"COMPARATIVE STUDY TO ASSESS THE EFFECT OF ROPIVACAINE AND A MIXTURE OF LIDOCAINE-BUPIVACAINE ON INTRAOCULAR PRESSURE AFTER PERIBULBAR ANAESTHESIA FOR CATARACT SURGERY AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI"

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ABSTRACT

Aim:

The purpose of this study was to compare the efficacy of ropivacaine with a lidocaine-bupivacaine mixture in peribulbar anaesthesia for cataract surgery. The effects of the two anaesthetic solutions were compared in terms of post block intraocular pressure, akinesia and intraoperative pain.

Methods:

A one-year comparative study was done to compare the two anaesthetic solutions in peribulbar anaesthesia for cataract surgery, during the time period January 2020 – December 2020 at KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belagavi. The study was approved by the ethical and research committee. Two hundred patients between the age 40 – 70 years with uncomplicated cataract, normal intraocular pressure(7-21mmHg), normal baseline ECG rhythm and American Society of Anaesthesiologists grade I, II or III and who were scheduled to undergo small incision cataract surgery with posterior chamber intraocular lens implantation under peribulbar anaesthesia were included in the study. They were randomly allotted into one of the two groups of 100 each i.e., group A – 0.75% ropivacaine and group B–1:1 mixture of 2% lidocaine with 0.5% bupivacaine. Patients with profound cognitive impairment, history of allergies to lidocaine, bupivacaine, ropivacaine and hyaluronidase, patients requiring sedatives and analgesics, unwilling to participate in the study and patients with any preceding eye disorder other than cataract were excluded from the study. A single site inferotemporal block was given. The local anaesthetic solution was given till total eyelid drop was observed and the volume of anaesthetic used was noted. Digital pressure was given for 1 minute (min) after block. The intraocular pressure was measured at 4 time points: before block (control), 1min, 5mins and 15 mins after block with

tonometer. Extra ocular movements were noted every minute till 10 mins after block. An akinesia score of equal to or more than four at the end of 10 mins was considered inadequate. If intra-operative pain occurred during any step, the patient indicated by squeezing the attender's hand and steps during which pain occurred was noted.

Results:

The 1 min post block mean intraocular pressure (IOP) in both groups was higher than the baseline levels(control), Group A is 14.91±4.14 mmHg and Group B is 15.50 ± 4.26 mmHg, this reflects the raised intra-orbital pressure secondary to peribulbar injection of local anaesthetic. However, the rise in 1min post block IOP is significantly less in ropivacaine group when compared to lidocaine-bupivacaine group. The 5 mins and 15 mins post block mean IOP values in ropivacaine group was significantly lower than the corresponding values of lidocaine-bupivacaine group and the baseline(control) ropivacaine values.

Onset of akinesia was significantly faster in lidocaine-bupivacaine group, 1.37 ± 1.05mins. Adequate akinesia (akinesia score < 4) was achieved in lidocaine-bupivacaine group at 4mins (mean score 3.97 ± 3.63) and at 6mins in ropivacaine group. Beyond 6 mins the akinesia score amongst the two groups was not significant. Furthermore, at 10 mins 25 patients of group A(n=100) and 11 patients of group B (n=100) had not achieved adequate akinesia (akinesia score <4).

Pain did not occur in any case in ropivacaine group during surgery versus six cases of lidocaine-bupivacaine group which was statistically significant ($p<0.05$).

Conclusion:

The results of this study support that ropivacaine as a local anaesthetic for peribulbar block for small incision cataract surgery can be a good alternative to the lidocaine-bupivacaine

combination. Further studies involving a larger sample size can be done to consider ropivacaine as a superior drug over the lidocaine-bupivacaine combination.

KEYWORDS: peribulbar anaesthesia, ropivacaine, lidocaine, bupivacaine, intraocular pressure

LIST OF ABBREVIATIONS USED

GA - GENERAL ANAESTHESIA

IOP - INTRAOCULAR PRESSURE

SICS - SMALL INCISION CATARACT SURGERY

mL – MILLILITRE

EOM – EXTRA OCULAR MUSCLE

CN – CRANIAL NERVE

NMJ – NEUROMUSCULAR JUNCTION

Na^+ channel – SODIUM CHANNEL

pKa – IONIZATION CONSTANT

mg – MILLIGRAM

CNS – CENTRAL NERVOUS SYSTEM

OCR – OCULOCARDIAC REFLEX

mins- MINUTES

kg – KILOGRAM

OPD - OUT-PATIENT DEPARTMENT

PCIOL - POSTERIOR CHAMBER INTRAOCULAR LENS

MRC - MEDICAL RESEARCH CENTRE

mmHg – MILLIMETRES OF MERCURY

ECG – ELECTROCARDIOGRAM

ASA – AMERICAN SOCIETY OF ANAESTHESIA

min - MINUTE

VAS – VISUAL ANALOG SCALE

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INTRODUCTION

Cataract being the most common treatable cause of visual impairment, is still amongst the most prevalent causes of visual impairment in the world.[1]

The sole treatment for cataract is its surgical removal which is a common ophthalmic surgical procedure and like most orbital surgeries, cataract surgery is also routinely performed under regional anaesthesia at our hospital.[2]

Anaesthesia, being a critical aspect of any surgery, requires an agreeable setting for both the surgeon and the patient throughout the procedure and a speedy risk-free recovery of function.

Although General anaesthesia (GA) gives a nearly complete ideal surgical setting in terms of anaesthesia, akinesia, the surgeon and the patient comfort and has no substantial injection risks, it has a limited role in cataract surgeries.[2] The application of GA is restricted to cases where regional anaesthesia or topical anaesthesia is contraindicated.[2] This limitation is because GA necessitates the use of anaesthetic personnel and apparatus, requires a lengthier convalescence and is costly. Furthermore, laryngoscopy and endotracheal intubation can increase intraocular pressure (IOP).[3–5] This might be the result of the stress response associated with tracheal intubation which causes increased heart rate and blood pressure. And because the eye is such a vital organ, increased blood flow to it is linked to an increase in IOP.[3]

GA had opened the path for early ophthalmic surgery until the advent of the hypodermic needle, which allowed for the use of local anaesthetics in the ophthalmic region. Advantages of retrobulbar block include complete ocular akinesia and adequate analgesia intraoperatively. Notable drawbacks included-subsequent need for facial nerve block to prevent orbicularis oculi muscle activity. Literature has also

shown that IOP can rise by 80% from baseline following just 3 mL retrobulbar injection of local anaesthetic solution.[6] Increased intra-orbital pressure with consequent elevation of the IOP leads to complications like iris prolapse and vitreous loss during surgery.[6] Furthermore concerns about the related complications like globe perforation, entry into the cerebrospinal fluid and vascular structures behind the eye, causing respiratory depression and cardiovascular collapse contributed to the decline in the practice of retrobulbar block technique in ophthalmic anaesthesia.[7–9]

Later, the retrobulbar block technique was modified to peribulbar block which gives admirable akinesia and analgesia. Lesser chances of sight-threatening complications than those associated with the retrobulbar block.[10] This method is easy to perform and relatively safe as the anaesthetic agent is deposited in the extraconal space.[10]

Not only the technique of peribulbar block but also the local anaesthetic used can affect the outcome of the surgery in terms of intra-operative complications, patient compliance and level of surgeon comfort.

Lidocaine is a commonly used local anaesthetic, whose onset of action is rapid.[11] Whereas Bupivacaine is a long-acting local anaesthetic that has a comparatively slower onset of action. Due to its long duration of action and high-quality sensory blockade, it is combined with the faster-acting lidocaine for peripheral nerve blocks.[12]

A newer, long-acting local anaesthetic is ropivacaine that has comparable or superior neuronal blocking potential to Bupivacaine.[13]

This study compares 0.75% ropivacaine with a 1:1 mixture of 2% lidocaine with 0.50 % bupivacaine and assesses their efficacy for the peribulbar block in

cataract surgeries in terms of the post block IOP, akinesia and pain during administration of anaesthetic drug and intraoperative analgesia.

OBJECTIVE

Primary objective:

To compare the effects of ropivacaine and lidocaine-bupivacaine combination on intraocular pressure, after peribulbar anaesthesia for cataract surgery.

Secondary objective:

To compare the effects of ropivacaine and lidocaine-bupivacaine combination on akinesia and perioperative pain in peribulbar anaesthesia for cataract surgery.

REVIEW OF LITERATURE

"Anaesthesia" is derived from a Greek word *anaisthēsia* - "an" means without and "*aisthēsis*" means sensation, a state of being devoid of sensation.(14) Anaesthesia has been an integral part of ophthalmology since the very beginning of this profession and has constantly evolved with it. The evolution and acceptability of peribulbar anaesthesia are linked to the evolution of cataract surgery. When larger incisions at the sclero-limbal region were required in the past, complete anaesthesia or retrobulbar anaesthesia was the preferred anaesthetic modality. As phacoemulsification, clear cornea incision and small incision cataract surgery(SICS) grew more common, the trauma and discomfort associated with cataract surgery became less severe and various anaesthetic techniques gained acceptance.(15)

HISTORICAL PERSPECTIVE

PERIBULBAR ANAESTHESIA(16)

The blocks being used in ophthalmic surgeries now have been developed and modified over the years since Koller's remarkable discovery. In the later years of the 19th century, after the breakthrough discovery of local anaesthetic property of cocaine, H. Knapp explained a blocking technique similar to that of the retrobulbar block, but it never gained popularity as the blocks were often inadequate and caused hypertension, tachycardia and a feeling of euphoria.

Later, in 1905, procaine was synthesized and used clinically. This drug was an ester-type local anaesthetic that had a predictable onset and duration of action, but it didn't gain recognition.

In 1934, W. S. Atkinson described the classic retrobulbar block. He used procaine and made his patients gaze in upward and inward direction for executing the

block. This technique was very effective and it gradually gained acceptance. However, as we already know, this technique can cause considerable complications. So in due course, other alternatives were pursued and a cadaveric study showed that local anaesthetics deposited in the extra-conal space could infiltrate inside the cone and anaesthetize the eye.[17]

Kelman, in 1970, performed the first peribulbar anaesthesia, but it was unpublished, later it was described by Davis & Mandel in 1985 in which they studied 16,224 peribulbar blocks and found it to be effective and had a low complication rate.[10,18]

APPLIED ANATOMY

THE BONY ORBIT AND THE GLOBE

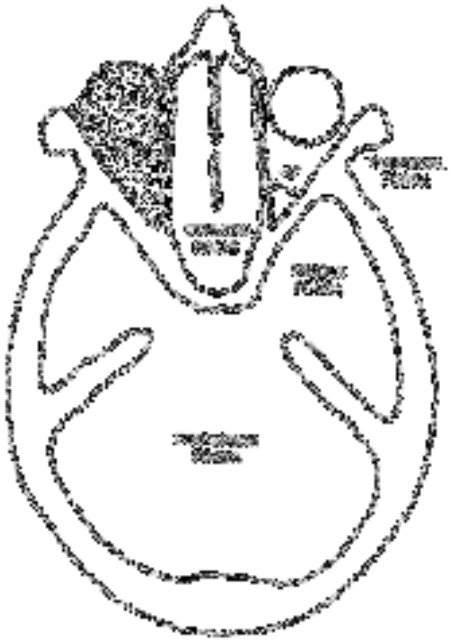


Figure 1: Volume, angle and relations of the orbit. [11]

A comprehensive understanding of anatomy is vital to successful anaesthesia. The orbit is shaped like a quadrilateral pyramid, with the base pointing forwards, laterally and somewhat downwards and corresponds to orbital margin. The

conjunctiva, the surface of the cornea and the lids form the base. The apex is situated in-between the optic foramen and the medial end of the superior orbital fissure.[19] The apex is formed by the annulus of Zinn, which is a fibrous ring that arises from the superior orbital fissure.

The volume of the orbit is 30 milliliter (mL) of which the globe occupies one-fifth, which is 7mL (*Figure 1*). The remainder of the volume of the orbit is inhabited by extraocular muscles, nerves, fascia and fat.[19]

The globe occupies the anterior portion of orbit and it is nearer to the lateral wall than the medial wall and nearer to the roof than the floor. This link helps decide the path of the needle in local blocks. Thus the needle should be guided either medially in the upper margin of orbit or laterally in the lower margin of orbit because here the space between the globe and orbit is maximum.[19]

EXTRA OCULAR MUSCLE(EOM) (*Figure 2)*

Extra ocular muscles are six in number i.e., four recti muscles and two obliques. The extra ocular muscles coordinate the eye movements and their muscle tone influences the IOP.[20]

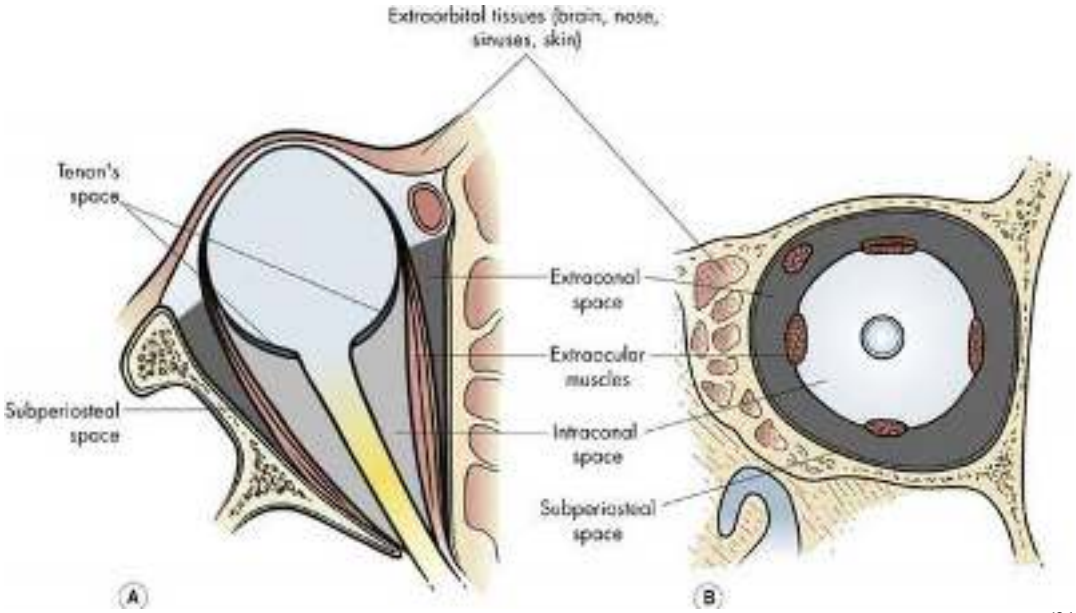


Figure 2: Extraocular Muscles; Extraconal Space (Peripheral Surgical Space) [21]

The recti arise from a fibrous tendinous ring (annulus of Zinn) near the apex of the orbit, travel anteriorly as they form the muscle cone and attach in the front of the equator of the globe.[21] These four recti with their intermuscular septum form peripheral surgical space and it is the site for peribulbar injections.[21] The distance from the inferior temporal orbital rim to the optic foramen is 42-54mm.[22,23] This anatomy serves as a reference for the terms *"intraconal"* or *"extraconal."* Structures in the extraconal space include the lacrimal gland, superior oblique muscle, nerves and vessels with the orbital fat.[21]

NERVE SUPPLY OF THE ORBIT[24]

The optic nerve is the Cranial nerve (CN) II, the oculomotor nerve (CN III) along with its both superior and inferior branches, the abducent nerve (CN VI), the nasociliary nerve (branch of CN V), the ciliary ganglion and vessels are contained in the annulus of Zinn and the muscle cone.

The superior branch of CN III runs superior to the optic nerve and gives motor innervation to levator palpebrae superioris and the superior rectus. The inferior branch of CN III which runs inferior to the optic nerve supplies the medial and inferior recti and the inferior oblique muscles. CN VI supplies the lateral rectus muscle.[25] CN IV passes outside and above the annulus of Zinn and provides innervation to the superior oblique muscle (retained activity of this muscle is often seen because CN IV runs an extraconal course).

Motor nerves *(Figure 3)* pierce the muscle bellies of the four rectus muscles on their conal surface, 1-1.5 cm from the apex.[20] Local anaesthetic agents have to reach 5 – 10mm exposed portion of these motor nerves in posterior intraconal space so that the nerve conduction block and akinesia of muscles that these nerves supply to, can occur.

