“SAFTEY AND EFFICACY OF SODIUM BICARBONATE VERSUS HYALURONIDASE IN PERIBULBAR ANAESTHESIA FOR CATARACT SURGERY”

BY

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DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, KOLAR, KARNATAKA

In partial fulfilment of the requirements for the degree of

MASTER OF SURGERY
IN
OPHTHALMOLOGY

Under the Guidance of

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Safety and Efficacy of Sodium Bicarbonate versus Hyaluronidase in Peribulbar anesthesia for Cataract surgery

ABSTRACT

BACKGROUND:

The primary objective of an ideal anesthesia for any intraocular ophthalmic procedure is to provide optimal pain relief and anesthesia without any complications. For eye surgeons, it is crucial to attain excellent ocular anesthesia, hypotonic & akinesia, to ensure a favorable visual acuity. Numerous studies have examined efficiency of hyaluronidase, bupivacaine & lidocaine, in peribulbar anesthesia, while some studies have explored 'Sodium bicarbonate' as a viable substitute agent. There are few studies that have raised doubts about efficiency of hyaluronidase in increasing the anesthesia quality. Additionally, the cost, reduced shelf life, and the potential danger of anaphylaxis associated with the enzymatic nature, poses further concern. Therefore, our aim is to determine and compare globe akinesia, quality of analgesia, onset and duration of anaesthesia and complications between Hyaluronidase and 'Sodium bicarbonate' groups.

MATERIALS AND METHODS:

A prospective comparative study was carried out in Ophthalmology department at K.L. Jalappa Hospital and Research Centre in Kolar, spanning from August 2022 to December 2023. A total of 162 participants were randomly allocated into two groups after obtaining informed consent from the recruited participants. Group A was administered hyaluronidase, while Group B was given 'Sodium bicarbonate'. Prior to commencing the study, we acquired ethical clearance from the relevant institutional authorities. Prior to commencing the trial,

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Safety and Efficacy of Sodium Bicarbonate versus Hyaluronidase in Peribulbar anesthesia for Cataract surgery ABSTRACT BACKGROUND: The primary objectives of an ideal anesthesia for any intraocular operation are to achieve optimal pain relief and anesthesia without any complications. For eye surgeons, it is crucial to attain excellent surface anesthesia, hypotony & akinesia, to ensure a favorable visual acuity. Numerous studies have examined efficiency of hyaluronidase, bupivacaine & lidocaine, in peribulbar anesthesia, while some studies have explored 'Sodium-bicarbonate' as a viable substitutive agent. There are few studies that have raised doubts about efficiency of hyaluronidase in increasing the anaesthesia quality. Additionally, the cost, reduced shelf life, and the potential danger of anaphylaxis associated with the enzymatic nature poses further concern. Therefore, our aim is to determine and compare globe akinesia, quality of analgesia, onset and duration of anaesthesia and complications between Hyaluronidase and 'Sodium-bicarbonate' groups. MATERIALS AND METHODS: A prospective comparative study was carried out in Ophthalmology department, R. L. Jalappa Hospital and Research Centre in Kolar, spanning from August 2022 to December 2023. A total of 182 participants were randomly allocated into two groups after obtaining informed consent from the recruited participants. Group A was administered hyaluronidase, while Group B was given 'Sodium- bicarbonate'. Prior to commencing the study, we acquired ethical clearance from the relevant institutional authorities. Prior to commencing the trial, STATISTICAL ANALYSIS: The data was analyzed using the software SPSS version 22. The categorical data was represented using frequencies and proportions. The Chi-square test was used to determine the importance of qualitative data, whereas the independent t test was employed to determine the relevance of quantitative variables. A p-value less than 0.05 was deemed to be statistically significant. RESULTS: In Group A, the participants' average age was 67.86 ± 10.457 years, while in Group B it was 64.19 ± 9.396 years. Most individuals in both groups were females. The majority of individuals in both categories were female. The time it took for anesthesia to take effect in Group A was 0-5 minutes in 48.4% of cases, 6-10 minutes in 13.2% of cases, and 11-15 minutes in 38.5% of cases. In Group B, anesthesia took effect in 0-5 minutes in 65.9% of cases, 6-10 minutes in 6.6% of cases, and 11-15 minutes in 27.5% of cases. Within Group A, 59.3%, 34.1% and 6.6%, of individuals reported experiencing no, mild & moderate pain respectively. Within Group B, 75.8% of individuals reported an absence of pain, whereas 22% and 2.2% respectively, reported mild & moderate pain. Within Group A, 51.6% of individuals exhibited Grade 1 Akinesia, 36.3% exhibited Grade 2 Akinesia, and 12.1% exhibited Grade 3 Akinesia. Within Group B, 70.3% of individuals exhibited Grade 1 Akinesia, whereas 24.2% displayed Grade 2 Akinesia, and 5.5% demonstrated Grade 3 Akinesia. There were notable disparities in the time of onset, pain score, and akinesia between the two groups. CONCLUSION: Our study revealed, 'Sodium-bicarbonate' can be a substitute for hyaluronidase in peribulbar anesthesia, offering quicker anesthetic action, a longer duration of anesthesia, and satisfactory akinesia. KEY WORDS: Hyaluronidase, 'Sodium-bicarbonate', Peribulbar Anaesthesia, Cataract Surgery INTRODUCTION Anesthesia for intraocular surgery should be safe and effective, with the goals being to minimize complications and provide the best possible anesthesia and pain relief. An essential requirement for an Ophthalmologist is to produce effective surface anesthesia, akinesia, & hypotony to obtain positive visual prognosis. Knapp's initial description of retrobulbar anesthesia about a century ago, it has been the preferred method of anesthesia1. However, more recently, ocular surgeons worldwide.have reported local and systemic problems associated with this technique. Subsequently, the quest for a more secure method to accomplish anesthesia and immobility commenced, leading to the endorsement of the peribulbar approach. This approach has less problems in comparison to retrobulbar anesthesia. The anesthetic drug diffuses through the different compartments due to its pressure and volume. Peribulbar block offers the benefit of circumventing the problems linked to retrobulbar anesthesia and eliminates the need to administer distinct facial nerve block. Nevertheless, drawbacks include a prolonged & irregular start of anesthesia, a longer period required to become proficient, and the need for a higher amount of anesthetic solution. The occurrence of anesthesia and akinesia is a result of the blockage of sensory and motor nerves. EOM relaxation leads to hypotony, resulting in a reduction of muscular tone. The anesthetic mixture used includes 2% lignocaine & 0.5% bupivacaine, which requires diffusion for distribution. Hence, hyaluronidase has been employed to promote better spread of the anesthetic. This enzyme aids in breaking down hyaluronic acid into smaller molecules, transforming the gel-like barrier between tissues into a liquid form. It helps to spread the anesthetic solution more easily. Galido2 found that adjusting the local anaesthetic solution's pH using 'Sodium-bicarbonate' could reduce the duration it takes for the anesthetic to take effect and significantly enhance the effectiveness of the nerve block. Alkaline form being an active form of drug has been demonstrated to enhance drug's non-cationic form. This effectively permeates soft tissue & nerve sheath, leading to a quicker commencement of action. The discomfort during injection is reduced due to the alkaline composition of the substance. Multiple research projects have been conducted to find out regarding efficacy of lidocaine, bupivacaine & hyaluronidase in peribulbar anesthesia. Additionally, only a few studies have explored the potential of 'Sodium-bicarbonate' as an alternate agent with similar efficacy. Recent investigations have raised doubts about the effectiveness of hyaluronidase in enhancing the quality of anesthesia. In addition to these factors, there is the consideration of cost, the limited amount of time the product can be stored, the inability to reuse it in the same sitting, and the potential danger of allergy due to its enzymatic properties. Therefore, it is necessary to investigate the efficacy of 'Sodium-bicarbonate' as a substitute for hyaluronidase due to its affordability, accessibility, and alkaline properties that can alkalinize the anesthetic solution without the potential for allergy. AIM AND OBJECTIVES AIM: This study aims to evaluate and compare effectiveness & safety of 'Sodium- bicarbonate' & Hyaluronidase in Peribulbar anesthesia for small incision cataract operation. OBJECTIVES: 1. Determining and contrasting the globe akinesia of two groups 2. To determine and compare quality of analgesia between two groups 3. To determine and compare onset and duration of anaesthesia 4. To determine and compare complications associated with anaesthetic procedure. 5. To compare patient and surgeon satisfaction with the procedure A HISTORICAL OVERVIEW AND LITERATURE REVIEW Effective anesthesia, akinesia, analgesia, & ocular hypotony are crucial for the safety of intraocular surgeries. The current methods of anesthesia in ocular surgery include: a) Local / Regional Anesthesia b) Topical Anesthesia c) General Anesthesia While Regional anesthesia being used widely, topical anesthesia has become popular, especially for outpatient cataract surgeries and clear corneal phacoemulsification. General anesthesia is seldom used, except in cases involving children, individuals with mental challenges, or patients who are particularly anxious and uncooperative. History of ocular anaesthesia In 1884, Koller conducted a demonstration showing the impact of local anesthesia on ophthalmic surgery. He used topical cocaine, which effectively eliminated discomfort but did not induce akinesia1,3,4. The obvious progression from the previous step was to administer additional cocaine into orbit such that globe akinesia will be achieved and pain in deep tissues gets reduced. With cocaine discovered was lauded for its ability to induce minimal discomfort upon injection, powerful vasoconstriction, and blockade of sensory & motor neurons. However, orbital injections resulted in optic nerve damage, incurred high expenses, and led to blindness. There have been cases of fatalities resulting from injections administered at the orbital apex or posterior to the ethmoid nerves 5-8. In addition, they induced infrequent but unpleasant side effects such as syncope, cold sweats, and hallucinations, which were uncommon when applied topically or locally infiltrated within a six-minute 7 timeframe. Local anesthetic medicines, such as procaine, were introduced as safer alternatives to cocaine. Procaine was found to be the safest option and was initially utillzed for subconjunctival injection. The advantages of the product were its enhanced

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LIST OF ABBREVIATIONS

BCVA - Best corrected visual acuity

CN - Central nervous system

CRVO - Central retinal vein occlusion

ECCE - Extra capsular cataract extraction

GA - General anaesthesia

Hyalase - Hyaluronidase

IO - Inferior oblique

IOL - Intra ocular lens

IOP - Intraocular pressure

IR - Inferior rectus

LA - Local anaesthesia

LPS - Levator palpebrae superioris

LS - Lateral rectus

MR - Medial rectus

SO - Superior oblique

SR - Superior rectus

ON - Optic nerve

Phaco - Phacoemulsification

SICS - Small incision cataract surgery

UNVA - Uncorrected visual acuity

VA - Visual acuity

VAS - Visual Analouge Pain Scale

LA - Local anaesthetics

ml - millilitre

mEq - milli equvivalents

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“SAFTEY AND EFFICACY OF SODIUM BICARBONATE VERSUS HYALURONIDASE IN PERIBULBAR ANAESTHESIA FOR CATARACT SURGERY”

ABSTRACT

BACKGROUND:

The goals of safe and effective anaesthesia for intra ocular surgery are to obtain good analgesia and anaesthesia without complications. The most ideal pre-requisite for an eye surgeon is to achieve good surface anaesthesia, akinesia and hypotony for a favorable visual outcome. There are various studies on the efficacy of lidocaine, bupivacaine and hyaluronidase in peribulbar anaesthesia and a few studies on sodium bicarbonate as an effective alternative agent. Recently some studies have doubted the efficacy of hyaluronidase in improving the quality of anaesthesia. Added to this is the cost factor, limited shelf life and re usage in the same sitting along with the risk of anaphylaxis due to its enzyme nature. Hence this study was conducted with the objectives. To determine and compare globe akinesia, quality of analgesia, onset and duration of anaesthesia and complications between Hyaluronidase and Sodium bicarbonate groups.

MATERIAL AND METHODS:

A Prospective Comparative study was conducted in the department of Ophthalmology, R. L. Jalappa Hospital and Research Centre at Kolar from August 2022 to December 2023. 182 subjects were randomly divided in to two groups. Group A received hyaluronidase and Group B received Sodium bicarbonate. Institutional Ethical clearance was obtained prior to the start of the study. Informed consent was obtained from all the patients recruited prior to the start of the study.

STATISTICAL ANALYSIS: Data was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. **Chi-square test and Independent t test** was used as test of significance for qualitative data and quantitative variables respectively. **p value** of <0.05 was considered as statistically significant.

RESULTS: Mean age of subjects in Group A was 67.86 ± 10.457 years and in Group B was 64.19 ± 9.396 years. In Both groups majority of subjects were females. Majority were females in both groups. Time of Onset of Anaesthesia in Group A was 0-5 mins in 48.4%, 6-10 mins in 13.2% and in 11-15 mins in 38.5%, in Group B was 0-5 mins in 65.9%, 6-10 mins in 6.6% and in 11-15 mins in 27.5%. In Group A, 59.3% had No pain, 34.1% had mild pain and 6.6% had moderate pain. In Group B, 75.8% had no pain, 22% had mild pain and 2.2% had moderate pain. In Group A, 51.6% had Grade 1 Akinesia, 36.3% had Grade 2 Akinesia, 12.1% had Grade 3 Akinesia. In Group B, 70.3% had Grade 1 Akinesia, 24.2% had Grade 2 Akinesia, 5.5% had Grade 3 Akinesia. There was significant difference in Time of onset, pain score and akinesia between two groups.

CONCLUSION:

From the study it was concluded that sodium bicarbonate is an effective alternative to hyaluronidase in peribulbar anaesthesia with a faster onset of anaesthetic action, longer duration of anaesthesia and Good akinesia.

KEY WORDS: Hyaluronidase, Sodium bicarbonate, Peribulbar Anaesthesia, Cataract Surgery

INTRODUCTION

INTRODUCTION

The goals of safe and effective anaesthesia for intra ocular surgery are to obtain good analgesia and anaesthesia without complications. The most ideal pre-requisite for an eye surgeon is to achieve good surface anaesthesia, akinesia and hypotony for a favorable visual outcome. Ever since Knapp H[1] described retrobulbar anaesthesia almost 10 decades ago, it remained the choice of anaesthesia till about recently when ocular surgeons all over the world described local and systemic complications due to it. Then began the search for a safer technique to achieve anaesthesia and akinesia, hence the peribulbar technique was advocated. This technique has lesser complications when compared to retrobulbar anaesthesia. The anaesthetic agent spreads by virtue of its pressure and volume throughout the various compartments.

The advantage of peribulbar block is that it avoids the complications associated with retrobulbar anaesthesia and there is no need for a separate facial nerve block. However, the disadvantages are delayed and inconsistent onset of anaesthesia, longer learning curve and usage of larger volume of anaesthetic solution. The anaesthesia and akinesia occur due to sensory and motor nerve blockade. Hypotony occurs due to loss of tone of extra ocular muscles. The anaesthetic solution used contains 2% Lignocaine and 0.5% Bupivacaine. This has to spread by diffusion. Hyaluronidase was used to aid in the better diffusion of anaesthetic solution. It is an enzyme which catalyzes the depolymerization of hyaluronic acid to a tetrasaccharide which leads to the liquefaction of the gelatinous interstitial barrier.

It thereby facilitates the diffusion of the anaesthetic solution. Galindo A[2] first reported that altering the pH of the local anaesthetic solution with Sodium bicarbonate, the time of onset could be reduced and the spread of the neural blockade could be enhanced significantly. It is also proved that the alkaline form of the drug is its active form, it increases the non-cation form of the

drug. This penetrates through the soft tissue and the nerve sheath better resulting in the shortening of the onset of action. Because of its alkaline nature the pain during injection is also decreased. There are various studies on the efficacy of Lidocaine, Bupivacaine and Hyaluronidase in peribulbar anaesthesia and a few studies on Sodium bicarbonate as an effective alternative agent. Recently some studies have doubted the efficacy of Hyaluronidase in improving the quality of anaesthesia. Added to this is the cost factor, limited shelf life and re-usage in the same sitting along with the risk of anaphylaxis due to its enzyme nature. Hence the need for studying the efficacy of Sodium bicarbonate as an alternative to Hyaluronidase as it is cheap, easily available, has a basic nature which alkalinizes the anaesthetic solution without any risk of anaphylaxis.

AIM AND

OBJECTIVES

AIM AND OBJECTIVES

AIM: To compare the efficacy and safety of Peribulbar anesthesia with Sodium bicarbonate and Hyaluronidase for cataract extraction

OBJECTIVES:

1. To determine and compare Globe akinesia between two groups.
2. To determine and compare quality of analgesia between two groups.
3. To determine and compare onset and duration of anaesthesia.
4. To determine and compare complications associated with anaesthetic procedure.
5. To compare patient and surgeon satisfaction with the procedure.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Good anaesthesia, akinesia, analgesia and ocular hypotony are essential for safe intra ocular surgery. Ocular surgery currently employs the following methods of anaesthesia namely

a) Local / regional anaesthesia
b) Topical anaesthesia
c) General anaesthesia

Although regional anaesthesia is most commonly employed, topical anaesthesia is soon gaining popularity specially for daycare cataract surgery. Clear corneal phacoemulsification. General anaesthesia is rarely used, except in children, mentally challenged individuals, apprehensive and uncooperative patients.

History of ocular anaesthesia

Koller C[3] demonstrated in 1884 the effect of local anaesthesia for ophthalmic surgery using topical cocaine which abolished pain although it did not provide akinesia [1,3,4]. Further injection of cocaine in the orbit to provide akinesia of the Globe and freedom from pain of deeper structures was the logical extension of the above. Discovery of cocaine was praised because it caused little pain on injection, potent vasoconstriction and it blocked sensory and motor nerves. But orbital injections caused optic nerve toxicity, was costly and caused blindness. There were reports of death from intra orbital injections in the apex of the orbit or posterior to ethmoid nerve [5,6,7,8]. They also caused uncomfortable side effects like syncope, cold sweats, hallucinations, which were rare with topical administration or local infiltration within six minutes. Safer local anaesthetic drugs replaced cocaine, safest of which was procaine, which was first used for sub conjunctival injection.

Advantages were – It was more stable in solution and had longer shelf life, less expensive and as free from drug abuse. It had fewer undesirable autonomic and cerebral effects. But substituting procaine for cocaine had little pharmacologic benefit because it had to be reinforced with addition of a block of the facial nerve or eye lids to prevent lid squeezing during surgery. Large doses of procaine caused sudden death and elevation of IOP. It was short acting unless combined with Epinephrine in 1:3,000 to 1:5,000 concentrations.[9]

Procaine was then replaced with tetracaine and tetracaine was gradually replaced with Lidocaine. Atkinson first commented on the improved penetrating properties and duration of action of Lidocaine over procaine.[10] Again Lidocaine did not last long enough for more time consuming ECCE surgeries, so longer lasting Mepivacaine gained popularity. But it caused more pain on injection[11]. So, to increase the duration of action Bupivacaine gained popularity[12]. The long-acting Bupivacaine had less spreading effect and much slower onset than Lidocaine, this became an incentive to add greater volume of total solution[13]. Volumes more than 5 ml started to be in use, provided longer blocks and post-operative analgesia[14]. Epinephrine then came into use with Lidocaine / Bupivacaine to signal IV injection. When injected with the above 2 agents Epinephrine reduced the toxic effects of Bupivacaine[15,16].

Atkinson in 1943 stated that, Hyaluronidase was an enzyme which was in wide use, and it could be also used in ophthalmic surgery to prevent complications such as vitreous loss[10]. Although Hyaluronidase tended to shorten the duration of anaesthesia, this effectively countered by administering it with Epinephrine [17,18]. After Hyaluronidase was purified and available for routine use, dosage was stabilized at an amount that produced noticeable proptosis (4-8ml) in 1964[18]. Thus, the combination of Hyaluronidase, larger anaesthetic volume, prolonged deliberate pressure over the orbit produced hypotony of the globe necessary for cataract extraction. It reduced the vitreous volume allowing space for IOL implantation[19]. The quest for an ideal

anaesthetic agent led Zahl K et al., to add Sodium bicarbonate for pH adjustment during peri bulbar block. They advocated a mixture of 0.75% Bupivacaine with 15 units of Hyaluronidase (pH 5.45 ±0.12) or addition of 0.15 mEq of Sodium bicarbonate per 30ml of 0.75% Bupivacaine to give a final pH of (6.82±-0.09). Patients were assigned to 2 groups. Onset of akinesia was determined to the nearest minute. The group receiving pH adjusted Bupivacaine had a statistically faster onset time for complete akinesia than did the control group. Thus, pH adjustment of a solution of Bupivacaine and Hyaluronidase with Sodium bicarbonate hastens the onset time and improves the initial success rate of peribulbar block [20].

The above publications were further supported by Lewis P et al., in 1992. They divided the patients undergoing cataract surgery into two groups. Patients were randomized to receive either plain (pH 5.4) or pH adjusted [pH range (6.7-6.9)] of 0.75% Bupivacaine. Hyaluronidase was added to both solutions prior to peribulbar block. The time of onset of akinesia and need for supplementary injections was recorded. Patients who returned for surgery for the second eye received the alternative local anaesthetic solution for the second peribulbar block. The results were as follows- eyes receiving peribulbar block with pH adjusted solution showed a shorter time to partial akinesia of the Globe. However, this study showed no difference between the solutions in the time to complete akinesia of the Globe. The disadvantage of the pH adjusted solution was that the number of supplementary injections required for effective block was increased [21].

Roberts E.J., Bernard A., Macleod and Hollands R.H. conducted a double-blind randomized study to determine the effect of pH and addition of Hyaluronidase to a mixture of Lidocaine and Bupivacaine on the efficacy of peribulbar anaesthesia. Here he assigned 100 patients to five groups. All groups received a solution of 2 parts of Bupivacaine (0.75%) and one part of Lidocaine (2%) with 1:100,000 Adrenaline as the base components of anaesthesia.

- Group 1: Only Bupivacaine with Lidocaine pH-3.9
- Group 2: Above plus Hyaluronidase pH 5.1

- Group 3: Above plus Sodium bicarbonate pH 5.1
- Group 4: Above mixture with Hyaluronidase alkalinized to a pH of 6.7
- Group 5: Bupivacaine and Lidocaine mixture alkalinized to a pH of 6.7

Efficacy of each block was graded according to the degree of residual movement 30 min following injection[22]. The solution containing Hyaluronidase and pH adjusted to 6.7 was most effective. They found the presence of Hyaluronidase without alkalinization did not improve efficacy of the mixture and similarly alkalinization in the absence of Hyaluronidase was ineffective. Results reflected that pH and temperature dependent properties of local anaesthetics and pH dependent activity of Hyaluronidase[23].

Further studies in this regard by Minasian C. M. et al. at the Kingston Thames to determine the relation between pH of the anaesthetic solution and patient perception of pain with peribulbar injection of local anaesthesia. Here the patients were divided into two groups. One group received a peribulbar block with either a standard acidic local anaesthetic of 5 ml of 2% Lignocaine and 5 ml of 0.5% Bupivacaine (solution A) or an alkalinized solution composed of the same anaesthetic solution with pH of 7.44 (solution B). The pain was graded using visual analogue scale. The mean pain scores were higher in group B who received buffered solution compared to group A who received plain solution. This study concluded that there was no significant difference in the reduction in pain experienced by patients undergoing peribulbar anaesthesia with pH buffered local anaesthetic[24].

Studies done in 2001 by the American academy of ophthalmology suggested the absence of Hyaluronidase in peribulbar anaesthesia increased the risk for post-operative strabismus, diplopia and pain during injection was greater. But this was not supported widely, and further studies needed to be conducted in this regard[25]. Galindo A et al., had reported that by altering the pH of local anaesthetic solution with Sodium bicarbonate solution in a 1:10 mixtures with

Lidocaine or Bupivacaine the time of onset and spread of neural blockade could be enhanced significantly[2]. Buffering was both simple and inexpensive.

An article regarding efficacy of Sodium bicarbonate as an alternative to Hyaluronidase in ocular anaesthesia was published by Srinivasan M., et al. in 2000.[26] The study was conducted in two parts. Part 1 evaluated the safety and efficacy of Sodium bicarbonate buffered Lidocaine mixture in patients scheduled for cataract surgery. In part 2**,** they compared the efficacy of Sodium bicarbonate buffered Lidocaine with Hyaluronidase. Those with grade 3 anaesthesia had a supplement injection of the same mixture. In both groups of patients, it was noted that there was no difference in the heart rate, mean systolic blood pressure and diastolic blood pressure pre and post block. There was no anaesthetic local adverse effects such as lid edema, chemosis and congestion during the post-operative period. Fundus examination did not reveal damage to the optic nerve or retinal toxicity, thereby confirming the efficacy of Sodium bicarbonate to be equal to Hyaluronidase.

Further most local anaesthetics are supplied as acidic salts to avoid precipitation. It has been demonstrated that the alkaline form is the active form of the drug [27,28] and alkalinization of the local anaesthetic agent with Sodium bicarbonate increases the non-cation form which penetrates the soft tissue and nerve sheath faster. It therefore decreases the time of onset and increases the potency of anaesthesia. The disadvantage of alkalinization is that precipitation might occur when Sodium bicarbonate is added to Lidocaine as a bolus. This can be avoided by slowly adding it to Lidocaine [28].

Eccarius S.J.et al.[29], reposted significant reduction of pain when buffered injections were used compared to unbuffered injection for eyelid anaesthesia. Zahl K.et al.[28], have described the effect of bicarbonate on mixtures of Lidocaine, Bupivacaine with or without Hyaluronidase[30]. Local anaesthesia without Hyaluronidase results in sub optimal anaesthetic effect and patients

experience pain during surgery. Therefore, pH adjustment of Lidocaine with Epinephrine using Sodium bicarbonate could be safe, well tolerated and painless method which effectively shortens the onset of anaesthesia and achieves akinesia compared to Lidocaine and Hyaluronidase mixture providing a cost-effective alternative [31].

A Similar study was published by Gupta R.P, Kapoor G., They compared two groups of patients undergoing cataract surgery with peribulbar anaesthesia. One group had Hyaluronidase mixed anaesthetic & other Sodium bicarbonate buffered anaesthetic solution. In conclusion Sodium bicarbonate was shown to reduce the time of onset and increase the successful block rate without any adverse effects[32].

