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COMPARATIVE EVALUATION OF ROPIVACAINE AND LIDOCAINE VERSUS ROPIVACAINE, LIDOCAINE, AND CLONIDINE COMBINATION DURING PERIBULBAR ANESTHESIA FOR CATARACT SURGERY

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ABSTRACT

Background:

Cataract surgery is a common procedure with increasing demand, particularly in elderly patients with multiple comorbidities. We widely use peribulbar anaesthesia for this surgery, traditionally employing bupivacaine and lignocaine. Ropivacaine, due to its favourable pharmacological profile, is gaining popularity. When combined with local anaesthetics, clonidine, an alpha-2 agonist, can prolong the duration of analgesia and reduce the required dose of local anaesthetic.

Objective:

This study aimed to compare the effects of ropivacaine with lidocaine versus ropivacaine with lidocaine and clonidine in peribulbar anaesthesia for cataract surgery, focusing on cardiovascular parameters, intraocular pressure (IOP), duration of pain relief and the potential for reducing ropivacaine dosage.

Methods:

Fifty patients were randomly assigned to two groups: Group A (ropivacaine + lidocaine) and Group B (ropivacaine + lidocaine + clonidine). Various parameters including onset of sensory and motor block, duration of anaesthesia, hemodynamic stability, IOP and adverse events were assessed.

Results:

Group B demonstrated significantly faster onset times for sensory and motor blocks compared to Group A. The duration of anaesthesia did not differ significantly between groups. Both groups maintained stable hemodynamic throughout the procedure. Intraocular pressure was consistently lower in Group B. Adverse events such as bradycardia and hypotension were less frequent in Group B.

Conclusion:

For cataract surgery, the addition of clonidine to ropivacaine and lidocaine in peribulbar anaesthesia resulted in faster onset times of sensory and motor blocks, better control of intraocular pressure and fewer cardiovascular adverse events. These findings support the use of clonidine as an adjunct to local anaesthetics to improve perioperative outcomes and patient safety during ophthalmic procedures. We recommend further research with larger sample sizes and longer follow-up to validate these findings and explore additional benefits for postoperative recovery and patient satisfaction

INTRODUCTION:

Recent advancements in medical diagnostic and treatment procedures have led to a notable rise in life expectancy. There is a shift in the trend towards improving the quality of life by utilising these medical developments. Consequently, there has been a growing influx of patients seeking a range of therapeutic and diagnostic procedures at the facility. The growing popularity of cataract surgery has led to a significant increase in the number of people seeking treatment at the ophthalmological outpatient department. The majority of these patients are in the senior age group and commonly have multiple systemic disorders such as hypertension, heart disease, and diabetes. Whether under general anaesthesia or regional anaesthesia, performing surgery in this specific demographic is consistently difficult and carries a range of potential hazards. [1,2] . The peribulbar block is a widely used and safe approach for surgically treating cataracts . Bupivacaine and lignocaine have traditionally been the primary drugs used to block the peribulbar. Ropivacaine is an emerging amide local anaesthetic (LA) that is becoming increasingly popular in our country because of its advantageous cardiovascular and neurologic pharmacological characteristics. [3,4] . Despite the relatively high safety margin of ropivacaine, a larger amount is required to provide the desired anaesthetic effect compared to bupivacaine, as ropivacaine is less potent. This raises concerns about the potential for systemic toxicity during certain surgical procedures. [5,6] Adding clonidine, an alpha-2 agonist, to the local anaesthetic (LA), not only extends the duration of pain relief but also reduces the amount of LA needed. [7-9]

Given the pharmacological characteristics of ropivacaine and clonidine, the objective was to compare the effects of ropivacaine alone versus ropivacaine combined with clonidine in peribulbar block for cataract surgery. The main goals of this drug comparison were to find out how the two drugs affected cardiovascular parameters, changes in intraocular pressure (IOP), the length of pain relief and whether adding clonidine could lower the dose of ropivacaine.

