

Comparison of 0.5% Levobupivacaine and 0.5% Bupivacaine for Retrobulbar Anesthesia in Cataract Surgery

Katarakt Cerrahisinde Retrobulber Anestezi İçin %0.5 Levobupivakain ile %0.5 Bupivakainin Karşılaştırılması

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ABSTRACT Objective: The aim of the study is to compare the efficacy of local anesthetics, levobupivacaine and bupivacaine, for achievement of retrobulbar anesthesia and to determine patient and surgeon satisfaction in cataract surgery. **Material and Methods:** One hundred and twenty patients scheduled for cataract surgery were randomised, in a double-blind fashion to receive 5 ml of 0.5% levobupivacaine or 5 ml of 0.5% bupivacaine via inferotemporal injection for achievement of retrobulbar anaesthesia. Motor block durations and pain onset times were recorded. Severity of intra and postoperative pain was assessed by using visual analogue pain scale. The efficiency of anesthesia, patient and surgeon satisfaction, and akinesia durations were assessed by using point scoring scales. Hemodynamic data and adverse events were recorded. **Results:** Pain on injection (levobupivacaine 18%, bupivacaine 36.7%) was found to be more frequent in group B. The akinesia score after 10 minutes (median; 0, 1 respectively) and sensorial block onset time (2, 3 min) in levobupivacaine group was lower than bupivacaine group but, akinesia scores in both groups were under 4 and adequate for surgery. Surgeon and patient satisfaction regarding anesthesia were also higher in levobupivacaine group (median 10 and 10) compared to bupivacaine group (median 9 and 9) although the medians of two groups were close. **Conclusions:** Levobupivacaine provides better surgeon and patient satisfaction compared to bupivacaine for retrobulbar anesthesia in cataract surgery, and this finding should be supported by new and comprehensive clinical studies.

Key Words: Leobupivacaine; bupivacaine; cataract

ÖZET Amaç: Bu çalışmanın amacı katarakt cerrahisinde retrobulber anestezi sağlanmasında lokal anestetikler levobupivakain ile bupivakainin etkinliğinin ve hasta ve cerrah memnuniyetinin karşılaştırılmasıdır. **Gereç ve Yöntemler:** Katarakt cerrahisi yapılması planlanan 120 hasta infratemporal enjeksiyonla retrobulber anestezi sağlamak için 5 ml %5 levobupivakain veya 5 ml %0.5 bupivakain verilecek şekilde çift kör olarak rastgele dağıtıldı. Motor blok süreleri ve ağrının ortaya çıkış zamanları kaydedildi. Ameliyat sırasındaki ve ameliyattan sonraki ağrının şiddeti görsel analog ağrı skalası kullanılarak değerlendirildi. Anestezinin etkinliği, hasta ve cerrah memnuniyeti ve akinezi süreleri nokta skorlama skalaları kullanılarak değerlendirildi. Hemodinamik veriler ve yan etkiler kaydedildi. **Bulgular:** Grup B'de enjeksiyon sırasında ağrı daha sık bulundu (levobupivakain %18, bupivakain %36.7). On dakika sonraki akinezi skoru (sırasıyla ortalama 0, 1) ve duysal blok başlama zamanı (2, 3 dakika) levobupivakain grubunda bupivakain grubuna göre daha düşüktü fakat akinezi skorları her iki grupta da 4'ün altındaydı ve ameliyat için yeterliydi. Ameliyata bağlı olarak cerrah ve hasta memnuniyeti bupivakain grubuyla (ortalama 9 ve 9) karşılaştırıldığında levobupivakain grubunda (ortalama 10 ve 10) istatistiksel olarak daha yüksek olmasına rağmen, ortalama değerler birbirine çok yakın bulundu. **Sonuç:** Levobupivakain katarakt cerrahisinde retrobulber anestezi için bupivakainden daha iyi cerrah ve hasta memnuniyeti sağlar ancak bu konu yeni ve geniş kapsamlı klinik çalışmalarla desteklenmelidir.

