Comparison Of Epidural Bupivacaine 0.5% With Epidural Ropivacaine 0.75% For Lower Limb Orthopedic Procedures

S Shaikh, K Rohini

Citation
S Shaikh, K Rohini. Comparison Of Epidural Bupivacaine 0.5% With Epidural Ropivacaine 0.75% For Lower Limb Orthopedic Procedures. The Internet Journal of Anesthesiology. 2012 Volume 30 Number 2.

Abstract
Epidural blockade is becoming one of the most useful and versatile procedures in modern anesthesiology. Bupivacaine is a long acting amide local anaesthetic which is widely used since many years. However, it is associated with a number of side effects like Central Nervous System (CNS) toxicity and cardiotoxicity. Ropivacaine is a newly introduced long acting amide local anaesthetic drug in India which has been developed as a possible alternative to Bupivacaine. It has a lower lipophilicity than bupivacaine and hence associated with a decreased potential for CNS and cardiotoxicity. Aims: The aim of the study was to compare the time of onset of sensory block and duration of sensory and motor blockade of epidural anaesthesia produced by bupivacaine 0.5% and ropivacaine 0.75% for lower limb surgery. Methods: 60 patients, aged between 18-60 years, ASA 1 and 2, undergoing various lower limb surgeries were randomly allocated to 2 groups of 30 each. Group A received 15 ml of 0.75% ropivacaine and group B received 15 ml of 0.5% bupivacaine epidurally. The time for loss of pinprick at T10, intensity of motor block, duration of sensory and motor block and hemodynamic changes were assessed. Results: 1. The time of onset and duration of sensory block was comparable for both the drugs. 2. Bupivacaine 0.5% produced more intensity and longer duration of motor block than ropivacaine 0.75%. 3. Both the drugs were comparable with respect to hemodynamic changes. Conclusion: Epidural ropivacaine 0.75% can be safely used as a possible alternative to bupivacaine 0.5% in lower limb orthopedic procedures.

INTRODUCTION
Regional anaesthesia and analgesia has the potential to provide excellent operating conditions and prolonged post operative pain relief.  

Epidural blockade is becoming one of the most useful and versatile procedures in modern anesthesiology. It is more versatile than spinal anesthesia, giving the clinician the opportunity to provide anaesthesia and analgesia, as well as enabling chronic pain management. It provides better postoperative pain control and more rapid recovery from surgery. For orthopaedic surgery, the provision of pain relief enables early post operative mobilization, accelerates rehabilitation and return to normal function.

Bupivacaine is a long acting amide local anaesthetic which has been in use for more than 40 years. Its introduction in 1957 is a very important step in the evolution of regional anaesthesia. It is commercially available as a racemic mixture containing equal proportions of the S(-) and R(+) isomers. Despite its popularity, it is associated with a number of side effects like unwanted motor blockade, CNS and cardiotoxicity. There have been many reports of death attributable to bupivacaine induced cardiotoxicity after accidental intravenous injection. These cases resulted in the continued search for new and safer local anaesthetic agents. Ropivacaine, a new long acting amide local anaesthetic was thus introduced as an answer to bupivacaine induced cardiotoxicity. Although it is available from a long time internationally, it has only been launched recently in Indian market.

Ropivacaine is developed as a pure S(-) enantiomer of propivacaine. It is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres resulting in a relatively reduced motor blockade. The reduced lipophilicity is also associated with decreased potential for CNS and cardiotoxicity. Thus ropivacaine appears to be an important option for regional anaesthesia and for the management of post operative and labour pain.

The present study is designed to evaluate the time of onset and duration of sensory and motor blockade of ropivacaine 0.75% and bupivacaine 0.5% when administered epidurally for lower limb surgeries.
Comparison Of Epidural Bupivacaine 0.5% With Epidural Ropivacaine 0.75% For Lower Limb Orthopedic Procedures

MATERIALS AND METHODS

A total of 60 patients between the age group 18-60 years of ASA I and II physical status, scheduled to undergo various surgical procedures on the lower limb under epidural anaesthesia were randomly allocated into two groups and a prospective double blind study was conducted.

