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Comparative study of 0.5% bupivacaine and 0.5% levobupivacaine both along with 2% lignocaine in peribulbar block for cataract surgery

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Abstract

Background: Levobupivacaine, the pure S (−) enantiomer of bupivacaine, is strongly emerging as safer alternative along with equal efficacy when compared with its racemic sibling, bupivacaine, for regional anesthesia.

Materials and Methods: 100 patients undergoing cataract surgery were randomly allocated in two groups. **Group B** patients received injection Bupivacaine 0.5% (5mL) + Lignocaine 2% (5mL) + Hyaluronidase (0.1mL) and **Group L** patients received injection Levobupivacaine 0.5% (5mL) + Lignocaine 2% (5mL) + Hyaluronidase for peribulbar block to provide anesthesia for cataract surgery. We compared hemodynamic parameters, sensory and motor block characteristics and akinesia score between these two groups.

Results: Hemodynamic values such as mean arterial blood pressures, heart rate and SPO_2 and akinesia scores showed no statistically significant intra group differences during the entire study period. The onset of sensory block in group B was 129.40 ± 15.960 seconds where in group L, it was 130.00 ± 17.613 seconds which was statistically non-significant ($p>0.05$). The onset of motor block in group B was 180.60 ± 21.325 seconds where in group L, it was 183.80 ± 18.170 seconds which was statistically non-significant ($p>0.05$).

Conclusion: This study has demonstrated that levobupivacaine and bupivacaine are equally successful in achieving clinically satisfactory peribulbar anaesthesia for cataract surgery. Levobupivacaine has a wide therapeutic index so emerging as a safer alternative to bupivacaine for peribulbar block in cataract surgery in elderly population in whom intercurrent diseases are common.

Keywords: bupivacaine, levobupivacaine, lignocaine, peribulbar block

Introduction

Levobupivacaine[1], the pure S (−)enantiomer of bupivacaine, has strongly emerged as a safer alternative[2] for regional anesthesia than its racemic sibling, bupivacaine. Levobupivacaine has been found to be equally efficacious as bupivacaine, but with a superior pharmacokinetic profile. The available literary evidence in anesthesia practice indicates that levobupivacaine and bupivacaine produce comparable surgical sensory block, similar adverse side effects and provision of similar analgesia with good comparable patient outcome.

Bupivacaine, the widely used local anesthetic in regional anesthesia is available in a commercial preparation as a racemic mixture (50:50) of its two enantiomers, levobupivacaine, S (−) isomer and dextrobupivacaine, R (+) isomer. Severe central nervous system and cardiovascular adverse reactions reported in the literature after inadvertent intravascular injection or intravenous regional anesthesia have been linked to the R (+) isomer of bupivacaine. The levorotatory isomers were shown to have a safer pharmacological profile, with less cardiac and neurotoxic adverse effects and these effects are attributed to its faster protein binding rate.

Materials and Methods

After obtaining institutional ethical committee clearance for the study, we have taken informed written consent from 100 adult patients of both the genders

Inclusion criteria

1) Age between 18 to 70 years
2) ASA class I, II and III

3) Surgical duration less than 1 hour

Exclusion criteria

1) History of allergy to amide local anesthetic
2) Local sepsis
3) Serious impairment in coagulation
4) Orbital abnormalities
5) History of previous surgery in the study eye
6) Uncooperative patients and those with communication barrier (language barrier and hearing impairment)

After routine preanaesthetic assessment (history, physical examination, routine investigation, grading), a peripheral intravenous (i.v.) line was inserted in 6 hours fasted patient and standard monitoring was conducted and recorded, including heart rate (HR), noninvasive arterial blood pressure (BP), electrocardiogram (5 leads), and peripheral oxygen saturation (SpO2). Premedication was given with injection glycopyrrolate 0.2mg i.v. and injection ondansetrone 4 mg i.v. 10 min before surgery. All the patients were randomly divided in two groups**,** **Group B** patients received injection Bupivacaine 0.5% (5mL) + Lignocaine 2% (5mL) + Hyaluronidase (0.1mL) and **Group L** patients received injection Levobupivacaine 0.5% (5mL) + Lignocaine 2% (5mL) + Hyaluronidase for peribulbar block to provide anesthesia for cataract surgery. Under all aseptic and antiseptic conditions, preparation of drug mixture should be done according to group. Then gently press on the lower lid between the orbital margin and the globe to feel the inferior orbital notch. Percutaneous peribulbar injection is given at the junction of the outer one third & inner two third of the lower orbital rim by using a 23-G hypodermic needle. The needle was advanced in an anteroposterior direction for half of its length and then obliquely in the direction of the optical foramen. After negative aspiration, 5 mL of the study drug solution was slowly (over 30-40 seconds) injected in both the groups. The time required for the inferior injection takes its effect is 3-5 min**.** Motor block was evaluated by assessment of akinesia in four quadrants using general akinesia scoring system in which all four recti muscles are individually assessed in terms of movements after injection of local anesthetics and categorized as following scoring system:

