Comparison of ropivacaine 0.75% and bupivacaine 0.5% in peribulbar block for cataract surgery.

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Abstract
The low cardiovascular and neurological toxicity of ropivacaine has led to its application as a local anaesthetic in a wide variety of specialist application including peribulbar block for cataract surgery. The aim of the study was to evaluate the efficacy of ropivacaine 0.75% with hyaluronidase 50 IU/ml and to compare the block quality with bupivacaine 0.5% with hyaluronidase 50 IU/ML. Method: We examined 60 patients subjected to small incision cataract surgery who were randomly divided into two groups according to the anaesthetic used, namely ropivacaine 0.75% or bupivacaine 0.5% with addition of hyaluronidase. Evaluation included assessment of sensory onset, motor onset using akinesia score, time of sensory and motor offset, changes in intraocular pressure, hemodynamic changes and satisfaction of surgeon and patient. Result: with respect to bupivacaine, ropivacaine showed greater reduction in IOP. (p < 0.05). Other parameters were comparable between the two groups (p > 0.05). Conclusion: Ropivacaine 0.75% is comparable to bupivacaine 0.5% in respect to anaesthetic properties in peribulbar block for cataract surgery. Ropivacaine has better hemodynamic profile with greater reduction in IOP as compared to bupivacaine.

INTRODUCTION
Ropivacaine is an amino amide local anaesthetic agent with greater margin of safety than bupivacaine for cardio toxicity and neurotoxicity.\(^1,2\) the efficacy and safety of ropivacaine for anaesthesia during cataract surgery is well studied abroad,\(^3,4\)with most of the studies using peribulbar technique and hyaluronidase to facilitate the onset of anaesthesia and akinesia. Topical anaesthesia is much more preferred technique than regional anaesthesia as revealed by survey.\(^9\) However, topical anaesthesia may not be appropriate for all and regional anaesthesia would be required for certain cases.\(^10\)

There is reduced risk for globe perforation and optic nerve damage with peribulbar (extraconal) than retrobulbar (intraconal) block. However greater volume of anaesthetic solution must be used and peribulbar anaesthesia may be associated with post operative diplopia, transient intra ocular pressure (IOP) elevation and shorter duration of anaesthesia.\(^11,12,13\) Retrobulbar is still a common technique at many institutions especially when hyaluronidase is not available and fast and reliable akinesia is needed.

Ropivacaine is recently being introduced in Indian market and needs to be evaluated in Indian perspective. Hence, we decided to evaluate efficacy of ropivacaine as local anaesthetic with hyaluronidase in peribulbar block for cataract surgery including its effect on IOP and its comparison with bupivacaine with hyaluronidase.

METHODS
After having obtained research ethics committee approval, we selected 60 ASA physical status I & II patients undergoing small incision cataract surgery in a randomized double blind study. After thorough preanaesthetic evaluation patients refusing consent, taking anticoagulants, allergic to amide local anaesthetic or hyaluronidase, patients with psychiatric illness, with major systemic diseases, on medication affecting IOP and with a single eye were excluded from the study.

After written informed consent from the patients they were randomized to receive peribulbar anaesthesia using 0.75% ropivacaine with hyaluronidase 50 IU/ml in group R (n=30) or 0.5% bupivacaine with hyaluronidase 50 IU/ml in group B (n=30). Standard monitoring was established, vital parameters were recorded and intravenous access was secured in non dominant hand. One drop of 0.5 % proparacaine was administered topically on the day of operation at 8:00 am to measure baseline IOP with Schiotz tonometer. The anaesthetic solution was prepared individually immediately before block. The investigators
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Performing the injections and assessment were blinded to the solution used. Peribulbar injection of local anaesthetic was given by using 25 G, 1 inch needle at the junction of lateral one-third and medial two-third directed deliberately toward the orbital floor and drug was injected until peribulbar fullness was observed or to a maximum volume of 7 ml. Light massage over the globe was applied for the spread of solution for a minute. Residual ocular movement, IOP were recorded at 1, 3, 5, 10 and 15 min. interval after the block. Movements in superior, inferior, medial and lateral quadrants were scored according to akinesia score as 0 (no movement), 1 (< 2 mm) and 2 (>2 mm). This gave a range of 0 (complete akinesia) to 8 (full movement). IOP was recorded using Schiotz tonometer. Systolic, diastolic and mean arterial pressure (MAP), heart rate (HR) and SpO₂ were monitored non-invasively at 1, 3, 5, 10, 15 and then every 15 minutes till the completion of surgery. A decrease in systolic BP > 20 % below pre anaesthetic base line was considered as hypotension and treated with inj. Mephentremine 5 mg intravenously in incremental doses. A decrease in heart rate below 50 bpm was treated with inj. Atropine 0.25 mg intravenously in incremental doses. Intra operative adverse effects were assessed by anaesthesiologist who was unaware of the drug given. Postoperatively, surgeon and patient was asked to rate their experience of operative conditions as per the grading shown in Table-1.

