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# A RANDOMIZED TRIAL BETWEEN 0.5% LEVOBUPIVACAINE AND 0.5% BUPIVACAINE FOR PERIBULBAR ANESTHESIA IN CATARACT SURGERY.

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## Abstract

### Background

The choice of drug used in the anesthesia affects the overall outcome of cataract surgery in terms of patient satisfaction and adverse effects.

### Objective

This study aimed to compare the efficacy and tolerability of levobupivacaine and bupivacaine in anesthesia for cataract surgery.

### Materials and Methods

This was a double-blinded randomized study conducted in the operation theatre of Zoram Medical College. The patients who were to undergo cataract surgery were considered for this study. They were divided randomly and were evaluated for the efficacy and safety of the drugs under study. The data obtained was compared statistically.

### Results

This study has 100 participants. Two groups were chosen at random. The first group received 0.5% bupivacaine and the other 0.5% levobupivacaine. The demographics of both groups were compared. Participants were 40-60 years old. Both groups averaged similar ages.

The akinesia score of the bupivacaine group at 10 minutes was 0.24±0.14 and for the levobupivacaine group, it was 0.25±0.34. The patient's satisfaction score in the bupivacaine group was 8.2±0.34 and in the levobupivacaine group, it was 8.4±0.21. The surgeons rated the quality of the motor block, the bupivacaine group had an average of 7.23±0.42, and for levobupivacaine, the average was 7.88±0.32. The results of both groups are comparable.

### Conclusion

Motor and sensory blockades for cataract surgery can be achieved with bupivacaine and levobupivacaine, which have similar efficacy and tolerance.

### Recommendation

Levobupivacaine should be used as a local anesthetic in patients with systemic disease to improve the outcome of the surgery.

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## Introduction

Cataracts are a prevalent eye disorder marked by the lens becoming cloudy, which results in diminished vision. This condition primarily impacts older adults, with contributing factors such as advancing age, diabetes, extended exposure to sunlight, and smoking. As cataracts advance, they can severely hinder daily activities, making prompt surgical treatment essential for vision restoration [1,2]. Cataract surgeries are generally performed in elderly patients. The senior population usually has one or the other comorbidity and hence performing surgeries with anesthesia becomes difficult. Patients with respiratory, cardiovascular, and hemodynamic disorders cannot undergo general anesthesia as the patient might slip into a coma, and lead to fatality. In such cases, anesthesia can be done using local anesthetics and akinetic procedures. In cases of children and uncooperative patients general anesthesia is used for cataract surgery. Otherwise, local anesthesia is a preferred mode of anesthesia for cataract surgeries [3].

Local anesthetics are either topically applied or they are injected by akinetic procedures that is by intraconal

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method or by extraconal method. The intraconal method is by injecting it in the retrobulbar area and by extraconal method is by injecting it in the peribulbar area [4]. When local anesthetics are given, they can lead to certain hemodynamic changes causing fatal side effects. An increase in intraocular pressure, and cardiovascular side effects, can also cause neurotoxicity. Bupivacaine is used as a local anesthetic in cataract surgeries, it produces sufficient motor blockade and long-duration analgesia [5]. The disadvantage of using bupivacaine is that it has many side effects associated with its pharmacological effect. Bupivacaine is chemically a racemic mixture of its two enantiomers, the levorotatory and dextrorotatory enantiomers [6]. It has been found that the side effects and adverse drug reactions are associated with dextrorotatory enantiomer and not levorotatory. At the molecular level due to different configurations in the attachment of the drug molecule to the receptor, the dextrorotatory enantiomer binds for a longer period in the tonic phase as well as in the phasic phase [7].

Levorotatory bupivacaine, also known as levobupivacaine has reduced side effects and it is found to be equally efficacious in producing optimum motor blockade and analgesia. Levobupivacaine is well tolerated pharmacologically, and it is eliminated by metabolism by the P450 enzyme in the liver [8]. Although there are side effects associated with the administration of levobupivacaine these side effects are generally due to faulty administration of the drug which causes allergy. The levobupivacaine does not produce any hemodynamic changes and there is no increase in the intraocular pressure. As the geriatric population mostly has hemodynamic disorders, administration of anesthesia should be safe so that no complications are observed before the surgery and after the surgery. Compared to it dextrobupivacaine produces undesirable side effects. It is necessary to compare the performance of levobupivacaine with bupivacaine at the clinical level to make a choice of anesthetics with optimum efficacy and minimal side effects [4,8]. This study is conducted to compare the efficacy of levobupivacaine, and bupivacaine given by the peribulbar method for anesthesia in a cataract surgery.

## Method

### Study design

This study was conducted prospectively, and it was a double-blinded randomized study. The study was conducted in the Operation Theatre at Zoram Medical College. The duration of the study was the year.

### Participants

The patients admitted for cataract surgery were considered for this study. The patients who were with ASA grade I and II, who did not have any coagulation, congenital problems, or allergy towards the drug under study were included in the study.