Anahtar Kelimeler: Levobupivakain; bupivakain; katarakt

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Cataract is a major cause of blindness worldwide. Cataract surgery is usually performed under local anesthesia.¹ Day case ophthalmic surgery under local anesthesia has been proven to be safe.^{2,3}

The age and medical characteristics of patients undergoing cataract surgery such as old age like diabetes mellitus and cardiovascular problems, made local anesthesia the most preferred method performed in order to reduce the risks and morbidity.⁴

Bupivacaine and levobupivacaine are long acting local anesthetic drugs (LA).^{5,6} Levobupivacaine is an isolated S (-) stereoisomer of racemic mixture of bupivacaine. Levobupivacaine has significantly less central nervous system and cardiovascular system toxicity compared to bupivacaine.^{7,8}

Peribulbar and retrobulbar blocks are common forms of injectable anesthesia techniques in ophthalmic surgery and are considered to have similar effects during cataract surgery.⁹ Peribulbar anaesthesia requires relatively larger volumes of LA, which may increase the risk of systemic toxicity.¹⁰ Topical and sub-Tenon administration of local anesthetics are the other types of frequently used anesthesia techniques for phacoemulsification surgery. However phacoemulsification under topical or sub-Tenon anesthesia can be more painful and harder to perform in an uncooperative patient.^{9,11}

The primary aim of this study is to compare the efficacy of local anaesthetics 0.5% bupivacaine and its isomer 0.5% levobupivacaine for achievement of retrobulbar anaesthesia and to determine patient and surgeon satisfaction in cataract surgery.

MATERIAL AND METHODS

Following local ethics committee approval, informed consents were obtained from all of the participants. One hundred and twenty patients scheduled for cataract surgery in the ophthalmology unit were enrolled in the study. All of the patients were in group 1-3 according to the physical status classification of American Society of Anesthesiologists (ASA), and none of the patients were given any premedication or sedation.

Patients with a history of allergy to local anesthetic solutions, any sign of local infection, congenital or acquired coagulation deficits, orbital abnormalities, neurological or psychiatric disorders or who just refused the anesthetic technique were excluded. Pulse oximetry, electrocardiography, heart rate and non-invasive arterial blood pressure monitoring were performed in a standard fashion, and an intravenous (i.v.) cannula was placed. The topical anesthesia of conjunctiva was achieved by administering 2-3 drops of tetracaine 1% into the conjunctival sac. Patients were randomly allocated into two groups according to a computer-generated list of random numbers which were placed in opaque sealed envelopes; Group LB (n= 60) was administered levobupivacaine, and Group B (n= 60) bupivacaine. All retrobulbar blocks were performed by the same anesthetist and phacoemulsification surgeries were performed by the same surgeon. The surgeon was blinded to the type of anesthetic. The data was collected by an anesthesiologist and surgeon blinded about the patient group assessment. Retrobulbar anesthesia was performed with a standard percutaneous inferotemporal approach using a 31-mm, 27-gauge needle (PrecisionGlide; Becton Dickinson, Franklin Lakes, NJ). The retrobulbar block was performed with 5 ml of levobupivacaine 0.5% (Chirocaine 5 mg ml⁻¹, Abbott) in group LB (n= 60) whereas 5 ml of bupivacaine 0.5% (Marcaine 5 mg ml⁻¹, Astra-Zeneca) was used in group B (n= 60). The patients who suffered from pain during injection were recorded. After the conclusion of injection, 30-50 mmHg of pressure was applied to the eye for 5 min and the eye was inspected every 1 min to evaluate motility. Sensation of the cornea was assessed with the tip of a bended cotton and interval between injection and onset of the sensorial block was recorded. The degree of motor block was assessed by using the akinesia scoring system as given in Table 1. Motility of the eye was evaluated in four quadrants using a 3-point scoring system. Total akinesia score of 4 or less was accepted as suitable for surgery. If the level of achieved motor block in the fields of ductions tested after 10 min of injections was inadequate, further injection of 3 ml of studi-

TABLE 1: Scoring system for degree of akinesia.