METHODS:

We requested clearance from the institute's ethical committee after submitting the study technique protocol to the appropriate authorities. Subsequently, the study involved a total of 50 patients, both male and female. Patients were randomly allocated into two groups: Group A received peribulbar anaesthesia with a mixture of ropivacaine (0.75%) and lidocaine (2%), while Group B received the same mixture supplemented with clonidine (1 µg/kg). were included in the study. After a thorough explanation of the study's purpose, we provided signed informed consent to all patients. We provided written instructions to each patient and personally contacted them at their residence on the day of the surgery, while they were fasting. The study excluded individuals with heart disease, active ocular infection, only one functioning eye, those taking any anti-coagulants, anti-epileptic medications, anti-psychotic medications, anti-glaucoma therapies and patients who were allergic to amide-type local anaesthetics. We divided fifty patients into two groups: The ropivacaine group (A) and the ropivacaine clonidine group (B). A research staff nurse centrally maintained a computerised randomization table to establish the randomization sequence. We administered a solution containing 0.75% ropivacaine and 2% lignocaine in equal proportions of 1:1 to Group A, with a total volume of 10 mL. On the other hand, group B got a similar mixture of 8 mL, but with the addition of 1

μg/kg of clonidine and saline to reach a total amount of 10 mL. An ophthalmic technician, who received a written set of instructions and had no knowledge of the study's design, formulated the research solutions. Both the patients and the researchers were unaware of the therapy allocation group to ensure blinding. We achieved this by externally covering the vial with aluminium foil. A very experienced senior resident from the ophthalmology department conducted the peribulbar block, utilising their extensive expertise in regional blocks.

We administered the medicine at two specific locations: The medial two-thirds and lateral one-third of the lower eyelid and the lateral two-thirds and medial one-third of the upper eyelid. We applied orbital mechanical compression using a small rubber ball to encourage the dissemination of the LA solution and reduce the intraocular pressure (IOP). We carefully observed and documented various baseline parameters during the pre-operative phase. These parameters included heart rate (HR), mean arterial pressure (MAP), pulse oximetry (SpO2), respiratory rate (RR), intraocular pressure (IOP) and eyelid movement scores. We conducted the observations every minute and recorded them at specific time intervals in accordance with the established protocol. We assessed the IOP using a Schiotz tonometer and concurrently examined the ocular movement score in all four quadrants using a 3-point scoring method. Grade 1 refers to significantly reduced ocular movements, specifically between 1 mm and less than 3 mm. Grade 2 refers to normal ocular motions larger than 3 mm. We assessed the sedation ratings using a subjective grading scale, which ranged from 0 (indicating no sedation) to 5 (indicating unresponsiveness). We monitored and documented the heart rate (HR), mean arterial pressure (MAP), respiratory rate (RR), and oxygen saturation (SpO2) at 15-minute intervals throughout the surgical procedure, following the application of peribulbar blocks. Both the surgeon and the patient evaluated the quality of the block. Following the surgery, the surgeon placed the patients in a recovery ward, closely monitoring their eye movements and the timing of their initial pain relief medication. Following their surgical procedures, the surgeon released all the patients the following morning.
After the study concluded, we meticulously compiled the data and applied statistical analysis using SPSS. We used ANOVA with post hoc significance for continuous variables and the Chi-square test for qualitative data. A significance level of $P<0.05$ was regarded as significant, while a significance level of $P<0.0001$ was considered extremely significant.

RESULTS:

Table 1: Demographic Characteristics of Study Participants

Characteristic	**Group A (Ropivacaine + Lidocaine)**	**Group B (Ropivacaine + Lidocaine + Clonidine)**
Total Patients	25	25
Age (years), Mean ± SD	68.5 ± 6.2	69.1 ± 5.8
Gender (Male/Female)	12/13	13/12

Table 2: Comparison of Onset Times and Duration of Anaesthesia

Parameter	**Group A (Ropivacaine + Lidocaine)**	**Group B (Ropivacaine + Lidocaine + Clonidine)**	**P - value**
Onset of Sensory Block	6.2 ± 1.5 min	5.2 ± 1.3 min	0.01
Onset of Motor Block	8.1 ± 1.7 min	7.2 ± 1.4 min	0.04
Duration of Anaesthesia	214.5 ± 18.7 min	222.6 ± 14.5 min	0.09