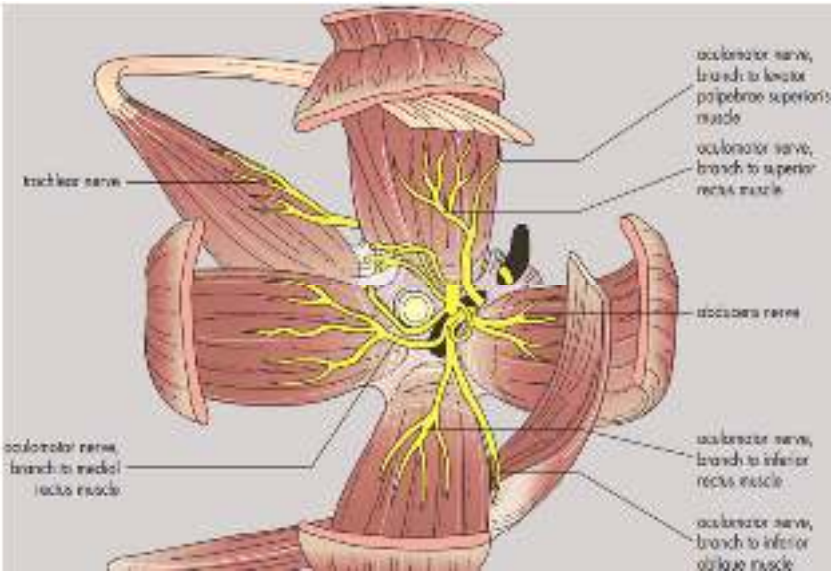


Figure 3: Motor Innervation of Extra-Ocular Muscles (26)

Ciliary ganglion (parasympathetic ganglion) is situated between the optic nerve and the ophthalmic artery about 15mm behind the globe and 7-10mm posteriorly from the orbital apex*(Figure 4)*.[19] It receives long sensory nerves containing sensory fibers from the cornea, iris and ciliary body via the short ciliary nerves. Short motor nerves carry parasympathetic axons to supply pupillary sphincter and ciliary muscle. The sympathetic root (does not relay in the ganglion) supplies innervation to pupillary dilatation and functions of smooth muscles of eyelids.[27]

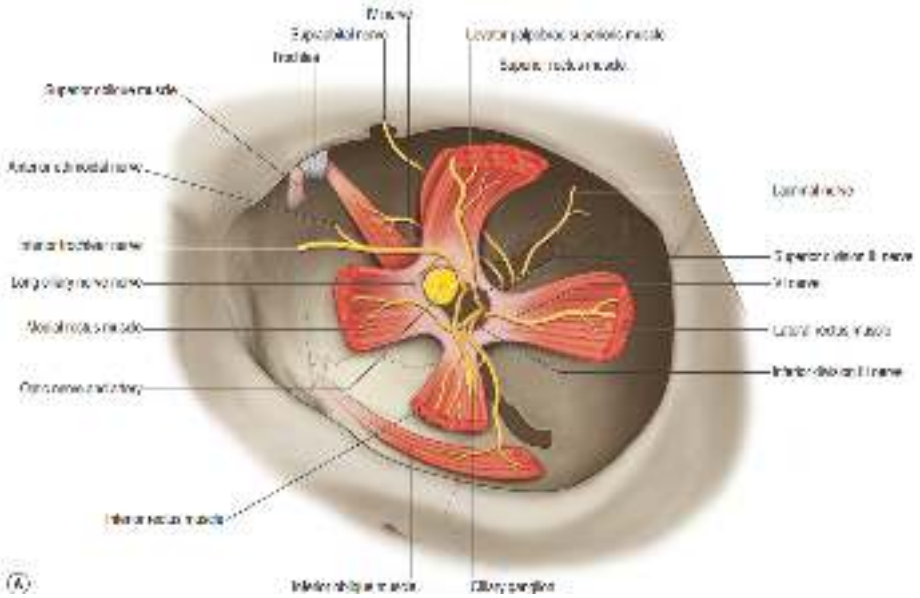


Figure 4: Ciliary Ganglion Anatomy and Relations[28]

Sensory innervation of the cornea, the perilimbal conjunctiva and the superonasal quadrant of peripheral conjunctiva is effected through the nasociliary nerve which lies within the muscle cone *(Figure 5)*. The remaining peripheral conjunctival sensations are mediated through the lacrimal, frontal and infraorbital nerves which runs an extra-conal course.[22,27]

Local anaesthetic agent injected inferotemporally into the lateral adipose compartment will block nasociliary, lacrimal, frontal, supraorbital and supratrochlear branches of the ophthalmic division of the trigeminal nerve and infraorbital branch of maxillary division.[29]

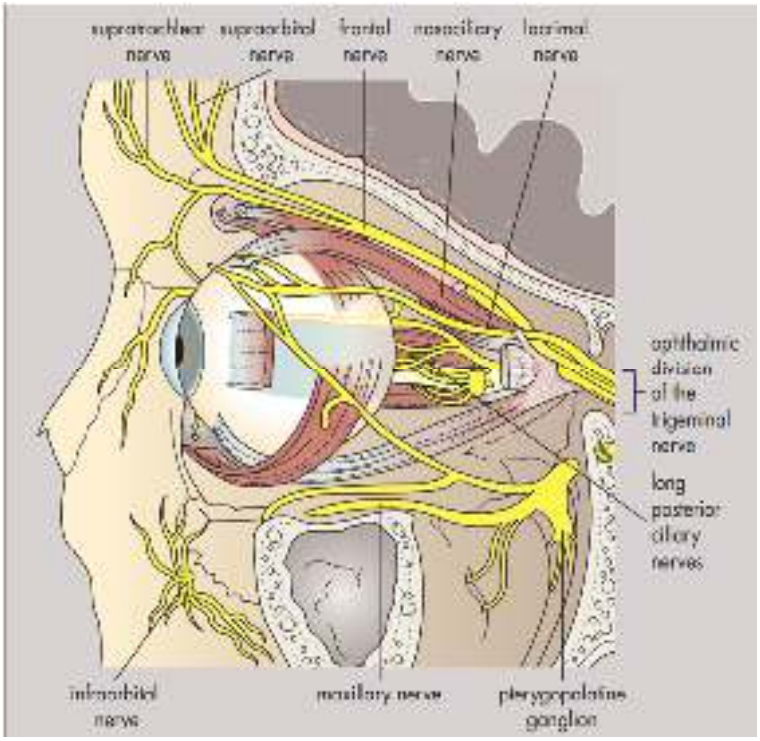


Figure 5: Afferent(sensory) Innervation Of The Orbit [30]

The ocular sensitivity is based on terminal nerve endings of CN V supplying to the cornea and ciliary body in the anterior part of the eye. These fibers are non-myelinated type A-delta and type C. They carry sensations of pain, temperature, touch, proprioception and skeletal muscle tone.[31] As the anaesthetic drug encounters the non-myelinated fibers or nodes of Ranvier of the myelinated fibers, they exert

their activity. So to suppress the impulse propagation, blockade of 3 to 5 nodes of Ranvier for a length of 3 to 7 mm is a must.[32]

LOCAL ANAESTHETICS: PHARMACOLOGY

Local anaesthetic agents reversibly block transmission [33,34]of impulses along the central and peripheral nerve pathways. With higher concentrations of the drug, the conduction of motor, autonomic and sensory impulses is prevented.

LOCAL ANAESTHETICS: CHEMICAL STRUCTURE

Local anaesthetics have the following parts: a lipophilic unsaturated aromatic ring and a hydrophilic tertiary amine[32,34,35] joined by a connecting hydrocarbon (intermediate chain) which can be ester (–CO) or an amide (–NHC–) bond *(Figure 6)*. The lipophilic portion of the drug defines its anaesthetic activity.

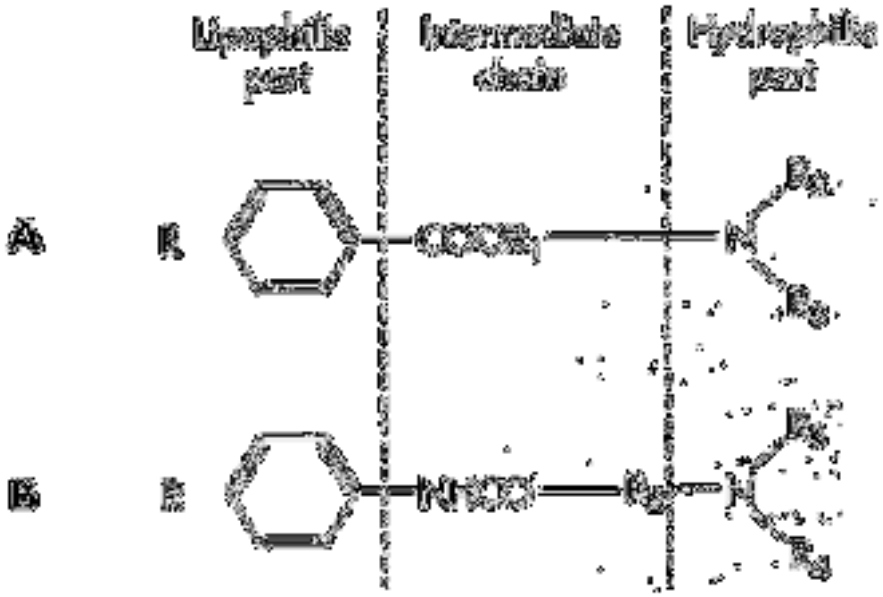


Figure 6: Chemical Structure of Local Anaesthetics.

"CLASSIFICATION OF LOCAL ANAESTHETICS" [35]

Local anaesthetic drugs are classified on basis of their chemistry or potency and duration of action.

Esters

- Cocaine
- Procaine
- Chloroprocaine
- Tetracaine

Amide

- Lignocaine
- Prilocaine
- Mepivacaine
- Bupivacaine
- Levobupivacaine
- Ropivacaine

Only cocaine is a vasoconstrictor, the rest are vasodilators.

LOCAL ANAESTHETICS: MECHANISM OF ACTION

Theoretically, the local anaesthetic agent is deposited outside the muscle cone and with time it diffuses into the muscle cone and acts at the neuromuscular junction(NMJ) and blocks the action potentials responsible for nerve conduction of the EOM and ciliary ganglion.[36] Therefore, when a local anaesthetic agent encounters a nerve trunk, it can bring about both sensory and motor paralysis of the area innervated by that nerve.[33]

Local anaesthetics reversibly binds to a specific receptor site within sodium (Na^+)channels and result in direct inhibition of NMJ by blocking ion movement

through the channel.[33,34] These effects are seen with clinically pertinent concentrations of local anaesthetics. These effects are reversible with a complete gain of nerve function and doesn't cause damage to the nerve fibres.[33]

Hydrophilic local anaesthetic bases are sparsely soluble in water but relatively soluble in organic solvents. Thus, to make it a stable solution, most local anaesthetic agents are available as a water-soluble hydrochloride salt.[37]

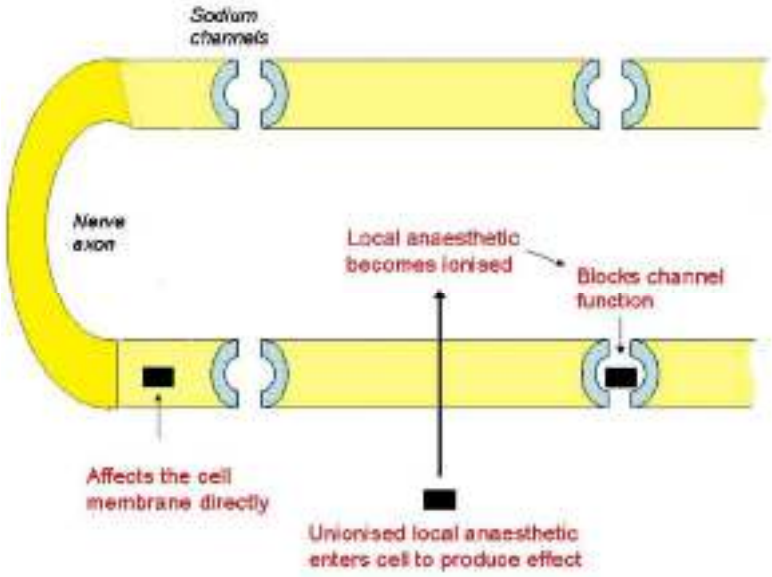


Figure 7: Local Anaesthetic Drugs Mechanism of Action

At physiological pH, these molecules are partially ionized and partially unionized. Only the partially unionized local anaesthetic molecules enter the nerve fibre (*Figure 7)*. The equilibrium between the ionized cationic form [BH+] and the unionized base form[B] depends on the ionization constant (pKa) of the local anaesthetic drugs.

Once the local anaesthetic molecules enter the nerve fibre, they bind to voltage-gated sodium channels [38] and decrease the further entry of sodium ions into the cell. Thus, inhibiting the conduction of the nerve impulse. The velocity of propagation of action potential and the maximum depolarisation will reduce. Local depolarization will fail to achieve the threshold potential and it will result in a

conduction block. The threshold potential and resting membrane potential are not altered by local anaesthetic drugs.

The sodium channel is a transmembrane protein that has 2 subunits – a larger alpha sub-unit and a smaller beta sub-unit. Alpha sub-unit binds to the drug and permits the conduction of ions. The beta subunit monitors the binding of the drug to the alpha sub-unit. Local anaesthetics bind to the inner side of the sodium channel called the Internal gate or H gate and exhibit its action.

After administering a local anaesthetic, the order in which the nerve function loss occurs is as follows-pain, temperature, touch, proprioception and skeletal muscle tone.[12]

FACTORS MODULATING CLINICAL PHARMACODYNAMICS AND PHARMACOKINETIC OF LOCAL ANAESTHETICS

- **ONSET OF ACTION**

pKa determines the onset of action. Ideally, drugs should have a pKa value close to physiological pH, so that non-ionized forms exist more in number and thus it will hasten the onset of action*(Figure8)*. Ropivacaine has a high pKa when compared to lidocaine.[37,39]

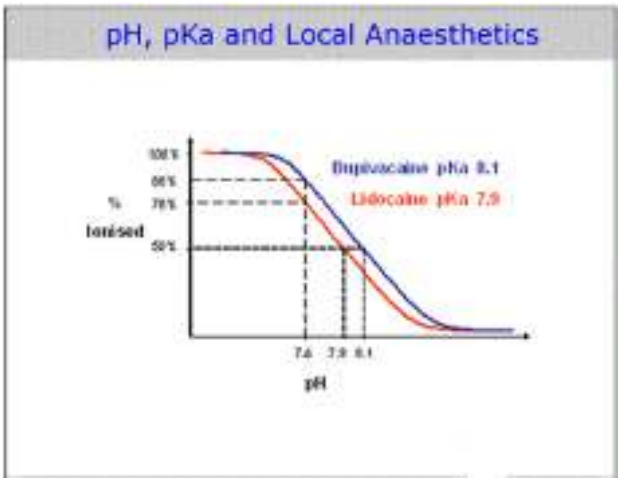


Figure 8: pH, pKa of bupivacaine and lidocaine.

- **ANAESTHETIC POTENCY**

The potency of local anaesthetics is determined by their hydrophobic nature.[34,40,41] Hydrophobic drugs are more potent and long-acting.

- **DURATION OF ACTION**[42,43]

The addition of peripheral vasoconstrictor drugs like adrenaline to local anaesthetic solution prolongs the duration of action by decreasing their rate of removal from the site of injection and thus they reduce systemic toxicity of local anaesthetics.

- **DIFFERENTIAL BLOCKADE** [44]

With a lower concentration of drug selective sensory anaesthesia is seen. In general, smaller and non-myelinated fibres are easily blocked. A-delta and C-type fibres are believed to be independent of the lipophilicity of local anaesthetics. Therefore, theoretically, the less lipophilic ropivacaine should be more selective to sensory blockade than the more lipophilic bupivacaine.[39]

PHARMACOKINETICS[45]

- **ABSORPTION**

It is dependent on the dose of drug, site of injection, use of peripheral vasoconstrictors and pharmacodynamics of drugs like-lipid solubility, protein binding.

- ✓ LIPID SOLUBILITY[37]

Lipid solubility determines the potency of the drug. The aromatic ring and aliphatic substitutions enhance the lipid solubility of the local anaesthetic. So, if a drug is highly lipid-soluble, more concentration of drug can enter the neurons at a lower dosage. Since bupivacaine (prepared as a 0.5% concentration (5 mg/mL)) is

more lipid-soluble therefore more potent when compared to ropivacaine(prepared as 0.75 % (7.5 mg/ mL)) and lidocaine(prepared as 2% concentration (20 mg/mL)).[39]

✓ PROTEIN BINDING

Different amide local anaesthetic drugs differ in their propensity to bind to α1 acid glycoprotein in plasma, whereas ester local anaesthetic drugs have insignificant protein binding activity. This property of protein binding corresponds to their affinity for protein at the receptor site within Na+ channels and it determines the time duration they will sustain neural blockade. Bupivacaine is the longest-acting local anaesthetic due to its highest percentage of protein binding.[37]

BIOTRANSFORMATION AND EXCRETION

Ester local anaesthetics undergo hydrolysis in plasma by Pseudocholinesterase enzymes whereas amide local anaesthetics undergo hydrolysis, dealkylation by liver microsomes and have renal excretion.

LOCAL ANAESTHETICS: ADVERSE EFFECT

The adverse effects due to local anaesthetic drugs can be limited to the orbit(local) or systemic and can range from simple to serious.[46]

The systemic adverse effects associated with local anaesthetics are related to the total dosage, vascularity at the site of injection, the type of drug used and the speed of injection and use of peripheral vasoconstrictors like adrenaline.

MYOTOXICITY [11,46,47]

Damage to EOM can occur as a result of direct needle trauma, injecting large amounts of the drug can lead to ischemic pressure necrosis. Direct myotoxic effects of the local anaesthetic agent on EOM can occur. Symptoms include the presence of diplopia and ptosis post-operatively and its persistence beyond 6 weeks of surgery.

The inferior rectus muscle is most commonly affected. Therefore, to avoid directly injecting into the muscle, inferotemporal site is preferred.

ALLERGIC REACTIONS

Preservatives like methylparaben are added to provide sterility(due to antibacterial activity) to the local anaesthetic but they can cause allergic reactions.[48] In addition, metabolites of local anaesthetics like para-aminobenzoic acid can also evoke allergic reactions. Thus, a test dose is advised before administering these drugs.

CENTRAL NERVOUS SYSTEM (CNS) TOXICITY[45,46,49]

Accidental intra-arterial injection of the anaesthetic solution may lead to retrograde flow of the drug via the ophthalmic artery to the cerebral or internal carotid artery leading to CNS spread of anaesthesia. The signs and symptoms may consist of violent shivering, contralateral amaurosis, with or without loss of consciousness, apnoea, hemiplegia, paraplegia, or quadriplegia. Blockade of CN VIII to CN XII can cause deafness, tinnitus, vertigo, dysarthria, dysphagia and aphasia. This is an emergency and delay inappropriate diagnosis and management can lead to death of the patient. To reduce the risk of encountering and inadvertently injecting into a blood vessel, the following precautions can be taken- firstly, a negative aspiration must be done before injecting the drug. Secondly, the needle should not go beyond a depth of 31mm from the orbital rim as that area has a dense vascular supply.

CARDIOVASCULAR TOXICITY

Unintentional intra-arterial injection of anaesthetic drugs can lead to cardiovascular suppression as they reduce myocardial contractility, automaticity and velocity of conduction. The signs include hypotension, bradycardia, cardiac dysrhythmias, collapse and cardiac arrest.

PERIBULBAR BLOCK: TECHNIQUES

In peribulbar block, the local anaesthetic solution is deposited in the extraconal compartment.[51] It diffuses into the muscle cone and results in paralysis of nerves. Peribulbar injection avoids the anterior and posterior ciliary vessels and vortex vein.[47]

SITES OF PERIBULBAR INJECTION

Figure 9: Inferior Nasal Injection

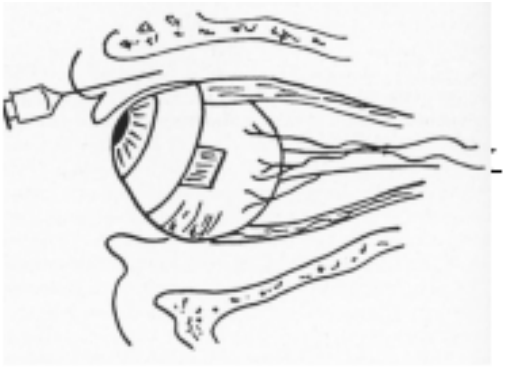


Figure 10: Superior Temporal Injection

TECHNIQUES

The techniques employed for peribulbar block: single site injection technique and two site injection technique.[47]

In the single-site injection technique, anaesthetic agent is administered in the inferior temporal region (*Figure 9)*. They provide sufficient anaesthesia and akinesia.

