

**COMPARATIVE EVALUATION OF ROPIVACAINE
AND LIGNOCAINE WITH ROPIVACAINE,
LIGNOCAINE AND CLONIDINE COMBINATION
DURING PERIBULBAR ANAESTHESIA FOR
CATARACT SURGERY**

Dissertation submitted to

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfillment for the award of the degree of

**DOCTOR OF MEDICINE
IN
ANAESTHESIOLOGY
BRANCH X**



**INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE
MADRAS MEDICAL COLLEGE
CHENNAI- 600003**

APRIL 2017

CERTIFICATE OF GUIDE

This is to certify that this dissertation titled “**COMPARATIVE EVALUATION OF ROPIVACAINE AND LIGNOCAINE WITH ROPIVACAINE, LIGNOCAINE AND CLONIDINE COMBINATION DURING PERIBULBAR ANAESTHESIA FOR CATARACT SURGERY**” is a bonafide research work done by DR.K.KALA in partial fulfillment of the requirement for the degree of DOCTOR OF MEDICINE in Anaesthesiology.

Prof.Dr.G.R.RAJASHREE, MD.,
Professor of Anaesthesiology,
Institute of Anaesthesiology and Critical Care,
Rajiv Gandhi Govt.General Hospital,
Madras Medical College, Chennai

Date :
Place : Chennai

CERTIFICATE

This is to certify that this dissertation titled “**COMPARATIVE EVALUATION OF ROPIVACAINE AND LIGNOCAINE WITH ROPIVACAINE, LIGNOCAINE AND CLONIDINE COMBINATION DURING PERIBULBAR ANAESTHESIA FOR CATARACT SURGERY**” Submitted by DR.K.KALA in partial fulfillment for the award of the degree of DOCTOR OF MEDICINE in Anaesthesiology by The Tamilnadu Dr.M.G.R medical university, Chennai is a bonafide record of work done by her in the INSTITUTE OF ANAESTHESIOLOGY& CRITICAL CARE, Madras Medical College,during the academic year 2014 -2017 .

Prof Dr.B.KALA, MD,DA
Director and HOD,
Institute of Anaesthesiology&
Critical care,
Madras Medical College,
Chennai.

Dr.M.K.MURALITHARAN, M.S.,M.ch
The Dean,
Madras Medical College,
Chennai.

DECLARATION

I, Dr. K. KALA, solemnly declare that the dissertation
“**COMPARATIVE EVALUATION OF ROPIVACAINE AND
LIGNOCAINE WITH ROPIVACAINE, LIGNOCAINE AND
CLONIDINE COMBINATION DURING PERIBULBAR
ANAESTHESIA FOR CATARACT SURGERY**” is a bonafide work
done by me in the Institute of Anaesthesiology and Critical Care , Madras
Medical College, Chennai, after getting approval from the Ethical Committee,
under the able guidance of **Prof.Dr.G.R.RAJASHREE, MD.**, Professor,
The Institute of Anaesthesiology and Critical Care ,Madras Medical College,
Chennai in partial fulfillment of the regulations for the award of the
degree of M.D (Anaesthesiology), examination to be held in April 2017.
This study was conducted in Regional Institute of Ophthalmology and
Govt Hospital Chennai.

I have not submitted this dissertation previously to any journal or
any university for the award of any degree or diploma.

DR.K.KALA

Date :
Place : Chennai

ACKNOWLEDGEMENT

I am extremely thankful to **Dr.M.K.MURALITHARAN, M.S, M.ch**, The Dean, Madras medical college, for his kind permission to carry out this study.

I sincerely extend my thanks to **Prof.DR.B.KALA, M.D, D.A**, Director and Head of the Institute of Anaesthesiology and Critical Care ,Madras Medical College, for her concern and support in conducting study.

I am extremely grateful and indebted to my guide **Prof.Dr.G.R.RAJASHREE, MD.**, Professor, Department of Anaesthesiology, Institute of Anaesthesiology and Critical Care ,Madras Medical College for her concern, inspiration, meticulous guidance, expert advice and constant encouragement in doing and preparing this dissertation.

I am extremely thankful to my Assistant Professor **Dr.R.RADHAKRISHNAN M.D, D.A.**, for his constant motivation and valuable suggestions for doing my study.

I am extremely grateful to my Assistant Professors in Regional Institute of Ophthalmology and Govt Hospital, **DR.BRINDA D.A, DR.AZHAGUVEL D.A, DR.CHANDRA D.A** for their guidance and expert advice in carrying out this study.

I am thankful to **Dr.WAHEEDA NAZIR, M.S.,D.O**, Professor and Head of the Regional Institute of Ophthalmology and Govt Hospital for her constant motivation and valuable suggestions.

My sincere thanks to all my Assistant Professors for their help and support throughout the study.

My special thanks to all my colleagues of the Department of Anaesthesiology for their support.

I am grateful to my family and friends for their moral support and encouragement.

Finally, I would like to extend my sincere gratitude to all my patients in whom this study was conducted for their kind cooperation.

INDEX

Sl.NO	CONTENTS	PAGE NO
1	INTRODUCTION	1
2	AIM OF STUDY	3
3	ANATOMY OF ORBIT	4
4	TECHNIQUE OF PERIBULBAR BLOCK	10
5	PHARMACOLOGY OF LOCAL ANAESTHETICS	17
6	PHARMACOLOGY OF LIGNOCAINE	25
7	PHARMACOLOGY OF ROPIVACAINE	29
8	PHARMACOLOGY OF CLONIDINE	33
9	REVIEW OF LITERATURE	39
10	MATERIALS AND METHOD	50
11	OBSERVATION, RESULTS AND ANALYSIS	55
12	DISCUSSION	70
13	SUMMARY	75
14	CONCLUSION	76
15	BIBLIOGRAPHY	
16	ANNEXURE a. Ethical Committee b. Antiplagarism Screen Shot c. Patient Information Form d. Patient Consent Form e. Proforma f. Master Chart	

INTRODUCTION

Regional Anaesthesia is the common technique for most of the surgeries within orbit. In our Institution, cataract surgery is commonly carried out under regional anaesthesia.⁹

Regional anaesthesia for ophthalmic surgery can be administered by anaesthesiologist, provided they receive appropriate training in performing the technique and are fully conversant with the associated risks and complications and can treat them accordingly. Regional anaesthesia is a better alternative, whenever general anesthesia is undesirable or contraindicated.⁹

Today anaesthesia for cataract surgery needs a comfortable environment for both patient and surgeon during surgery and recovery of function quickly without risk. There is only a limited role for General anaesthesia which is indicated especially in cases where topical or local anaesthesia is contraindicated.⁹

The two mostly commonly used ^{9,16,18} regional anaesthesia techniques are retrobulbar block and peribulbar block. They provide adequate anaesthesia for surgery of cornea, anterior chamber, and lens. Retrobulbar block technique involves deposition of drug into the muscle cone, so termed as Intraconal block. Peribular block technique involves deposition of drug outside the muscle cone so termed as Extra conal block.^{38,40}

Peribulbar anaesthesia was first performed by Kelman in 1970, which was unpublished. Then the use of peribulbar block was reported by Davis & Mandel in 1985.^{14,15} It offers a measure of safety as drug is deposited outside the muscle cone but within the orbit. It is very easy to perform and less painful. No need for accessory facial nerve block. Less chance of Retrobulbar haemorrhage, perforation of globe and optic nerve injury.

The complications and need for accessory facial nerve block in case of Retrobulbar block has lead to popularity of peribulbar block in ocular anaesthesia.

In our study, we compare the efficacy of Peribulbar block in Cataract surgeries with combination of 1:1 mixture of 0.75% Ropivacaine with 2% Lignocaine and 1:1 mixture of 0.75% Ropivacaine with 2% Lignocaine with 1µg/Kg of Clonidine regarding the time of onset of sensory blockade, motor blockade, intraoperative hemodynamics, and duration of analgesia.

AIM AND OBJECTIVES OF THE STUDY

AIM

To compare the onset of blockade and duration of analgesia using Ropivacaine and Lignocaine with Ropivacaine and Lignocaine and Clonidine combination for Peribulbar block in Cataract surgery

SECONDARY OUTCOMES

- 1) Intraoperative Haemodynamics
- 2) Intraocular pressure changes
- 3) Incidence of side effects

ANATOMY OF ORBIT

BONY ORBIT

The shape of bony orbits are quadrangular ⁶ similar to a truncated pyramid, whose upper border is bounded by anterior cranial fossa, lower border bounded by maxillary sinuses. It is a shape of a pyramid with orbital opening at the base and optic foramen as its apex. Total volume of the orbit is 30ml of which globe occupies one fifth, which is approximately 7ml. Remaining four fifth volume is occupied by extraocular muscles two oblique and four recti muscles, oculomotor nerve, trochlear nerve, abducent nerve, fascia and fat of orbit.

The anterior portion of orbit is occupied by globe which is closer to roof and lateral wall. This relationship will be useful in choosing the direction of needle during regional anaesthesia. The needle access should be either medially in upper margin of orbit or laterally in lower margin of orbit because the gap between globe and orbit is large in these areas.

EXTRA OCULAR MUSCLES

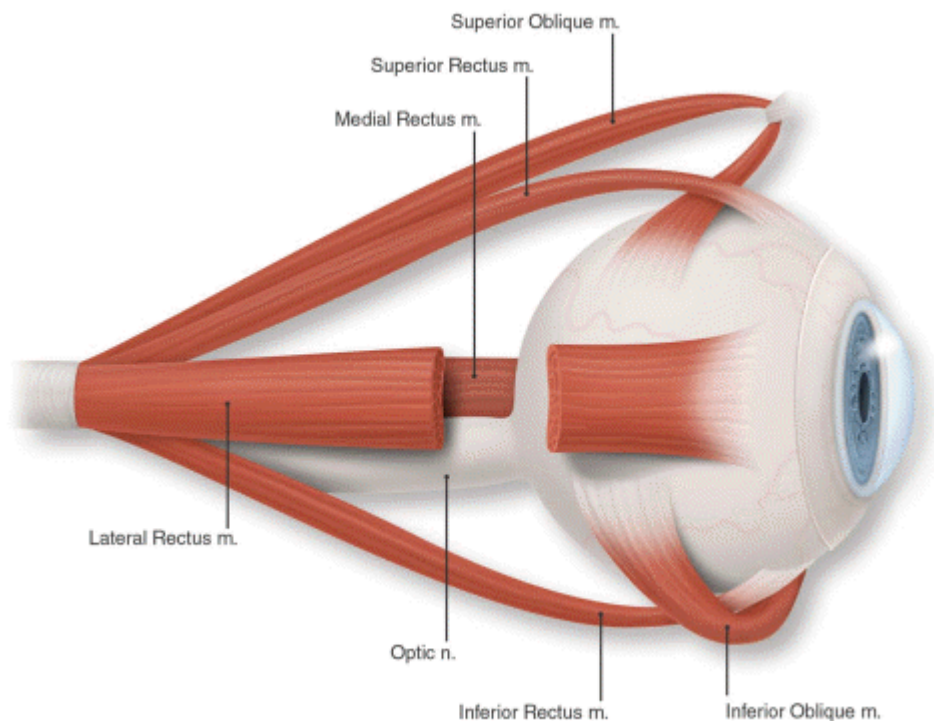
Extraocular muscles are six in number, oblique two in number, recti four in number. From body of sphenoid bone arises the superior oblique muscle which overlaps the origin of levator palpebrae superioris. Inferior oblique muscle arises from orbital plate of maxilla.

Of the two muscles only inferior oblique muscle arises from front of orbit and goes backward.

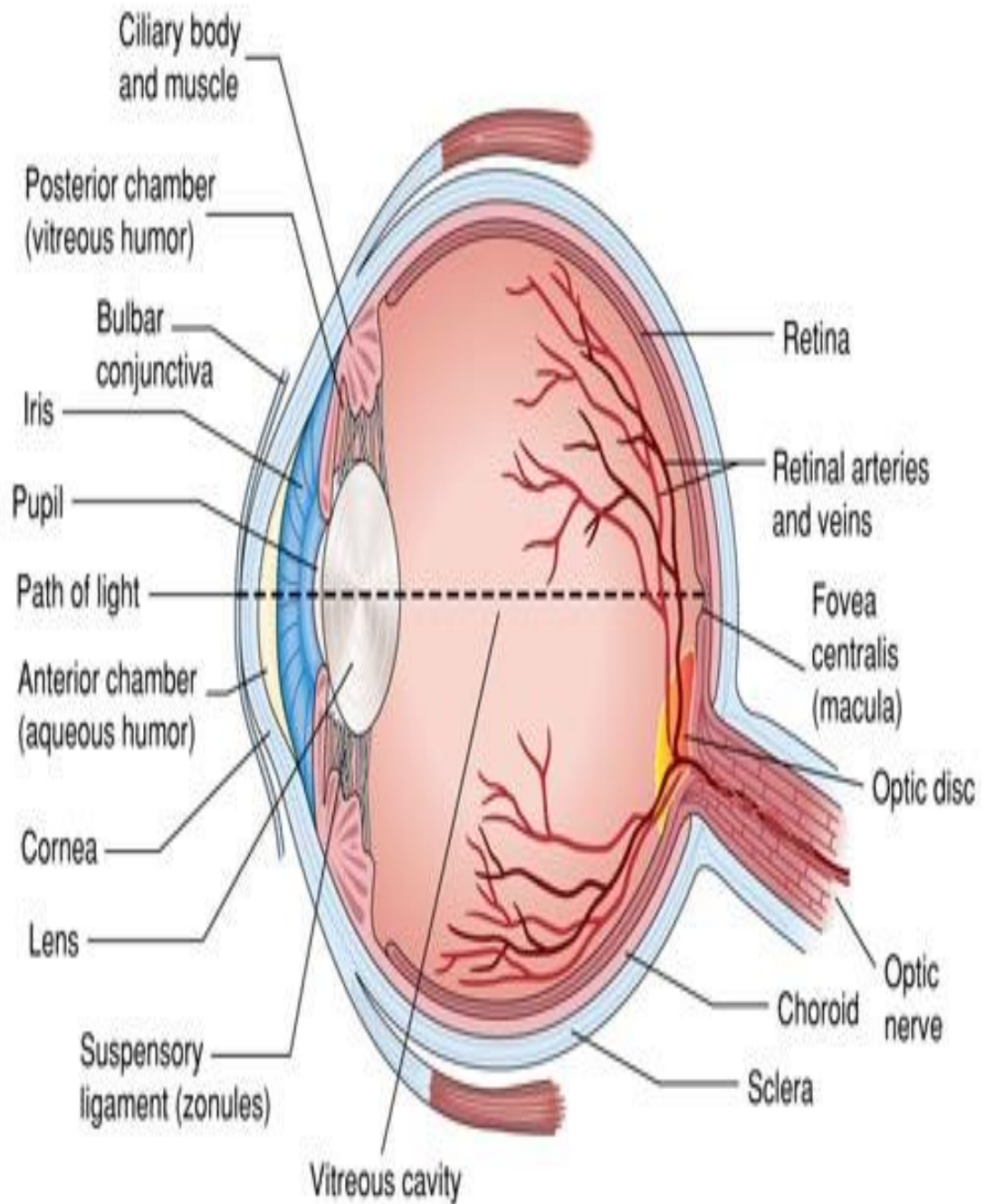
Common tendinous ring (or) Annulus of zinn is the site of origin of all four recti muscles. From the medial part arises medial rectus, from lateral part arises lateral rectus, from the superior part the superior rectus arises and from the inferior part the inferior rectus muscle arises.

All these extraocular muscle co-ordinate the eye movements and has control over the intraocular pressure.

