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EFFECT OF A MIXTURE OF BUPIVACAINE AND LIDOCAINE VERSUS BUPIVACAINE ALONE USED FOR PERIBULBAR BLOCKS FOR CATARACT SURGERIES

Ramana Reddy V Moolagani — M.D., Assistant professor, Department of Anaesthesiology, Gayatri Vidya Parishad Institute of Health care and Medical Technology (GVPIHC&MT), Marikavalasa, Visakhapatnam, Andhra Pradesh, India.

Shanker R Burla* — M.D., Associate professor, Department of Anaesthesiology, Gayatri Vidya Parishad Institute of Health care and Medical Technology (GVPIHC&MT), Marikavalasa, Visakhapatnam, Andhra Pradesh, India. *Corresponding Author

Bhaskara R Neethipudi — M.D., Professor & HOD, Department of Anaesthesiology, Gayatri Vidya Parishad Institute of Health care and Medical Technology (GVPIHC&MT), Marikavalasa, Visakhapatnam, Andhra Pradesh, India.

ABSTRACT

Background : Mixtures of 0.5% bupivacaine and 2% lidocaine are commonly used in peribulbar blocks for cataract surgery. It is not clear whether 0.5% bupivacaine used alone can provide similar block characteristics and also whether the addition of adrenaline to bupivacaine will modify block characteristics.

A prospective, randomized, double blind, parallel group study was conducted on a total of 80 patients with an aim to evaluate the peribulbar block characteristics using 0.5 % bupivacaine as a single agent (with or without adrenaline) versus mixture of 0.5% bupivacaine and 2% lidocaine (with or without adrenaline).

Material and Methods : With computer generated random grouping software, patients were allocated to four groups of 20 each (n=20). Peribulbar block was given with eight ml of 0.5% bupivacaine and 0.02ml normal saline in group B, eight ml of 0.5% bupivacaine and 20 µg adrenaline in 0.02ml normal saline in group BA, four ml of 0.5% bupivacaine and four ml of 2% Lidocaine and 0.02ml normal saline in group BL and four ml of 0.5% bupivacaine and four ml of 2% lidocaine with adrenaline and 0.02ml normal saline in group BLA. Hyaluronidase 200IU was added to the anesthetic drugs for all the patients in the four groups.

Data were analyzed in SPSS V22. Kruskal Wallis test and Chi-Square test were applied to find statistical significance. The P value of ≤ 0.05 was considered as statistically significant.

Results: Onset of the block and duration of analgesia and the side effect profile were comparable in all the groups.

Principle Conclusions: In peribulbar blocks 8.02ml of bupivacaine 0.5% used alone appears to be equally effective as that of a 8.02ml of 1:1 mixture of bupivacaine 0.5% and lidocaine 2%. Addition of adrenaline to the anesthetic agents had no statistically significant effect on block characteristics.

KEYWORDS : adrenaline, bupivacaine, lidocaine, peribulbar block

INTRODUCTION:

Peribulbar block is most commonly used for cataract surgery in preference to other methods [1] as it is associated with less hemodynamic instability, less respiratory depression, better postoperative pain relief, and less nausea and vomiting than general anaesthesia [2,3] and is a much simpler, rapid, and safe technique, especially in elderly patients [4] who have multiple systemic diseases such as diabetes, cardiovascular disease and kidney diseases .[5]

Mixtures of 0.5% bupivacaine and 2% lidocaine (with or without adrenaline) in various proportions in 8 to 10 ml volume are used extensively for these blocks. Lidocaine used in this mixture is believed to provide quicker onset of the block, whereas bupivacaine is considered to provide the longer duration of the block. Recently there are several published reports of transient neurological symptoms associated with the use of lidocaine in regional techniques and hence several centres are avoiding using lidocaine in regional blocks. [6,7] While using bupivacaine 0.5% and lidocaine 2% as a 1:1 mixture, the effective concentration of both the drugs gets reduced to half of their original concentration thereby weakening their anesthetic potency. It is not clear whether 0.5% bupivacaine used alone can provide similar block characteristics as when it is used in combination with lidocaine plain or lidocaine with adrenaline. It was hypothesized that bupivacaine used alone at a higher concentration of 0.5% can obviate the requirement of using it in combination with lidocaine for obtaining the desired block characteristics thereby avoiding untoward neurological complications associated with lidocaine.[8] It was also desired to assess the effect of adding adrenaline to bupivacaine in enhancing the onset and the duration of the block.