Ocular movements	
Full movement	3
Moderate movement	2
Quivering	1
No movement	0

ed anesthetic was performed. Motility was reevaluated at 5 min intervals thereafter. The motor block onset time and akinesia scores were measured and recorded. Three drops of 1% tetracaine was administered to the patients suffering from pain during the operation. Oxygen was administered via a nasal cannula under the sterile drapes during the whole operation.

Analgesia in the postoperative period was assessed by determination of the severity of pain perceived by using a 10-cm visual analog pain score scale (VAS) ranging from 0 to 10 (0 = no pain, 10 = the worst pain possible). VAS score of 4 or more was accepted as significant pain. Patients who had VAS score > 4 in the postoperative period received naproxene sodium for providing analgesia. The duration of surgery, duration of motor block and pain onset time were recorded.

The patient and surgeon satisfaction was assessed by using a 10-point scale as: 0 = not satisfied, 10 = fully satisfied. Short time interruptions and patient movements during operation and difficulties for carrying on operation were taken into consideration when assessing the surgeon satisfaction. Non-invasive systolic and diastolic arterial blood pressures and heart rate monitorization were recorded at baseline, 5 min after the local anesthetic injection, 5 min after commencement of the operation, on 15th min intraoperatively and after the operation. Patients were reevaluated by the same anesthetist in the next day and the level of motor blocks and residual akinesia were scored with the same system used before surgery. Any postoperative symptoms were questioned and noted if present.

SPSS for Windows Version 15.0 (SPSS Inc., Chicago, IL) was used for statistical analysis. Bet-

ween-group comparisons of parametric data were analyzed with t-test with normal distribution values. Comparisons in groups were analyzed with repeated measures of ANOVA. Non-parametric data were analysed using the Chi-square test or parametric data without normal distribution values were analysed using Mann-Whitney U-test. Results were considered significant if value of p was <0.05.

We had two groups with 10 patients in each, a total of 20 patients, as a preliminary study to find the sample size of this study. The primary endpoint of this study was to evaluate surgeon satisfaction scores. We determined that a sample size of 59 patients per group was required to find a difference in surgeon satisfaction of 20%. Using this estimate, and $\alpha = 0.05$ and $\beta = 0.2$, the proposed sample size of 59 patients per group was detected. The patients in Group LB had 90% adequate (10 point) surgeon satisfaction, and the Group B showed 70% adequate (10 point) surgeon satisfaction through power analysis using sample-size software (Version 10.1.6 - © 1993-2009 MedCalc Software).

RESULTS

The mean ages of patients were 54.5 (21-79) years in Group LB and 61 (18-80) years in Group B. The mean weights of patients were 77.1 ± 12.4 kg in Group LB and 75.7 ± 11.3 kg in Group B. The gender of patients in two groups were similar. The duration of surgery was 20 (12-45) in Group LB min and 19 (11-47) min in Group B. No difference was noted between the groups with respect to patient characteristics, ASA physical status ($p = 0.188$) and the duration of surgery ($p = 0.093$) (Table 2).

Hemodynamic values such as noninvasive systolic and diastolic arterial blood pressures and heart rate, showed no statistically significant inter or intragroup differences during the entire study period ($p > 0.05$). Statistical analysis of motor block onset times showed no significant difference between the two groups ($p = 0.065$) (Table 3). Statistical analysis revealed that sensorial block onset time was found to be low in group LB ($p = 0.024$) (Table 3). Statistical analysis of the akinesia scores (10 min after block) was found to be lower in group LB ($p = 0.007$) (Table 3). The number of patients who re-

TABLE 2: Demographic characteristics of the subjects.

	Group LB (n = 60) (mean ± SD)	Group B (n = 60) (mean ± SD)	p
Age (yr)	54.5 (21-79) °	61 (18-80) °	0.075†
Height (cm)	168.0 ± 6.8	165.8 ± 8.5	0.108*
Weight (kg)	77.1 ± 12.4	75.7 ± 11.3	0.537*
Sex (Male/Female) (n)	28 / 32	33 / 27	0.233‡
Duration of surgery (min)	20 (12-45) °	19 (11-47) °	0.093†
ASA physical status I / II / III (n)	18 / 33 / 9	18 / 38 / 4	0.188‡

Level of significance $p < 0.05$.

