

Comparative Evaluation of Ropivacaine and Lignocaine with Ropivacaine, Lignocaine, and Clonidine Combination during Peribulbar Anesthesia for Cataract Surgery

G R Rajashree¹, K Kala², Heber Anandan³

¹Professor, Department of Anaesthesiology, Institute of Anaesthesiology and Critical Care, Rajiv Gandhi Government General Hospital, Madras Medical College, Tamil Nadu, India, ²Senior Resident, Department of Anaesthesiology, Velammal Medical College Hospital and Research Institute, Madurai, Tamil Nadu, India, ³Senior Clinical Scientist, Department of Clinical Research, Dr. Agarwal's Eye Hospital, Tamil Nadu, India

Abstract

Background: Peribulbar is the most commonly used technique of anesthesia in cataract surgery, and ropivacaine is a new amino amide local anesthetic with the safer pharmacological profile.

Aim: A double-blind, prospective, and randomized study carried out in our institution after getting approval from the Ethical Committee, to compare the anesthetic effects of ropivacaine with the combination of ropivacaine and clonidine in the administration of peribulbar block in cataract surgery.

Materials and Methods: A total of 80 patients of both sexes aged 40–80 years of ASA PS I, II, scheduled for cataract surgery was included in this study. Patients were allocated to two groups of 40 each; ropivacaine, lignocaine group (R group) who received peribulbar block with 2.5 ml of lignocaine (2%) + 2.5 ml of ropivacaine (0.75%) + 50 units of hyaluronidase to a total volume of 5 ml and ropivacaine, lignocaine, clonidine group (RC group) received peribulbar block with 2 ml lignocaine (2%) + 2 ml of ropivacaine (0.75%) + 50 units of hyaluronidase + 1 µg/kg of clonidine to a total volume of 5 ml. Heart rate (HR), mean arterial pressure (MAP), pulse oximetry (SpO₂), intraocular pressure (IOP), and quality of peribulbar block were observed throughout the intraoperative period at regular intervals. Duration of analgesia was observed in the post-operative period.

Results: Demographic characteristics, SpO₂ were comparable in both groups. The onset of sensory and motor blockade was significantly earlier in RC group. IOP does not vary significantly in both groups. The HR, MAP was on the lower side in RC group. The duration of analgesia was prolonged in RC group (6.16 h) as compared to R group (3.48 h).

Conclusion: On adding clonidine to local anesthetic agent augments early onset and prolonged offset of sensory analgesia. It also reduces the volume of local anesthetic requirement. They maintain the hemodynamic throughout the procedure.

Key words: Peribulbar block, Ropivacaine, Clonidine, Cataract surgery

INTRODUCTION

Regional anesthesia is the common technique for most of the surgeries within the orbit. In our institution, cataract surgery is commonly carried out under regional anesthesia.^[1]

Regional anesthesia for ophthalmic surgery can be administered by the anesthesiologist, provided they receive appropriate training in performing the technique and are fully conversant with the associated risks and complications and can treat them accordingly. Regional anesthesia is a better alternative, whenever general anesthesia is undesirable or contraindicated.^[1]

Today anesthesia for cataract surgery needs a comfortable environment for both patient and surgeon during surgery and recovery of function quickly without risk. There is only a limited role for general anesthesia which is indicated especially in cases where topical or local anesthesia is contraindicated.^[1]

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Corresponding Author: Dr. K Kala, Department of Anaesthesiology, Velammal Medical College Hospital and Research Institute, Madurai, Tamil Nadu, India. Phone: +91-9486549716. E-mail: drkalak@gmail.com

The two most commonly used regional anesthesia techniques are retrobulbar block and peribulbar block. They provide adequate anesthesia for surgery of cornea, anterior chamber, and lens. Retrobulbar block technique involves deposition of the drug into the muscle cone, so termed as the intraconal block. Peribulbar block technique involves deposition of the drug outside the muscle cone so termed as an extraconal block.^[1-4]

Peribulbar anesthesia was first performed by Kelman in 1970, which was unpublished. Then, the use of peribulbar block was reported by Davis and Mandel in 1985.^[5] It offers a measure of safety as the drug is deposited outside the muscle cone but within the orbit. It is very easy to perform and less painful. No need for accessory facial nerve block less chance of retrobulbar hemorrhage, perforation of the globe and optic nerve injury.