Technique of Anaesthesia:

Earlier topical cocaine was used to achieve anaesthesia. It was however found that topical cocaine did not diffuse deep to abolish sensation from the iris and did not eliminate pain from pull on the muscle. Later surgeons chose sub conjunctival infiltration of cocaine to decrease pain from pulling or cutting the iris. This was inadequate to anaesthetise the iris so sedatives were added. Van lint introduced orbicularis akinesia by nerve block in 1914.[33] This was improved upon by Wright, O'brien and Atkinson preventing the patient from closing or squeezing their lids during cataract surgery [34,35,36]. However patients still complained of pain. Infiltration along the conjunctiva and muscles reduced pain but infiltration through inflamed tissues was time consuming and difficult [37].

Knapp in 1884 first described blocking the ciliary nerves behind the eye to ease pain. This was first used for enucleation.[38] But with this the patients experienced cold sweats and syncopal attacks; it was thought to be due to toxicity of cocaine in the vascular orbit. Therefore, he believed that amounts of cocaine smaller than the volume he used to be necessary for infiltration into the orbit. With the use of Epinephrine with cocaine in 1908 total block could be achieved by

less than half accepted toxic dose of cocaine.[39] Atkinson and Gifford S.R. realized that freedom from pain, akinesia of lids and lowering IOP during surgery gave excellent results.[40] During 1934 – 1964 Atkinson published many papers wherein he encouraged ciliary ganglion block by cone infiltration, Facial block and globe paresis for cataract surgery. This gave good results but patients still complained of pain and some globes did not become akinetic. So, others adopted the apical technique and simply added more local anaesthetic.[41] He advocated the infratemporal quadrant as being safe, relatively avascular and having best angle approach to the intraconal space. The range of depth of his needle was 2.5-3.5 cm. He used the up and in position. This position has been abandoned in modern practice as there is a chance of damage to the macular area in case of scleral perforation. The disadvantage was that restricted quantity of anaesthethic solution that could be injected in the muscle cone and non-availability of Hyaluronidase caused poor akinesia of the globe and inadequate anaesthesia of the superior limbus. To counter this Atkinson used a supplemental sub conjunctival injection of local anaesthetic at the site to achieve patient comfort.[39]

Atkinson in 1943 commented on improving penetrating properties and duration of Lidocaine over procaine, adding Hyaluronidase to prevent vitreous loss during surgery, but Epinephrine used countered the action of Hyaluronidase [10]. With the use of the above agents 3-4 cc could be injected into the muscle cone and greatly improved analgesia and akinesia could be obtained [17,42]. In 1970 references started trickling in about the risk of injury of the optic nerve, Globe perforation, brain stem apnea, CRVO, Retrobulbar hemorrhage, cardiac and CNS depression, seizures following retrobulbar injection.[43,44,45] What was accepted as a totally safe procedure was now being questioned by practitioners.

Peribulbar anaesthesia:

In 1970 Kelman described this technique of anaesthesia. He gave the injection of anaesthetic agent outside the muscle cone of the eye and showed good anaesthetic effects. He used 24-gauge needle bent at the hub at 70 degree and placed it through the fornix and needle was held parallel to the orbital floor. 4-5 cc of Lidocaine and Hyaluronidase was injected followed by pressure of 12 ounces placed over the eye for 15 minutes.[46] In 1983 Bloomberg used periocular anaesthetic technique wherein he combined 2% Lignocaine, 0.5% Bupivacaine, Hyaluronidase and Sodium bicarbonate. He warmed the solution and used 27 gauge, 3/4th inch long needle inferotemporally at the junction of outer third and inner 2/3rd of the lid. It is directed towards the floor of the orbit away from the eye. 8-10 cc of anaesthetic is injected, 12-20 minutes are required for the anaesthetic to disperse and become effective. It diffuses into the retro bulbar space producing ocular anaesthesia and diffuses into the anterior orbit to produce peri ocular anaesthesia.[47,48]

Davis and Mendel in 1986 introduced the term peribulbar anaesthesia for injection of anaesthesia outside the muscle cone. They used anaesthetic mixtures of Lignocaine, Bupivacaine and Hyaluronidase. They injected 6-8 ml into the peribulbar space followed by placement of a pinky ball for 15-30 minutes[49]. Ramamurthy in 1989 used 2% Lidocaine and 1% Bupivacaine in equal proportions for two different sites of injection. First at junction of medial ¾ th and lateral ¼ th of the lower lid, directed along the floor of the orbit. The second injection was given in the upper lid along the same site. This was found to be less painful, good hypotony and anaesthetic effect could be obtained [50].

Kishore K. et al., in 1989 evaluated peribulbar anaesthesia using 26-gauge needle with 2% Lidocaine with Adrenaline, Hyaluronidase and 0.5% Bupivacaine. With this there was good lid and globe akinesia, anaesthesia and adequate pupillary dilatation for ECCE[51]. House P.H., in

1991 determined the effectiveness of various combinations of Lidocaine, Epinephrine, Hyaluronidase and Bupivacaine. All patients were given 9ml peribulbar block by the same surgeon and graded assessment of anaesthesia and analgesia was made later[52].

Arnold P in 1992 demonstrated the efficacy of a single injection of peribulbar anaesthesia in the inferotemporal quadrant is sufficient to obtain akinesia and anaesthesia with reduced risk of complications[53]. Agarwal V et al., demonstrated efficacy of a single injection low volume periocular anaesthesia. The method was found to be very effective. The complications were minimal. Supplementary anaesthesia was required in only 0.2% cases. Chemosis was noted in 12.75% of cases[54].

David B.D., Richard M evaluated the efficacy and complication rates of 16, 224 consecutive peribulbar blocks which were single point. The incidence of complications was low. Orbital hemorrhage occurred in 0.74% cases, Globe perforation in 0.006%, expulsive choroidal hemorrhage in 0.013% and grand-mal seizures in 0.006%[55,56]. Hustead R. et al., evaluated medial orbital injection of anaesthetic solution as an alternative to supranasal injection when an inferotemporal injection resulted in incomplete anaesthesia. They found this technique effective and safe means for secondary block[57].

Rao V.A et al., evaluated a modified technique of peribulbar anaesthesia, consisting of a single injection of 5 cc anaesthetic solution with a 26-gauge needle. They observed complete anaesthesia in 15 minutes with no significant complications. They concluded it to be a safe, simple, economical means of anaesthesia[58].

Peribulbar anaesthesia with or without Hyaluronidase

The goals of safe and effective anaesthetic presentation for intra ocular surgery are to obtain adequate anaesthesia and akinesia without complications including significant rise in IOP. Traditionally the anaesthetic solution was a mixture of 30ml of 2% Lidocaine with 1: 200,000

dilution of Epinephrine and 450 Units of Hyaluronidase. Hyaluronidase is an enzyme which catalyzes the depolymerization of hyaluronic acid to a tetra saccharide. It improves the efficacy of local anaesthetic by breaking down interstitial cell barriers thereby facilitating diffusion of the anaesthetic solution [59]. However, there is no evidence for increased spread across fascial planes [59].

Galido et al reported that by altering the pH of local anaesthetic solution with Sodium bicarbonate in a 1: 10 mixture with Lidocaine or Bupivacaine the time of onset and the spread of neural blockade could be enhanced significantly[2]. Hyaluronidase is used to improve the spread of local anaesthetic agent through the tissue planes. The breakdown of intercellular barrier presumably aided the rapidity and completeness of the diffusion of anaesthetic agents. However, De Felce and associates did not find the enzyme of any value in enhancing the diffusion rate [60]. Szmyd et al reported a reduction in duration of anaesthesia after using Hyaluronidase in the anaesthetic mixture [60].

Mindel J.S. studied the value of Hyaluronidase in ocular surgical akinesia. He found Hyaluronidase to be of value in decreasing the induction time of both facial nerve block and retro bulbar block. However, the use of Hyaluronidase did not significantly alter the success rate of retro bulbar block [59]. Nicoll J.M. et al., studied 100 patients who received retrobulbar block for ophthalmic surgery to compare the efficacy of local anaesthetic with or without Hyaluronidase. A consistently better motor blockade was received with Hyaluronidase.[61]

Lange W, Denffer V.H. et al., in their study comparing the effect of 0.75% Bupivacaine with 0.75% Bupivacaine with 2% Mepivacaine in retrobulbar anaesthesia and the effect of adding Hyaluroniodase. They found effect of anaesthesia enhanced by adding 75 IU of Hyaluronidase.[62] Abelson M.B., Mandel E., in their study on value of addition of Hyaluronidase to the anaesthetic mixture concluded that addition of Hyaluronidase resulted in more profound

blocks[63]. Morsman C.D, Holden R., studied the effect of Adrenaline, Hyaluronidase on peribulbar anaesthesia. They found the addition of Hyaluronidase significantly increased the proportion of patients achieving good anaesthesia. The need for supplementary injections were reduced with Hyaluronidase. However, they found no effect of the addition of Adrenaline to anaesthetic solution.[64]

In 1994 Crawford M. et al., studied the efficacy of Hyaluronidase in peribulbar blocks.[65] Bowman R. J. et al in 1997 conducted a prospective randomized controlled study to investigate if Hyaluronidase improved the efficacy of peribulbar anaesthesia. They did not find significant difference between the two groups.[66]

Dempesy G.A. in 1997 conducted a study to assess the efficacy of Hyaluronidase and also effect of increasing the concentration of Hyaluronidase on the quality of anaesthesia achieved. They found Hyaluronidase in concentrations of 50 IU/ml and 300 1U/ml improved the quality of block and 300 IU/ml concentration also increased the speed of onset.[67] In 1999, Costa P et al., conducted a study to compare efficacy of Bupivacaine alone and a mixture of Bupivacaine, Mepivacaine and Hyaluronidase in both retrobulbar and peribulbar blocks. They found quality of anaesthesia, speed, need for further anaesthesia was better in retrobulbar blocks.[68] In 2000 Rowley S.A. et al., conducted a prospective randomised study to investigate quality of block with sub tenons anaesthesia. They reported Hyaluronidase significantly improved the quality of motor blockade but had no significant effect on the sensory blockade.[69]

Effect on peribulbar anaesthesia with alkalinization:

The modification of local anaesthetics by addition of agents like Sodium bicarbonate has been studied for a long time. Modifications of local anaesthetics were usually carried out to either speed the onset of blockade that is by adding Sodium bicarbonate or prolonging the duration of blockade by adding Epinephrine. The theory behind the practice of adding Sodium bicarbonate is

that, most local anaesthetics while being weak bases with pKa varying from 7.7-8.9 are supplied in the solutions that are acidic. This is done to improve the stability of the preparation. A number of studies have been reported with comparisons between alkalinized and plain preparations of local anaesthetics. They compared Lidocaine 2%, Bupivacaine- plain or alkalinised.[70,71,72]

Minasian MC. et al., did a pain perception with a pH buffered peri bulbar anaesthesia pilot study and concluded that there was no difference in reduction of pain experienced by patients undergoing peribulbar anaesthesia with pH buffered local anaesthetic. Pain threshold was found to be a confounder.[73] Srinivasan M. et al in 2000 conducted a study wherein they compared Sodium bicarbonate as an alternative to Hyaluronidase in ocular anaesthesia for cataract surgery. In conclusion they found earlier onset of akinesia and anaesthesia with Sodium bicarbonate although the quality of anaesthesia was not different[26]. Gupta R. P., Kapoor G. in 2006 published a study where safety and efficacy of Sodium bicarbonate was compared with Hyaluronidase in peribulbar anaesthesia and concluded that onset of anaesthesia with Sodium bicarbonate was faster. The duration and quality of anaesthesia was independent of the agent. The incidence of complications was similar in the two groups[32].

ANATOMY OF THE ORBIT

BONY ORBIT[74]

Orbits are truncated pyramids. The total volume of the orbit is 29ml.The ratio ofthe volume of the orbit to the Globe is 4.5:1.

The boundaries of the orbit are:

- Anterior cranial fossa above and maxillary sinuses below
- Medial walls are parallel to each other and separated from nasal cavities by ethmoid and sphenoid sinuses.
- Lateral wall is inclined at an angle of 45˚ to medial wall and 90˚ with respect to each other. Middle cranial fossa lies posteriorly and the muscular temporal fossa lies anterior to the orbit.
- The orbit is formed by 7 bones- frontal, ethmoid, lacrimal, palatine, maxilla, zygomatic and sphenoid
- Intra orbital width- between medial margins is 25 mm.
- Extra orbital width- between lateral margins is 100 mm.

$$\text{Orbital index} = \frac{Height}{Width} \times 100$$

- >89 – megasemes (orientals)
- 83-89 – mesosemes (caucasians)
- <83 – microsemes (blacks)

WALLS OF THE ORBIT:

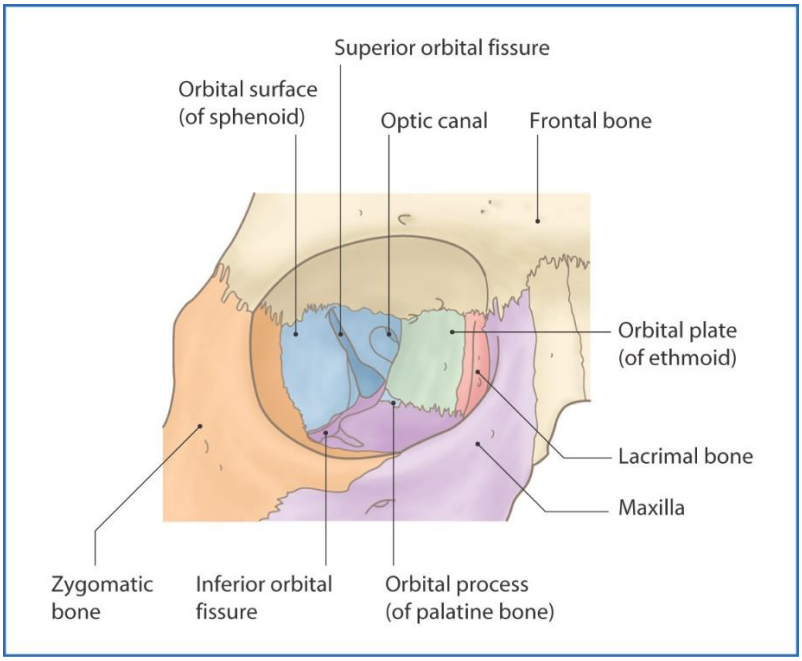


Figure 1: Walls of the Orbit

4 walls – medial, lateral, roof and floor. They meet at the superior and inferior external and superior and inferior internal angles of the orbit.

Medial wall:[75]

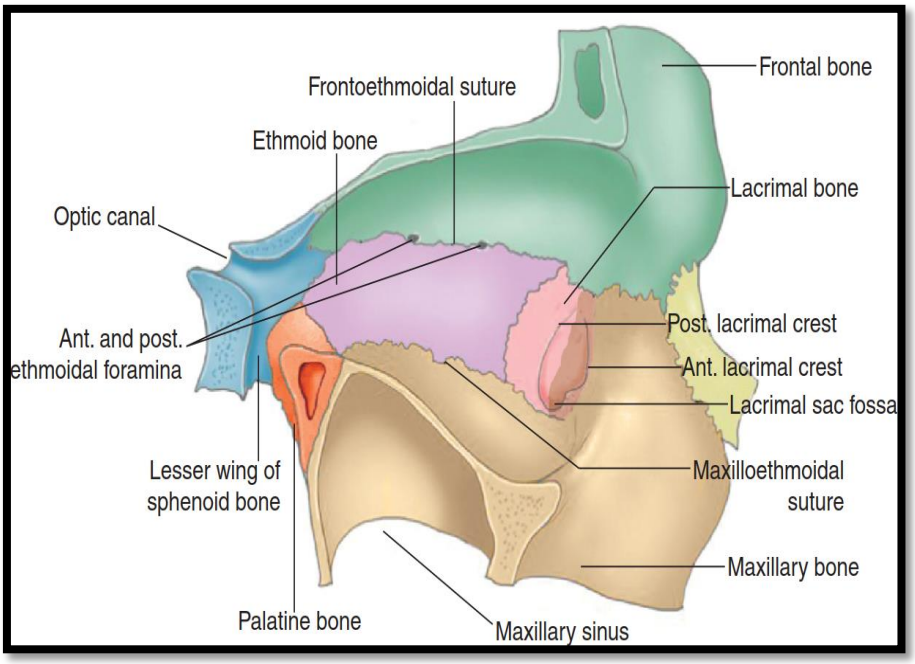


Figure 2: Medial Wall of the Orbit.[75]

The medial wall is quadrilateral. It is formed by the frontal process of maxilla, lacrimal bone, orbital plate of ethmoid and body of sphenoid. Anteriorly lies the lacrimal groove.

Structures have attachment just behind the posterior lacrimal crest.

- Horner's muscle (lacrimal fibres of orbicularis)
- Septum orbitale
- Check ligament of medial rectus.

RELATIONS OF MEDIAL WALL:

- Medially lies the anterior, middle and posterior ethmoidal sinuses, middle meatus of nose and sphenoid sinus.
- From the orbital surface it is related to superior oblique near the roof, medial rectus in the middle part, between these the anterior and posterior ethmoidal nerves, infratrochlear nerve and terminal branch of ophthalmic artery run.

APPLIED ANATOMY:

Medial wall – thinnest wall

- Ethmoiditis can lead to orbital cellulitis especially in children.
- It is frequently eroded by cysts and tumors of the sinuses.
- Easily fractured during orbitotomy, trauma.
- Hemorrhage during surgery due to injury to ethmoidal vessels
- Visualized with routine PA radiographs.

INFERIOR WALL (FLOOR)[76]

- It is formed by 3 bones the orbital surface of maxillary bone medially, orbital surface of zygomatic bone laterally and palatine bone posteriorly.
- Separated from the lateral wall posteriorly by the inferior orbital fissure.
- Fissure → infraorbital canal → infraorbital foramen just below infraorbital rim.
- Transmits infraorbital vessels and nerve[76].

Inferior wall:

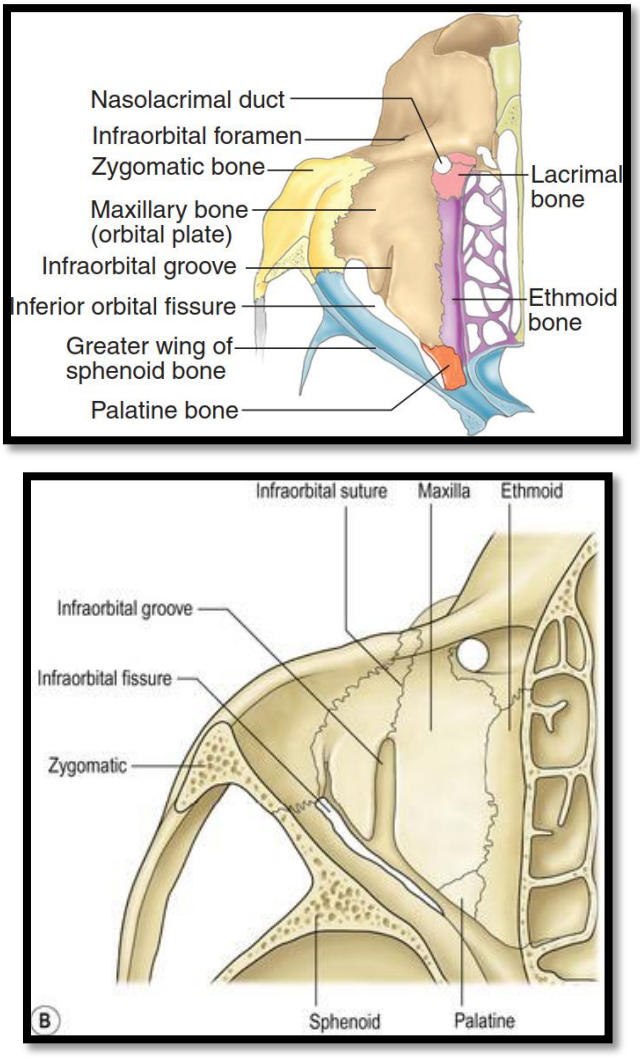


Figure 3: Inferior Wall of the Orbit[76].

RELATIONS: Inferiorly lies the maxillary sinus and palatine air cells. Superiorly it is related to the inferior rectus, inferior oblique, nerve to inferioroblique.

APPLIED ANATOMY: This wall is thin. It is most commonly involved in blow-out fractures and invadedby tumors of maxillary sinus.

LATERAL WALL[77]

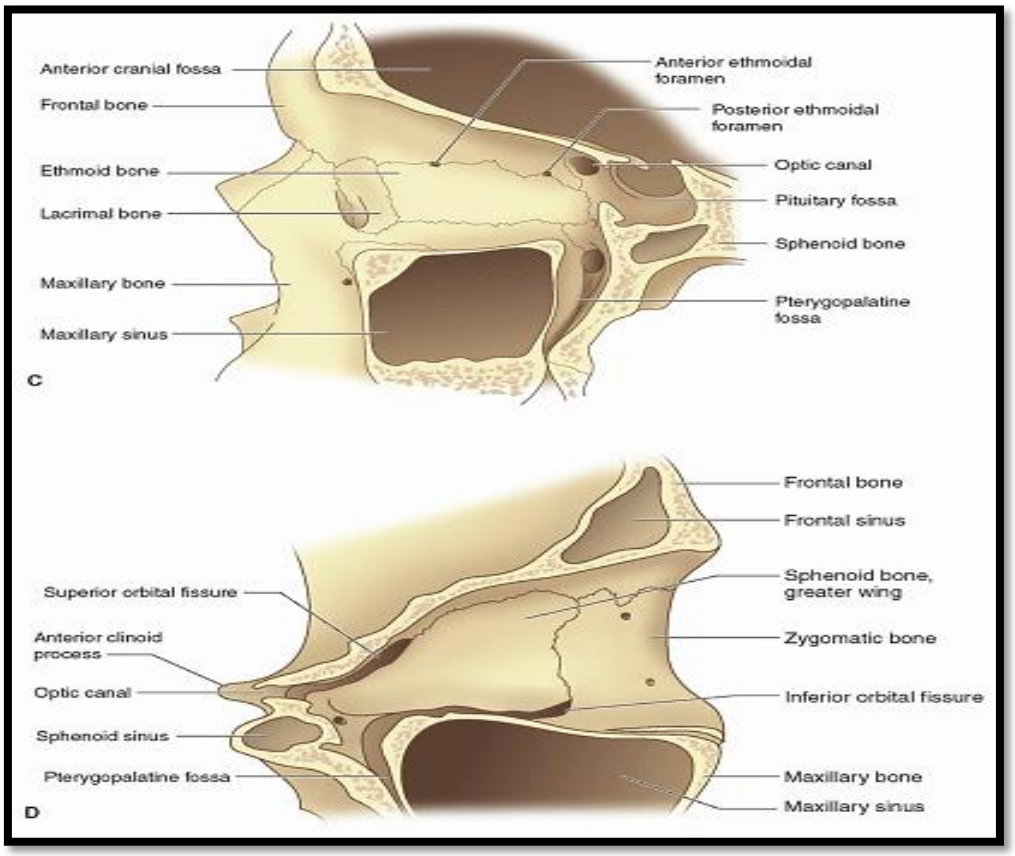


Figure 4: Lateral wall of the orbit[77].

- It is formed anteriorly by zygomatic bone and posteriorly by greater wing of sphenoid.
- It is separated from roof by superior orbital fissure and floor by inferior orbital fissure.
- Spina recti lateralis is a bony projection posteriorly, gives origin to part of lateral rectus.
- Zygomatic groove and foramina lie anteriorly and is traversed by zygomatic nerve and vessels
- Lateral orbital tubercle of Whitnall lies anteriorly on the frontal process of the zygoma gives attachment to check ligament of lateral rectus, suspensory ligament of eyeball and aponeurosis of levator palpebrae superioris[77].

RELATIONS:

- Laterally it is related to the temporal fossa anteriorly and the middle cranial fossa posteriorly.
- Orbital surface related to lateral rectus, lacrimal nerve and vessels, zygomatic nerve and communication between zygomatic and lacrimal nerves.

APPLIED ANATOMY:

Lateral wall is deficient anteriorly and covers only the posterior half of the eyeball therefore the palpation of retrobulbar tumours is easier from the lateral side. It is devoid of foramina as a result it can be approached without serioushemorrhage. Lateral rim of the orbit is the strongest portion of the orbit.