Full movement	2
Partial movement	1
No movement	0

Sum total of all four muscles score was done and then the effectiveness of the block was evaluated. Maximum score of 8 for the four muscles (superior, inferior, medial, lateral rectus) and minimum score is 0. Block should be considered failed if sum total akinesia score of all four muscles was 4 or more. If after 5 minutes of first injection akinesia score was 4 or more, supplementary injection on the superior aspect of the orbital margin was given. Superior (supplementary) injection was given usually nasally just above the medial canthus. The 23 G hypodermic needle was advanced in an anteroposterior direction for half of its length. After negative aspiration, 5mL of the study drug solution was slowly (over 30-40 seconds) injected. Mechanical orbital compression was then applied for 2 min in both groups. Fullness of the upper lid points to an increase in the orbital volume and correct site of injection. The block can only be considered successful, if the akinesia score was 3 or less after injection.

Sensory block was considered along with abolition of the corneal reflex next to instillation of drops of physiological solution (normal saline) on the conjunctiva and cornea.

The incidences of any complications were routinely recorded. After giving the study drug intra-operative hemodynamic, onset time of sensory block, onset time of complete motor block akinesia scores, supplementary injection required were recorded. Patient is shifted to post-operative ward after completion of surgery. Post-operative rescue analgesia is given to the patient when patient complains pain in the form of tablet brufen 500 mg orally. Satisfaction of surgeon and patient at the end of surgery are noted.

Statistical analysis

Statistical analyses of collected data (demographic profile, heart rate, and mean arterial blood pressure, sensory and motor characters) of both groups were done using student t-test.

Results

There were no differences between the groups with respect to demographic profile as shown in Table 1, ASA physical status, akinesia score as show in Table 2 and surgeon and patient satisfaction. Hemodynamic values such as heart rate as shown in Figure 1, mean arterial blood pressure as shown in figure 2 and sensory and motor characters as shown in figure 3 showed no statistically significant intra group differences during the entire study period.

Requirement of supplementary injection for achieving satisfactory akinesia are 30% in Group B and 34% in group L.

Discussion

Ophthalmic surgery is one of the most frequent surgical procedure requiring anesthesias in developing country. And most procedures are performed under regional anesthesia like retrobulbar or peribulbar blocks or topical anesthesia. Regional anesthesia is more preferable because it is economical, easy to perform and the risk involved is less. Regional anesthesia has rapid onset of action and easily provides favorable surgical condition.

Eye blocks have long been limited to blocks performed by the surgeon with only monitored anesthesia care or no anesthesiologist assistance at all. So we are trying to provide the local anesthetic agent having safest therapeutic index along with motor and sensory block characteristics compatible to conventional agents. The quest for searching newer and safer anesthetic agents for regional anaesthesia has always been one of the primary needs in anesthesiology practice.

This study has demonstrated that levobupivacaine and bupivacaine are equally successful in achieving clinically satisfactory peribulbar anaesthesia. The peribulbar technique we used was chosen owing to its safe reputation, being distant from the vessel-rich medial compartment and easy to perform along with minimization of the needle related risks of retrobulbar hemorrhage and intraneural injection. Peribulbar anesthesia requires relatively large volume of local anesthetics and concerns have been expressed about potential for systemic toxicity. The incidence of peribulbar blocks requiring supplementary injection has been reported as high as 30% in group B and 34% in group L in this study. So the ideal agent for peribulbar anesthesia should have a wide therapeutic index, rapid onset of dense motor and sensory block and duration of action sufficient for surgery. The common combination of bupivacaine and lignocaine achieves many of these aims. The principal drawbacks lie in cardiac and neurological toxicity. Of the two agents lignocaine has wider therapeutic index, but when used as a sole agent for peribulbar anesthesia, the duration of anesthesia is often too short.

