Efficacy of Plain and pH Adjusted Bupivacaine with Hyaluronidase for Peribulbar Block in Cataract Surgery

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Abstract

200 consecutive patients scheduled for intraocular cataract surgery under peribulbar block (PBB) were randomly divided into two groups of 100 patients each. All patients before cataract surgery randomly received peribulbar block either plain (pH 5.4) or pH-adjusted (pH 6.8 range 6.7–6.9) 0.75% bupivacaine labelled A and B respectively. This was done to make anesthetic unaware of the mixture to be administered for peribulbar block (Double Blind Technique). Hyaluronidase was added to both solutions prior to peribulbar block. Observation of ocular movements in all four quadrants at interval of 1 minute was assessed upto maximum 20 minutes and the time of onset of akinesia of the globe was noted. After 20 minutes interval of time no effect of PBB then the need for supplementary injections were also recorded by an independent observer (Supervisor). The relative efficacy of the different anesthetic solutions A or B was compared in patients who underwent intraocular cataract surgery. In both groups of patients, eyes receiving peribulbar block with the pH-adjusted solution showed a shorter onset of time to partial akinesia of the globe (P < 0.05). However, there was no difference between the solutions in the time to complete akinesia of the globe, but the number of supplementary injections required for an effective block with the pH-adjusted solution was increased. Onset time to akinesia of the lateral and superior rectus muscles was shortened in patients receiving the pH-adjusted solution but there were minimal effects on the medial and inferior recti muscle.

Keywords: Peribulbar, Block, Local Anaesthetics, Bupivacaine, Hyaluronidase, pH-adjusted, akinesia, Double Blind Technique.

INTRODUCTION

Cataract is still the most common cause of treatable blindness in the world. The only cure for most cataracts is the surgical removal of cataractous lens. Either local or general anaesthesia may be used in the cataract surgery [1]. Local anaesthesia is frequently employed in the ophthalmic surgeries, especially, indicated in patients with concomitant cardio-vascular, pulmonary or some endocrinal diseases, where general anaesthesia is relatively contra-indicated. Elderly patients admitted for cataract extraction, represent a high risk group for general anaesthesia. In such cases, local anaesthesia gives less interference with vital organ functions provides prolonged post operative analgesia and decrease incidences of nausea and vomiting [2]. The quest for a safer anaesthetic technique leads to the description of peribulbar anaesthesia. In 1970 Kelman [3] described this technique of ophthalmic anaesthesia. Davis and Mendel [4] with their publication of peribulbar anaesthesia in 1986 first used the term peribulbar anaesthesia. They gave injection of lignocaine along with bupivacaine and hyaluronidase outside the muscle cone of the eye in the infero-temporal and supero-nasal quadrants and showed good anaesthetic effect, coupled with lack of amaurosis. Several injectable local anaesthetics are available for peribulbar anaesthesia.

Bupivacaine local anesthetic agent is commonly used alone or with lignocaine anesthetic agent because of its high potency and long duration action. Only due to its delayed onset of action, Bupivacaine is not preferred in the busy operation theatre. Alkalination of Bupivacaine along with the routine use of hyalurinase makes the onset of action quick and thus can be used in the routine operation theatre without comprising the quality of block [5]. Surgical anaesthesia with accompanying akinesia of the globe and eyelids, i.e. no detectable movement in response to stimulus, are the objectives when regional anaesthesia is performed for eye surgery. Globe akinesia may be achieved with small volume of local anaesthetic using Retrobulbar block with drug placement near the apex of the orbit. However this
technique carries a small but significant risk of complications [5, 6]. More anterior placement of large amounts of anesthetic, by one or more injections, is the basis of peribulbar blocking which reduces the risk of brainstem anaesthesia or damage to the optic nerve [6]. Koornneef [5, 8] has stressed that orbital connective tissue are important in determining how local anaesthetics spread around the globe. Anatomical differences may account for the delayed or incomplete akinesia seen with peribulbar block in some patients perhaps due to failure of anaesthetic spread to the orbital apex.