30 patients of Group A received 15 ml of 0.75% Ropivacaine epidurally
30 patients of Group B received 15 ml of 0.5% Bupivacaine epidurally

Patients who had any contra-indications to epidural anaesthesia, any neurologic, cardiopulmonary, psychiatric disease, active liver or kidney disease, those receiving anti arrhythmics/beta blockers/anticoagulants and pregnant women were excluded from the study.

All patients included in the study were visited on the previous day of surgery and a detailed pre anaesthetic examination was carried out. An informed valid written consent was taken. Premedication with tablet diazepam 10mg and tablet ranitidine 150mg was given orally the night before surgery. Patients were asked to maintain nil per oral status for at least 6 hours.

In the operation theatre, baseline blood pressure and pulse was recorded. An 18 G IV cannula was inserted and all patients received 20 ml/kg of Ringers lactate solution to increase their circulating fluid volume before the epidural block. Patients were placed in sitting position and skin infiltration with lignocaine 2% 2 ml was performed. Then the epidural space was located at L2-L3 interspaces with a 18 G Tuohy needle using the midline approach and a loss of resistance technique. After negative aspiration for blood, 3 ml of lignocaine with 1:200000 adrenaline test dose was administered to exclude intrathecal and intravascular placement of the needle. Then after a 5 min period, the study drug was injected incrementally over 2 min.

All assessments were made by an anesthetist who did not know the solution used.

Measurement of blood pressure, pulse rate, respiratory rate were recorded at 0,1,3,5,10,15,20 min and thereafter every 15min. Intraoperatively and postoperatively, complications like fall in blood pressure, variation in heart rate were noted, treated and tabulated. Sensory blockade using pinprick sensation was assessed every 5 min until complete loss of sensation at T10 (taken as onset of sensory block) and then every 5 min to determine the time taken for maximum height of block and thereafter every 15 min to determine the time for two segment regression and regression of sensory block at T12, (taken as duration of sensory block). When sensory block reached T10 motor block was assessed using a modified Bromage score-

Recovery from motor block was assessed at the end of surgery. During surgery, patients were sedated with inj midazolam (0.05 mg/kg iv) according to the needs. Bradycardia was treated with atropine 0.5 mg IV and hypotension with mephentermine 6 mg IV.

The statistical analysis of data was done using-

RESULTS

Demographic profile of the two groups was comparable. The mean time for onset of sensory block at T10 was 16.06±3.82 min for group A and 15.76±2.95 min for group B (p=0.73).

Time for regression of sensory block to T12 (duration of sensory block) was 193±17.93 min and 189.5±11.47 min for group A and group B respectively (p=0.37).

When the sensory block reached T10 the mean modified Bromage grade of motor block achieved in group A was 1.6 and in group B was 2.1. Statistical analysis using students unpaired t-test shows that this difference is statistically significant (p=0.002).

In group A, 13 patients (43.33%) had a maximum height of sensory block up to T6, 8 patients (26.66%) upto T7 and 9 patients (30%) up to T8. In group B, 11 patients (36.66%) had a maximum sensory block upto T6, 6 patients (20%) up to T7 and 12 patients (40%) upto T8 and one patient (3.33%) upto T5. Statistical analysis by chi square test shows that the two groups are comparable (p>0.05)

Total duration of motor block was 134±12.41 min in group A and 151±11.09 min in group B. Statistical analysis by Student’s unpaired t-test shows that this difference is highly significant. (p<0.001)

Changes in heart rate, blood pressure and respiration were similar between the groups.
Comparison Of Epidural Bupivacaine 0.5% With Epidural Ropivacaine 0.75% For Lower Limb Orthopedic Procedures

Figure 1
Table 1: Demographic profile and duration of surgery in the two groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Ropivacaine (n=30)</th>
<th>Bupivacaine (n=30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>25.8±11.35</td>
<td>23.8±9.43</td>
<td>NS</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>184.2±2.24</td>
<td>183.2±3.49</td>
<td>NS</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>56.7±12.52</td>
<td>58.9±18.22</td>
<td>NS</td>
</tr>
<tr>
<td>Sex (Male/Female)</td>
<td>18/12</td>
<td>19/11</td>
<td>NS</td>
</tr>
<tr>
<td>Duration of surgery (min)</td>
<td>111.8±23.4</td>
<td>112.7±36.2</td>
<td>NS</td>
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</table>

