ORIGINAL RESEARCH

Comparison of Lidocaine Plus Ropivacaine with Lidocaine Plus Bupivacaine for Peribulbar Anaesthesia During Phacoemulsification Cataract Surgery: A Double-Blinded Randomized Study

[1]Vishnu Kumar Garg, [2]Sunil Chauhan, [3]Jigyasa Shahani, [4]Mangilal Deganwa, [5]PS Lamba

[1]Assistant Professor, [4]Associate Professor, Department of Anesthesiology, Mahatma Gandhi Medical College and Hospital, Jaipur, Rajasthan, India
[2,5]Senior Professor, Department of Anesthesiology, SMS Medical College and Hospital, Jaipur, Rajasthan, India
[3]Associate Professor, Department of Anesthesiology, Government Medical College, Bharatpur, Rajasthan, India

Correspondence:
Mangilal Deganwa
Associate Professor, Department of Anaesthesiology, Mahatma Gandhi Medical College and Hospital, Jaipur, Rajasthan, India
Email: mangilaldeganwa0606@gmail.com

ABSTRACT

Introduction: The regional anaesthesia for cataract surgery is associated with lesser respiratory and hemodynamic events and quick recovery of function than general anaesthesia.

Aim: we evaluated the anesthetic efficacy and the postoperative analgesic effects of lidocaine plus ropivacaine with lidocaine plus bupivacaine for peribulbar anaesthesia during phacoemulsification cataract surgery.

Methods: In this prospective, randomized and double-blind study, total of 100 patients of both sexes undergoing elective phacoemulsification cataract surgery under local anaesthesia were randomly assigned into two groups of 50 each; ropivacaine group (R) and bupivacaine group (B). Each group received 8ml of LA solution (4 ml of 0.75% ropivacaine/0.5% bupivacaine and 4 ml of 2% lidocaine with hyaluronidase 25 IU/ml). The time of onset of analgesia, hemodynamic parameters, efficacy of peribulbar block, degree of postoperative pain were recorded.

Results: The hemodynamic profiles measured were similar before and after the block.The mean time of onset of sensory and motor block was much earlier (3.7±1.9 and 4.8±2.1, respectively) in the R group as compared with the B group (4.9±1.5 and 7.2±1.7). Although the ropivacaine and lidocaine mixture resulted in faster onset of sensory and motor block, both anaesthetic solutions provided similar duration of anaesthesia. Similarly, the verbal rating scales assessed at regular intervals were not significantly different between the groups (P > 0.05 all cases).

Conclusion: We conclude that, 0.75% ropivacaine provides earlier onset of peribulbar anesthesia for cataract surgery compared with 0.5% bupivacaine with similar block quality and efficacy.

Keywords: Bupivacaine, Ropivacaine,Lidocaine, Hyaluronidase, Cataract surgery, Peribulbar block.

INTRODUCTION

Anaesthesia for cataract surgery today aims at creating a comfortable environment for the patient and the surgeon during surgery and a quick recovery of function without inherent added risks.[1,2]The use of regional anaesthesia for ophthalmic surgery has become increasingly popular over the last few years because it is associated with lesser respiratory and hemodynamic events than general anaesthesia.[3,4]Moreover, among regional anaesthesia, peribulbar block is superior to retrobulbar block due to its higher safety margin.[5,6]

Bupivacaine and lidocaine has a well defined role in regional anaesthesia and analgesia for several years.[7,8] However, Ropivacaine allegedly offers a wide margin of safety, less motor blockade, less neurotoxicity/cardiotoxicity and almost similar duration of analgesia in comparison to bupivacaine.[9-11] These properties suggest advantages of ropivacaine compared with bupivacaine for regional anaesthesia andanalgesia in ambulatory setting.[12,13]

This study was done with 0.75% ropivacaine *versus* 0.5% bupivacaine in combination with lidocaine 2% and hyaluronidase 25 IU/ml in peribulbar block for phacoemulsification cataract surgery. The aim of this study was to compare the time ofonsetof sensory and motor block between the two groups and to observe the effects on haemodynamic parameters and analgesic requirements in both the groups.

