30	urnal or Pa	ORIGINAL RESEARCH PAPER		Anaesthesiology		
Indian	PARIPET EVAL PERIB MIXT ROPIN TONC		JATION OF CHANGES IN INTRAOCULAR PRESSURES AFTER JLBAR BLOCK USING BUPIVACAINE 0.5%-LIGNOCAINE 2% JRE, ROPIVACAINE 0.75%-LIGNOCAINE 2% MIXTURE, ACAINE 0.75% AND BUPIVACAINE 0.5% USING PEN® APPLANATION TONOMETER	<b>KEY WORDS:</b> Intraocular pressure, Ropivacaine, Bupivacaine, Lignocaine, Ocular tonometry, TonoPen.		
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ABSTRACT	<b>Background:</b> Anesthetic mixture containing Bupivacaine 0.5%-lignocaine 2% mixture is commonly used for Peribulbar block Elevated intraocular pressure (IOP) is a known complication in the immediate post injection period. The effect of different local anaesthetic mixtures was not known. <b>Methods:</b> 120 patients undergoing cataract surgery were randomised into four groups (30 patients each). Baseline IOP was recorded on day of surgery using Tonopen® Applanation Tonometer (Reichert Technologies,USA) as an average of three measurements (on a pre-specified format). Peribulbar block followed by ocular massage was performed as per standard protoco by same anaesthesiologist using drug mixture as per group allocation. Group A–(7ml Bupivacaine(0.5%)+3ml Lignocaine (2% Group B–7ml Ropivacaine (0.75%)+3ml Lignocaine (2%), Group C–10ml Bupivacaine(0.5%) and Group D–10m Ropivacaine(0.75%). IOP was recorded again using the same device at 3min, 6min, 9min time intervals after administering block All patient data was tabulated in <i>MS Excel</i> worksheet and statistical analysis performed using <i>WinPePi</i> software. <b>Results:</b> Demographics and haseline IOP were similar among all four groups. At 3min interval after block					

**Results:** Demographics and baseline IOP were similar among all four groups. At 3min interval after block, IOP readings were significantly higher in all groups except Group D(Ropivacaine (0.75%)). At 6min and 9 min intervals, there was no significant elevation in IOP readings in both Group C (Bupivacaine (0.5%) and Group D (Ropivacaine (0.75%)). No statistically significant increase in IOP from baseline was recorded in Group D (10ml Ropivacaine 0.75%) at 3, 6 or 9min.

**Conclusion:** Anaesthetic mixtures for Peribulbar block containing Ropivacaine(0.75%) cause significantly less IOP elevations when compared to Bupivacaine(0.5%), Ropivacaine(0.75%)-Lignocaine (2%) or Bupivacaine(0.5%)-Lignocaine(2%) mixture.

### Introduction

Cataract surgery is commonly performed under various types of Anaesthesia like Peribulbar block, Retrobulbar block, Topical anaesthesia and supplementary facial nerve blocks. Bupivacaine-Lignocaine mixture admixed with Hyaluronidase is commonly used for Peribulbar Block. Ropivacaine (0.75%) is an alternative to Bupivacaine (0.5%) used in Spinal anaesthesia, Epidural anaesthesia and various peripheral nerve blocks. The major advantage when employed in regional anaesthesia in place of Bupivacaine is its better cardiovascular toxicity profile. Ropivacaine when used as Peribulbar anaesthetic solution causes comparable onset and quality of ocular akinesia (1). Injection of large volume of anaesthetic solution in peribulbar block is likely to increase intraocular pressure (IOP) due to sudden changes in volume of orbital contents that is detrimental in certain patients. Lignocaine, Bupivacaine and Ropivacaine have varied effects on vascular tone. However, the varied effects of local anaesthetics on vasculature could further affect IOP (2). The present study aims to evaluate the effect of four different mixtures of Peribulbar local anaesthetic solutions on IOP at definite time intervals.

# **Material & Methods**

Study setting: Tertiary care hospital in Assam, India

**Study design:** Randomised controlled trial with 4 intervention arms, contaiing different mixtures of local anesthetic drugs.

**Study population:** Patients scheduled for Cataract Surgery by Phacoemulsification technique under Peribulbar block underwent Pre-anaesthetic evaluation for recruitment into study. Informed written consent was obtained from all patients.

# Inclusion criteria:

1. Adults in ASA grade 1 or 2

2. Age 18 years and above

3. Scheduled for Cataract surgery under Peribulbar block

### **Exclusion criteria:**

1. Patients in ASA grade 3 or 4

2. Patients with Retinal vein occlusions as diagnosed by the www.worldwidejournals.com

Ophthalmologist.