EXTRAOCULAR MUSCLES



VERTICAL SECTION OF EYE



NERVE SUPPLY OF EYE

Nerve Supply	
Motor supply	Sensory Supply
Superior oblique- Trochlear nerve Lateral rectus- Abducent nerve Other muscles- Oculomotor nerve	By Trigeminal nerve - Ophthalmic division supply sclera, cornea intraconally and upper lid extraconally - Maxillary nerve- supply lower lid and inferior conjunctiva extra conally

THE CILIARY GANGLION

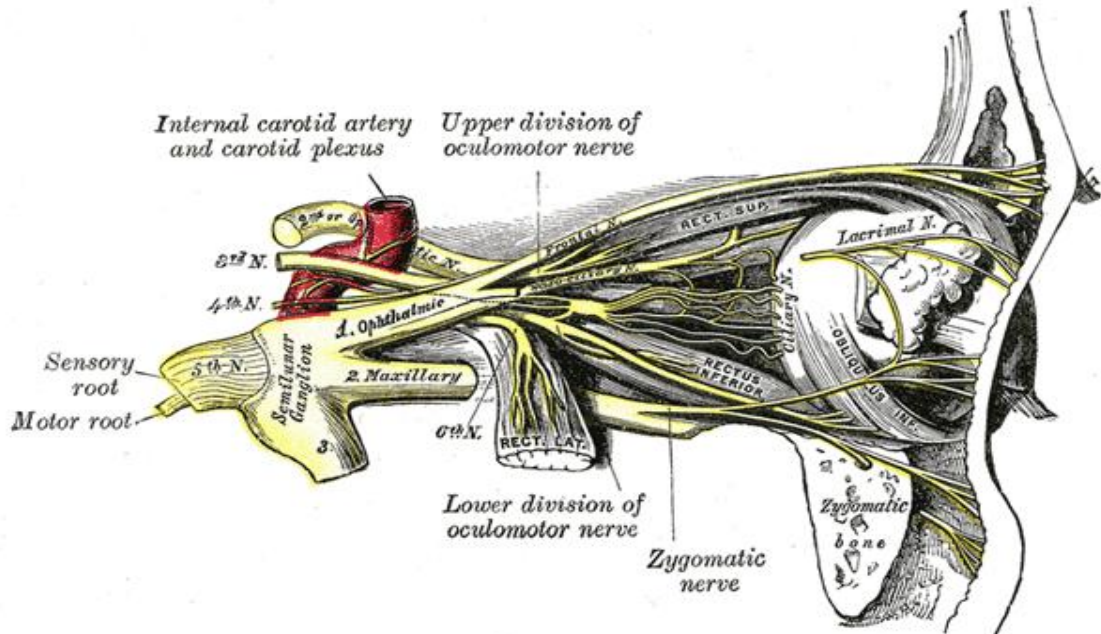
Between the optic nerve and ophthalmic artery, on an average of 1 cm from posterior boundary of orbit is ciliary ganglion which is a parasympathetic ganglion. It has 3 roots

- 1) **Sensory root:** Originates from nasociliary nerves and supply cornea, iris through short ciliary nerves.
- 2) **Sympathetic root:** Originates from internal carotid plexus. They pass along short ciliary nerves to supply blood vessels of globe.
- 3) **Parasympathetic root:** Originates from oculomotor nerve, supply ciliary body and pupillary sphincter muscles.

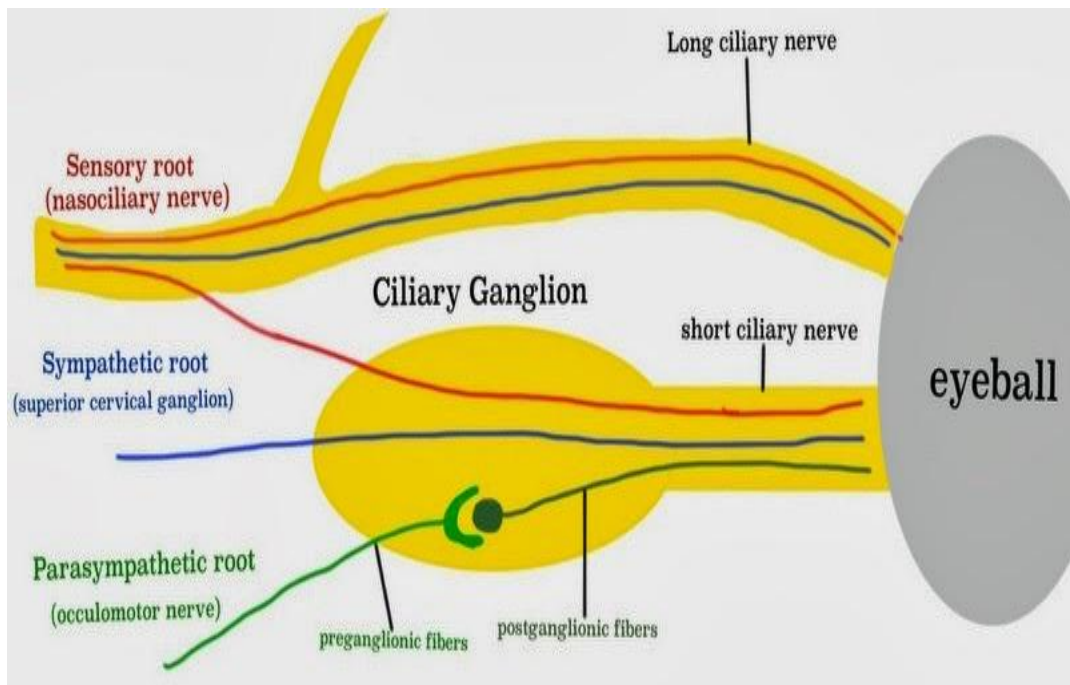
Here the sensory and sympathetic root do not relay in ciliary ganglion, only the parasympathetic root relay in ciliary ganglion.

Short ciliary nerves are approximately ten in number, which are branches of ciliary ganglion. There are two or three Long ciliary nerves which arise from nasociliary nerve. Long ciliary accompanies the short ciliary nerve from ciliary ganglion. They pass between sclera and choroid to reach the ciliary muscle.

NERVE SUPPLY OF EYE



THE CILIARY GANGLION



TECHNIQUE OF PERIBULBAR BLOCK

In peribulbar block, the anaesthetic drug mixture is placed in the orbit outside the muscle area.^{31,36} They spread by diffusion and causes blockade of orbital nerves, even the trochlear nerve. Two commonly used techniques for peribulbar block are single site injection technique and two site injection technique.¹⁰

In single site injection technique¹⁷ needle is passed through lower border of the orbit, at the junction of lateral one third and medial two-third. In this technique, complete akinesia is not achieved but this technique itself is sufficient for ophthalmic surgery. They provide good anaesthesia.

In two site injection technique, one needle is passed through lower border of the orbit, at the junction of lateral one third and medial two-third. Second needle is passed through upper border of orbit, at the junction of lateral two third and medial one third. This technique provides complete relaxation and paralysis of muscles.

PREPARATION

The patient should be explained prior to procedure about the technique of injection in their own language. Proper reassurance should be provided. Informed consent to be obtained in patient's own language.

Good oxygen source, good working Boyle's machine, anaesthetic equipment, all emergency drugs and multipara monitors should be

available. Intravenous line should be secured with 18G venflon. Monitoring of oxygen saturation, pulse rate, blood pressure, ECG is compulsory.

PERIBULBAR BLOCK TECHNIQUE:^{10,17}

- ❖ The operating eye should be wiped with 5% povidone iodine gauze.
- ❖ Ask the patient to look straight in sitting position.
- ❖ A 5ml syringe with 2.5cm 25G needle is used for this technique.

SINGLE SITE INJECTION

Needle is passed through inferior orbital margin, at the junction of lateral one third and medial two-third.³⁵ The needle should be directed along the floor of orbit upto mid orbit, then needle is directed upward and inward to avoid optic nerve injury. 5ml of local anaesthetic drug is given after confirming negative aspiration.

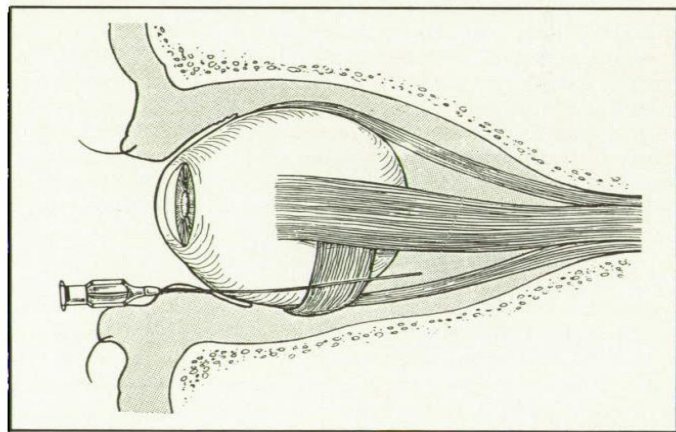
TWO INJECTION TECHNIQUE

Following the single injection in inferior orbital margin, second injection is given by passing the needle through superior orbital rim just above the medial canthus to a depth of 2cm. 3ml of local anaesthetic drug is given after confirming negative aspiration.

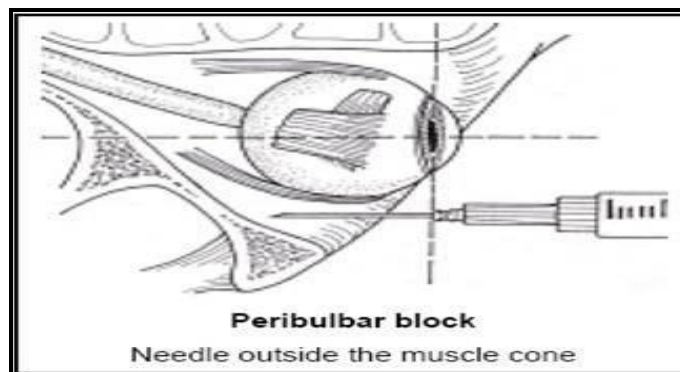
The second injection is deferred²⁴ until the first injection takes its effect approximately in 3.5 minutes. It is done so as to judge the adequacy of blockade.

Correct placement of local anaesthetic drug is confirmed by fullness of upper lid with ptosis. After the injection intermittent orbital compression is given for spread of the drug.

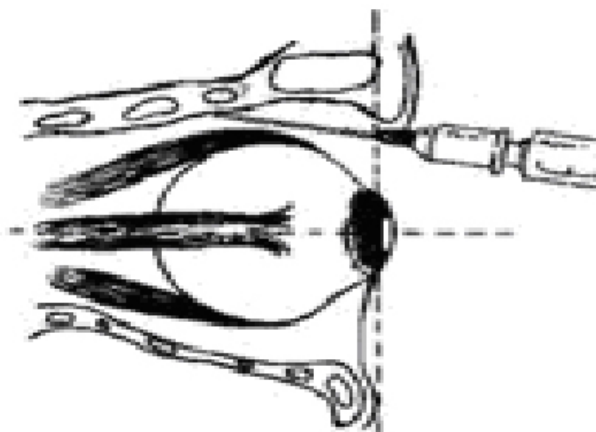
RETROBULBAR BLOCK



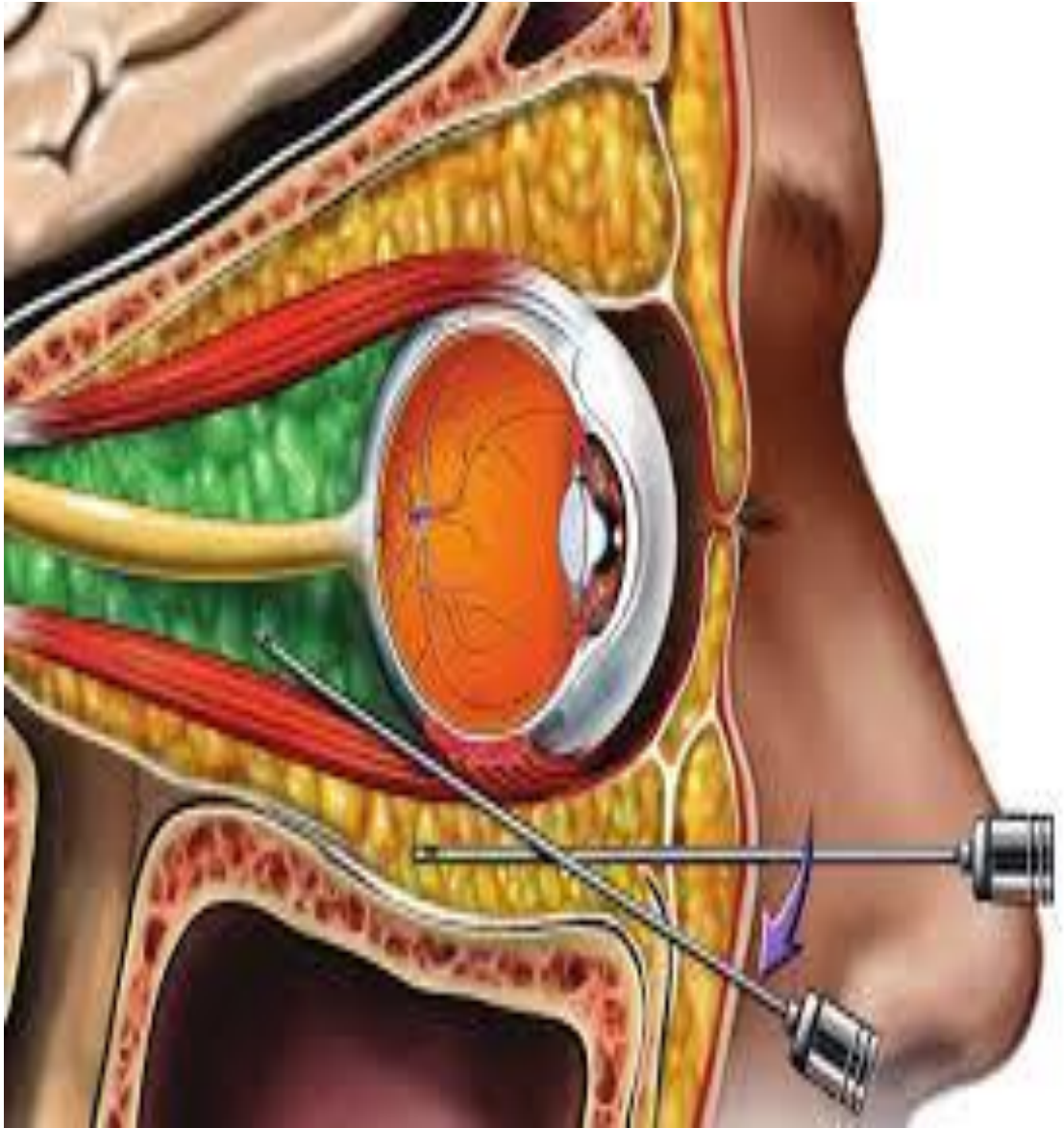
PERIBULBAR BLOCK- INFERIOR INJECTION



PERIBULBAR BLOCK- SUPERIOR INJECTION



COMPARISON OF RETROBULBAR AND PERIBULBAR BLOCK



COMPLICATION OF PERIBULBAR BLOCK

CHEMOSIS

Chemosis is the most common complication, which resolves completely with orbital compression.

GLOBE PUNCTURE²²

If there is a perforation of globe, patient will complain of ocular pain and becomes restless. Perforation of globe occurs more commonly in myopic patients. Perforation of globe leads to retinal detachment and hemorrhage. Treatment includes laser retinopexy or vitrectomy.

CENTRAL RETINAL ARTERY OCCLUSION³³

This complication occurs as a result of retrobulbar hemorrhage and leads to total loss of vision, if not promptly diagnosed. In case of retrobulbar hemorrhage monitoring of central retinal artery pulsation and intraocular pressure is needed.

INADVERTENT BRAIN STEM ANAESTHESIA²¹

As a result of perforation of meningeal sheath around optic nerve during injection leads to placement of anaesthetic solution into cerebrospinal fluid. Symptoms include amaurosis fugax, aphasia, hemiplegia, unconsciousness, convulsions and cardiorespiratory arrest. Treatment includes early recognition and supportive measures like airway control, respiratory support and possible cardiac intervention.

ALLERGIC REACTIONS

Ester type local anaesthetics drugs like cocaine, procaine, tetracaine causes allergic reactions.

ADVANTAGES OF PERIBULBAR BLOCK OVER RETROBULBAR BLOCK

- ❖ Incidence of retrobulbar hemorrhage is less
- ❖ Less incidence of optic nerve injury
- ❖ Less incidence of perforation of globe
- ❖ As local anaesthetic solution is placed extraconally, risk of intradural placement is less.

DISADVANTAGES OF PERIBULBAR BLOCK

- ❖ Akinesia is not adequate
- ❖ Onset is slower
- ❖ More volume of local anaesthetic drug is required
- ❖ More time is required for satisfactory block
- ❖ Increased incidence of chemosis
- ❖ Increased incidence of peribulbar ecchymosis.