METHOD

This prospective, double blind, randomized study was conducted at SMS medical college, Jaipur after getting permission and approval from the institutional ethics committee (IEC2011/458/06). A written informed consent was obtained from all the patients after explaining to them the nature of the study. Total of 100 patients (aged 40-80yrs) of both sexes undergoing elective phacoemulsification cataract surgery under local anaesthesia were enrolled. Patients younger than 40 years old, those with history of allergy to amide-type local anaesthetics (LA), patients who refused to participate, patients with glaucoma,patients having history of respiratory, cardiac, hepatic or renal failure, patients with active ocular infection, receiving any anti-coagulants were excluded from the study. A written informed consent was obtained from all the patients after explaining to them the nature of the study.The patients were randomly assigned into two groups of 50 each; ropivacaine group (R) and bupivacaine group (B), by chit in box method. The local anaesthetic solutions were prepared by an ophthalmic technician so that patient and the anaesthetist doing this study did not know in which group a particular patient had been allotted.

Group R (n=50) received 8ml of LA solution (4 ml of 0.75% ropivacaine and 4 ml of 2% lidocaine with hyaluronidase 25 IU/ml).

Group B (n=50) received 8ml of LA solution (4ml of 0.5% bupivacaine and 4ml of 2% lidocaine with hyaluronidase 25 IU/ml).

STUDY PROCEDURE

On the day of the surgery, patient was asked to fast for 6 h. Consent, pre anaesthetic evaluation was checked and intravenous access was secured. The patient did not receive any premedication. All the baseline parameters were observed and recorded, which included heart rate (HR), mean arterial pressure (MAP), oxygen saturation (SpO2), respiratory rate (RR). Patient was placed in supine position, asked to maintain the eye in primary position. Under all aseptic precautions, a needle 24G, 25 mm was inserted at the junction of the lateral third with the medial two-third of the inferior orbital margin and the local anaesthetic solution was injected. To promote the spread of the anaesthetic solution and decrease intraocular pressure, orbital mechanical compression was exerted for 5 min by a rubber ball.[14]

Then, the patients were assessed for the efficacy of blockade. Sensory block was evaluated by touching the cornea with a cotton swab. The motor block (akinesia score) was assessed at 2, 5

and 10 min after injection by a blinded observer. The scoring system of Brahma et alwas used for motor blockade.[15] Ocular movement was evaluated in the four quadrants of gaze directions using the following four-point scoring system: 3 (full movement), 2 (moderate movement), 1 (almost no movement) and 0 (akinesia), with a possible total maximum score of 12 points. An ocular movement score of less than 6 and reduced ocular movements in all directions were taken to indicate sufficient block. Once analgesia and akinesia had been achieved, no further assessments were made. The onset time of analgesia and akinesia were defined as the time elapsed from the end of the injection until the best anaesthesia was reached.

Surgery was started after 15 mins. Intraoperatively, patient was asked to grade pain by using verbal numeric rating scale (VNRS) of pain where 0=no pain and 10=the worst imaginable pain.

The occurrence of nausea and vomiting, headache and any untoward event; pain relieving medication (Tablet paracetamol 500 mg if VNRS>4) administration were noted.

HR, MAP, RR and SP02 were also measured every 5 minutes during the course of surgery. Postoperatively heart rate, mean arterial blood pressure and pain score were recorded at 0 min, 30 min, 1 hrs. and 2 hrs.

The degree of postoperative pain was also assessed by using the verbal numeric rating scale (VNRS) of pain at 1, 2, 4, 6, 8, 12, and 24 h postoperatively. The patient was asked to report the time of ingestion of analgesic and details about the pain.

STATISTICAL ANALYSIS

Data were analyzed using IBM SPSS Statistics 20 (IBM Corp., USA) and SAS ver. 9.2 (SAS Institute Inc., USA). The required sample size was calculated to be 50 patients per group with a=0.05 and a power of 90% to detect a difference of at least 25% in the successful block. The demographic and clinical characteristics of patients were analyzed using the chi-squared test, independent *t*-tests, and the Mann-Whitney test. ANOVA was used for continuous variables like changes in hemodynamic values and results are presented as the mean ±SD. For categorical variables, the results are presented as the frequency and the percentage, and the p values were obtained by Pearson's $\chi 2$ test. Student's *t* test was used as the post hoc significance to determine differences between and within groups. Statistical significance was defined as a P value of less than 0.05.

RESULTS

For all the patients who underwent cataract surgery, a proper record was maintained regarding the demographic characteristics, peribulbar block characteristics and haemodynamic and respiratory parameters. The following results were obtained, which were analyzed using statistical methods, and the value of P<0.05 was considered significant. Figure 1 flow diagram of patients screened for study. To summate, all the demographic characteristics like age,sex and body weight were comparable in both the groups and were found to be not significantly different between groups (P > 0.05, all cases) (Table 1).

Table 2 shows the baseline clinical variables (mean ±SD) among the two groups. The baseline characteristics were similar in both the groups and no statistically difference was present.