ROOF OF THE ORBIT[78]

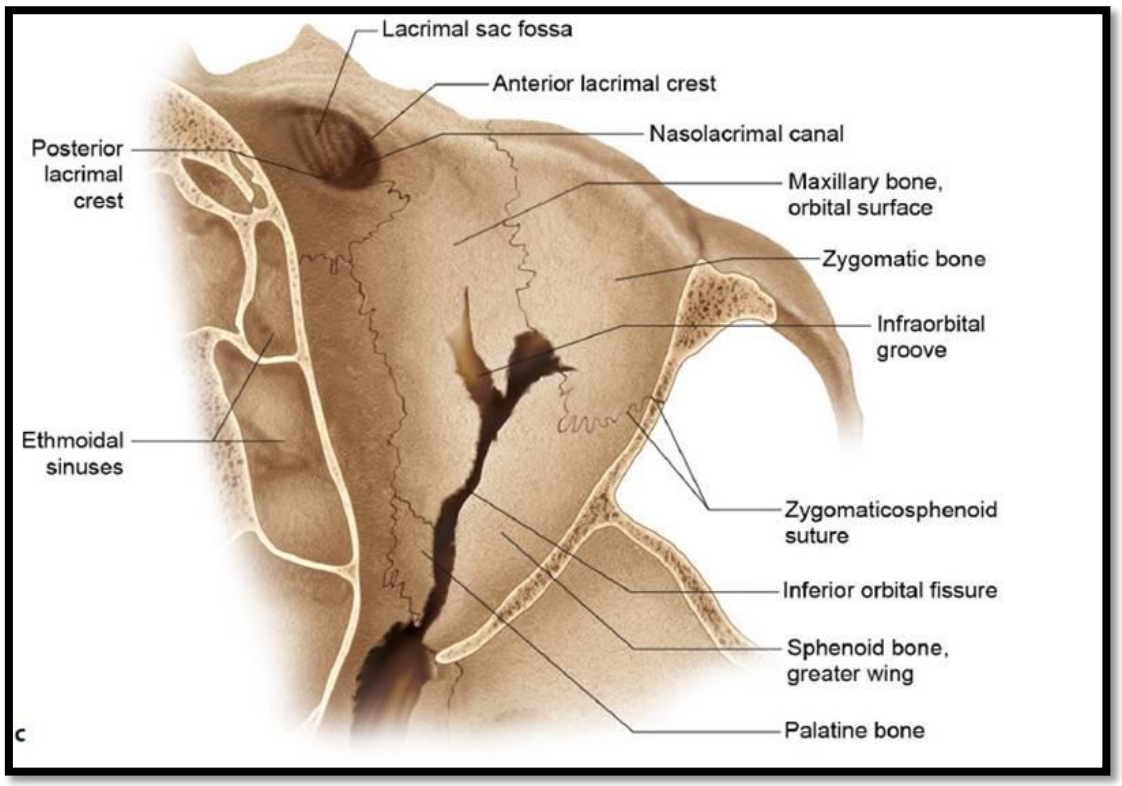


Figure 5: Roof of the Orbit[78]

- Formed by orbital plate of frontal bone mainly and posteriorly by lesser wing of sphenoid
- Fossa for lacrimal gland – anterolateral, pitted by attachments of suspensory ligament of lacrimal gland
- Trochlear fossa – fovea for the pulley of superior oblique[78].

RELATIONS:

- Superiorly lies the frontal lobe and its meninges.
- Inferiorly is the periorbita, frontal nerve, levator palpebrae superioris, superior rectus, superior oblique, trochlear nerve and lacrimal gland.
- Anterior and posterior ethmoidal canals are at the junction of roof and medial wall.
- Superior orbital fissure at junction of roof and lateral wall.

APPLIED ANATOMY:

- As it rather thin walled, sharp objects entering the orbit may penetrate the roof and damage frontal lobe.
- Is not perforated by any major vessel or nerve – can be easily nibbled away in transfrontal orbitotomy.

BASE OF THE ORBIT[79]

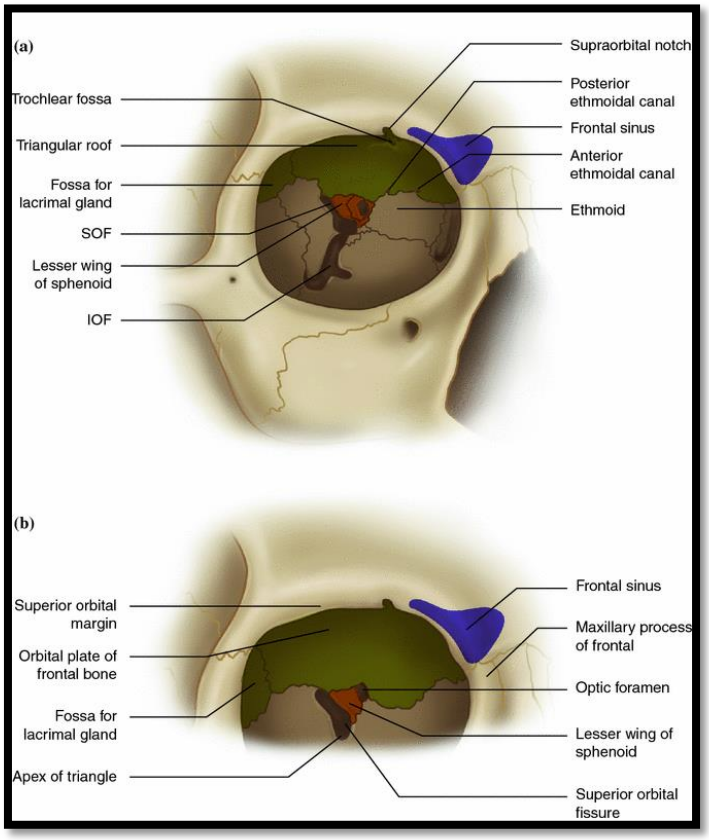


Figure 6: Base of the Orbit[79]

- ***Lateral margin*** is strongest, formed by zygomatic process of frontal bone andzygomatic bone.
- ***Inferior margin*** is formed by zygomatic bone laterally and maxilla medially.
- Medially continuous with anterior lacrimal crest. 4-5mm below lies the infra orbital foramen
- ***Medial margin*** is formed by anterior lacrimal crest on the frontal process of maxillaand above by frontal bone.[79]

APEX OF THE ORBIT[80]

Is where the 4 walls converge. It has 2 orifices – optic canal and superior orbital fissure situated in the sphenoid. Optic Canal lies within lesser wing of sphenoid, connects orbit to middle cranial fossa. It transmits optic nerve and its meninges and ophthalmic artery. It is 6-11mm long.

SUPERIOR ORBITAL FISSURE:

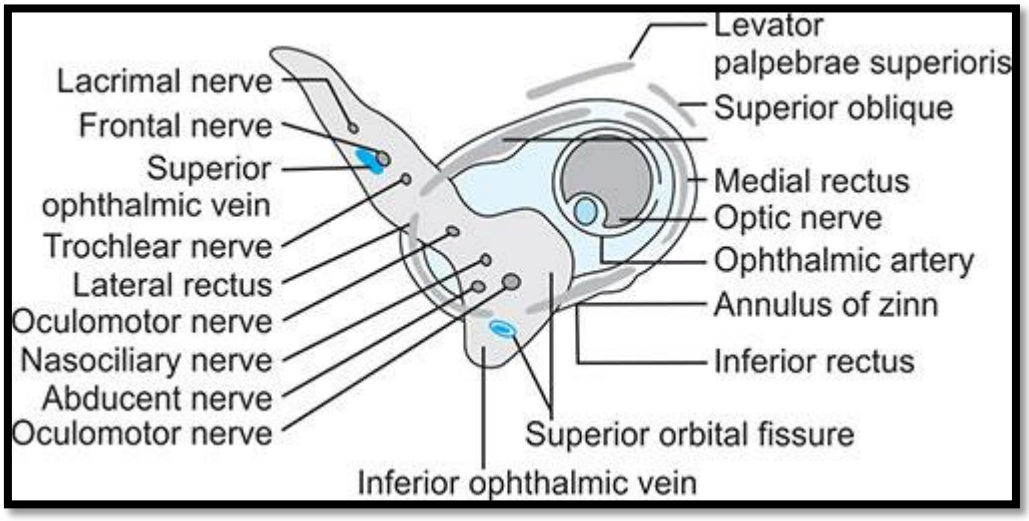


Figure 7: Superior Orbital Fissure[80].

- It is a comma shaped aperture bounded by lesser and greater wings of sphenoid.
- Lies lateral to optic foramen.
- Common tendinous ring divides it into upper, middle and lower parts[80].

INFERIOR ORBITAL FISSURE

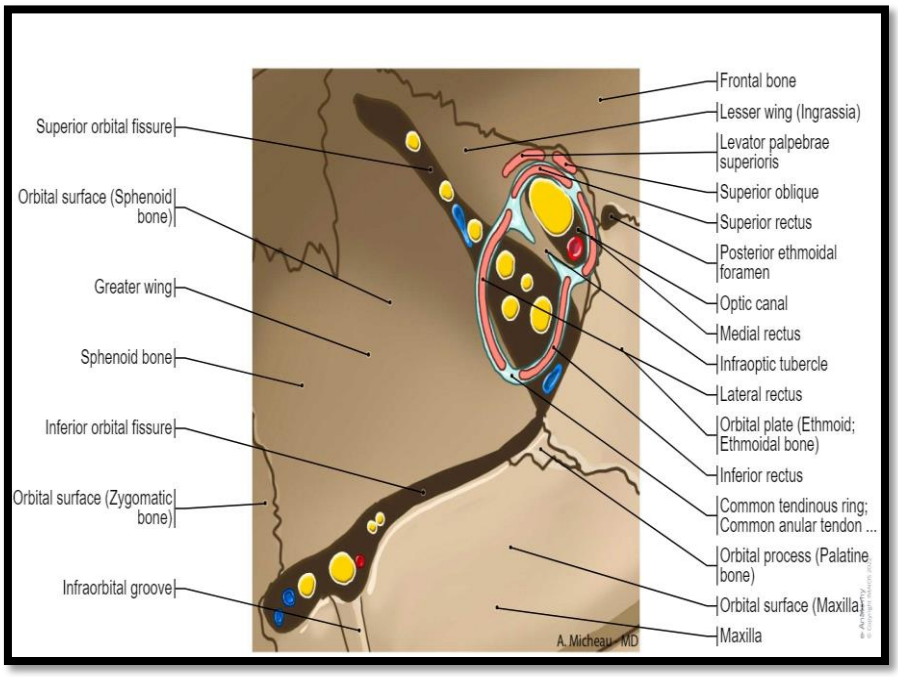


Figure 8: Inferior Orbital Fissure[80].

- Lies between greater wing of sphenoid and maxilla
- Closed by periorbita and muscle of Muller.
- Communicates with pterygopalatine and infratemporal fossae
- Transmits infraorbital nerve.

PERIORBITA

- Periosteum lining the surface of the orbital bones.
- Loosely adherent to bone. Firmly adherent at orbital margin, superior and inferior fissures, optic canal, lacrimal fossa and sutures.
- Dura of the optic nerve is adherent to it.
- Thickened at the orbital margin to form arcus marginale to which septum orbitale is attached.
- Splits at posterior lacrimal crest to enclose lacrimal sac and reunites at anterior lacrimal crest.
- Thickened at the orbital apex to form the common tendinous ring of Zinn.
- Sensory supply ophthalmic nerve.

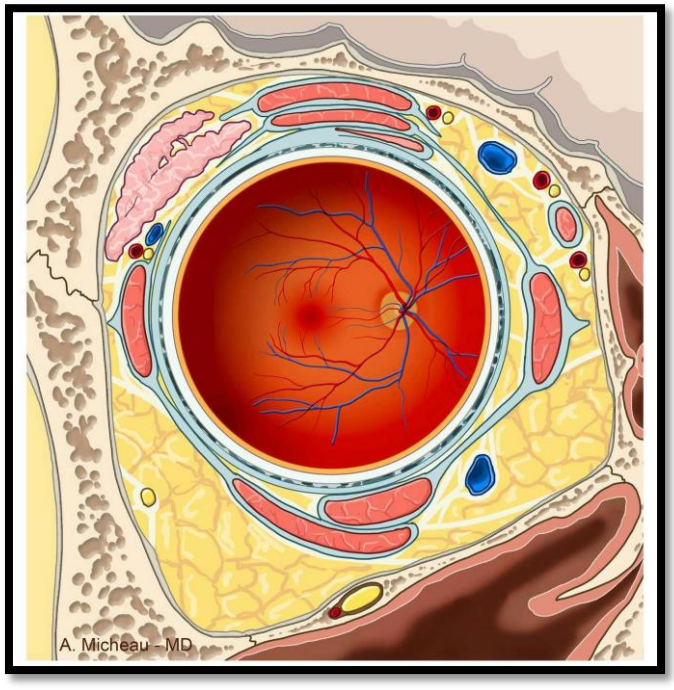


Figure 9: Peri Orbita[80].

ORBITAL FASCIA: Thin connective tissue membrane lining the various intra-orbital structures.

FASCIA BULBI (TENON'S CAPSULE)

Envelops Globe from limbus to the optic disc. Inner surface is firmly attached tosclera by fine trabeculae. Outer surface lies in contact with orbital fat posteriorly and subconjunctival tissue anteriorly with it merges at the limbus. At the distal end of opticnerve, it fuses with the dural sheath. It is pierced posteriorly by the optic nerve, ciliary nerves and vessel just behind the equator by venae vorticose anteriorly by extra ocular muscles.

FASCIAL SHEATHS OF EXTRAOCULAR MUSCLES:

At the points where the fascia bulbi is pierced by the muscles, it is reflected onto the muscle forming a sheath over it which becomes continuous with the perimysium.

FASCIAL EXPANSIONS

- Expansion of superior rectus is attached to the levator palpebrae superioris –ensure synergistic action.
- Expansion from inferior rectus is attached to capsulopalpebral fascia – analogueof levator aponeurosis.
- Expansion from superior oblique passes to the trochlea.
- Expansion from inferior oblique passes to lateral part of roof the orbitSuspensory ligament of Lockwood –Thickened sling of fascia.
- Extent - posterior lacrimal crest to lateral orbital tubercle.

Fusion of expansions from muscular sheaths of medial rectus, lateral rectus, inferior rectus, inferior oblique joined with thickened inferior part of Tenon's capsule. Superior transverse ligament of Whitnall – extends from trochlear pulley to lacrimal gland and its fossa. Superior sheath of levator + sheath of reflected tendon of superior oblique. Suspensory ligaments of fornices –

1. Superior: forward continuation of fibrous tissue between superior rectus andlevator. If cut during ptosis surgery →prolapse of upper fornix.
2. Inferior: forward continuation of fibrous tissue of lower lid retractors

ORBITAL SEPTA:

- Orbital septa – elastic and collagenous tissue, pass inward from periorbita to fascia bulbi. It forms supportive channels for ophthalmic veins.
- Intermuscular septa/ membrane: formed by the sheaths of the 4 recti.

APERTURES AT THE BASE OF THE ORBIT[80]

1. Superior aperture: comma shaped, between roof and upper surface of LPS.
2. Superomedial aperture: vertically oval, between reflected tendon on SO and medial check ligament. Infratrochlear nerve, dorsal nasal artery & angular vein pass through. Fat herniation common in old people.
3. Inferomedial aperture: vertically oval, between medial check ligament, origin of inferior oblique and lacrimal sac.
4. Inferior aperture: triangular, between IO, arcuate expansion of IO and floor.
5. Inferolateral aperture: oval, between arcuate expansion of IO and lateral check ligament.

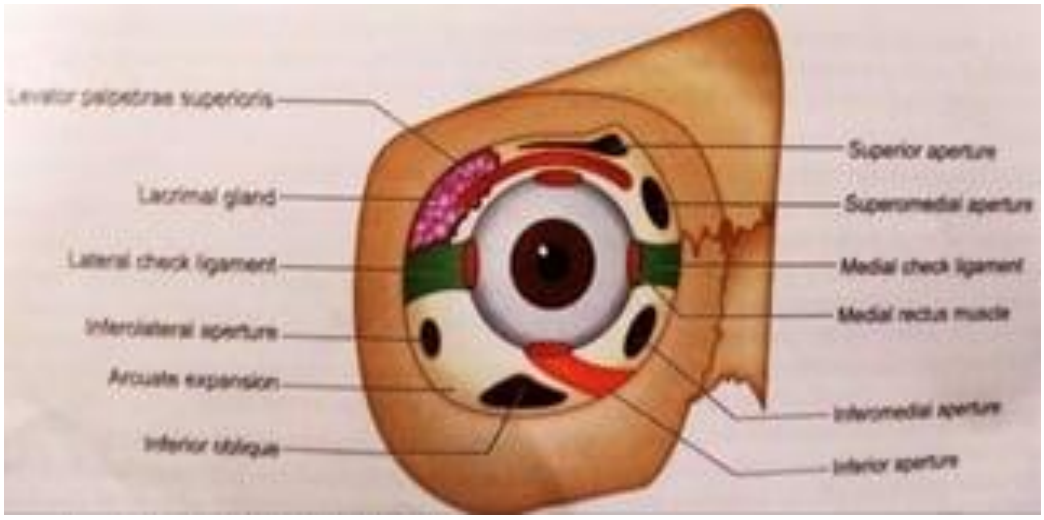


Figure 10: Apertures at the base of the orbit[80].

BLOOD VESSELS OF THE ORBIT[80]

Branches of the ophthalmic artery:

1. Central retinal artery
2. Lacrimal artery – lateral palpebral artery
3. Recurrent meningeal artery
4. Long and short posterior ciliary arteries
5. Muscular branches – anterior ciliary arteries
6. Supraorbital artery
7. Medial palpebral artery
8. Posterior and anterior ethmoidal arteries
9. Dorsal nasal artery
10. Supratrochlear artery

VENOUS DRAINAGE

Superior and inferior venous networks

Superior – lies above LPS

Inferior – near the floorMain

Venous Channels –

- Superior ophthalmic vein
- Inferior
- Middle
- Medial
- Angular vein
- Cavernous sinus

Nerves

- Occulomotor
- Trochlear
- Abducent
- Ophthalmic

SURGICAL SPACES IN THE ORBIT

SUBPERIOSTEAL SPACE:

- Between orbital bones and periorbita.
- Limited anteriorly by firm adhesion of periorbita to orbital rim

SUB-TENON'S SPACE

- Potential space between sclera and Tenon's capsule[81]

PERIPHERAL / ANTERIOR SPACE:

- Bounded peripherally by periorbita, internally by 4 recti and their intermuscular septa and anteriorly by septum orbitale
- Posteriorly merges with the central space.
- Tumours – cause eccentric proptosis
- Contents – fat, SO, IO, LPS, lacrimal, frontal, trochlear, anterior and posterior ethmoidal nerves, superior and inferior ophthalmic veins, lacrimal gland, part of the lacrimal sac
- Approach – anterior orbitotomy[82]

CENTRAL SPACE (muscular cone / posterior / retrobulbar)

- Bounded anteriorly by Tenon's capsule, peripherally by recti and their intermuscular septa.
- Posteriorly where the septa are deficient it is continuous with the peripheral space.
- Contents: ophthalmic nerve and its meninges, occulomotor, abducent, nasociliary nerve and narosciliary ganglion, ophthalmic artery, superior ophthalmic vein, fat.
- Tumours→cause axial proptosis.
- Approach – lateral orbitotomy[83].

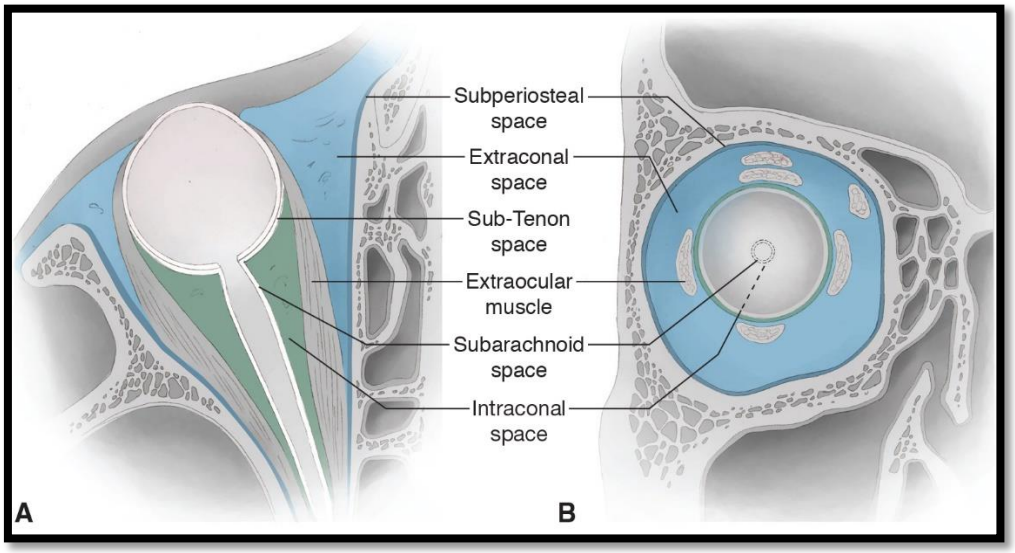


Figure 11: Surgical spaces in the orbit[83].

TECHNIQUES OF OCULAR ANAESTHESIA[84]

Topical anaesthesia: Commonly used agents:

1. Lignocaine: 1-4%
2. Proparacaine: 0.5%
3. Benoxinate: 0.4%
4 Bupivacaine: 0.5-0.75%
5. Tetracaine: 0.5%

Variations in Topical anesthesia

1. Bloomberg's ophthalmic ring
2. Rosenthal deep topical fornix applied pressurized sponges soaked in anaesthetic, are placed in the superior and inferior fornices after which honan balloon is placed over the closed eye and a pressure of 30-35 mmHg is applied.
3. Topical anaesthesia combined with perilimbal anaesthesia is used to perform painfree scleral tunnel incisions.
4. Intra cameral anaesthesia.

To improve analgesia LA is injected into the anterior chamber. Most widely used to adjunct to topical anaesthesia for cataract surgery. Drug should be preservative free. Lignocaine 1% is the most popular solution used. Anaesthetic solutions are washed using viscoelastic after 15-20 seconds.

Orbital injections:

Peribulbar block: Here the anaesthetic solution is injected into the extraconal space.

Technique:

The patient in supine position is asked to look straight ahead in primary position. A 24-25 mm long 23-26 Gauge needle is injected transconjunctivally or trans cutaneously at the junction of the medial 2/3rd and lateral 1/3rd of the lower lid held perpendicular to the orbital margin and

advanced adjacent and parallel to the orbital floor for about 2.5 cm. 5 ml is injected into the lateral adipose tissue of the orbit after aspiration to rule out possible entry into the blood vessel. Filling of the superior lid furrow and drooping of the upper lid are early signs of the block coming into action. This is the technique of single point anaesthesia. Then ocular compression is applied for about 10 minutes. Then just medial to the medial canthus same needle is inserted to a depth of 2.5 cm and further 3 ml is injected. Alternatively, second injection may be given just inferomedial to the supra orbital notch. This is two-point anaesthesia. Anaesthesia and analgesia begin in 5 minutes and maximum within 15 minutes. Supplemental injections may be necessary inferiorly for persisting inferolateral movements and superiorly for residual superior and medial movements. Proptosis and conjunctival oedema are common and benign.

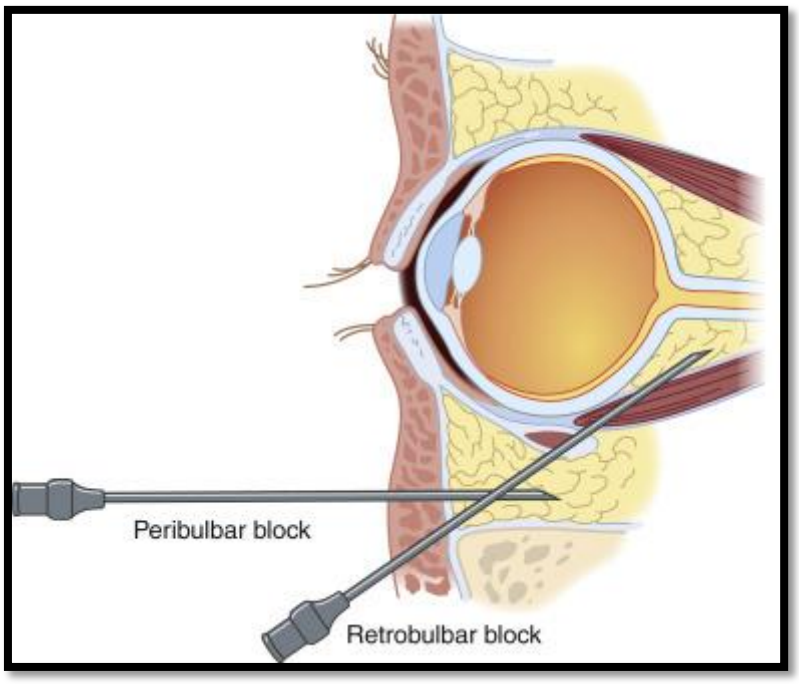


Figure 12: Peribulbar block[84].

Uses:

- Cataract surgery
- Glaucoma surgery
- Keratoplasty
- Vitreoretinal surgery
- Strabismus surgery

Complications:

- Spread sub cutaneously to the other eye
- Larger injected volume 6-8 ml can cause increase in intra ocular pressure
- Peri orbital ecchymosis
- Transient brightness on initial exposure to operating microscope, less visual extinction
- Potential for Globe perforation
- Vertical diplopia due to myotoxicity of the inferior rectus muscle
- Post-operative ptosis, due to involvement of levator palpebrae muscle.

RETROBULBAR BLOCK:

PROCEDURE:

Here the anaesthetic agent is injected into the intraconal space. A 31mm long 25-gauge needle is injected transconjunctivally or transcutaneously in inferotemporal quadrant at the junction of the lateral 1/3rd and medial 2/3rd of the inferior orbital margin. The needle is directed posteriorly, upward and medially towards the lower edge of the inferior orbital fissure at the apex of the orbit or towards midway between the occiput and the opposite mastoid process. Needle enters the central space behind the Globe. As the needle pierces the intermuscular septum between the lateral and inferior rectus the feel is altered. Globe is continuously observed during the needle placement. 2-4 ml injected after aspiration. Ocular compression enhances the effect. It does not however result in akinesia of the orbicularis muscle. So separate facial block needs to be given if total lid akinesia and absence of squeezing is desired. The classic retrobulbar block described by

Atkinson, the patient was asked to gaze up and in to move the facial elements connecting the recti muscles out of the path of the needle. However, it brings the macula and the optic nerve directly in the path of the needle. So, it is recommended that the patients gaze be directed straight ahead or slightly down and out.