Group LB = levobupivacaine 0.5% group; Group B = bupivacaine 0.5% group.
SD = standard deviation

*Parametric data were analyzed with t-test

‡ Non-parametric data were analysed using the Chi-square test

† Non-parametric data were analysed using the Mann Whitney U test

° Median (min-max)

quired administration of supplementary block for achievement of adequate akinesia before the commencement of operation was similar between the study groups (two patients in Group LB, four patients in Group B). There was no statistically significant difference regarding the motor block durations ($p = 0.115$) and pain onset times between the groups studied ($p = 0.338$) (Table 3). Pain during injection was found to be more frequent in group B (22 patients) compared to group LB (11 patients) ($p = 0.04$) (Table 4). The number of patients who experienced pain during the operation and the need for administration of postoperative analgesia were

TABLE 3: Motor block onset time, motor and sensorial block durations, akinesia score.

	Group LB (n= 60) (mean ± SD)	Group B (no= 60) (mean ± SD)	p
Motor block onset time (min)	2 (1-4) °	2 (1-4) °	0.065†
Motor block duration (min)	327.5 ± 5 1.6	345.9 ± 73.6	0.115*
Sensorial block onset time (min)	2 (1-6) °	3 (1-5) °	0.024†
Pain onset time (min)	185 (90-750) °	240 (50-480) °	0.338†
Akinesia score (10 min after block)	0 (0-3) °	1 (0-3) °	0.007†

Level of significance $p < 0.05$.

Group LB = levobupivacaine 0.5% group; Group B = bupivacaine 0.5% group.
SD = standard deviation

* Parametric data were analyzed with t-test

† Non-parametric data were analysed using the Mann Whitney U test

° Median (min-max)

similar in two groups ($p = 0.600$) (Table 4). The level of satisfaction for both the surgeon and patients were better in Group LB compared to Group B, and this was statistically significant ($p < 0.001$) (Table 4). No postoperative complications were noted in any of the groups.

DISCUSSION

The characteristics of patients undergoing cataract surgery, such as old age and presence of systemic diseases makes local anesthesia preferable for cataract surgery. Although adequate motor and sensory block with good hemodynamic stability were ac-

TABLE 4: Supplementary block requirement, pain scores and patient and surgen satisfaction scores.

	Group LB (n= 60) n (%)	Group B (n = 60) n (%)	p
Supplementary block requirement	2 (3.3)	4 (6.7)	0.340‡
Injection pain	11 (18.3)	22 (36.7)X	0.040‡
Intraoperative pain	0 (0)	1 (1.7)	0.600‡
Postoperative analgesic need	0 (0)	1 (1.7)	0.600‡
Patient satisfaction	10 (8-10) ° (10 point %65) ‡	9(6-10) ° * (10 point %36.7)‡	<0.001†
Surgeon satisfaction	10 (7-10) ° (10 point %83.3)‡	9(6-10) ° *	<0.001† (10 point %48.3)‡

Level of significance $p < 0.05$.

Group LB = levobupivacaine 0.5% group; Group B = bupivacaine 0.5% group.
SD = standard deviation

* Significant reduction compared to Group LB ($p < 0.05$).

X Significant increase compared to Group LB ($p < 0.05$).

† Non-parametric data were analysed using the Mann Whitney U test

‡ Non-parametric data were analysed using the Chi-square test

° Median (min-max)

hieved with both of the drugs studied, 0.5% levobupivacaine provided better patient and surgeon satisfaction compared to 0.5% bupivacaine.

Di Donato et al. compared 0.75% levobupivacaine with 4% lidocaine for topical anaesthesia in cataract surgery and reported better patient and surgeon satisfaction scores in the levobupivacaine-treated group.¹² Patient satisfaction was reported as 83% in lidocaine-bupivacaine treated group and 97% in ropivacaine treated group in a study which compared peribulbar anesthesia with either 0.75% ropivacaine or 2% lidocaine-0.5% bupivacaine mixture for vitreoretinal surgery.¹³ In another study, researchers reported a trend towards better satisfaction in patients administered levobupivacaine compared to ropivacaine at 24 hours following operation.¹⁴ In our previous study, we found better patient and surgeon satisfaction scores in 0.5% levobupivacaine-administered group when compared to 0.5% bupivacaine and 2% lidocaine administered groups in patients who had retrobulbar anaesthesia for vitreoretinal surgery.¹⁵ In the present study, we also found better patient and surgeon satisfaction scores in the levobupivacaine group (median; 10 and 10) compared to the bupivacaine group (median; 9 and 9), although the medians of both groups were close.