CONTRAINDICATIONS FOR PERIBULBAR BLOCK :

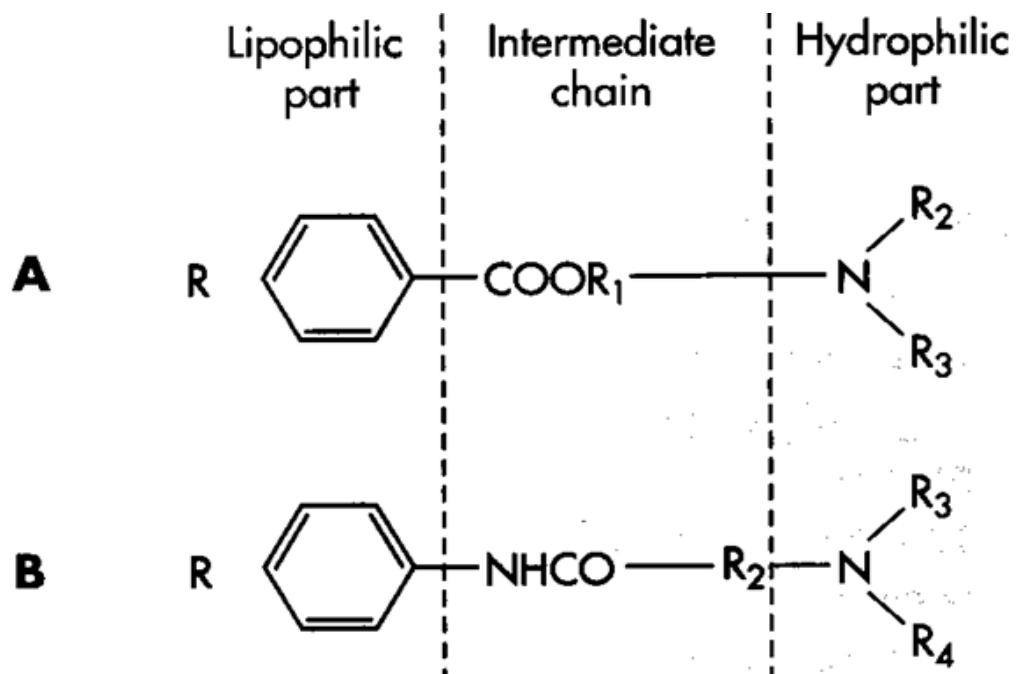
- ❖ Infected eye
- ❖ Any open eye injury
- ❖ Axial length >26mm
- ❖ Patient with cardiovascular instability
- ❖ Patient taking anticoagulant drugs,the dose should be adjusted to reduce INR less than two.

PHARMACOLOGY OF LOCAL ANAESTHETICS

Local anaesthetic drugs causes reversible conduction blockade¹ of impulses along central and peripheral nerve pathway. With increasing drug concentration, the transmission of autonomic, sensory and motor impulses are blocked.

CHEMICAL STRUCTURE

Local anaesthetics has a lipophilic unsaturated aromatic ring and a hydrophilic tertiary amine^{1,3} joined by a connecting hydrocarbon which may be ester (–CO) or an amide (–NHC–) bond. The anaesthetic activity is based on the lipophilic portion.



CLASSIFICATION OF LOCAL ANAESTHETICS ³ :

Esters

- ❖ Cocaine
- ❖ Procaine
- ❖ Chlorprocaine
- ❖ Tetracaine

Amide

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

All drugs are vasodilators except cocaine which is a vasoconstrictor.

MECHANISM OF ACTION

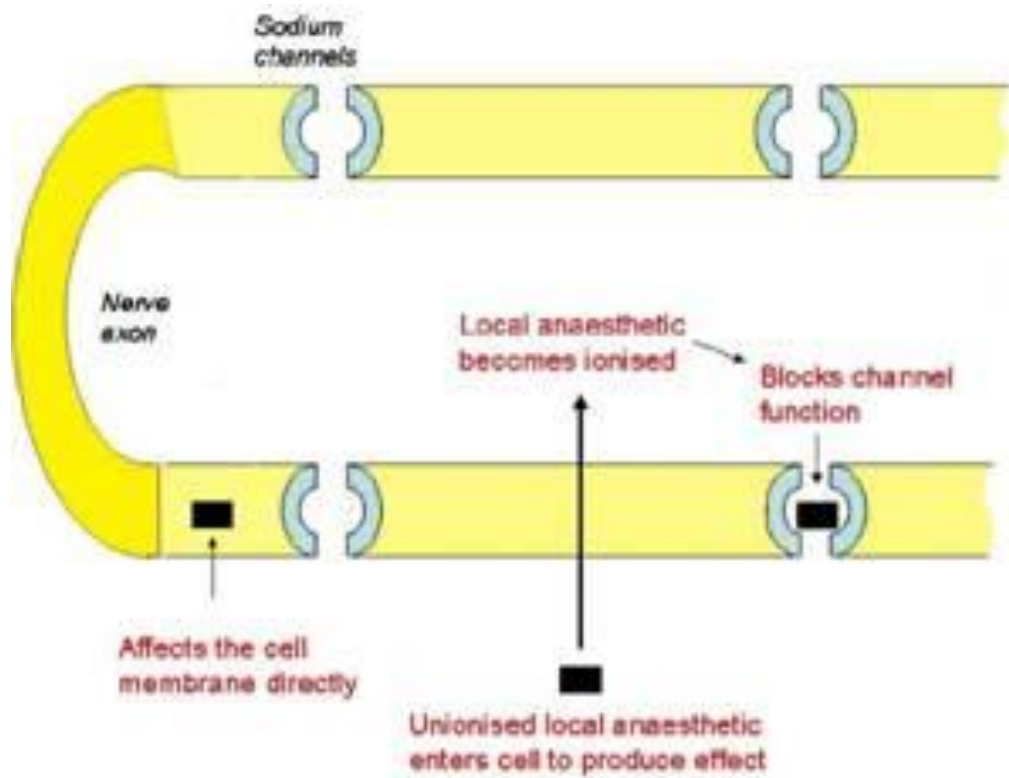
Local anaesthetics are marketed as water soluble hydrochloride salt. At physiological PH, these molecules are partially ionized and

partially unionized. Only the partially unionized molecules can penetrate the nerve fibre.

After penetrating the nerve fibre, local anaesthetics acts by binding to voltage gated sodium channels.²³ As they bind to sodium channels, they decrease the entry of sodium ions into the cell. Thus they block the transmission of nerve impulse and action potential. The resting membrane potential and threshold potential is not altered by local anaesthetic drugs.

Sodium channel is a transmembrane protein which contain large alpha subunit and small beta subunit. Nine different subtypes of sodium channels are identified based on nine genes that forms the alpha subunit. Alpha subunit allows ion conduction and binds to local anaesthetics. Alpha subunit has four subunits (D1-D4). The beta subunits acts by modulating the local anaesthetic binding to alpha subunit. Local anaesthetics bind to inner side of sodium channel called Internal gate or H gate and exhibit its action.

LOCAL ANAESTHETIC DRUGS MECHANISM OF ACTION



FACTORS AFFECTING CLINICAL PHARMACOLOGY OF LOCAL ANAESTHETIC AGENTS

ONSET OF ACTION

PKa is a important factor for determining the onset of action. PKa ideally should have a value close to physiological PH. Drugs with PKa close to physiological PH where non ionized form exist in more number, has faster onset of action.

ANAESTHETIC POTENCY

Potency of Local anaesthetics is determined by their hydrophobic nature. ²¹Hydrophobic drugs are more potent and long acting.

DURATION OF ACTION

Addition of vasoconstrictor drugs like adrenaline to local anaesthetics prolongs the duration of action .This also reduces the systemic toxicity by decreasing their rate of removal.

DIFFERENTIAL BLOCKADE :¹²

When lower concentrations of local anaesthetics are used it selectively causes sensory blockade without motor blockade.The diameter and type of nerve fibre determines the sensitivity.In general smaller and non myelinated fibres are easily blocked.

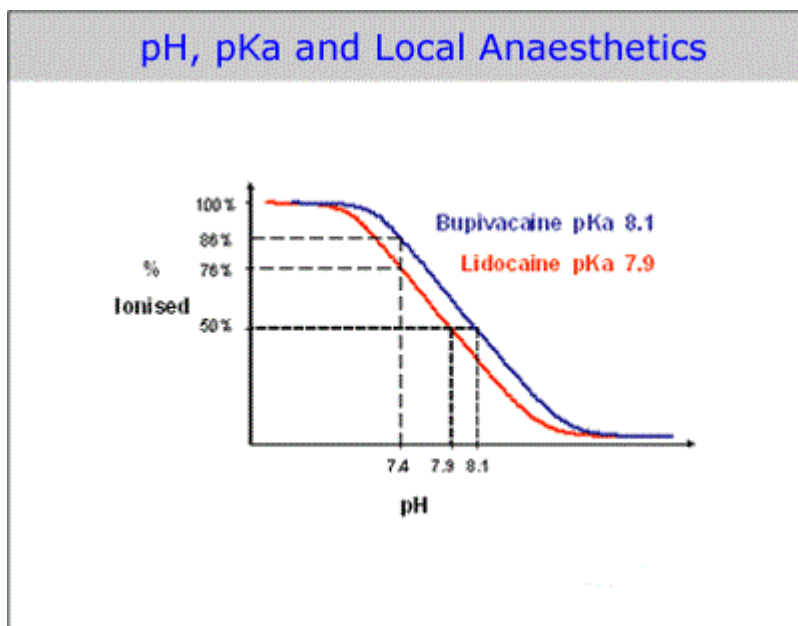
PHARMACOKINETICS³⁹

ABSORPTION

Absorption depends on dosage, injection site, use of adrenaline and pharmacodynamics of local anaesthetics like lipid solubility, protein binding. The absorption and plasma concentration also depends on patient factors like age, cardiovascular status, hepatic blood flow and tissue blood flow.

BIOTRANSFORMATION AND EXCRETION

Pseudocholinesterase enzymes present in plasma hydrolyse the ester local anaesthetics and Liver microsomes degrade the amide local anaesthetics by hydrolysis, dealkylation and excretion via renal system



ADVERSE EFFECT OF LOCAL ANAESTHETICS

CNS TOXICITY : ³

Low concentration – decreased sensation over tongue and circumoral tissues.

High concentration – vertigo, restlessness, tinnitus, skeletal muscle rigidity, slurred speech, fear of impending death.

Very High concentration – seizures, respiratory arrest and death.

CVS TOXICITY

CVS toxicity occurs with very high plasma concentrations of local anaesthetics. They depress the myocardial contractility, automaticity and conduction velocity. This occurs as these drugs block the voltage-gated sodium channels. Large dose or intraarterial injection of local anaesthetic leads to hypotension, bradycardia, cardiac dysrhythmias, AV block, ventricular tachycardia, collapse and cardiac arrest.

ALLERGIC REACTIONS

Allergic reactions are commonly due to addition of preservatives like methylparaben. In addition to this the metabolite of local anaesthetics like paraaminobenzoic acid evoke allergic reactions. The incidence of allergic reactions is 1% only. Symptoms like hypotension, rashes, bronchial asthma can occur.

LOCAL TISSUE TOXICITY :

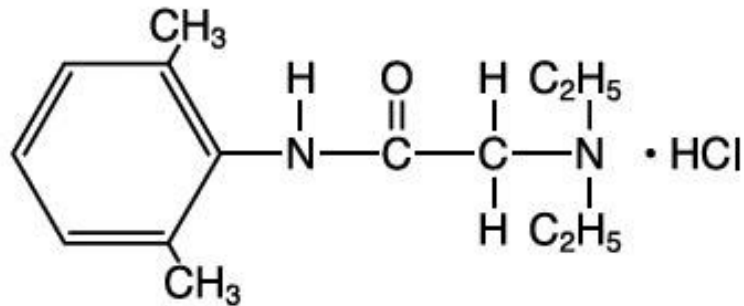
Bupivacaine has highest incidence of local tissue toxicity Use of adrenaline may cause local tissue damage..So adrenaline is not used for blocks with end arteries like penile block ,digital block.

PHARMACOLOGY OF LIGNOCAINE

Lignocaine, the first amide type of local anaesthetic synthesised in 1943 by Swedish chemist Nils Logren. Bengt Lundquist, colleague of Lofgren performed first injection on himself. In 1949, lignocaine was marketed. In addition to local anaesthetic property it also has antiarrhythmic properties.

STRUCTURE ³

2-(Diethylamino)-N-(2,6 dimethylphenyl)-acetone



PROPERTIES

Molecular weight	:	234
Lipid solubility	:	2.9
PKa (25°C)	:	7.9
Protein binding	:	70 %

PHARMACOKINETICS

Metabolism of lignocaine is extensive such that its clearance depends on hepatic blood flow.

LIGNOCAINE

(oxidative dealkylation in liver by CYP3A4)



Monoethylglycinexylidide → has 80% activity of lignocaine



On Hydrolysis



Xylidide → has 20% activity of lignocaine



4, hydroxy 2 , 6 dimethylaniline



Excreted in urine

CLINICAL USES

- 1) Topical anaesthesia
- 2) Infiltration anaesthesia
- 3) Peripheral nerve blocks
- 4) Central neuraxial blockade
- 5) Intravenous regional anesthesia

PREPARATIONS

- ❖ 0.5% Lignocaine for infiltration with adrenaline
- ❖ 4% Lignocaine for topical anaesthesia
- ❖ 1.5-2% Lignocaine for nerve block and extradural block
- ❖ 5% heavy Lignocaine (2ml ampoule) for spinal anaesthesia
- ❖ 1-2% Lignocaine jelly available for skin and mucocutaneous areas
- ❖ 10% Lignocaine spray .

DOSAGE

- ❖ 7 mg / Kg with adrenaline
- ❖ 3 mg / Kg without adrenaline

Maximum single dose for infiltration :

- ❖ 210 mg without adrenaline
- ❖ 490 mg with adrenaline

Duration of action

60- 120 minutes

ADVANTAGES

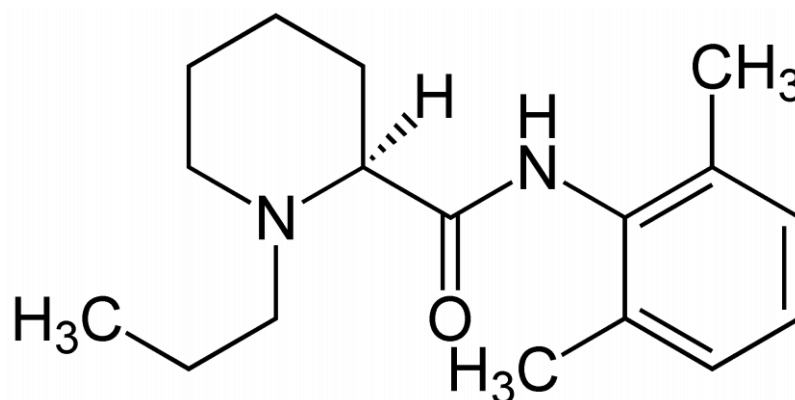
- 1) Rapid onset
- 2) Short duration
- 3) Class Ib Antiarrhythmic drug

PHARMACOLOGY OF ROPIVACAINE

Ropivacaine is a new aminoamide drug which belongs to piperidoloxylidides group of local anaesthetic drugs.²⁹ In the piperidine nitrogen atom of molecule, propyl group is added. Ropivacaine is a single 'S' enantiomer with 99.5% of enantiomer purity. It is prepared by alkylation of S enantiomer of dibenzoyl- L-tartaric acid.

STRUCTURE

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



PROPERTIES

Molecular Weight	:	274
Lipid Solubility	:	6.1
PKa (25 ⁰ C)	:	8.1
Protein Binding	:	94%

PHARMACOKINETICS :²⁷

Undergoes hepatic biotransformation

Ropivacaine



Hepatic Cytochrome P450 enzyme



2, 6 Pipecoloxylidide +

3, hydroxy ropivacaine



Excreted in urine

-Only 1% excreted uncharged in urine.

Elimination half time : 111±62min

Volume of distribution : 59± 7min

Clearance : 0.82± 0.16 L/min

Compared to bupivacaine it has small volume of distribution, greater clearance, less lipid soluble, shorter elimination half life. But both have same protein binding and PKa.

CLINICAL USES²⁸

- 1) Infiltration Anaesthesia
- 2) Peripheral nerve block
- 3) Central neuraxial blocks (Spinal, epidural, caudal)

ADVANTAGES OF ROPIVACAINE OVER BUPIVACAINE :³⁷

Both Bupivacaine and Ropivacaine are chiral drugs as they possess an asymmetric carbon atom. Bupivacaine is a mixture of S and R enantiomers in ratio of 50:50. Ropivacaine is a pure S enantiomer. R enantiomers are responsible for neurotoxicity and cardiotoxicity. R enantiomers bind to sodium channel more firmly and very slowly.

R enantiomers are more arrhythmogenic and slow the ventricular conduction than S enantiomers. Thus as Ropivacaine is a pure S-enantiomer, they have an advantage of less cardiotoxicity compared to Bupivacaine. Ropivacaine also has less CNS effects and if seizures occur it is of shorter duration only.

PREPARATIONS

1%, 0.75%, 0.5% Ropivacaine available.

Dosage: 3.5mg/kg

Toxic plasma concentration >4µg/ml

Maximum single dose for infiltration: 225mg

DURATION OF ACTION

2 to 6 hours.