Figure 1
Table-1: Quality of peribulbar block

<table>
<thead>
<tr>
<th>Grade</th>
<th>Surgeon’s assessment of block</th>
<th>Patient’s assessment of block</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>Poor</td>
<td>Moderate discomfort</td>
</tr>
<tr>
<td>Grade I</td>
<td>Good</td>
<td>Mild discomfort</td>
</tr>
<tr>
<td>Grade II</td>
<td>Very Good</td>
<td>No discomfort</td>
</tr>
</tbody>
</table>

Postoperatively, patients were shifted to the post anaesthesia care unit and monitored for the regression of ocular muscle movement and time for the first rescue analgesic required. Data collected were subjected to statistical analysis using Jindal sigma statistical software version 2.0. Mean with standard deviation (S.D.) for all the parameters were calculated and comparison between the groups was made using student’s T test for quantitative data and chi square test for qualitative data. Value of p < 0.05 was considered statistically significant.

RESULTS
Patient’s characteristics were similar and comparable between the two study groups. (Table 2)

Figure 2
Table 2: Demographic data of patients

<table>
<thead>
<tr>
<th></th>
<th>GROUP R Mean ± SD</th>
<th>GROUP B Mean ± SD</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>58.80 ± 9.65</td>
<td>62.60 ± 10.81</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td>Sex : M: F</td>
<td>14:16</td>
<td>13:17</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>144.17 ± 11.41</td>
<td>147.07 ± 7.37</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>47.97 ± 10.15</td>
<td>47.70 ± 15.62</td>
<td>&gt; 0.05</td>
</tr>
</tbody>
</table>

There was no statistical difference in akinesia score observed between the two groups at 1, 3, 5, 10 and 15 min after peribulbar block. (Figure 1)

Figure 3
Figure 1: Akinesia score after peribulbar block

There was no statistical significant difference between study groups in terms of base line IOP before injection. In both the groups, IOP reduced significantly from the base line at 15 min after block. (P < 0.002) On comparison between the two groups, there was significant reduction in IOP at 1, 3, 5, 10 and 15 minutes after injection in group R than in group B. (Figure 2)

Figure 4
Figure 2: changes in intra ocular pressure
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There is no statistical difference in term of pulse rate between study groups (p>0.05) as seen in figure 3. Two patients in group B developed bradycardia (HR < 50) which responded to atropine.

**Figure 5**
Figure 3: changes in pulse rate after peribulbar block

There is no statistical difference in terms mean arterial pressure between study groups (p > 0.05) seen in Figure 4.

**Figure 6**
Figure 4: Change in mean arterial pressure

There is no statistical difference in terms of SpO2 between study groups (p > 0.05) seen in Figure 5.

**Figure 7**
Figure 5: Change in SpO2

95% of patients in group R and 98% in group B reported no discomfort during surgery. The remaining complained of mild discomfort.