In the backdrop of the above facts, we undertook this prospective, randomized, double blind, single centre, parallel group comparative study with the primary objective of evaluating the onset and the duration of the peribulbar block with a 1:1 mixture of 0.5% bupivacaine and 2% lidocaine (with or without adrenaline) versus 0.5 % bupivacaine alone (with or without adrenaline),used in 8.02 ml volume with hyaluronidase added as adjuvant in a concentration of 25 IU/ml. Hyaluronidase has been shown to hasten the onset-time and enhance the quality of the peribulbar block.[9]

The secondary outcome measures studied were alterations in pulse rate (PR), mean arterial pressure (MAP), respiratory rate (RR), Saturation of arterial oxygen saturation (SaO2), adverse drug effects, total analgesic requirement in the first 24 hours after surgery and other complications encountered in the intra operative and the post operative period.

METHODS:

The procedures followed in our study protocol were in accordance with the ethical standards of the committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2000**.** Institutional ethical committee had granted approval for our study vide its letter Rc.No: IEC/11/17072018 dated 17 July 2018 and before enrolling patients for clinical trial, our study was registered with clinical trial registry vide registration number CTRI/2018/08/015541 dated 30-8-2018. **Selection and Description of Participants:** From among the 200 adult patients attending our Medical College Hospital for elective cataract surgery, one hundred were enrolled for our study by adapting simple random sampling by lottery method. This reference population of 100 was subjected to screening by applying inclusion and exclusion criteria as per our study protocol. Patients refusing to participate in the trial were excluded from the study and finally 80 participants were enrolled. Details of the study protocol, the methodology and all consequent risks and benefits were explained to all the participants in their mother tongue before enrolling them for the study and a written informed consent was obtained in the presence of witnesses. The exclusion criteria for our study included patients with known allergy to study drugs, those refusing the regional block, those on anticoagulant therapy, high myopia (axial length of eye ball greater than 28 mm), previous ophthalmic surgery such as buckling surgery, glaucoma, ocular infection, orbital anomaly, mental retardation, uncontrolled hypertension, diabetes, posterior staphyloma and chronic obstructive pulmonary disease.

The study population consisted of both male and female with an age range between 20 and 80 years and were of American Society of Anesthesiologists (ASA) physical status grades I and II and were allocated to four study groups of 20 each (n = 20) through a computer generated random grouping software: group B, group BA, group BL and group BLA. Patients of group B were given 8 ml of 0.5% bupivacaine and 0.02ml normal saline; Patients of group BA were given 8 ml of 0.5% bupivacaine and 20 µg adrenaline in 0.02ml; Patients of group BL were given 4 ml of 0.5% bupivacaine and 4ml of 2% lidocaine and 0.02ml normal saline; Patients of group BLA were given 4 ml of 0.5% bupivacaine and 4 ml of 2% lidocaine with adrenaline and 0.02ml normal saline. Hyaluronidase 200 IU was added to the anesthetic agents in all the four groups and the total volume of the anesthetic agents administered was 8.02 ml for each patient and hyaluronidase concentration of 25 IU/ml. Adrenaline was used in a concentration of one in 4 00 000 (2.5 µg/ml) in groups BA and BLA. The study was undertaken between the period 2nd September 2018 and 20th December 2018.

Prior to taking up for surgery all the patients were examined in the pre anesthetic clinic by thorough history taking and physical examination. Investigations such as coagulation profile, fasting blood sugar, electrocardiogram , chest X-ray, kidney function tests and A-scan echography to know the axial length of the eye ball were carried out wherever indicated. A serially numbered sealed opaque envelope method was used for ensuring blinding technique. Patients were advised to remain fasting from the midnight and no premedication was given and no topical anesthetics were used before or during the block administration and in the intra operative period.