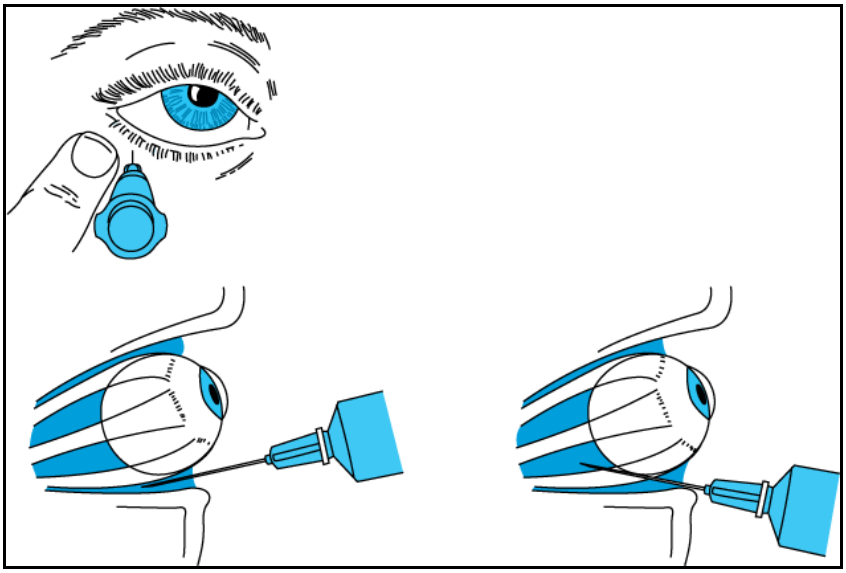


Figure 13: Retrobulbar block

Complications:

- Retrobulbar hemorrhage –more common in older patients with fragile vessels, patients with hematological and vascular disease, coagulation failure and drug therapy with aspirin or NSAID. It can lead to proptosis, increase in intra ocular pressure and subconjunctival hemorrhage. If necessary, a lateral canthotomy is required to relieve the optic nerve compression.
- Direct trauma to the optic nerve, scleral perforation.
- CNS toxicity due to absorption of the local anaesthetic along the optic nerve sheath
- Trigemino-vagal reflex/oculocardiac reflex-manifested as bradycardia, hypotension, cardiac arrhythmia due to traction on the extra ocular muscle. If severe atropine can be given. Dose – 0.007 mg/kg.
- Brain stem anaesthesia-amaurosis, gaze palsy, dysphagia, cardiac arrest, shivering apnea, tachycardia, hypertension, loss of consciousness, dilation of pupils, seizures can occur.

SUB TENONS OR PARABULBAR BLOCK:

Surface anaesthesia followed by dissection, insertion of a canula and administration of LA in to sub tenons space. Inferonasal quadrant dissection is the commonest approach avoiding the area of surgery and risk of damage to the vortex veins. The lower lid is retracted with a lid speculum. Conjunctiva and tenons grasped with a non-toothed forceps 3-5mm from the limbus. Small snip 1-2mm made through the two layers with spring scissors. Sub tenons canula 12mm D shaped and 2 mm in diameter mounted on a syringe filled with LA passed into the sub tenons space. Small volume is injected initially to open up the space and reduce pain. Second injection larger in volume and is injected slowly. Volume may vary from 1-11 ml. Smaller volumes produce Globe anaesthesia while larger volumes are needed for globe akinesia. Previous detachment surgery, medial rectus or pterygium surgery in these cases insertion of the canula may be difficult. Care should be taken in myopes because of the presence of scleral thinning and staphyloma[85].

Complications:

- Pain on injection
- Chemosis
- Conjunctival hemorrhage
- Short action on muscle paresis
- Orbital hemorrhage
- Scleral perforation.

Unlike topical anaesthesia subtenons, retrobulbar, peribulbar block easily abolish iris, ciliary body sensation and can be used to produce globe akinesia.

FACIAL BLOCK: For intra ocular surgery it is necessary to block the facial nerve which supplies the orbicularis muscle so that the patient does not squeeze his lids. Orbicularis akinesia can be achieved by blocking the facial nerve at its terminal branches (van lint), superior branches (Atkinson block), proximal trunk (O'brien or Nadbath block)

VAN LINT BLOCK: Small skin wheal is raised at the lateral orbital rim and needle inserted along the inferotemporal rim for an inch or more and 3-5 ml of the anaesthetic is injected as the needle is withdrawn. Through the same wheal similar injection is given along the superotemporal rim. Side effects – oedema of the lids.

ATKINSONS BLOCK: Facial nerve is blocked midway between its emergence from the stylomastoid foramen and the orbicularis muscle. Needle is introduced through a skin wheal at the inferior border of the zygoma directly inferior to the lateral orbital rim. First directed along the inferior edge of the zygomatic bone and then superiorly across the zygomatic arch aiming at the top of the ear. About 3 ml is injected.

SPAETH BLOCK: Proximal to the classical approach of O Brien over the mandibular condyle thereby catching the facial nerve before it divides. Fingers are placed over the posterior border of the mandible as superiorly as possible; needle is placed just anterior to the superior most finger. Then 5 ml is injected. Almost complete unilateral facial palsy is seen in 30 seconds.

NADBATH BLOCK: Injection in the concavity between mastoid process and the posterior border of the mandible. Skin wheal 1-2 mm anterior to the mastoid process. A 12 mm 26-gauge needle is used to the full depth of the needle, total of 3 ml. If the nerves in the jugular foramen are blocked it can cause dysphonia, dysphagia and respiratory arrest.

FRONTAL BLOCK: Frontal nerve has two branches-supra orbital and supra trochlear nerves supplyingthe upper lid. Useful for surgeries such as ptosis. A 4cm long needle is used to enter the orbit transcutaneously just below the midpoint of the supra orbital margin. The needle is directed towards the roof of the orbit and follows the contour for a distance of 4 cm, plunger is

aspirated to ensure that the needle is not in a blood vessel and about 2 ml of the anaesthetic is injected.

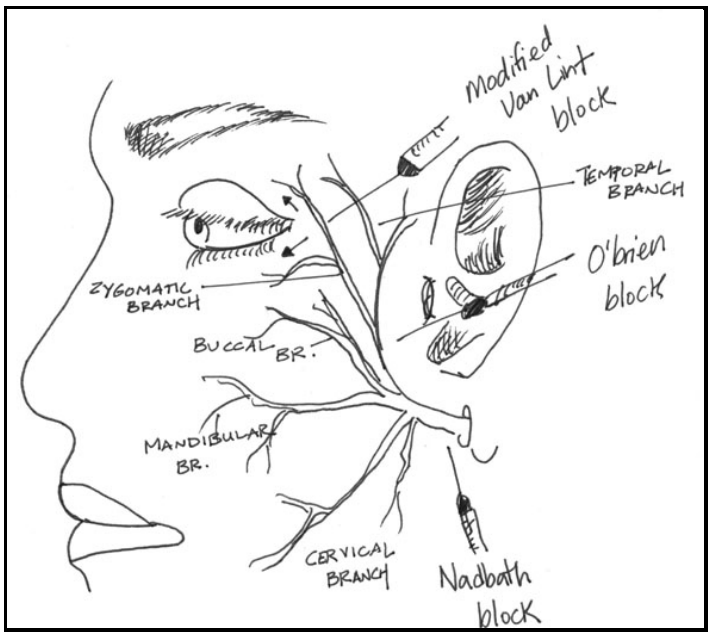


Figure 14: Facial nerve blocks

Other blocks in ophthalmic surgeries:

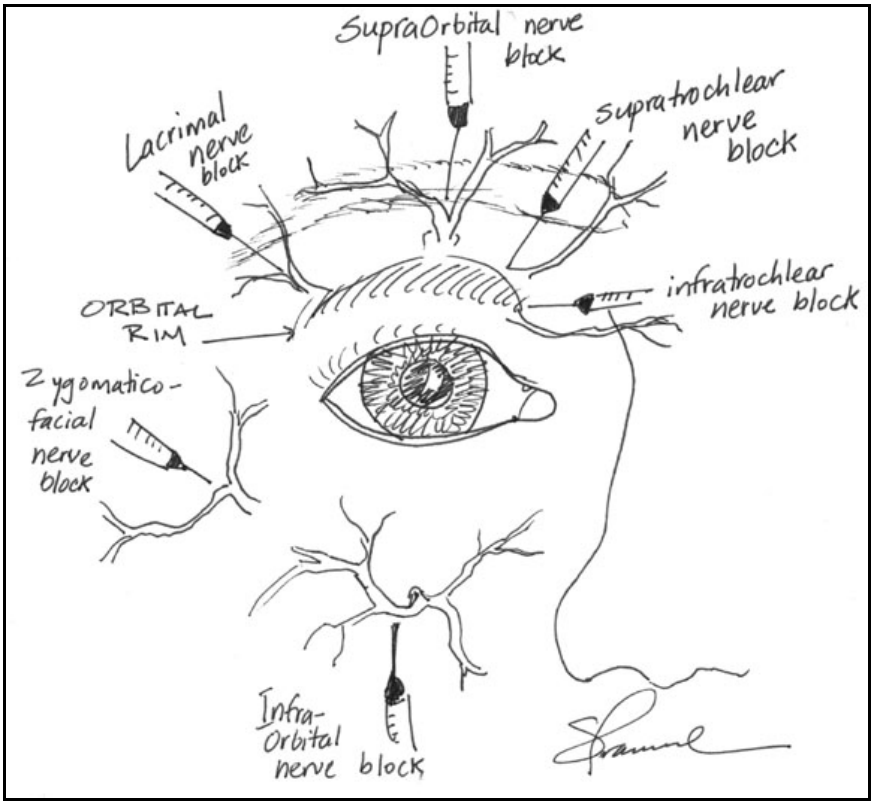


Figure 15: Other blocks in ophthalmic surgeries.

Complications:

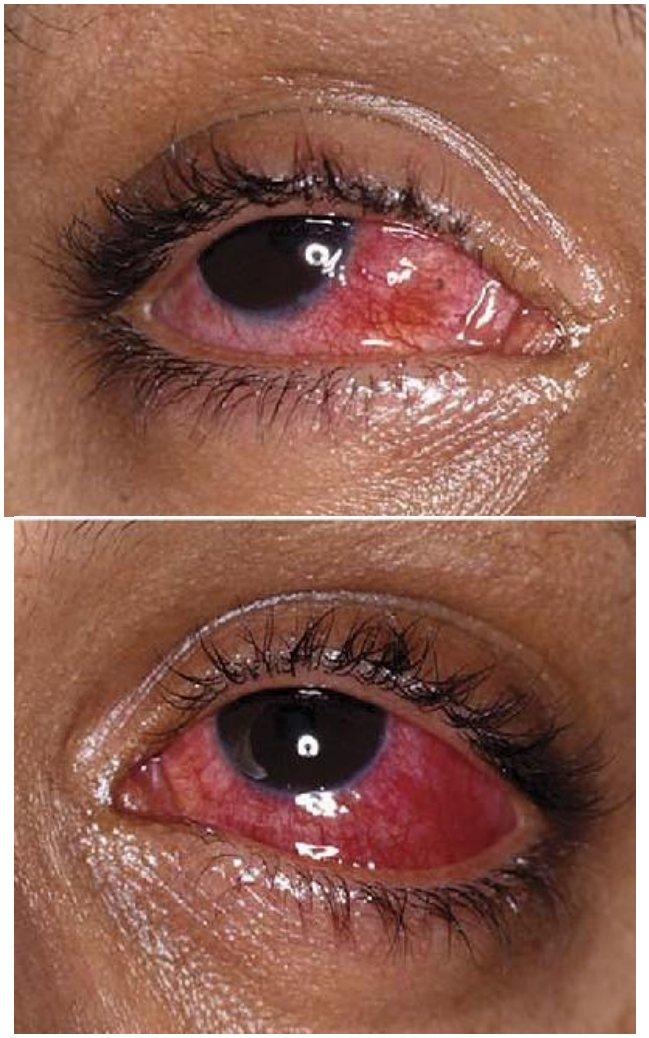


Figure 16: Chemosis and Congestion

Figure 17: Sub conjunctival hemorrhage

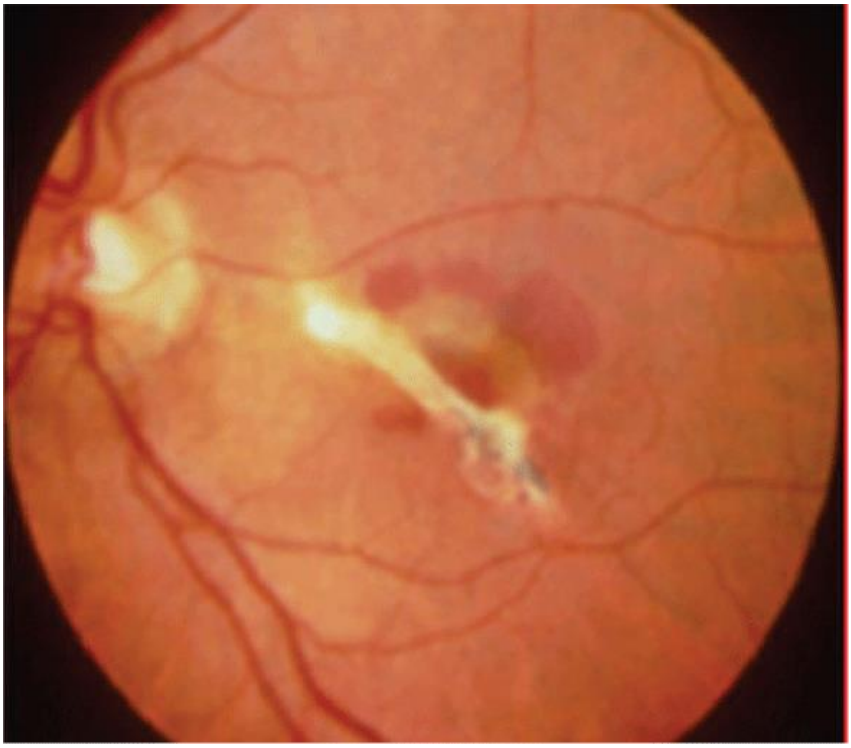


Figure 18: A needle tract and intra retinal hemorrhage following Globe perforation in retrobulbar anaesthesia.

CLASSIFICATION OF LOCAL ANAESTHETICS

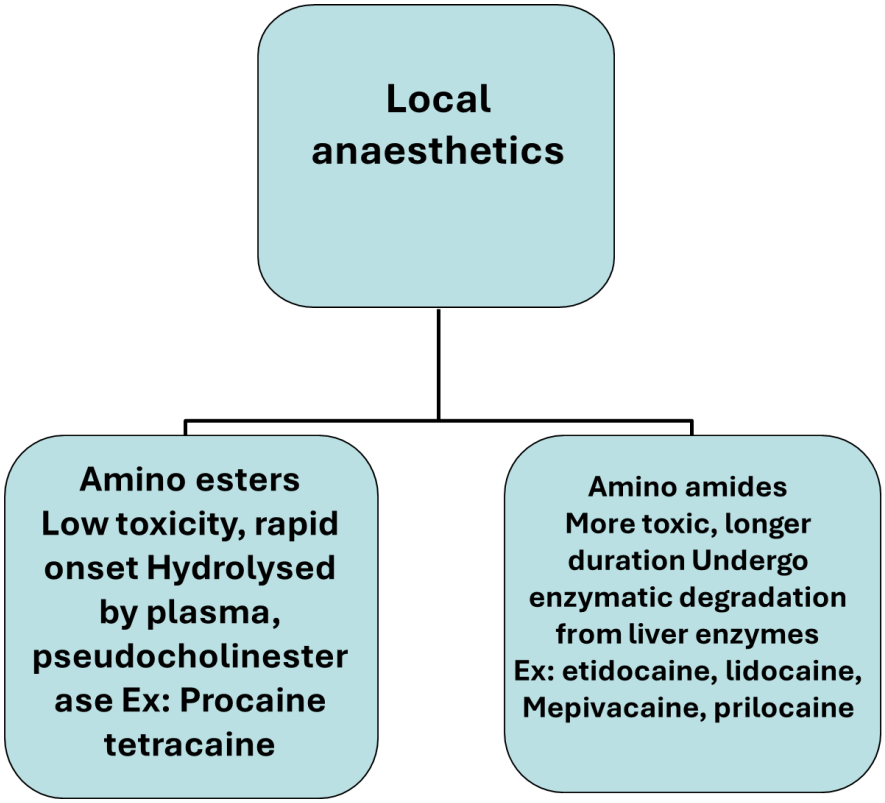


Figure 19: Classification of Local Anaesthetics

MECHANISM OF ACTION: Local anaesthesia blocks movement of sodium across nerve membranes so thatthe depolarization never reaches the threshold potential.

Effectiveness of the local anaesthetic dependent on various properties:

1. Nerve membrane is made up of mostly lipid. So, the intrinsic activity depends onthe lipid solubility.
2. Duration of action depends on the binding affinity for proteins in the nerve membrane.
3. Rapidity of onset depends on the pH and pKa. The proportion of the agent in thebase form determines the onset of action.
4. Spectrum of local anaesthetics available to produce anaesthesia are as short as 20 minutes to 12-24 hours.

Table 1: Spectrum of Local Anaesthetics Available

LA	ONSET FACTOR	DURATION	CONCENTRATION
Benoxinate	6-20 sec	15 minutes	Topical (0.4%)
Proparacaine	15-30 sec	15-20 min	Topical (0.5%)
Amethocaine	10-25 sec	10-20 min	Topical (0.5-1%)
Lignocaine	10-35 sec 5-10 min	15-20 min 30-60 min	Topical (4%) Infiltration (0.5-1%)
Bupivacaine	moderate	75-90 min	Infiltration (0.25-0.75%)
Ropivacaine	moderate	11/2-6 hours	Infiltration (1%)

LIGNOCAINE:

Lignocaine first introduced in 1948, is now the most widely used local anaestheticfor both topical and infiltration anaesthesia. It is an amide linked local anaesthetic with the following structure.

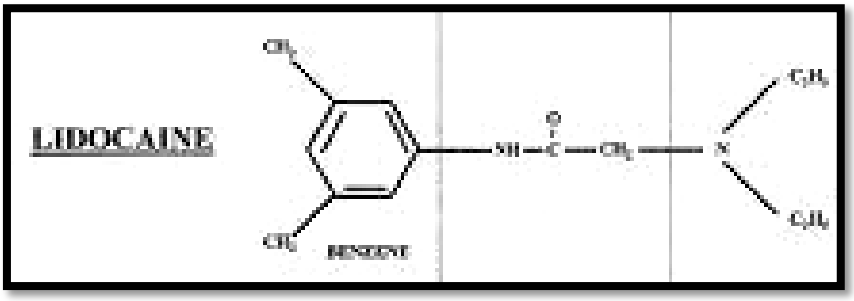


Figure 20: Structure of Lignocaine

Lignocaine has a faster onset of action as compared to Bupivacaine. It interacts with receptors situated in the voltage sensitive sodium channels and raises the threshold for the channel to open, decreasing the entry of sodium ions during the upstroke of action potential. Thus, they block the generation and conduction of the nerve impulse. The adverse effects of Lignocaine include hypersensitivity reactions, cardiovascular toxicity manifested as bradycardia, cardiac arrythmias, vascular collapse, hypotension and CNS toxicity in the form of tremors, convulsions and even respiratory arrest.

BUPIVACAINE: Bupivacaine 0.5% is a stable long-acting amide linked to local anaesthetic with a slower onset of action and potency as compared to Lignocaine. Its chemical structure is as follows

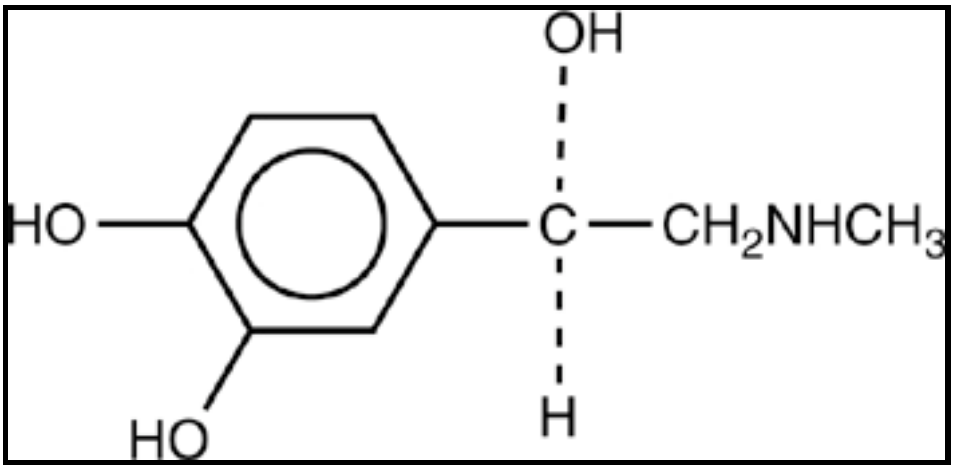


Figure 21: Structure of Bupivacaine.

EPINEPHRINE: Local anaesthetics produce vasodilation by direct relaxant effect on vascular smooth muscle. Epinephrine in dilute concentrations (1:200000) will counter vasodilatation producing longer acting block. It also counters depressing effects on the CVS and reduces bleeding.

Hyaluronidase: Is as enzyme preparation that reversibly depolymerizes the polysaccharide hyaluronic acid present in the intracellular matrix. Commercially available Hyaluronidase is of bovine origin and is supplied for clinical use as a white freeze-dried, water-soluble powder containing 1500 1U per ampule. It also contains traces of tyrosine. The powder was dissolved in 1 cc of Lignocaine to give a concentration of 50 IU/cc. It limits the transient rise in IOP that may occur transiently after peribulbar injection. There have been cases of allergy recorded, hence caution is advised in atopic individuals.

SODIUM BICARBONATE: Sodium bicarbonate is available as a 7.5% solution in 10 ml vials. It was mixed with Lignocaine 2% for use in anaesthetic solution. 1 ml of Sodium bicarbonate was added to 30 ml Lignocaine slowly to prevent precipitation. Sodium bicarbonate is a basic substance which reduces the acidic nature of the anaesthetics available for use in peribulbar anaesthesia.

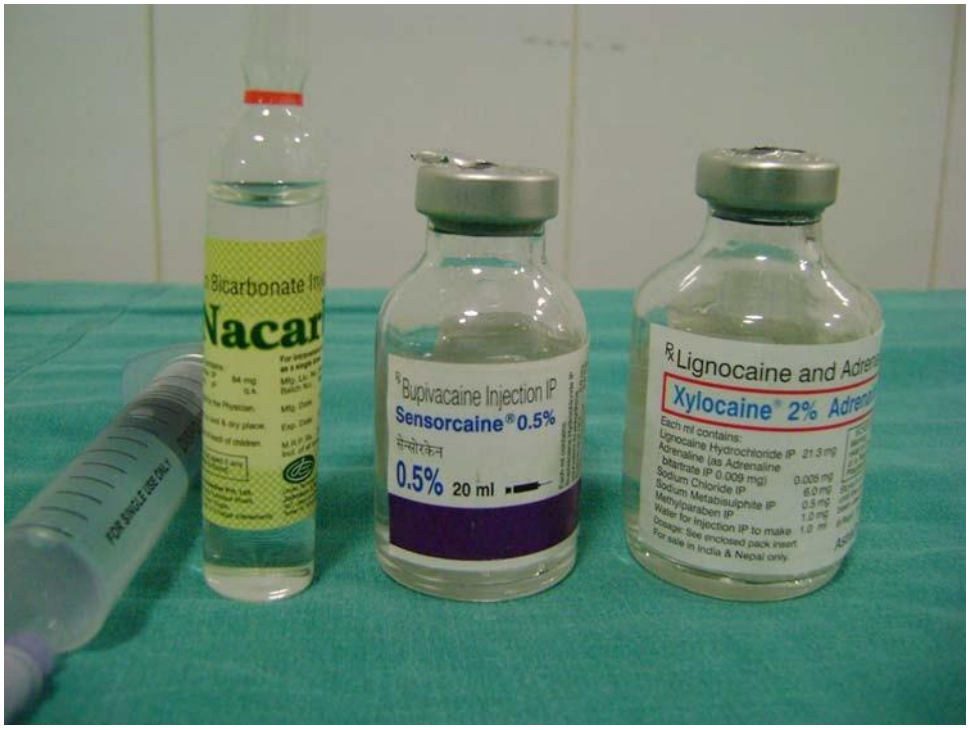


Figure 22: Ocular anaesthetic agents

MATERIALS AND METHODS

MATERIALS AND METHODS

SOURCE OF THE DATA: This study was conducted in the department of Ophthalmology, R. L. Jalappa Hospital and Research centre at Kolar.

STUDY TYPE: Prospective, comparative study

DURATION OF STUDY: August 2022 to December 2023

INCLUSION CRITERIA: All patients of either sex above 40 years of age undergoing cataract surgery with normal investigations were included in the study.

EXCLUSION CRITERIA:

1. Hypersensitivity to anaesthetic agent.
2. Pre-existing ocular muscle paresis, neurological deficit.
3. Co-existing inflammatory conditions of eye.
4. Hypertensive patients.
5. History of trauma to the eye
6. Complicated cataracts.
7. History of previous surgical intervention in the eyes.

Sampling Method: Simple randomization was used for allocation of subjects into two groups.

Even number = Group A

Odd number = Group B

Sample size:

Was estimated based on the difference in proportion of subjects who had time of onset 11-15mins between group A (with Hyaluronidase) and group B (Sodium bicarbonate). Proportion of subjects who had time of onset 11-15mins in group A (with Hyaluronidase) was 25.5% and in group B (Sodium bicarbonate) was 9% from the study by **Col RP Gupta**[32]. Using these values in the below mentioned formula

$$N = \frac{2\left(\left(Z_{\alpha/2} + Z_{\beta}\right)^2 \times P \times (1-P)\right)}{(P_1 - P_2)^2}$$

Where,

- $Z_{\alpha/2=} Z_{0.05/2}=Z_{0.025}$ = 1.96 at type 1 error of 5%
- $Z_{\beta}=Z_{0.20}$= 1.28= At 80% power
- $p_1 - p_2$= Difference in proportion in the two different groups = 16.5%
- P= Pooled prevalence =

$$\frac{[\,Proportion\ in\ group\ A\ (Sodium\ bicarbonate)\ (P_1)\ +\ group\ 2\ (Hyaluronidase)\ (P_2)]}{2}$$

$$= \frac{[25.5\ +\ 9]\ =\ 17.25}{2}$$

$$N\ =\ \frac{(2\ \times\ 17.25\ \times\ 82.75\ (1.96\ +\ 0.84)^2)\ =\ \ 82\ in\ each\ group}{16.5 \times 16.5}$$

Considering non-response rate of 10%, 82 + 8.2 = 90.2 ≈ **91** minimum subjects were included in each group.