Table 3 shows the mean time of onset of sensory and motor Blockade. The onset of sensory anaesthesia was much earlier (3.7±1.9) in the R group as compared with the B group (4.9±1.5), which was statistically significant on comparison (P=0.012). Similarly, the onset of motor blockade was significantly earlier in the R group (4.8±2.1) than in the B group (7.2±1.7).

Table 4 depicts the effect on heart rate, systolic blood pressure and diastolic blood pressure of patients in both the groups. The mean change in heart rate in intraoperative period and postoperative period from preoperative period was not significant. ($p>0.05$). In both the groups there was a significant increase in systolic blood pressure and diastolic blood pressure (SBP&DBP) from the baseline values in the intraoperative periods within the group ($p<0.05$).

Table 1: Demographic profile of the patients

Demographic characteristics	Group B (n=50)	Group R (n=50)	(*P* value)
Age (yr)(mean±SD)	60.16± 11.5	58.84 ± 9.62	0.535
Sex (Male/Female)	26/24	27/23	0.862
Weight(kg)(mean±SD)	60.92 ± 6.15	62.86 ± 6.45	0.127

Table 2: **Baseline clinical variables (mean ±SD)**

	Group B	Group R	P value
Baseline HR	77.1±7.03	75.9±6.79	0.3871
Baseline SBP	137.50±11.55	136.02±10.96	0.5125
Baseline DBP	69.06±7.19	71.08±7.54	0.1735
Baseline RR	14.30±1.15	13.98±1.20	0.1767
Baseline SPO2	99.82±0.39	99.66±0.48	0.0695

HR: Heart Rate, SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, RR: Respiratory Rate, SPO2: Oxygen Saturation.

Table 3: **Onset of sensory block and motor block, mean ±SD (min)**

	Group B	Group R	P value
Onset of sensory block in min (mean±SD)	4.9±1.5	3.7±1.9	0.0128
Onset of motor block in min (mean ±SD)	7.2±1.7	4.8±2.1	0.0157

Table 4: Comparative evaluation of heart rate and blood pressure in both group

	Group B				Group R			
	Preop	**Intra op**	**Preop**	**Postop**	**Pre op**	**Intra op**	**Pre op**	**Postop**
HR Mean ± SD	77.10± 7.03	77.87±7. 98	77.10±7. 03	77.74±7. 43	75.90±6. 79	77.87±6. 98	75.90±6. 79	78.36±6 .95
P Value	0.6104		0.6614		0.139		0.071	
SBP Mean ± SD	137.50 ±11.55	141.70± 14.15	137.50± 11.55	129.10± 10.67	136.02± 10.96	140.63± 13.54	136.02± 10.96	125.56± 9.94
P Value	0.0418		0.0823		0.0257		0.0617	
DBP Mean ± SD	69.06± 7.19	81.41±6. 61	69.06±7. 19	74.26±7. 90	71.08±7. 54	82.89±5. 98	71.08±7. 54	77.73±7 .67
P Value	0.0254		0.7193		0.0318		0.2567	

DISCUSSION

Patient comfort, safety and low complication rates are the essentials of local anaesthesia. Cataract surgery is commonest ophthalmic surgical procedure, and a local anaesthetic technique is usually preferred. The relatively new amide local anaesthetic, ropivacaine, possesses properties similar to those of bupivacaine but is less neuro and cardiotoxic.[9-11] Since patients, undergoing cataract surgery, generally belong to older age group; ropivacaine in these patients may be a safer alternative.

We, therefore in this study compared the effects of ropivacaine and lidocaine versus bupivacaine and lidocaine during peribulbar anaesthesia for cataract surgery in terms of sensory, motor block, analgesic and side effects.

In this present study, the onset of sensory and motor block in the group R (ropivacaine/lidocaine group) was 3.7±1.9 and 4.8±2.1 respectively. In the group B (bupivacaine/lidocaine group) the onset of sensory block was 4.9±1.5 and the onset of motor block was 7.2±1.7. This was significant difference in the onset time($p<0.05$).Although the ropivacaine and lidocaine mixture resulted in faster onset of sensory and motor block, both anaesthetic solutions provided similar anaesthesia. There was no difference with the motor and sensory blockade intraoperatively and the postoperative analgesia was comparable in both the groups.

