Original Article

Ropivacaine plus lidocaine versus bupivacaine plus lidocaine for peribulbar block in cataract surgery: A prospective, randomized, double-blind, single-center, comparative clinical study

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Abstract

Background and Aims: Cataract surgery in ophthalmology is usually done under peribulbar block with a mixture of 0.5% bupivacaine and 2% lidocaine. Several case reports of fatalities associated with bupivacaine has necessitated a search for alternative safe agents. The aim of this study was to compare peribulbar block characteristics using a mixture of 0.5% bupivacaine and 2% lidocaine with a mixture of 0.5% ropivacaine and 2% lidocaine.

Material and Methods: Eighty patients were allocated to two random groups of 40 each. Patients of groups BL and RL were given 4 ml of 0.5% bupivacaine and 4 ml of 0.5% ropivacaine each in a mixture with 4 ml of 2% lidocaine and 100 IU of hyaluronidase respectively. Block characteristics, hemodynamic variables, adverse drug interactions and other complications were recorded.

Results: Demographic characteristics were comparable in both the groups. Duration of onset of the block and the side effect profile was comparable in both the groups but the total duration of the block and the time for first rescue analgesia was found to be longer in group BL than in group RL.

Conclusions: Ropivacaine 0.5% and lidocaine 2% as a 1:1 mixture in a volume of 8 ml with 100 IU of hyaluronidase is as effective as a 1:1 mixture of bupivacaine 0.5% and lidocaine 2% in a volume of 8 ml with 100 IU of hyaluronidase with regards to onset and total duration of the block and side effects and hemodynamic changes.

Keywords: Bupivacaine, hyaluronidase, lidocaine, peribulbar block, ropivacaine

Introduction

Peribulbar block is the most common regional anesthetic technique employed worldwide to provide anesthesia for the Cataract Extraction and Intra Ocular Lens Implantation (CE and IOLI), as it is a safe and simple technique with very few complications and which produces effective analgesia and akinesia of the eye.[1,2] Most of the patients for this surgery are elderly and have multiple coexisting diseases. Regional techniques offer a great advantage in this population.[3]

A mixture of equal volumes of 0.5% bupivacaine and 2% lidocaine had been widely used for peribulbar blocks with or without adjuvants. Lidocaine is believed to hasten the onset

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of the block and bupivacaine to provide prolonged duration of motor and sensory block extending to postoperative period. Hyaluronidase hasten spread of the local anesthetic agents through tissue planes and has been shown to enhance the onset and quality of peribulbar block.[4,5]

All local anesthetics, especially bupivacaine can cause rapid and profound cardiovascular depression after rapid intravascular administration of a large. Cardiac resuscitation is more difficult after bupivacaine-induced cardiovascular collapse. In view of this, new drugs ropivacaine and levo-(S) bupivacaine were introduced into anesthetic practice which showed a relatively safer cardiovascular, neurological and pharmacological profiles.[6-8] Ropivacaine exhibits a similar sensory and motor block pattern to bupivacaine. It is also reported to have a vasoconstrictive effect, which helps in lowering the intraocular pressure (IOP) by decreasing the intraocular blood volume.[9]

Considering the above reports, we designed this prospective, randomized, double-blind, single-center, comparative study with the hypothesis that a mixture of 0.5% ropivacaine and 2% lidocaine employed in 8 ml volume administered for peribulbar block will produce comparable block characteristics with that of a mixture of 0.5% bupivacaine and 2% lidocaine. Hyaluronidase was added to the anesthetic mixture in both the groups in a concentration of 12.5 IU/ml i.e. 100 IU per 8 ml of anesthetic mixture. The primary objective of the study was to evaluate the onset of block and duration of motor and sensory block in the study groups. The secondary objective was to assess for the changes in hemodynamic variables, adverse drug effects and the occurrence of other complications, assessment of surgeon and patient satisfaction with the anesthetic technique and the total analgesic medications consumed in the first 24 hours of postoperative period.