METHOD OF COLLECTION OF DATA:

All the 182 patients fulfilling the inclusion criteria were divided into Group A (Hyaluronidase) and Group B (Sodium bicarbonate) randomly. After obtaining the written informed consent all the patients underwent similar protocol for standard cataract evaluation, which consisted of thorough history of the illness, previous ocular surgery, recording of visual acuity, intraocular pressure, slit lamp examination, fundus evaluation and intraocular lens calculation by Sanders-Retzlaff-Kraff 2 method followed by certain basic investigations such as CBC, Blood sugar levels, HIV, HBsAg, ECG.

GROUP A: Injection of 2% Lidocaine with Hyaluronidase

GROUP B: Injection of 2% Lidocaine with Sodium bicarbonate buffer

All patients were on oral Ciprofloxacin 500mg BD and Ciprofloxacin 0.3% eye drops hourly one day before the surgery. Preoperatively pupils were dilated with tropicamide with phenylephrine 0.5% or 1% drops along with flurbiprofen 0.03% drops.

TECHNIQUE:

Compulsory "Test dose" of the local anaesthetic injection was given before peribulbar block in both the groups with the respective anaesthetic solutions prepared under aseptic precautions.

GROUP A: Injection of 2% Lidocaine with Hyaluronidase 0.5% Bupivacaine (3ml) and 2% Lignocaine (3ml) with Hyaluronidase (1500 IU in 30ml of Lignocaine) was injected at the infero temporal quadrant, using one inch 24-gauge needle, 3ml injected at the junction of medial 2/3 and lateral 1/3 of the lower eyelid with eye in primary position of gaze, remaining 3ml of the solution was injected at superior orbital notch of the upper eyelid**.**

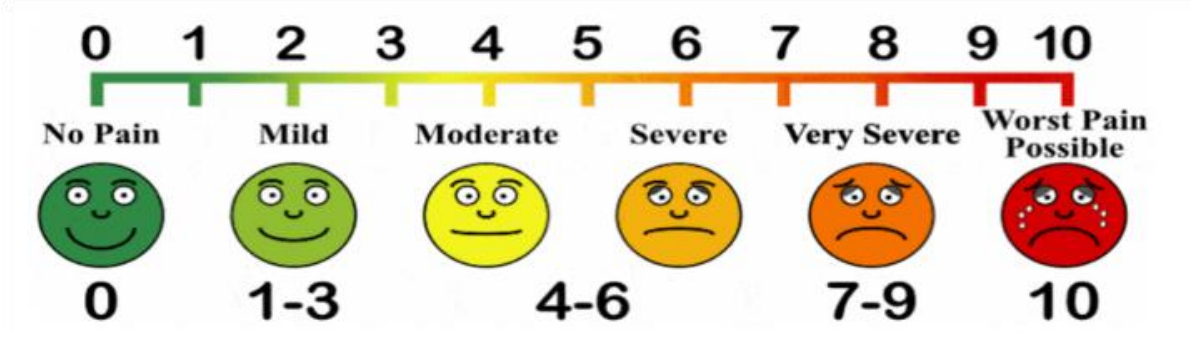
GROUP B: Injection of 2% Lidocaine with Sodium bicarbonate buffer 0.5% Bupivacaine (3ml) and 2% Lignocaine (3ml) with 7.5% sodium bicarbonate (1ml in 30cc of Lignocaine), using one inch 24-gauge needle 3ml injected at the junction of medial 2/3 and lateral 1/3 of the lower eyelid with eye in primary position of gaze, remaining 3ml of the solution was injected at superior orbital notch of the upper eyelid, for every patient and were observed for any adverse reaction.

Routine Manual Small incision cataract surgery was performed through a 6mm sclerocorneal tunnel incision. Analgesia and akinesia were graded using the following criteria in both the groups.

ANALGESIA: was assessed and graded by subjective grading called Visual Analogue pain scale (VAS).[86]

- Pain at the time of administration of block.
- Intraoperative.
- Post-operative analgesia (4hrs after surgery)

1. Grade 0 - No pain
2. Grade 1-3 - Mild pain
3. Grade 4-6 - Moderate to severe pain
4. Grade 7-9 - Severe to very severe pain
5. Grade 10 - worst possible pain



AKINESIA:

Grade 1-

- ❖ Complete anaesthesia and akinesia as demonstrated by:
- ❖ Complete absence of eye movements
- ❖ Complete anaesthesia of cornea and conjunctiva
- ❖ Painless insertion of superior rectus bridle suture

Grade 2 – Akinesia and anaesthesia considered adequate as demonstrated by: Eye movements less than 15° in any direction of gaze as above

Grade 3- Unsuccessful akinesia and anaesthesia as judged by: Eye movements more than 15° in any gaze Painful insertion of superior rectus bridle suture

Evaluation of lid akinesia: (lid closure and squeezing by orbicularis and lid opening by the levator palpebrae muscle) using a three-point scale (0–2) in which:

1. 0 refers to complete akinesia.
2. 1 refers to partial movement in either or both eyelid Margins.
3. 2 refers to normal movement in either or both eyelid margins.

For assessment of lid akinesia, the patients were asked to open their eyelids and then squeeze them together maximally.

Statistical analysis [87,88,89]

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. Chi-square test was used as test of significance for qualitative data. Continuous data was represented as mean and standard deviation.

Normality of the continuous data, was tested by Kolmogorov–Smirnov test and the Shapiro–Wilk test.

Independent t test was used as test of significance to identify the mean difference between two quantitative variables.

Graphical representation of data: MS Excel and MS word were used to obtain various types of graphs such as bar diagram.

p value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Statistical software: MS Excel**,** SPSS version 22 **(**IBM SPSS Statistics, Somers NY, USA) was used to analyze data.

Ethical consideration:

1. Institutional Ethical clearance was obtained prior to the start of the study
2. Informed consent was obtained from all the patients recruited prior to the start of the study
3. Standard of Care was provided to all the patients during the study period and follow-up.

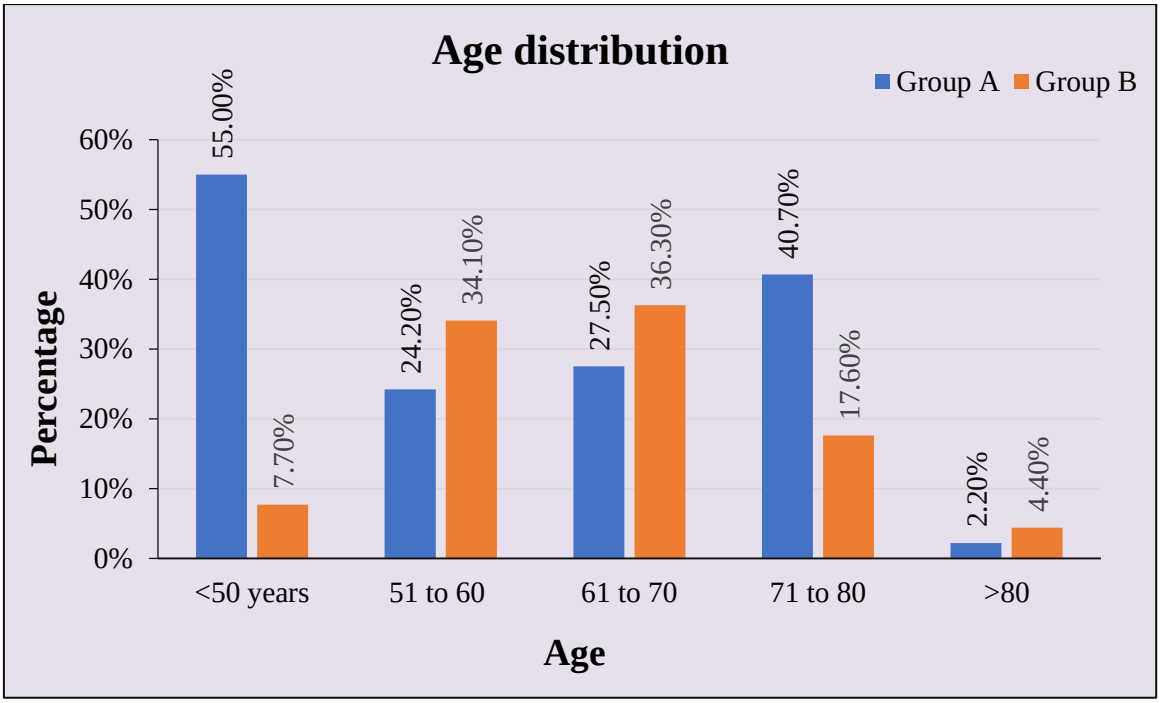
OBSERVATIONS AND RESULTS

OBSERVATIONS AND RESULTS

In Group A, majority of subjects were in the age group 71 to 80 years (40.7%) and in Group B, majority of subjects were in the age group 61 to 70 years (36.3%). There was significant difference in age distribution between two groups.

Age	Group A		Group B	
	Count	%	Count	%
<50 years	5	5.5	7	7.7
51 to 60 years	22	24.2	31	34.1
61 to 70 years	25	27.5	33	36.3
71 to 80 years	37	40.7	16	17.6
>80 years	2	2.2	4	4.4
Total	91	100	91	100
χ 2 =11.953, df =4, p =0.018* **[Chi-square test]**				

Table 2: Age distribution comparison between two groups

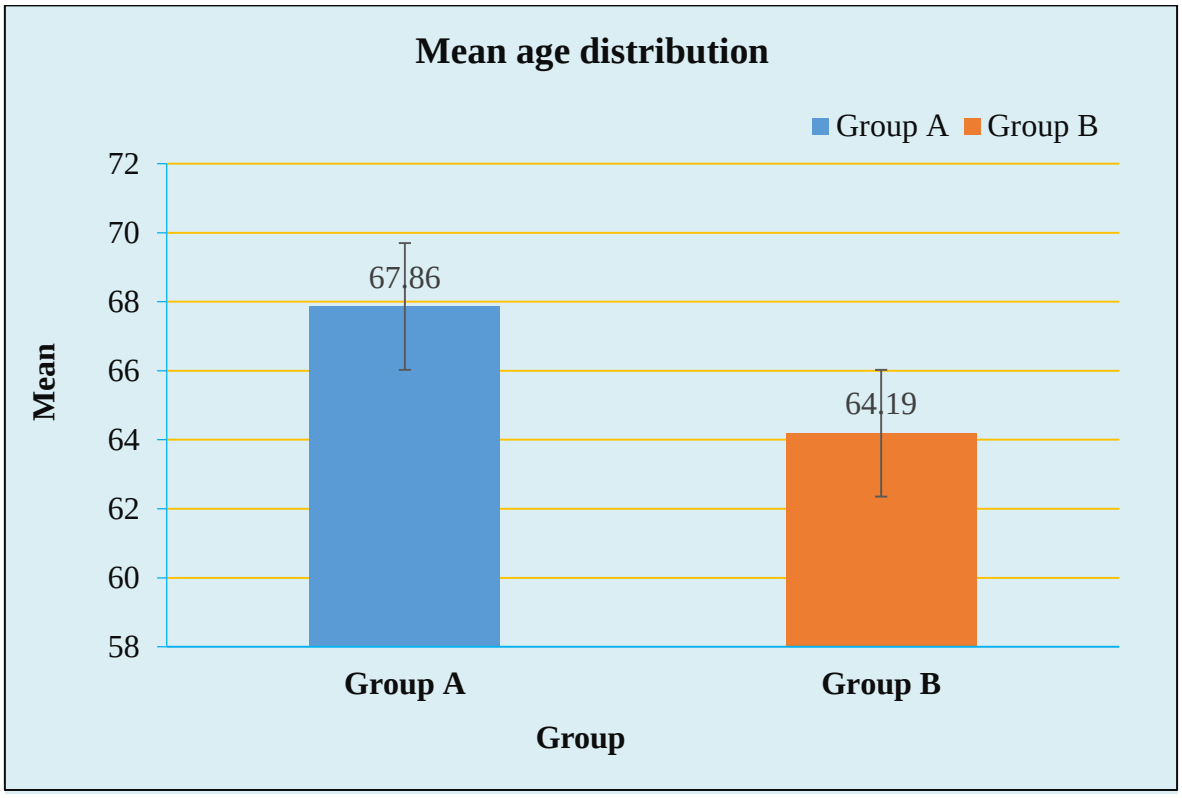


Graph 1: Bar diagram showing Age distribution comparison between two groups

Age	N	Mean	SD	P value
Group A	91	67.86	10.457	0.014*
Group B	91	64.19	9.396	
Independent Samples Test				

Table 3: Mean age distribution between two groups

Mean age of subjects in Group A was 67.86 ± 10.457 years and in Group B was 64.19 ± 9.396 years. There was significant difference in mean age between two groups.

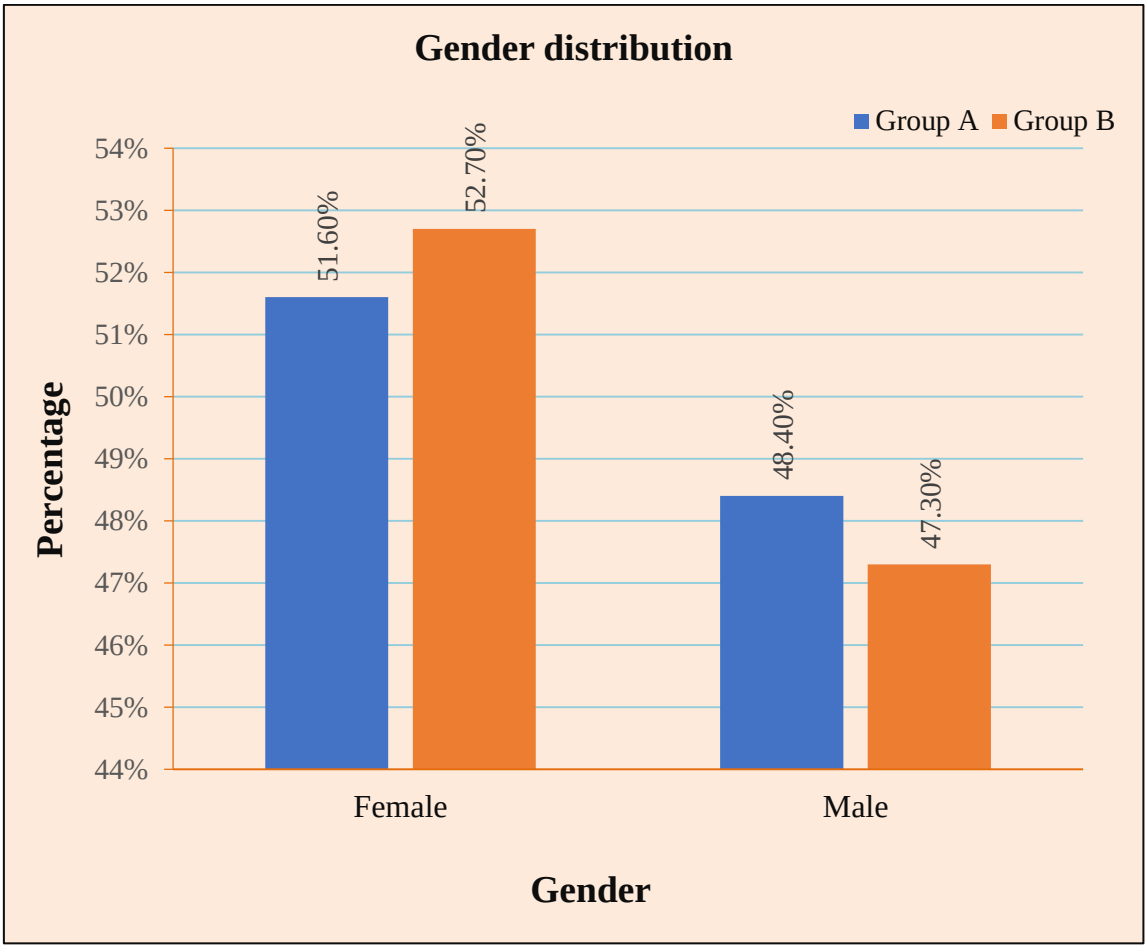


Graph 2: Bar diagram showing Mean age distribution between two groups

Gender	Group A		Group B	
	Count	%	Count	%
Female	47	51.6	48	52.7
Male	44	48.4	43	47.3
Total	91	100	91	100
χ 2 =0.022, df =1, p = 0.882 **[Chi-square test]**				

Table 4: Gender distribution comparison between two groups

In Group A, 51.6% were females and 48.4% were females and in Group B, 52.7% were females and 47.3% were females. There was no significant difference in Gender distribution between two groups.

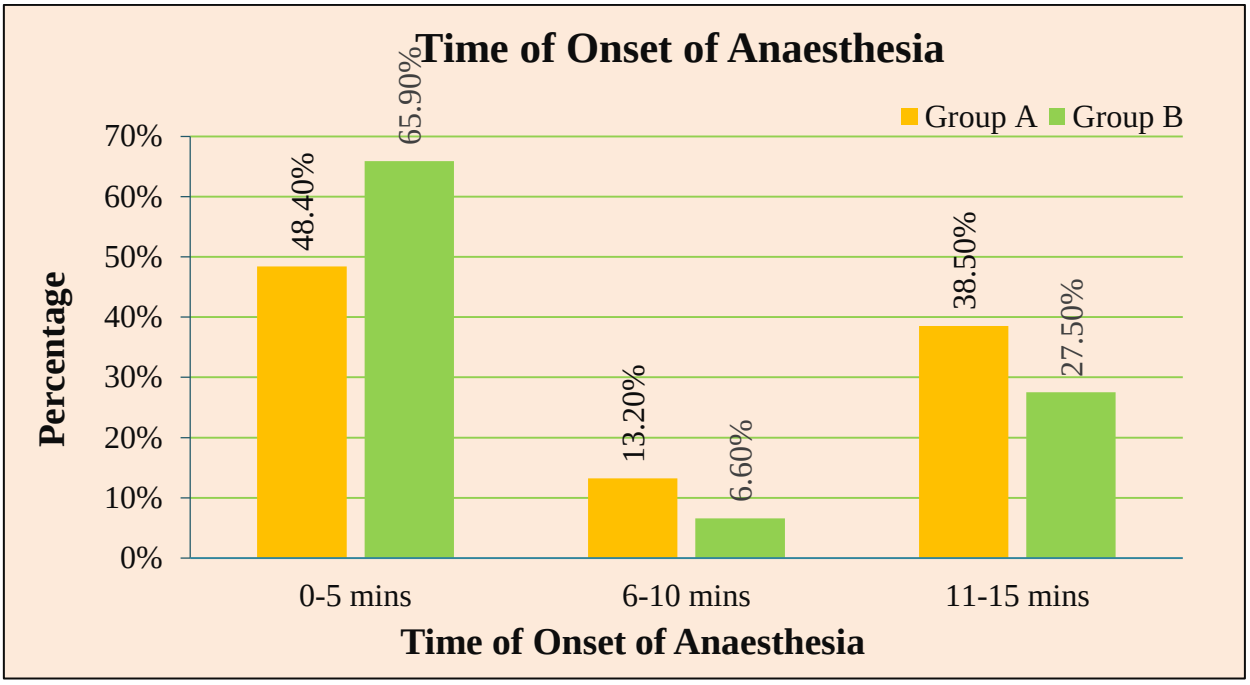


Graph 3: Bar diagram showing Gender distribution comparison between two groups.

Time of Onset of Anaesthesia	Group A		Group B	
	Count	%	Count	%
0-5 mins	44	48.4	60	65.9
6-10 mins	12	13.2	6	6.6
11-15 mins	35	38.5	25	27.5
Total	91	100	91	100
χ 2 =6.128, df =2, p = 0.047* **[Chi-square test]**				

Table 5: Time of Onset of Anaesthesia comparison between two groups.

Time of Onset of Anaesthesia in Group A was 0-5 mins in 48.4%, 6-10 mins in 13.2% and in 11-15 mins in 38.5%, in Group B was 0-5 mins in 65.9%, 6-10 mins in 6.6% and in 11-15 mins in 27.5%. There was significant difference in Time of Onset of Anaesthesia between two groups. Group B had lower time of onset compared to Group A.

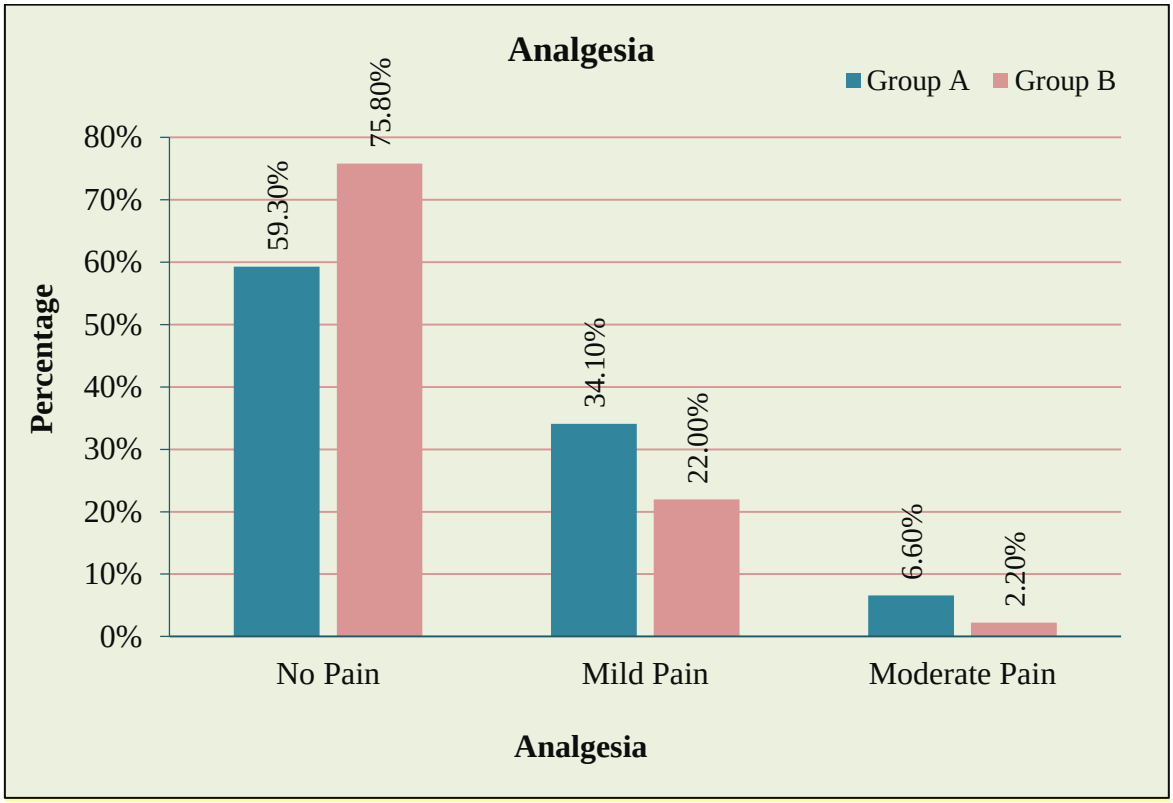


Graph 4: Bar diagram showing Time of Onset of Anaesthesia comparison between two groups.

Analgesia	Group A		Group B	
	Count	%	Count	%
No Pain	54	59.3	69	75.8
Mild Pain	31	34.1	20	22
Moderate Pain	6	6.6	2	2.2
Total	91	100	91	100
χ 2 =6.202, df =2, p =0.045* **[Chi-square test]**				

Table 6: Analgesia comparison between two groups

In Group A, 59.3% had No pain, 34.1% had mild pain and 6.6% had moderate pain. In Group B, 75.8% had no pain, 22% had mild pain and 2.2% had moderate pain. There was significant difference in Analgesia between two groups. Better Analgesia was achieved in Group B.

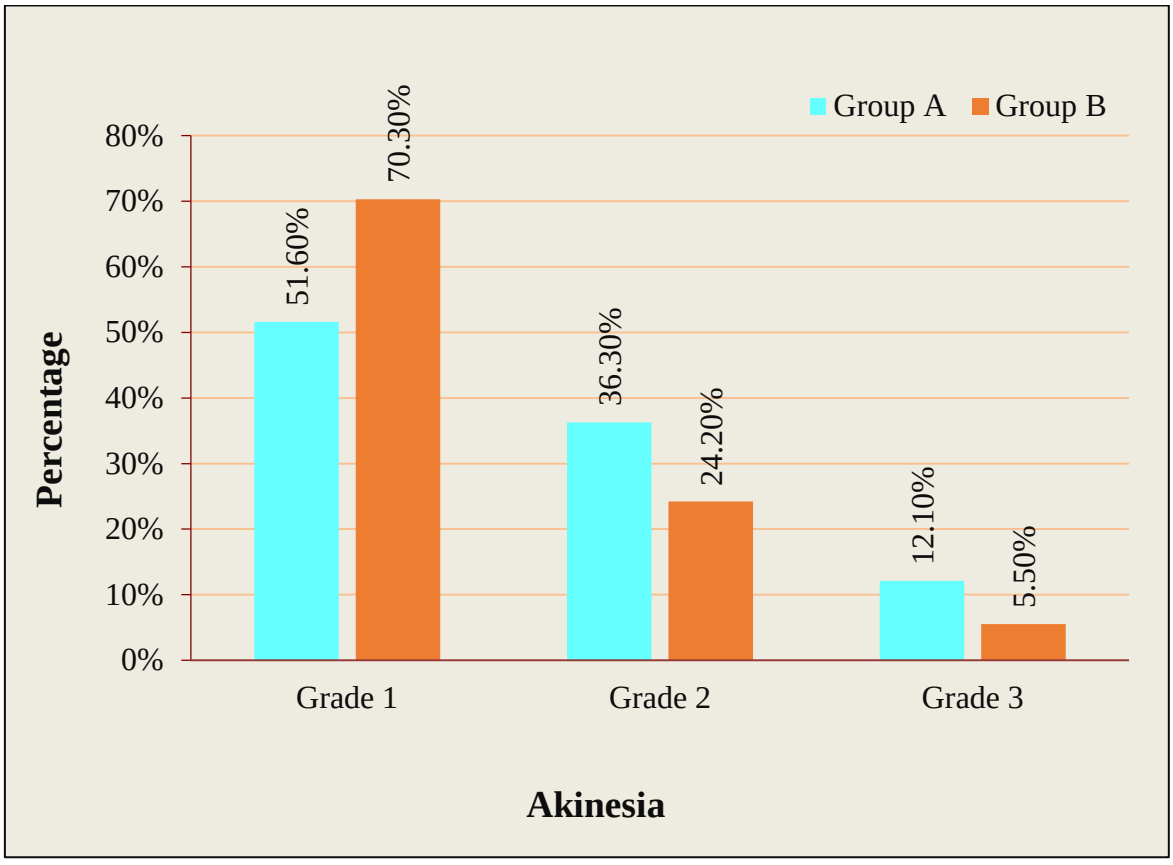


Graph 5: Bar diagram showing Analgesia comparison between two groups.