Measures to improve spread and nerve penetration have included increasing the amount of drugs in the non-cationic form by alkalinization [3] and adding hyaluronidase to the anaesthetic solution. Hyaluronidase improves onset time and enhances akinesia of extraocular muscles [9-11]. Depolarization of hyaluronic acid by hyaluronidase lead to liquefaction of the gelatinous interstitial barrier [12] but there is no increased spread of anaesthetic solution across fascial planes [13, 14]. Local anaesthetic potency (degree of conduction block) depends on the concentration of charged ions at the sodium channel. This is determined by the quantity of drug, its volume of distribution within each compartment, drugs kPa, local pH and lipid solubility of the free base which crosses the axonal membrane. Zahl et al., [5] in their study of regional anaesthesia for cataract extraction surgery, found highly significant differences in onset time and a reduction requirement for repeat injections when pH adjusted bupivacaine with bupivacaine was compared with plain bupivacaine with hyaluronidase for peribulbar blocks in different patients.

The modification of local anaesthetics by addition of sodium bicarbonate has been studied for a long time. Lewis P, Hamilton RC, Loken RJ, Malty JR, Strunin L [15] conducted one such study in 1992 in which he used plain and ph adjusted 0.75% bupivacaine. Hyaluronidase was added to both solutions prior to the block. The onset of anaesthesia was shortened with alkalinization but the number of supplementary injections in pH adjusted solution was increased. Therefore we have compared efficacy of plain and pH adjusted bupivacaine (0.75%) with hyaluronidase for peribulbar block in cataract surgery and proved that alkalinization of local anesthetic pH adjusted bupivacaine (0.75%) with hyaluronidase could be effective alternative in terms of efficacy to plain bupivacaine (0.75%) with hyaluronidase.

MATERIAL & METHODS

In our study 200 consecutive patients scheduled for intraocular cataract surgery under peribulbar block (PBB) were randomly divided into two groups of 100 patients each in Group A and B. In each group all were above the age of 35 years with cataract without any systemic and other ocular problems. Patients undergo cataract surgery received peribulbar block from one of the two freshly prepared bupivacaine with hyaluronidase solution labelled A & B so as to make anaesthetic unaware of the mixture to be administered for peribulbar block (PBB) i.e. with Double Blind Technique. Out of the two anaesthetic solutions one mixture contained 10 ml of 0.05 % bupivacaine (Sensorcaine) solution with 150 IU of hyaluronidase. While the other solution besides first mixture also contained 0.05 mEq/L (0.05 ml of 8.4 % NaHCO₃). Value of the pH of the solutions labelled A & B were measured with pH meter and disclosed by the supervisor at the end of the study in that patient to remove any chances of becoming biased while testing onset times of extraocular recti muscle akinesia. All two points peribulbar blocks were performed by the same anaesthetist who was unaware of the choice of anaesthetic solution as was the observer. After peribulbar block steady intermittent digital pressure given for two minutes and observations of ocular movements in all the four quadrants at interval of one minute were assessed up to maximum 20 minutes time. Onset time of complete akinesia of globe was noted. Movements of the globe were scored according to the method described by Nicoll et al., [16].

- No block effect. Full movement of the associated rectus muscle.
- Partial block effect. Partial movement of the associated rectus muscle
- Complete block effect. Complete paralysis of the associated rectus muscle

Scoring continued until complete akinesia of the globe was achieved i.e. total score of 8 or until 20 minutes had elapsed. Total score of 4 was designated as partial akinesia. In cases of incomplete/partial PBB after 20 minutes, same injection of anaesthetic solution with same technique, were repeated to achieve complete akinesia.

OBSERVATIONS & RESULT

All study patients achieved a satisfactory block for cataract surgery either before or after supplementary blocks. Majority of the patients in both the groups A and B were in the age group of 51-70 years. The mean age of the patients in group A was 63 years as compared to 64 years of age in group B. Thus there was no significant difference regarding age distribution in two study groups. Similarly in respect to sex distribution of the study patients, 40% (40) patients were male 60% (60) were female. In comparison in group B, 50% (50) patients were male and female each. Therefore males and females in both the groups were having similar demographic profile with no statistically difference. In respect to ocular akinesia.

