxic than the butyl derivative (bupivacaine). Further work revealed that the S enantiomer of the propyl derivative (ropivacaine) was less cardiotoxic and hence chosen for further development.

Ropivacaine has been associated with a lower grade of motor block than bupivacaine. Plus with its efficacy and reduced potential for CNS and cardiac toxicity, it appears to be an important option for regional anesthesia for lower limb surgeries.\(^2,3\) The drug ropivacaine, relieves the psychological distress of being immobile for a longer period of time after lower abdominal surgeries.

This study intends to compare efficacy of intrathecal ropivacaine with fentanyl and bupivacaine with fentanyl for spinal anesthesia for lower abdominal and lower limb surgeries, with regard to onset and duration of sensory and motor blockade.

METHODOLOGY

After the approval from institutional ethics committee and obtaining informed and written consent from patients, this prospective randomized controlled study was carried out on 100 randomly selected patients. All ASA grade I and II adults between 18 to 75 years undergoing lower abdominal and lower limb surgeries under spinal anesthesia were included in the study. Written informed consent was obtained from all patients. Cases were divided by computer generated randomization into two groups,

Group R: received plain ropivacaine (0.75%) 15 mg with 20 µg fentanyl intrathecally.

Group B: received plain bupivacaine (0.5%) 10 mg with 20 µg fentanyl intrathecally.

Patients having any contraindications for spinal anesthesia, past history of allergy to local anesthetics, coexisting severe cardiovascular, respiratory or neurological disorders and pregnant women and lactating mothers were excluded from the study.

All the patients underwent routine preanesthetic check up on the previous day of surgery. A detailed medical history was obtained, general and systemic examinations were carried out and relevant investigations were advised.

After preloading with crystalloid solution 10 ml -15 ml per kg of body weight over the period of 15-20 min, subarachnoid block was given with the study drug. No premedication was given. Operating table was kept horizontal till the spinal level was fixed. Pulse rate and blood pressure were recorded every 5 min till spinal level was fixed. Criterion for tachycardia, bradycardia, hypotension and hypertension, was an increase or decrease of more than 20% from the base line, but treatment was given only if clinically indicated (systolic BP < 80 mmHg or heart rate < 50 / min). Incidence of nausea and vomiting if any was noted.

The upper and lower spread of sensory block was determined using loss of sensation to pin prick; and motor block was 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 time intervals of 0, 2, 5, 10, 15, 20, 25, 30, 45, 60, 90, 120, 150 and 180 min after injecting the drug. Assessment was continued till complete regression of sensory and motor block.

All patients received inj midazolam 0.03 mg/kg IV for sedation 20 min after spinal injection.

Statistical analysis: Statistical analysis was performed with Student’s t-test for quantitative data and Chi-square test for qualitative data.

RESULTS

The preoperative characteristics of the study groups were as follows. The average age was 35.4 y in Group B and 34.42 y in Group R. Average height was 60.68 cm in Group B and 61.76 in Group R. Average weight of patients was 164.80 kg in Group B and 165.36 kg in Group R. The difference in age, height and weight was not statistically significant.

The gender distribution was comparable and there was no significant difference. In Group B 46% of the
patients were females and 54% were males, whereas in Group R 48% were female and 52% were males. In both groups 94% of total patients were ASA I and 6% were ASA grade II and there was no statistical difference among both groups.

The surgeries conducted in both groups of the study are shown as Table 1.

In this study, the mean onset time of sensory block in Group B was 5.26 min which was significantly low as compared to 6.24 min in Group R. The mean time duration of sensory blockade of Group B was 191.38 min and in Group R was 191.24 which was comparable in both groups. (Table 2)

Table 2: Onset & duration of sensory and motor blockade in the two groups [Data given as Mean ± SD]

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Groups</th>
<th>p value</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensory blockade onset</td>
<td>5.26 ± .986</td>
<td>6.24 ± 1.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Sensory blockade duration</td>
<td>191.38 ± 3.562</td>
<td>191.24 ± 3.414</td>
<td>.841</td>
</tr>
<tr>
<td>Motor blockade onset</td>
<td>9.72 ± 1.691</td>
<td>3.18 ± 2.569</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Motor blockade grade III duration</td>
<td>157.46 ± 3.632</td>
<td>102.04 ± 4.957</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Motor blockade total duration</td>
<td>189.92 ± 4.476</td>
<td>121.04 ± 4.594</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

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

The mean onset time of motor blockade was 9.72 min in Group B which was significantly low as compared to 13.18 min in Group R. The mean duration of Grade III motor block was 102.04 min in Group R which was significantly low as compared to 157.46 min in Group B. The mean time duration for motor block was 121.04 min in Group R which was again significantly lower than 189.92 min in Group B.