Bupivacaine significantly prolongs the duration of surgical anesthesia but thought to have a slower onset. Additionally there is concern about injecting high concentration of bupivacaine into vascular orbital fat. Bupivacaine toxicity may cause severe, refractory ventricular arrhythmias and death [3, 4]. The conventional form of bupivacaine is supplied as racemic mixture of equal quantities of two stereo isomers R(+) dextrobupivacaine and S(-) levobupivacaine. These two compounds have differing toxic effects. LD_{50} studies in rats and mice indicate the dextro bupivacaine isomer to be 30-40% more cardio and neuro toxic than levo rotated counterpart [5].

The main mechanism of cardiotoxicity is probably through its local anesthetic action on blocking sodium channel of heart. Dextro isomer has more affinity for these sodium channels than levo isomer. The reduced sodium channel affinity and improved potential for safety of levobupivacaine does not seem to occur at the expense of its local anesthetic action on nerve cells.

The onset of action of levobupivacaine and racemic bupivacaine is longer than much ophthalmic operation. This has obvious implication of turnover of surgical patients. In the present study, addition of hyaluronidase to the study drug mixture of both groups significantly reduces the time of onset. It causes increase in pH that is directly proportional to the amount administered and enhances the diffusion of local anesthetic into the nerves without increasing the plasma drug concentration [6, 7, 8, and 9]. Enzyme act on hyaluronic acid, a component of connective tissue, liquefies the interstitial barrier and increases local anesthetic spread through tissue planes.

In our study, both local anesthetic preparations appeared to be well tolerated and produced good surgical conditions. There were no statistical significant difference in onset of complete motor block, and onset of sensory block. Hemodynamic stability, need for supplemental injection and patient and surgeon's satisfaction are also same in both groups.

The outcome of our study correlates with the similar other studies. We are unable to assess the duration of motor block as patient's eyes were covered with bandaged post operatively. **H. A. Mclure and A. P. Rubin** [10] compared 0.75% levobupivacaine with 0.75% racemic bupivacaine for peribulbar anesthesia. In their study they have concluded that there is no statistically significant difference in time to satisfactory block (levobupivacaine -13(5.6) min; racemic bupivacaine -11(4.4) min), perioperative pain score or frequency of adverse events. They concluded that safer pharmacological profile of levobupivacaine may offer significant advantages in elderly population undergone cataract extraction in which intercurrent disease is common.

Birt and cummings [11] reported similar efficacy of 0.75% levobupivacaine and 0.75% bupivacaine both mixed with hyaluronidase for peribulbar block. The time for the onset

of satisfactory anesthesia and akinesia were compared between these two drugs. The only differences were the concentration of the drug they used and they didn't use lignocaine for mixture in study drug. In our study we have used more diluted form (0.5%) of study drug and we combined both of our study drugs with lignocaine. Results are similar in both studies. In addition Birt and Cummings reported similar incidence of pattern post operative pain and requirement of first post-operative analgesia in both groups, which also correlates with our study.

We reported very good amount of patient and surgeon's satisfaction in similar study conducted by **A. M. Ghali** [12] from muscut. In their study, they have compared 0.75% levobupivacaine with 0.75% ropivacaine both with addition with hyaluronidase for peribulbar block for vitreoretinal surgery.

Recep aksu, cihangir bicer [13], compared 0.5% levobupivacaine, 0.5% bupivacaine and 2% lignocaine for retrobulbar anesthesia in vitreoretinal surgery. They concluded that levobupivacaine provides longer sensory and motor duration, good hemodynamic stability and higher patient and surgeon satisfaction than lignocaine and bupivacaine when used for retrobulbar block.

Pacella E, Collini S [14] compared efficacy and safety of 0.5% levobupivacaine versus 0.5% bupivacaine for peribulbar anesthesia. They also added 10 IU/ml hyaluronidase in both groups of patient. The time to onset (12 ± 2.6 min versus 13 ± 2.8 min) and duration of anesthesia (185 ± 33.2 min versus 188 ± 35.2min) were similar in both the groups. Complete akinesia was obtained more frequently when hyaluronidase was added to both groups. They concluded that levobupivacaine is a longer acting local anesthetic with limited cardiotoxicity and neurotoxicity and may be considered landmark for vitreoretinal surgery in elderly patient.