Material and Methods

Institutional Ethical committee approval was obtained vide letter No Rc.No: IEC/9/31032018 dated 31st March 2018. We registered our study with Clinical Trial Registry vide CTRI registration No CTRI/2018/04/013538 dated 27th April 2018 (Reference No REF/2018/04/019430). The xclusion criteria adapted for our study were patients with known allergy to study drugs, patient refusal of local anesthetic block, high myopia, glaucoma, orbital anomaly, ocular infection, mental retardation, uncontrolled hypertension, coagulation abnormalities, patients with axial length of eyeball more than 26 mm, posterior staphyloma, diabetes and chronic obstructive pulmonary disease. From among 200 adult patients attending our Medical College Hospital for elective CE and IOL surgery, one hundred were enrolled for our study by adapting simple random sampling by lottery. After screening, patients not meeting the criteria or not willing to participate in the trial were excluded from the study 80 participants were enrolled in the study. The participants were of age between 20 and 80 years and of American Society of Anesthesiologists (ASA) physical status grade I and II of either sex. The study was undertaken between the period 1st May 2018 and 30th July 2018. Written informed consent was obtained from all the participants after explaining in detail about the study protocol, all consequent risks and benefits in their mother tongue.

All the patients were examined in the preanesthetic clinic (PAC) prior to surgery by thorough history taking and physical examination and specific enquiry was made regarding previous ophthalmic surgery such as any buckling surgery, glaucoma and the presence of any staphyloma. Required investigations were carried out such as fasting blood sugar, ECG (electrocardiogram), chest X-ray, kidney function tests, coagulation profile and A-scan echography to know the axial length of the eyeball. Details of the technique of peribulbar block and cataract surgery were explained to the patients at the PAC clinic and patients were also instructed about the visual analog scale (VAS) used for assessing the severity of pain during the study period.

The patients were allocated to two groups of 40 each, bupivacaine group (group BL, $n = 40$) and ropivacaine group (group RL, $n = 40$), using a computer-generated random grouping software. The group allocation was kept confidential an independent consultant who also monitored the preparation of the study drugs. Patients of group BL were given a mixture of 4 ml of 0.5% bupivacaine and 4 ml of 2% lidocaine and 100 IU of hyaluronidase and those in group RL received 4 ml of 0.5% ropivacaine and 4 ml of 2% lidocaine and 100 IU of hyaluronidase. The total volume of the anesthetic agents administered was 8 ml for each patient in both the groups with hyaluronidase at 12.5 IU per ml. All patients were advised nil per orally for 6 hours prior to the surgery and were premedicated with alprazolam 0.25 mg and tablet ranitidine 150 mg orally the night before surgery.

The anesthesiologist administering the block and making a subsequent assessment of the block characteristics as well as the surgeon performing the operation, the patients, the data entry operator and the statistician were blinded to the drugs being administered. A separate data sheet was maintained for each patient with all relevant clinical data for statistical analysis. On arrival in the induction room, baseline vital parameters were measured and recorded. Standard monitoring was started with non-invasive blood pressure (NIBP), ECG, and pulse oximeter and intravenous access established with 20 gauge intravenous cannula. Concealment of allocation

was ensured through a blinded anesthesiologist opening the serially numbered sealed opaque envelop to determine drug preparation immediately before administration. The anesthetic agents to be injected were drawn into a 10 ml syringe. Peribulbar block was carried out by another blinded anesthesiologist. A single anesthesiologist performed all the blocks. Patients were asked to fix their eyes in the neutral gaze position. Under strict aseptic precautions the block was administered via a single inferotemporal, transcutaneous injection through the lower eyelid using a 24 gauge, 25 mm long needle. After a negative aspiration test for blood for excluding inadvertent intravascular injection, 8 ml of the local anesthetic mixture was injected over 30–40 s. Manual compression through gentle intermittent digital pressure was applied to the eyeball, to facilitate the spread of the anesthetic solution.[10]