Akinesia	Group A		Group B	
	N	%	N	%
Grade 1	47	51.6	64	70.3
Grade 2	33	36.3	22	24.2
Grade 3	11	12.1	5	5.5
Total	91	100	91	100
χ 2 =7.054 df =2, p = 0.029* **[Chi-square test]**				

Table 7: Akinesia comparison between two groups

In Group A, 51.6% had Grade 1 Akinesia, 36.3% had Grade 2 Akinesia, 12.1% had Grade 3 Akinesia. In Group B, 70.3% had Grade 1 Akinesia, 24.2% had Grade 2 Akinesia, 5.5% had Grade 3 Akinesia. There was significant difference in Akinesia between two groups. Good Akinesia was achieved by Group B compared to Group A.

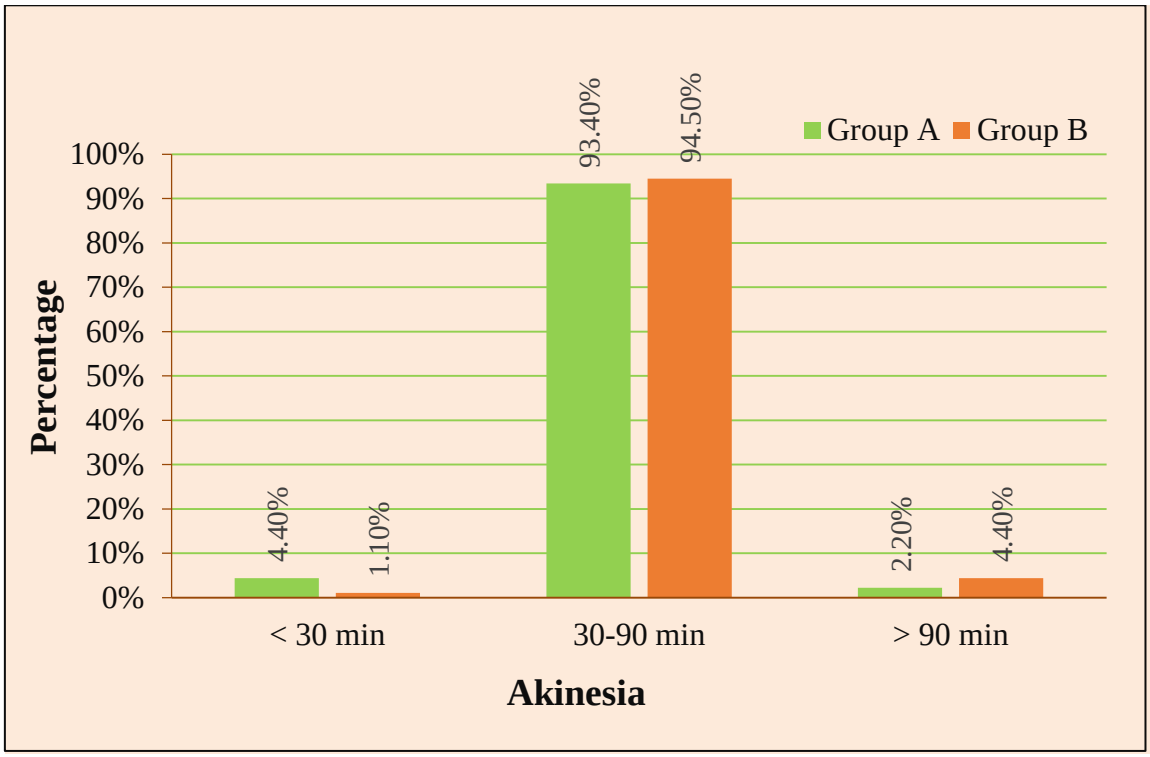


Graph 6: Bar diagram showing Akinesia comparison between two groups.

Duration of Anaesthesia	Group A		Group B	
	Count	%	Count	%
< 30 min	4	4.4	1	1.1
30-90 min	85	93.4	86	94.5
> 90 min	2	2.2	4	4.4
Total	91	100	91	100
χ 2 =2.473, df =2, p = 0.290 **[Chi-square test]**				

Table 8: Duration of Anaesthesia comparison between two groups

Duration of Anaesthesia in Group A was < 30 min in 4.4%, 30-90 min in 93.4% and >90 min in 2.2% and in Group B was < 30 min in 1.1%, 30-90 min in 94.5% and >90 min in 4.4%. Although Duration of anaesthesia was more in Group B, there was no significant difference in Duration of Anaesthesia between two groups.

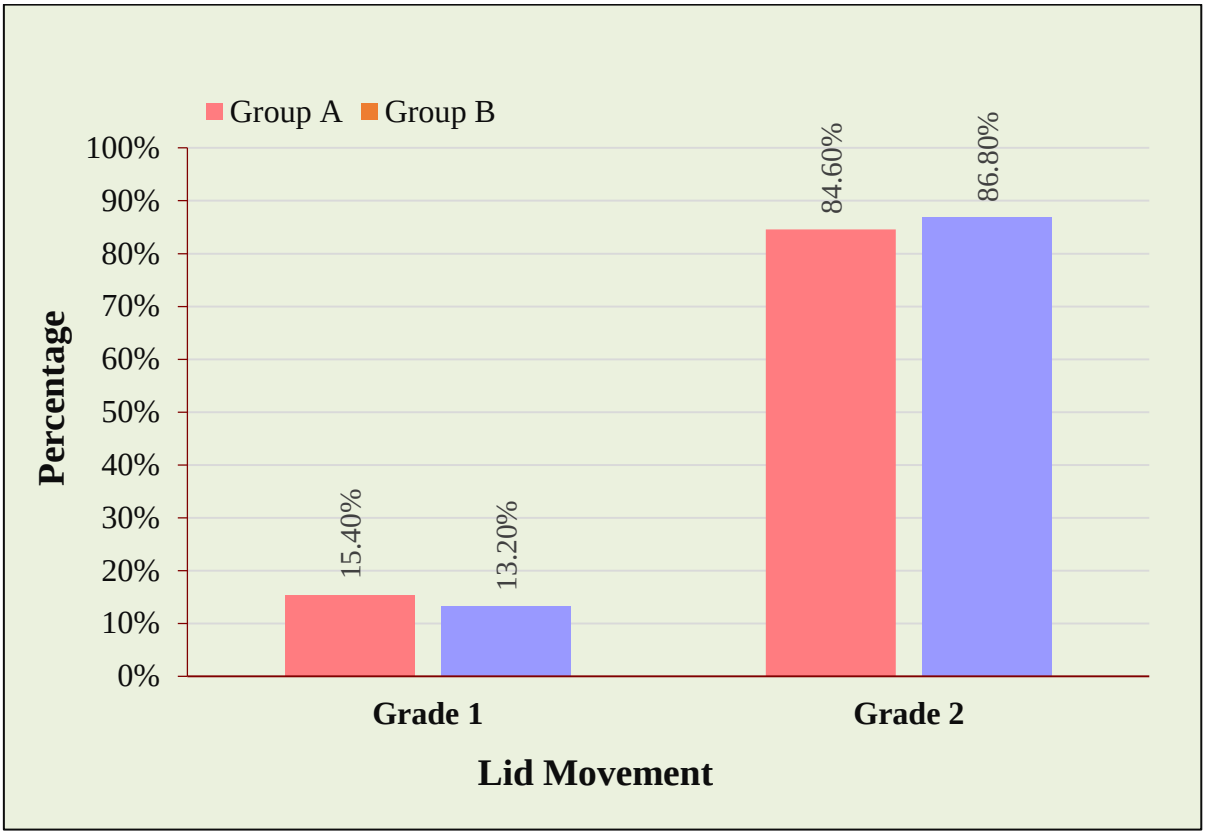


Graph 7: Bar diagram showing Duration of Anaesthesia comparison between two groups

Lid Movement	Group A		Group B	
	Count	%	Count	%
Grade 1	14	15.4	12	13.2
Grade 2	77	84.6	79	86.8
Total	91	100	91	100
χ 2 =0.179, df =1, p =0.672 **[Chi-square test]**				

Table 9: Lid Movement comparison between two groups

In Group A, 15.4% had Grades 1 and 84.6% had Grade 2 Lid movement and in Group B, 13.2% had Grades 1 and 86.8% had Grade 2 Lid movement. There was no significant difference in Lid movement between two groups.

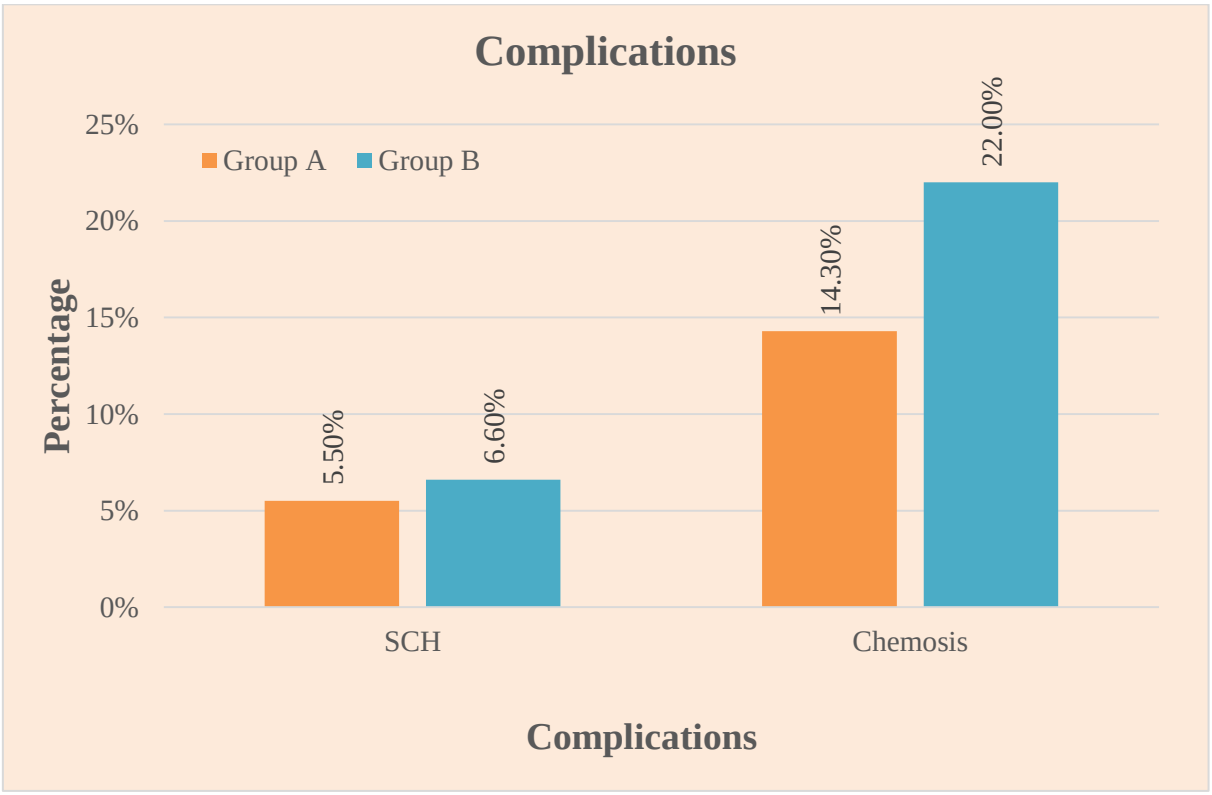


Graph 8: Bar diagram showing Lid Movement comparison between two groups.

Complications		Group A		Group B		P value
		Count	%	Count	%	
SCH	No	86	94.5	85	93.4	0.756
	Yes	5	5.5	6	6.6	
Chemosis	No	78	85.7	71	78	0.178
	Yes	13	14.3	20	22	
Ecchymosis	No	91	100	91	100	-
Lid Haemorrhage	No	91	100	91	100	-
Globe Perforation	No	91	100	91	100	-
Ptosis	No	91	100	91	100	-
Pearson Chi-Square Test						

Table 10: Complications comparison between two groups

In Group A, 5.5% had SCH, 14.3% had chemosis. In Group B, 6.6% had SCH and 22% had Chemosis. Both the groups had no Ecchymosis, Lid Haemorrhage, Globe Perforation and Ptosis. There was no significant difference in Complications between two groups. CX



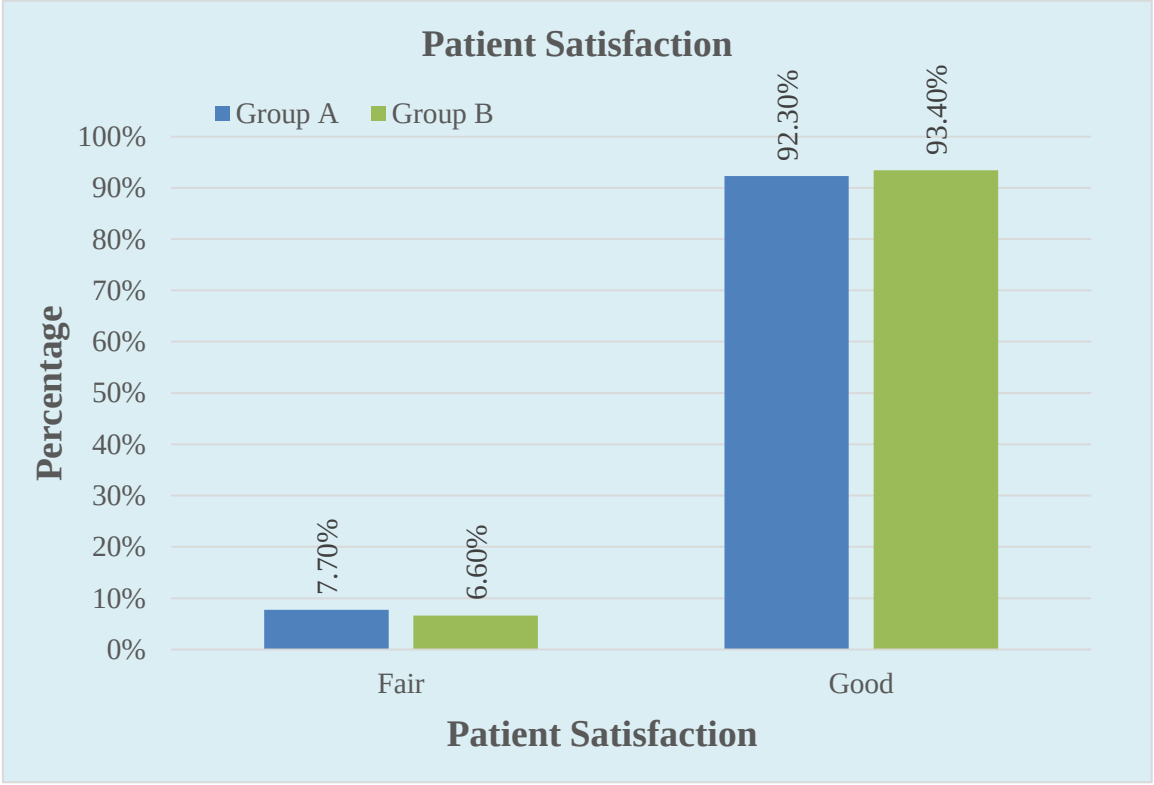
Graph 9: Bar diagram showing Complications comparison between two groups.

Patient Satisfaction	Group A		Group B	
	Count	%	Count	%
Fair	7	7.7	6	6.6
Good	84	92.3	85	93.4
	91	100	91	100

Table 11: Patient Satisfaction comparison between two groups

$\chi 2 = 0.083$, df =1, p =0.773 **[Chi-square test]**

In Group A, 7.7% had Fair and 92.3% had Good Patient satisfaction and in Group B, 6.6% had Fair and 93.4% had Good Patient Satisfaction. There was no significant difference in patient satisfaction between two groups.



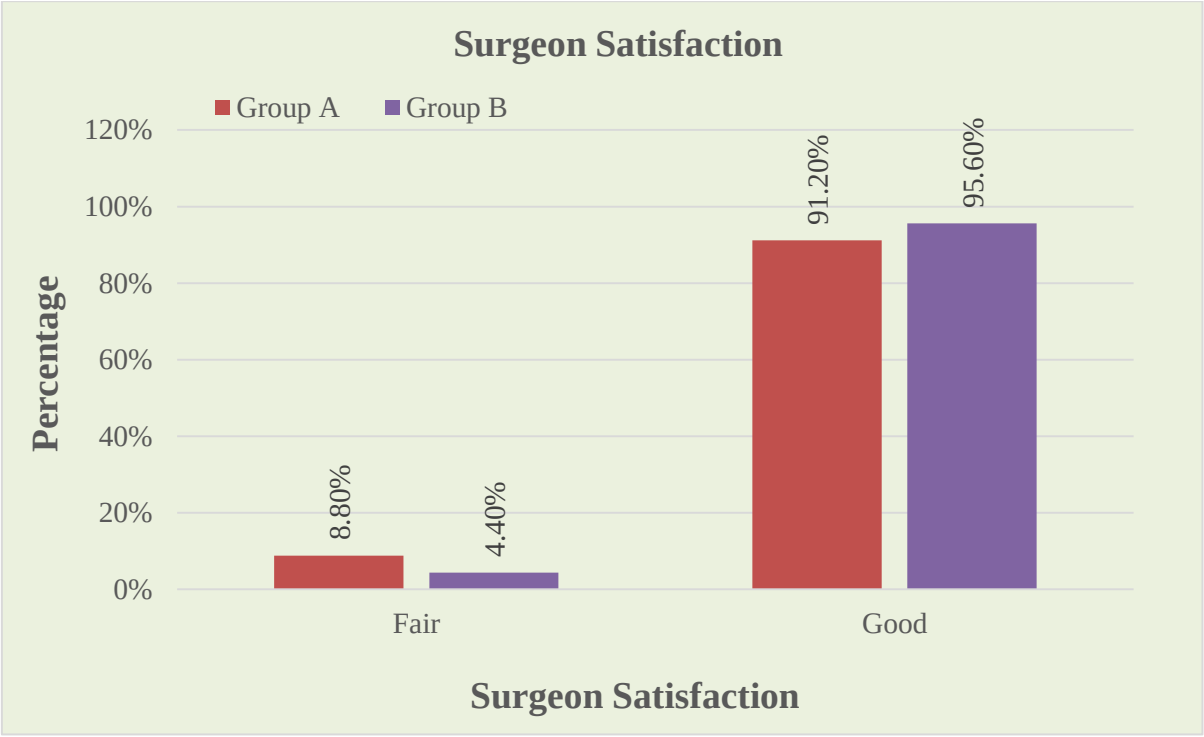
Graph 10: Bar diagram showing Patient Satisfaction comparison between two groups.

Surgeon Satisfaction	Group A		Group B	
	Count	%	Count	%
Fair	8	8.8%	4	4.4%
Good	83	91.2%	87	95.6%
Total	91	100.0%	91	100.0%

Table 12: Surgeon Satisfaction comparison between two groups.

$\chi 2 = 1.427$, df =1, p =0.232 **[Chi-square test]**

In Group A, 8.8% had fair, 91.2% had good and in Group B, 4.4% had Fair and 95.6% had good Surgeon Satisfaction. There was no significant difference in Surgeon Satisfaction between two groups.



Graph 11: Bar diagram showing Surgeon Satisfaction comparison between two groups.

DISCUSSION

DISCUSSION

Anaesthesia plays a vital role in ophthalmic surgery. Most ophthalmic surgeries are carried out under local anaesthesia although topical anaesthesia is soon gaining popularity. But for most surgeons' local peribulbar anaesthesia is a prerequisite for cataract surgery. The goal of anaesthesia in cataract surgery is to provide adequate analgesia and akinesia. It should be safe and effective and should not be associated with any untoward side effects. The peribulbar technique has gained much popularity when compared to its predecessor, the retrobulbar technique. Peribulbar anaesthesia has an added advantage of causing hypotony of the Globe due to the loss in tone of the extra ocular muscles.

Several adjuvants are used to aid in effective anaesthesia and analgesia. Hyaluronidase is a commonly used enzyme, it was first introduced by Atkinson in 1949[19], it aids in the diffusion of the anaesthetic agent. The mechanism of action is to depolymerize the hyaluronic acid reversibly thereby aiding the spread of the local anaesthetic through the extra cellular matrix. Its role in retrobulbar and peribulbar anaesthesia has been open to question. The effect of hyaluronidase on ocular anaesthesia has been reported in previous studies. Their results are conflicting, some studies state that it facilitates the onset of ocular akinesia whereas others report no difference. However, there is little literature on its effect on the levator and orbicularis function in peribulbar anaesthesia.

Hence a Prospective Comparative study was conducted in the department of Ophthalmology, R. L. Jalappa Hospital and Research Centre at Kolar from August 2022 to December 2023. 182 subjects were randomly divided in to two groups. Group A received Hyaluronidase and Group B received Sodium bicarbonate. Institutional Ethical clearance was obtained prior to the start of the study. Informed consent was obtained from all the patients recruited prior to the start of the study.

Profile of subjects:

In Group A, most subjects were in the age group 71 to 80 years (40.7%) and in Group B, most subjects were in the age group 61 to 70 years (36.3%). There was significant difference in age distribution between two groups. The mean age of subjects in Group A was 67.86 ± 10.457 years and in Group B was 64.19 ± 9.396 years. This infers that people above the age of 60 and Females are more prone for cataract. Gender matching was achieved in the present study.

Gupta RP et al.,[32] in their study observed that in Hyaluronidase Group, 86 patients (43%) and in Sodium bicarbonate Group, 91 patients (45.5%) were in the age group of 50-60. In Hyaluronidase Group, 84 (42%) patients and in Sodium bicarbonate Group, 78(39%) patients underwent phacoemulsification. Nazareth N et al.,[90] observed that 27 (54%) patients in Hyaluronidase Group were females and 23 (46%) were males and in Sodium bicarbonate Group, 27 (54%) were females and 23(46%) were males. In Hyaluronidase Group, 2 (4%), 12 (24%),17 (34%) and 19 (38%) patients were present in age group of 40-49, 50-59, 60-69, 70-79 years respectively. The mean age of patients in Hyaluronidase Group and Sodium bicarbonate Group 64.74 and 63.34 years respectively.

In the study by Sodani P. et al.,[91] in Group 1, 26 subjects were males and 24 were females, mean age was 64.9 ± 10.77 years and in Group 2, 27 subjects were males, and 23 subjects were females and mean age was 62.8 ± 11.17 years. Males were in majority in both groups. There was age and gender matching between two groups. The findings were like the present study findings for age and was differencing with gender distribution.

Onset of analgesia and duration of analgesia:

In the present study Time of Onset of Anaesthesia in Group A was 0-5 mins in 48.4%, 6-10 mins in 13.2% and in 11-15 mins in 38.5%, in Group B was 0-5 mins in 65.9%, 6-10 mins in 6.6% and in 11-15 mins in 27.5%. There was significant difference in Time of Onset of Anaesthesia between two groups. Group B had lower time of onset compared to Group A. Duration of Anaesthesia in Group A was < 30 min in 4.4%, 30-90 min in 93.4% and >90 min in 2.2% and in Group B was < 30 min in 1.1%, 30-90 min in 94.5% and >90 min in 4.4%. Although Duration of anaesthesia was more in Group B, there was no significant difference in Duration of Anaesthesia between two groups.

Gupta RP et al.,[32] in their study observed that in Hyaluronidase Group, 16% patients had an onset of anaesthesia within 5 minutes, 53% between 5-10 Minutes, 25.5% between 10-15 minutes and 5.5% after 15 minutes. In Sodium bicarbonate Group, 27.5% patients had onset with 5 minutes, 59% between 5-10 minutes, 9% between 10-15 minutes and 4.5% after 15 minutes. There was significant difference in onset of anesthesia between two groups. They also observed that there was no significant difference in duration of anesthesia between two groups.

Sachin D et al.,[92] in their study observed that the mean onset of anaesthesia for Sodium bicarbonate Group was 4.88 ± 3.24 min, and for Hyaluronidase group was 5.27 ± 2.99 min. There was a significant difference in time of onset of anaesthesia between two groups. In Sodium bicarbonate Group, 18% had within 1-2 min and 82% of subjects had within 2-5 min. In Hyaluronidase group, 6% had onset within 1-2 min and 94% had within 2-5 min. Nazareth N et al.,[90] observed that 92% patients attained anaesthesia within 5 minutes in Hyaluronidase Group whereas all the 100% of patients in Sodium bicarbonate Group attained anaesthesia in five minutes. The remaining 4(8%) of patients of Hyaluronidase Group attained anaesthesia after ten minutes of administering local anaesthesia. P value 0.059 which was statistically not significant.