ADVANTAGES

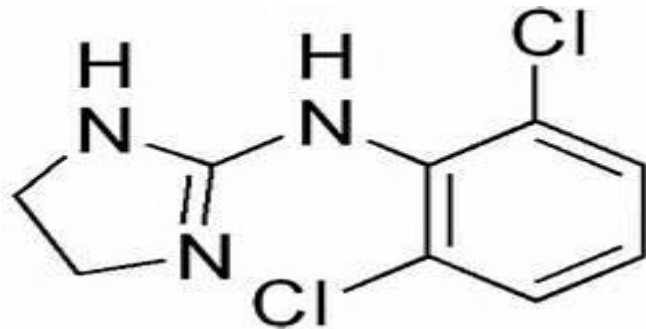
- ❖ Less cardiotoxicity
- ❖ Less Neurotoxicity
- ❖ Greater clearance.

PHARMACOLOGY OF CLONIDINE

Clonidine, an imidazole derivative, is a selective agonist for central α_2 -adrenoceptor² with a ratio of 200:1 (α_2 : α_1). It was initially used as an antihypertensive agent.

STRUCTURE

N-(2, 6 dichlorophenyl)-4,5-dihydro-1H-imidazole-2-amine



-Available as one ml ampoule containing 150 $\mu\text{g/ml}$.

Dosage: 1 $\mu\text{g/kg}$ when used as adjuvant to local anaesthetic agents



PHARMACODYNAMICS

- ❖ Bioavailability is 100% after oral administration, most completely and rapidly absorbed.
- ❖ Elimination half life is 6-24 hours.
- ❖ About 50% drug is metabolised in liver to inactive metabolite and excreted in urine.

MECHANISM OF ACTION

Clonidine binds to α_2 receptors in rostral ventrolateral medulla⁴



Activates inhibitory neurons



Decrease sympathetic activity, Increase parasympathetic activity

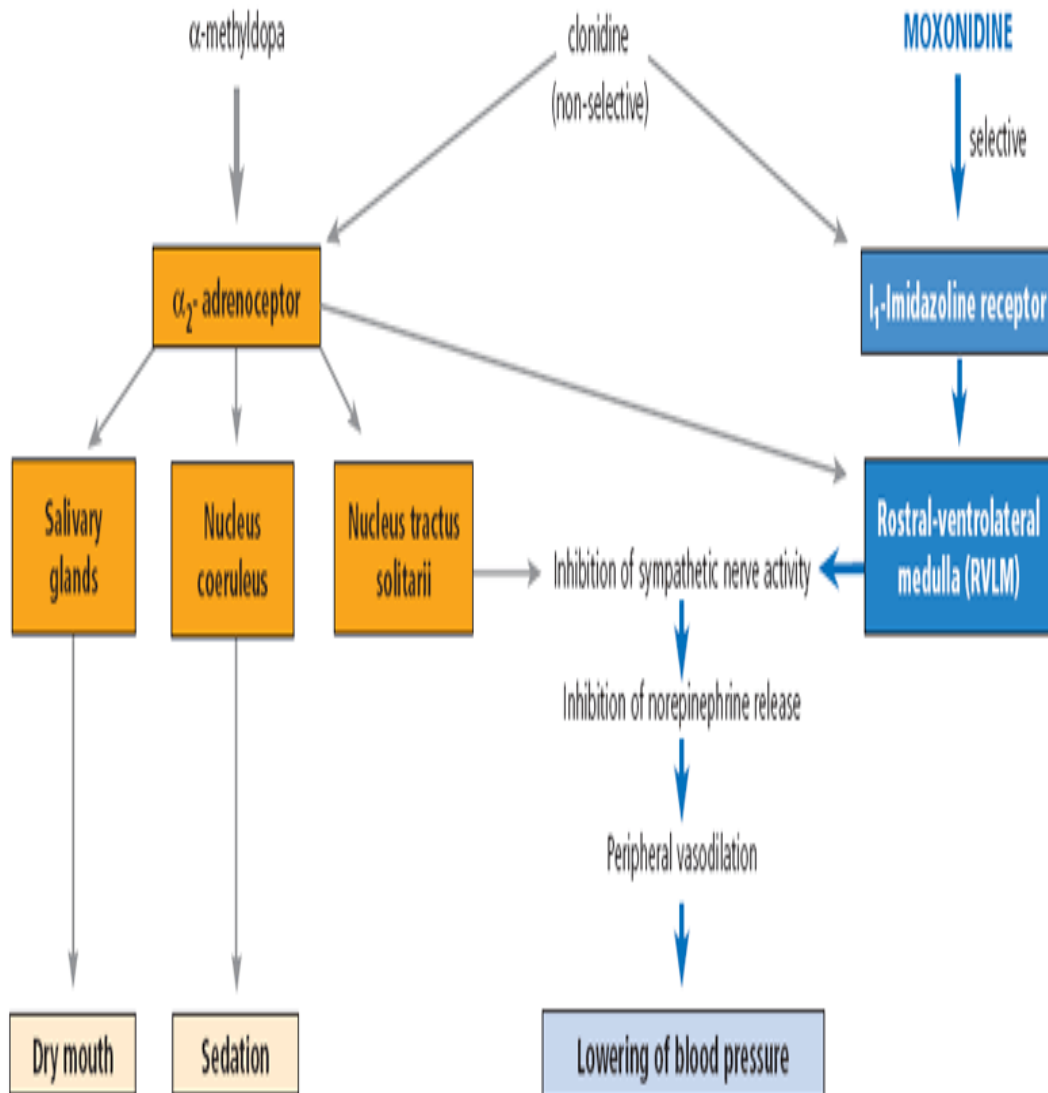


Reduce catecholamines



Decrease BP, Decrease Heart rate

MECHANISM OF ACTION OF CLONIDINE



ANALGESIC EFFECTS

Clonidine binds to pre and post synaptic α_2 -receptor in spinal cord and thus block nociceptive transmission.

ADJUVANTS TO LOCAL ANAESTHESIA :³²

Clonidine interrupts with neural transmission of pain stimuli in A delta and C fibres and augments the blockade of local anaesthesia by increasing the conductance of K⁺ ions in nerve fibres. It also has vasoconstriction effects on smooth muscle and results in decreased absorption of local anaesthesia and prolongs the duration of analgesia.

EFFECTS ON VARIOUS ORGANS

Central nervous system

- ❖ Causes central sedation
- ❖ Anxiolysis
- ❖ Potent analgesic

Cardiovascular system

- ❖ Initial hypertension followed by prolonged hypotension.
- ❖ Bradycardia
- ❖ Anti arrhythmic properties

Respiratory system

Causes much less depression of respiratory system than narcotics. In addition nebulised clonidine decreases bronchoconstriction in asthmatic patients.

Endocrine System

Causes suppression of stress response after surgical stimulation. Increase the secretion of growth hormone and it inhibits steroidogenesis.

Gastrointestinal system

One of the advantage of clonidine is that it decreases salivary flow. So it is used as premedication in anaesthesia.

Renal System

Causes diuresis by

- 1) Inhibition of ADH release
- 2) Increase in GFR
- 3) Release of atrial natriuretic factor

Hematological system

Clonidine causes platelet aggregation.

Uses of Clonidine in Anaesthesia

Clonidine is used

- 1) As a premedication.

- 2) Used as an antihypertensive agent.
- 3) Intrathecal and extradural usage of clonidine as an adjuvant to spinal anaesthesia and post operative analgesia respectively
- 4) As an Adjuvant to local anaesthesia in peripheral nerve block.
- 5) Systemic clonidine for relief of neuropathic pain.

REVIEW OF LITERATURE

1) *Connelly NR et al. (1999)*¹¹ Use of clonidine as a component of the peribulbar block in patients undergoing cataract surgery. This study was a randomized, double-blinded study designed to determine whether administration of clonidine as a component of a peribulbar block enhanced analgesia increased sedation, improved akinesia, or decreased intraocular pressure.

Forty outpatients undergoing cataract surgery under peribulbar blockade were evaluated. Patients received either 100 microg (1 mL) clonidine with the local anesthetic (7 mL 1% preservative-free lidocaine). A Honan adapter was applied for 10 minutes after block placement. The outcome measures included sedation scores, intraocular pressure (IOP) before and after peribulbar block, need for supplemental block, 24-hour analgesic requirement, and patient satisfaction.

There were no differences between groups with respect to pain, sedation, or satisfaction scores. There was no difference with respect to onset of akinesia. This study revealed no significant difference in baseline IOP and postperibulbar IOP.

2) *Mjahed K et al(1999)*³⁰ Lidocaine-clonidine retrobulbar block for cataract surgery in the elderly. This study was designed to investigate the efficacy of lidocaine-clonidine retrobulbar block for

cataract surgery with respect to its effect on IOP, analgesic action, and sedative effects.

Sixty elderly patients (ASA status I and II) were allocated randomly to receive in a prospective double-blind manner retrobulbar block for cataract surgery. Group I (n = 30) received 3-4 mL of 2% lidocaine with 1 mL saline, while group 2 (n = 30), received 3-4 mL of 2% lidocaine with clonidine 2 micrograms/kg.

A large decrease in intraocular pressure and a small but significant reduction of both systolic and diastolic blood pressure were observed 20 minutes after the retrobulbar block in patients receiving clonidine, while no changes occurred in the control group. The median duration of analgesia and akinesia was greater in the lidocaine-clonidine group (241 +/- 88 minutes and 80 +/- 20 minutes, respectively) as compared with the lidocaine group (128 +/- 24 minutes and 70 +/- 20 minutes, respectively) ($P < .01$, $P < .05$).

They concluded that addition of clonidine to lidocaine causes a decrease in intraocular pressure and an increased duration of analgesia and akinesia, with relatively stable hemodynamic parameters.

3) *Gillart T et al.(1999)*²⁰ Lidocaine Plus Ropivacaine Versus Lidocaine Plus Bupivacaine for Peribulbar Anesthesia by Single Medial Injection. This study was designed to compare the effects of ropivacaine

and bupivacaine, each combined with lidocaine, during peribulbar anesthesia by single medial injection for cataract surgery.

. One hundred patients were included and randomly divided into two groups of 50, given a mixture of 50% bupivacaine (0.5%) and 50% lidocaine (2%) or 50% ropivacaine (1%) and 50% lidocaine (2%), and 25 U hyaluronidase per mL with each combination. After the first injection, patients given ropivacaine exhibited significantly better akinesia than those given bupivacaine. Hemodynamic profiles were similar in the two groups, and no major side effects were noted during the observation.

They concluded that one percent ropivacaine may be a more appropriate agent than 0.5% bupivacaine for peribulbar anesthesia by single medial injection. Combined with lidocaine, it provides better akinesia and similar analgesia.

4) G Nicholson et al.(2000)¹⁹ Comparison of 1% ropivacaine with 0.75% bupivacaine and 2% lidocaine for peribulbar anaesthesia .They used the time to adequate block for surgery, and ocular and eyelid movement scores at 8 min after block as clinical end-points.

Ninety patients were allocated randomly to receive 7-10 ml of a mixture of equal parts of 0.75% bupivacaine and 2% lidocaine or an equal volume of 1% ropivacaine alone. Hyaluronidase 15 iu ml⁻¹ was added to both solutions. There were no differences between groups in

clinical end-points. Median time at which the block was adequate to start surgery was 8 min (interquartile range 4-10 min) in each group. Median eyelid movement scores were similar in both groups, but the bupivacaine and lidocaine mixture produced a significantly decreased ocular movement score at 2, 4 and 6 min ($P < 0.05$). There was no difference between groups in the incidence of minor complications. Based on clinical end-points, time to adequate block for surgery and median ocular and eyelid movement scores at 8 min.

They concluded that 1% ropivacaine as the sole agent for peribulbar anaesthesia was comparable with a mixture of 0.75% bupivacaine and 2% lidocaine.

5) Luchetti M et al.(2000)²⁵ A prospective randomized double-blinded controlled study of ropivacaine 0.75% versus bupivacaine 0.5% - mepivacaine 2% for peribulbar anesthesia. This study aims to compare the safety and the efficacy of ropivacaine 0.75% with that of a 1:1 mixture of bupivacaine 0.5% and mepivacaine 2% for peribulbar anesthesia.

Two thousand patients undergoing peribulbar anesthesia for elective cataract phacoemulsification were prospectively studied over a 1-year period and randomly assigned to 1 of 2 groups according to the local anesthetic used. One thousand patients were administered peribulbar anesthesia with 9 mL of ropivacaine 0.75% plus 1 mL of

hyaluronidase (group R), and 1,000 patients received peribulbar anesthesia with 4 mL of bupivacaine 0.5% plus 4 mL of mepivacaine 2% plus 1 mL of hyaluronidase plus 1 mL of sodium bicarbonate (group BM).

Assessment of pain on local anesthetic injection, ocular and eyelid akinesia, need for top-up injections, onset time and duration of anesthesia, intraoperative analgesia, duration of surgery, hemodynamic parameters, and incidence of perioperative complications.. No difference between the groups was found regarding the onset time and the duration of anesthesia. Perioperative analgesia was satisfactory in both groups with no significant difference. An increase in mean arterial blood pressure and heart rate was observed in both groups 1 minute after injection of local anesthetic.

They concluded that Peribulbar anesthesia with ropivacaine provided better ocular akinesia than a bupivacaine-mepivacaine mixture, which reduced the need for top-up injections. Ropivacaine also caused less pain on injection.

6) Perello A et al.(2000)³⁴ A double-blind randomised comparison of ropivacaine 0.5%, bupivacaine 0.375% ± lidocaine 1% and ropivacaine 0.5% ± lidocaine 1% mixtures for cataract surgery. This study evaluated the efficacy and side-effects of plain ropivacaine

compared with ropivacaine ± lidocaine and bupivacaine ± lidocaine mixtures for peribulbar blocks in cataract surgery.

Ninety consecutive patients undergoing cataract surgery under local anaesthesia were allocated, using random number tables, to receive either bupivacaine 0.75% 5 ml with lidocaine 2% 5 ml (bupivacaine/lidocaine group), ropivacaine 1% 5 ml with lidocaine 2% 5 ml (ropivacaine/lidocaine group) or ropivacaine 0.5% 10 ml (ropivacaine group). Hyaluronidase 500 IU was added to all mixtures before injection.

There was evidence that the ropivacaine group had a higher mean akinesia score than the ropivacaine/lidocaine group throughout the assessment period. There was no significant evidence of a difference between the groups in terms of blood pressure, heart rate or oxygenation before or after the blocks.

They concluded that the use of plain 0.5% ropivacaine as a single drug for peribulbar blockade in cataract surgery

7) *D. K. Woodward et al. (2000)*¹³ Peribulbar anaesthesia with 1% ropivacaine and hyaluronidase 300 IU ml⁻¹: comparison with 0.5% bupivacaine/2% lidocaine and hyaluronidase 50 IU ml⁻¹ investigated the onset and quality of ocular akinesia.

80 patients randomized to receive 1% ropivacaine plus hyaluronidase 300 IU ml⁻¹ (group 1), or bupivacaine 0.5%/Lidocaine 2% plus 50 IU ml⁻¹ hyaluronidase (group 2). Ocular akinesia was scored from 0 (no movement) to 8 (full movement) every 2 min for 20 min. The groups showed no difference in the rate of onset or degree of akinesia achieved (analysis of variance with repeated measures; $P=0.34$). Sixty per cent of patients in group 1 and 55% in group 2 achieved akinesia scores of ≤ 4 by 6 min (χ^2 test; $P=0.5$).

They concluded that both peribulbar solutions produce equivalent onset and quality of ocular akinesia.

8) *Luigi Gioia et al.(2003)*²⁶ A Prospective, Randomized, Double-Blinded Comparison of Ropivacaine 0.5%, 0.75%, and 1% Ropivacaine for Peribulbar Block. To evaluate the efficacy of three different concentrations of ropivacaine (0.5%, 0.75%, and 1%) together with a single concentration of hyaluronidase administered for peribulbar block.

68 ASA physical status I, II, and III patients undergoing elective cataract surgery. Patients were randomly allocated to receive peribulbar block with 6.5 mL of either 0.5% (Group Ropi-5) or 0.75% (Group Ropi-7.5) or 1% ropivacaine (Group Ropi-10) In all patients, 0.5 mL of hyaluronidase was added to the local anesthetic solution.

A larger proportion of patients in Groups Ropi-7.5 (82%) and Ropi-10 (83%) showed complete motor block 15 minutes after injection compared with Group Ropi-5 (55%;p). Seven hours after surgery, a smaller proportion of Group Ropi-10 patients (64%) showed complete recovery of sensory function as compared with both Group Ropi-5 (94%) and Group Ropi-7.5

They concluded that ropivacaine is a good option for Peribulbar block. This study demonstrated that use of 0.75% or 1% concentrations are preferred in that they provide quick sensory and motor blockade .