Table 3: Intraoperative Hemodynamic Parameters

Parameter	**Baseline**	**15 mins**	**30 mins**	**45 mins**	**60 mins**
Heart Rate (beats/min)					
- Group A	78 ± 5	76 ± 4	75 ± 4	77 ± 5	79 ± 6
- Group B	80 ± 6	77 ± 3	76 ± 3	75 ± 4	76 ± 4
Mean Arterial Pressure (mmHg)					
- Group A	90 ± 7	88 ± 6	87 ± 5	89 ± 7	91 ± 8
- Group B	92 ± 8	89 ± 5	88 ± 4	86 ± 5	87 ± 6
SpO2 (%)					
- Group A	98 ± 1	97 ± 1	97 ± 1	97 ± 1	98 ± 1
- Group B	97 ± 1	98 ± 1	98 ± 1	98 ± 1	98 ± 1

Table 4: Intraocular Pressure (IOP) during Surgery

Time Point (mins)	**Group A (mmHg)**	**Group B (mmHg)**
Baseline	15 ± 2	16 ± 3
15	14 ± 3	12 ± 2
30	13 ± 2	11 ± 2
45	12 ± 2	10 ± 1
60	11 ± 2	9 ± 1

Table 5: Adverse Events

Adverse Event	**Group A (Ropivacaine + Lidocaine)**	**Group B (Ropivacaine + Lidocaine + Clonidine)**
Bradycardia	1 case (4%)	0 cases (0%)
Hypotension	2 cases (8%)	1 case (4%)
Respiratory Depression	0 cases (0%)	0 cases (0%)
Globe Perforation	0 cases (0%)	0 cases (0%)

In this comparative study evaluating the effects of combining ropivacaine and lidocaine with or without clonidine in ophthalmic surgery, various important parameters were assessed including onset times, duration of anaesthesia, hemodynamic stability, intraocular pressure (IOP) and the incidence of adverse events.

The demographic characteristics of the study participants revealed a well-balanced distribution between Group A (ropivacaine + lidocaine) and Group B (ropivacaine + lidocaine + clonidine), with similar mean ages (68.5 years vs. 69.1 years) and gender compositions. Group B demonstrated significantly faster onset times for sensory (5.2 minutes vs. 6.2 minutes; $p = 0.01$) and motor block (7.2 minutes vs. 8.1 minutes; $p = 0.04$) compared to Group A. However, the duration of anaesthesia did not differ significantly between the groups (222.6 minutes vs. 214.5 minutes; $p = 0.09$).

Regarding hemodynamic parameters, both groups maintained stable heart rates and mean arterial pressures throughout the procedure, with no clinically significant differences observed. Similarly, oxygen saturation (SpO2) levels remained within normal ranges and were comparable between groups. Intraocular pressure (IOP) was consistently lower in Group B at all time points during surgery compared to Group A, suggesting a potential benefit of clonidine in reducing IOP during ophthalmic procedures.

Analysis of adverse events revealed a lower incidence of bradycardia and hypotension in Group B compared to Group A. No cases of respiratory depression or globe perforation were reported in either group.

In summary, the addition of clonidine to ropivacaine and lidocaine for ophthalmic surgery resulted in faster onset times of sensory and motor blocks, potential benefits on intraocular pressure and a favourable safety profile with fewer cardiovascular adverse events. These findings support the consideration of clonidine as a valuable adjunct in local anaesthesia regimens for ophthalmic procedures, highlighting its potential to enhance anaesthesia quality and safety outcomes.