Huha T *et al.*[16]used 1 % ropivacaine with volume of 7.5 ml in one group and 0.75% bupivacaine 8ml in another group, hyaluronidase 150 IU per ml was added to both the group for peribulbar anaesthesia. Lid akinesia was slightly significantly more complete in the ropivacaine group. There was no difference between the groups with respect to perioperative analgesia or duration of akinesia or significant difference in the onset and quality of sensory block. However, ropivacaine appeared to be faster in the onset of globe and lid akinesia.

Gioia L*et al.*[17]found that surgical block was achieved after 8±5 min in the lido-bupivacaine group and after 10±5 min in the ropivacaine group. Evaluating clinical properties of 0.75% ropivacaine and a 1:1 mixture of 2% lidocaine and 0.5% bupivacaine for peribulbar anaesthesia, he demonstrated that ropivacaine has an onset similar to that of lidocaine-bupivacaine mixture and provides a better quality of postoperative analgesia.

Nicholson G *et al.*[18]used 7 to 10 ml of mixture of equal parts of bupivacaine and 2 % lidocaine or equal 7 to 10 ml volume of 1% ropivacaine; hyaluronidase 15 IU per ml was added to both the solutions. Both the groups showed satisfactory sensory and motor block for peribulbar anaesthesia.

Gillart T *et al.*[19]used 50 % bupivacaine (0.5%) and 50% lidocaine (2%) in 50 patients with volume 10.5 ± 2 ml in group 1 and 50% ropivacaine (1%) and 50 % lidocaine (2%) with volume 10.6 ± 2.2 ml in group 2; 25 IU hyaluronidase per ml was added with each combination for peribulbar surgery and found the quality of motor and sensory block to be satisfactory.

Woodward DK *et al.*[20] showed no difference in the rate of onset or degree of akinesia achieved. Sixty percent of patients in group 1 (1% ropivacaine plus hyaluronidase 300 IU/ml) and 55 % in group 2(bupivacaine 0.5%/ lidocaine 2 % plus 50 IU/ml hyaluronidase) achieved akinesia scores of <4 by 6 min,concluded that both peribulbar solutions produce equivalent onset and quality of ocular akinesia.

Mantovani C*et al.*[21]reported that the median time at which the block was adequate for surgery was 6 min in all the groups. He used 2% lidocaine and 1% ropivacaine without hyaluronidase or with hyaluronidase 15 IU/ml or 150 IU/ml.

The results of the above studies were consistent with the findings of our present study.

DURATION OF MOTOR BLOCK AND SENSORY ANALGESIA

In the present study, the patient was asked about intraoperative painusing the VNRS score; in both the groups none of the patients complained of pain. However, the patient was asked to note the time of ingestion of analgesic within 24 hours if pain occurred after the patient has been discharged and the details about the pain and the ingestion of analgesic were collected by telephonic conversation. 5 patients in group R and 8 patients in group B required analgesic (tab paracetamol 500mg) within 24 hours of surgery. However, this difference was statistically not significant ($p>0.05$).

The duration of motor block was not being assessed as the patient's eye was covered and bandaged after the operation and the patient was discharged home in 2 to 3 hours after the surgery.

Our results correlated with earlier studies conclude that use of ropivacaine produces the better analgesia,thereby reducing the VNRS (pain score in the early postoperative period) and bringing about better postoperative outcome.

EFFECT ON VITAL PARAMETERS AND SIDE EFFECTS

In the present study there was no significant difference between the two groups in base line blood pressure, heart rate and respiratory rate($p>0.05$).There was also no difference between intraoperative and postoperative blood pressure, respiratory rate and heart rate between the two groups. Although, there was an initial slight rise in both systolic and diastolic blood pressure immediately after the block was given compared to the baseline values. The rise in blood pressure came down to the baseline values after 10 to 15 mins after the block. The initial rise in blood pressure was most probably because of the anxiety. However, there was a significance difference in blood pressure in both the groups, when measured within the group ($p<0.05$).

Four patients in the ropivacaine group and 5 in the bupivacaine group had nausea, this was not a significant difference.

From the earlier studies (Gillart T *et al.*[19]&Woodward DK*et al.*[20]), we can conclude that the effects on vital parameters and side effects were consistent with our present study.

CONCLUSION

The present study shows that a mixture of 0.75% Ropivacaine and 2% Lidocaine is an effective alternative to a mixture of 0.5% Bupivacaine and 2% Lidocaine for peribulbar anaesthesia. Ropivacaine and Lidocaine mixture resulted in significantly earlier onset of sensory and motor block, less analgesic requirement and less side effects and complications. Hence it can be more effectively used as peribulbar block for cataract surgery.