Table 1: Surgeries conducted in both groups [%]

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Group B</th>
<th>Group R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendicectomy</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Hernioplasty</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>TBW #Patella</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Below knee amputation</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>ORIF #Tibia</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Knee Arthroscopy</td>
<td>12</td>
<td>14</td>
</tr>
<tr>
<td>ORIF Potts#</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>IM nailing #Tibia</td>
<td>12</td>
<td>18</td>
</tr>
</tbody>
</table>

Figure 1 reveals that the mean arterial BP among Group B and Group R at 120 and 180 min show statistically significant difference.

The mean systolic and diastolic BP among Group B and Group R at 120 and 180 min also show statistically significant difference

Figure 2 shows the mean heart rate among Group B and Group R at 2, 5, 10 and 180 min. Again the differences are statistically significant.

DISCUSSION

Central neuraxial blockade has been a preferred alternative in the provision of surgical anesthesia and postoperative analgesia in the last few decades. With increasing awareness of the potential benefits of regional anesthesia, there has been a resurgence of interest in central neuraxial blockade. Developments in multimodal analgesia, newer local anesthetics and ad-juvant 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 pure S(-) enantiomer of propivacaine and is a long acting amide local anesthetic agent eliciting nerve block via reversible inhibition of sodium influx in nerve fibers.

This study was conducted to compare the efficacy
of intrathecal ropivacaine (0.75%) 15 mg with 20 µg fentanyl and bupivacaine (0.5%) 10 mg with 20 µg fentanyl for spinal anesthesia for lower abdominal surgeries and lower limb surgeries.

The demographic profile of both sets of patients was comparable in terms of age, gender, height and weight.

Mean onset time in group B was found to be 5.26 ± 0.986 min, while it was 6.24 ± 1.001 min in Group R. The difference was significant and we conclude that onset of sensory blockade was earlier in Group B compared to Group R. In our study we found that time duration of sensory blockade was 191.38 ± 3.562 min in Group B and 191.24 ± 3.414 min in Group R, the difference was not found to be statistically significant.

Whiteside JB et al. compared ropivacaine 0.5% (in glucose 5%) with bupivacaine 0.5% (in glucose 8%) for spinal anesthesia for elective surgery. They found that onset of sensory blockade was earlier with bupivacaine as compared to ropivacaine. This was comparable with our results.

Some authors compared extradural ropivacaine and bupivacaine. 110 patients were studied and received one of the 5 solutions: 0.5, 0.75 or 1% ropivacaine or 0.5 or 0.75% bu-pivacaine. There was little difference between the groups with respect to speed of onset of sensory block. The duration of analgesia was increased by increasing the concentration of both drugs, but this had minimal effect on onset time or extent of block.

In our study the onset time of motor blockade was 9.72 ± 1.691 min in Group B and 13.18 ± 2.569 min in Group R, the difference being statistically significant. The time duration of grade III motor blockade using the modified Bromage scale was significantly higher in Group B (157.46 ± 3.632 min) than in Group R (102.04 ± 4.957 min). In our study, there was statistically significant difference in the duration of motor blockade between the two groups. The duration of motor blockade in Group B -189.92 ± 4.476 min was significantly higher as compared to 121.04 ± 4.594 min in Group R.

Malinovasky JM, et al. compared intrathecal anesthesia with ropivacaine and bupivacaine in transurethral resection of bladder and prostate and found that total duration of motor blockade was not different with both drugs.

A study compared intrathecal plain solutions containing ropivacaine 20 or 15 mg versus bupivacaine 10 mg in lower limb surgeries. They found that ropivacaine provided faster motor recovery as compared to bupivacaine. Some authors 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. Kolka K, et al. compared equipotent doses of ropivacaine-fentanyl and bupivacaine-fentanyl in spinal anesthesia for lower abdominal surgery. They found that duration and intensity of motor block was shorter with ropivacaine as compared with bupivacaine.

Danelli G, et al. studied spinal ropivacaine or bupivacaine for cesarean delivery and found that spinal anesthesia produced with 20 mg ropivacaine plus 0.1 mg morphine is as effective and safe as that provided by 15 mg bupivacaine plus 0.1 mg morphine, with an earlier recovery of sensory and motor functions after surgery.
fentanyl with spinal ropivacaine or bupivacaine

CONCLUSION

We conclude that both bupivacaine and ropivacaine with fentanyl 20 µg intrathecally provide satisfactory anesthesia for lower limb and lower abdominal surgeries. The spinal anesthesia with ropivacaine 15 mg provides a faster motor recovery as compared to bupivacaine 10 mg, which is more suitable for ambulatory surgery on lower limb and lower abdominal region of approximately two hours.

Conflict of interest: None declared by the authors

Authors’ contribution:

AS: Concept, Conduct of Study work, manuscript editing
AR: Concept, literature search, manuscript editing
RC: Literature search & manuscript editing
SBohra: Manuscript editing
SBhargava: Statistical analysis

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