In two site injection technique, the anaesthetic drug is administered at two sites-one site is the inferior-temporal site and the second site is the superior-nasal site in the orbit (*Figure 10)*. This technique brings about complete relaxation and paralysis of muscles.

The efficacy of single site (inferior temporal) peribulbar injection technique is comparable to that of the two-injection peribulbar technique.[51,52]

COMPLICATION OF PERIBULBAR BLOCK

- **CHEMOSIS AND SUBCONJUNCTIVAL HAEMORRHAGE**

  They are common and resolve fully.

- **GLOBE PUNCTURE**[53]

Globe puncture is a serious sight-threatening complication that can lead to retinal detachment and vitreous haemorrhage. It causes excruciating ocular pain and the patient becomes restless. Its occurrence is more common in myopic patients. Treatment includes laser retinopexy or vitrectomy.

- **OCULOCARDIAC REFLEX (OCR)**[5]

Traction on the EOM, pain and pressure on the eyeball can evoke a trigeminal vagal reflex response that is manifested by a variety of cardiac dysrhythmias, hypotension, cardiac arrest. In awake patients, OCR may be associated with somnolence and nausea. It can occur in any age group. Although more commonly seen during strabismus surgery and in pediatric patients, it can be evoked in other ocular procedures including cataract extraction, enucleation and retinal detachment repair.

- **ADVANTAGES OF PERIBULBAR BLOCK OVER RETROBULBAR ADMINISTRATION OF ANAESTHESIA**[47,54]

1. Because the needle is injected outside the muscle cone, there is no risk of penetrating the optic nerve or coming in contact with subdural and subarachnoid space or central retinal artery. [36]
2. Soft eyeball makes the surgical procedure safer to perform.
3. The deep posterior chamber makes cataract surgery of even hard nuclear cataracts easier to perform.

4. The periocular facial block is not needed so intra-operative bleeding is less and the patient can chew and smile shortly after surgery. Therefore, the patient is much more comfortable with this type of anaesthesia.
5. No risk of retrobulbar haemorrhage.
6. Peribulbar anaesthesia can be used for any type of extraocular surgery, including radial keratotomy, as well as intraocular surgery.

DISADVANTAGES OF PERIBULBAR BLOCK[54]

- Akinesia is not complete.
- Onset is slower.
- More volume of local anaesthetic drugs is required.
- More time is required for a satisfactory block.
- Increased incidence of chemosis.
- Increased incidence of peribulbar ecchymosis.

ABSOLUTE CONTRAINDICATIONS FOR PERIBULBAR BLOCK [23]

- Patient un-willing/denies consent.
- Allergy to local anaesthetic drug.
- Infection/marked inflammation of orbit.

RELATIVE CONTRAINDICATIONS FOR PERIBULBAR BLOCK [23]

- Children.
- High myopes (Axial length >26mm).
- Un-cooperative patients (learning disability, profound deafness, etc).
- Patients who can't lay in supine position for the required duration. (cardiorespiratory distress, involuntary movements etc).

- Patient on anticoagulants, the dosage should be adjusted to reduce international normalized ratio (INR) to less than two.
- Presence of a scleral buckle or any space-occupying lesions within the orbit.

LIDOCAINE

PHARMACOLOGY OF LIDOCAINE [55]

Lidocaine was earlier known as Lignocaine. It is the first amide type of local anaesthetic and it was synthesized in the year 1943 by Nils Lofgren, a Swedish chemist. Bengt Lundquist, a colleague of Lofgren, first tried injection on himself. In 1949, lignocaine was sold to a pharmaceutical company.

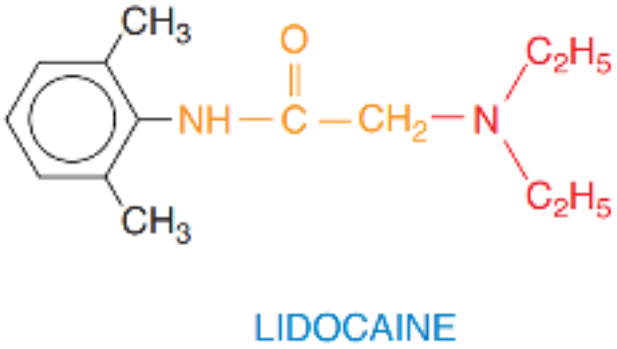


Figure 11: CHEMICAL STRUCTURE OF LIDOCAINE

Chemical formula:

3 2-(Diethylamino)-N-(2,6 dimethylphenyl)-acetamide or C14H22N2O

Table no. 1: PHYSIOCHEMICAL PROPERTIES: LIDOCAINE [44,55,55–58]

Molecular weight	234 g/mol
Lipid solubility	2.9
PKa (25˚C)	7.7
Protein binding	65 % (approx)
Onset of action	2 - 6 minutes (mins)
Duration of action	60- 120 mins (with adrenaline) 40- 60 mins without adrenaline
elimination half-life	90–120 mins

CLINICAL USES

1) Peripheral nerve blocks

2) Topical anaesthesia

3) Infiltration anaesthesia

4) Central neuraxial blockade

5) Intravenous and regional anaesthesia

PREPARATIONS [55]

- 4% lidocaine for topical anaesthesia
- 1-2% lidocaine gel available for skin and mucocutaneous areas
- 10% lidocaine spray.
- 0.05 to 0.1% lidocaine for infiltration
- 1.5-2% lidocaine for nerve block and extradural block
- 5% lidocaine ointment, on mucous membranes like skin or in the rectum.

DOSAGE [55]

7 mg/kg with adrenaline [56]

3 mg/kg without adrenaline

ADVANTAGES

1) Rapid onset

2) Short duration

3) Class Ib Antiarrhythmic drug

BUPIVACAINE

PHARMACOLOGY OF BUPIVACAINE

Bupivacaine [44,59–65] is an amide type local anaesthetic drug. It is a hydrochloride salt of 1-butyl-N-(2, 6-dimethylphenyl) piperidine-2- carboxamide and is present as a racemic mixture. It was developed by Ekenstem in 1957. Telivuo was first to publish an article on its application in 1963. It is a derivative of Mepivacaine and is very stable complex and can be autoclaved repetitively.

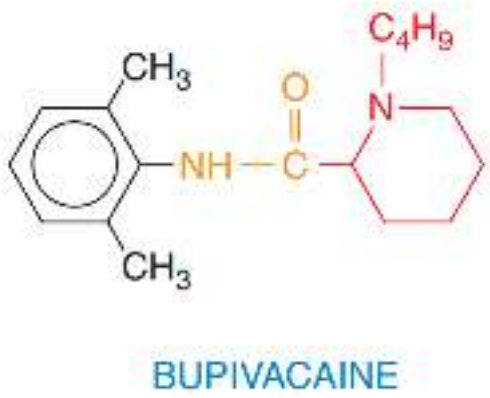


Figure 12: CHEMICAL STRUCTURE: BUPIVACINE [33]

Table No: 2 PHYSIOCHEMICAL PROPERTIES: BUPIVACAINE[44,56–58]

Molecular weight	288 g/mol
Lipid solubility	28
Pka	8.1
Protein binding	95% (approx)
Onset of action	5-10 mins
Approximate duration of action	175 mins
Elimination half-life	210 mins

PHARMACOKINETICS

It is rapidly absorbed from the site of injection. High lipid solubility of Bupivacaine makes it easy for nerve and vascular tissue penetration. 80-95% of the absorbed Bupivacaine binds to the plasma proteins.

Toxic plasma concentration - >3µg/mL

AVAILABILITY[12,56]

Ampoules - 0.5% Bupivacaine hydrochloride 4cc, 0.5% Bupivacaine hydrochloride with Dextrose (heavy) 4cc.

Vials - 0.25%, 0.5%, 0.75% Bupivacaine hydrochloride.

DOSAGE - Maximum dosage 3mg/kg of body weight (approx. 175mg)

USES [12,59]

- Peripheral nerve block
- Spinal anaesthesia
- Epidural anaesthesia
- Local infiltration

ROPIVACAINE

PHARMACOLOGY OF ROPIVACAINE [57]

Ropivacaine is an aminoamide of the pipecoloxylidides family of local anaesthetics. It was developed in 1957. It is a single 'S' enantiomer with 99.5% of enantiomer purity. It is formed by alkylating S-enantiomer of dibenzoyl- L-tartaric acid.

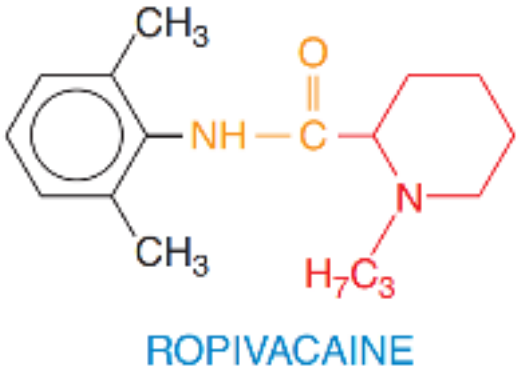


Figure 13: CHEMICAL STRUCTURE [33]

N-(2,6 dimethyl phenyl)- 1- Propylpiperidine-2 carboxamide.

Table No. 3 : PHYSIOCHEMICAL PROPERTIES: ROPIVACAINE [57,66]

Molecular Weight	274
Lipid Solubility	6.1
PKa (25˚C)	8.1
Protein Binding	90-94%
Onset of action	5-8 mins
Duration of action	2 to 6 hours.
Elimination half time:	111 ± 62mins

In comparison to bupivacaine, it has a small volume of distribution, greater clearance, less lipid-soluble, shorter elimination half-life. Both drugs have similar protein binding and pKa.

CLINICAL USES [57,66]

1) Infiltration anaesthesia (0.25%)

2) Peripheral nerve block (0.5% - 0.75%)

3) Central neuraxial blocks (Spinal, epidural, caudal) (upto 1%)

ADVANTAGES OF ROPIVACAINE OVER BUPIVACAINE[67]

The presence of an asymmetric carbon atom in Bupivacaine and Ropivacaine makes them chiral drugs. Bupivacaine is a 50:50 combination of S and R enantiomers. Neurotoxicity and cardiotoxicity are caused by R enantiomers as they bind to the sodium channel more firmly and slowly than the S enantiomers.

When compared to S enantiomers, R enantiomers are more arrhythmogenic and they slow down ventricular conduction. As a result, 99.5% pure S enantiomer Ropivacaine, has a lower cardiotoxic effect than Bupivacaine. Ropivacaine also has fewer CNS side effects and seizures that do occur are usually brief.

AVAILABILITY[57] **:** 1%, 0.75%, 0.5% preparations are available.

Dosage: 3.5mg/kg

Toxic plasma concentration >4μg/ml

Maximum single dose for infiltration: 225mg

ADVANTAGES

- Less cardiotoxicity
- Less neurotoxicity
- Greater clearance.

MATERIALS AND METHODS

SOURCE OF DATA

Patients of 40-70 years of age attending the Ophthalmology out-patient department (OPD) with uncomplicated cataract and who were scheduled to undergo SICS with posterior chamber intraocular lens (PCIOL) implantation under peribulbar anaesthesia at KLES Dr.Prabhakar Kore Hospital and Medical Research Centre (MRC), Belagavi, were the source of data.

METHOD OF COLLECTION OF DATA:

STUDY DESIGN: A one-year comparative study.

STUDY PERIOD: January 2020 – December 2020.

STUDY POPULATION:

Patients between 40-70 years of age attending the Ophthalmology OPD with uncomplicated cataract and who were scheduled to undergo SICS with PCIOL implantation under peribulbar anaesthesia at KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi.

SELECTION CRITERIA:

Inclusion criteria: Individuals within 40-70 years of age,

- Uncomplicated cataract,
- Normal IOP(7-21 mmHg)[68],
- Normal baseline electrocardiogram (ECG) and
- American Society of Anesthesiologists(ASA) grade I, II or III [69]

Exclusion criteria: Patients with

- Profound cognitive impairment[70]
- Apprehension, requiring sedatives and analgesics[70]

- Allergy to hyaluronidase, lidocaine, bupivacaine and ropivacaine.
- Any preceding eye disorder other than cataract[70] and
- Unwilling to participate in the study.

SAMPLE SIZE:

The minimum sample size formula based on mean and standard deviation was calculated as follows -

$$n = \frac{(z_\alpha + z_\beta)^2(s_1^2 + s_2^2)}{(\bar{X}_1 - \bar{X}_2)^2}$$

where z_α is linked with the level of significance and z_β is linked with the power of the test. For 5% level of the significance z_α =1.96 and z_β =0.84 for 80% power of the test.

Ref: $\bar{X}_1$ is the mean of the first group (12.6) and $\bar{X}_2$ is the mean of the second group (15.6). s_1 is the standard deviation of the first group (2.3) and s_2 is the standard deviation of the second group (2.2).

With these values the sample size obtained was just 10.

To make the study more confirmative, the sample size was raised to 100

There were two groups each with sample size: 100.

SAMPLING METHOD: Simple random sampling.

INSTRUMENTS USED FOR DATA COLLECTION

1. Proforma and Consent form.

STATISTICAL ANALYSIS

The study was focused on comparison of two groups. For the continuous quantitative variables mean and standard deviation were calculated. The inter group continuous variables were compared using suitable tools of statistics like unpaired

student's t test. Two quantitative variables, within a group, were compared using student's paired t test.

Discrete variables were represented by median. Suitable graphs were used to depict the comparison.

The categorical data was expressed in terms of rates, ratios and percentages. The association between the outcome, clinical and demographic characteristics was tested using Chi-square test or Fisher's exact test.

Nonparametric tests were used for discrete variables.

For all the tests the value of p less than 5% (0.05) was considered significant.

Group A: Ropivacaine group: n= 100

Group B: Lidocaine-bupivacaine group: n=100

The study subjects were randomized into two groups using simple random sampling method.

METHODOLOGY

Patients who satisfy the above-mentioned criteria were enrolled in the study as subjects.

1. A detailed written and informed consent was obtained from all patients after explaining the procedure and the associated risk.

2. After enrolment, 200 patients were randomized into 2 groups, 100 in each group; to receive peribulbar injection from any one of the following solutions: 0.75 % ropivacaine with 75 units hyaluronidase or mixture 2 % lidocaine with 0.50 % bupivacaine with 75 units hyaluronidase.

3. On the day prior to surgery a detailed history of the patient was taken and noted in the proforma and the following examination and investigations were done:

EXAMINATION

a) The uncorrected visual acuity and the best-corrected visual acuity were noted using Snellen's visual acuity chart.

b) Detailed Slit-lamp examination was done to exclude other ocular co-morbidities.

c) Posterior segment evaluation was done using direct or indirect ophthalmoscopy.

INVESTIGATION

a) IOP was measured using a tonometer.

b) Lacrimal sac syringing was done to check the patency of the lacrimal passages.

c) Vital parameters such as pulse rate, blood pressure and random blood sugar levels were assessed.

d) A-Scan biometry was done to calculate the power of the PCIOL to be implanted.

e) B-scan biometry was done only in cases where fundus details couldn't be made out.

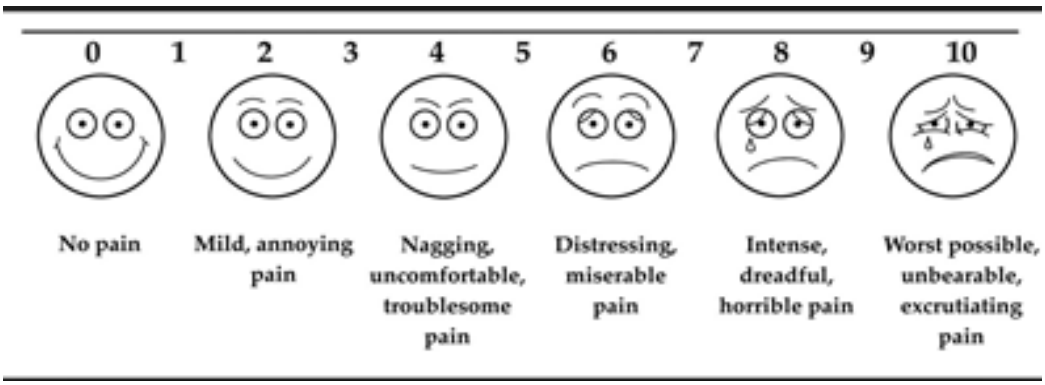
4. Antibiotic drops were instilled in eyes of the patient 4-6 times on the day before the surgery.
5. Patients did not undergo fasting and did not receive any anaesthetic pre-medication, perioperative sedation, or supplementary oxygen.
6. On the day of surgery, before the procedure tropicamide 0.8% (weight/volume) and phenylephrine 5% (weight/volume) dilating eye drops were instilled in the eye to be operated.
7. A test dose of the anaesthetic drug was given for sensitivity.
8. On the day of surgery, pre-block(control) IOP was measured with a tonometer.