9) Bajwa SJ et al.(2003)⁷ Comparison of epidural ropivacaine and ropivacaine clonidine combination for elective cesarean sections. The aim is to determine the qualitative and quantitative aspects of epidural block of ropivacaine 0.75% versus ropivacaine 0.75% with clonidine for elective cesarean section

A randomized double-blind study was conducted among 51 healthy parturients, scheduled for elective cesarean section. Epidural block was administered with 20 ml of ropivacaine 0.75% (group R) and ropivacaine 0.75% clonidine 75 µg (group RC) and anesthetic level was achieved minimum until T6–T7 dermatome. Onset time of analgesia, sensory and motor block levels, maternal heart rate and blood pressure, neonatal Apgar scores, postoperative analgesic dose and adverse events were recorded.

Groups were comparable with regard to demographic data, neonatal Apgar scores and incidences of side effects except for the higher incidence of dry mouth in patients of RC group. Onset of analgesia was much shorter in RC group along with prolonged duration of analgesia. The incidence of bradycardia and hypotension was more in RC group as compared to R group which was statistically significant. The dose requirement for postoperative pain relief was significantly lesser in RC group.

They concluded that the addition of 75 µg clonidine to epidural ropivacaine results in longer, complete and effective analgesia with similar block properties and helped to reduce the effective dose of ropivacaine when compared with plain ropivacaine for cesarean delivery.

10) Balbir Khan et al.(2102)⁸ Comparative evaluation of ropivacaine and lignocaine with ropivacaine, lignocaine and clonidine combination during peribulbar anaesthesia for double blind, prospective study was carried out to compare the anaesthetic effects of ropivacaine with the combination of ropivacaine and clonidine in administration of peribulbar block

200 patients, aged 50–80years both male and female of ASA PS I II , scheduled for cataract surgery under monitored anaesthesia care,

were included in this for the study. Patients were allocated into two groups

of 100 each; Ropivacaine group (R) and Ropivacaine clonidine group (RC). R group was given 10mL of LA solution having 5mL of 2% lignocaine, 5mL of 0.75% ropivacaine and 100 units of hyaluronidase and RC group was given 8mL of a same mixture with the addition of clonidine 1µg/kg and saline to a total volume of 10mL.

Heart rate (HR), pulse oximetry (SpO₂), mean arterial pressure (MAP), respiratory rate (RR), intraocular pressure (IOP), quality of peribulbar block and eye muscle movement scores were observed and recorded throughout the study period at regular intervals. At the end of the research project, the data was compiled systematically and was subjected to statistical analysis using the ANOVA test with post hoc significance for continuous variables and Chi-square test for qualitative data

Demographic characteristics, SpO₂ and RR were comparable in both the groups. Mean HR and MAP were also comparable after a significant variation in the first 2–3min (P<0.05). Onset and establishment of sensory and motor blocks were significantly earlier in the RC group (P<0.05). IOP decreased significantly during the first 6–7min in the RC group after the administration of the peribulbar block. Duration of analgesia was prolonged in the RC group (6.5±2.1h) as

compared with the R group (4.2 ± 1.8 h). The side-effect profile revealed a higher incidence of nausea, vomiting, headache and dizziness in GroupR, while a considerably higher incidence of dry mouth was observed in GroupRC.

They concluded that addition of clonidine to ropivacaine not only decreases the total volume of LA to be used but also augments early onset and prolonged offset of sensory analgesia as well as provides smooth operating conditions with a good sedation level as well by providing a wider safety margin of LA.

MATERIALS AND METHODS

Eighty patients of ASA grade I and II patients of both sexes aged 40-80 years undergoing cataract surgery are included in this clinical trial. Written informed consent is obtained from all patients.

DESIGN OF THE STUDY

This study is a prospective, randomized double blind study conducted in Regional Institute of Ophthalmology, Egmore, after getting approval from the ethical committee. 80 patients were allocated into two groups- R Group ,RC Group on the basis of simple randomization.

R Group – consists of 40 Patients, who were given peribulbar block with Lignocaine and Ropivacaine.

RC Group - consists of 40 patients, who were given peribulbar block with Lignocaine, Ropivacaine and Clonidine.

Patients in both the groups were of comparable demographic status.

INCLUSION CRITERIA

- ❖ Adults 40-80 years
- ❖ Both Sex
- ❖ ASA PS I, II
- ❖ Side of eye R/L

- ❖ Duration of surgery 20-50 minutes
- ❖ Weight 40-80 Kg

EXCLUSION CRITERIA

- ❖ Patient with active ocular infection
- ❖ Patient on any antiglaucoma medications
- ❖ Patient with single eye
- ❖ Patient allergic to amide type local anaesthetics
- ❖ Patient with cardiac disease
- ❖ ASA PS, III, IV
- ❖ Patient refusal.

STUDY GROUPS

R Group: Receive peribulbar block with 2.5ml of Lignocaine (2%)+ 2.5ml of Ropivacaine (0.75%) +50 Units of Hyaluronidase.

RC Group: Receive peribulbar block with 2ml Lignocaine (2%)+ 2ml of Ropivacaine (0.75%) + 50 Units of hyaluronidase +1µg/kg of Clonidine.

All patients are examined thoroughly in preoperative room. Base line parameter like heart Rate, blood pressure, ECG and baseline

investigations like hemoglobin, blood sugar, urea, creatinine, should be checked.

Informed consent was obtained and procedure was explained to patient in his/her own language. An initial preoperative counselling and reassurance was done.

In operation room, Boyle's machine, oxygen source, oxygen cylinder, appropriate airway equipment and emergency drugs were made ready.

Patient was shifted to operating room. The monitors were connected. Intravenous access was secured. Baseline heart rate, noninvasive blood pressure, ECG, oxygen saturation noted and intraocular pressure was also recorded using Eye care machine.

Peribulbar block was performed as described by Davis and Mandel technique which was modified by Bloomberg.

TECHNIQUE OF PERIBULBAR BLOCK :

Patient was asked to maintain the eye in primary gaze directly ahead. Eye was painted with povidine iodine. A 22G 2.5cm needle was inserted in inferotemporal region through the skin at the junction of lateral 1/3rd and medial 2/3rd of lower orbital margin once the needle was under the globe, it was directed along the orbital floor up to the depth of midorbit in the lateral extra conal space and not in upward and

inward direction to avoid injury to optic nerve. After careful negative aspiration, 3ml of local anaesthetic drug was given.

The second injection was given in supranasal area by inserting the same needle through upper eyelid vertically above the medial canthus to a depth of 2cm. 2ml of local anaesthetic was given. Manual compression and massage of eyeball was done to spread the local anaesthetic solution.

Patient was assessed for sensory block at 2,3,4,5,6,7 minutes, motor block at 4,5,6,7,8,9,10 minutes, intraocular pressure at 1st minute. The heart rate, systolic blood pressure, diastolic pressure was monitored at 1,5,10,15,20,30,40 minutes.

SENSORY BLOCK

Sensory block was tested by loss of sensation of cornea with a wisp of cotton. This assessment was done at 2,3,4,5,6,7 minutes after injection. Onset of sensory block was taken from the time from injection to loss of sensation of cornea.

MOTOR BLOCK :

Ocular globe mobility was tested in four quadrants using 3 point scoring system.

Score-0 Akinesia (ocular movement <1mm)

Score-1 Reduced movement (Ocular movement >1mm but <4mm)

Score-3 Normal movement (ocular movement >4mm)

This scoring system gives a maximal aggregated score of 8 for the four muscles. A score <2, reduced movement in all direction, was taken to indicate successful block. Once successful block had been achieved, no further assessment were made.

QUALITY OF SURGICAL ANAESTHESIA

Surgical anaesthesia was graded as follows

- ❖ Excellent: No pain at any time during surgery
- ❖ Good: Minimal pain or discomfort
- ❖ Poor: Failed block

Intraoperatively oxygen 4 litres/ minute was given through nasal cannula to all patients under sterile drapes.

ASSESSMENT OF PAIN

Patient was shifted to postoperative ward after completion of surgery. Duration of pain relief was assessed in these patients. Pain assessment was done using VAS score. VAS score >3 indicates pain.

Duration of effective analgesia was defined as time interval between peribulbar block and the time to reach VAS score >3.

Resolution of motor blockade could not be assessed, as these patients eye were bandaged and covered after operation.

OBSERVATION, RESULTS AND ANALYSIS

The data collected were subjected to statistical analysis .The patient group were comparable in distribution of age and sex. These characteristics were analysed using Student's t test and Pearson's chi square (X²) test.

Table 1: Demographic profile of the patients who underwent cataract surgery

Demographics	Group R	Group RC
Age in yrs (mean±SD)	57.65± 8.8	57.48± 8.9
Gender (%)		
Male	14(35)	18(45)
Female	22(65)	22(55)

The mean age of the participants in the R group was 57.65 years and RC group was 57.48 years . 35 % were males and 65% were females in the R group. 45% were males & 55% were females in the RC group

Table 2: Comparison of peribulbar block characteristics using independent sample 't'test

Block characteristics	Mean difference	S.E Difference	95% C.I		p value
			Lower bound	Upper bound	
Onset of sensory anesthesia (min)	2	0.138	1.73	2.27	<0.01*
Onset of motor blockade (min)	2.68	0.222	2.23	3.12	<0.01*
Duration of analgesia (hrs)	-2.68	0.165	3.01	-2.35	<0.01*

Table 3: Comparison of peribulbar block characteristics in both groups

Block characteristics (mean±SD)	Group R	Group RC
Onset of sensory blockade (min)	4.93± 0.656	2.93 ±0.572
Onset of motor blockade (min)	8.23 ±0.974	5.55 ± 1.01
Duration of analgesia (hrs)	3.48 ±0.72	6.16 ± 0.75

Figure 1

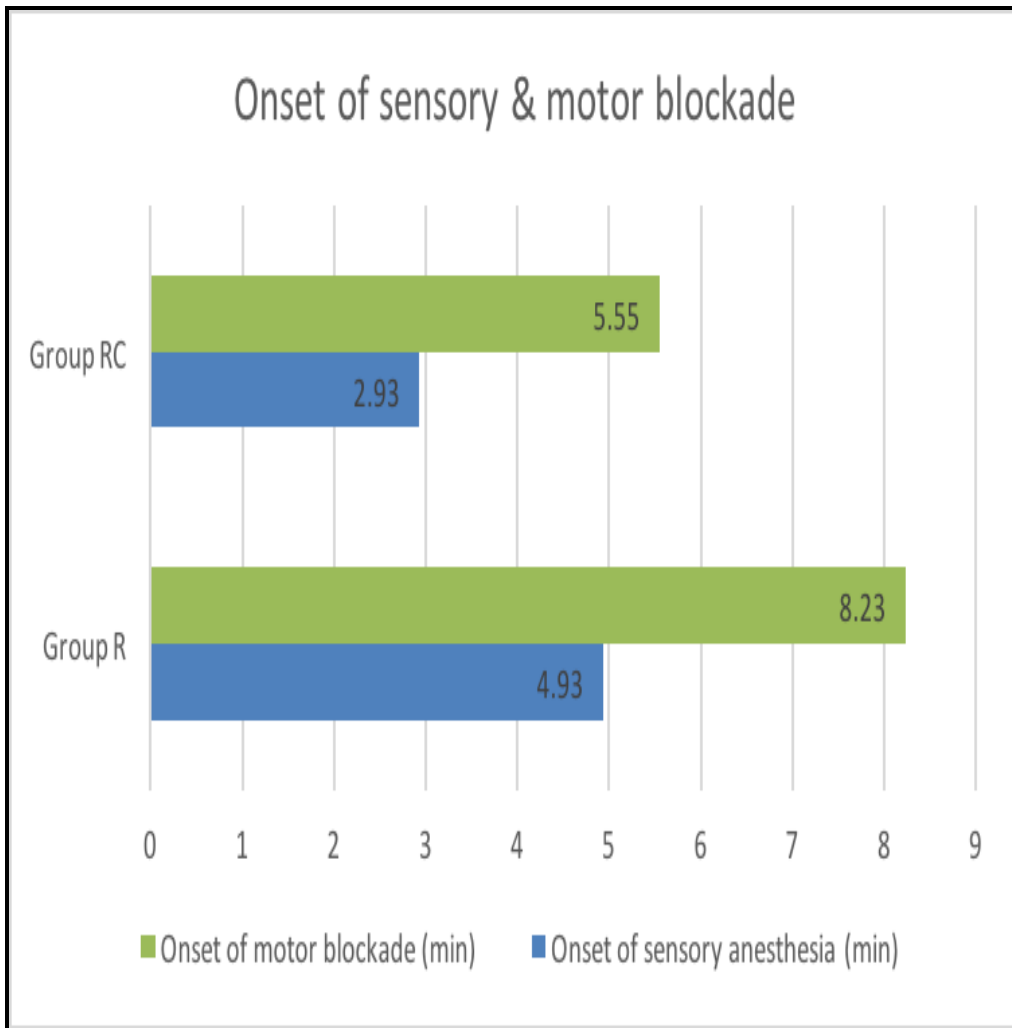
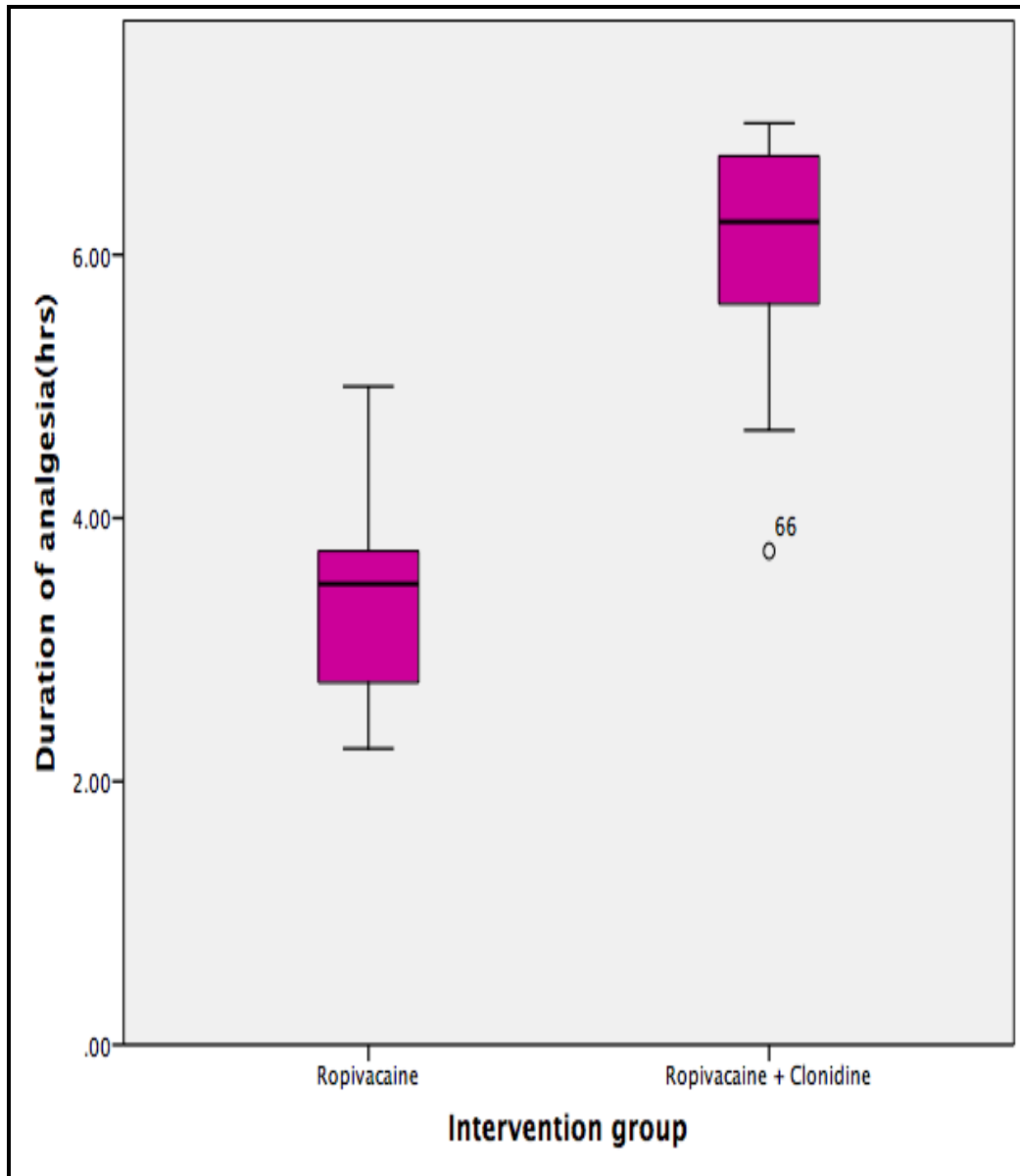


Figure 2



-Statistically significant

The mean time of onset of sensory blockade in the R group was 4.93 minutes & RC group was 2.93 minutes. The mean difference was 2, with 95% C.I ranging from 1.73 to 2.27. The onset of sensory anaesthesia was 2 min earlier on an average in the RC group. The difference was statistically significant.