The complications and need for accessory facial nerve block in case of the retrobulbar block have lead to the popularity of peribulbar block in ocular anesthesia.

In our study, we compare the efficacy of peribulbar block in cataract surgeries with combination of 1:1 mixture of 0.75% ropivacaine with 2% lignocaine and 1:1 mixture of 0.75% ropivacaine with 2% lignocaine with 1 µg/Kg of clonidine regarding the time of onset of sensory blockade, motor blockade, intraoperative hemodynamics, and duration of analgesia.

Aim

The aim of the study was to compare the onset of blockade and duration of analgesia using ropivacaine and lignocaine with ropivacaine and lignocaine and clonidine combination for a peribulbar block in cataract surgery.

MATERIALS AND METHODS

A total of 80 patients of ASA Grades I and II patients of both sexes aged 40–80 years undergoing cataract surgery are included in this clinical trial. Written informed consent is obtained from all patients.

This study is a prospective, randomized, double-blind study conducted in Regional Institute of Ophthalmology, Chennai, after getting approval from the Ethical Committee. Informed consent was obtained, and the procedure was explained to the patient in his/her own language. An initial preoperative counseling and reassurance were done.

80 patients were allocated into two groups - R Group, RC Group on the basis of simple randomization.

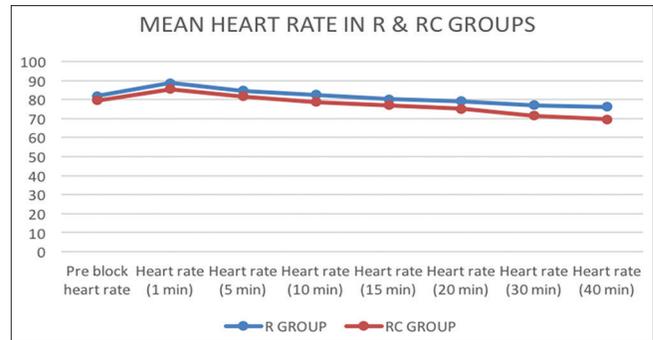


Figure 1 : Comparison of mean heart rate in R group and RC group

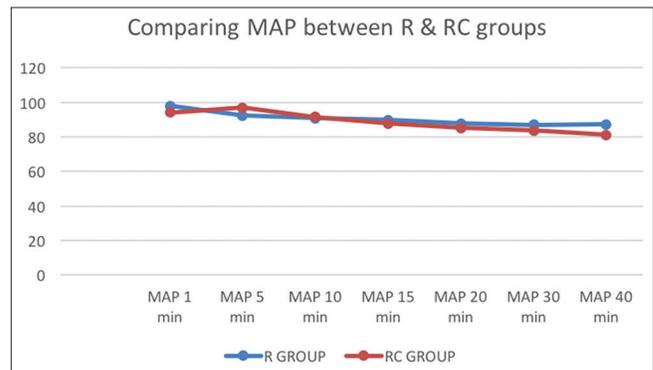


Figure 2: Comparison of mean arterial pressure in R group and RC group

R Group - consists of 40 patients receive peribulbar block with 2.5 ml of lignocaine (2%) + 2.5 ml of ropivacaine (0.75%) + 50 units of hyaluronidase.

RC Group - consists of 40 patients receive peribulbar block with 2 ml lignocaine (2%) + 2 ml of ropivacaine (0.75%) + 50 units of hyaluronidase + 1 µg/kg of clonidine.

Patients in both the groups were of comparable demographic status.

Inclusion Criteria

The following criteria were included in this study:

- Adults 40–80 years
- Both sex
- ASA PS I and II
- Side of eye R/L
- Duration of surgery 20–50 min
- Weight 40–80 Kg.