Return of ocular muscle movement was comparable in both the groups and all the patients had ocular muscle movement scale 8 (full movement) at 24 hours post operatively. (Table 3)

**Figure 8**
Table 3: Return of ocular muscle movement

<table>
<thead>
<tr>
<th>Time</th>
<th>GROUP R Mean ± SD</th>
<th>GROUP B Mean ± SD</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before block</td>
<td>8.0</td>
<td>8.0</td>
<td>1</td>
</tr>
<tr>
<td>1 minute after block</td>
<td>3.77</td>
<td>3.77</td>
<td>0.53</td>
</tr>
<tr>
<td>3 minute after block</td>
<td>3.23</td>
<td>2.83</td>
<td>0.53</td>
</tr>
<tr>
<td>5 minute after block</td>
<td>2.17</td>
<td>2.33</td>
<td>0.78</td>
</tr>
<tr>
<td>10 minute after block</td>
<td>1.90</td>
<td>1.53</td>
<td>0.51</td>
</tr>
<tr>
<td>15 minute after block</td>
<td>1.67</td>
<td>1.17</td>
<td>0.32</td>
</tr>
</tbody>
</table>

Table 4 shows the time for first rescue analgesic requested by the patient.

**Figure 9**
Table 4: Time for first analgesic request.

<table>
<thead>
<tr>
<th>Time</th>
<th>GROUP R Mean ± SD</th>
<th>GROUP B Mean ± SD</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>276.83 ± 78.49 minute</td>
<td>257.83 ± 72.64 minute</td>
<td>p&lt;0.05</td>
</tr>
</tbody>
</table>

**DISCUSSION**

With the recent availability of ropivacaine in the Indian market and its better safety profile as compared to other established local anaesthetics, there is wide area of research open and desirable with ropivacaine.

Going through the literature, our impression with 1% ropivacaine was that onset of akinesia was delayed. Addition of high concentration of hyaluronidase (300 IU/ml) in peribulbar local anaesthesia promotes speed of onset and quality of block.

However, a number of other studies of peribulbar ropivacaine combined with hyaluronidase 0-75 IU/ml were published and they found this to be as effective as higher doses of hyaluronidase. Hence we wished to determine whether 0.75% ropivacaine with lower dose of hyaluronidase (50 IU/ml) as a sole anaesthetic could be a better anaesthetic in providing satisfactory akinesia for ocular surgery as compared to 0.5% bupivacaine, particularly as other clinical applications have demonstrated motor sparing properties of ropivacaine.

Differences in the methods used in different studies make
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direct comparison difficult. This includes site of injection, akinesia scoring system, definition of successful block, indication for and methods of supplementation and type of surgery. We used a technique of a single injection at the junction of medial 2/3 and lateral 1/3 of lower orbital margin, needle directed deliberately towards the orbital floor according to our established practice in ophthalmology department. With this technique, we were able to achieve adequate anaesthesia for cataract surgery within 15 minutes after the injection in all patients in both the groups and on comparison between the two groups we found no statistically significant difference in respect to the rate of development of akinesia, sensory anaesthesia and experience of surgeon and patient in respect to quality of block. Our method of ocular mobility assessment was simple and semi quantitative. We felt this method to be more objective and reproducible than quantitative methods described by others because our ophthalmic surgeon used to perform phaco emulsification under topical anaesthesia alone and are used to tolerate considerable eye movements.

The only notable difference between the two groups was the magnitude of reduction in IOP. Though, both the drugs 0.75% ropivacaine and 0.5% bupivacaine reduced intraocular pressure significantly from the base line value but ropivacaine decreased the IOP to a greater extent than bupivacaine. This finding is similar to reduction in IOP when used in peribulbar block. An unsuccessful block therefore related with problems of analgesia rather than akinesia with a correspondingly low supplementation rate (0), compared with other studies.

No patient in ropivacaine group developed any of the side effects observed where two patients in bupivacaine group developed bradycardia immediately after block. This proves improved hemodynamic profile of ropivacaine in comparison to bupivacaine.

CONCLUSION

We found that 0.75% ropivacaine with hyaluronidase 50 IU/ml is a suitable mixture for peribulbar block with onset, quality of anaesthesia and post operative analgesia similar to that achieved with 0.5% bupivacaine with hyaluronidase 50 IU/ml. However 0.75% ropivacaine was found to be better than 0.5% bupivacaine under the same standard conditions for lowering IOP in intraocular surgery. Reduction in IOP is probably due to relaxation of extra ocular muscles with both local anaesthetics and in addition smaller intra ocular blood volume due to vasoconstriction in case of ropivacaine. We also conclude that ropivacaine has better safety profile for cardiac toxicity than bupivacaine.

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