On arrival in the pre operative room an intravenous access was established with 20 gauge intravenous cannula and standard monitoring was started with non-invasive blood pressure , pulse oximeter and electro cardiogram . Peribulbar blocks were administered by a single anesthesiologist who is blinded to the drugs being injected. The anesthesiologist making the assessment of the block characteristics, the surgeon performing the operation, the patients, the data entry operator and the statistician were blinded for the drugs being administered. All relevant clinical data for statistical analysis was recorded on a separate case sheet for each patient.

Patients were asked to fix their eyeballs in neutral gaze position and observing strict aseptic precautions, the block was administered via a single trans cutaneous injection [10] through the lower eyelid in the inferotemporal quadrant, using a 24 gauge, 25 mm long needle. After a negative aspiration test for blood for excluding inadvertent intra vascular injection, total 8.02 ml of the local anesthetic mixture was injected over 30–40 s. Manual compression was exerted over the eye ball with gentle, intermittent digital pressure to facilitate spread of the anesthetic solution and to lower the intraocular pressure.[11,12]

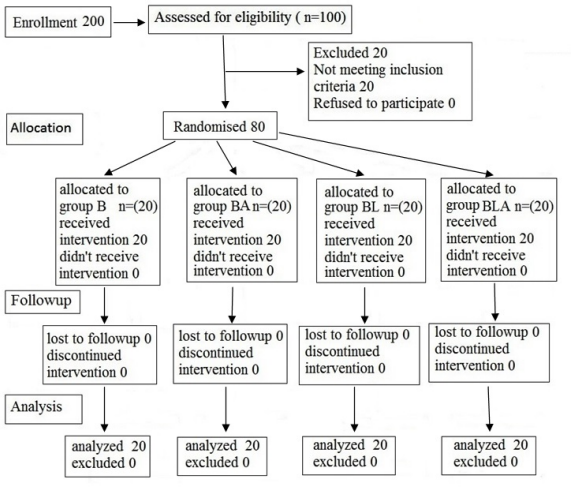
Assessment of loss of movement of the eyelid and loss of movement of the eyeball (akinesia) in all directions was tested every minute starting one minute from the completion of the peribulbar block to the time when total akinesia of the eyeball was achieved. Sensory block was evaluated by testing for loss of sensation of the conjunctiva with a wisp of cotton wool. The primary outcome measures studied were time elapsed for the onset of the block both motor and sensory and the total duration of the block as measured by the time elapsed from the total block to the time when patients complain of pain and request for rescue analgesia. The total analgesic requirement in the first 24 hours was also recorded. Secondary outcome measures studied included haemodynamic variables, number of supplemental injections given to attain the adequate block, the total analgesic requirement in the first 24 hours and adverse drug interactions and other complications. Eyeball movements were scored on a 3 point scale for each direction of gaze in superior, inferior, medial and lateral directions with a scoring system; (score 0 = A flicker of movement or no movement of eye ball in the respective direction; score = 1 Partial movement in the respective direction or sluggish movement; scale = 2 brisk and full range of movement). The possible maximum score is a total of 8 points for each examination. Eyelid movements were also assessed on a 3 point scale; (scale 0 = complete inability to open the eyelids; scale 1= able to open eyelids partially; scale = 2 able to open the eyelids completely). Eyeball and eyelid movements were assessed at every minute starting from one minute to 10 minutes of completion of the block. If the block was inadequate after 10 minutes, supplementary injection was given with a further dose of up to four ml of the same anesthetic drug. The time to adequate surgical anesthesia and the need for supplementary injections were noted. Loss of sensation of the conjunctiva associated with a total eyelid movement score of zero (0) and total eyeball movement score of zero (0) was considered as adequate for taking up for surgery. Complications arising during or after injection were recorded.