It was found that the onset time to akinesia score 4 was shorter in lidocaine group compared to levobupivacaine group in a study which compared 2% lidocaine and 0.75% levobupivacaine. The final akinesia scores at the end of the surgery were similar.¹⁶ McLure and Rubin compared 0.75% levobupivacaine with 0.75% racemic bupivacaine mixture for achievement of peribulbar anaesthesia and they reported that the akinesia score onset times were similar in two groups.⁴ In this study, the akinesia score in levobupivacaine group was lower than bupivacaine group, however akinesia scores in both groups were under 4 and adequate for surgery.

Lai et al. have compared 0.75% levobupivacaine and 2% lidocaine combination with 0.75% bupivacaine and 2% lidocaine combination for peribulbar anaesthesia in cataract surgery.¹⁷ They

have found that 0.75% levobupivacaine and 2% lidocaine combination was significantly less effective than 0.75% bupivacaine, 2% lidocaine combination for achievement of peribulbar anaesthesia in terms of speed of anesthesia onset. This finding was in contradiction to other studies. In our previous study, we have found that both motor block duration and motor block onset time were similar between the 0.5% levobupivacaine and 0.5% bupivacaine administered patients having vitreoretinal surgery under retrobulbar anaesthesia.¹⁵

In our present study, we found the motor block duration and pain onset time similar in two groups, but shorter sensorial block onset time found in group levobupivacaine was ignored clinically.

Newsom et al. reported the percentage of mild and severe pain on injection as 15.5% and 5.57%, respectively in a study which evaluated the effects of local anesthesia in 1221 vitreoretinal procedures. Of the 1221 LA blocks, 13.4% were intraconal and 10.6% were peribulbar only, remaining 75% were a combination of both.¹⁸ Wahl et al. reported pain on injection of bupivacaine with epinephrine was significantly greater than that of prilocaine plain in dental blocks.¹⁹ In our previous study, we also have found greater injection pain with bupivacaine compared to levobupivacaine in retrobulbar blocks.¹⁵

In the present study, the VAS score of pain sensation 4 or more was found to be less during levobupivacaine injections (18.3%) compared to bupivacaine injections (36.7%).

It is reported that intracameral injections of bupivacaine and levobupivacaine, like other local anesthetics, induced significant apoptotic endothelial cell loss and led to morphologic changes in the corneal endothelial cells in the early period in rabbits. This effect was temporary, with recovery in seven days.^{20,21}

Nicoll et al. reported 16 patients developing signs and symptoms attributable to the direct spread of local anesthetic agents to the central nervous system in 6000 patients in whom retrobulbar anesthesia was performed.²² Teichmann and Uthoff re-

ported postoperative ischemic optic neuropathy in one of 13 000 patients who underwent cataract surgery with retrobulbar anesthesia by curved needle technique.²³ No complications like perforation, retrobulbar hematoma, brain stem anesthesia or chemosis were noted in our study.

McLure and Rubin compared 0.75% levobupivacaine with 0.75% racemic bupivacaine mixture for achievement of peribulbar anaesthesia, and they reported that the volume of anesthetics and the number of injections required were similar in

two groups.⁴ In our study, 0.5% levobupivacaine with 0.5% bupivacaine for achievement of retrobulbar anaesthesia and the volume of anaesthetic and the number of injections required were similar in two groups.

We conclude that 0.5% levobupivacaine alone provides better patient and surgeon satisfaction compared to 0.5% bupivacaine, and this finding should be supported by new and comprehensive clinical studies. Retrobulbar anesthesia can be a suitable choice in cataract surgery.

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