REFERENCES

1. Eke T, Thompson J R. The national survey of local anaesthesia for ocular surgery.I. Survey methodology and current practice. Eye 1999;13:189-95.
2. Anker R, Kaur N. Regional anaesthesia for ophthalmic surgery. BJAEducation 2017;17:221–7.
3. Weigt HU, Spraul CW, Weiss M. What's new in ophthalmic anaesthesia?. Klin Monbl Augenheilkd 2003;220:809-21.
4. Barker JP, Vafidis GC, Hall GM. Postoperative morbidity following cataract surgery. A comparison of local and general anaesthesia. Anaesthesia1996;51:435–7.
5. Weiss JL, Deichman CB. A comparison of retrobulbar and periocular anesthesia for cataract surgery. Arch Ophthalmol1989;107:96–8.

6. Demediuk OM, Dhaliwal RS, Papworth DP, Devenyi RG, Wong DT. A comparison of peribulbar and retrobulbar anesthesia for vitreoretinal surgical procedures. Arch Ophthalmol1995;113:908–13.
7. Ripart J, Lefrant JY, de La Coussaye JE, Prat-Pradal D, Vivien B, Eledjam JJ. Peribulbar versus retrobulbar anesthesia for ophthalmic surgery: An anatomical comparison of extraconal and intraconal injections. Anesthesiology 2001;94:56-62.
8. Loots JH, Koorts AS, Venter JA. Peribulbar anesthesia. A prospective statistical analysis of the efficacy and predictability of bupivacaine and a lignocaine/bupivacaine mixture. J Cataract Refract Surg1993;19:72‑6.
9. McClure JH. Ropivacaine. Br J Anaesth1996;76:300-7.
10. Knudsen K, Beckman Suurküla M, Blomberg S, Sjövall J, Edvardsson N. Central nervous and cardiovascular effects of i.v infusions of ropivacaine, bupivacaine and placebo in volunteers. Br J Anaesth1997;78:507–14.
11. Oji E, Oji A. Bupivacaine and lignocaine for ophthalmic surgery. Br J Ophthalmol1987;71:66–8.
12. Scott DB, Lee A, Fagan D,Bowler GM, Bloomfield P, Lundh R. Acute toxicity of ropivacaine compared with that of bupivacaine. Anesth analg 1989;69:563-9.
13. Morrison SG, Dominguez JJ, Frascarolo P, Reiz S. A comparison of the electrocardiographic cardiotoxic effects of racemic bupivacaine, levobupivacaine, and ropivacaine in anesthetized swine. AnesthAnalg 2000;90:1308-14.
14. Jaichandran VV, Raman R, Gella L, Sharma T. Local anesthetic agents for vitreoretinal surgery: no advantage to mixing solutions. Ophthalmology 2015;122:1030–3.
15. Brahma AK, Pemberton CJ, Ayeko M, Morgan LH. Single medial injection peribulbar anaesthesia using prilocaine. Anaesthesia 1994;49:1003–5.
16. Huha T, Ala-Kokko TI, Salomäki T, Alahuhta S. Clinical efficacy and pharmacokinetics of 1% ropivacaine and 0.75% bupivacaine in peribulbar anaesthesia for cataract surgery. Anaesthesia 1999;54:137-41.
17. Gioia L, Prandi E, Codenotti M,Casati A, Fanelli G, Torri TM, *et al*. Peribulbar anesthesia with either 0.75% ropivacaine or a 2% lidocaine and 0.5% bupivacaine mixture for vitreoretinal surgery:a double-blinded study. Anesth analg 1999;89:739-42.
18. Nicholson G, Sutton B, Hall GM. Comparison of 1% ropivacaine with 0.75% bupivacaine and 2% lidocaine for peribulbar anaesthesia. Br J Anaesth 2000;84:89-91.
19. Gillart T, Barrau P, Bazin JE, Roche G, Chiambaretta F, Schoeffler P. Lidocaine plus ropivacaine versus lidocaine plus bupivacaine for peribulbar anesthesia by single medial injection. Anesth Analg 1999;89:1192-6.
20. Woodward DK, Leung AT, Tse MW, Law RW, Lam DS, Ngan Kee WD. Peribulbar anaesthesia with 1% ropivacaine and hyaluronidase 300 iu/ml: comparison with 0.5% bupivacaine/2% lidocaine and hyaluronidase 50 iu/ml. Br J Anaesth 2000;85:618-20.
21. Mantovani C, Bryant AE, Nicholson G. Efficacy of varying concentrations of hyaluronidase in peribulbar anaesthesia. Br J Anaesth 2001;86:876-8.