TECHNIQUE OF PERIBULBAR BLOCK

- The eye to be operated was identified and painted and draped with 10% betadine solution.
- A 26-gauge 0.5-inch disposable needle was used.
- Site of injection: The point between medial 2/3rd and lateral 1/3rd of lower orbital margin adjacent to infraorbital notch.
- With the bevel of needle facing towards the globe, the needle was cautiously advanced parallel to the orbital floor and no redirection was done as in retrobulbar block. Care was taken so that the hub of needle did not go beyond the inferior orbital rim. Correct positioning of the needle was confirmed by comparing the range of eye movement to the base line values to exclude tethering of the globe.[52] After a negative aspiration for blood, upto 10 mL local anaesthetic agent was injected over 30 – 40 seconds.[50] Volume of local anaesthetic drug that produced total upper eyelid drop, i.e. sufficient depression of the eyelid to cover the whole of the cornea, was considered as end point of injection.[52]
- After injection at the inferotemporal quadrant, the globe was massaged with the middle 3 fingers placed over a sterile gauze pad. Gentle pressure was applied using the middle finger placed directly over the eyeball for 1 minute (min). For every 30 seconds, pressure was released for 5 seconds to allow for vascular pulsations to occur.[71]
- The quality of the block was assessed in terms of akinesia using a three-point akinesia scoring system based on the reduction of globe motility in each quadrant (akinesia score). Ocular movements were scored for each direction of gaze in the superior, inferior, medial and lateral directions. The score for movement in each direction of gaze will thus be the sum of scores for the two corresponding

quadrants – minimum score possible = 0 and maximum score possible 3 X 4 = 12.[72] The block was considered inadequate for surgery if eyeball movement score is 4 or more in any direction at 10 mins.[73]

- IOP was measured at four time points: before block (control), 1 min after block, 5 mins after block and 15 mins after block with tonometer.[69]
- After the procedure, participants were instructed to assess the degree of pain experienced while administration of the anaesthetic injection, with the help of a visual analog scale (VAS).[74]



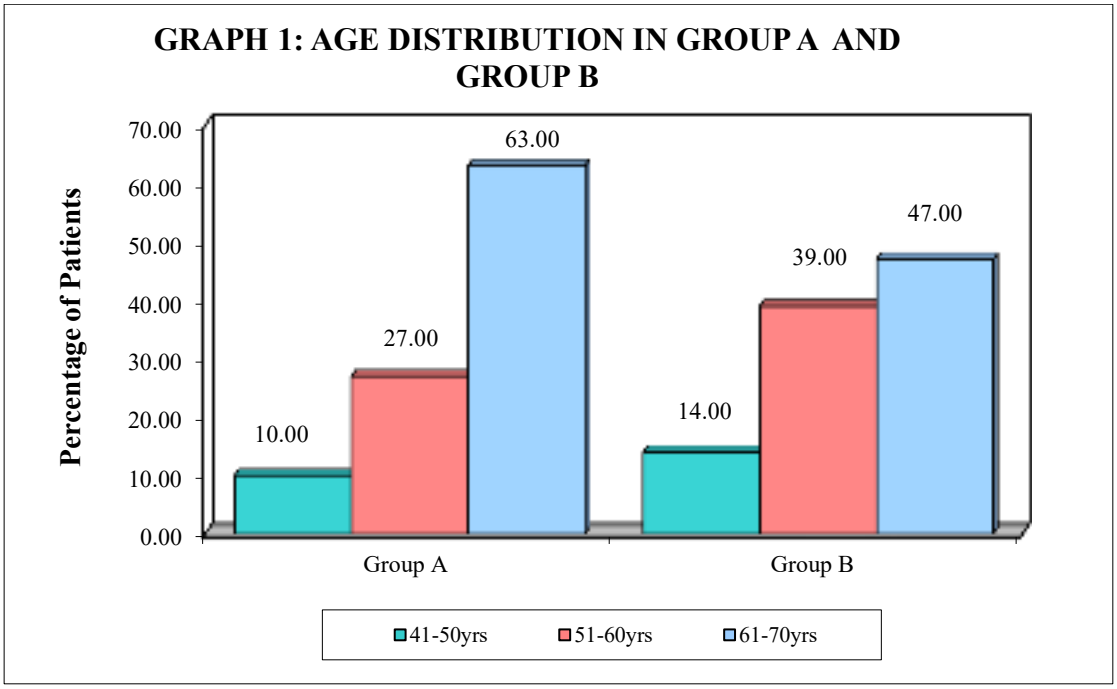
- The patients were told to grip the investigator's hand and squeeze it every time they felt pain and the surgical step during which they felt pain was documented.[74] If pain occurred at any step, topical anaesthetic was instilled.
- Post-surgery the participants were specifically instructed to assess for the pain experienced during surgery with help of a VAS. [74]

RESULTS

The present study "comparative study to assess the effect of ropivacaine and a mixture of lidocaine-bupivacaine on intraocular pressure after peribulbar anaesthesia for cataract surgery at KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi" was conducted on 200 patients during the study period January 2020 to December 2020. The patients were divided into two groups as: Group A (patients who underwent SICS with ropivacaine as the peribulbar anaesthetic) and Group B (patients who underwent SICS with a mixture of lidocaine – bupivacaine as the peribulbar anaesthetic). The data obtained were tabulated as below:

Table No. 4: AGE DISTRIBUTION IN GROUP A AND GROUP B

Age groups	**Group A (n = 100)**	**%**	**Group B (n=100)**	**%**	**Total**	**%**
41-50yrs	10	10.00	14	14.00	24	12.00
51-60yrs	27	27.00	39	39.00	66	33.00
61-70yrs	63	63.00	47	47.00	110	55.00

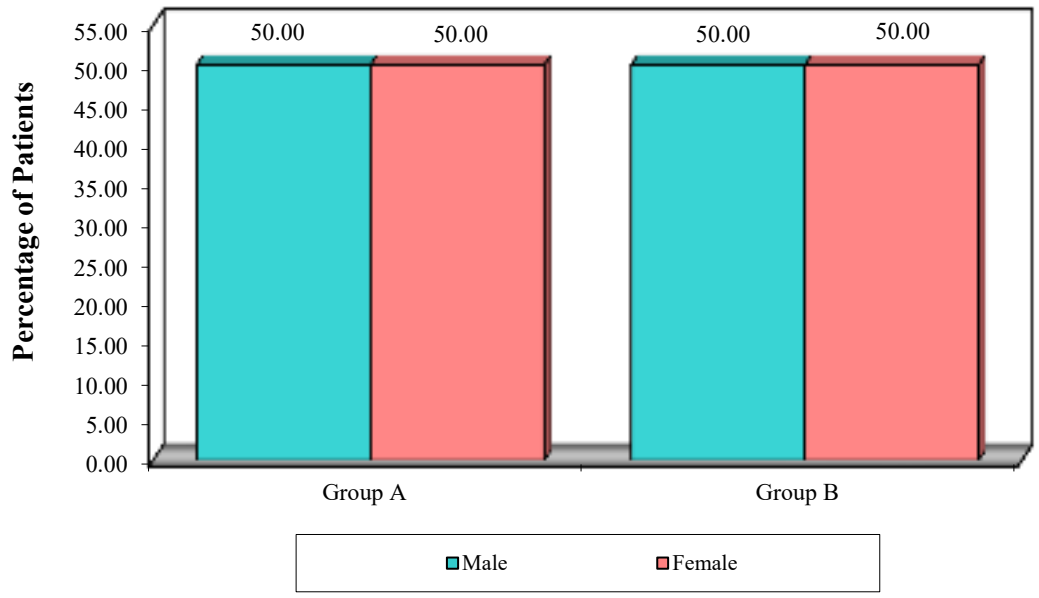


In our study, 12% of patients belonged to age group of 41-50years of age, 33% belonged to 51-60 years of age and 55% belonged to 61-70 years of age group. Mean age was 60.46 years.

TABLE No. 5: GENDER DISTRIBUTION IN GROUP A AND GROUP B

Gender	Group A (n = 100)	Group B (n=100)	Total	%
Male	50	50	100	50.00
Female	50	50	100	50.00
Total	100	100	200	100.00

GRAPH 2: GENDER DISTRIBUTION IN GROUP A AND GROUP B



Out of 200 patients, 100 were men and 100 were women. And in both groups men were 50 and women were 50.

Table No. 6: COMPARISON OF GROUP A(ROPIVACAINE) AND GROUP B (LIDOCAINE-BUPIVACAINE) WITH PRESENCE OF DIABETES MELLITUS AND HYPERTENSION

Co-morbidity	**Group A**	%	**Group B**	%	Total	%	χ^2	P-value
Diabetic Mellitus								
Yes	23	23.00	17	17.00	40	20.00	1.1250	0.2890
No	77	77.00	83	83.00	160	80.00		
Hypertension								
Yes	36	36.00	30	30.00	66	33.00	0.2890	0.3670
No	64	64.00	70	70.00	134	67.00		
Total	100	100.00	100	100	200	100.0		

In Group A 23 patients (23%) had diabetes mellitus and 36 patients (36%) had hypertension.

In Group B 17 patients (17%) had diabetes mellitus and 30 patients (30%) had hypertension.

Table No. 7: CORRELATION BETWEEN VOLUME OF ANAESTHETIC AGENT WITH IOP (mmHg) AT 1min, 5mins, 15mins BY ONE WAY ANOVA

Groups	Volume of anaesthetic	IOP 1min		IOP 5mins		IOP 15mins	
		Mean	SD	Mean	SD	Mean	SD
Group A	3--6	14.23	4.04	14.15	3.83	13.69	3.25
	7--8	14.87	4.58	13.23	3.01	12.74	2.84
	9--10	15.09	3.97	14.00	3.56	13.54	3.34
	Total	14.91	4.14	13.78	3.42	13.31	3.17
F-value		0.2248		0.5950		0.7284	
P-value		0.7991		0.5536		0.4853	
Group B	3--6	16.00	2.45	16.58	3.03	15.75	5.17
	7--8	15.17	3.73	15.62	3.89	15.90	3.56
	9--10	15.56	4.80	16.19	4.45	17.25	5.28
	Total	15.50	4.26	16.07	4.12	16.68	4.84
F-value		0.1710		0.2843		1.0188	
P-value		0.8431		0.7532		0.3649	

*$p<0.05$

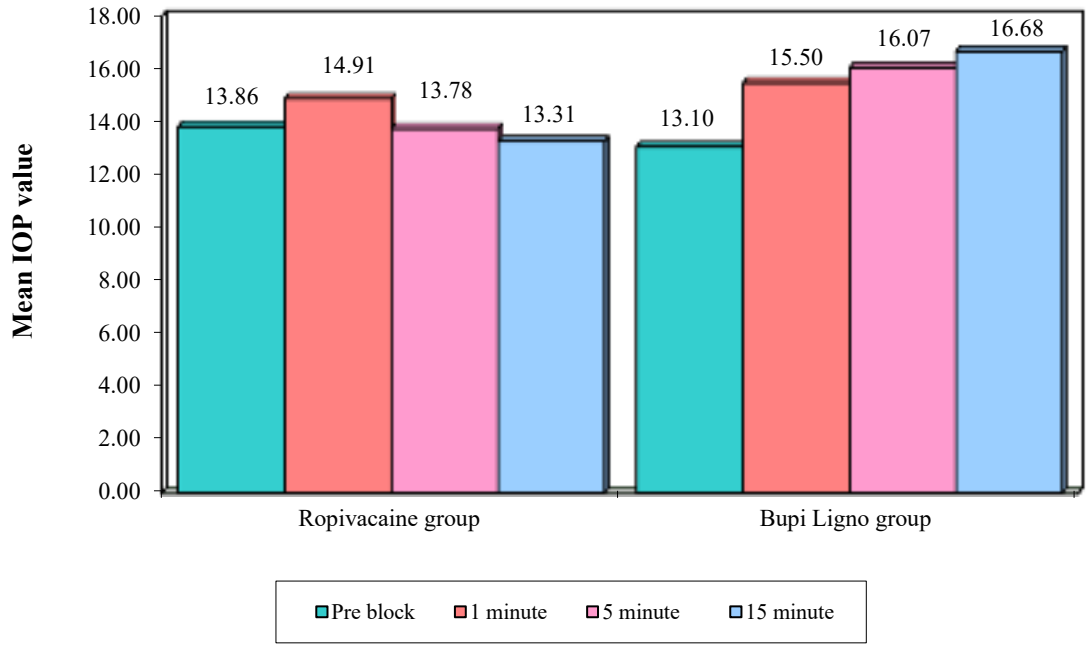
Volume of anaesthetic injected and the post-block IOP within the respective groups was not significant ($p>0.05$) at any time point.

Table No. 8: COMPARISON OF GROUP A (ROPIVACAINE) AND GROUP B (LIDOCAINE-BUPIVACAINE) WITH IOP (mmHg) AT DIFFERENT TREATMENT TIMES BY INDEPENDENT T TEST

Treatment times	Group A		Group B		Mean Difference	t-value	p-value
	Mean	SD	Mean	SD			
Pre block IOP (control)	13.86	3.06	13.10	3.01	0.76	1.7701	0.0783
Post block IOP							
1 min	14.91	4.14	15.50	4.26	-0.59	-0.9924	0.3222
5 mins	13.78	3.42	16.07	4.12	-2.29	-4.2728	0.0001*
15 mins	13.31	3.17	16.68	4.84	-3.37	-5.8259	0.0001*
Pre block-1min	-1.05	2.30	-2.40	3.13	1.35	3.4743	0.0006*
Pre block-5mins	0.08	1.55	-2.97	2.83	3.05	9.4454	0.0001*
Pre block-15 mins	0.55	1.69	-3.58	3.93	4.13	9.6626	0.0001*

*p<0.05

GRAPH 3: COMPARISON OF GROUP A AND GROUP B WITH IOP (mmHg) AT DIFFERENT TREATMENT TIMES



Pre-block(control) mean IOP in group A was 13.86±3.06 mmHg and Group B is 13.13±3.01 mmHg and it is not significant.

The 1 min post-block mean IOP in both groups is higher than their baseline levels (pre-block) which is Group A is 14.91±4.14 mmHg and Group B is 15.50 ± 4.26 mmHg, but it is not significant.

However the rise in 1min post block mean IOP is significantly less in ropivacaine group (group A).

The 5 mins and 15 mins post block mean IOP values in Group A is significantly lower than the corresponding group B values and also the baseline Group A values.

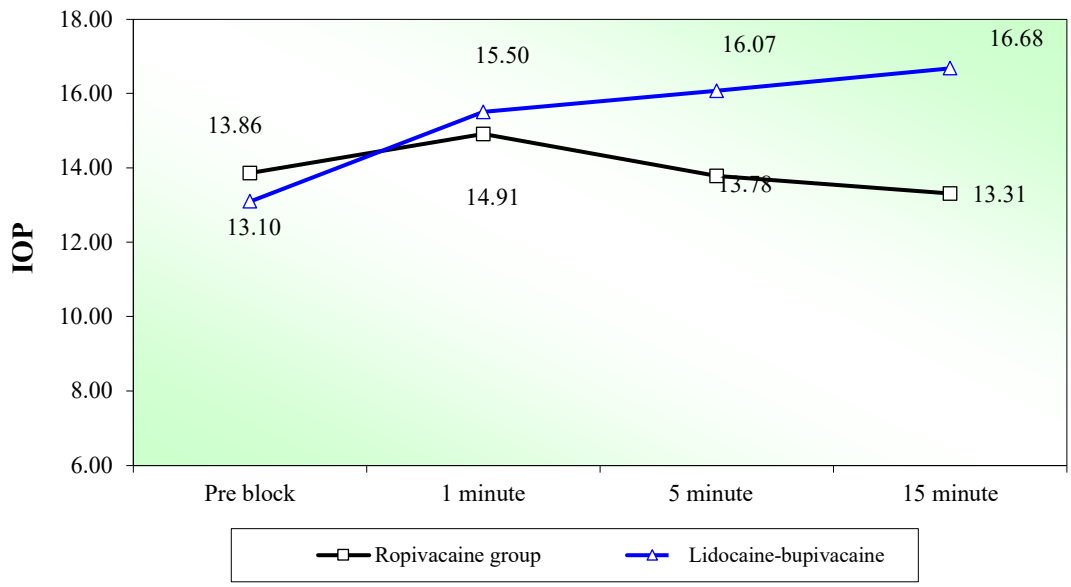
Table No. 9: COMPARISON OF DIFFERENT TREATMENT TIMES WITH IOP(mmHg) IN GROUP A (ROPIVACAINE) AND GROUP B (LIDOCAINE-BUPIVACAINE) BY DEPENDENT T-TEST.

Group	Treatment times	Mean	SD	Mean Diff.	SD Diff.	Paired t	P-value	Effect size
Group A	Pre block IOP	13.86	3.06	-1.05	2.30	-4.5694	0.0001*	0.2880
	1 min	14.91	4.14					
	Pre block IOP	13.86	3.06	0.08	1.55	0.5167	0.6065	
	5 mins	13.78	3.42					
	Pre block	13.86	3.06	0.55	1.69	3.2545	0.0016*	
	15 mins	13.31	3.17					
	1 min	14.91	4.14	1.13	1.99	5.6838	0.0001*	
	5 mins	13.78	3.42					
	1 min	14.91	4.14	1.60	2.53	6.3226	0.0001*	
	15 mins	13.31	3.17					
	5 mins	13.78	3.42	0.47	1.07	4.4010	0.0001*	
	15 mins	13.31	3.17					
Group B	Pre block IOP	13.10	3.01	-2.40	3.13	-7.6594	0.0001*	0.5440
	1 min	15.50	4.26					
	Pre block	13.10	3.01	-2.97	2.83	-10.4813	0.0001*	
	5 mins	16.07	4.12					
	Pre block	13.10	3.01	-3.58	3.93	-9.1189	0.0001*	
	15 mins	16.68	4.84					
	1 min	15.50	4.26	-0.57	2.48	-2.2991	0.0236*	
	5 mins	16.07	4.12					
	1 min	15.50	4.26	-1.18	4.31	-2.7354	0.0074*	
	15 mins	16.68	4.84					
	5 mins	16.07	4.12	-0.61	2.65	-2.3051	0.0232*	
	15 mins	16.68	4.84					

*$p<0.05$

The effect size is more in group B which indicates a larger IOP variation.

GRAPH 4: COMPARISON OF DIFFERENT TREATMENT TIMES WITH IOP(mmHg) IN GROUP A AND GROUP B



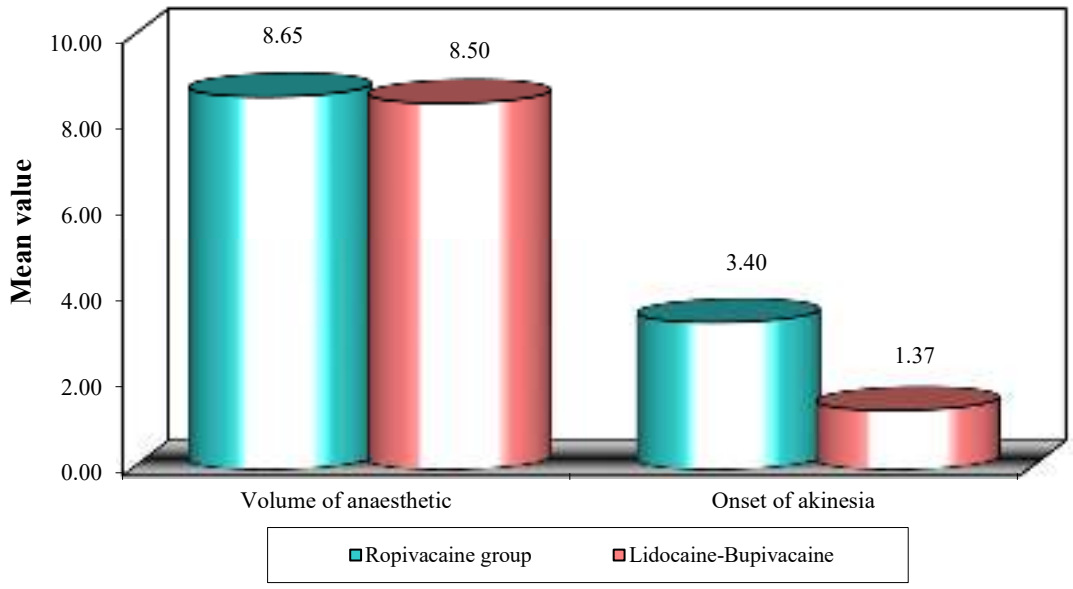
In Group A, the IOP 15 mins after block is 13.31 ± 3.17 mmHg and it is significantly lower (0.0016*) than the pre-block(control) IOP, which is 13.86 ± 3.06 mmHg. In Group B, the IOP 15 mins after block is 16.68 ± 4.84 mmHg and it is significantly higher (0.0001*) than the pre-block(control) IOP, which is 13.10 ± 3.01 mmHg.