3. Patients with prior history of allergy to study medications

**Recruitment:** A total of 120 patients meeting the inclusion and exclusion criteria were recruited.

**Randomisation and sequence generation:** After informed written consent, 120 participants, who satistfied the inclusion criteria were randomized into four groups of 30 patients each using Block randomization. Bock randomization was done to ensure equal number of participants in each of the intervention arms. The block size used was 12, with 3 subjects randomized to each of the three treatment groups, within each block. The sequencing of interventions, within each block was done by simple random sampling using the random number tables in a predetermined direction, after choosing the first number randomly.

Allocation concealment technique: Sequentially Numbered, Opaque Sealed Envelopes (SNOSE) method as described by Doig G.S has been used for allocation concealment in the study. The allocated intervention sequence was kept in individual, serially numbered sealed opaque covers and was kept under the custody of a senior faculty of the department. The card board with the intervention name was covered with a silver foil to prevent the visibility. Each time when the participant was recruited the opaque cover was opened and the intervention was communicated to the investigator.

**Implementation of intervention:** On the day of surgery, patients were admitted to hospital, demographic characteristics and baseline IOP recorded using Tonopen<sup>®</sup> Applanation Tonometer (Reichert Technologies, USA) as an average of three measurements were recorded in a pre-specified format.

**Intervention in four groups:** The local anaesthetic mixtures with Hyaluronidase (75 U/ml) were prepared by physician who was blinded to group allocation of patients and labelled as:-

Group A-10ml (7ml Bupivacaine(0.5%)+3ml Lignocaine(2%))

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Group B–10ml (7ml Ropivacaine (0.75%)+3ml Lignocaine(2%)) Group C–10ml Bupivacaine(0.5%) Group D–10ml Ropivacaine(0.75%)

**Blinding:** Peribulbar block as per randomisation was administered by an Anaesthesiologist who was blind to drug contents. All blocks were performed by the same anaesthesiologist. The participant, person measuring the IOP and the statisticain analyzing the data were also blinded regarding the intervention.

**Peribulbar block:** A uniform technique of block application was performed in all patients by single anaesthesiologist who had previously performed more than 150 blocks. 25G needle was used for administering the block. Under appropriate aseptic precautions, a uniform technique of 7ml of anaesthetic solution at the junction of medial 2/3rd and lateral 1/3rd of lower lid just above the inferior orbital rim with needle directed along the orbital floor followed by 3ml injection at pit between the caruncle and the medial canthus at a depth of 15 to 20mm was injected (Peribulbar block) in all recruited patients. Orbital pressure using standardised weights was administered by the same anaesthesiologist . Time was recorded at the end of application of block.

**Outcome measurement:** IOP was recorded again using the same device (Tonopen <sup>®</sup> Applanation Tonometer (Reichert Technologies, USA)) used for basline IOP measurements. IOP was recorded at 3min, 6min, 9min time intervals after administering block. Patients were taken up for surgery after recording IOP at 9 min. All blocks were successful and did not require supplementation by the surgeon.

**Data recording & Statistical methods:** All patient data were tabulated in MS Excel worksheets. Statistical analysis was performed using WinPePi statistical software (Abramson, J.H. WINPEPI updated: computer programs for epidemiologists, and their teaching potential. Epidemiologic Perspectives & Innovations 2011, 8:1). Mean with SD was calculated for all continuous variables. Change in the IOP value at different time intervals, when compared to the baseline, within each intervention group was taken as primary outcome. Student t test was used for analysing quantitative data. Paired t test was employed for comparison within the groups. P values < 0.05 were considered statistically significant.

### Results

Baseline demographics were similar in all groups (Table 1). There was no statistical difference in IOP readings at baseline among the four groups. At 3 min interval after administering the block, IOP readings were significantly higher in all groups except group D (Ropivacaine (0.75%)). At 6min and 9 min interval, there was no significant elevation in IOP readings in both Group C (Bupivacaine (0.5%)) and Group D (Ropivacaine (0.75%)) (Table 2). No statistically significant increase in IOP from baseline was recorded in Group D (10ml Ropivacaine 0.75%) at 3,6 or 9min (Figure). CONSORT 2010 Flow Diagram is appended as Supplementary data.