A) Mean of Onset Time of Akinesia of Recti Muscle
Table 1: Mean of Onset Time of Akinesia of Recti Muscle in both A & B groups

<table>
<thead>
<tr>
<th>Anaesthetic Group</th>
<th>Individual Rectus Muscles</th>
<th>Superior (Min.)</th>
<th>Inferior (Min.)</th>
<th>Medial (Min.)</th>
<th>Lateral (Min.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A- (Plain Bupivacaine)</td>
<td>08.0 ± 0.55</td>
<td>08.6 ± 0.62</td>
<td>11.7 ± 0.71</td>
<td>13.5 ± 0.76</td>
<td></td>
</tr>
<tr>
<td>Group B- (pH Adjusted Bupivacaine)</td>
<td>3.2 ± 0.48</td>
<td>3.2 ± 0.48</td>
<td>4.2 ± 0.51</td>
<td>4.9 ± 0.52</td>
<td></td>
</tr>
</tbody>
</table>

In group A, The arithmetic mean of onset of time of akinesia of Superior Rectus (SR) muscle was 8.0 ± 0.55 minutes, Inferior Rectus (IR) muscle 8.6 ± 0.62 minutes, Medial Rectus (MR) muscle 11.7 ± 0.71 minutes and that of Lateral Rectus (LR) muscle was 13.5 ± 0.76 minutes.

Similarly in group B, the arithmetic mean of onset of time of akinesia of Superior Rectus (SR) & Inferior Rectus muscles was 3.2 ± 0.48 minutes, Medial Rectus (MR) muscle 4.2 ± 0.51 minutes and that of Lateral Rectus (LR) muscle was 4.9 ± 0.52 minutes (Table 1).

B) Mean of the Onset Time of Complete Ocular Akinesia

Table 2: Mean of Onset Time of Complete Ocular Akinesia in both A & B groups

<table>
<thead>
<tr>
<th>Group</th>
<th>No. of Patients</th>
<th>Mean of Onset Time (Total Cases) (Min.)</th>
<th>No. of Patients</th>
<th>Mean of Onset Time (Excluding Cases of Suppl. Blocks) (Min.)</th>
<th>No. of Patients</th>
<th>Mean of Onset Time (Cases of Suppl. Blocks) (Min.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>100</td>
<td>13.9 ± 0.74</td>
<td>90</td>
<td>12.4 ± 0.49</td>
<td>10</td>
<td>27.2 ± 1.57</td>
</tr>
<tr>
<td>B</td>
<td>100</td>
<td>4.96 ± 0.52</td>
<td>98</td>
<td>4.55 ± 0.34</td>
<td>02</td>
<td>25.0 ± 0.00</td>
</tr>
</tbody>
</table>

P < 0.05 Significant
P < 0.05 Highly Significant

In Group A, the mean of onset time of complete ocular akinesia of total cases was found to be 13.9 ± 0.74 minutes as compared in Group B where the mean of onset time of complete ocular akinesia of total cases was found to be 4.96 ± 0.52 minutes. Hence when mean of onset time of complete ocular akinesia of total patients in group A and group B were compared, the p value comes out to be significant. (Student t test p < 0.05)

Similarly in Group A, the mean of onset time of complete ocular akinesia in total cases, excluding the cases with supplementary blocks, was 12.42 ± 0.49 where as the mean of onset time of complete ocular akinesia in patients excluding the supplementary blocks was 04.55 ± 0.34. Both groups when compared, the p value comes out to be highly significant. (Student t test p <0.001).

Since number of cases required supplementation of blocks after 20 minutes of incomplete ocular akinesia in Group B was only 2 as compared to 5 in cases in the Group A. So no comparison could be made statically (Table 2).