Nauman Ahmed, Abdool Zahoor [15] and friends had compared levobupivacaine 0.5% or bupivacaine 0.5% both in mixture with lignocaine 2% for superficial extraconal block. They concluded that there is no statistically significant difference between levobupivacaine 0.5% and bupivacaine 0.5% in terms of akinesia score, supplementary injection, surgeon and patient satisfaction, and verbal pain score. This study is identical to our study in regards to drug concentration, and its results.

F Lai, B. Sutton [16] had compared levobupivacaine 0.75% and lignocaine 2% with bupivacaine 0.75% with lignocaine 2% for peribulbar anesthesia. They also added hyaluronidase in their study drug. They used median ocular and eyelid movement scores and number of patients requiring supplementary injection and developed complication. They divided the patients in two groups. They concluded that 0.75% levobupivacaine in combination with 2% lignocaine was significantaly less effective in terms of speed of onset of anesthesia than bupivacaine 0.75% and lignocaine 2% for peribulbar block. This result is contrast with our study where levobupivacaine 0.5% and bupivacaine 0.5% both along with lignocaine 2% are equally effective in speed of onset of anesthesia.

Conclusion

Levobupivacaine is a longer acting local anesthetic agent with limited cardio toxicity and neurotoxicity as compared to bupivacaine and may be considered as a landmark for cataract surgery in elderly patient having co-existing systemic diseases.

References

1. Bajwa and Kaur et al. Levobupivacaine in regional anesthesia. Journal of Anaesthesiology Clinical Pharmacology. 2013Oct-Dec; 29(4)530-539.

2. Jaichandran VV et al. Ophthalmic regional anaesthesia: A review and update. Indian J Anaesth. 2013 Jan-Feb; 57(1)7-13.

3. Albright G et al. Cardiac arrest following regional anesthesia with etidocaine or bupivacaine. Anesthesiology 1979; **51:** 285–7.

4. Heath M et al. Deaths after intravenous regional anaesthesia. British Medical Journal 1983; **285:** 913–4.

5. Crina L Burlacu and Donal J Buggy et al. Ther Clin Risk Manag. Update on local anesthetics: focus on levobupivacaine Apr 2008; 4(2): 381–392. Published online. PMCID: PMC2504073, Department of Anesthesia, Intensive Care and Pain Medicine, Mater Misericordiae, University Hospital, Dublin, Ireland.

6. Mantovani C, Bryant AE, Nicholson G et al. Efficacy of varying concentration of hyaluronidase in peribulbar anaesthesia. Br J Anaesth. 2001;**86**:876–878

7. Kallio H, Paloheimo M, Maunuksela EL et al. Hyaluronidase as an adjuvant in bupivacaine-lidocaine mixture for retrobulbar block. Anesth Analg. 2000;**91**:934–937.

8. Bowman RJ, Newman DK, Richardson EC, Callear AB, Flanagan DW et al. Is hyaluronidase helpful for peribulbar anesthesia? Eye (Lond) 1997;**11**(Pt 3):385–388

9. Dempsey GA, Barrett PJ, Kirby IJ et al. Hyaluronidase and peribulbar block. Br J Anaesth. 1997;**36**:67–83

10.H. A. McLure and A. P. Rubin et al. Comparison of 0.75% levobupivacaine with 0.75% racemic bupivacaine for peribulbar anaesthesia, Anaesthesia, 1998, **53**, pages 1160–1164

11.Birt DJ, Cummings GC et al. The efficacy and safety of 0.75% levobupivacaine vs 0.75% bupivacaine for peribulbar anaesthesia. Eye (Lond) 2003; 17:200–6.

12.Asharaf M. Ghali et al. The efficacy of 0.75% levobupivacaine versus 0.75% ropivacaine in peribulbar anesthesia for vitreoretinal surgery; Saudi j anesthesiology 2012 jan-mar:6(1)22-26

13.Recep aksu, cihangir bicer et al. Comparison of 0.5% levobupivacaine, 0.5% bupivacaine, and 2% lidocaine for retrobulbar anesthesia in vitreoretinal surgery, European Journal of Ophthalmology;2009, 19 no. 2, 280-284

14.Pacella E, Collini S et al. Efficacy and safety of 0.5% levobupivacaine versus 0.5% bupivacaine for peribulbar anesthesia, Clin Ophthalmol. 2013; 7: 927–932. Published online May 21, 2013.