Akinesia was tested every minute starting one minute from the completion of peribulbar injection to the time when total akinesia and analgesia was achieved. The primary outcome measures studied were the time to onset of motor and sensory block and the total duration of the block. Secondary outcome measures included changes in hemodynamic variables like pulse rate (PR), mean arterial pressure (MAP), respiratory rate (RR), pulse oximetry (SpO_2), allergic reactions to the study drugs, chemosis conjunctiva, nausea, vomiting, dryness of mouth and any other adverse events like globe perforation and oculocardiac reflex, surgeon and patient satisfaction scores. Onset of sensory block was taken as the time elapsed from completion of peribulbar injection to loss of sensation to the touch of a wisp of cotton wool on the conjunctiva. To assess motor block, eyeball movements were scored on a 3 point scale for each direction of gaze in superior, inferior, medial and lateral directions: where 0 = a flicker of movement or no movement of eyeball in the respective direction; 1 = partial movement in the respective direction or sluggish movement; and 2 = brisk and full range of movement. The possible maximum score was a 8 points for each examination. A total score of zero (0) was taken as an indication of a successful block.

Eyelid movements were assessed on a three point scale, where 0 = complete inability to open the eyelids; 1 = ability to open eyelids partially; and 2 = ability to open the eyelids completely. Eyeball and eyelid movements were assessed every minute starting one minute from completion of peribulbar injection to the time when total akinesia and analgesia of the eyeball was achieved. A total eyelid movement score of zero (0) and total ocular movement score of zero (0) were considered adequate for surgery. If the block was found inadequate after 10 minutes, a supplementary injection was given with a further dose of up to 4 ml of the anesthetic mixture by the same technique. The time taken to attain adequate surgical anesthesia and the total volume of supplementary injections was noted.

In the operation theatre, patients were placed supine on the operation table and routine monitoring equipment was applied with PR, SpO_2, ECG, RR and MAP being monitored and recorded every 5 minutes throughout the operation period and then every 15 minutes while the patient remained in postanesthesia care unit (PACU) for 2 hours. Intraoperatively patients were given oxygen at 4 l/minute through nasal prongs whenever there was a drop in oxygen saturation to less than 95%. Adverse events such as bradycardia (HR <50 beats/min), hypotension (fall in MAP below 20% from the baseline or an absolute MAP <60 mmHg), bradypnea (RR <8 breaths/min), desaturation (Spo_2 <95%), nausea, vomiting, dryness of mouth, chemosis conjunctiva, diplopia or any other adverse events during or within 2 hours after the procedure were noted and treated appropriately.

After the completion of surgery patients were shifted to the PACU, where postoperative pain was assessed using VAS on a 0 to10 scale and rescue analgesia was provided with diclofenac 50 mg orally when the patients had pain > VAS 3. Total duration of the sensory block was taken as the time between successful block and the first request of the patient for pain relief. Total analgesic requirement for the first 24 hours after completion of surgery was recorded. Patients were asked regarding their satisfaction about the anesthetic experience on a 3 point verbal rating scale where 1 = extremely dissatisfied, had severe pain and adverse events; 2 = satisfied, had minimal pain only; 3 = extremely satisfied, no pain or adverse events and comfortable during the block and surgery. Surgeon satisfaction was also recorded by asking him to rate his satisfaction with operative conditions at the end of surgery, using the three point verbal rating scale. where 1 =, not satisfactory as surgery was interrupted; scale 2 =, satisfactory with only minor issues but not necessitating interruption of surgery; 3 =, good with satisfactory operating conditions and patient having no pain. A score of >1 was taken as acceptable satisfaction level both in the case of patients and the surgeons.

Power analysis was based on the results of a pilot study and sample size calculation was based on a population standard deviation of 1.4 with respect to the duration of onset of the block, with 80% power and an alpha error of 5%. To detect a mean difference in duration of onset of a block of 1.2 min between groups, a sample size of 38 patients per group was required. We included 40 patients in each group to compensate for any possible dropouts in the middle of the study.

Data were expressed as a mean ± standard deviation for quantitative variables (parametric data), and as a number and proportions/percentages for categorical variables. Parametric data were analyzed using unit normal variate Z test or Mann Whitney U test as applicable and categorical data (non-parametric data) were analyzed using Z test for proportions as the sample size in our study was >30. A *P* value of 0.05 was considered statistically significant. Statistical analysis was carried out using SPSS version 16.0 (trial ve rsion) and Microsoft Office Excel 2007.