The onset of motor blockade in R group was 8.23 min and RC group was 5.55 min. The mean difference was 2.68 with 95% C.I ranging from 2.23 to 3.12. The onset of motor blockade was 2.68 min earlier on an average in the RC group. The difference was statistically significant.

The mean duration of analgesia in the R group was 3.48 hours and RC group was 6.16 hours.

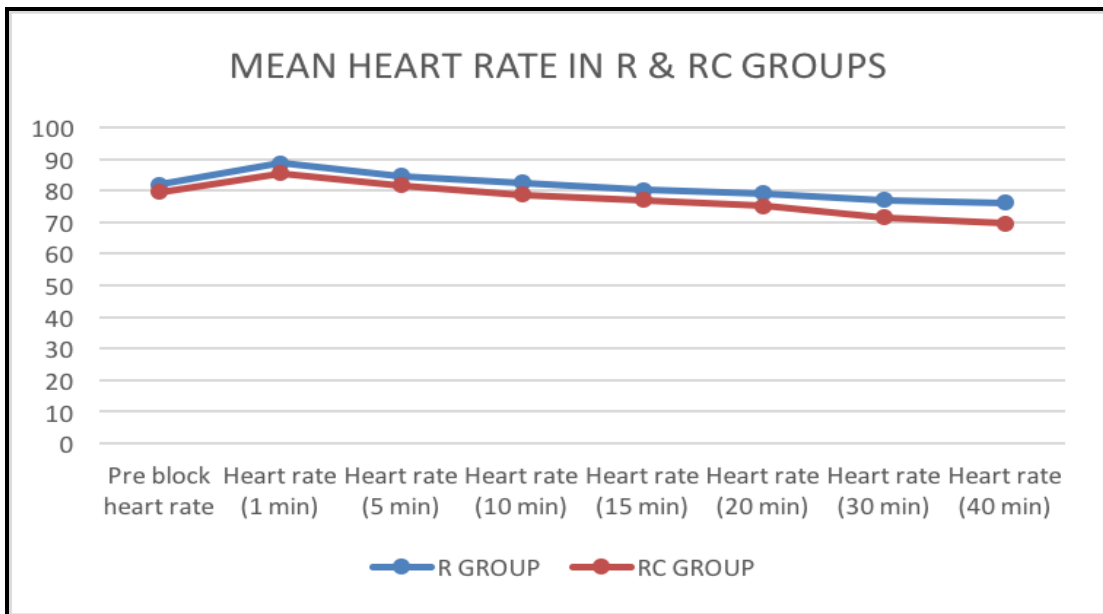
The mean difference was -2.68 with 95% C.I ranging from -3.01 to -2.35.

The difference was statistically significant. Participants in the RC group had analgesia lasting for an average of 2.68 hours more than the R group.

Table 4.: Comparison of Mean HR across R & RC groups

Heart rate	R Group	RC Group	Mean difference	S.E Difference	95% C.I		p value
					Lower bound	Upper bound	
Pre block heart rate	81.95±9.38	79.48±8.00	2.475	1.95	-1.407	6.357	0.208
Heart rate (1 min)	88.55±9.43	85.5±9.31	3.05	2.096	-1.124	7.224	0.15
Heart rate (5 min)	84.52±9.27	81.63±8.33	2.9	1.971	-1.023	6.823	0.145
Heart rate (10 min)	82.55±8.76	78.75±7.86	3.8	1.861	0.095	7.505	0.045*
Heart rate (15 min)	80.23±9.29	76.95±7.95	3.275	1.933	-0.574	7.124	0.094
Heart rate (20 min)	79.13±9.05	75±8.04	4.125	1.914	0.315	7.935	0.034*
Heart rate (30 min)	77.03±9.35	71.4±7.14	5.625	1.86	1.923	9.327	0.003*
Heart rate (40 min)	76.07±8.52	69.58±7.03	6.5	1.747	3.023	9.977	<0.001*

Figure 3.



There was a transient increase in Heart rate in the first minute after administering peribulbar block in both the groups. It declined gradually after that. Patients in the RC group had a more stable decline in HR compared to the R group, the difference was statistically significant after 20 minutes

Overall, the RC group of patients had a significantly lower HR on an average than the R group.

Figure 4

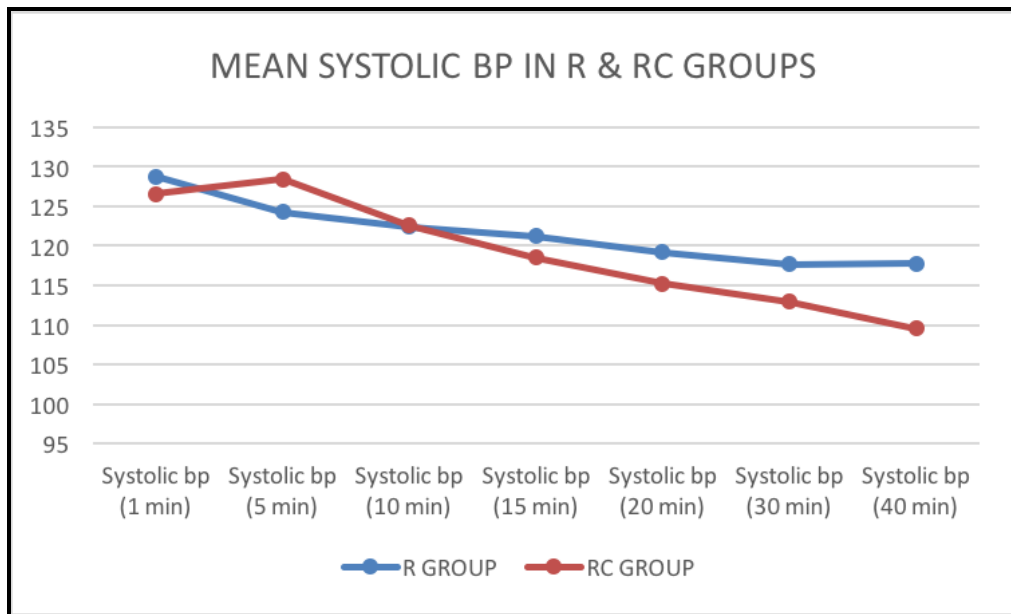


Figure 5

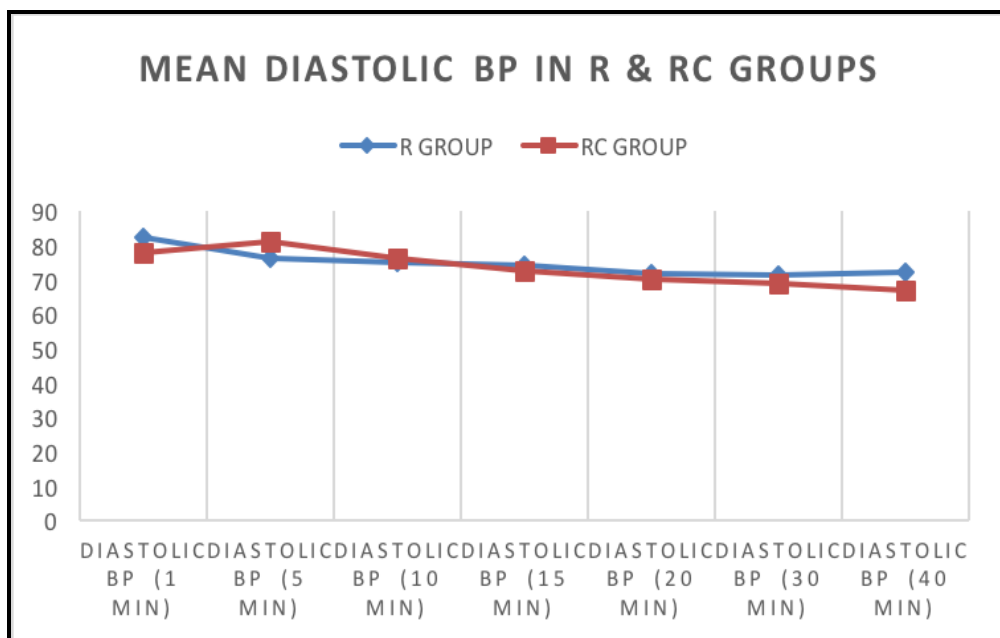


Figure 6.

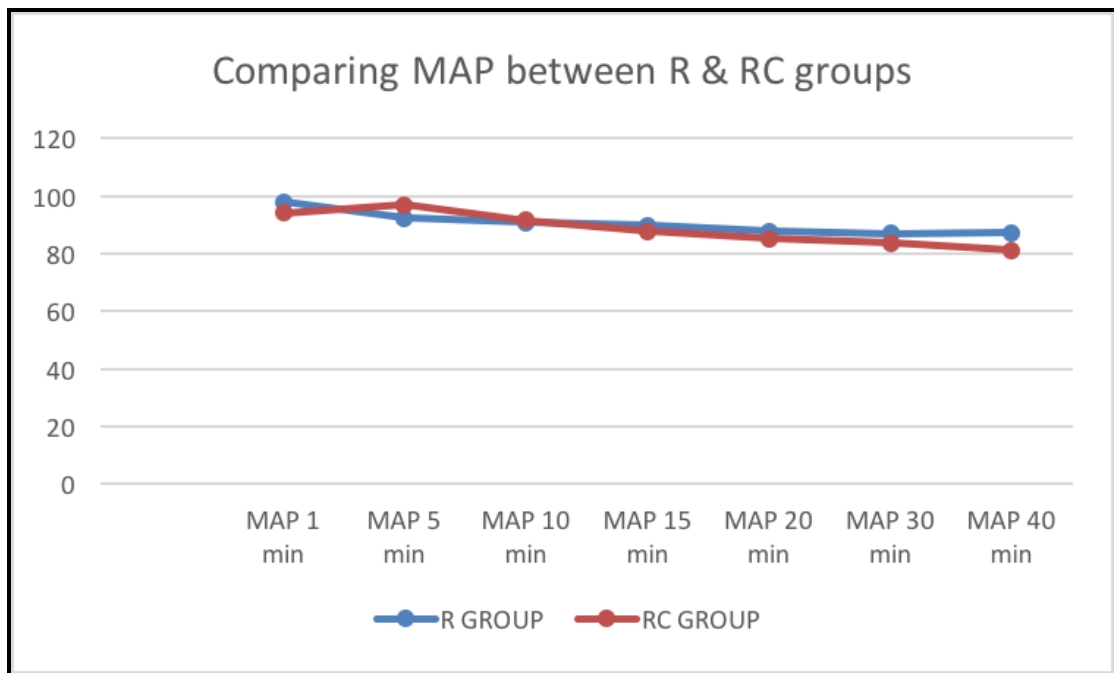


Table 5. : Comparison of Mean Systolic BP across R & RC groups

Systolic BP	R Group	RC Group	Mean difference	S.E Difference	95% C.I		p value
					Lower bound	Upper bound	
Systolic Bp (1 min)	128.8±9.15	126.6±10.2	2.2	2.18	-2.13	6.53	0.32
Systolic Bp (5 min)	124.3±8.53	128.4±9.81	-4.1	1.98	-8.05	-0.15	0.04*
Systolic Bp (10 min)	122.4±7.62	122.5±7.69	-0.15	1.71	-3.56	3.26	0.93
Systolic Bp (15 min)	121.2±7.63	118.5±6.14	2.75	1.55	-0.33	5.83	0.08*
Systolic Bp (20 min)	119.2±7.99	115.2±6.74	3.95	1.65	0.66	7.24	0.019*
Systolic Bp (30 min)	117.7±6.74	112.9±6.18	4.8	1.44	1.923	7.67	0.001*
Systolic Bp (40 min)	117.7±6.81	109.5±6.66	8.2	1.5	5.18	11.17	<0.001*

Table 6. : Mean diastolic BP across R & RC groups

Heart rate	R Group	RC Group	Mean difference	S.E Difference	95% C.I		p value
					Lower bound	Upper bound	
Diastolic BP (1 min)	82.5±5.84	77.9±6.4	4.63	1.38	1.89	7.36	.001*
Diastolic BP (5 min)	76.2±4.33	81.1±4.8	-4.95	1.03	-6.99	-2.9	<0.001*
Diastolic BP (10 min)	75.1±4.57	76.1±5.6	-0.98	1.15	-3.27	1.32	0.401
Diastolic BP (15 min)	74.1±5.26	72.4±4.9	1.63	1.15	-0.66	3.9	0.16
Diastolic BP (20 min)	72±4.17	70.5±3.0	1.75	0.81	-0.013	3.37	0.035*
Diastolic BP (30 min)	71.6±5.03	69.1±4.7	2.53	1.09	0.35	4.69	0.023*
Diastolic BP (40 min)	72.15±4.4	67.0±5.5	5.1	1.11	2.88	7.32	<0.001*

Table 7: Comparison of Mean arterial pressure between R & RC groups

MAP	R Group	RC Group	Mean difference	S.E Difference	95% C.I		p value
					Lower bound	Upper bound	
MAP (1 min)	97.95±5.97	94.13±6.95	3.82	1.44	0.933	6.7	0.01
MAP (5 min)	92.23±5.12	96.9±5.53	-4.67	1.19	-7.03	-2.29	<0.001
MAP (10 min)	90.9±4.54	91.6±5.03	-0.7	1.07	-2.83	1.43	0.51
MAP (15 min)	89.82±5.31	87.82±3.92	2	1.04	-0.79	4.07	0.059
MAP (20 min)	87.73±4.65	85.25±3.38	2.48	0.9	0.67	4.29	0.008
MAP (30 min)	86.98±4.51	83.7±4.51	3.28	1.01	1.28	5.29	0.002
MAP (40 min)	87.34±4.25	81.22±4.80	6.13	1.01	4.1	8.14	<0.001

Similar results were observed with the systolic BP, diastolic BP and MAP between the R group and RC group of patients. Throughout the entire period, RC group of patients had a lower BP on an average, and the difference was statistically significant.

Table 8: Intraocular pressure between R & RC Groups

Intra Ocular Pressure	Mean SD	Mean difference	S.E Difference	95% C.I		p value
				Lower bound	Upper bound	
Pre block IOP						
R Group	11.28 ±1.36	0.35	0.33	-0.3	1	0.28
RC Group	10.93± 1.56					
Post block IOP						
R Group	15.18 ±1.89	-0.75	0.43	-1.6	0.103	0.08
RC Group	15.93± 1.94					

The difference in IOP between the two groups pre block and after administering the block was not statistically significant. There was no significant variation in IOP between the two groups.

Figure 7

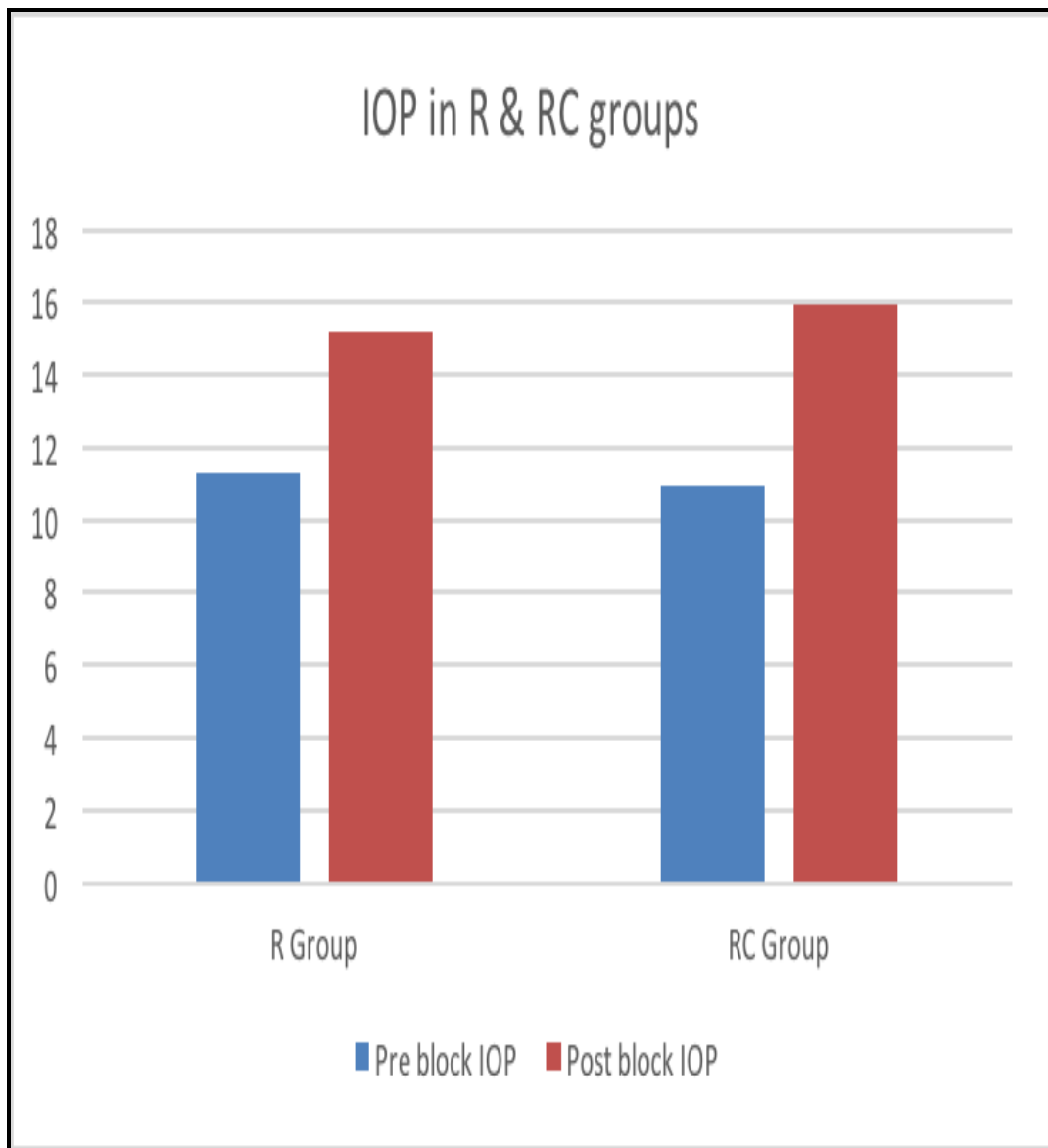


Table 9: Incidence of Side effects

Side Effects	R Group	RC Group
Nausea	0(0)	0(0)
Headache	3(7.5)	2(5)
Vomiting	1(2.5)	0(0)
Dry mouth	0(0)	3(7.5)

None of the participants experienced nausea. 3 participants in the R group had headache, compared to 2 in the RC group. 1 participant in the R group had vomiting, while none in the RC group. 3 participants in the RC group reported dry mouth as a side effect, which was absent in the R group.