15.Nauman Ahmad, Abdool Zahoor et al. Comparison of levobupivacaine 0.5% or bupivacaine 0.5% both in mixture with lignocaine 2% for superficial extraconal blockage, Middle east after j ophthalmol ;19(3);jul-sep 2012:330-333

16.F. Lai, B. Sutton and G. Nicholson; comparison of levobupivacaine 0.75% with lignocaine 2% and bupivacaine 0.75% with lignocaine 2% for peribulbar anesthesia, British journal of anesthesia 90(4):512-14(2001).

List of figure and Tables.

Table-1:Demographic data

Characteristics		Group B	Group L	P value	Significance
Total no. of patients(n)		50	50		
Age (years)		59.48 ± 9.696	57.52 ± 9.329	0.306	N.S.
Weight(kg)		61.25 ± 9.601	61.74 ± 8.521	0.784	N.S.
Sex	Male	21	24		
	Female	29	26		

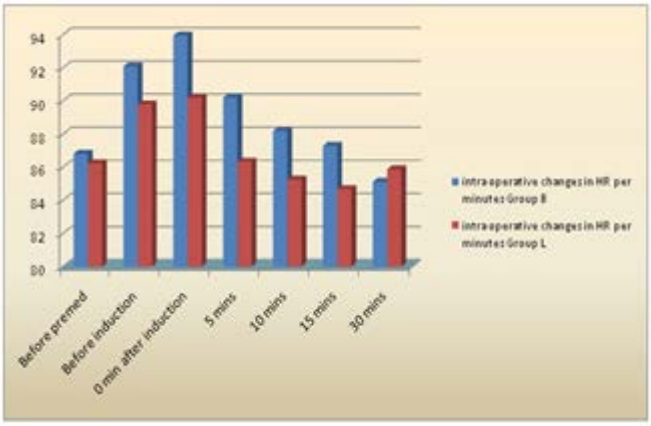
P value > 0.05 is statistically not significant

Table- 2: Akinesia score for both groups

Akinesia score	Group B	Group L
0	40	36
1	34	40
2	22	18
3	4	4

When comparing both groups, there is no significant difference between akinesia score.

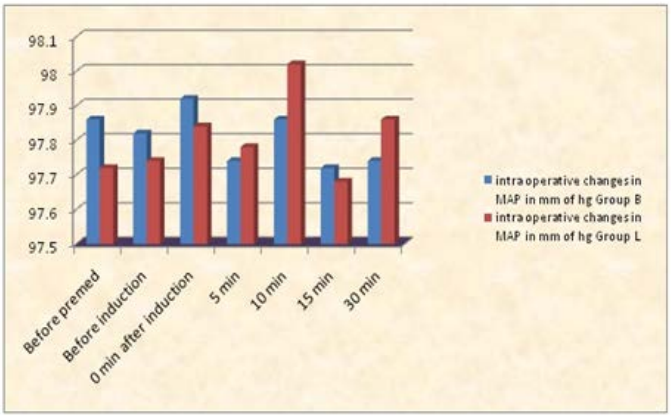
Figure – 1: Intra operative changes in heart rate



When comparing both the groups, there is no statistically significant difference between

Intra operative heart rate (P value > 0.05)

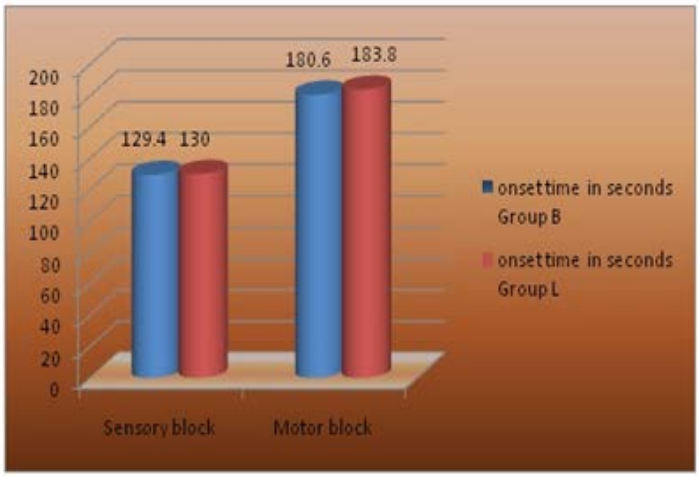
Figure – 2:Intra operative changes in mean arterial pressure



When comparing both the groups, there is no statistically significant difference between

Intra operative mean arterial blood pressure (P value > 0.05).

Figure – 3: Sensory and Motor characters



When comparing both the groups, there is no statistically significant difference between

Sensory and motor characters (P value > 0.05)