# **Table 1. Baseline characteristics**

Baseline	Group A	Group B	Group C	Group D	р
characteri	(Bupivacain	(Ropivacain	(Bupivacai	(Ropivacai	value
stics	e +	e +	ne)	ne)	
	Lignocaine)	Lignocaine)			
Age	62.6±11.57	60.53±9.8	58.8±12.	56.16±14.	0.459
-		3	5	2	
IOP	11.1±2.12	11.23±1.9	13.3±2.8	12.6±2.32	>0.5
Baseline		7	9		

# Table 2. Changes in IOP at various time intervals in four groups

OP at	Group A	Group B	Group C	Group D
various time	(Bupivacain	(Ropivacain	(Bupivacaine)	(Ropivacain
intervals	e +	e +		e)
(mm Hg)	Lignocaine)	Lignocaine)		
Baseline	11.1±2.12	11.23±1.97	13.3±2.89	12.6±2.32
At 3 min	20.8±13.76	16.73±9.57	19.46±13.11	13.86±4.40

p value	0.00033	0.003	0.015	0.169
At 6 min	15.9±7.37	15±6.97	18.13±15.45	13.23±3.77
p value	0.001	0.006	0.098	0.437
At 9 min	15.5±6.95	13.56±5.92	16.53±13.78	12.8±3.47
p value	0.002	0.045	0.214	0.794

Figure. Changes in IOP at each time interval.

#### Discussion



Goldmann Applanation tomometry is the gold standard for measurement of IOP. TonoPenXL has been found comparable to Goldmann Applanation Tonometer for providing IOP measurements. The mean difference between measurements of TonoPen and Goldmann Applanation Tonometer, by Bland Altmann analysis, was found to be 0.7±2.5mm Hg (4). It is also suitable for use in preoperative room before the patient is shifted for surgery. A significant difference in the mean IOP measured by air-puff tonometry when compared with Goldmann applanation tonometer, was noted by Qasim Farhood in a study involving 98 patients (5). Hence, TonoPen ® Applanation Tonometer (Reichert Technologies, USA) has been employed to assess changes in IOP at various time intervals. Hyaluronidase improved the success of peribular block along with improvement in akinesia and reduced the need for supplementary block (6). Hyaluronidase (75 IU/ml) has been added to anaesthetic mixtures in all groups in the present study. Peribulbar block for ocular surgery is a commonly employed anaesthetic technique. It is important to minimise the elevations in IOP after administration of local anaesthetic solutions as part of Peribulbar block. In a study of 50 patients randomised into two groups, where either Ropivacaine (0.75%) or Lignocaine (2%) was administered in peribulbar block, the IOP was found to be significantly lower in Ropivacaine group at 10 min after the block (7). In addition, the mean visual analogue pain scores were higher in Lignocaine group. In a study of 60 patients randomised to receive either Ropivacaine (0.75%) or Bupivacaine (0.5%) in peribulbar block, the IOP reduced significantly from baseline in Ropivacaine group (p<0.05) at 15 minutes interval (8). Clonidine has been studied as an additive to Ropivacaine in peribulbar blockade. When Clonidine was added to Ropivacaine, the onset and establishment of sensory and motor blockade was significantly earlier along with prolonged duration of analgesia. IOP was also reduced (9). Ropivacaine has a direct vasoconstrictive effect on vascular tone (2). Ropivacaine causes a reduction in ocular pulse amplitude when used in peribulbar block (10). Ropivacaine caused reduction in IOP at 10min as compared to Bupivacaine (-4.54% vs +16.56%) (10). In our study, there was minimal percentage elevation in IOP from baseline at 3 min (+13.35±34.21), 6 min (+9.10±32.32) and 9 min (5.45±29.7) when compared to all other groups. At time intervals where IOP was recorded i.e., 3min, 6min and 9 min, Ropivacaine caused significantly lower IOP elevations from baseline. This finds Ropivacaine in Peribulbar block beneficial for patients with borderline elevated IOP where further elevations in IOP should be avoided

### Limitations

Ocular akinesia and time to onset were not evaluated in the present study as it was primarily aimed at assessing the changes in IOP at various time intervals with four types of local anaesthetic solutions. However, ocular akinesia was found to be satisfactory in

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all patients when taken up for surgery as no supplementation was done by the surgeon for any patient. The duration of motor block was not assessed as the patient eye was bandaged and covered postoperatively.

# Conclusion

Ropivacaine(0.75%) causes significantly less elevations in IOP when compared to Bupivacaine (0.5%), Ropivacaine(0.75%) - Lignocaine(2%) or Bupivacaine(0.5%) - Lignocaine(2%) mixture when used as an anaesthetic solution with Hyaluronidase (75 U/ml) in Peribulbar block.

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