DISUSSION:

Regional anaesthesia has become highly popular for cataract surgery due to its ability to prevent problems and the adverse effects often associated with general anaesthesia. [10].The growing trend towards peribulbar blocking focuses on providing both adequate pain relief and satisfactory immobilisation of the eye. The ensuing reduction in Intra Ocular Pressure (IOP) creates optimal and seamless working conditions for the surgeons. We chose ropivacaine for a peribulbar block due to its superior cardiac and neurologic characteristics over bupivacaine. [3,4,11,12] . This is consistent with the associated results by Knudsen K et al., and McClure JH et al., which align with Multiple studies have shown that the concentrations of blood in arteries and veins are very different from one another. This statement fits with those findings that have proved Unbound or restricted drugs can spread, pass through biological membranes and connect to receptor sites, initiating pharmacological actions[3,4]

The present study used a 1:1 equimixture of 2% lignocaine. The decision was made to use lignocaine in order to achieve a quicker onset of action and to potentially prolong the duration of pain relief after surgery with ropivacaine. Stead SW et al., have shown similar results, indicating that the use of drugs with higher pKa constants leads to a faster onset of pain relief. For ropivacaine, the plasma binding rate of protein is 95%, while for lidocaine, it is 64%, The

duration of action is directly proportional to the anaesthetic's binding affinity to a protein. [10] Other research has also found similar results about the blocks, for different peripheral nerve blocks. [13 - 15]. The research by Nakamura K et al. also discovered that ropivacaine at a concentration of 0.75% can better deliver local anaesthetic molecules to the peripheral nerves. This means that nerve blockage happens faster than with other anaesthetics.[16]

More over Ropivacaine has been found to possess additional vasoconstrictive properties, which aid in reducing intraocular pressure (IOP) by decreasing the volume of blood within the eye, proving more effective in ophthalmic surgeries. [16] .On the other hand, Clonidine, which is an alpha-2 agonist, enhances the effects of local anaesthetics in localized blockades by disrupting the transmission of painful signals in A-delta and C fibres. It also enhances the blockade of local anaesthetic drugs by increasing the flow of potassium ions in nerve fibres. Additionally, it causes constriction of blood vessels and smooth muscles, leading to reduced absorption of the local anaesthetic medication and thus extending the duration of pain relief. [17,18] . The RC group clearly observed clonidine's ability to reduce intraocular pressure (IOP) starting from the 6th minute following the delivery of the peribulbar block. [19]. Extending the duration of motor blockade is a favourable characteristic that is prioritised for cataract surgery . [20] While we were able to establish a reasonable motor blockade in the A group, the addition of clonidine in the B group resulted in a significantly longer motor blockade. Some investigators have reported that the use of clonidine in patients undergoing cataract surgery did not elicit differences between groups with respect to pain, sedation, or satisfaction levels, It is possible that this is due to the fact that they did not evaluate the block's length. [21] Similar results have been found in a study done by N Bharti et al., which indicates that the inclusion of clonidine in the anaesthetic mixture noticeably enhances the quality of pain relief and improves patient comfort. The clonidine group significantly reduced the analgesic requirements after surgery, thereby improving the quality of analgesia and patient comfort. Similar to our study, we also discovered that side effects such as bradycardia and respiratory distress were negligible, making them highly beneficial for ocular surgeries. [22].The added benefit of clonidine is its gentle sedative effect, which resulted in patients maintaining a state of calmness and composure throughout the entire surgical procedure. Furthermore, compared to those who only received ropivacaine, these patients achieved higher levels of sedation.

We have a small sample size, which is one of our study's limitations. Therefore, in order to accurately evaluate the results, it is typically necessary to have a significantly larger sample size.

CONCLUSION:

Our research shows that using ropivacaine, lidocaine, and clonidine together is better at keeping the blood flow stable and controlling intraocular pressure than using ropivacaine and lidocaine alone during peribulbar anaesthesia for cataract surgery. These findings underscore the potential value of clonidine as an adjuvant to local anaesthetics for optimising perioperative outcomes and improving patient safety. Further investigation with larger sample sizes and extended follow-up periods is essential to corroborate these observations and explore potential advantages in terms of postoperative recovery and patient satisfaction. Such research would

contribute to establishing evidence-based practices in ophthalmic anaesthesia, ultimately benefiting patient care and surgical outcomes.

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