Sachin D et al.,[92] also observed that Time required for complete anaesthesia and akinesia in Sodium bicarbonate Group was 6.79 ± 2.28 min and for Hyaluronidase group was 8.08 ± 1.72 min. In Sodium bicarbonate Group, 44% took <5 min, 35% took 5-10 min and 21% took >10 min for Complete anaesthesia. In Hyaluronidase group, 12% took <5 min, 70% took 5-10 min and 18% took >10 min for complete anaesthesia. There was significant difference in Time required for complete anaesthesia between two groups. Sodani P et al.,[91] observed that onset of anesthesia was 3.40±0.95 min in Group 1 and 2.62±1.21 in Group 2. And duration of anaesthesia was 31.22±4.56 min in Group 1 and 33.18±3.68 in Group 2. There was significant difference in onset and duration of anaesthesia between two groups.

Several studies have noted improved onset time with alkalinization of local anaesthetic solutions. Galido et al.,[2] reported reduction in the time of onset with alkalinization. Zahl et al.,[28] also demonstrated faster onset with Sodium bicarbonate in ocular anaesthesia. Sodium bicarbonate when added to local anaesthetics causes them to be more basic by rising their pH. This causes the drug to exist in the non-ionized form which crosses the perineural sheath more easily thereby reducing the time of onset. It is also the active form of the drug, non-cat ion form which increases the bio availability and thereby the onset of action. Srinivasan et al.,[26] showed similar duration for both the groups which was like the present study.

Sachin D et al.,[92] in their study observed that Time of onset of post-operative pain in Sodium bicarbonate Group was 102.85 ± 32.14 min and was 76.45 ± 30.43 in Hyaluronidase group. Onset of postop pain in Sodium bicarbonate Group was >120 min majority of subjects and in Hyaluronidase group, onset of post op pain was 61-90 min in majority of subjects.

Akinesia:

In the present study in Group A, 51.6% had Grade 1 Akinesia, 36.3% had Grade 2 Akinesia, 12.1% had Grade 3 Akinesia. In Group B, 70.3% had Grade 1 Akinesia, 24.2% had Grade 2 Akinesia, 5.5% had Grade 3 Akinesia. There was significant difference in Akinesia between two groups. Good Akinesia was achieved by Group B compared to Group A. Gupta RP et al.,[32] observed that in Hyaluronidase Group, 78% patients had Grades I and 19% had Grade II anaesthesia. In Sodium bicarbonate Group, 81.5% had Grades I and 16.5% had Grade II anaesthesia. Nazareth N et al.,[90] observed that in Hyaluronidase Group, 17 (34%), 22 (66.7%), 8(72.7%) and 3(100%) patients had a score of 0 representing total akinesia at end of 5, 10, 15 and 20 minutes respectively. In Sodium bicarbonate Group, 4(8%), 22(47.8%), 14(58.3%) and 4(80%) patients had a score of 0 representing total akinesia at end of 5, 10, 15 and 20 minutes respectively.

Sachin D et al.,[92] in their study observed that Time required for complete anaesthesia and akinesia in Sodium bicarbonate Group was 6.79 ± 2.28 min and for Hyaluronidase group was 8.08 ± 1.72 min. In Sodium bicarbonate Group, 44% took <5 min, 35% took 5-10 min and 21% took >10 min for Complete anaesthesia. In Hyaluronidase group, 12% took <5 min, 70% took 5-10 min and 18% took >10 min for complete anaesthesia. There was a significant difference in time required for complete anaesthesia between the two groups. Sodani P et al.,[91] observed, that mean onset of akinesia in Group 1 was 4.76±2.06 min and in Group 2 was 6.64±2.18 min. Mean grading of anaesthesia and akinesia in Group 1 was 1.20±0.40 and in Group II was 1.50 ±0.51. There was significant difference in mean Grading of anaesthesia and akinesia between two groups.

On the contrary the studies conducted by Srinivasan et al.,[26] conclude that there was no significant difference between the two groups regarding akinesia. David B.D., Mandel M. et al.,[56]

concluded that the onset of akinesia was better in the pH adjusted group. Agarwal V, Athanikar N.S. et al.,[54] had demonstrated the efficacy of single point inferotemporal anaesthesia. Similar results were also reported by Arnold P.N with single point peribulbar anaesthesia[53]. While Morsman CD, Holden R.[64] Found a high success rate of anaesthesia with Hyaluronidase and reduced the need for supplementation.

Lid Movements:

In the present study in Group A, 15.4% had Grades 1 and 84.6% had Grade 2 Lid movement and in Group B, 13.2% had Grades 1 and 86.8% had Grade 2 Lid movement. There was no significant difference in Lid movement between the two groups. In the study by Al-Azhary MA et al.,[93] it was observed that mean lid akinesia in Group I at 1 minute was 2±0, at 3 minutes was 1.2±0.41, at 6 minutes was 0.1±0.31 and at 9 minutes was 0±0. Similarly in Group II, mean Lid akinesia score at 1 minute was 1.65±0.49, at 3 minutes was 0.7±0.57, at 6 minutes was 0.05±0.22 and at 9 minutes was 0±0. There was significant difference in Lid akinesia at 1 min and 3 min between two groups. Also, they observed at 1 min in Group I, 100% had Grade 2 and in Group 2, 35% had Grades 1 and 65% had Grade II score and at 3 min, 80% had Grades 1 and 20 had Grade 2 in Group I and in Group 2, 35% had Grade 0, 60% had Grades 1 and 5% had Grade 2. Although the present study only compared lid movements only once. There was no significant difference in Lid movements between the two groups.

Ocular Complications:

The ocular complications considered were chemosis, lid edema, sub conjunctival hemorrhage, peribulbar hemorrhage, vitreous bulge, Globe perforation. In the present study in Group A, 5.5% had SCH, 14.3% had chemosis. In Group B, 6.6% had SCH and 22% had Chemosis. Both the groups had no Ecchymosis, Lid Haemorrhage, Globe Perforation and Ptosis.

There was no significant difference in Complications between two groups. Nazareth N et al.,[90] observed that the most common side effect seen was Chemosis which was present in 32% of patients in Hyaluronidase Group and 34% in Sodium bicarbonate Group. None of the patients of Hyaluronidase Group had lid Edema whereas 34% of Sodium bicarbonate Group developed lid Edema following injection. Sub conjunctival haemorrhage occurred in 6% of Hyaluronidase Group and 8% of Sodium bicarbonate Group. Peribulbar haemorrhage was not seen in any patient of Hyaluronidase Group, while it was noted in 4% of Sodium bicarbonate Group. Globe perforation was not seen in any of the groups. Vitreous bulge and forward thrust, with increased IOP was seen in 2% of Hyaluronidase Group and 24% of Sodium bicarbonate Group.

David B.D., Richard M.,[55] evaluated the efficacy and complication rates of 16,224 consecutive peribulbar blocks which were single point. The incidence of complications was low. Orbital hemorrhage occurred in 0.74% cases, Globe perforation in 0.006%, expulsive choroidal hemorrhage in 0.013% and grand mal seizures in 0.006% 61,62. Rao V.A et al.,[58] evaluated peribulbar anaesthesia, consisting of a single injection of 5 cc anaesthetic solution with a 26-gauge needle. They observed complete anaesthesia in 15 minutes with no significant complications. Therefore, deemed it as a safe, simple, economical means of anaesthesia.

Patient satisfaction and Surgeon Satisfaction:

In the present study in Group A, 7.7% had Fair and 92.3% had Good Patient satisfaction and in Group B, 6.6% had Fair and 93.4% had Good Patient Satisfaction. There was no significant difference in patient satisfaction between the two groups. Similarly in Group A, 8.8% had fair, 91.2% had good and in Group B, 4.4% had Fair and 95.6% had good Surgeon Satisfaction. There was no significant difference in Surgeon Satisfaction between two groups.

CONCLUSION

CONCLUSION

The present study showed that Sodium bicarbonate is an effective alternative to Hyaluronidase in peribulbar anaesthesia with a faster onset of anaesthetic action, longer duration of anaesthesia and Good akinesia. Patient satisfaction and surgeon satisfaction were similar in both groups. Also, there was no significant difference in complications. Hence Sodium bicarbonate can become an effective alternative agent to Hyaluronidase.

RECOMMENDATIONS

From the study findings it is recommended that Sodium bicarbonate can become an effective alternate agent to Hyaluronidase in peribulbar analgesia due to its better efficacy and similar complications, patient satisfaction and surgeon satisfaction.

LIMITATIONS

1. Since the efficacy was measured between two drugs, randomized controlled trial is ideal study design.
2. Cost effectiveness of both the drugs was not estimated.

SUMMARY

SUMMARY

A Prospective Comparative study was conducted in the department of Ophthalmology, R. L. Jalappa Hospital and Research Centre at Kolar from August 2022 to December 2023. 182 subjects were randomly divided in to two groups. Group A received Hyaluronidase and Group B received Sodium bicarbonate. Institutional Ethical clearance was obtained prior to the start of the study. Informed consent was obtained from all the patients recruited prior to the start of the study.

1. Mean age of subjects in Group A was 67.86 ± 10.457 years and in Group B was 64.19 ± 9.396 years.
2. In Both groups majority of subjects were females. There was no significant difference in Gender distribution between two groups.
3. Time of Onset of Anaesthesia was shorter in Group B Compared to Group. There was significant difference in Time of Onset of Anaesthesia between two groups
4. Better Analgesia was achieved in Group B. There was significant difference in Analgesia between two groups.
5. Good Akinesia was achieved by Group B compared to Group A. There was significant difference in Akinesia between two groups.
6. Duration of anaesthesia was higher in Group B compared to Group A. However, there was no significant difference in Duration of Anaesthesia between two groups.
7. Lid movement was similar in both groups and there was no significant difference between two groups.
8. In the present study there was no significant difference in Complications between two groups.
9. In the present study there was no significant difference in patient satisfaction between two

groups.

10. In the present study there was no significant difference in Surgeon Satisfaction between two groups.

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ANNEXTURE

ANNEXTURE I: PROFORMA

CASE PROFORMA	
Name:	IP No:
Age:	Group:
Sex:	Case No:
Occupation:	DOS:
Address:	

Chief complaints:

Past history:

DM / HTN / BA / Epilepsy

Family history:

Personal history:

Appetite – Sleep – Bowel –

Diet – Habits – Bladder –

GPE:

Pallor / Edema /Icterus / Cyanosis / Clubbing / Lymphadenopathy

Vital signs:

a. Pulse – c) RR –

b. BP – d) Temp –

Systemic examination:

a. CVS – b. RS – c. P/A – d. CNS –

OCULAR EXAMINATION		
	RE	**LE**
1. Head Posture **2. Ocular Posture** **3. Facial Symmetry**		
4. Ocular Movements		
5. Visual Acuity a) Distant b) Near		
6. Anterior Segment		
7. Fundus (IDO & Slit Lamp +90D)		
8. B Scan		
9. Keratometry K1 K2		
10. Axial length		
11. Intraocular lens power		
12. Intraocular pressure		

A) TIME TO ONSET OF ANAESTHESIA

Time to onset of anaesthesia	Group A	Group B
0-5 mins		
6-10 mins		
11-15 mins		
> 15 mins		

B) DURATION OF ANESTHESIA

Duration of anaesthesia	Group A	Group B
< 30 min		
30-90 min		
> 90 min		

C) ANALGESIA(Visual Analogue pain scale)

Grades	Severity of pain	At the time of administration	Intraoperative	Post-operative (after 4 hrs of surgery)
Grade 0	No pain			
Grade 1-3	Mild pain			
Grade 4-6	Moderate pain			
Grade 7-9	Severe pain			
Grade 10	Very severe pain			

D) AKINESIA:

Grades	5 min after Inj	10 min after Inj	15 min after Inj
Grade 1: Absence of eye movements Anaesthesia of cornea and conjunctiva Painless superior rectus bridle suture			
Grade 2 Eye movements < 15° in any gaze As above			
Grade 3 Eye movements > 15° in any gaze			

Painful bridle suture			

E) <u>COMPLICATIONS</u> (after anaesthesia)

S.No	Complications		Yes / no
1	Sub conjunctival haemorrhage	Grade 0	
		Grade 1	
		Grade 2	
		Grade 3	
2	Chemosis	Grade 0	
		Grade 1	
		Grade 2	
		Grade 3	
3	Ecchymosis		
4	Lid haemorrhage		
5	Retrobulbar haemorrhage		
6	Globe perforation		
7	Postoperative transient ptosis		

ANNEXTURE II: INFORMED CONSENT FORM

Case no: **Group:**

IP no:

TITLE: "SAFETY AND EFFICACY OF SODIUM BICARBONATE VERSUS HYALURONIDASE IN PERIBULBAR ANAESTHESIA FOR CATARACT SURGERY"

I, the undersigned, agree to participate in this study and authorize the collection and disclosure of personal information as outlined in this consent form.

I understand the purpose of this study, the risks and benefits of the technique and the confidential nature of the information that will be collected and disclosed during the study. The information collected will be used only for research.

I have had the opportunity to ask questions regarding the various aspects of this study and my questions have been answered to my satisfaction.

I understand that I remain free to withdraw participation from this study at any time and this will not change the future care.

Participation in this study does not involve any extra cost to me.

Name		Signature	Date	Time
Patient:				
Witness:				
Primary Investigator/ Doctor:				

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR – 563101

ತಿಳಿವಳಿಕೆಸಮ್ಮತಿನಮೂನೆ

ಶೀರ್ಷಿಕೆ : **" ಕಣ್ಣಿನ ಪೊರೆ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಗಾಗಿ ಪೆರಿಬುಲ್ಬಾರ್ ಅರಿವಳಿಕೆಯಲ್ಲಿ ಸೋಡಿಯಂ ಬೈಕಾರ್ಬನೇಟ್ ವಿರುದ್ಧ ಹೈಲುರೊನಿಡೇಸ್ನ ಸುರಕ್ಷತೆ ಮತ್ತು ಪರಿಣಾಮಕಾರಿತ್ವ"**

ಈ ಸಂಶೋಧನೆಗೆ ರೋಗಿಯ ಗುರುತಿನ ಸಂಖ್ಯೆ: ಗುಂಪು:

ಐಪಿ ಸಂಖ್ಯೆ:

ಅಂಗೀಕರಿಸಿದ ನಾನು, ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ಒಪ್ಪುತ್ತೇನೆ ಮತ್ತು ಈ ಸಮ್ಮತಿಯ ರೂಪದಲ್ಲಿ ವಿವರಿಸಿರುವಂತೆ ನನ್ನ ವೈಯಕ್ತಿಕ ಮಾಹಿತಿಯ ಸಂಗ್ರಹಣೆ ಮತ್ತು ಬಹಿರಂಗಪಡಿಸುವಿಕೆಯನ್ನು ದೃಢೀಕರಿಸುತ್ತೇನೆ.

ನಾನು ಈ ಅಧ್ಯಯನದ ಉದ್ದೇಶ, ತಂತ್ರಗಳ ಅಪಾಯಗಳು ಮತ್ತು ಪ್ರಯೋಜನಗಳನ್ನು ಮತ್ತು ಅಧ್ಯಯನದಲ್ಲಿಸಂಗ್ರಹಿಸಿದ ಮತ್ತು ಬಹಿರಂಗಪಡಿಸುವ ಮಾಹಿತಿಯ ಗೌಪ್ಯತೆಗೆ ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ. ಸಂಗ್ರಹಿಸಿದ ಮಾಹಿತಿಯನ್ನು ಸಂಶೋಧನೆಗೆ ಮಾತ್ರ ಬಳಸಲಾಗುತ್ತದೆ.

ಈ ಅಧ್ಯಯನದ ವಿವಿಧ ಅಂಶಗಳನ್ನು ಕುರಿತು ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ನನಗೆ ಅವಕಾಶವಿದೆ ಮತ್ತು ನನ್ನ ತೃಪ್ತಿಗೆ ನನ್ನ ಪ್ರಶ್ನೆಗಳಿಗೆ ಉತ್ತರ ನೀಡಲಾಗಿದೆ. ಈ ಸಂಶೋಧನೆಯಿಂದ ಹೊರಬರುವ ಮಾಹಿತಿಯನ್ನು ವೈದ್ಯರು ಯಾವುದೇ ಜರ್ನಲ್ನಲ್ಲಿ ಅಥವಾ ಕಾನ್ಫೆರೆನ್ಸ್ನಲ್ಲಿ ಪ್ರಕಟಿಸಲು ಅನುಮತಿ ಸೂಚಿಸಿರುತ್ತೇನೆ

ನಾನು ಈ ಅಧ್ಯಯನದಿಂದ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಹಿಂತೆಗೆದುಕೊಳ್ಳಲು ಮುಕ್ತವಾಗಿರುತ್ತೇನೆ ಮತ್ತು ಇದು ನನ್ನ ಮುಂದಿನ ಕಾಳಜಿಯನ್ನು ಬದಲಿಸುವುದಿಲ್ಲ ಎಂದು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ.

ಈ ಸಂಶೋಧನಾ ಯೋಜನೆಯ ಭಾಗವಹಿಸುವಿಕೆ ನನಗೆ ಯಾವುದೇ ಹಣಕಾಸಿನ ಹೊರೆ ಒಳಗೊಂಡಿರುವುದಿಲ್ಲ.

ಹೆಸರು		ಸಹಿ	ದಿನಾಂಕ	ಸಮಯ
ರೋಗಿಯ:				
ಸಾಕ್ಷಿ 1:				
ಸಾಕ್ಷಿ 2:				
ಪ್ರಾಥಮಿಕ ತನಿಖೆದಾರ / ಡಾಕ್ಟರ್:				

ANNEXTURE III: PATIENT INFORMATION SHEET

TITLE: "SAFETY AND EFFICACY OF HYALURONIDASE VERSUS SODIUM BICARBONATE IN PERIBULBAR ANAESTHESIA FOR CATARACT SURGERY"

This information is to help you understand the purpose of the study "Safety and Efficacy of Sodium bicarbonate versus Hyaluronidase in Peribulbar anesthesia for Cataract surgery"

You are invited to take part voluntarily in this research study, it is important that you read and understand purpose, procedure, benefits and discomforts of the study.

To find the severity of pain and anaesthesia during peribulbar block before cataract surgery.

There are no risks associated with the various investigations to be done which includes slit lamp examination, fundoscopy, Keratometry and Biometry. Test dose of the anaesthetic solution will be done prior to the actual procedure of peribulbar anaesthesia.

Participation in this research study may not change the final outcome of your eye condition. However, patients in the future may benefit as a result of knowledge gained from this study. You will not be charged extra for any of the procedures performed during the research study. Your taking part in this study is entirely voluntary.

You may refuse to take part in the study or you may stop your participation in the study at any time, without any penalty or loss of any benefits to which you were otherwise entitled before taking part in this study.

CONFIDENTIALITY

Your medical information will be kept confidential by the study doctor and staff and will not be made publicly available. Your original records may be reviewed by your doctor or ethics review board. For further information, /clarification please contact Dr. MEGHA VARNIKA, SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR – 563101.

DOCTOR'S DETAILS:

DR. J. MEGHA VARNIKA, MBBS, (MS)
3rd YEAR RESIDENT
DEPARTMENT OF OPHTHALMOLOGY,
SDUMC, KOLAR – 563101
Contact no:9182400945
Mail ID: rainbow.colours.js@gmail.com

ಶೀರ್ಷಿಕೆ : "ಕಣ್ಣಿನ ಪೊರೆ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಗಾಗಿ ಪೆರಿಬುಲ್ಬಾರ್ ಅರಿವಳಿಕೆಯಲ್ಲಿ ಸೋಡಿಯಂ ಬೈಕಾರ್ಬನೇಟ್ ವಿರುದ್ಧ ಹೈಲುರೊನಿಡೇಸ್ನ ಸುರಕ್ಷತೆ ಮತ್ತು ಪರಿಣಾಮಕಾರಿತ್ವ"

ಈ ಮಾಹಿತಿಯು ಅಧ್ಯಯನದ ಉದ್ದೇಶವನ್ನು ಅರ್ಥಮಾಡಿಕೊಳ್ಳಲು ನಿಮಗೆ ಸಹಾಯ ಮಾಡುತ್ತದೆ. ಈ ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿ ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಭಾಗವಹಿಸಲು ನಿಮ್ಮನ್ನು ಆಹ್ವಾನಿಸಲಾಗಿದೆ, ನೀವು ಹೇಳಿದ ಮತ್ತು ಉದ್ದೇಶವನ್ನು ಅರ್ಥಮಾಡಿಕೊಳ್ಳುವುದು ಬಹಳ ಮುಖ್ಯ.

ಕಣ್ಣಿನ ಪೊರೆ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಗೆ ಮುನ್ನ ಪೆರಿಬಲ್ಬಾರ್ ಬ್ಲಾಕ್ ಸಮಯದಲ್ಲಿ ನೋವು ಮತ್ತು ಅರಿವಳಿಕೆ ತೀವ್ರತೆಯನ್ನು ಕಂಡುಹಿಡಿಯಲು. ಸ್ಲಿಟ್ ಲ್ಯಾಂಪ್ ಪರೀಕ್ಷೆ, ಫಂಡೋಸ್ಕೋಪಿ, ಕೆರಾಟೋಮೆಟ್ರಿ ಮತ್ತು ಬಯೋಮೆಟ್ರಿಯನ್ನು ಒಳಗೊಂಡಂತೆ ಮಾಡಬೇಕಾದ ವಿವಿಧ ತನಿಖೆಗಳೊಂದಿಗೆ ಯಾವುದೇ ಅಪಾಯಗಳಿಲ್ಲ.ನಾವು ಸ್ಕಿರ್ಮರ್ಸ್ ಪರೀಕ್ಷೆ, ಕಣ್ಣೀರಿನ ಚಲನಚಿತ್ರವು ಸಮಯವನ್ನು ಮುರಿಯುತ್ತದೆ. ಅಂತಹ ತೊಡಕುಗಳನ್ನು ಅವನು ಗುರುತಿಸುವುದು ಅಥವಾ ಅಭಿವೃದ್ಧಿ ಹೊಂದುವ ಅಪಾಯವು ಅದರ ಸಂಭವವನ್ನು ಕಡಿಮೆ ಮಾಡಲು ಬೇಕಾದ ಬದಲಾವಣೆಗಳ ನಿರ್ಣಯದಲ್ಲಿ ಮಹತ್ವದ್ದಾಗಿರುತ್ತದೆ, ಹೀಗಾಗಿ ತೀವ್ರವಾದ ಆಕ್ಯುಲರ್ ಆವಿಷ್ಕಾರದ ಹೊರೆಯನ್ನು ಕಡಿಮೆ ಮಾಡುತ್ತದೆ ನಮ್ಮ ವೀಕ್ಷಣೆ ಸಹ ಪ್ರಾಮುಖ್ಯತೆಯನ್ನು ಹೊಂದಿರಬಹುದು

ಪೆರಿಬುಲ್ಬಾರ್ ಅರಿವಳಿಕೆಯ ನಿಜವಾದ ಕಾರ್ಯವಿಧಾನದ ಮೊದಲು ಅರಿವಳಿಕೆ ದ್ರಾವಣದ ಪರೀಕ್ಷೆಯ ಪ್ರಮಾಣವನ್ನು ಮಾಡಲಾಗುತ್ತದೆ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮ ಪಾಲ್ಗೊಳ್ಳುವಿಕೆಯು ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ. ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ನೀವು ನಿರಾಕರಿಸಬಹುದು ಅಥವಾ ಈಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವುದಕ್ಕಿಂತ ಮೊದಲು ನೀವು ಯಾವುದೇ ಅರ್ಹತೆಗೆ ಯಾವುದೇ ದಂಡವಿಲ್ಲದೆ ಅಥವಾ ನಷ್ಟವಿಲ್ಲದೆಯೇ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ನಿಲ್ಲಿಸಬಹುದು. ಈ ಸಂಶೋಧನೆಯಿಂದ ಹೊರಬರುವ ಮಾಹಿತಿಯನ್ನು ವೈದ್ಯರು ಯಾವುದೇ ಕಾನ್ಫೆರೆನ್ಸ್ನಲ್ಲಿ ಪ್ರಕಟಿಸಲು ಅನುಮತಿ ಸೂಚಿಸಿರುತ್ತೇನೆ

ಗೌಪ್ಯತೆ

ನಿಮ್ಮ ವೈದ್ಯಕೀಯ ಮಾಹಿತಿಯನ್ನು ಅಧ್ಯಯನದ ವೈದ್ಯರು ಮತ್ತು ಸಿಬ್ಬಂದಿ ಗೌಪ್ಯವಾಗಿಡಲಾಗುವುದು ಮತ್ತು ಸಾರ್ವಜನಿಕವಾಗಿಲಭ್ಯವಿರುವುದಿಲ್ಲ.ನಿಮ್ಮಮೂಲದಾಖಲೆಗಳನ್ನು ನಿಮ್ಮ ವೈದ್ಯರು ಅಥವಾ ನೈತಿಕ ವಿಮರ್ಶೆ ಮಂಡಳಿ ಪರಿಶೀಲಿಸಬಹುದು.

ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ ಸಂಪರ್ಕಿಸಿ

ಡಾ. ಜೆ. ಮೇಘಾ ವರ್ಣಿಕಾ, ಎಂ ಬಿ ಬಿ ಎಸ್, (ಎಂ ಎಸ್)

ಎಸ್ ಡಿ ಯು ಎಮ್ ಸಿ.