Results

The data of all eighty patients were included in the statistical analysis. The flow chart of patients participating in our study.

The demographic characteristics were comparable in both groups [Table 1]. Baseline vital signs (HR, MAP, SpO_2, RR, ECG) were comparable in both groups. The MAP, PR, RR and SpO_2 during the administration of the block, during surgery and at 2 hours post-operative period were comparable.

Onset time of sensory analgesia was 2.0 ± 0.9 min in group BL as against 3.0 ± 3.3 in group RL; onset of motor block was 4.2 ± 3.9 min in group BL as against 4.7 ± 4.5 in group RL and onset of lid akinesia was 2.8 ± 2.2 min in group BL as against 4.2 ± 4.3 in group RL. The optimum time when the block was considered adequate for surgery was 4.2 ± 3.9 min in group BL, whereas it was 4.7 ± 4.5 min in group RL, but this difference in time was not statistically significant Table 2. Duration of globe analgesia (time required for rescue analgesic) was minimum 63 min, maximum 554 min, median 20.6 and IQR (inter-quartile range) 165.8 and range 491 min in group BL as against 60, 493, 192.5, 118.3 and 433 min respectively in group RL and this difference is not statistically significant (*P* value 0.15, Mann Whitney U test). Total number of supplementary injections given for peribulbar block and the total analgesic requirement in the first postoperative day measured by the number of doses of tablet diclofenac sodium 50 mg given orally was not statistically significant between the groups [Table 2].

A limitation of our study was that we could not assess the duration of the motor block by examining ocular movements as the patients' eyes were bandaged postoperatively. Therefore a request for analgesia was taken to indicate the duration of motor block as well as the end point of sensory block.

There were no instances of systemic toxicity, drug allergy, oculocardiac reflex, nausea, vomiting, or dry mouth due to the local anesthetic doses employed in our study. In group BL, there were two instances of hypotension, one of bradycardia, and three of SPO_2 <95% which responded to injection mephentermine 6 mg, injection atropine 0.5 mg and supplemental oxygen at 4L/min respectively. In group RL there were two instances of hypotension, three of bradycardia

Table 1: Demographic details of the patients

Demographic characteristics	Group BL *n*=40	Group RL *n*=40	*P*
Age (years) (mean±SD)	62.9±9.5	59.3±12.4	0.136
Gender (numbers) male/female	16/24	16/24	1.0
Weight (kg) (mean±SD)	51.5±9.7	52.2±11.6	0.772
Side of eye operated (numbers-Right/Left)	16/24	15/25	0.818
Axial length eye ball (cm) (mean±SD)	22.8±1.0	22.6±0.8	0.309
ASA grade I/II	36/4	34/6	0.762
Duration of surgery (min) (mean±SD)	17.5±6.0	18±6.2	0.697

ASA=American Society of Anesthesiologists. BL bupivacaine-lidocaine group RL ropivacaine-lidocaine group

Table 2: Block characteristics mean±SD

Block characteristics	Group BL *n*=40	Group RL *n*=40	*P*
Onset of sensory block (min)	2.0±0.9	3.0±3.2	0.06
Onset of motor block (min)	4.2±3.9	4.7±4.5	0.49
Onset of lid akinesia (min)	2.8±2.2	4.2±4.3	0.06
Supplementary injection (numbers) (%)	7 (17.5%)	6 (15%)	0.76
Time of rescue analgesic (minimum duration of sensory block)	63	60	
Time of rescue analgesic (maximum duration of sensory block)	554	493	0.15
Time of rescue analgesic (median)	206	192.5	
Time of rescue analgesic (IQR)	165.8	118.3	
Total analgesic requirement first day (mg)	100	100	1.0

BL=Bupivacaine lidocaine group RL ropivacaine lidocaine group. IQR Inter Quartile Range

and one of SPO_2 <95% which responded to above methods. These incidences were not statistically significantly different. Chemosis conjunctiva was seen in five patients in group BL and four in group RL. It subsided after 5 minutes of gentle manual compression of the eyeballin all cases. The patient and surgeon satisfaction scores were similar in both the groups with no requirement of postponing any case and no adverse events were recorded during the surgery and in the first 24 hours of postoperative period.