Table No. 10: COMPARISON OF GROUP A (ROPIVACAINE) AND GROUP B (LIDOCAINE-BUPIVACAINE) WITH VOLUME OF ANAESTHETIC (mL) AND ONSET OF AKINESIA (in min) BY INDEPENDENT T TEST

Variable	Groups	Mean	SD	Mean Diff.	t-value	P-value
Volume of anaesthetic	Group A	8.65	2.00	0.15	0.5761	0.5652
	Group B	8.50	1.67			
Onset of akinesia	Group A	3.40	9.99	2.03	2.0199	0.0447*
	Group B	1.37	1.05			

*p<0.05

GRAPH 5: COMPARISON OF GROUP A AND GROUP B WITH VOLUME OF ANAESTHETIC (mL) AND ONSET OF AKINESIA (IN MIN)



Mean volume of anaesthetic used in group A is 8.65 ± 2.00 mL and Group B 8.50 ± 1.67 mL is not statistically significant (p>0.05).

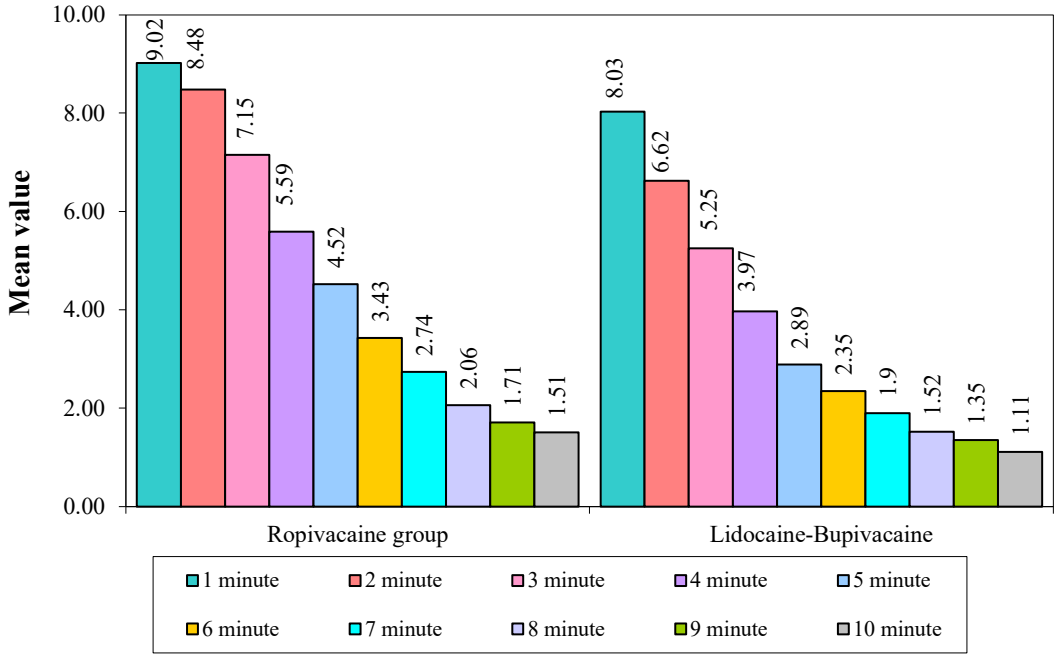
Onset of akinesia is faster in group B, 1.37 ± 1.05 mins and was statistically significant (p<0.05).

Table No. 11: COMPARISON OF GROUP A (ROPIVACAINE) AND GROUP B (LIDOCAINE-BUPIVACAINE) WITH AKINESIA SCORES AT DIFFERENT TREATMENT TIMES BY INDEPENDENT T TEST

Treatment times	Group A		Group B		Mean Difference	t-value	p-value
	Mean	SD	Mean	SD			
1 min	9.02	3.35	8.03	3.00	0.99	2.1999	0.0290*
2 mins	8.48	3.50	6.62	3.29	1.86	3.8703	0.0001*
3 mins	7.15	3.89	5.25	3.85	1.90	3.4692	0.0006*
4 mins	5.59	4.31	3.97	3.63	1.62	2.8760	0.0045*
5 mins	4.52	4.51	2.89	3.27	1.63	2.9258	0.0038*
6 mins	3.43	4.12	2.35	3.08	1.08	2.0989	0.0371*
7 mins	2.74	3.69	1.90	2.66	0.84	1.8449	0.0665
8 mins	2.06	3.10	1.52	2.30	0.54	1.3992	0.1633
9 mins	1.71	2.83	1.35	2.04	0.36	1.0317	0.3035
10 mins	1.51	2.59	1.11	1.75	0.40	1.2800	0.2020
1 min-2mins	0.54	1.32	1.41	1.69	-0.87	-4.0580	0.0001*
1 min-3mins	1.87	2.40	2.78	2.68	-0.91	-2.5303	0.0122*
1 min-4mins	3.43	2.97	4.06	2.90	-0.63	-1.5185	0.1305
1 min-5mins	4.50	3.45	5.14	2.90	-0.64	-1.4221	0.1566
1 min-6mins	5.59	3.29	5.68	2.94	-0.09	-0.2039	0.8386
1 min-7mins	6.28	3.32	6.13	2.81	0.15	0.3452	0.7303
1 min-8mins	6.96	3.11	6.51	2.69	0.45	1.0941	0.2753
1 min-9mins	7.31	3.17	6.68	2.66	0.63	1.5234	0.1293
1 min-10mins	7.51	3.14	6.92	2.63	0.59	1.4407	0.1513

*$p<0.05$

GRAPH 6: COMPARISON OF ROPIVACAINE GROUP AND LIDOCAINE-BUPIVACAINE GROUP WITH AKINESIA SCORES AT DIFFERENT TREATMENT TIMES



Adequate akinesia (akinesia score < 4) was achieved in group B at 4 mins (mean score 3.97 ± 3.63) and was faster than Group A (mean score 3.43 ± 4.12 at 6 mins) which was statistically significant ($p<0.05$).

Akinesia score at 10 mins in both groups is similar and not statiscically significant (Group A 1.51±2.59 and Group B is 1.11±1.75)

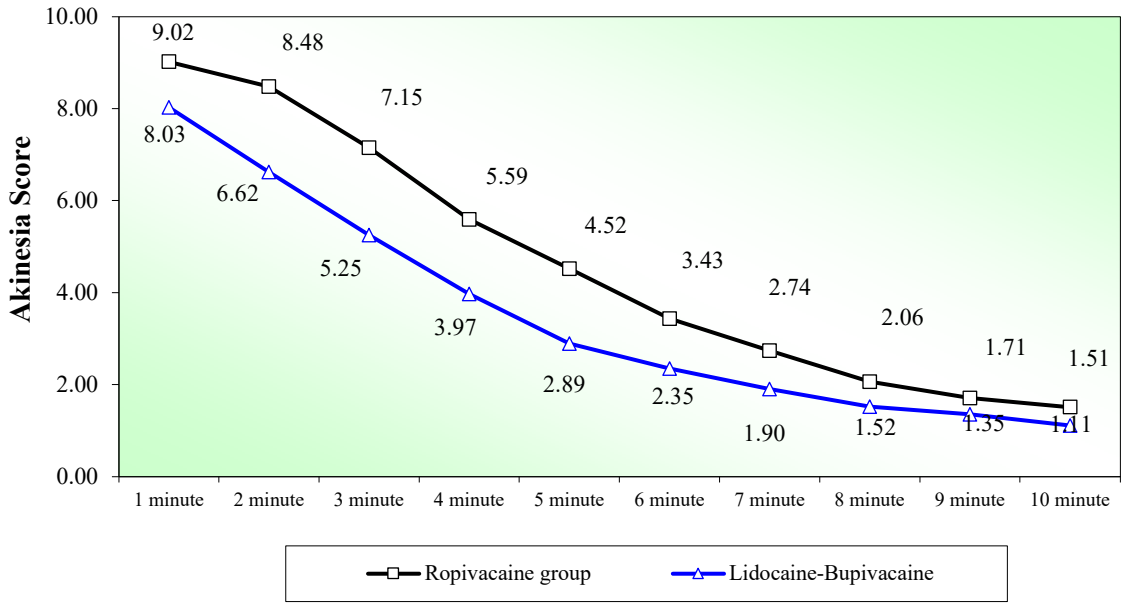
Table No. 12: COMPARISON OF DIFFERENT TREATMENT TIMES WITH AKINESIA SCORES IN GROUP A (ROPIVACAINE) AND GROUP B (LIDOCAINE-BUPIVACAINE) BY DEPENDENT T-TEST

Group	Treatment times	Mean	SD	Mean Diff.	SD Diff.	Paired t	P-value	Effect size
Group A	1 min	9.02	3.35					0.8560
	2 mins	8.48	3.50	0.54	1.32	4.0869	0.0001*	
	1 min	9.02	3.35					
	3 mins	7.15	3.89	1.87	2.40	7.7980	0.0001*	
	1 min	9.02	3.35					
	4 mins	5.59	4.31	3.43	2.97	11.5538	0.0001*	
	1 min	9.02	3.35					
	5 mins	4.52	4.51	4.50	3.45	13.0620	0.0001*	
	1 min	9.02	3.35					
	6 mins	3.43	4.12	5.59	3.29	16.9861	0.0001*	
	1 min	9.02	3.35					
	7 mins	2.74	3.69	6.28	3.32	18.9422	0.0001*	
	1 min	9.02	3.35					
	8 mins	2.06	3.10	6.96	3.11	22.3759	0.0001*	
	1 min	9.02	3.35					
	9 mins	1.71	2.83	7.31	3.17	23.0768	0.0001*	
	1 min	9.02	3.35					
	10 mins	1.51	2.59	7.51	3.14	23.9063	0.0001*	
Group B	1 min	8.03	3.00					0.8800
	2 mins	6.62	3.29	1.41	1.69	8.3515	0.0001*	
	1 min	8.03	3.00					
	3 mins	5.25	3.85	2.78	2.68	10.3724	0.0001*	
	1 min	8.03	3.00					
	4 mins	3.97	3.63	4.06	2.90	14.0080	0.0001*	
	1 min	8.03	3.00					
	5 mins	2.89	3.27	5.14	2.90	17.7513	0.0001*	
	1 min	8.03	3.00					

	6 mins	2.35	3.08	5.68	2.94	19.3192	0.0001*	
	1 min	8.03	3.00					
	7 mins	1.90	2.66	6.13	2.81	21.8206	0.0001*	
	1 min	8.03	3.00					
	8 mins	1.52	2.30	6.51	2.69	24.1903	0.0001*	
	1 min	8.03	3.00					
	9 mins	1.35	2.04	6.68	2.66	25.1258	0.0001*	
	1 min	8.03	3.00					
	10 mins	1.11	1.75	6.92	2.63	26.3390	0.0001*	

*p<0.05

GRAPH 7: COMPARISON OF DIFFERENT TREATMENT TIMES WITH AKINESIA SCORES IN ROPIVACAINE GROUP AND LIDOCAINE-BUPIVACAINE GROUP



In both the groups, the 10mins post-block akinesia score was significantly less than 1min post block akinesa score, but group B had a larger effect size implying that akinesia was more in group B.

Table No. 13: COMPARISON OF GROUP A AND GROUP B WITH AKINESIA SCORE<4

Treatment times	Group A	Group B	Total
1 min	8	8	16
2 mins	11	16	27
3 mins	18	35	53
4 mins	28	47	75
5 mins	45	61	106
6 mins	57	68	125
7 mins	64	73	137
8 mins	69	79	148
9 mins	74	85	159
10 mins	75	89	164
Chi-square=5.4450, p=0.7940			

At 10 mins 25 patiens of group A (n=100) and 11 patientts of group B (n=100) had not achieved adequate akinesia (akinesia score <4).

Table No. 14: COMPARISON OF GROUP A AND GROUP B WITH PAIN DURING ADMINISTRATION OF LOCAL ANAESTHETIC DRUG

Pain during administration	Group A	%	Group B	%	Total	%
0--1	2	2.00	13	13.00	15	7.50
2--3	91	91.00	74	74.00	165	82.50
4--5	7	7.00	11	11.00	18	9.00
6--7	0	0.00	2	2.00	2	1.00
8-10	0	0.00	0	0	0	0
Total	100	100.00	100	100.00	200	100.00
Chi-square= 12.7070, p=0.0050*						

*p<0.05

In Group A(n=100), 2 patients had no pain(pain 0-1) during the administration of the anaesthetic(Ropivacaine), 91 patients had mild, annoying pain(pain score 2-3) and 7 patients had nagging pain(pain score4-5). No patients had a pain score higher than 5 in this group.

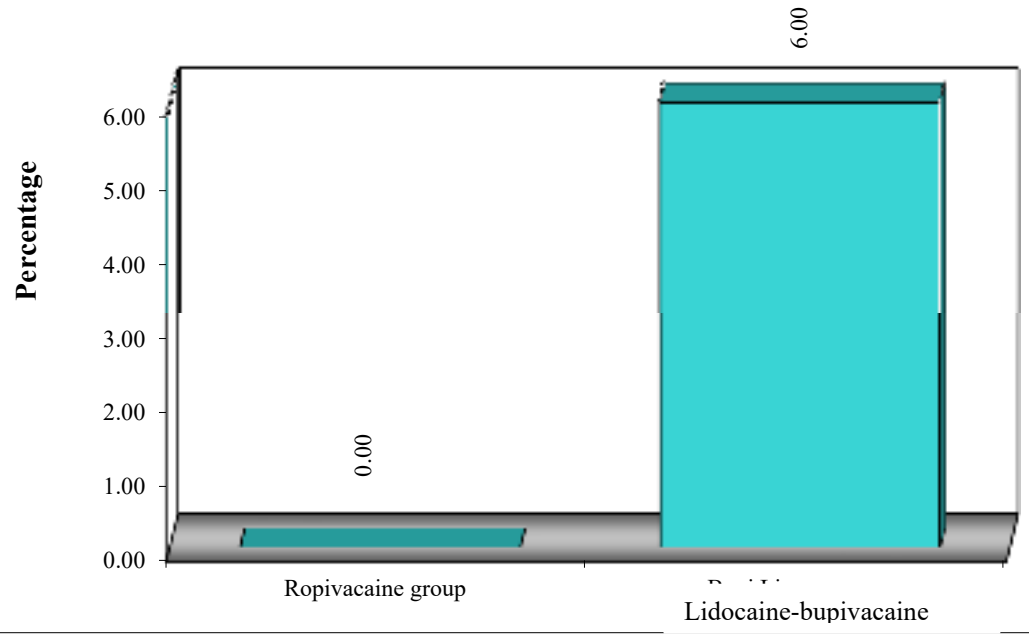
In Group B(n=100), 13 patients had no pain(pain 0-1) during the administration of the anaesthetic(lidocaine-bupivacaine), 74 patients had mild, annoying pain(pain score 2-3) and 11 patients had nagging pain(pain score4-5). 2 patients had a pain score 6-7 (distressing pain) in this group.

Table No. 15: COMPARISON OF GROUP A (ROPIVACAINE) AND GROUP B (LIDOCAINE-BUPIVACAINE) WITH PRESENCE OF PAIN DURING SURGERY

Pain during surgery	Group A	%	Group B	%	Total	%	χ^2	P-value
Yes	0	0.00	6	6.00	6	3.00	Yates χ^2 4.296	0.0380*
No	100	100.00	94	94.00	194	97.00		
Total	100	100.00	100	100.00	200	100.00		

*p<0.05

GRAPH 8: COMPARISON OF GROUP A AND GROUP B WITH PRESENCE OF PAIN DURING SURGERY



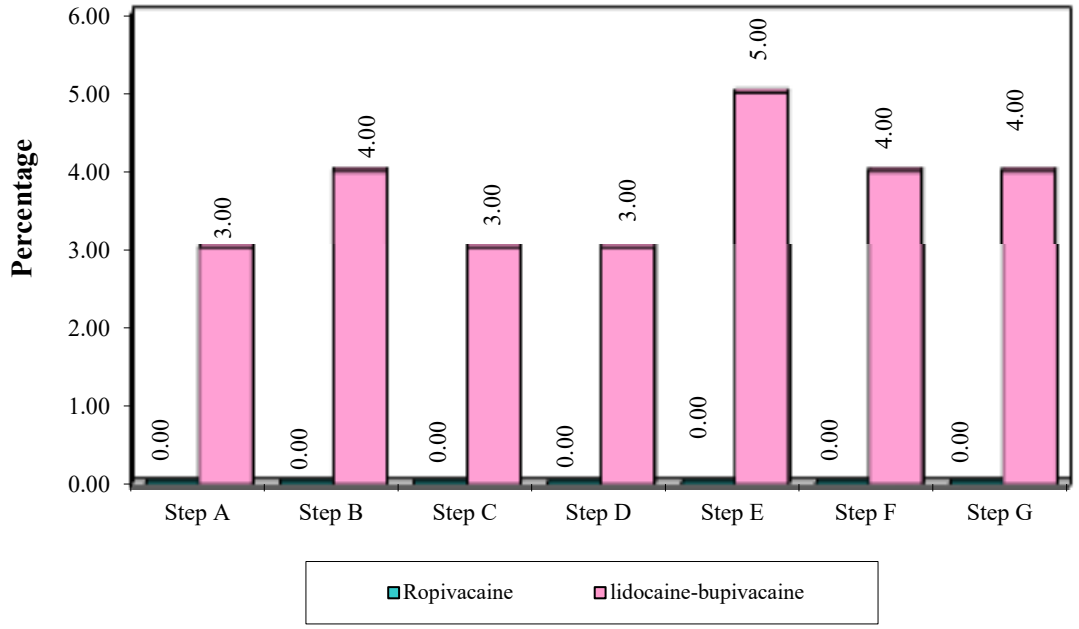
Intra-operative pain did not occur in any case in group A versus six cases of group B which was statistically significant (p<0.05).