In the operation theatre routine monitoring equipment was applied with PR, MAP and SaO2 being monitored and recorded throughout the operation period at every five minutes till the end of surgery and then every 30 minutes while the patient remained in the post-anaesthesia care unit . Adverse events such as bradycardia, hypotension, bradypnoea, nausea, vomiting, and dryness of mouth were noted and appropriately treated. Post-operative pain was assessed using visual analogue score on 0 to 10 scale, if the score was >3, rescue analgesia was provided with tablet diclofenac 50 mg orally and the time when rescue analgesic was given was noted for assessing the total duration of the block. Assessment of the eyeball movements in post operative period was not done so as to avoid the handling of the operated eye and the duration of the block was assessed based on appearance of pain in the operated eye.

Sample size calculation was based on a population standard deviation of one minute with respect to the onset of the block and one hour with respect to duration of the block. With 80% power and 5% alpha error to detect a difference in duration of onset of block of one minute between groups, a sample size of 15 patients per group was required. We included 20 patients in each group for better validation of the results and to compensate for any possible dropouts in the middle of the study. The primary outcome measures studied were the time elapsed for the onset of the block (both motor and sensory) and the total duration of the block and the secondary outcome measures studied were the need for supplementary injections for getting adequate surgical conditions, the occurrence of adverse reactions, alterations in PR,MAP, RR, SaO2.

Statistics: Data were expressed as mean ± sd (standard deviation) for parametric variables, and as the number and percentages for categorical variables. Data were entered in MS-Excel and analyzed in SPSS V22.Descriptive statistics were represented with percentages, median and inter quartile range . Kruskal Wallis test and Chi-Square test were applied to find statistical significance and a value of $P < 0.05$ was considered as statistically significant.

Results: There were 20 patients in each group and the data of all the patients were included in the statistical analysis. The flow chart of patients participating in our study is depicted as Figure 1.



Flow diagram showing patient progress through the study phases

The demographic characteristics such as age, gender, weight, ASA grade, side of the eye operated, the axial length of the eyeball and the duration of the surgery were comparable in all the four groups as shown in Table 1.

Data- mean ± standard deviation or number

Table1: Demographic data of the groups B,BA,BL and BLA					
Variables	**GroupB(n=20)**	**GroupBA(n=20)**	**GroupBL(n=20)**	**GroupBLA(n=20)**	**P-value**
Age (years)	56.1±7.3	59.1± 7.9	59.7± 8.9	59.1±11.5	0.02*
Weight(Kg)	52.1±10.2	50.9±11.4	50.4±13.6	57.9±13.3	0.39*
Sex(M:F)	10:10	09:11	09:11	12:08	0.91*
ASA grade (I:II)	14:06	13:07	14:06	12:08	0.57*
Axial length of eye ball(cm)	22.7±1.2	22.5±0.8	22.6±0.9	22.5±1.0	0.98*
Duration of surgery(min)	21.3±10.3	21.0±6.9	22.4±9.4	22.1±10.0	0.94*

SD Standard deviation ASA American society of anaesthesiologists
*Not significant at P value < 0.05

Onset time of sensory analgesia was 3.5 ± 2.9, 4.5 ± 4.4, 2.6 ± 2.2 and 4.7 ±3.3 min in group B, BA, BL and BLA respectively (table 2). The onset time was shorter in group BL compared to the other three groups but this difference was not found statistically significant. Addition of adrenaline as adjuvant to the anesthetic mixture had the effect of delaying the onset time as seen in group BA and group BLA. Onset time of paralysis of the eyelid was 4.5 ± 3.7, 4.7 ± 4.5, 2.8 ± 2.6 and 6.1 ± 5.0 min in groups B,BA, BL and BLA respectively

Table 2: Data of block charactaristics of the groups B,BA,BL and BLA					
Variables	**GroupB(n=20)**	**GroupBA(n=20)**	**GroupBL(n=20)**	**GroupBLA(n=20)**	**P-value**
Onset of sensory loss of conjunctiva (min)	3.5±2.9	4.5± 4.4	2.6± 2.2	4.7±3.3	0.09*
Onset of paralysis of eye lid (min)	4.3±3.7	4.7±4.5	2.8±2.6	6.2±5.0	0.09*
Onset of complete motor block(min)	7.7±2.7	5.1±5.2	2.6±2.9	6.8±5.8	0.12*
Total sensory block (min)	936.7±707.6	843.9.7±574.3	704.2±550.4	567.2±495.7	0.23*
Total supplementay injections (numbers)	6	7	5	7	0.29*
Total analgesic requirement(mg)	27.5±25.5	32.5±24.5	37.5.3±22.2	42.5±18.3	0.09*