Exclusion Criteria

The following criteria were excluded from the study:

- Patient with active ocular infection
- Patient on any anti-glaucoma medications
- Patient with a single eye
- Patient allergic to amide-type local anesthetics

Table 1: Comparison of peribulbar block characteristics

| Block characteristics | Mean difference | S.E difference | 95% C.I | | P |
|-----------------------------------|-----------------|----------------|-------------|-------------|-------|
| | | | Lower bound | Upper bound | |
| Onset of sensory anesthesia (min) | 2 | 0.138 | 1.73 | 2.27 | <0.01 |
| Onset of motor blockade (min) | 2.68 | 0.222 | 2.23 | 3.12 | <0.01 |
| Duration of analgesia (h) | -2.68 | 0.165 | 3.01 | -2.35 | <0.01 |

S.E: Standard error, C.I: Confidence interval

Table 2: Comparison of peribulbar block characteristics in both groups

| Block characteristics (mean±SD) | Group R | Group RC | P |
|---------------------------------|------------|------------|-------|
| Onset of sensory blockade (min) | 4.93±0.656 | 2.93±0.572 | <0.01 |
| Onset of motor blockade (min) | 8.23±0.974 | 5.55±1.01 | <0.01 |
| Duration of analgesia (h) | 3.48±0.72 | 6.16±0.75 | <0.01 |

SD: Standard deviation

- Patient with cardiac disease
- ASA PS, III, and IV
- Patient refusal.

All patients are examined thoroughly in pre-operative room. Baseline parameter such as heart rate (HR), blood pressure (BP), electrocardiography (ECG), and baseline investigations such as hemoglobin, blood sugar, urea, and creatinine, should be checked.

In operation room, Boyle's machine, oxygen source, oxygen cylinder, appropriate airway equipment, and emergency drugs were made ready.

The patient was shifted to the operating room. The monitors were connected. Intravenous access was secured. Baseline HR, non-invasive BP, ECG, oxygen saturation noted, and intraocular pressure (IOP) were also recorded using eye care machine.

Peritubular block was performed as described by Davis and Mandel technique which was modified by Bloomberg.

The patient was asked to maintain the eye in primary gaze directly ahead. Eye was painted with povidone-iodine. A 22G 2.5 cm needle was inserted in inferotemporal region through the skin at the junction of lateral 1/3rd and medial 2/3rd of lower orbital margin once the needle was under the globe, it was directed along the orbital floor up to the depth of midorbit in the lateral extraconal space and not an upward and inward direction to avoid injury to optic nerve. After careful negative aspiration, 3 ml of the local anesthetic drug was given.

The second injection was given in supranasal area by inserting the same needle through upper eyelid vertically above the medial canthus to a depth of 2 cm. 2 ml of local

anesthetic was given. Manual compression and massage of eyeball were done to spread the local anesthetic solution.

The patient was assessed for a sensory block at 2–7 min, motor block at 4–10 min, and IOP at the 1st min. The HR, systolic BP, and diastolic pressure were monitored at 1, 5, 10, 15, 20, 30, and 40 min.

Sensory Block

Sensory block was tested by the loss of sensation of cornea with a wisp of cotton. This assessment was done at 2–7 min after injection. The onset of sensory block was taken from the time from injection to loss of sensation of the cornea.

Motor Block

Ocular globe mobility was tested in four quadrants using three-point scoring system.

Score-0 Akinesia (ocular movement <1 mm)

Score-1 Reduced movement (ocular movement >1 mm but <4 mm)

Score-3 Normal movement (ocular movement >4 mm).

This scoring system gives a maximal aggregated score of 8 for the four muscles. A score <2, reduced movement in all direction, was taken to indicate a successful block. Once successful block had been achieved, no further assessment was made.

Quality of Surgical Anesthesia

Surgical anesthesia was graded as follows:

- Excellent: No pain at any time during surgery
- Good: Minimal pain or discomfort
- Poor: Failed block.

Intraoperatively oxygen 4 L/min was given through nasal cannula to all patients under sterile drapes.

The patient was shifted to the post-operative ward after completion of surgery. Duration of pain relief was assessed in these patients. Pain assessment was done using visual analog scale (VAS) score. VAS score >3 indicates pain.

Duration of effective analgesia was defined as time interval between peribulbar block and the time to reach VAS score >3.