DISCUSSION

The use of regional anaesthesia is popular in ophthalmic surgery because it is associated with less hemodynamic and less respiratory complications with good recovery compared to general anaesthesia .This is because of improved surgical technology, reduced operating time and improvement in anaesthetic techniques.

The two commonly used regional anaesthesia technique in ophthalmic surgery are retrobulbar block and peribulbar block.

The complications of retrobulbar block are rare but severe when it occurs. The complications are severe retrobulbar haemorrhage, extraocular muscle paralysis, direct optic nerve injury, central retinal vascular occlusion , ocular perforation, contralateral amaurosis and systemic local anaesthetic toxicity.

To avoid these complications, Davis and Mandel introduced peribulbar block .It is associated with less complications when compared to retrobulbar block.

So nowadays peribulbar block is chosen as a safe and effective technique.

In our Institute of Ophthalmology the protocol is to use Lidocaine alone for cataract surgery. But the Lidocaine –Ropivacaine mixture for peribulbar block has an advantage of Lidocaine's faster onset time and Ropivacaine's longer postoperative pain relief. Thus this mixture is better compared to Lignocaine alone.

This study was conducted in our institution where we used mixture of Ropivacaine, Lignocaine and clonidine. The aim of the study is to find out the usefulness of clonidine in prolongation of duration of analgesia .

On statistical analysis of the data obtained from the group of 80 patients with similar demographic profile showed that there is a statistically significant difference between R group and RC group with regard to sensory and motor blockade. The onset of sensory blockade was 2 minutes earlier on an average in RC group. . The onset of motor blockade was 2.68 minutes earlier on an average in RC group. This corresponds to study done by **Balbir khan et al** , who concluded that the addition of clonidine augments early onset of sensory blockade.

Regarding duration of analgesia our study showed statistically significant difference in prolongation of duration of analgesia in RC group. The analgesia lasting for an average of 2.68 hours in RC group compared to R group which corresponds to study done by **Mjahed et al** which showed addition of clonidine prolongs the duration of action .

The total volume of local anaesthetics used in R group is 5 ml [with 2.5ml lignocaine (2%)+ 2.5ml of Ropivacaine (0.75%) +50 U Hyaluronidase.] and in RC group is 5 ml [with 2ml lignocaine (2%)+ 2ml of Ropivacaine (0.75%)+50 Units of hyaluronidase +1µg/kg of clonidine].From our study the total volume of local anaesthetics required for blockade is reduced.This corresponds to study by **Bajwa SJ et al** which showed the addition of clonidine to ropivacaine results in effective,complete and longer analgesia with similar blockade and there is reduction in the effective dose of ropivacaine when compared with plain ropivacaine for caesarean delivery.

From the statistical analysis obtained from our study the difference in IOP between the two groups pre block and after administering the block was not statistically significant. There was no significant variation in IOP between the two groups.This corresponds to the study by **Connelly et al** which concluded that there was no differences between groups with respect to pain. There was no difference with respect to onset of akinesia. This study revealed no significant difference in baseline IOP and postperibulbar IOP

In our study we have used 0.75% Ropivacaine . Ropivacaine is a pure S-enantiomer drug compared to Bupivacaine which contains both S and R enantiomer .Ropivacaine is less cardiotoxic and has better akinesia which corresponds to study by

Gillart et al. which showed that one percent ropivacaine may be a better agent than 0.5% bupivacaine for single medial injection technique of peribulbar anesthesia. This in addition of lidocaine, it provides better akinesia and similar analgesia.

This also corresponds to the study by **Luigi Gioia et al** which concluded that use of 0.75% or 1% concentrations are preferred in that they provide quick sensory and motor blockade

The results in our study showed that there is a statically significant difference in Heart rate, Blood pressure in two groups. . Patients in the RC group had a more stable decline in HR compared to the R group, the difference was statistically significant after 20 minutes. Throughout the entire period, RC group of patients had a lower BP on an average. This corresponds to study by **Mjahed K et al**, they concluded that the addition of clonidine to lidocaine increase the duration of analgesia and akinesia, with relatively stable hemodynamic parameters.

There is increase in heart rate and blood pressure at 1 minute in both the groups. This corresponds to study of **Luchetti M et al.** which compares Ropivacaine 0.75% versus Bupivacaine 0.5% -Mepivacaine 2% for peribulbar block. After injection of local anesthetic drug increase in MAP and HR noted in both the groups after 1 minute.

In our study the incidence of side effects in both groups were observed. No one experienced nausea. 3 participants in the R group had

headache, compared to 2 in the RC group.1 participant in the R group had vomiting, while none in the RC group.3 participants in the RC group reported ,dry mouth as a side effect, which was absent in the R group.

This corresponds to study of Balbir Khan et al.which showed side-effect profile revealed a higher incidence of nausea, vomiting, headache and dizziness in R Group, while a considerably higher incidence of dry mouth was observed in RC Group.

SUMMARY

Nowadays cataract surgery is commonly done under Peribulbar block which is focussing not only to achieve adequate analgesia but also a satisfactory akinesia of the eye . Topical anaesthesia is a much more preferred technique than regional anaesthesia as revealed by a survey . However, topical anaesthesia may not be not be appropriate for all cases.

Ropivacaine is an aminoamide local anaesthetic agent with a greater margin of safety than bupivacaine for cardiotoxicity and central nervous system toxicity . Clonidine has been shown to prolong anaesthesia via a mechanism involving direct action on nerve fibres . This action might involve a drug interaction as it has been shown that very low dose clonidine increases the C-fibre blockade .

So in our study we compared the onset of sensory blockade, motor blockade and duration of analgesia in two groups ,in which one group consist of 40 patients who were given Ropivacaine ,Lignocaine and another group of 40 patients who were given Ropivacaine ,Lignocaine,clonidine mixture.

From our study we found out that on adding clonidine to local anaesthetic mixture,it significantly prolongs the duration of analgesia ,reduces the time of onset of sensory and motor blockade.The heart rate and blood pressure were stable in the intraoperative period.There was no difference in intraocular pressure in both groups.The only side effect profile observed in RC group is dry mouth.Thus RC group appears to be superior to R group.

CONCLUSION

We conclude from our study that addition of clonidine to Ropivacaine –Lignocaine mixture provides better sensory, motor blockade and significantly prolongs the duration of analgesia compared to Ropivacaine –Lignocaine mixture alone. It reduces the volume of local anaesthetics. It maintains stable hemodynamics throughout the procedure.

BIBLIOGRAPHY

- 1) Ronald D Miller(2015): Local anaesthetics. In: Miller's Anesthesia, 8th edn. Philadelphia: Elsevier, Saunders; 1028-1053
- 2) Stoelting RK Centrally acting Non Opioid Analgesics In Pharmacology and Physiology in Anaesthesia Practice,Wolter Kulver 2015; 257-258 .
- 3) Stoelting RK Local Anaesthetics In Pharmacology and Physiology in Anaesthesia Practice,Wolter Kulver 2015; 282-313
- 4) Paul G.Barash Clinical Anaesthesia :Autonomic Nervous System ,Physiology and Pharmacology,Wolter Kluwer 2013 7Ed ,392
- 5) Parson 's Diseases of the Eye. 22nd Ed Sihota and Tandon
- 6) Ziari Choudary Ocular Anaesthesia vol 1,Roshmi gupta,Santhosh G Honovar Chapter 13.1,Orbit basic concepts.pg 1279-1282.

REFERENCES

- 7) Bajwa SJ, Bajwa S, JasbirKaur. Comparison of epidural ropivacaine and ropivacaine clonidine combination for elective cesarean sections. Saudi J Anaesth 2010;4:47-54.
- 8) Balbir Khan, Sukhminder Jit Singh Bajwa1, Ravi Vohra, Sukhwinder Singh, Rajwinder Kaur, Vartika, Asha et al , Indian

Journal of Anaesthesia Vol. 56, Issue 2012, Comparative evaluation of ropivacaine and lignocaine with ropivacaine, lignocaine and clonidine combination during peribulbar anaesthesia for phacoemulsification cataract surgery. ;56:21-6.

- 9) Barker JP, Vafidis GC & Hall GM (1996): Postoperative morbidity following cataract surgery. A comparison of local and general anaesthesia. *Anaesthesia* 51: 435–437.
- 10) Bloomberg LB. Administration of peribulbar anesthesia. *J Cataract Refract Surg* 1986;12:677–9.
- 11) Connelly NR, Camerlenghi G, Bilodeau M, Hall S, Reuben SS, Papale J. Use of clonidine as a component of the peribulbar block in patients undergoing cataract surgery. *Reg Anesth Pain Med* 1999;24:426-9
- 12) Covino BG. Pharmacology of local anaesthetic agents. *British journal of Anaesthesia* 1986: 58: 701-716.
- 13) D. K. Woodward¹, A. T. S. Leung², M. W. I. Tse², R. W. K. Law², D. S. C. Lam² and W. D. Ngan Kee¹ Peribulbar anaesthesia with 1% ropivacaine and hyaluronidase 300 IU ml⁻¹: comparison with 0.5% bupivacaine/2% lidocaine and hyaluronidase 50 IU ml⁻¹ *Br J Anaesth* 2000; 84: 618–20.

- 14) Davis DB II, Mandel MR. Posterior peribulbar anesthesia: an alternative to retrobulbar anesthesia. *J Cataract Refract Surg* 1986;12:182–5.
- 15) Davis DV & Mandel MR (1994): Efficacy and complication rate of 16,224 consecutive peribulbar block: a prospective, multicentre study. *J Cataract Refract Surg* 20: 327–337.
- 16) Demediuk OM, Ranjit SD, Papwort DP, et al. A comparison of retrobulbar and periocular anesthesia for vitreoretinal surgical procedures. *Arch Ophthalmol* 1995;113:908 –13.
- 17) Demirok A, Simsek S, Cinal A, et al Peribulbar anesthesia: One versus two injections *Ophthalmic Surg Lasers* 1997 Dec. 28(12):998–1001. [PubMed] The single peribulbar injection was found to be as effective as the standard two-injection peribulbar technique.
- 18) Donlon JV Jr .Anaesthesia for Ophthalmic Surgery In : Barash P(Ed) :ASA Refresher course lectures vol 16 Philadelphia, JB Lippincott 1988, pg 81.
- 19) G Nicholson, B Sutton, George M Hall et al , Comparison of 1% ropivacaine with 0.75% bupivacaine and 2% lidocaine for peribulbar anaesthesia *BJA British Journal of Anaesthesia* 84(1):89-91 · January 2000.

- 20) Gillart T, Barrau P, Bazin JE, Roche G, Chiambaretta F, Schoeffler P: (1999): Lidocaine plus ropivacaine versus lidocaine plus bupivacaine for peribulbar anaesthesia by single medical injection. *Anesth Analg* 89:1192-1196.
- 21) Hamilton RC. Brain-stem anesthesia as a complication of regional anesthesia for ophthalmic surgery. *Can J Ophthalmol* 1992;27:323-5.
- 22) Hay ,A ., Flynn ,H.W. JR., Hoffman,J.I. and Rivera ,A.H.(1991) Needle penetration of the globe during retrobulbar and peribulbar injections.*Ophthalmology* 98 ,1017 -24.
- 23) Lofstrom JB, Bengtsson M.Physiology of nerve conduction and local anaesthetic drugs . In : Healy TEJ, Cohen PJ ,eds. *Wylie and Churchill Davidson's A Praticce of Anaesthesia* London , Edward Arnold 1995; 175-186.
- 24) Loken RG, Hamilton RC. Medial canthus (caruncle) single injection periocular anesthesia. *Anesth Analg* 1997;85:707- 8.
- 25) Luchetti M, Magni G, Marraro G (2000)A prospective randomized double-blinded controlled study of ropivacaine 0.75% versus bupivacaine 0.5% -mepivacaine 2% for peribulbar anesthesia. *Reg Anesth Pain Med* 25:195-200.

- 26) Luigi Gioia, MD*, Edi Prandi, MD*, Marco Codenotti, MD†, Andrea Casati, MD*, Guido Fanelli, MD*, Tiziana Monica Torri, BS*, Claudio Azzolini, MD†, and Giorgio Torri, MD Peribulbar Anesthesia with Either 0.75% Ropivacaine or a 2% Lidocaine and 0.5% Bupivacaine Mixture for Vitreoretinal Surgery: A Double-Blinded Study . *Anesth Analg* 1999;89: 739-42 .
- 27) Markham A, Faulds D. Ropivacaine: a review of its pharmacology and therapeutic use in regional anesthesia. *Drugs* 1996;52: 429–49.
- 28) McClellan KJ & Faulds D (2000): Ropivacaine. An update of its use in regional anaesthesia. *Drugs* 60: 1065–1093.
- 29) McClure IH. Ropivacaine. *Br J Anaesth* 1995;74:458–60.
- 30) Mjahed K, el Harrar N, Hamdani M, Amraoui M, Benaguida M. Lidocaine-clonidine retrobulbar block for cataract surgery in the elderly. *RegAnesth* 1996;21:569-75.
- 31) Nicholson G, Sutton B & Hall GM (2000): Comparison of 1% ropivacaine with 0.75% bupivacaine and 2% lidocaine for peribulbar anaesthesia. *Br J Anaesth* 84: 89–91 .
- 32) Paul G.Barash *Clinical Anaesthesia :Epidural and spinal* , Wolter Kluwer 2013 7Ed ,919-920.

- 33) Pautler ,S.E.,Grizzard ,W.s., Thompson ,L.N. and wing, G.L.(1986). Blindness from retrobulbar injection into the optic nerve. *Ophthalmic surg.*17,334-7.
- 34) Perello A, George J, Skelton V, Pateman J (2000) A double-blind randomized comparison of ropivacaine 0.5% , bupivacaine 0.375%-lidocaine 1% and ropivacaine 0.5% - lidocaine 1% mixtures for cataract surgery. *Anesthesia* 55: 1003-1024.
- 35) R.C Hamilton ,Techniques of Orbital Anaesthesia *Br.J.Anaesthesia* 1995 88-92
- 36) Ripart J, Lefrant JY, Lalourcey L, et al. Medial canthus (caruncle) single injection periocular anesthesia. *Anesth Analg.* 1996;83: 1234–8.
- 37) Scott DB, Lee A, Fagan D, et al. Acute toxicity of ropivacaine compared with that of bupivacaine.
- 38) Sharma T, Gopal L, Shanmugam MP, Bhende P, George J, Samanta TK & Mukesh BN (2002): Comparison of pHadjusted bupivacaine with a mixture of non-pH-adjusted bupivacaine and lignocaine in primary vitreoretinal surgery. *Retina* 22: 202–207.
- 39) Tucker GT. Pharmacokinetics of local anaesthetics . *British journal of Anaesthesia* 1983: 58: 717-731.

- 40) Weiss JL & Deichman CB (1989): A comparison of retrobulbar and periocular anaesthesia for cataract surgery. *Arch Ophthalmol* 107:96–98.