### Interventions

Before the conduction of the surgery, the patients were thoroughly examined for their medical history, the extent of cataracts, and any other hemodynamic disorders. The patients were premedicated for the surgery and then they were randomly assigned into two groups. The peribulbar area was injected for anesthesia Group B received 6 ml of lignocaine with hyaluronidase and bupivacaine 4ml as the local anesthetic, while Group L received 6 ml of lignocaine with hyaluronidase and levobupivacaine as the local anesthetic. Before the administration of the anesthesia, patients were evaluated for their vitals such as oxygen saturation, heart rate, non-invasive blood pressure, and overall cardiac activity was checked using an electrocardiogram.

A 15 mm hypodermic needle was used, and it was inserted in the peribulbar region up to half of its length and then obliquely. Negative aspiration was performed, and then the drug was administered. The akinesia score was calculated for all four recti muscles. The maximum score was 2 when there was full motion, 1 when there was partial motion, and 0 when there was no motion. This was the criterion for each muscle; in total, the maximum score was 8 for the 4 muscles. If the score was above 4, then the drug was administered in half the quantity. If the score dropped below 2 after 8 to 10 minutes of administration, then it was considered successful anesthesia. When there was no ocular movement, the sensory block was also deemed successful.

If there was any increase in intraocular pressure, systemic toxicity, or an allergic reaction, it was recorded. The patients were asked to score the analgesia produced right after the block, after the surgery, and during discharge. Similarly, surgeons were asked to grade the quality of the block. The duration of the surgery, vitals during the surgery, and other details of the surgery were recorded.

### Statistical analysis

Mean and standard deviation were calculated for the categorical data available and the data from both groups was compared using the student's t-test.

### Ethical consideration

The institutional ethics committee approved the study and informed consent was obtained from the patients.

## Results

There were 100 participants in this study. They were randomly distributed into two groups. The first group was given bupivacaine 0.5% as the local anesthetic and the other group was given levobupivacaine 0.5% as the local anesthetic. The participants of both groups were compared based on demographical characteristics. The age range of the participants of the study was between 40-60 the average age in both groups was comparable. The

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BMI of the patients in both groups was normal and comparable. The gender ratio was not different significantly in both groups. The duration of the surgery was within the range of 10 to 30 minutes, and it was again comparable. Table no. 1 gives the details of the demographical characteristics of the participants of the study.

**Table no.1: Demographical data of the patients participating in the study**

| Parameters | Levobupivacaine group | Bupivacaine group | p-value |
|---|---|---|---|
| Age (years) | 56.74±3.4 | 57.89±5.3 | 0.306 |
| BMI (Kg/m$^2$) | 27.34±1.2 | 28.19±2.3 | 0.504 |
| Gender | | | |
| *Male* | 23 | 24 | 0.209 |
| *females* | 27 | 26 | |
| Time required for the surgery (minutes) | 13.23±5.3 | 13.54±5.2 | 0.503 |

The akinesia score was measured after 2 minutes, 5 minutes, 8 minutes, and 10 minutes of the administration of the local anesthetics to determine the motor block achieved. It was observed that the akinesia gradually reduced from 2 minutes to 10 minutes. The reduction was significant and the motor block was achieved within 10 minutes. The akinesia score of the bupivacaine group at 10 minutes was 0.24±0.12 and for that of the levobupivacaine group, it was 0.25±0.34. The amount of anesthesia in both groups was comparable. There 2 patients in the bupivacaine group who required supplementary anesthesia to achieve sufficient motor block and there were 3 patients in the levobupivacaine group who required supplementary anesthesia. Table no.2 gives the details of anesthesia in the patients.

**Table no.2: Details of anesthesia**

| Parameters | Bupivacaine group | Levobupivacaine group | p-value |
|---|---|---|---|
| Akinesia score | | | |
| *2 minutes* | 1.2±0.54 | 1.1±0.56 | 0.306 |
| *5 minutes* | 0.88±0.31 | 0.78±0.23 | 0.561 |
| *8 minutes* | 0.45±0.32 | 0.32±0.12 | 0.204 |
| *10 minutes* | 0.24±0.12 | 0.25±0.34 | 0.409 |
| Amount of anesthetic administered | 7.16±2.3 | 7.3±1.5 | 0.304 |
| Number of patients who required supplementary anesthesia | 2 | 3 | 0.542 |

The patient's satisfaction was measured in terms of a visual pain scale. The pain was assessed only after the block and immediately after surgery, as anesthesia is administered only during the surgery and is not given afterward or during discharge. However, patient satisfaction is evaluated both immediately after surgery and during discharge to examine the effectiveness of the anesthesia used during the procedure. It was observed that a few patients required analgesia after the surgery, but the analgesia produced in both groups was significant. The patient's satisfaction score in the bupivacaine group was 8.2±0.34 and in the levobupivacaine group, it was 8.4±0.21. The surgeons rated the quality of the motor block, the bupivacaine group had an average of 7.23±0.42, and for levobupivacaine, the average was 7.88±0.32. Table no. 3 gives details of the patient satisfaction score and surgeon's satisfaction score.