Data- mean ± standard deviation or number
*Not significant at P value < 0.05

The onset time was shorter in group BL compared to the other three groups but this difference was not found statistically significant. Addition of adrenaline as adjuvant to the anesthetic mixture had the effect of delaying the onset time of lid paralysis as seen in groups BA and BLA.

Onset time of motor block of the eyeball (akinesia) was 7.7 ± 2.7, 5.1 ± 5.2, 2.6 ± 2.9 and 6.8 ± 5.8 min in groups B,BA, BL and BLA respectively. (Table 2) The onset time was shorter in group BL compared to the other three groups but this difference was not found statistically significant. Addition of adrenaline as adjuvant to the anesthetic mixture had the effect of reducing the onset time of akinesia of the eyeball in group BA but has the opposite effect in BLA.

Duration of the block as assessed by the reporting of the appearance of pain in the operated eye was 936.7 ± 707.6, 843.9 ± 574.3, 704.3 ± 550.4 and 567.3 ± 495.7 min in groups B, BA, BL and BLA respectively. The total block duration was longer in group B compared to the other three groups but this difference was not found statistically significant. Addition of adrenaline as adjuvant to the anesthetic mixture had the effect of reducing the total duration of the block attained as seen in groups BA and BLA.

Baseline vital signs such as HR, MAP, SaO2 and RR were comparable in all the groups and their fluctuations during administration of the block and during the surgery at intervals of 5, 10, 15, 20,25,30,60 and 120 minutes showed minimal changes and these were not statistically significant.(Figure 2)

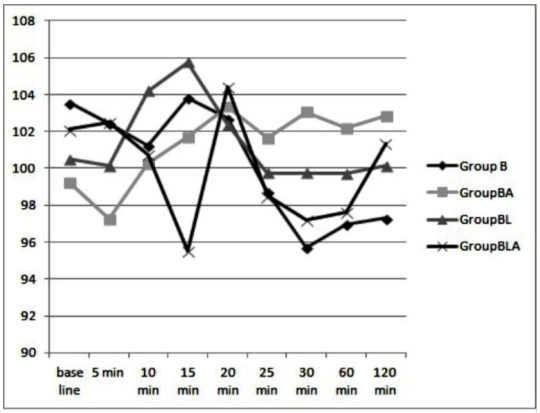


Figure 2: Comparison of mean arterial pressure changes in four groups

The occurrence of hypotension, bradycardia, chemosis conjunctiva and fall in SaO2 in all the groups are comparable and the differences are not statistically significant.

The complications noted during surgery and in the post-operative period, number of supplements given for obtaining effective block and the total analgesic requirement were comparable in all the groups. We did not encounter instances of systemic toxicity, drug allergy, oculo cardiac reflex, nausea, vomiting and dry mouth in any of the patients.

Strengths and limitations: We were unable to assess the duration of motor block by examining eyeball movements as patients' eyes were bandaged postoperatively and hence request for analgesia was taken to indicate the duration of the motor block as well as lasting of sensory block. Further we did not measure intra ocular pressure during block administration and in the postoperative period. Addition of hyaluronidase and adrenaline as adjuvants act as a confounding variable in this study.

Future research directions: Large scale studies excluding confounding variables are warranted for validation of our findings**.**

DISCUSSION:

Generally aged patients with several coexisting systemic diseases report for cataract surgery and regional technique like peribulbar block is most commonly used because of its safety profile. [13,14] Though mixtures of bupivacaine and lidocaine are used traditionally for administering the peribulbar blocks, recent instances of adverse effects like transient neurologic symptoms associated with use of lidocaine necessitated a search for newer safer alternatives methods avoiding the use of lidocaine. We decided to evaluate 0.5% bupivacaine used alone against a mixture of 0.5% bupivacaine and 2% lidocaine. It was also desired to assess the effect of adding adrenaline as adjuvant to the anesthetic agents bupivacaine and lidocaine.