C) Supplementary Blocks after 20 minutes of incomplete Ocular Akinesia

Table 3: Supplementary Blocks after 20 minutes

<table>
<thead>
<tr>
<th>Group</th>
<th>Ocular Akinesia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of Patients</td>
</tr>
<tr>
<td>A</td>
<td>100</td>
</tr>
<tr>
<td>B</td>
<td>100</td>
</tr>
</tbody>
</table>

In Group A, out of 100 patients, 90 (90%) had complete ocular akinesia and no supplementary block was needed. 10 (10%) patients had full or partial ocular akinesia and supplementation of additional anesthetic solution of same group mixture solution repeated after 20 minutes of incomplete ocular akinesia.

Similarly in Group B, out of 100 patients 98 (98%) had complete ocular akinesia and required no supplementary block while only 02 (2%) patients had inadequate ocular akinesia and supplementation block

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of same group mixture solution repeated after 20 minutes of incomplete ocular akinesia.

Both the Groups A and B when compared, supplementary blocks needed after 20 minutes of incomplete ocular akinesia where found to be significantly higher in Group A (10 %) than when supplementary blocks needed after 20 minutes of incomplete ocular akinesia compared in Group B (2%).

D) Complications of Peribulbar Block

<table>
<thead>
<tr>
<th>Group</th>
<th>Lid Ecchymosis No. (%)</th>
<th>Conj. Chemosis No. (%)</th>
<th>Sub Conj. Haemorrhage No. (%)</th>
<th>Scleral Perforation No. (%)</th>
<th>CRAO or CRVO No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>4 (4%)</td>
<td>12 (12%)</td>
<td>2 (2%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>B</td>
<td>-</td>
<td>6 (6%)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Lid Ecchymosis

In group A, 4 (4%) patients developed skin eyelid Ecchymosis following peribulbar block whereas no such case found in group B patients. Lid Ecchymosis in both the groups when compared was not much significant.

Conjunctival Chemosis

Out of 100 patients in each group, only 12 (12%) patients in group A and 6 (6%) in group B had conjunctival chemosis following the peribulbar block but the surgery was completed without any problem. The incidence of conjunctival chemosis in Group A found to be significantly higher than in Group B.

Sub- Conjunctival Haemorrhage

In Group A 2 (2 %) patient had sub-Conjunctival haemorrhage after peribulbar block but no difficulty occurred during cataract surgery whereas no such case was found to be in Group B. Sub Conjunctival haemorrhage was not significant in both the groups.

None of the patients in both the groups had any complications such as scleral perforation, orbital floor perforation, optic nerve damage or any systemic complications.

DISCUSSION

In the present study the patients were divided into Group A and B depending upon the type of anaesthetic solutions used for their peribulbar block. The key identify of the anaesthetic solution was disclosed at the end of the study and grouped the patients accordingly into Group A and Group B. In our study conducted on 200 consecutive patients, the time of onset of ocular akinesia in both the groups were studied and compared at the end of study. The mean of onset time of complete ocular akinesia in Group who received plan 0.5 % bupivacaine with hyaluronidase (pH 5.54) was found to be 13.9 ± 0.79 minutes. As compared to Group B, patients who received 0.05 % pH adjusted bupivacaine with hyaluronidase (pH 7.05), the mean of onset time of complete ocular akinesia was 4.96 ± 0.52 minutes. This was significantly more rapid in onset then in Group A (p<0.05). The findings of this study are in accordance with those of Zahl’s et al., [16] who also reported the mean of onset time of complete ocular akinesia of 14.03 ± 2.3 minutes with plain 0.75% bupivacaine and hyaluronidase. As compared, the mean of onset time of complete ocular akinesia with pH adjusted bupivacaine and hyaluronidase was reported to be 5.3 ± 1.2 minutes. Similarly Zahl’s et al., [16] in their study of pH adjusted lignocaine and lignocaine-epinephrine mixture, reported quicker onset time for peribulbar anaesthesia as compared to non pH adjusted same anaesthetic solutions lignocaine and lignocaine and epinephrine mixture for peribulbar block.