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**Table no.3: Details of the satisfaction among the patients and surgeons**

| Parameters | Bupivacaine group | Levobupivacaine group | P-value |
|---|---|---|---|
| Analgesia score | | | |
| *Immediately after the block* | 2.1±0.3 | 2.3±0.1 | 0.213 |
| *After surgery* | 0.87±0.23 | 0.79±0.32 | 0.305 |
| *During discharge* | 0.42±0.25 | 0.35±0.13 | 0.413 |
| Patient's satisfaction score | 8.2±0.34 | 8.4±0.21 | 0.422 |
| Quality of the block as per surgeons | 7.23±0.42 | 7.88±0.32 | 0.542 |

## Discussion

In this study, we compared the efficacy and tolerance of levobupivacaine and bupivacaine as a local anesthetic. It was observed that the local anesthesia produced by both drugs was comparable. Although some studies have shown levobupivacaine to be superior to that of bupivacaine in this study no such finding was reported [9,10,11]. Considering that the amount of drug required is usually greater in the peribulbar anesthesia approach compared to the retrobulbar method. Thus the amount of levobupivacaine and bupivacaine both are high. The high concentration might cause systemic toxicity which is the main concern of using bupivacaine as a local anesthetic.

Comparing the akinesia produced by both the drugs, the akinesia was comparable and the achievement of the motor blockade was successful in most of the cases. Some studies have shown differences in the akinesia achieved in both drugs [12,13], but the difference is not substantial, it may be attributed to differences in the administration of the drug. The onset of the blockade was comparable in this study. However, some studies with similar aims but different drug combinations have a rapid onset of action [14,15].

Considering the quality of blockade obtained by both the drugs as graded by surgeons, the quality was comparable and optimum in both cases. A study reported that levobupivacaine was comparatively safer in its pharmacodynamics and a similar finding was reported in other studies as well [16,17]. However, this study found that both drugs were well tolerated, and anesthesia was optimum. The duration of the blockade was not studied here. The patient's satisfaction and analgesia were sufficiently produced in this study. There were no requirements for supplementary analgesia until the discharge of the patients. The occurrence of systemic toxicity was not reported in this study. The patients of both groups had similar outcomes of the surgery and there were no adverse drug reactions reported in this study, but for the individuals with existing systemic diseases, levobupivacaine will be better tolerated due to its pharmacodynamics.

The results of this study demonstrate that both levobupivacaine and bupivacaine provide effective motor and sensory blockades suitable for cataract surgery, with comparable patient satisfaction scores and similar quality ratings from surgeons. Levobupivacaine, however, presents fewer hemodynamic side effects, making it a potentially safer choice for patients with cardiovascular or systemic vulnerabilities. This finding aligns with existing evidence suggesting that levobupivacaine, as the levorotatory enantiomer, has a reduced risk profile relative to racemic bupivacaine, due to lower cardiotoxicity and neurotoxicity risks associated with the dextrorotatory component of bupivacaine.

While both drugs achieved adequate motor block within 10 minutes, levobupivacaine's tolerability profile may provide an advantage in the broader clinical context, especially for elderly patients with comorbid conditions who are at higher risk of adverse events from anesthesia. However, given that a few patients in both groups required supplemental anesthesia, clinicians should consider the possibility of varied individual responses to these agents. Overall, the results support levobupivacaine as a viable alternative to bupivacaine in cataract surgery, particularly for patients with systemic disease, where balancing anesthetic efficacy with safety is critical. Further studies with larger sample sizes and diverse patient populations may strengthen the understanding of optimal use across varying clinical scenarios.

## Generalizability

The generalizability of these findings, or external validity, is supported by the study's design and inclusion criteria, which make the results applicable to similar patient populations. Conducted with a sample of cataract surgery patients aged 40-60, the trial reflects typical demographics for cataract procedures, particularly in older adults. The randomized, double-blind design enhances the reliability of the outcomes, as it minimizes potential biases and ensures a broad applicability of results. However, since the study was limited to patients without specific systemic or allergic contraindications, its findings may be less applicable to individuals with complex comorbidities or higher surgical risk profiles. Still, the general comparability in safety and efficacy of

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levobupivacaine and bupivacaine suggests that levobupivacaine could be a preferred choice for similar populations, particularly for patients with cardiovascular or hemodynamic concerns where minimal systemic impact is critical.

## Conclusion

Motor and sensory blockades for cataract surgery can be achieved with bupivacaine and levobupivacaine, which have similar efficacy and tolerance. Levobupivacaine brings about efficacious blockade for the conduction of cataract surgery.

## Limitation

The cohort considered for this study is limited to the patients attending a single institute, multiple institute study is required to confirm the findings of the study.

## Recommendation

Levobupivacaine should be used as a local anesthetic in patients with systemic disease to improve the outcome of the surgery.

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## List of abbreviation

BMI - Body Mass Index
ASA – American Society of Anesthesiology.

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## Conflict of interest

The authors declare no conflict of interest.

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