ಟಮಕ, ಕೋಲಾರ

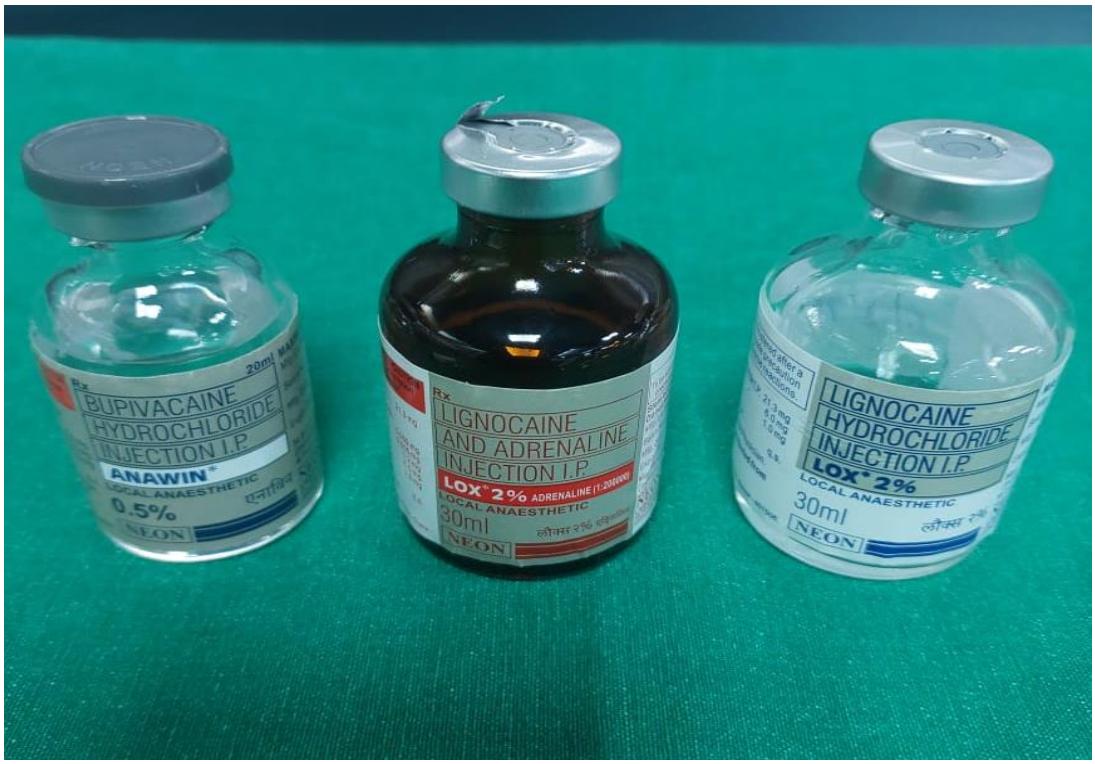
ಸಂಪರ್ಕ ಸಂಖ್ಯೆ: 91825400945

Mail ID: rainbow.colours.js@gmail.com

ANNEXTURE IV: PHOTOGRAPHS

PHOTOGRAPH 1: SLIT LAMP EXAMINATION

PHOTOGRAPH 2: PERIBULBAR BLOCK



PHOTOGRAPH 3: LOCAL ANAESTHETICS

PHOTOGRAPH 4: SODIUM BICARBONATE SOLUTION

WITH MY GUIDE: PROF. DR. MANJULA. T. R (Professor, Department of Ophthalmology)

KEY TO MASTER

CHART

MASTER CHART

SL. NO.	UHIDNO	NAME	AGE	Age1	GENDER	TIME OF ONSET OF ANAESTHESIA	ANALGESIA	AKINESIA	Group	Group_A
1	198674	RAMAKKA	68	3	F	0-5 mins	MILD PAIN	GRADE 2	1	A
2	198667	ADHILAKSHMAMMA	59	2	F	6-10 mins	NO PAIN	GRADE 3	1	A
3	198668	BASHA	79	4	M	6-10 mins	NO PAIN	GRADE 3	1	A
4	198661	KADIRAMMA	50	1	F	11-15 mins	MILD PAIN	GRADE 1	1	A
5	198671	ERAPPA	65	3	M	0-5 mins	MILD PAIN	GRADE 2	1	A
6	198669	VENKATARAYAPPA	83	5	M	0-5 mins	MILD PAIN	GRADE 3	1	A
7	198659	BAERAREDDY	58	2	M	0-5 mins	NO PAIN	GRADE 1	1	A
8	196494	NARAYANAMMA	75	4	F	6-10 mins	MILD PAIN	GRADE 2	1	A
9	196487	NAGARAJ	45	1	M	6-10 mins	MILD PAIN	GRADE 2	1	A
10	196490	LAKSHMAMMA	63	3	F	6-10 mins	MILD PAIN	GRADE 2	1	A
11	196488	MUNISWAMY	88	5	M	0-5 mins	NO PAIN	GRADE 2	1	A
12	197841	LAKSHMINARASAMMA	80	4	F	0-5 mins	MILD PAIN	GRADE 3	1	A
13	197848	PYARIJAN	56	2	F	6-10 mins	NO PAIN	GRADE 3	1	A
14	197575	NANDAMMA	56	2	F	0-5 mins	NO PAIN	GRADE 3	1	A
15	197845	VENKATARAVANAMMA	50	1	F	6-10 mins	MODERATE PAIN	GRADE 2	1	A
16	197844	CHANDRASHEKAR	60	2	M	6-10 mins	NO PAIN	GRADE 3	1	A
17	186183	MOHAMMED HAMEED	70	3	M	6-10 mins	NO PAIN	GRADE 3	1	A
18	184941	CHINNAPPA	78	4	M	6-10 mins	NO PAIN	GRADE 2	1	A
19	184946	LAKSHMAMMA	68	3	F	6-10 mins	MILD PAIN	GRADE 1	1	A
20	184951	MUNIYAPPA	66	3	M	11-15 mins	MODERATE PAIN	GRADE 1	1	A
21	244560	CHIKKA VENKATARAYAPPA	55	2	M	6-10 mins	NO PAIN	GRADE 1	1	A
22	251436	DASARISUBBARAYAPPA	63	3	M	6-10 mins	MILD PAIN	GRADE 1	1	A
23	251445	LAKSHMI NARAYANA	73	4	M	6-10 mins	MILD PAIN	GRADE 1	1	A
24	251440	MUNI REDDY	75	4	M	0-5 mins	NO PAIN	GRADE 1	1	A

SL. NO.	UHIDNO	NAME	AGE	Age1	GENDER	TIME OF ONSET OF ANAESTHESIA	ANALGESIA	AKINESIA	Group	Group_A
25	251447	HEMAKKA	54	2	F	0-5 mins	NO PAIN	GRADE 2	1	A
26	251907	MUNIVENKATARAMAPPA	65	3	M	0-5 mins	NO PAIN	GRADE 1	1	A
27	243807	SRI RAMACHANDRA	68	3	M	11-15 mins	MODERATE PAIN	GRADE 2	1	A
28	253173	NANJUNDAPPA	59	2	M	6-10 mins	MILD PAIN	GRADE 2	1	A
29	250251	GANGAMMA	65	3	F	6-10 mins	NO PAIN	GRADE 1	1	A
30	250246	VENKATAMMA	74	4	F	6-10 mins	NO PAIN	GRADE 2	1	A
31	250266	BUDDAPPA	64		M	0-5 mins	NO PAIN	GRADE 2	1	A
32	250252	VENKATAMMA	75	4	F	6-10 mins	MODERATE PAIN	GRADE 2	1	A
33	250717	ANNAYAPPA	74	4	M	6-10 mins	MODERATE PAIN	GRADE 1	1	A
34	250241	VENKATARAYAPPA	70	3	M	6-10 mins	MODERATE PAIN	GRADE 3	1	A
35	262178	KADIRAPPA	64	3	M	6-10 mins	NO PAIN	GRADE 3	1	A
36	253183	AMBUJA	55	2	F	0-5 mins	MILD PAIN	GRADE 2	1	A
37	181159	NAGESH	41	1	M	6-10 mins	MILD PAIN	GRADE 2	1	A
38	253453	MUNISHAMAPPA	60	2	M	0-5 mins	NO PAIN	GRADE 2	1	A
39	254530	BYRAMMA	65	3	F	0-5 mins	NO PAIN	GRADE 1	1	A
40	254526	PAPAMMA	60	2	F	6-10 mins	MILD PAIN	GRADE 1	1	A
41	262431	MUNIYAMMA	74	4	F	6-10 mins	NO PAIN	GRADE 2	1	A
42	351589	MUNIYAPPA	66	3	M	0-5 mins	NO PAIN	GRADE 1	1	A
43	351803	NARAYANAPPA	66	3	M	0-5 mins	MILD PAIN	GRADE 2	1	A
44	351812	RUKMANI	54	2	F	0-5 mins	MILD PAIN	GRADE 2	1	A
45	351802	NANJAMMA	61	3	F	0-5 mins	NO PAIN	GRADE 2	1	A
46	351809	KRISHNAPPA	55	2	M	6-10 mins	MILD PAIN	GRADE 2	1	A
47	354123	RAJAMMA	72	4	F	6-10 mins	NO PAIN	GRADE 1	1	A
48	356432	SAVITHRAMMA	70	3	F	6-10 mins	MILD PAIN	GRADE 1	1	A
49	321745	RAMESH	56	2	M	6-10 mins	NO PAIN	GRADE 1	1	A
50	332521	ANJANEYULU	56	2	M	11-15 mins	MILD PAIN	GRADE 1	1	A

SL. NO.	UHIDNO	NAME	AGE	Age1	GENDER	TIME OF ONSET OF ANAESTHESIA	ANALGESIA	AKINESIA	Group	Group_A
51	321675	SHANKARAMMA	75	4	F	0-5 mins	NO PAIN	GRADE 1	1	A
52	325412	CHOWDAMMA	78	4	F	0-5 mins	MILD PAIN	GRADE 1	1	A
53	357315	KRISHNAMMA	61	3	F	0-5 mins	MILD PAIN	GRADE 2	1	A
54	324321	MUNIYAMMA	53	2	F	0-5 mins	MILD PAIN	GRADE 2	1	A
55	352285	BHARATHI	49	1	F	0-5 mins	MILD PAIN	GRADE 2	1	A
56	312191	NARAYANAMMA	54	2	F	11-15 mins	NO PAIN	GRADE 1	1	A
57	354503	LAKSHMAMMA	60	2	F	6-10 mins	NO PAIN	GRADE 1	1	A
58	354506	VENKATALAKSHMAMMA	71	4	F	0-5 mins	NO PAIN	GRADE 1	1	A
59	354511	MURTHAPPA	65	3	M	0-5 mins	NO PAIN	GRADE 1	1	A
60	354462	SIDDAPPA	75	4	M	0-5 mins	NO PAIN	GRADE 2	1	A
61	354554	NARASAMMA	64	3	F	0-5 mins	MILD PAIN	GRADE 2	1	A
62	354439	ERAMMA	68	3	F	6-10 mins	NO PAIN	GRADE 1	1	A
63	368025	SAJEEDA BEGUM	80	4	F	11-15 mins	MILD PAIN	GRADE 2	1	A
64	368028	VENKATARAVANAMMA	80	4	F	11-15 mins	NO PAIN	GRADE 1	1	A
65	368027	MUNIKRISHNAMMA	80	4	F	11-15 mins	NO PAIN	GRADE 1	1	A
66	368031	SRINIVAS	80	4	M	11-15 mins	NO PAIN	GRADE 1	1	A
67	368056	JAREEN TAJ	80	4	F	0-5 mins	NO PAIN	GRADE 1	1	A
68	364569	MUNIVENKATAPPA	80	4	M	0-5 mins	NO PAIN	GRADE 1	1	A
69	368054	RAJESHWARI	80	4	F	0-5 mins	NO PAIN	GRADE 1	1	A
70	370092	SHAHANAZ BEGUM	80	4	F	0-5 mins	NO PAIN	GRADE 1	1	A
71	369562	SAMPANGANNA	80	4	M	6-10 mins	MILD PAIN	GRADE 2	1	A
72	372366	ANJAPPA	80	4	M	6-10 mins	MILD PAIN	GRADE 2	1	A
73	372364	MARKONDAPPA	80	4	M	0-5 mins	NO PAIN	GRADE 2	1	A
74	372363	NARAYANAMMA	80	4	F	6-10 mins	NO PAIN	GRADE 1	1	A
75	372361	GOPALAPPA	80	4	M	6-10 mins	NO PAIN	GRADE 1	1	A
76	372375	MANJULA	80	4	F	0-5 mins	NO PAIN	GRADE 1	1	A

SL. NO.	UHIDNO	NAME	AGE	Age1	GENDER	TIME OF ONSET OF ANAESTHESIA	ANALGESIA	AKINESIA	Group	Group_A
77	372369	SHAMSHAD BEE	80	4	F	0-5 mins	NO PAIN	GRADE 1	1	A
78	371769	NARAYANSWAMY	80	4	M	0-5 mins	NO PAIN	GRADE 1	1	A
79	371781	VENKATAMMA	80	4	F	0-5 mins	NO PAIN	GRADE 1	1	A
80	371765	MUNIVENKATAPPA	80	4	M	11-15 mins	NO PAIN	GRADE 1	1	A
81	371097	RUDHRAYYA	80	4	M	11-15 mins	NO PAIN	GRADE 1	1	A
82	364354	LAKSHMIDEVAMMA	58	2	F	0-5 mins	NO PAIN	GRADE 1	1	A
83	364082	MUNIYAPPA	79	4	M	0-5 mins	MILD PAIN	GRADE 3	1	A
84	364031	CHIKKANNA	72	4	M	0-5 mins	NO PAIN	GRADE 1	1	A
85	364643	NANJUNDAMMA	64	3	F	0-5 mins	NO PAIN	GRADE 1	1	A
86	368808	VENKATAMMA	65	3	F	11-15 mins	MILD PAIN	GRADE 2	1	A
87	364456	NARAYANAPPA	69	3	M	0-5 mins	NO PAIN	GRADE 1	1	A
88	363846	PADMAMMA	54	2	F	0-5 mins	NO PAIN	GRADE 1	1	A
89	358853	SYED AMEER KHAN	76	4	M	0-5 mins	NO PAIN	GRADE 1	1	A
90	364545	VENKATAMMA	59	2	F	6-10 mins	MILD PAIN	GRADE 2	1	A
91	364574	MUNISWAMY	60	2	M	0-5 mins	NO PAIN	GRADE 1	1	A
92	215297	NARAYAN REDDY	70	3	M	6-10 mins	NO PAIN	GRADE 3	2	B
93	215316	SRINIVAS	49	1	M	6-10 mins	NO PAIN	GRADE 3	2	B
94	218319	VENKATAMMA	73	4	F	6-10 mins	NO PAIN	GRADE 3	2	B
95	215291	NAREMMA	59	2	F	0-5 mins	NO PAIN	GRADE 3	2	B
96	215298	NARAYANAMMA	60	2	F	0-5 mins	NO PAIN	GRADE 3	2	B
97	215301	RATHNAMMA	68	3	F	0-5 mins	NO PAIN	GRADE 1	2	B
98	216961	GOWRAMMA	78	4	F	0-5 mins	NO PAIN	GRADE 1	2	B
99	215299	RATHNAMMA	70	3	F	0-5 mins	NO PAIN	GRADE 1	2	B
100	215321	CHANDRAMMA	68	3	F	0-5 mins	MILD PAIN	GRADE 2	2	B
101	215290	RATHNAMMA	58	2	F	6-10 mins	MILD PAIN	GRADE 1	2	B
102	215284	CHINNAPPAIAH	74	4	M	0-5 mins	NO PAIN	GRADE 1	2	B

SL. NO.	UHIDNO	NAME	AGE	Age1	GENDER	TIME OF ONSET OF ANAESTHESIA	ANALGESIA	AKINESIA	Group	Group_A
103	215295	SAROJAMMA	69	3	F	0-5 mins	NO PAIN	GRADE 2	2	B
104	204165	MANJULA	58	2	F	6-10 mins	MILD PAIN	GRADE 1	2	B
105	215322	MUNIRAJU	60	2	M	0-5 mins	NO PAIN	GRADE 1	2	B
106	215294	GOWRAMMA	60	2	F	6-10 mins	MILD PAIN	GRADE 2	2	B
107	215310	LAKSHMIDEVAMMA	63	3	F	11-15 mins	NO PAIN	GRADE 2	2	B
108	215311	GANGAPPA	53	2	M	0-5 mins	NO PAIN	GRADE 1	2	B
109	215327	KRISHNAMURTHY	48	1	F	0-5 mins	NO PAIN	GRADE 1	2	B
110	215296	SRINIVAS.C.P	50	1	F	6-10 mins	NO PAIN	GRADE 1	2	B
111	215287	YASHODAMMA	68	3	F	6-10 mins	MILD PAIN	GRADE 2	2	B
112	224367	KANAKAMMA	56	2	F	0-5 mins	MILD PAIN	GRADE 1	2	B
113	226543	RAMALAKSHMAMMA	51	2	F	6-10 mins	NO PAIN	GRADE 1	2	B
114	224587	NAGAMMA	62	3	F	0-5 mins	MODERATE PAIN	GRADE 2	2	B
115	225786	MUTHAPPA	65	3	M	6-10 mins	MILD PAIN	GRADE 2	2	B
116	258154	NARAYANAPPA	78	4	M	6-10 mins	NO PAIN	GRADE 1	2	B
117	253171	RAVI KUMAR	35	1	M	11-15 mins	NO PAIN	GRADE 1	2	B
118	253180	GOVINDA SINGH	64	3	M	0-5 mins	NO PAIN	GRADE 1	2	B
119	253110	MANGAMMA	65	3	F	6-10 mins	NO PAIN	GRADE 2	2	B
120	253174	LAKSHMAMMA	65	3	F	0-5 mins	MILD PAIN	GRADE 1	2	B
121	253167	LAKSHMAMMA	82	5	F	6-10 mins	MILD PAIN	GRADE 2	2	B
122	253185	NARAYANAMMA	73	4	F	6-10 mins	NO PAIN	GRADE 1	2	B
123	253159	RATHNAMMA	46	1	F	0-5 mins	NO PAIN	GRADE 1	2	B
124	253177	MUNIVENKATAMMA	60	2	F	0-5 mins	NO PAIN	GRADE 2	2	B
125	253175	CHOWDAMMA	59	2	F	0-5 mins	NO PAIN	GRADE 1	2	B
126	253170	CHOWDAMMA	60	2	F	6-10 mins	NO PAIN	GRADE 1	2	B
127	255693	VENKATESH	50	1	M	0-5 mins	NO PAIN	GRADE 1	2	B
128	255697	LAKSHMAKKA	50	1	F	11-15 mins	NO PAIN	GRADE 2	2	B

SL. NO.	UHIDNO	NAME	AGE	Age1	GENDER	TIME OF ONSET OF ANAESTHESIA	ANALGESIA	AKINESIA	Group	Group_A
129	255703	SAVITHRAMMA	65	3	F	0-5 mins	NO PAIN	GRADE 1	2	B
130	256130	NARASIMHAPPA	55	2	M	0-5 mins	NO PAIN	GRADE 1	2	B
131	256295	ADILAKSHMAMMA	68	3	F	6-10 mins	NO PAIN	GRADE 1	2	B
132	253453	MUNISHAMAPPA	60	2	M	0-5 mins	NO PAIN	GRADE 1	2	B
133	254530	BYRAMMA	65	3	F	0-5 mins	NO PAIN	GRADE 1	2	B
134	253440	MUNIVENKATAPPA	83	5	M	0-5 mins	MILD PAIN	GRADE 1	2	B
135	254526	PAPAMMA	60	2	F	0-5 mins	NO PAIN	GRADE 1	2	B
136	256130	NARASIMHAPPA	55	2	M	0-5 mins	NO PAIN	GRADE 2	2	B
137	256150	AADINARAYANAPPA	68	3	M	6-10 mins	NO PAIN	GRADE 1	2	B
138	256271	ADILAKSHMAMMA	68	3	F	0-5 mins	NO PAIN	GRADE 1	2	B
139	256153	SHARADAMMA	65	3	F	11-15 mins	MILD PAIN	GRADE 2	2	B
140	256135	NARASAMMA	55	2	F	0-5 mins	NO PAIN	GRADE 1	2	B
141	260129	GOWRAMMA	87	5	F	0-5 mins	NO PAIN	GRADE 1	2	B
142	260130	KEMPAMMA	67	3	F	0-5 mins	NO PAIN	GRADE 1	2	B
143	260131	SUBBAMMA	68	3	F	11-15 mins	MILD PAIN	GRADE 2	2	B
144	260132	ESHWARAPPA	54	2	M	0-5 mins	NO PAIN	GRADE 2	2	B
145	260133	MUNIYAMMA	67	3	F	0-5 mins	NO PAIN	GRADE 1	2	B
146	260134	NARAMMA	67	3	F	0-5 mins	NO PAIN	GRADE 1	2	B
147	260133	NANJUNDACHARI	57	2	M	0-5 mins	NO PAIN	GRADE 1	2	B
148	260134	BALAJAPPA	67	3	M	0-5 mins	MILD PAIN	GRADE 1	2	B
149	260135	LAKSHMINARAYANA	61	3	M	0-5 mins	NO PAIN	GRADE 1	2	B
150	259214	RAMAVATH	56	2	M	6-10 mins	MILD PAIN	GRADE 1	2	B
151	259215	CHANDRAPPA	76	4	M	0-5 mins	NO PAIN	GRADE 1	2	B
152	259227	SATHYANARAYANA	67	3	M	0-5 mins	NO PAIN	GRADE 1	2	B
153	259332	PULLAIAH	57	2	M	0-5 mins	NO PAIN	GRADE 1	2	B
154	270954	MUNIYAPPA	53	2	M	0-5 mins	NO PAIN	GRADE 1	2	B

SL. NO.	UHIDNO	NAME	AGE	Age1	GENDER	TIME OF ONSET OF ANAESTHESIA	ANALGESIA	AKINESIA	Group	Group_A
155	278901	SHANKARNARAYANA	75	4	M	6-10 mins	NO PAIN	GRADE 2	2	B
156	354511	MURTHAPPA	65	3	M	0-5 mins	NO PAIN	GRADE 2	2	B
157	354503	LAKSHMAN REDDY	60	2	M	0-5 mins	NO PAIN	GRADE 1	2	B
158	354506	VENKATALAKSHMAMMA	71	4	F	6-10 mins	NO PAIN	GRADE 1	2	B
159	354502	SIDDAPPA	70	3	M	0-5 mins	NO PAIN	GRADE 1	2	B
160	354309	ERAMMA	80	4	F	0-5 mins	NO PAIN	GRADE 1	2	B
161	356203	GANGAMMA	74	4	F	6-10 mins	NO PAIN	GRADE 2	2	B
162	356218	DHANUKUMAR	66	3	M	6-10 mins	NO PAIN	GRADE 1	2	B
163	356212	GANGAPPA	62	3	M	0-5 mins	MILD PAIN	GRADE 2	2	B
164	356221	SHANTHAMMA	68	3	F	0-5 mins	MILD PAIN	GRADE 1	2	B
165	356221	JAMPAPPA	80	4	M	0-5 mins	NO PAIN	GRADE 1	2	B
166	356207	NARASAPPA	76	4	M	0-5 mins	NO PAIN	GRADE 1	2	B
167	356582	CHINNAPPA	65	3	M	0-5 mins	MILD PAIN	GRADE 1	2	B
168	356198	MALLAIAH	84	5	M	6-10 mins	NO PAIN	GRADE 1	2	B
169	356578	BALASUNDAR	60	2	M	0-5 mins	NO PAIN	GRADE 1	2	B
170	356581	CHINNAMAIAH	60	2	M	0-5 mins	NO PAIN	GRADE 1	2	B
171	356570	LAKSHMIDEVAMMA	65	3	F	6-10 mins	NO PAIN	GRADE 2	2	B
172	356575	CHANDRAMMA	60	2	F	0-5 mins	NO PAIN	GRADE 2	2	B
173	351801	AKKALAMMA	78	4	F	0-5 mins	NO PAIN	GRADE 1	2	B
174	297654	NARAYANAPPA	75	4	M	0-5 mins	MILD PAIN	GRADE 1	2	B
175	354898	NAZEER AHMED	72	4	M	0-5 mins	NO PAIN	GRADE 1	2	B
176	356202	VENKATESH	54	2	M	6-10 mins	MODERATE PAIN	GRADE 1	2	B
177	338861	MEENAKSHI	57	2	F	11-15 mins	MILD PAIN	GRADE 2	2	B
178	359764	NARAYANSWAMY	60	2	M	0-5 mins	NO PAIN	GRADE 1	2	B
179	339767	VISHWANATH REDDY	54	2	M	0-5 mins	NO PAIN	GRADE 1	2	B
180	359760	KAMALAMMA	72	4	F	0-5 mins	NO PAIN	GRADE 1	2	B

SL. NO.	UHIDNO	NAME	AGE	Age1	GENDER	TIME OF ONSET OF ANAESTHESIA	ANALGESIA	AKINESIA	Group	Group_A
181	360211	VENKATAPPA	60	2	M	0-5 mins	NO PAIN	GRADE 1	2	B
182	345243	MUNIYAPPA	70	3	M	0-5 mins	MILD PAIN	GRADE 1	2	B

DURATION OF ANAESTHESIA	LID MOVEMENT	SCH	CHEMOSIS	ECHYMOSIS	LID HEMORRHAGE	GLOBE PERFORATION	PTOSIS	PATIENT SATISFACTION	SURGEON SATIFACTION
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	YES	No	No	No	No	FAIR	FAIR
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
> 90 min	GRADE 1	No	YES	No	No	No	No	GOOD	FAIR
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	FAIR	FAIR
< 30 min	GRADE 1	YES	YES	No	No	No	No	FAIR	FAIR
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD

30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	YES	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
< 30 min	GRADE 1	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
< 30 min	GRADE 1	YES	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	FAIR
30-90 min	GRADE 1	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD

30-90 min	GRADE 2	YES	No	No	No	No	No	FAIR	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	FAIR
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	YES	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	YES	No	No	No	No	FAIR	FAIR
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
> 90 min	GRADE 1	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	YES	No	No	No	No	FAIR	GOOD

30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
< 30 min	GRADE 1	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	FAIR	FAIR
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
> 90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	FAIR	FAIR
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
< 30 min	GRADE 1	No	YES	No	No	No	No	FAIR	FAIR
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	YES	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD

30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	YES	YES	No	No	No	No	FAIR	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	YES	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	FAIR	FAIR
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	YES	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	YES	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD

30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	FAIR	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	YES	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD
> 90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	No	No	No	No	No	GOOD	GOOD

30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD
> 90 min	GRADE 1	No	No	No	No	No	No	FAIR	FAIR
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
> 90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 1	No	No	No	No	No	No	GOOD	GOOD
30-90 min	GRADE 2	No	YES	No	No	No	No	GOOD	GOOD