Figure 2
Table 2: Sensory block

<table>
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</thead>
<tbody>
<tr>
<td>Onset of sensory block (min)</td>
<td>16.6±4.82</td>
<td>15.7±2.94</td>
<td>0.79 (NS)</td>
</tr>
<tr>
<td>Time for maximum height of sensory block (min)</td>
<td>33.3±5.25</td>
<td>33.1±4.13</td>
<td>0.68 (NS)</td>
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<tr>
<td>Time for two segment regression (min)</td>
<td>99.5±13.34</td>
<td>102±13.87</td>
<td>0.48 (NS)</td>
</tr>
<tr>
<td>Time for regression of sensory block to T12 (min)</td>
<td>193±17.95</td>
<td>186.5±11.47</td>
<td>0.37 (NS)</td>
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</table>

Figure 3
Table 3: Motor block

<table>
<thead>
<tr>
<th>Characteristic</th>
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<th>Bupivacaine</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total duration of motor block (min)</td>
<td>134±12.41</td>
<td>151±11.00</td>
<td>&lt;0.001 (ES)</td>
</tr>
<tr>
<td>Modified Frankel grading of motor block</td>
<td>1.6</td>
<td>2.1</td>
<td>0.002 (ES)</td>
</tr>
</tbody>
</table>

Figure 4
Fig 1: Time for onset of sensory block, two segment regression and regression of sensory block to T12 and total duration of motor block between ropivacaine 0.75% and bupivacaine 0.5%

Figure 5
Table 4: Incidence of complications- number of patients in each group

<table>
<thead>
<tr>
<th>Complication</th>
<th>Ropivacaine</th>
<th>Bupivacaine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypotension</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Nausea/Vomiting</td>
<td>3</td>
<td>3</td>
</tr>
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</table>

Figure 6
Fig 2: Incidence of hypotension, bradycardia, nausea/vomiting between ropivacaine and bupivacaine groups

DISCUSSION
Orthopedic surgeries are usually associated with perioperative pain which is a potent trigger for the stress response and autonomic system and is thought to be an indirect cause of various adverse effects like myocardial ischaemia, infarction, thromboembolic phenomena, impaired pulmonary function, ileus, fatigue, muscle catabolism, postoperative infection and postoperative confusional states.

Epidural anaesthesia and analgesia is considered by many as the gold standard technique for major surgery. It has the potential to provide complete analgesia for as long as the epidural is continued. Epidural techniques are particularly effective at providing dynamic analgesia, allowing the patient to mobilize and resume normal activities unlimited by pain. It also improves the postoperative outcome and attenuates the physiologic response to surgery, in particular, significant reduction in pulmonary infections, pulmonary embolism, ileus, acute renal failure and blood loss.4,6,7

Bupivacaine is an excellent drug for epidural anaesthesia, but its major disadvantage is its cardiotoxicity when used in high volumes required for epidural block. Ropivacaine is a long acting regional anaesthetic which has been developed for the purpose of reducing the potential toxicity associated with bupivacaine. It is developed as a pure S(-) enantiomer. R and S enantiomers of local anaesthetics have been demonstrated to have a different affinity for the different ion channels of sodium, potassium and calcium which results in a significant reduction of CNS and cardiac toxicity of the S(-) compared to R(+) enantiomers.4,6,7
The present study included 60 patients of ASA I and II physical status aged between 18-60 yrs, undergoing various orthopedic procedures on the lower limb under epidural anaesthesia. The mean age incidences and sex distribution between the groups were comparable. The mean height, weight and duration of surgery were similar.

We found that the onset of sensory block with ropivacaine and bupivacaine was comparable. Studies have shown that there was no statistical difference in the onset of analgesia between the drugs.