Table No. 16: COMPARISON OF GROUP A (ROPIVACAINE) AND GROUP B (LIDOCAINE-BUPIVACAINE) WITH PAIN SCORE AT VARIOUS STEPS

Steps	Group A	%	Group B	%	Total	%	χ^2	p-value
Step A	0	0.00	3	3.00	3	1.50	3.046	0.0810
Step B	0	0.00	4	4.00	4	2.00	4.082	0.0430*
Step C	0	0.00	3	3.00	3	1.50	3.046	0.0810
Step D	0	0.00	3	3.00	3	1.50	3.046	0.0810
Step E	0	0.00	5	5.00	5	2.50	5.128	0.0240*
Step F	0	0.00	4	4.00	4	2.00	4.082	0.0430*
Step G	0	0.00	4	4.00	4	2.00	4.082	0.0430*

*$p<0.05$

GRAPH 9: COMPARISON OF ROPIVACAINE GROUP AND LIDOCAINE-BUPIVACAINE GROUP WITH PAIN SCORE AT VARIOUS STEPS



STEP A – INCISION AND SCLERAL TUNNEL

STEP B – CAPSULORRHEXIS

STEP C – HYDRODISSECTION

STEP D – DELIVERY OF LENS BY PHACOSANDWICH TECHNIQUE

STEP E – IRRIGATION/ASPIRATION

STEP F – PCIOL IMPLANTATION

STEP G – STROMAL HYDRATION

Six patients in group B had pain during surgery at various steps, which is as follows: 3 patients had pain in step A, 4 patients have pain in step B, 3 patients had pain in step C, 3 patients had pain in step D, 5 patients had pain in step E, 4 patients had pain in step F and 4 patients had pain in step G.

Table No. 17: LIST OF PAINFUL STEPS IN GROUP B (LIDOCAINE-BUPIVACAINE)

Painful steps during surgery	Number of patients that had intra-operative pain	Percentage (%)
AB	1	1.00
ABCDE	1	1.00
ABCDEFG	1	1.00
BCDEFG	1	1.00
EFG	2	2.00

STEP A – INCISION AND SCLERAL TUNNEL

STEP B – CAPSULORRHEXIS

STEP C – HYDRODISSECTION

STEP D – DELIVERY OF LENS BY PHACOSANDWICH TECHNIQUE

STEP E – IRRIGATION/ASPIRATION

STEP F – PCIOL IMPLANTATION

STEP G – STROMAL HYDRATION

Of the six patients that had intra-operative pain, only 1 patient had pain during all the steps of the surgery.

Table No. 18: DEGREE OF PAIN DURING SURGERY IN GROUP B (LIDOCAINE-BUPIVACAINE)

Degree of pain (VAS)	Number of patients that had intra-operative pain	Percentage (%)
2	2	2.00
4	3	3.00
5	1	1.00

Out of 100 patients in group B, six patients experienced pain during surgery. 2 patients had mild, annoying pain (pain score 2) and 3 patients had nagging pain (pain score 4). 1 patients had uncomfortable, troublesome pain (pain score 5) in this group. No patients had a pain score higher than 5 in this group.

DISCUSSION

In our study, we included 200 patients. They were assigned to either Group A or Group B using a simple random sampling method. Group A patients underwent SICS with Ropivacaine 0.75% as the local anaesthetic for peribulbar anaesthesia whereas Group B patients underwent SICS with a mixture of Bupivacaine 0.5% and with lidocaine 2% in 1:1 ratio as the local anaesthetic for peribulbar anaesthesia. Each group had 100 patients.

Most patients were in the age group of 61 to 70 years in either group with a mean age of 60.46 ± 7.39years. Gupta S K et al did a similar study, where the mean age of the patients was 64.2 years. [74]

Coincidently, each group had 50 males and 50 females. In a study by NOCITI et al 55.0 % were males and 45.0% were females which is not statistically significant.[75]

According to Frow et al, there are many methods to determine how much local anaesthetic drug to inject into the patients for peribulbar anaesthesia and akinesia. But there is no universally recognized and clinically consistent way to know the end-point of the local anaesthetic volume sufficient to provide akinesia and anaesthesia. [52] In our study, variable volume of local anaesthetic agent (<10 mL), was injected depending on the amount of filling of orbit seen during injection and rate of onset of ptosis (total upper eyelid drop). [50, 76] In our study, the volume of anaesthetic agents used in both groups was similar and the results were not statistically significant.

In our study, we had added hyaluronidase to both groups, as many studies have proven that hyaluronidase improves the quality of the block. [46, 77, 78]

According to most studies, the post-block IOP rise is positively linked to the increasing volumes of local anaesthetic solutions used. [79, 80] However, in our study, we didn't find any such correlation. The volume of anaesthetic injected and the post-block IOP within the respective groups was not significant. This suggests that the volume of local anaesthetic solution injected is not linked to the IOP rise. This might be because we have not used very large volumes of the anaesthetic solution. The results of our study are comparable to a similar study done by Frow et al. [52]

Mean values of IOP before block were similar between the two groups ($p>0.05$, independent t-test) which is also in agreement with a study done by Özcan et al which also had a similar mean pre block IOP between the two groups ($p>0.05$, Mann-Whitney test). [69]

A study by Frow et al showed that in all eyes, the mean (95% confidence limits) increase in IOP over baseline after peribulbar injection was 6.9 (4.9–8.8) mmHg, immediately post-injection ($p <0.00001$).[52] The present study shows a significant difference between the control (pre block values) and 1min post block IOP values. All eyes (both groups) had an increase in IOP over baseline (control) at 1 min after peribulbar injection and this increase in the 1min post block IOP was significantly less in the ropivacaine group when compared to the lidocaine-bupivacaine group.

Overall, the mean readings of IOP post-block were significantly less in Group A (ropivacaine) in comparison to Group B(lidocaine-bupivacaine). In our study, group A 1min post block IOP was 14.91±4.14mmHg which was not statistically significant in comparison to Group B which was 15.50±4.26mmHg. This was not in agreement with a study done by Nociti et al, in which variation in IOP was different in both the groups i.e., ropivacaine and bupivacaine for a peribulbar block. In their

study – in the ropivacaine group, the mean values obtained at all the three-time points after block were significantly lower than the controls, this effect is probably due to vasoconstriction produced by ropivacaine leading to smaller intraocular blood volume[70,75], but in the bupivacaine group, the mean value of IOP rose significantly 1min after block and was lower than control only 15 mins after block. [75]

In our study, the mean values of IOP after block were significantly lower in the ropivacaine group in comparison to the lidocaine-bupivacaine group at 5 mins and 15mins time points after block. These results were in agreement with the studies done by Nociti et al [75] and Govêia, Magalhães.[81]

In a study done by G.Olmez et al, the authors compared ropivacaine with a mixture of lidocaine-adrenaline observed that there were no significant differences in IOP levels between the two groups at three times points i.e. 1min, 5 mins and 10mins, which is not in agreement with our study. However, the IOP levels in the ropivacaine group at 10mins were significantly lower than its baseline values, which is in agreement with our study.[76] A transient rise in IOP can be due to the peribulbar block itself secondary to the increase in orbital pressure. But as the extra-ocular muscles relax, there is a rapid fall in IOP.[76] As already discussed above, this effect of ropivacaine could be due to vasoconstriction produced by it.[76] Another cause of lower IOP levels seen ropivacaine group can be attributed to its property of high lipid solubility which allows it to diffuse through tissues faster than lidocaine.[76] In our study we have highly lipid-soluble ropivacaine which is compared with a mixture of bupivacaine (which is also highly lipid-soluble) and lidocaine (less lipid-soluble). So higher post block IOP in group B (lidocaine-bupivacaine group) can be attributed to being less lipid solubility of lidocaine.

Ozcan et al[69] observed that lidocaine-bupivacaine combination increased IOP from 15.1±2.5mmHg to 17.8±2.5mmHg after the peribulbar anaesthesia, whereas ropivacaine decreased IOP from 15.8±2.3 to 13.5±2.3mmHg.

In a double-blind randomized study done by Corke et al, the authors found no significant difference in the ocular movement score at 1, 5 and 10 minutes between the ropivacaine group and the lidocaine-bupivacaine group for peribulbar anaesthesia in cataract surgery.[82] In our study, the volume of anaesthetic required in either group was not statistically significant (group A 8.65 ± 2.00 mL and Group B 8.50±1.67mL). However, the onset of akinesia is was achieved faster in group B, 1.37 ± 1.05 mins and was statistically significant ($p<0.05$).

In a similar study by Nicholson et al comparing 0.75% Ropivacaine with a mixture of lidocaine 2%- Bupivacaine 0.5% for peribulbar anaesthesia in cataract surgery, the authors found out that the lidocaine- bupivacaine resulted in a significantly lower ocular movement score at 2mins, 4mins, 6mins, but at 8mins both anaesthetic solutions had provided similar akinesia which was not statistically significant. They attributed the faster action of the lidocaine bupivacaine to be due to the properties of lidocaine.[50] Our study had replicated similar results as well, in Group A (Ropivacaine) adequate akinesia (akinesia score less than 4) was achieved 6mins post block whereas in Group B the same was achieved at 4mins. But both the groups had similar adequate akinesia at 10 mins which were not statistically significant.

For ocular akinesia, we used a scoring system described by Brahma et al.[73] The block was considered inadequate if the akinesia score was more than three 10mins after block. At 10 mins 25 patients of group A (n=100) and 11 patients of group B (n=100) had not achieved adequate akinesia (akinesia score <4). Various

studies have shown variable outcomes and there is no way to compare these results as different studies have compared different anaesthetic agents. In a study by Devi NS et al, comparing a lignocaine-adrenaline mixture with bupivacaine- lignocaine mixture showed that 18% of patients had inadequate akinesia in the lignocaine-adrenaline group versus 40% patients in the lignocaine group. [(72)] In another study by Luchetti et al, comparing Ropivacaine 0.75% with a mixture of Bupivacaine 0.5%–Mepivacaine 2% for peribulbar anaesthesia, both groups, supplementary injections were given solely because of inadequate akinesia.[(83)] Nevertheless, in our study, these patients were taken up for the surgery without any additional injection. Vocal encouragement was given and topical anaesthetic was used wherever necessary.

Pain during administration of local anaesthetic injection was graded with help of visual analog scale. In ropivacaine group (n=100), 2 patients had a almost no pain (VAS pain score 0-1) during the administration of the anaesthetic, 91 patients had mild, annoying pain (VAS pain score 2-3) and 7 patients had nagging pain (pain score4-5). No patients had a pain score higher than 5 in this group. In lidocaine-bupivacaine group (n=100), 13 patients had no pain (VAS pain score 0-1) during the administration of the anaesthetic, 74 patients had mild, annoying pain (VAS pain score 2-3), 11 patients had nagging pain(VAS pain score 4-5) and 2 patients had distressing pain (VAS pain score 6-7). In our study, lidocaine-bupivacaine injections were more painful than ropivacaine injections.

No patient in the ropivacaine group and 2 patients in the lidocaine-bupivacaine group had distressing pain. This may be because ropivacaine, an amide local anaesthetic, has high pK_a (≈8.2) and low lipid solubility, so ropivacaine has a property of preferentially blocking nerve fibres which are responsible for pain transmission (Aδ-type and C-type fibres) rather than motor function (Aβ-type fibres). [(66)] Having

said that, the fact that different individuals have different levels of pain tolerance, unfortunately, cannot be quantified.

In the present study, six patients of the lidocaine-bupivacaine group had pain intraoperatively and required the use of topical anaesthetic, whereas irrespective of the evident akinesia in the ropivacaine group, no patient had pain during the surgery. Thus topical anaesthetic was not required in any patient in the ropivacaine group in our study. This can be justified by the fact that ropivacaine has property of preferential sensory blockade than motor blockade. [39,44,66] This is in line with the results of a study done by Luchetti et that compared Ropivacaine 0.75% with a mixture of Bupivacaine 0.5%–Mepivacaine 2% for Peribulbar block which observed more incidence of pain in the bupivacaine-Mepivacaine group. [83]

CONCLUSION

The results of this study support that Ropivacaine was more effective than lidocaine-bupivacaine combination for peribulbar anaesthesia for cataract surgery, as it adequately lowers the IOP and thus prevents the potential side-effects resulting from high post block intraocular pressures seen in the latter group. Ropivacaine also provided better intra-operative analgesia.

On the other hand, lidocaine-bupivacaine group provides adequate akinesia of the globe thus increasing the surgeon's comfort.

Therefore, ropivacaine as a local anaesthetic for peribulbar block for small incision cataract surgery can be a good alternative to the lidocaine-bupivacaine combination. Further studies involving a larger sample size can be done to consider ropivacaine as a superior drug over the lidocaine-bupivacaine combination for peribulbar block in small incision cataract surgery.

SUMMARY

This study was done to assess and compare the effect of ropivacaine and a mixture of lidocaine-bupivacaine on intraocular pressure after peribulbar anaesthesia for cataract surgery at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2021 to December 2021. Two hundred patients undergoing small incision cataract surgery were randomized into two groups of hundred each.

- The mean age of the patient was 60.46years.
- Males and females were equal in number (fifty in each group).
- Volume of anaesthetic injected in both groups was similar, i.e. is 8.65 ± 2.00 mL in group A and 8.50 ± 1.67 mL in Group B.
- Pre block (control) IOP mean in both groups was similar, i.e. group A was 13.86±3.06 mmHg and Group B is 13.13±3.01 mmHg.
- The 1 min post-block IOP mean in both groups is higher than the baseline levels (pre-block), Group A is 14.91±4.14 mmHg and Group B is 15.50 ± 4.26 mmHg, this reflects the raised intra-orbital pressure secondary to peribulbar injection of local anaesthetic.
- However the rise in 1min post block IOP is significantly less in ropivacaine group when compared to the lidocaine-bupivacaine group.
- The 5 mins and 15 mins post block mean IOP values in ropivacaine group are significantly lower than the corresponding values of lidocaine-bupivacaine group and also the baseline (control) ropivacaine values.
- The onset of akinesia was significantly faster in lidocaine-bupivacaine group, 1.37 ± 1.05mins.

- Adequate akinesia (akinesia score < 4) was achieved in lidocaine-bupivacaine group at 4 minutes (mean score 3.97 ± 3.63) and at 6 minutes in ropivacaine group. Beyond 6 mins the akinesia score amongst the two groups was not significant.
- Furthermore, at 10 mins 25 patients of group A(n=100) and 11 patients of group B (n=100) had not achieved adequate akinesia (akinesia score <4).
- Pain did not occur in any case in ropivacaine group during surgery versus six cases of lidocaine-bupivacaine group which was statistically significant ($p<0.05$).

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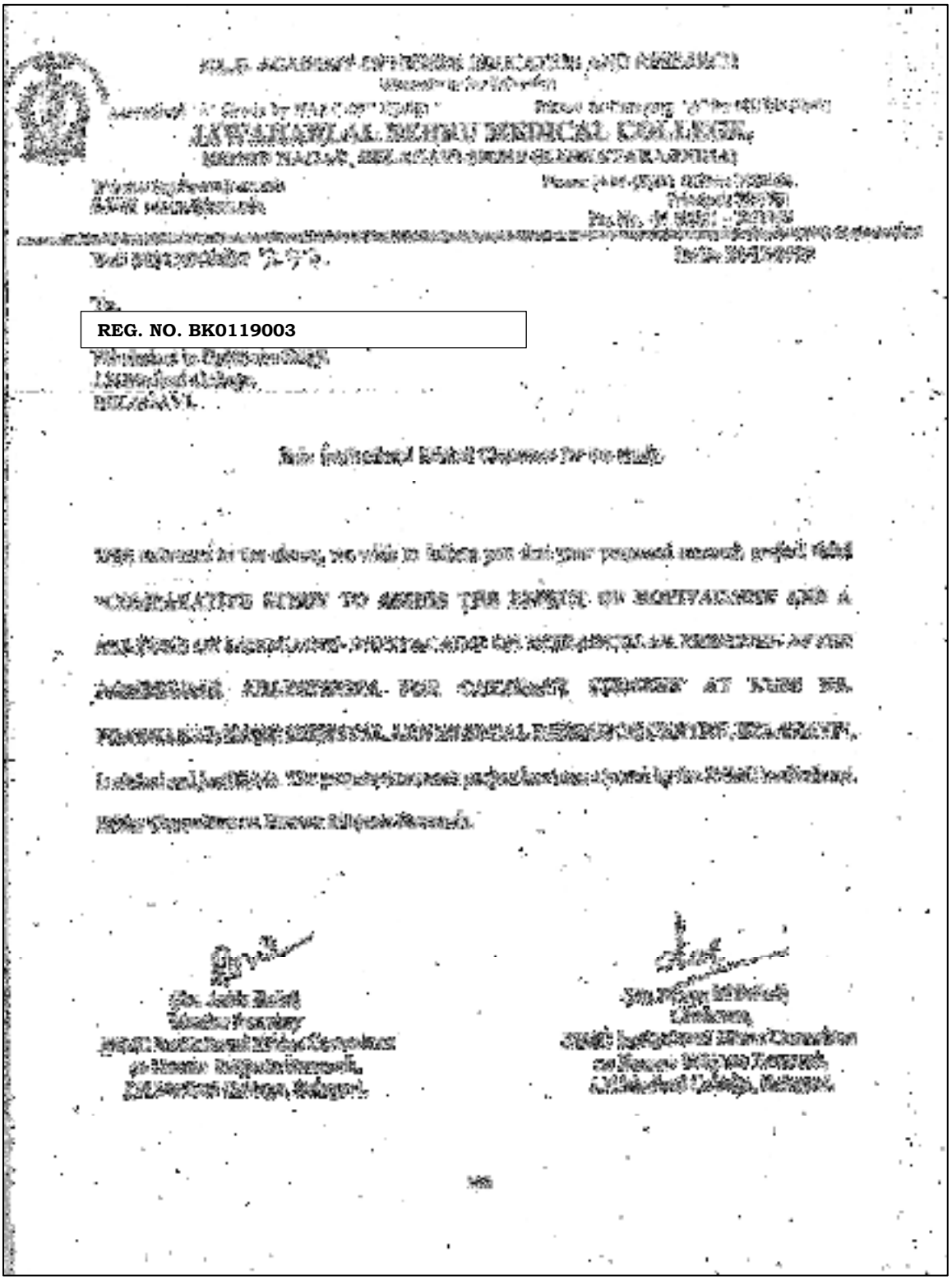
ANNEXURE I
ETHICAL CLEARANCE.