Table 3: IOP between R and RC groups

| Intraocular pressure | Mean±SD | Mean difference | S.E difference | 95% C.I | | P |
|----------------------|------------|-----------------|----------------|-------------|-------------|------|
| | | | | Lower bound | Upper bound | |
| Pre-block IOP | | | | | | |
| R group | 11.28±1.36 | 0.35 | 0.33 | -0.3 | 1 | 0.28 |
| RC group | 10.93±1.56 | | | | | |
| Post-block IOP | | | | | | |
| R group | 15.18±1.89 | -0.75 | 0.43 | -1.6 | 0.103 | 0.08 |
| RC group | 15.93±1.94 | | | | | |

IOP: Intraocular pressure, SD: Standard deviation, S.E: Standard error, C.I: Confidence interval

Table 4: Incidence of side effects

| Side effects | R group (%) | RC group (%) |
|--------------|-------------|--------------|
| Nausea | 0 (0) | 0 (0) |
| Headache | 3 (7.5) | 2 (5) |
| Vomiting | 1 (2.5) | 0 (0) |
| Dry mouth | 0 (0) | 3 (7.5) |

Resolution of motor blockade could not be assessed, as these patients eye were bandaged and covered after the operation.

The data collected were subjected to statistical analysis. The patient group was comparable in the distribution of age and sex. These characteristics were analyzed using Student's *t*-test and Pearson's Chi-square test.

RESULTS

The mean time of onset of sensory blockade in the R group was 4.93 min, and RC group was 2.93 min. The mean difference was 2, with 95% confidence interval (C.I) ranging from 1.73 to 2.27. The onset of sensory anesthesia was 2 min earlier on an average in the RC group. The difference was statistically significant.

The onset of the motor blockade in R group was 8.23 min, and RC group was 5.55 min. The mean difference was 2.68 with 95% C.I ranging from 2.23 to 3.12. The onset of motor blockade was 2.68 min earlier on an average in the RC group. The difference was statistically significant.

The mean duration of analgesia in the R group was 3.48 h, and RC group was 6.16 h. The mean difference was -2.68 with 95% C.I ranging from 3.01 to -2.35.

The difference was statistically significant. Participants in the RC group had analgesia lasting for an average of 2.68 h more than the R group Table 1 and 2.

There was a transient increase in HR in the 1st min after administering peribulbar block in both the groups. It declined gradually after that patient in the RC group had a

more stable decline in HR compared to the R group; the difference was statistically significant after 20 min.

Overall, the RC group of patients had a significantly lower HR on an average than the R group Figure 1.

Similar results were observed with the systolic BP, diastolic BP, and mean arterial pressure (MAP) between the R group and RC group of patients. Throughout the entire period, RC group of patients had a lower BP on an average, and the difference was statistically significant Figure 2.

The difference in IOP between the two groups pre-block and after administering the block was not statistically significant. There was no significant variation in IOP between the two groups Table 3.

None of the participants experienced nausea. 3 participants in the R group had a headache, compared to 2 in the RC Group, 1 participant in the R group had vomiting, while none in the RC Group, 3 participants in the RC group reported dry mouth as a side effect, which was absent in the R group Table 4.

DISCUSSION

The use of regional anesthesia is popular in ophthalmic surgery because it is associated with less hemodynamic and less respiratory complications with good recovery compared to general anesthesia. This is because of improved surgical technology, reduced operating time, and improvement in anesthetic techniques.

The two commonly used regional anesthesia technique in ophthalmic surgery is retrobulbar block and peribulbar block.

The complications of the retrobulbar block are rare but severe when it occurs. The complications are severe retrobulbar hemorrhage, extraocular muscle paralysis, direct optic nerve injury, central retinal vascular occlusion, ocular perforation, contralateral amaurosis, and systemic local anesthetic toxicity.

To avoid these complications, Davis and Mandel introduced peribulbar block. It is associated with less complication when compared to retrobulbar block.

Hence, nowadays, peribulbar block is chosen as a safe and effective technique.

In our Institute of Ophthalmology, the protocol is to use lidocaine alone for cataract surgery. However, the lidocaine-ropivacaine mixture for the peribulbar block has an advantage of lidocaine faster onset time and ropivacaine longer post-operative pain relief. Thus, this mixture is better compared to lignocaine alone.

