"ONE YEAR HOSPITA L BASED LONGITUDINAL STUDY TO KNOW THE SAFETY AND EFFICACY OF MINIMAL DOSE OF MITOMYCIN–C IN TRABECULECTOMY."

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IST OF ABBREVIATIONS USED

AC	-	anterior chamber
ACG	-	angle closure glaucoma
ARG	-	angle recession glaucoma
CACG	-	chronic angle closure glaucoma
5-FU	-	5 fluorouracil
IOP	-	intra ocular pressure
LE	-	left eye
Mm hg	-	millimeters of mercurt
MMC	-	Mytomycin-C
Min.	-	minutes
NCT	**-**	***noncontact tonometer***
NO	-	number
PCIOL	-	posterior chamber intra ocular lens
PI	-	peripheral iridectomy
POAG	-	primary open angle glaucoma
Post-op	-	post oprative
RE	-	right eye
SICS	-	small incision cataract surgery
Sx	-	surgery
VA	-	visual acuity
Vn	-	vision
PXF.G	-	pseudoexfoliative glaucoma

ABSTRACT

Background and objectives:

Glaucoma ranks second as the most common cause of blindness worldwide. Treatment of glaucoma is usually by medical therapy but in certain situations like poor compliance, lack of awareness, poor follow-up facilities and non-affordability, surgical intervention becomes the method of first choice.

Glaucoma surgery has many sight threatening complications and a high risk of failure. The cause of failure in these cases is scarring due to proliferation of fibroblasts at the surgical site so, to increase the success rates in the glaucoma filtration surgeries, antifibrotic agents are being used to modulate wound healing. However,it can cause increased risk of serious complications. The optimum regimen of Mitomycin-C administration has yet to be established. It is known that this anti-proliferative agent acts in a dose and time dependent way.So the study is aimed to establish the safety and efficacy of minimal dose of Mitomycin-C in trabeculectomy.

The aim of this study is to evaluate the safety of minimal concentration and exposure time of Mitomycin-C (0.1mg/ml for 2 minutes) as an adjunct to trabeculectomy and to evaluate the complications of minimal dose of mitomycin-c in trabeculectomy.

Methodology

The present one year longitudinal study was conducted in the Department of Ophthalmology, KLES Dr. Prabhakar Kore hospital and Medical Research Centre, Belagavi on patients undergoing glaucoma filtering surgery during the period of 1st January 2015-31st December 2015. The study was approved by the Ethical and

Research Committee of Jawaharlal Nehru Medical College, Belagavi. Thirty patients with low risk glaucoma underwent a complete ophthalmic assessment and then underwent trabeculectomy with 0.01mg/ml (for two minutes) Mitomycin-C .Visual acuity, bleb function and related complications, intra ocular pressure and any other complications were noted post operatively till three months.

Results :

-30 eyes of 30 patients has been undergone trabeculectomy with MMC or trabeculectomy with MMC with SICS with PCIOL.

-out of thirty patients, maximum number of patients(12 patients) were between 46-60 years age group, two patients belonged to 31-45 years age group, eleven patients belonged to 61-75 years age group and five patients were above 76 years.

-There were 21 male patients and 9 female patients.

-15 patients with POAG, 4 patients with CACG, 11 patients with pseudoexfoliative glaucoma underwent glaucoma filteration surgery.

-15 patients underwent trabeculectomy with MMC and 15 patients underwent SICS with PCIOL with trabeculectomy with MMC.

-On application of student “t” test it was statistically significant. ($P<0.001$)

-The initial IOP of 21 patients was between 21-30mmhg and IOP of 9 patients was between 31-55mmhg.

-The mean pre-op IOP was 30.18± 9.68 and mean IOP at the end of one day, one week, one month and three months was 11.65 ± 5.24,11.64±5.46,11.95±4.48 and 10.97±3.84 respectively.

-Complete success (IOP was less than 21 mm Hg without glaucoma medication) was observed in 90 % of cases and qualified success (IOP was less than 21 mm Hg with or without glaucoma medication) was noted in 10% of cases.

-VA was stable or improved in 93.3%. In 6.6% patients (3patients), VA was reduced because of cataract or pre-existing cataract (one patient- 3.33%) and choroidal detachment(one patient-3.33%)

-In one patient(3.33%), shallow AC was noted.