PATIENT INFORMATION SHEET

Investigator : Dr.K.Kala

Name of the participant :

TITLE:

Comparative evaluation of Ropivacaine and Lignocaine with Ropivacaine, Lignocaine and Clonidine combination during Peribulbar Anaesthesia for Cataract surgery

You are invited to take part in this research study. We have got approval from the IEC. You are asked to participate because you satisfy the eligibility criteria. We want to compare and study the onset of sensory and motor blockade and duration of blockade using Ropivacaine and Lignocaine with Ropivacaine, Lignocaine and Clonidine combination during Peribulbar Anaesthesia for Cataract surgery

WHAT IS THE PURPOSE OF THE RESEARCH

For Cataract surgeries, peribulbar block is given with ropivacaine and lignocaine in one group and with ropivacaine and lignocaine and clonidine in one group to compare with respect to

- Onset of blockade
- Intra-operative hemodynamics
- Duration of Analgesia

THE STUDY DESIGN

All the patients in the study will be divided into two groups.

Group R - Ropivacaine and Lignocaine

Group RC - Ropivacaine and Lignocaine and Clonidine

BENEFITS

Group RC provide early onset sensory and motor blockade.

Maintenance of intra operative hemodynamics.

Prolonged duration of Analgesia.

Reduces the side effects like headache, dizziness, nausea, vomiting.

DISCOMFORTS AND RISKS

Prolonged sedation,Hypotension,Bradycardia,Dry mouth.

Emergency drugs are readily available.

This intervention has been shown to be well tolerated as shown by previous studies.And if you do not want to participate you will have alternative setting of standard treatment and your safety is our prime concern.

Time :

Date :

Place :

Signature / Thumb Impression of Patient

Patient Name:

PROFORMA

TITLE:

Comparative evaluation of Ropivacaine and Lignocaine with Ropivacaine, Lignocaine and Clonidine combination during Peribulbar Anaesthesia for Cataract surgery

DATE:

ROLL NO:

NAME:

AGE/ SEX:

IP NO:

DIAGNOSIS:

SURGICALPROCEDURE:

PRE OP ASSESSMENT:

HISTORY :

ANY CO-MORBID ILLNESS :

H/O PREVIOUS SURGERIES :

H/O ANY DRUG ALLERGY :

ANY TREATMENT HISTORY :

INFORMED CONSENT IN TAMIL : YES/NO

EXAMINATION :

HR :

BP :

SPO2 :

CVS :

RS :

INTRAOCULAR PRESSURE :

GROUP R / RC (tick)

TIME AT WHICH PERIBULBAR BLOCK GIVEN :

DURATION OF SURGERY :

MEASURES OF STUDY OUTCOME

1)Heart rate and BP :

	HR	BP
1 MIN		
5MIN		
10 MIN		
15 MIN		
20 MIN		
25 MIN		
30 MIN		
40 MIN		

2)Intraocular pressure :

3)Onset of Sensory Blockade (in mins) :

4)Onset of Motor Blockade (in mins) :

5)Duration of Analgesia (in Hours):

6)Incidence of Side effects :

Nausea :-Yes / No

Vomiting :-Yes / No

Headache :-Yes / No

Dry mouth :-Yes / No

**INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003**

EC Reg.No.ECR/270/Inst./TN/2013
Telephone No.044 25305301
Fax: 011 25363970

CERTIFICATE OF APPROVAL

To
Dr.K.Kala
II Year Post Graduate in MD(Anaesthesia)
Madras Medical College/RGGGH
Chennai 600 003

Dear Dr.K.Kala,

The Institutional Ethics Committee has considered your request and approved your study titled **"COMPARATIVE EVALUATION OF ROPIVACAINE AND LIGNOCAINE WITH ROPIVACAINE, LIGNOCAINE AND CLONIDINE COMBINATION DURING PERIBULBAR ANAESTHESIA FOR CATARACT SURGERY" - NO.15022016.**

The following members of Ethics Committee were present in the meeting hold on **02.02.2016** conducted at Madras Medical College, Chennai 3

- | | |
|--|---------------------|
| 1.Dr.C.Rajendran, MD., | :Chairperson |
| 2.Dr.R.Vimala,MD.,Dean,MMC,Ch-3 | :Deputy Chairperson |
| 3.Prof.Sudha Seshayyan,MD., Vice Principal,MMC,Ch-3 | : Member Secretary |
| 4.Prof.B.Vasanthi,MD.,Inst.of Pharmacology,MMC,Ch-3 | : Member |
| 5.Prof.P.Raghumani,MS, Dept.of Surgery,RGGGH,Ch-3 | : Member |
| 6.Dr.Baby Vasumathi, Director, Inst. of O&G,Ch-8 | : Member |
| 7.Dr.K.Ramadevi,MD,Director, Inst.of Bio-Chem,MMC,Ch-3: | Member |
| 8.Prof.M.Saraswathi,MD.,Director, Inst.of Path,MMC,Ch-3: | Member |
| 9.Prof.Srinivasagalu,Director,Inst.of Int.Med.,MMC,Ch-3 | : Member |
| 10.Tmt.J.Rajalakshmi, JAO,MMC, Ch-3 | : Lay Person |
| 11.Thiru S.Govindasamy, BA.,BL,High Court,Chennai | : Lawyer |
| 12.Tmt.Arnold Saulina, MA.,MSW., | :Social Scientist |

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary - Ethics Committee

**MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003**

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சியின் தலைப்பு

கண்புரை அறுவை சிகிச்சைக்கு பெரிபல்பார் மயக்கமுறையில் ரோபிவெகெய்ன்-லிக்னோகெய்ன் மற்றும் ரோபிவெகெய்ன்-லிக்னோகெய்ன்-குளோனிடின் மருந்துக்கலவைகளின் மரத்துப்போகும் தன்மையை மதிப்பீடு செய்தல்

ஆய்வு நிலையம் : அரசு கண் மருத்துவமனை, எழும்பூர், சென்னை-8.
பங்கு பெறுவரின் பெயர் :
பங்குபெறுபவரின் எண் :

பங்குபெறுபவர் இதனை (✓) குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது.

நான் இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக்கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கின்றேன்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன் 'இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம் இடம்..... தேதி.....

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்

ஆய்வாளரின் கையொப்பம் இடம்..... தேதி.....

ஆய்வாளரின் பெயர்

ஆராய்ச்சி தகவல் தாள்

ஆராய்ச்சி தலைப்பு

கண்புரை அறுவை சிகிச்சைக்கு பெரிபல்பார் மயக்கமுறையில் ரோபிவெகெய்ன்-லிக்னோகெய்ன் மற்றும் ரோபிவெகெய்ன்-லிக்னோகெய்ன்-குளோனிடின் மருந்துக்கலவைகளின் மரத்துப்போகும் தன்மையை மதிப்பீடு செய்தல்

ஆராய்ச்சியாளர் பெயர் : மருத்துவர்.கா.கலா

பங்கேற்பாளர் பெயர் :

ஆராய்ச்சியின் நோக்கம்

கண்புரை அறுவை சிகிச்சைக்கு பெரிபல்பார் மயக்கமுறையில் ரோபிவெகெய்ன்-லிக்னோகெய்ன் மற்றும் ரோபிவெகெய்ன்-லிக்னோகெய்ன்-குளோனிடின் மருந்துக்கலவைகளின் மரத்துப்போகும் தன்மையை மதிப்பீடு செய்தல்.

- 1) மயக்கமருந்து எவ்வளவு விரைவாக வேலைசெய்கிறது.
- 2) அறுவை சிகிச்சைக்குப்பின் வலி நிவாரண நேரம்.
- 3) அறுவை சிகிச்சையின்போதும், அதன் பின்பும், நாடித்துடிப்பு, இரத்த அழுத்தம்.
- 4) பக்க விளைவுகள்

ஆய்வு முறை

ஆய்வில் பங்குபெறும் நோயாளிகள் மூன்று குழுக்களாகப் பிரிக்கப்படுவர்.

குழு-1 ரோபிவெகெய்ன் (0.75%) - லிக்னோகெய்ன் (2%)

குழு-2 ரோபிவெகெய்ன் (0.75%) - லிக்னோகெய்ன் (2%)
-குளோனிடின் (1µg/kg)

நன்மைகள்

- 1) குழு-2ல் மயக்கமருந்து மிக விரைவாக வேலை செய்கிறது.
- 2) அறுவை சிகிச்சையின்போது நாடித்துடிப்பு மற்றும் இரத்த அழுத்தம் சீராக உள்ளது.
- 3) அதிகநேரம் வலி நிவாரணம் இருக்கிறது.
- 4) அறுவை சிகிச்சைக்குப்பின் வாந்தி, மயக்கம், குமட்டல், தலைவலி ஆகிய பின் விளைவுகள் குறைக்கப்படுகிறது.

பக்கவிளைவுகள்

அறுவை சிகிச்சையின்போது, இரத்த அழுத்தம் குறைய வாய்ப்புள்ளது. இதய துடிப்பு குறைய வாய்ப்புள்ளது. நாக்கு, வாய் ஆகியவை வரண்டு போக வாய்ப்புள்ளது.

இந்த முறையான ஆய்வு ஏற்கனவே பல இடங்களில் நடத்தப்பட்டுள்ளது. மேலும் இதன் பாதுகாப்பு உறுதிசெய்யப்பட்டுள்ளது. நீங்கள் இந்த ஆய்வில் பங்குகொள்ள விரும்பவில்லை என்றால் எப்போதும் உபயோகிக்கப்படும் மருந்தே கொடுக்கப்படும். உங்கள் பாதுகாப்பே எங்களின் முக்கிய நோக்கம்.

இந்த ஆய்வு சம்பந்தமான எல்லா புள்ளி விவரங்கள் மற்றும் நோயாளிகளின் விவரங்கள் ரகசியமாக வைக்கப்படும். இந்த ஆய்வு சம்பந்தப்பட்ட எல்லா பரிசோதனைகள், மருந்துகள் மற்றும் மருத்துவ சேவைகள் அனைத்தும் நோயாளிகளுக்கு இலவசமாக வழங்கப்படும்.

ஆய்வாளரின் பெயர்

பங்குபெறுபவரின் பெயர்

ஆய்வாளரின் கையொப்பம்

பங்குபெறுபவரின் கையொப்பம்

ROPIVACAINE AND LIGNOCAINE- R GROUP

S. NO	NAME	AGE	SEX	IP NO	ONSET OF SENSORY BLOCKADE [MINS]							ONSET OF MOTOR BLOCKADE [MINS]							TOTAL DURATION OF ANALGESIA [MINS]											
					Min	2	3	4	5	6	7	Min	4	5	6	7	8	9	10	Min	1 to 60	60 to 120	120 to 180	180 to 240	240 to 300	300 to 360	360 to 420			
1	KATHAMUTHU	80	M	19710	5				√				8					v			240					√				
2	RAJAN	55	M	80354	4			√					7				√				300								√	
3	NATHIYA	48	F	77572	5				√				8					√			210					√				
4	KANNIYAMMA	55	F	80453	6						√		9						√		165			√						
5	VEDAVALLI	55	F	80487	5				√				7				√				270						√			
6	RANI BAI	80	F	23172	5				√				8					√			225					√				
7	FATHIMA	60	F	77171	6						√		10							√	135			√						
8	GEETHA	47	F	57364	4			√					8					√			210					√				
9	SARASWATHY	45	F	79648	4			√					8					√			225					√				
10	SUMATHY	53	F	73848	5				√				9						√		210					√				
11	RAHAMED	48	F	72728	6						√		8					√			165				√					
12	KAMALA	50	F	71774	5				√				8					√			180				√					
13	GOPAL	58	M	44526	6						√		10							√	150				√					
14	VENKATESH	47	M	73983	5				√				9						√		165				√					
15	CHANDRA	50	F	51874	4			√					8					√			150				√					
16	KANTHIDEVI	70	F	74353	6						√		10							√	135				√					
17	MURUGAN	49	M	51854	5				√				9						√		210					√				
18	RAMU	50	F	74602	5				√				9						√		225					√				
19	MENAKA	50	F	69350	6						√		8						√		150				√					
20	JAYA	58	F	52162	5				√				9						√		210					√				
21	GLORY	53	F	51884	5				√				8						√		210					√				
22	NATARAJAN	70	M	51885	6						√		9						√		225					√				
23	RAMAKRISHNAN	55	M	51847	4			√					9						√		165				√					
24	SATHAR	72	M	51881	5				√				7					√			210					√				
25	ANITHA	58	F	75444	4			√					6			√					210					√				
26	DHURAI	61	M	51889	5				√				8						√		165				√					
27	ARUMUGAM	70	M	75487	4			√					7					√			225					√				
28	DHANALAKSHMI	57	F	75414	5				√				7					√			210					√				
29	JAISUNDAR	65	M	51862	5				√				8						√		210					√				
30	BABU	56	M	82390	4			√					9						√		215					√				
31	VELAKANI	56	F	81367	5				√				8						√		135				√					

32	RAJENDRAN	62	M	81286	5			√		9				√		225				√			
33	SUNDARI	50	F	52020	5			√		8				√		270					√		
34	PITCHAIYA	60	M	52032	5			√		7			√			225				√			
35	SUSEELA	69	F	78755	5			√		9				√		240				√			
36	PARAVATHI	57	F	78744	4			√		8				√		270					√		
37	SARALA	60	F	70978	5			√		10					√	225				√			
38	THANGAM	55	F	74332	4			√		7			√			300					√		
39	RANI	49	F	52030	5			√		8				√		275					√		
40	SHANTHY	63	F	61961	5			√		7			√			210				√			

29	GOVINDHAMMAL	65	F	77389	3	√						6		√					390								√
30	KUPPAN	47	F	79698	3	√						5		√					405								√
31	LOGANATHAN	67	M	11490	3	√						5		√					420								√
32	PARTHASARATHY	60	M	51012	2	√						4		√					405								√
33	QUEEN MARY	53	F	66631	2	√						5		√					330							√	
34	AMMU	51	F	87643	3	√						5		√					400								√
35	RANI	53	F	82996	2	√						5		√					420								√
36	LILLY	60	F	77944	3	√						5		√					315							√	
37	RANJINI	65	F	51550	2	√						4		√					360							√	
38	RAGHUNATH	48	M	73203	4		√					6			√				420								√
39	MARY	54	F	38072	3	√						5		√					345							√	
40	CHANDRAN	49	M	82177	3	√						5		√					390								√

INTRODUCTION

Regional Anaesthesia is the common technique for most of the surgeries within orbit. In our Institution, cataract surgery is commonly carried out under regional anaesthesia.⁹

Regional anaesthesia for ophthalmic surgery can be administered by anaesthesiologist, provided they receive appropriate training in performing the technique and are fully conversant with the associated risks and complications and can treat them accordingly. Regional anaesthesia is a better alternative, whenever general anesthesia is undesirable or contraindicated.⁹

Match Overview

Match Number	Source	Similarity Percentage
1	www.ijaweb.org Internet source	1%
2	www.egja.org Internet source	1%
3	ispub.com Internet source	1%
4	"Euroanaesthesia 200... Publication	1%
5	www.deepdyve.com Internet source	1%
6	Marco Luchetti. "A pro... Publication	1%
7	lib.bioinfo.pl Internet source	1%
8	www.medknow.com Internet source	1%
9	Lujini Ginia "Perihulbar 10%	10%



Digital Receipt

This receipt acknowledges that Turnitin received your paper. Below you will find the receipt information regarding your submission.

The first page of your submissions is displayed below.

Submission author: 201420006 Md Anes K.KALA
Assignment title: 2015-2015 plagiarism
Submission title: COMPARATIVE EVALUATION OF R..
File name: Main_Book.doc
File size: 1.26M
Page count: 76
Word count: 8,209
Character count: 45,810
Submission date: 22-Sep-2016 09:43PM
Submission ID: 706651604

INTRODUCTION

Regional Anaesthesia is the common technique for most of the surgeries within orbit. In our Institution, cataract surgery is commonly carried out under regional anaesthesia.⁹

Regional anaesthesia for ophthalmic surgery can be administered by anaesthesiologist, provided they receive appropriate training in performing the technique and are fully conversant with the associated risks and complications and can treat them accordingly. Regional anaesthesia is a better alternative, whenever general anaesthesia is undesirable or contraindicated.⁹

Today anaesthesia for cataract surgery needs a comfortable environment for both patient and surgeon during surgery and recovery of function quickly without risk. There is only a limited role for General anaesthesia which is indicated especially in cases where topical or local anaesthesia is contraindicated.⁹

The two mostly commonly used^{9,16,18} regional anaesthesia techniques are retrobulbar block and peribulbar block. They provide adequate anaesthesia for surgery of cornea, anterior chamber, and lens. Retrobulbar block technique involves deposition of drug into the muscle cone, so termed as Intraconal block. Peribulbar block technique involves deposition of drug outside the muscle cone so termed as Extra conal block.^{38,40}