This study was conducted in our institution where we used the mixture of ropivacaine, lignocaine, and clonidine. The aim of the study is to find out the usefulness of clonidine in prolongation of the duration of analgesia.

On the statistical analysis of the data obtained from the group of 80 patients with similar demographic profile showed that there is a statistically significant difference between R group and RC group about sensory and motor blockade. The onset of sensory blockade was 2 min earlier on an average in RC group. The onset of motor blockade was 2.68 min earlier on an average in RC group. This corresponds to study conducted by Khan *et al.*,^[11] who concluded that the addition of clonidine augments early onset of sensory blockade.

Regarding duration of analgesia, our study showed a statistically significant difference in prolongation of the duration of analgesia in RC group. The analgesia lasting for an average of 2.68 h in RC group compared to R group which corresponds to study conducted by Mjehed *et al.*^[6] which showed the addition of clonidine prolongs the duration of action.

The total volume of local anesthetics used in R group is 5 ml (with 2.5 ml lignocaine [2%] + 2.5 ml of ropivacaine [0.75%] +50 U hyaluronidase) and in RC group is 5 ml (with 2 ml lignocaine [2%] + 2 ml of ropivacaine [0.75%] +50 units of hyaluronidase + 1 µg/kg of clonidine). From our study, the total volume of local anesthetics required for the blockade is reduced. This corresponds to study by Bajwa *et al.*^[7] which showed the addition of clonidine to ropivacaine results in effective, complete and longer analgesia with the similar blockade and there is the reduction in the effective dose of ropivacaine when compared with plain ropivacaine for cesarean delivery.

From the statistical analysis obtained from our study the difference in IOP between the two groups pre-block and after administering the block was not statistically significant.

There was no significant variation in IOP between the two groups. This corresponds to the study by Connolly *et al.*^[8] which concluded that there were no differences between groups with respect to pain. There was no difference with respect to onset of akinesia. This study revealed no significant difference in baseline IOP and posted peribulbar IOP.

In our study, we have used 0.75% ropivacaine. Ropivacaine is a pure S-enantiomer drug compared to Bupivacaine which contains both S and R enantiomer. Ropivacaine is less cardiotoxic and has better akinesia which corresponds to study by

Gillart *et al.* which showed that 1% ropivacaine may be a better agent than 0.5% bupivacaine for single medial injection technique of peribulbar anesthesia. This in addition of lidocaine, it provides better akinesia and similar analgesia.^[9]

This also corresponds to the study by Gioia *et al.* which concluded that use of 0.75% or 1% concentrations are preferred in that they provide quick sensory and motor blockade.^[10]

The results of our study showed that there is a statistically significant difference in HR, BP in two groups. Patients in the RC group had a more stable decline in HR compared to the R group; the difference was statistically significant after 20 min. Throughout the entire period, RC group of patients had a lower BP on an average. This corresponds to study by Mjehed *et al.*,^[6] they concluded that the addition of clonidine to lidocaine increase the duration of analgesia and akinesia, with relatively stable hemodynamic parameters.

There is an increase in HR and BP at 1 min in both the groups. This corresponds to study of Luchetti *et al.* which compares ropivacaine 0.75% versus bupivacaine 0.5% - mepivacaine 2% for the peribulbar block. After injection of local anesthetic drug increase in MAP and HR noted in both the groups after 1 min.^[11]

In our study, the incidence of side effects in both groups was observed. No one experienced nausea. 3 participants in the R group has headache, compared to 2 in the RC Group, 1 participant in the R group had to vomit, while none in the RC Group, 3 participants in the RC group reported, dry mouth as a side effect, which was absent in the R Group.

This corresponds to study of Khan *et al.* which showed side effect profile revealed a higher incidence of nausea, vomiting, headache, and dizziness in R Group, while a considerably higher incidence of dry mouth was observed in RC Group.^[11]

CONCLUSION

We conclude from our study that addition of clonidine to ropivacaine-lignocaine mixture provides better sensory, motor blockade and significantly prolongs the duration of analgesia compared to ropivacaine-lignocaine mixture alone. It reduces the volume of local anesthetics. It maintains stable hemodynamics throughout the procedure.

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