- The most common variety of bleb encountered was grade II or diffuse, mildly elevated and normally vascularised filtering bleb (according to Moorfield's classification) seen in 28cases (93.3%),in the last follow up. In 1 case (3.3%) we encountered grade I or diffuse, avascular, mildly elevated filtering bleb and in 1 case grade III or diffuse, mildly elevated and mildly vascularised bleb was encountered. (3.3%)

Conclusion and interpretation:

Intraoperative application of MMC in low doses (0.1mg/ml x 2 minutes) was associated with better control of IOP, stabilization of visual acuity, well functioning normally vascularised blebs, with minimal acceptable complications and can be used as a safe and efficacious adjuvant in primary filtering surgeries in low risk cases.

Key Words: trabeculectomy, MMC, IOP, bleb

CONTENTS

LIST OF TABLES AND GRAPHS

INTRODUCTION

Glaucoma is the second leading cause of blindness worldwide, with a disproportional morbidity among women and Asians.[1]

According to NPCB-WHO survey (1986- 89) glaucoma accounts for 5.80% of total blindness in India and primary angle closure glaucoma accounts for nearly 30% of all cases of glaucoma. A look at the number of persons who are blind or heading towards blindness due to glaucoma in 50+ population gives an inkling of the gravity of this problem. There are at least 12 million people in India affected with the Glaucoma,1.5 million are blind from the disease. In India, prevalence of Glaucoma ranging from 1%-6%.[2]

The concepts and definitions of glaucoma have evolved in the past 100 years. Today the term does not refer to a single disease entity, but rather to a group of diseases that differ in their clinical presentation, pathophysiology and treatment. [1]

These diseases are grouped together because they share certain features, including cupping and atrophy of the optic nerve head, which has attendant visual field loss and is frequently related to the level of intraocular pressure (IOP).[1]

Trabeculectomy has been used for the surgical management of glaucoma for more than 30 years and remains the most commonly used incisional surgery for glaucoma. Many studies have compared initial trabeculectomy with medical treatment and have found that trabeculectomy provides consistently lower intraocular pressures (IOPs) than medical therapy.[3]

The most common cause of failure of glaucoma filtering surgery is scarring at the filtration site. To increase the success rate of glaucoma filtering surgery, particularly in eyes with poor prognosis, antifibrotic agents have been used to modulate wound healing.First intrduced the use of mitomycin C as adjunct chemotherapy during trabeculectomy in 1981.[4]

Mitomycin C is an antineoplastic / antibiotic agent isolated from the soil bacterium *Streptomyces caespitosus*. Mitomycin-C, first found its way into ophthalmic use in 1969, in Japan, where recurrent pterygia were successfully treated with the drug. [5]

A single intraoperative application of this agent at the filtering site is beneficial but it has poor surgical prognoses. But with Mitomycin-c, higher the dose (0.2-0.5mg/ml for 3-5 min), more the complications like wound leak hypotony, hyphema, shallow AC were noted.[6]

So this study is to establish safety & efficacy of minimal dose of Mitomycin-C.(0.1mg/ml for 2min)

AIMS & OBJECTIVES

1. To evaluate the safety of minimal concentration and exposure time of Mitomycin-C (0.1mg/ml for 2 minutes) as an adjunct to trabeculectomy.
2. To evaluate the complications of minimal dose of mitomycin-c in trabeculectomy

REVIEW OF LITERATURE

The history of the meaning of the word Glaucoma:[7]

The discovery of the disease called glaucoma dates back to the 17th century. Initial comprehension of its pathogenesis and treatment belong to the 20th century.

The word glaucoma came from ancient Greek, meaning clouded or blue-green hue, most likely describing a person with a swollen cornea or who was rapidly developing a cataract, both of which may be caused by chronic elevated pressure inside the eye.

The definition of glaucoma has changed drastically since its introduction around the time of Hippocrates in approximately 400 BC. The first recognition of a disease associated with a rise in intraocular pressure and thus corresponding to what is now known as glaucoma occurs in the Arabian writings, "Book of Hippocratic treatment"(10^{th}century).

In European writings, Dr Richard Bannister (1622), an English oculist and author of the first book of ophthalmology in English, who makes the first original and clear recognition of a disease with a tetrad (four) of features: eye tension, long duration of the disease, the absence of perception of light and the presence of a fixed pupil.

All through the 18th century the term glaucoma was merely a label applied to an inflamed eye wherein the pupil appeared greenish-blue and the visual prognosis was bad, but the tension of the eye was not stressed.