We have used 15ml volume of both the drugs and our study demonstrated that in the ropivacaine group 43% patients had a maximum dermatomal level of sensory block to T6 and 30% to T8. In the bupivacaine group 37% had a maximum height of block to T6 and 40% to T8. Thus the maximum height of sensory block between the two groups was comparable when equal volumes were used. Similarly, A P Wolff et al in their study found out that the maximum cephalad spread between the two groups was comparable. They had used 20ml volume of ropivacaine and bupivacaine and the maximum cephalad spread was T4 with both the drugs.

Time for two segment regression was similar for both the drugs in our study. Wahedi et al in their study also observed that the two segment regression time was 140 ± 60 min for bupivacaine 0.5% and 124 ± 29 min for ropivacaine 0.75% and were comparable. We found that our results are in contrast to the results obtained by Katz et al who observed that the times to two segment regression were 2.7 ± 0.8 hours with bupivacaine 0.5% and 3.4 ± 1.0 hours with ropivacaine 0.75%, which was significantly longer than bupivacaine.

We have studied the duration of sensory block upto its regression to T12 after which supplemental analgesia was given with IV pentazocine 0.3mg/kg so that the patient doesn’t have discomfort with the various orthopaedic positions used. The time for regression of sensory block to T12 was similar for both the drugs and we were unable to demonstrate any statistically significant difference between the groups. Studies by D P McGlade et al and Katz et al also have shown that time for regression of sensory block to T12 was similar for both the drugs.

In our study, the mean modified Bromage grading of motor block was 1.6±0.6 with ropivacaine and 2.1±0.7 with bupivacaine when the sensory block reached T10. As this difference was found to be statistically significant, bupivacaine group is said to have a higher intensity of motor block than ropivacaine. Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate the large myelinated motor fibres resulting in a relatively reduced motor blockade. Thus it has a greater degree of motor and sensory differentiation which is useful when motor blockade is undesirable. Similar results have been reported in studies by Andrea Casati et al and L M M Morrison et al. This is in contrast to studies done by D P McGlade et al and David L Brown et al who failed to demonstrate a significant difference in the intensity of motor blockade between the two drugs. We have assessed the motor block when the sensory block reached T10 and then evaluated at the end of surgery only because of a possible interference with the surgeon during the procedure. This may explain why some of the patients had an inadequate motor block before the surgery. No problems were reported by the surgeons during the procedure.

The total duration of motor block was 134±12.41 min for ropivacaine and 151±11.09 min for bupivacaine. This difference was found to be statistically significant. Hence, ropivacaine has a shorter duration of motor block than bupivacaine. Our results are similar to a study done by David L Brown et al where the duration of motor block with 20 ml of 0.5% ropivacaine was 220±52 min and 0.5% bupivacaine was 276±52 min which was longer. This is in contrast to D P McGlade et al who failed to demonstrate a significant difference in the duration of motor blockade when 0.5% concentration of the drugs were used.

We observed that there was a fall in the systolic and diastolic blood pressure below the baseline after epidural administration at various intervals in both the groups. But this difference was not statistically significant (p>0.05). Two patients in group A and one patient in group B had clinically significant hypotension (SBP<30% baseline) which was corrected with IV mephentermine 6mg bolus. Pulse rate was assessed at various intervals after the administration of epidural anaesthesia and the change in mean pulse rate between the groups was not statistically significant (p>0.05). Two patients in group A and one patient in group B had bradycardia (heart rate <60) which was corrected with IV atropine 0.5mg bolus. There was no difference in the respiratory rate between the groups when measured at various intervals after administration of epidural anaesthesia.
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(p>0.05) Our results correlate with studies done by D P McGlade et al\textsuperscript{11} and David L Brown et al\textsuperscript{14} who also observed that there was no statistically significant difference between the groups with respect to hemodynamic changes.

CONCLUSIONS

Results of this study demonstrate that there was no statistically significant difference in the onset and duration of sensory blockade between ropivacaine 0.75% and bupivacaine 0.5%. The cardiovascular changes, ie the heart rate and blood pressure changes were similar between the groups. Bupivacaine 0.5% produced more intense motor blockade of longer duration compared to ropivacaine 0.75%.

In conclusion, epidural ropivacaine 0.75% can be safely used as a possible alternative to bupivacaine 0.5% in lower limb orthopedic procedures.

References

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