LAYALLAMAL SHAH MEDICAL COLLEGE,

REG. NO. BK0119003

ANNEXURE II

INFORMED CONSENT

S.NO: _____

OP NUMBER _____

IP NUMBER _____

TITLE OF THE STUDY

"COMPARATIVE STUDY TO ASSESS THE EFFECT OF ROPIVACAINE AND A MIXTURE OF LIDOCAINE-BUPIVACAINE ON INTRAOCULAR PRESSURE AFTER PERIBULBAR ANAESTHESIA FOR CATARACT SURGERY AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI."

PRINCIPAL INVESTIGATOR: Dr. EESHITA JAIN

GUIDE: DR. SHIVANAND.C. BUBANALE

INTRODUCTION AND PURPOSE:

Peribulbar anaesthesia has been the anaesthesia of choice for cataract surgery and is routinely performed with a mixture of local anaesthetics, most commonly bupivacaine and lidocaine. Lidocaine provides a rapid onset and bupivacaine a long duration of action. Most ophthalmic surgeries require akinesia of the globe and often, a reduction in intraocular pressure in addition to sensory block. These days increasing attention is being given to patient perceptions of intraocular pain and side effects of anaesthesia. The aminoamide, ropivacaine, a derivative of mepivacaine, was introduced in 1996 as an alternative to bupivacaine. It possesses properties similar to those of bupivacaine. Most studies done till now are extrapolating the conclusions derived from a study with small sample size. This warrants for a study which is comparative, multi-centered and has a larger sample size. Hence this study aims to compare the efficacy

of a mixture of 0.50% bupivacaine- 2% lidocaine mixture and 0.75 % ropivacaine in terms of post block intraocular pressure, globe akinesia and peri-operative analgesia.

PROCEDURE:

Once you have signed the informed consent, the investigator will take necessary personal information and detailed medical history. Uncorrected and best-corrected visual acuity will be recorded, thorough anterior and posterior segment examination done to rule out any ocular comorbidities, lacrimal sac syringing will be done, IOP and other vitals will be recorded. After this based upon randomization you will receive peribulbar injection from any one of the following solution: 7-10 ml of 0.50% bupivacaine- 2% lidocaine with 75 units hyaluronidase or 0.75 % ropivacaine with 75 units hyaluronidase. A 26-gauge 0.5-inch disposable needle is used for peribulbar injection.

SITE OF INJECTION:

The point between medial 2/3rd and lateral 1/3rd of lower orbital margin adjacent to infraorbital notch.

The volume of anaesthetic agent will be noted. IOP (pre-block and post-block), globe akinesia and peri-operative analgesia will be assessed using appropriate scoring systems.

BENEFITS:

Ropivacaine is a newer amide local anaesthetic available in our setup, which is gaining popularity on account of its favourable cardiovascular and neurologic pharmacological profile. Ropivacaine has a short and predictable onset of surgical anaesthesia with better control of post operative pain relief.

RISKS:

Allergic reaction and skin irritation to the drug used in the study are the possible risk factors

ALTERNATIVES:

If patient is not willing to take part in the study, his / her treatment or any other further investigations the patient wants to undergo in the future in KLE, will not be affected by his / her decision.

VOLUNTARY PARTICIPATION/WITHDRAWAL:

Taking part in this study is voluntary. I may choose not to take part in this study, or if I decide to take part I can later change my mind and withdraw from the study. My decision will not change the present or future health care or other services that I receive. The study doctor or the sponsor may stop my participation in this study. I will tell of any important new findings that may change my willingness to continue to take part. If I choose not to take part in the study, I will receive the standard treatment for patients with my condition.

COSTS: NIL

COMPENSATION:

In the event that I become injured as a result of taking part in this study, treatment will be offered to me. No reimbursement, compensation, or free medical care is given.

CONFIDENTIALITY:

All information collected about me during the course of the study will be kept confidential to the extent permitted by the law. The code numbers will identify me in this research record. Information from this study may be published but my identity will be confidential in any publication.

QUESTION:

If any inquiries in the future or in case of research related injury illness, you may contact following person.

1) PRINCIPAL INVESTIGATOR: REG. NO. BK0119003Postgraduate student, Department of Ophthalmology, J N Medical College, Belagavi.

2) GUIDE: _____ Professor, Department of Ophthalmology, Jawaharlal Nehru Medical College,K.L.E. University, Belagavi – 590010.

Even if you have any queries in the future, you may contact following person

3) Dr.ROOPA BELLAD M.D.DCH, Professor of Pediatrics, Chairman of JNMC Institutional Ethics Committee on Human Subjects Research, J N Medical College, Belagavi

CONSENT TO PARTICIPATE IN RESEARCH STUDY

I voluntarily agree to take part in this study by signing on the line below. I may withdraw at any time. I am not giving up any of my legal rights by signing this form. My signature below indicated that I have read this entire consent form or it has been read to me and has been explained to me in my vernacular language and had all my questions answered. I will be given a copy of this consent form.

- I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions.
- I understood that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
- I understood that sponsor of the clinical trial, others working on the sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my

permission to look at my health records both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understood that my identity would not be revealed in any information released to third parties or published.

- I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes.
- I agree to take part in the above study.

Signature /left thumb impression of the participant or legally authorized representative.

Participant's name: ……

Signature/ Left Thumb impression: ……..……

Name of the legally authorized representative: ……

Signature/ Left Thumb impression of the legally authorized representative:……..

Witness's Name: ……

Signature/ Left Thumb impression Witness's Name:……

Investigators name : ……

Investigators Signature : ……

Date and Place: ……

In this research record, the information from this study may be published but my identity will be confidential in any publication.

ANNEXURE III

PROFORMA

DATA COLLECTION INSTRUMENT

Title Of Research Study:

COMPARATIVE STUDY TO ASSESS THE EFFECT OF ROPIVACAINE AND A MIXTURE OF LIDOCAINE-BUPIVACAINE ON INTRAOCULAR PRESSURE AFTER PERIBULBAR ANAESTHESIA FOR CATARACT SURGERY AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI.

S.No. _____

NAME: _____

AGE: Years

SEX: ☐ (1-Male; 2-Female)

DDRESS:

CONTACT NUMBER: -

OP NUMBER:

IP NUMBER:

DATE OF ADMISSION:

DATE OF DISCHARGE:

IS THE PATIENT ELIGIBLE FOR STUDY? (1-YES; 2-NO) ☐

HAS INFORMED CONSENT BEEN GIVEN? (1-YES; 2-NO) ☐

GROUP: ☐ (1-Ropivacaine 0.75 %, 2- Lidocaine 2%+ Bupivacaine 0.50 %)

SURGEON'S NAME:

SURGEON'S SIGNATURE: _____

DATE:

CHIEF COMPLAINTS:

DIMINUTION OF VISION RE ☐

Duration: _____ days/ months/years

LE ☐

Duration: _____ days/ months/years

HISTORY OF PRESENT ILLNESS:

1 .DIMINUTION OF VISION 1- Gradual; 2- Sudden ☐

PAST HISTORY:

TRAUMA TO THE EYE: 1- Present; 2- Absent ☐

OCULAR SURGERY: 1- Present; 2- Absent ☐

Type of surgery: _____

Duration: ☐☐ months/years

DIABETES: 1- Present 2- Absent ☐

Duration: ☐☐ months/years

HYPERTENSION: 1- Present 2- Absent ☐

Duration: ☐☐ months/years

ANY OTHER MEDICAL DISORDERS: _____

SMOKING/TOBACCO ADDICTION: 1-Present 2-Absent ☐

Any known allergies: 1-Yes 2-No ☐

If allergies present, please specify_____

VITALS

PULSE_____beats/min

BLOOD PRESSURE _____ mmHg

RESPIRATORY RATE_____/min

TEMPERATURE_____

OCULAR EXAMINATION

VISUAL ACUITY	RIGHT EYE	LEFT EYE
DISTANT (UNCORRECTED)		
PINHOLE		
NEAR		
BEST CORRECTED (WITH SPECTACLES)		

ANTERIOR SEGMENT	RIGHT EYE	LEFT EYE
EYELID		
CONJUNCTIVA		
CORNEA		
ANTERIOR CHAMBER		
IRIS		
PUPIL		
LENS		

NASOLACRIMAL DUCT PATENCY	
RIGHT	
LEFT	

POSTERIOR SEGMENT	RIGHT EYE	LEFT EYE
GLOW		
MEDIA		
DISC		
C:D		
BLOOD VESSELS		
BACKGROUND		
MACULA		

DIAGNOSIS : _____

_____

INVESTIGATIONS

RANDOM BLOOD SUGAR:_____mg/dL(on day prior to surgery)

INTRAOCULAR PRESSURE:_____mmHg(on day prior to surgery)

FASTING BLOOD SUGAR:_____mg/dL(on day of surgery)

BASELINE ELECTROCARDIOGRAM RHYTHM_____

A-SCAN

	RIGHT EYE	LEFT EYE
K1 (IN DIOPTRE)		
K2 (IN DIOPTRE)		
AXIAL LENGTH (in mm)		
ANTERIOR CHAMBER DEPTH (in mm)		
PCIOL POWER (IN DIOPTRE)		

B-SCAN REQUIRED _____ (1-YES, 2-NO)

B-SCAN FINDINGS (IF B SCAN IS REQUIRED)

_____

_____

_____

_____

PRE OPERATIVE PARAMETERS

VOLUME OF ANAESTHETIC INJECTED INFERIORLY _____mL

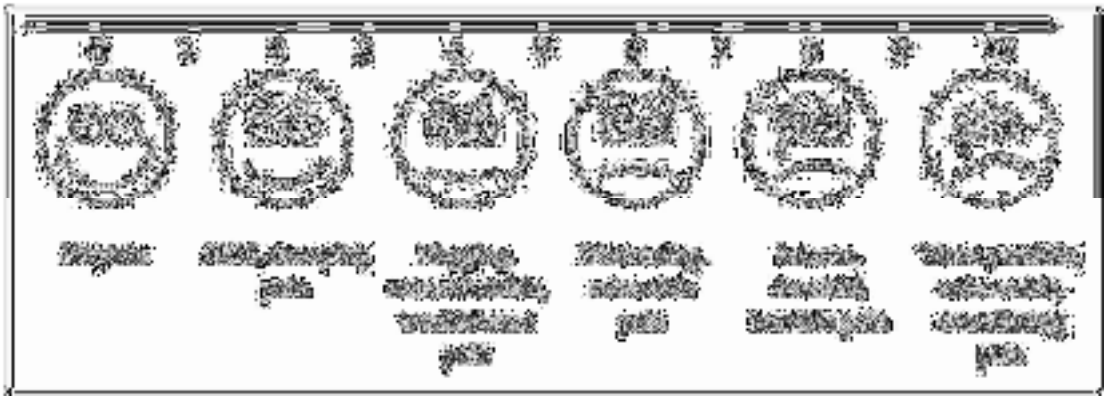
INTRAOCULAR PRESSURE MEASUREMENT BY TONOMETER

TIME	INTRAOCULAR PRESSURE (in mmHg)
BEFORE BLOCK	
AFTER BLOCK	
1 MIN	
5 MINS	
15 MINS	

AKINESIA SCORE

	SUPERIOR	INFERIOR	MEDIAL	LATERAL	TOTAL
1 min					
2 mins					
3 mins					
4 mins					
5 mins					
6 mins					
7 mins					
8 mins					
9 mins					
10 mins					

DEGREE OF PAIN DURING ADMINISTRATION OF ANAESTHESIA_____



INTRAOPERATIVE PARAMETERS

PAIN SCORES AT VARIOUS STEPS

LOCAL ANAESTHETIC USED:	PAIN: 1- YES, 2- NO
A. INCISION AND SCLERAL TUNNEL	
B. CAPSULORHEXIS	
C. HYDRODISSECTION	
D. DELIVERY OF LENS BY PHACOSANDWICH TECHNIQUE	
E. IRRIGATION ASPIRATION	
F. PCIOL IMPLANTATION	
G. STROMAL HYDRATION	

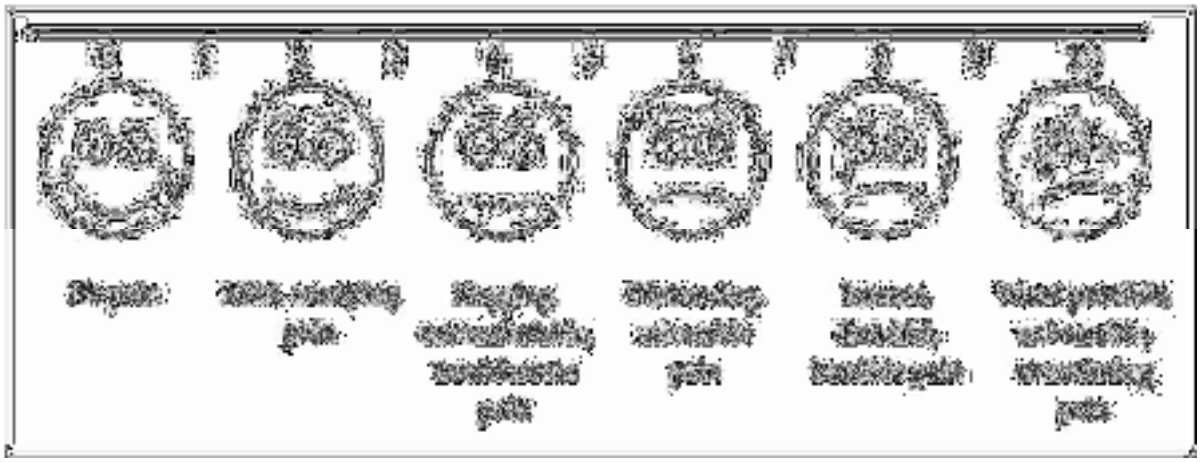
PAIN DURING SURGERY _____ (1-YES, 2-NO)

IF YES THEN, STEP BEING DONE WHEN PATIENT EXPRESSED PAIN____

(A/B/C/D/E/F/G)

REQUIREMENT OF TOPICAL ANAESTHESIA _____(1-YES, 2-NO)

DEGREE OF PAIN DURING SURGERY _____



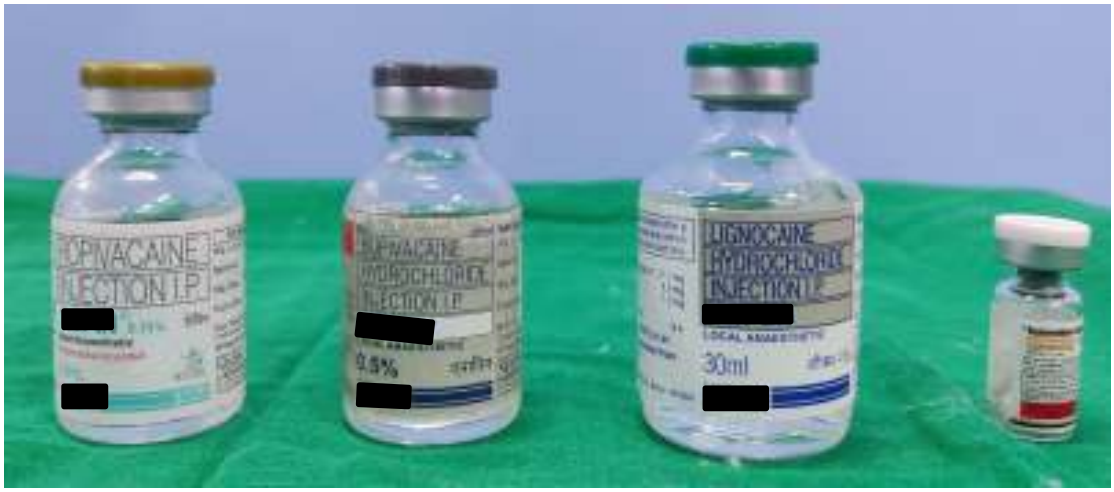
SIGNATURE OF INVESTIGATOR
(DR.EESHITA JAIN)

SIGNATURE OF GUIDE
(DR. S.C BUBANALE)

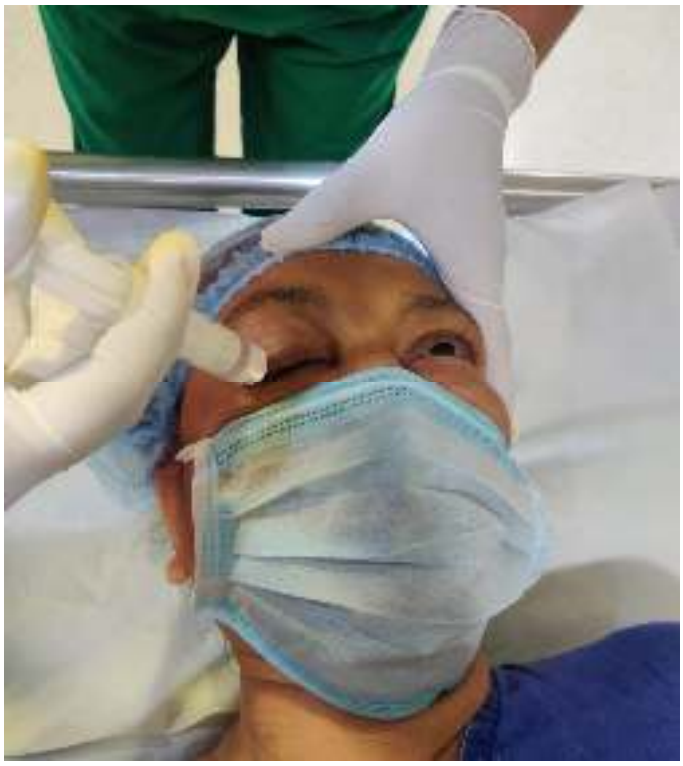
ANNEXURE IV

PHOTOGRAPHS

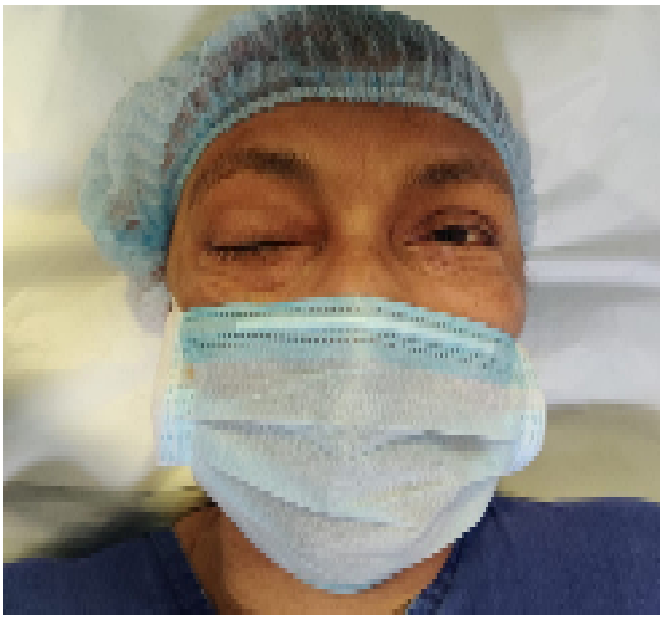
PHOTOGRAPH No. 1: INVESTIGATOR RECORDING THE INTRAOCULAR PRESSURE USING A TONOMETER.