In the present study, as evidenced by need of supplementation of peribulbar block after 20 minutes, it was observed that quality of ocular akinesia in terms of supplementation of blocks was better in patients where pH adjusted bupivacaine with hyaluronidase anaesthetic mixture as compared in patients where plain bupivacaine with hyaluronidase was used for peribulbar block. Out of 100 patients 98 (98%) had complete ocular akinesia and required no supplementary block in Group B while only two (2%) patients had inadequate ocular akinesia in supplementation block of same group mixture solution repeated after 20 minutes of incomplete ocular akinesia. In comparison 10 (10%) patients had inadequate ocular akinesia and supplementation block of same group mixture solution repeated after 20 minutes of incomplete ocular akinesia in group A where plain bupivacaine hyaluronidase solution was used for peribulbar block. Findings of our study are in agreement with the study that of Zahl’s et al who also reported a superior quality of peribulbar block in terms of supplementary injections after 20 minutes when pH adjusted 0.5 % bupivacaine with hyaluronidase mixture (pH 6.82) used for peribulbar blocks.

When we excludes the patients who required supplementary blocks after 20 minutes of peribulbar anaesthesia, the mean of onset time of complete ocular akinesia in both groups remain unaffected. In group A the mean of onset time (excluding supplementary block patients) was 12.42 ± 0.49 minutes as compared with
the mean of onset time of complete ocular akinesia was 4.55 ± 0.34 minutes in Group B. Students t-test (p<0.0001) was highly significant.

In the present study, it was observed that in both groups the mean of onset time of akinesia of individual recti muscles, the Superior Rectus (SR) muscle was earlier (8.0 ± 0.5 minutes in Group A and 3.2 ± 0.48 minutes in Group B) followed by Inferior Rectus (IR) muscle (8.6 ± 0.62 minutes in Group A and 3.2 ± 0.48 minutes in Group B), Medial Rectus (MR) muscle (11.7 ± 0.71 minutes in Group A and 4.2 ± 0.51 minutes in Group B) and lastly the mean of onset time akinesia was of Lateral Rectus (LR) muscle (13.5 ± 0.76 minutes in Group A and 4.9 ± 0.52 minutes in Group B). When mean of onset time complete akinesia of individual recti muscles of both the groups were compared, the mean of onset time of ocular akinesia of recti muscles was earlier in Group B patients where pH adjusted bupivacaine with hyaluronidase mixture of anaesthetic solution was used for peribulbar block.

Murdoch’s [17] studied, while comparing the peribulbar with retrobulbar anaesthesia, that the mean ocular movement of Medial Rectus muscle (1.9 mm) was more and anaesthetized last all recti, followed by Lateral Rectus muscle movements (1.6 mm), Inferior Rectus movements (1.0 mm) and Superior Rectus movements (0.8 mm). The present study slightly differs from Murdoch’s [17] study in terms of sequence of onset time of individual recti muscles. This could have been due to site location of anaesthetic mixture solution and local concentration of anaesthetic drugs near the muscle/nerve.

In the present study, the complications related to peribulbar block, the incidence of lid ecchymosis was more in Group A patients who received 0.05 % bupivacaine with hyaluronidase anaesthetic solutions as compared to nil patient of lid ecchymosis in Group B patients where pH adjusted bupivacaine with hyaluronidase anaesthetic mixture used. Similarly, only two (2%) had sub-conjunctival haemorrhage in group A patients at the time peribulbar block in comparison nil patients reported to develop sub-conjunctival haemorrhage. In our study, the sub-conjunctival chemosis was found to be most common complication in both the groups. In Group A, there were 12 (12 %) cases of sub-conjunctival chemosis during peribulbar block as compared to 6 (6%) in Group B patients in which pH adjusted bupivacaine with hyaluronidase anaesthetic solution used for peribulbar block.

CONCLUSION
It was concluded in the present study that the efficacy of pH adjusted bupivacaine with hyaluronidase anaesthetic solution (pH 7.05) produced better results in terms of rapid onset time of complete ocular akinesia, reduced requirements of supplementary injections and decreased incidences of complications following peribulbar blocks as compared to plain bupivacaine with hyaluronidase anaesthetic solution (pH 5.54). Alkalination of bupivacaine and hyaluronidase with sodium bicarbonate hastened the onset time, decreased need of supplementary blocks after partial ocular akinesia and improved the success rate of peribulbar block.

REFERENCE