Discussion

In view of the aged population of patients with several coexisting systemic diseases reporting for surgery of CE and IOL implantation, regional technique like peribulbar block rather than general anesthesia is the most popular form of anesthesia used as it is safe, simple to perform and devoid of respiratory and hemodynamic complications associated with general anesthesia.[11-13] Though mixtures of bupivacaine and lidocaine are used traditionally for peribulbar blocks, recent instances of adverse cardiac side effects associated with the use of bupivacaine necessitated a search for newer safer alternatives for bupivacaine. Several studies had demonstrated ropivacaine to be safer than bupivacaine with respect to cardiotoxicity and adverse neurological manifestations besides exhibiting comparable anesthetic profile.[14] We evaluated a mixture of 0.5% ropivacaine and 2% lidocaine with a mixture of 0.5% bupivacaine and 2% lidocaine as several studies had evaluated a higher concentrations of ropivacaine (0.75% or 1%).

The time to adequate surgical block was similar in both the groups and is in partial agreement with other studies. The side effect profiles were also similar.

Gioia *et al*.[15] and Gillart *et al*.[16] compared 0.75% ropivacaine with a mixture of 2% lidocaine and 0.5% bupivacaine for peribulbar anesthesia in vitreo-retinal surgery and concluded that ropivacaine produced better anesthesia. We observed that bupivacaine group (group BL) and ropivacaine group had shown similar block duration. The difference may be due to the higher concentration of ropivaceine used.

Ganesh *et al*.[17] compared a combination of 2% lidocaine with adrenaline and 0.75% ropivacaine with 2% lidocaine and 0.5% bupivacaine given in a 10 mL volume with a dual-injection technique and concluded that ropivacaine produced prolonged post-operative pain relief. They also reported onset time of sensory block as 2.7 ± 0.7 min in bupivacaine group and 2.6 ± 0.6 min in ropivacaine group which are different from our results. These differences are probably due to addition of adrenaline and a higher concentration of ropivacaine, as well as the use of a dual injection techinque.

Huha *et al*. used 1% ropivacaine and 0.75% bupivacaine in peribulbar anesthesia for cataract surgery and concluded that there was no clinically significant difference in the sensory blockade.[18] Woodward *et al*. studied peribulbar anesthesia with 1% ropivacaine and hyaluronidase 300 IU/mL in comparison with 0.5% bupivacaine, 2% lidocaine and hyaluronidase 50 IU/mL and reported no difference in the rate of onset and degree of akinesia achieved.[19] We achieved similar results while using a lower concentration of ropivacaine.

Dhanya *et al*.[20] used similar drugs as in our study and concluded that quality of motor block was better with ropivacaine. They did not comment about the duration of sensory block and postoperative analgesia. They did not employ hyaluronidase and used a variable the volume of anesthetic mixture of 7 -10 mL. They also employed a different injection technique of single medial injection as against single inferolateral injection For these reasons our studies are not comparable.

In a good number of cases, i.e., 7 (17.5%) cases in group BL and 6 (15%) cases in group RL, the onset of the block was found to exceed 10 min necessitating supplemental injection. Future studies can be designed to test whether a quicker onset of the block can be obtained by employing either a higher volume of an anesthetic mixture or dual injection technique at two different quadrants i.e., inferotemporal and superonasal quadrants.

A limitation of this study is that we did not measure intraocular pressure during block administration and in the postoperative period to avoid handling the operated eye in the immediate postoperative period. Inclusion of 2% lidocaine might have influenced the time of onset and duration of the block in this study.

Conclusion

We conclude that in peribulbar blocks, a 1:1 mixture of ropivacaine 0.5% and lidocaine 2% in a volume of 8 mL with 100 IU of hyaluronidase is as effective as a 1:1 mixture of bupivacaine 0.5% and lidocaine 2% in a volume of 8 mL with 100 IU of hyaluronidase as regards onset and duration of block, side effects and hemodynamic changes.

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Conflicts of interest
There are no conflicts of interest.

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