PHOTOGRAPH No. 2: VARIOUS DRUGS USED FOR PERIBULBAR ANAESTHESIA.



PHOTOGRAPH No. 3: ADMINISTRATION OF PERIBULBAR ANAESTHESIA: INFEROTEMPORAL SITE



PHOTOGRAPH No. 4: TOTAL UPPER EYELID DROP SEEN AFTER PERIPULBAR ANAESTHESIA

PHOTOGRAPH No. 5: PATIENT HOLDING INVESTIGATOR'S HAND DURING SURGERY TO INDICATE WHEN THEY EXPERIENCE PAIN

ANNEXURE V - KEY TO MASTERCHART

S.NO – SERIAL NUMBER

DM – DIABETES MELLITUS

HTN – HYPERTENSION

VOL OF DRUG(mL) - VOLUME OF DRUG INJECTED

PAIN SCORE AT VARIOUS STEPS

- 1 – PAIN PRESENT
- 2 – NO PAIN

STEP A – INCISION AND SCLERAL TUNNEL

STEP B – CAPSULORRHEXIS

STEP C – HYDRODISSECTION

STEP D – DELIVERY OF LENS BY PHACOSANDWICH TECHNIQUE

STEP E – IRRIGATION/ASPIRATION

STEP F – PCIOL IMPLANTATION

STEP G – STROMAL HYDRATION

PAIN DURING SURGERY

- 1 – PAIN PRESENT
- 2 – NO PAIN

TOPICAL ANAESTHESIA

- 1 – TOPICAL ANAESTHESIA REQUIRED
- 2 – TOPICAL ANAESTHESIA NOT REQUIRED

GROUP A – ROPIVACAINE 0.75%

S.NO	AGE	SEX	DM	HTN	IOP 1 DAY PRIOR	IOP (mmHg)				VOL OF DRUG (mL)	AKINESIA SCORE AT EVERY MINUTE										ONSET OF AKINESIA (min)	VAS PAIN SCORE DURING ADMIN ISTRATION OF ANAESTHETIC DRUG	PAIN SCORE AT VARIOUS STEPS							PAIN DURING SURGERY	PAINFUL STEPS	TOPICAL ANAESTHESIA	VAS PAIN SCORE DURING SURGERY
					(mm Hg)	PRE-BLOCK	POST-BLOCK				1	2	3	4	5	6	7	8	9	10													
						CONTROL	1 MIN	5 MINS	15 MINS														A	B	C	D	E	F	G				
1	70	2	2	2	13	9	8	8	8	7	4	4	4	4	4	4	2	0	0	0	1	2	2	2	2	2	2	2	2	2	-	-	0
2	70	2	2	2	12	9	9	10	13	10	0	0	0	0	0	0	0	0	0	0	1	4	2	2	2	2	2	2	2	2	-	-	0
3	65	2	2	2	10	9	10	10	10	9	2	2	2	0	0	0	0	0	0	0	1	4	2	2	2	2	2	2	2	2	-	-	0
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94	64	2	2	2	15	15	16	15	15	7	8	4	0	0	0	0	0	0	0	0	1	2	2	2	2	2	2	2	2	2	-	-	0
95	61	1	2	2	17	17	18	18	17	9	8	8	8	4	4	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	-	-	0
96	61	1	2	2	16	16	18	17	16	10	12	12	12	12	12	12	8	8	8	8	7	3	2	2	2	2	2	2	2	2	-	-	0
97	67	1	2	1	14	14	12	12	12	6	12	8	8	4	0	0	0	0	0	0	2	3	2	2	2	2	2	2	2	2	-	-	0
98	53	1	1	2	16	14	14	13	13	10	4	3	3	3	3	1	1	1	1	1	1	3	2	2	2	2	2	2	2	2	-	-	0
99	69	1	2	2	10	8	8	10	11	10	2	2	2	0	0	0	0	0	0	0	0	2	2	2	2	2	2	2	2	2	-	-	0
100	65	2	2	2	10	11	14	12	10	10	12	12	12	12	12	12	12	8	8	4	8	3	2	2	2	2	2	2	2	2	-	-	0

GROUP B – 2% LIDOCAINE + 0.5% BUPIVACAINE

S.NO	AGE	SEX	DM	HTN	IOP 1 DAY PRIOR	IOP (mmHg)				VOL OF DRUG (mL)	AKINESIA SCORE AT EVERY MINUTE										ONSET OF AKINESIA (min)	VAS PAIN SCORE DURING ADMINISTRATION OF ANAESTHETIC DRUG	VAS PAIN SCORE AT VARIOUS STEPS							PAIN DURING SURGERY	PAINFUL STEPS	TOPICAL ANAESTHESIA	VAS PAIN SCORE DURING SURGERY
					(mmHg)	PRE-BLOCK	POST-BLOCK																									
						CONTROL	1 MIN	5 MINS	15 MINS		1	2	3	4	5	6	7	8	9	10			A	B	C	D	E	F	G				
1	68	2	1	1	19	17	22	29	21	7	0	0	0	0	0	0	0	0	0	0	1	2	2	2	2	2	2	2	2	2		2	0
2	62	1	2	2	16	16	19	20	20	7	4	4	4	4	1	1	1	0	0	0	8	1	2	2	2	2	2	2	2	2		2	0
3	62	1	2	1	10	10	7	7	7	10	8	5	4	2	2	2	2	2	2	2	1	2	2	2	2	2	1	1	1	1	E, F, G	1	2
4	56	1	2	1	14	15	14	13	17	10	8	6	6	6	5	5	5	5	4	3	1	2	2	2	2	2	2	2	2	2		2	0
5	56	1	1	2	17	14	11	17	25	10	8	7	7	5	1	1	0	0	0	0	1	2	2	2	2	2	2	2	2	2		2	0
6	60	1	1	1	12	17	21	18	15	7	5	2	2	0	0	0	0	0	0	0	1	2	2	2	2	2	2	2	2	2		2	0
7	40	1	2	2	17	17	26	26	26	10	12	12	12	10	8	8	6	4	3	2	4	2	2	2	2	2	2	2	2	2		2	0
8	45	2	2	1	13	11	19	13	10	9	8	8	6	5	2	0	0	0	0	0	1	2	2	2	2	2	2	2	2	2		2	0
9	55	1	2	2	15	15	16	14	6.5	5	4	4	3	3	0	0	0	0	0	0	1	2	2	2	2	2	2	2	2	2		2	0
10	42	2	2	2	9	10	11	10	10	6.5	3	3	3	2	2	2	1	1	1	0	1	2	2	2	2	2	2	2	2	2		2	0
11	68	1	1	2	9	11	16	15	15	10	10	10	10	10	10	10	10	8	8	8	1	3	2	2	2	2	2	2	2	2		2	0
12	53	1	2	1	16	19	19	22	25	10	9	9	9	5	5	2	2	2	2	2	1	2	2	2	2	2	2	2	2	2		2	0
13	67	1	2	2	8	12	24	19	12	9	5	4	3	3	3	3	3	3	3	3	1	2	2	2	2	2	2	2	2	2		2	0
14	46	1	1	2	14	20	29	21	21	10	12	11	7	7	5	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2		2	0
15	64	2	2	2	17	15	13	15	19	8	8	7	6	5	5	3	3	1	1	1	1	1	2	2	2	2	2	2	2	2		2	0
16	55	2	2	2	13	13	15	15	18	8	10	9	8	8	7	4	4	4	3	3	1	6	1	1	1	1	1	2	2	1	A, B, C,D,E	1	4
17	60	2	1	1	12	15	19	18	16	10	12	9	9	7	6	6	4	4	4	4	2	3	1	1	1	1	1	1	1	1	A, B, C, D, E, F, G	1	4
18	55	2	2	1	15	17	16	17	15	8	5	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		2	0
19	59	2	2	1	11	10	18	19	14	9	8	5	3	3	3	3	3	2	2	2	2	1	2	2	2	2	2	2	2	2		2	0
20	61	2	2	2	17	12	10	14	13	8	12	9	9	7	4	3	3	3	3	2	2	1	2	2	2	2	2	2	2	2		2	0
21	60	1	2	2	19	13	17	17	18	10	12	9	7	5	4	4	4	4	3	3	2	3	2	2	2	2	2	2	2	2		2	0
22	52	1	2	2	12	12	13	15	15	6	4	4	0	0	0	0	0	0	0	0	1	1	2	2	2	2	2	2	2	2		2	0
23	70	1	2	2	14	16	18	20	20	6	9	8	7	6	3	0	0	0	0	0	1	1	2	2	2	2	2	2	2	2		2	0
24	60	2	2	2	11	12	16	19	23	8	6	2	0	0	0	0	0	0	0	0	1	2	2	2	2	2	2	2	2	2		2	0
25	69	2	2	1	12	12	24	19	21	6.5	5	5	3	2	1	0	0	0	0	0	1	5	2	2	2	2	2	2	2	2		2	0
26	42	2	2	2	12	11	12	15	15	8	12	12	10	7	6	4	3	2	2	2	3	3	2	2	2	2	2	2	2	2		2	0
27	42	2	2	2	10	9	10	14	16	9	12	9	8	7	6	5	5	5	4	3	2	6	1	1	2	2	2	2	2	1	A, B	1	5
28	70	1	2	1	17	17	18	19	19	4	8	4	1	1	0	0	0	0	0	0	1	0	2	2	2	2	2	2	2	2		2	0
29	68	2	1	2	13	13	19	19	21	9	11	5	4	4	3	3	2	2	2	2	1	1	2	2	2	2	2	2	2	2		2	0

30	52	1	2	2	14	14	16	18	18	9	12	12	12	9	9	7	7	7	7	7	4	4	2	2	2	2	2	2	2	2	0
31	52	1	2	2	19	19	18	21	21	5	8	4	0	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
32	58	1	1	2	16	16	18	18	23	9	10	9	9	6	6	5	3	3	3	2	1	1	2	2	2	2	2	2	2	2	0
33	61	1	2	1	12	12	15	18	21	10	12	10	10	7	6	4	4	3	3	3	2	2	2	2	2	2	2	2	2	2	0
34	68	1	1	2	15	15	15	17	21	10	9	9	9	9	9	9	9	8	7	4	1	2	2	2	2	2	2	2	2	2	0
35	50	1	2	2	13	14	14	18	18	10	12	12	12	9	9	9	9	9	9	6	4	0	2	2	2	2	2	2	2	2	0
36	55	2	2	1	17	17	15	13	13	7	8	5	2	1	0	0	0	0	0	0	1	1	2	2	2	2	2	2	2	2	0
37	63	1	2	1	18	17	18	19	19	6	9	6	4	0	0	0	0	0	0	0	1	0	2	2	2	2	2	2	2	2	0
38	62	1	2	1	10	10	13	15	15	9	11	9	5	4	1	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
39	62	2	2	1	17	17	19	20	23	9	12	9	9	8	7	6	5	4	4	3	1	4	2	2	2	2	2	2	2	2	0
40	63	1	2	2	14	13	14	16	19	7	5	2	0	0	0	0	0	0	0	0	1	2	2	2	2	2	2	2	2	2	0
41	56	1	2	2	15	15	17	20	22	9	11	9	9	5	1	1	1	0	0	0	1	2	2	2	2	2	2	2	2	2	0
42	61	2	1	2	16	14	15	18	20	10	8	8	4	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
43	68	1	2	2	11	13	15	17	20	9	9	8	4	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
44	69	1	2	2	11	11	13	15	16	8	4	0	0	0	0	0	0	0	0	0	1	2	2	2	2	2	2	2	2	2	0
45	65	1	2	2	13	12	13	16	19	7	8	8	4	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
46	59	1	1	1	11	12	14	15	19	10	9	9	9	9	7	7	4	3	3	3	1	2	2	2	2	2	2	2	2	2	0
47	65	1	2	2	8	9	11	13	17	7	9	8	7	3	0	0	0	0	0	0	1	2	2	2	2	2	2	2	2	2	0
48	60	1	2	2	13	13	15	15	19	10	9	9	9	8	7	6	4	1	1	1	1	2	2	2	2	2	2	2	2	2	0
49	60	1	2	2	7	7	8	11	15	9	9	8	4	0	0	0	0	0	0	0	1	2	2	2	2	2	2	2	2	2	0
50	60	1	2	2	15	15	17	19	20	8	9	8	4	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
51	60	2	2	2	11	13	15	17	21	10	8	3	2	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
52	60	2	2	1	12	14	18	22	27	10	10	10	10	10	10	9	9	6	5	5	1	4	2	2	2	2	2	2	2	2	0
53	70	2	1	2	14	13	18	20	22	10	2	1	1	0	0	0	0	0	0	0	1	2	2	2	2	2	2	2	2	2	0
54	65	2	2	1	11	11	11	12	14	10	2	1	0	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
55	65	1	2	2	17	17	18	20	23	9	9	8	8	4	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
56	62	1	2	2	19	19	17	19	19	7	9	5	0	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
57	65	2	2	2	12	12	13	13	15	9	8	2	0	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
58	65	2	1	2	9	9	13	15	16	10	10	8	4	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
59	60	2	1	2	14	12	14	17	19	10	9	5	0	0	0	0	0	0	0	0	1	5	2	2	2	2	2	2	2	2	0
60	60	2	2	2	15	9	9	10	12	8	8	4	0	0	0	0	0	0	0	0	1	5	2	2	2	2	2	2	2	2	0
61	40	2	2	1	15	14	17	22	23	9	8	4	0	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
62	45	2	2	2	9	9	10	13	15	9	8	4	0	0	0	0	0	0	0	0	1	4	2	1	1	1	1	1	1	1	B, C, D, E, F, G	1	4
63	69	1	2	1	16	18	20	22	22	10	9	9	9	7	7	5	3	3	3	0	1	1	2	2	2	2	2	2	2	2	0
64	64	2	2	2	10	20	21	24	27	9	11	9	9	8	8	7	5	5	4	4	1	3	2	2	2	2	2	2	2	2	0
65	60	2	1	2	13	10	14	15	18	10	8	4	0	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
66	66	1	2	1	10	7	7	7	7	10	10	10	9	9	6	6	5	5	3	3	1	4	2	2	2	2	2	2	2	2	0
67	55	2	2	2	14	12	14	15	18	6	4	4	0	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
68	55	2	1	1	18	18	18	19	19	6	2	0	0	0	0	0	0	0	0	0	1	4	2	2	2	2	2	2	2	2	0
69	50	2	2	2	13	13	14	15	15	10	9	9	5	4	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0
70	65	2	2	1	8	7	10	10	10	10	12	12	12	11	8	8	6	6	6	4	4	3	2	2	2	2	2	2	2	2	0
71	61	2	2	2	16	13	13	12	12	7	0	0	0	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2	0

72	65	1	2	2	8	7	8	8	8	14	12	12	12	12	8	8	8	8	4	4	5	3	2	2	2	2	2	2	2	2		2	0
73	62	1	2	2	13	10	10	9	9	7	8	8	4	2	2	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
74	60	1	2	2	13	13	14	18	20	10	10	10	7	6	6	5	4	4	4	4	1	3	2	2	2	2	2	2	2	2		2	0
75	62	1	2	1	12	13	13	14	14	9	0	0	0	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
76	70	2	2	2	10	10	10	11	11	10	4	0	0	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
77	58	2	2	2	15	13	11	11	10	5	0	0	0	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
78	70	2	2	2	12	13	19	17	16	10	9	9	9	9	8	8	8	4	4	4	1	3	2	2	2	2	2	2	2	2		2	0
79	70	2	2	2	12	13	19	17	16	8	9	9	9	9	8	8	5	1	1	1	1	3	2	2	2	2	2	2	2	2		2	0
80	66	1	2	2	12	12	16	15	15	7	9	8	8	8	8	4	4	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
81	63	2	2	2	12	12	13	12	11	7	8	8	8	8	4	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
82	54	2	2	2	13	13	14	13	13	7	8	8	8	4	4	4	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
83	52	2	2	2	16	16	17	17	16	7	8	8	8	4	4	0	0	0	0	0	1	2	2	2	2	2	2	2	2	2		2	0
84	62	1	2	2	11	11	21	18	17	10	8	8	8	8	8	8	4	4	4	0	1	3	2	2	2	2	2	2	2	2		2	0
85	65	2	2	2	16	16	21	20	18	9	8	8	8	4	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
86	59	2	2	2	12	12	18	16	15	7	8	8	8	4	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
87	60	2	2	2	11	11	14	13	13	10	8	4	1	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
88	57	2	2	2	13	13	17	14	14	9	8	8	4	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
89	50	1	2	2	12	13	13	13	13	7	8	8	8	4	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
90	59	2	2	1	15	15	18	17	17	6	8	8	8	8	4	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
91	48	2	2	2	10	10	19	17	15	9	12	8	8	8	4	4	0	0	0	0	2	4	2	2	2	2	2	2	2	2		2	0
92	70	1	2	1	13	13	14	13	13	9	8	8	8	4	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
93	60	2	1	2	13	10	14	15	18	10	8	4	0	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
94	66	1	2	1	10	7	7	7	7	10	10	10	9	9	6	6	5	5	3	3	1	4	2	2	2	2	2	2	2	2		2	0
95	55	2	2	2	14	12	14	15	18	6	4	4	0	0	0	0	0	0	0	0	1	3	2	2	2	2	2	2	2	2		2	0
96	70	2	2	2	12	13	19	17	16	8	9	9	9	9	8	8	5	1	1	1	1	3	2	2	2	2	2	2	2	2		2	0
97	40	1	2	2	17	17	26	26	26	10	12	12	12	10	8	8	6	4	3	2	4	2	2	2	2	2	2	2	2	2		2	0
98	45	2	2	1	13	11	19	13	10	9	8	8	6	5	2	0	0	0	0	0	1	2	2	2	2	2	2	2	2	2		2	0
99	55	1	2	2	15	15	16	14	6.5	5	4	4	3	3	0	0	0	0	0	0	1	2	2	2	2	2	2	2	2	2		2	0
100	62	1	2	1	10	10	7	7	7	10	8	5	4	2	2	2	2	2	2	2	1	2	2	2	2	2	1	1	1	1	E, F,G	1	2