The results of our study had shown that bupivacaine 0.5% used alone (with or without adrenaline added) in a volume of 8.02 ml with 200 IU of hyaluronidase to be equally effective as that of a mixture of bupivacaine 0.5% and lidocaine 2% (with or without adrenaline added). Addition of adrenaline to the anesthetic agents had the effect of delaying the onset time of the block and reducing the total duration of the block though the differences observed failed to show statistical significance.

A literature review of other works revealed that Reem H. El Kabarity and Mohamed Y. Khashaba [15] compared two groups with 5ml volume of a 1: 1mixture of bupivacaine 0.5% and lidocaine 2% with clonidine and dexmedetomidine added as adjuvants and reported that total duration of the block was 112.2 ±29.5 and 130.9 ±30.5 min in their two groups of patients whereas in our study we observed 936.7±707.6, 843.9±574.3, 704.2.7±550.4 and 567.2±495.7 min respectively in

group B,BA,BLand BLA. Our results differed with theirs as they used a smaller volume of 5 ml of the anesthetic agent as against 8.02 ml used by us.

Emile Calenda, MD; Jean Claude Quintyn, MD; Gerard Brasseur, MD, PhD [16] reported results of their study of 100 patients of vitreo retinal surgery using similar technique for peribulbar block with a mixed anesthetic solution of equal quantity of lidocaine 2% and bupivacaine 0.5% with clonidine in a mean volume of 14.5 ml ± 3.5 of the mixture and concluded that excellent surgical conditions were attained in 85% of the patients without supplements. In our study, we attained excellent surgical conditions in 68.75% of cases (55 out of 80) without any supplements. We employed hyaluronidase in 25 IU/ml for the block and the total anesthetic volume was limited to 10ml. Our results differed with them as they used clonidine as adjuvant and larger volume of 14.5ml which could have contributed for the higher number of successful blocks seen in their study.

Channabasappa SM, Shetty VR, Dharmappa SK, Sarma J [17] reported their study using three ml of 2% lidocaine and three ml of 0.5% bupivacaine mixture with 0.5 ml of dexmedetomidine as adjuvant in two different doses. The total block duration was stated as 187.2± 51.7 min in the control group without any adjuvants and 323.2 ± 79.57 and 251.2 ± 71.72 min in the other groups. Our results differed significantly from their results with the block durations of 936.7. ± 707.6, 843.9± 574.3, 704.3.2 ± 550.4 and 567.3.2 ± 495.7 in our four groups, as they used a dual puncture technique in injecting the drug and employed a lower volume of 6.5ml as against 8.02 ml used by us. They did not use adrenaline or hyaluronidase in their study.

Gioia L, Prandi E, Codenotti M,et al [18] in their study comparing 1:1 mixture of 2% plain lidocaine and 0.5% plain bupivacaine in 8 ml volume with ropivacaine reported the onset of surgical block as 8 +/- 5 min in the lido-bupivacaine group. Our results differed with their study as we recorded block onset times of 2.8 ± 2.6 and 6.8 ± 5.8 min in groups BL and BLA respectively. The earlier onset of motor block in our study may be due to employment of hyaluronidase and adrenaline in our study. They reported that supplemental injections were required in six cases out of 30 (20%) in lidocaine bupivacaine group for obtaining adequate surgical block. Our results are in partial agreement with their study as we observed that supplemental injections were required for obtaining adequate surgical block in 12 out of 40 (30%) cases in group BL and BLA.

CONCLUSION

On the basis of the findings of the present study, we conclude that bupivacaine 0.5% used alone (with or without adrenaline added) in a volume of 8.02 ml with 200 IU of hyaluronidase for peribulbar blocks appears to be equally effective to that of a mixture of bupivacaine 0.5% and lidocaine 2% (with or without adrenaline added). Addition of adrenaline to the anesthetic agents had no statistically significant effect on block characteristics.

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