It was not until the beginning of the 19th century that the first excellent description of glaucoma with raised ocular tension is given by the French Dr Antoine-Pierre Demours (1818). Thereafter the central concept of a rise in the intraocular pressure became fully established.

In London, Dr G.J. Guthrie (1823) recognized hardness of the eye as characteristic of a disease which he called GLAUCOMA.

Finally, the essential feature of raised eye tension was fully established by the great Dr William McKenzie, Scottish clinician (1835) who, in the second edition of his classical and widely read textbook, ascribed the raised tension in both chronic and acute glaucoma.

The final clinical observation in this epoch was the unifying concept of Dr Donders (1862) where he described an incapacitating increased eye tension occurring without any inflammatory symptoms as Simple Glaucoma.

The concept of glaucoma has been further refined, particularly over the last 100 years.

Dr Drance (1973) provided for the first time the definition of glaucoma as a disease of the optic nerve (an optic neuropathy) caused by numerous factors, called risk factors.

Currently, glaucoma refers to a group of eye conditions which cause characteristic damage to the optic nerve, the "cable" that transmits the visual message from the eye to the brain, and characteristic damage to the visual field. This damage is progressive, leads to loss of vision if untreated and often is caused by "higher pressure inside the eye" than the optic nerve can tolerate.

Aqueous humor outflow system Overview:[8]

Aqueous humor is formed by the ciliary processes, passes from the posterior chamber to the anterior chamber through the pupil, and exits the eye at the anterior chamber angle. Aqueous returns to the venous system primarily by means of the conventional or canalicular pathway (83–96% of flow).

The pathway is through the trabecular meshwork into Schlemm's canal (hence the canalicular pathway). The Schlemm's canal lumen communicates directly with the episcleral veins, completing the circulatory pathway for aqueous return to the heart.

Aqueous humor also returns to the heart by a secondary pathway known as the uveoscleral or unconventional route. The uveoscleral route accounts for from 5 to 15% of flow, an amount that decreases with age.

Functions of the conventional aqueous outflow system:[8]

1) It's a circulatory path for aqueous humor return to the vascular system

2) Permits bulk aqueous flow of aqueous out of the anterior chamber but prevents blood reflux into the anterior chamber.

3) Maintenance of a relatively stable intraocular pressure (IOP).

4) A fourth function is filtration of foreign material and debris.

Anatomy of the conventional outflow system:

Schwalbe's line:[8]

Schwalbe's line (composed of collagen and elastic tissue) is an irregular elevation 50–150 micro.m wide that runs circumferentially around the globe.

This line or zone marks the transition from trabecular to corneal endothelium, the termination of Descemet's membrane, and the insertion of the trabecular meshwork into the corneal stroma.

Scleral spur:[8]

The scleral spur is a fibrous ring that appears as a wedge projecting from the inner aspect of the anterior sclera .

The spur is attached anteriorly to the trabecular meshwork and posteriorly to the sclera and the longitudinal portion of the ciliary muscle.

When the ciliary muscle contracts, it pulls the scleral spur posteriorly . The largest trabecular lamellae near the anterior chamber are attached to the scleral spur and accordingly are rotated inward and posteriorly by ciliary muscle contraction.

Rotation alters the position not only of the large lamellae, but also moves the entire attached meshwork further inward and posteriorly. Inward movement of the trabecular meshwork results in an enlargement of intertrabecular spaces and an increase in the size of Schlemm's canal, reducing the tendency of the canal lumen to narrow or collapse.

Trabecular meshwork tissues:[8]

In meridional section, the trabecular meshwork has a triangular shape, with its apex at Schwalbe's line and its base at the scleral spur.

The inner layers of the trabecular meshwork border the anterior chamber and are referred to as the uveal meshwork. The next more superficial layer is the corneoscleral meshwork.

The juxtacanalicular space is the next layer, which is between the corneoscleral meshwork and Schlemm's canal inner wall endothelium.

Juxtacanalicular space and cells:[8]

The juxtacanalicular space is 2–20 μm thick in non pressurized eyes. The space separates the outer layers of the corneoscleral meshwork from the inner wall of Schlemm's canal

It has been called by a variety of names like cribriform space, pericanalicular space, and endothelial meshwork.

Juxtacanalicular, subendothelial, and cribriform cells are starshaped. Juxtacanalicular cell cytoplasmic processes attach to processes arising from Schlemm's canal inner wall endothelium.

By distributing IOP-induced stresses across the entire trabecular lamellae system that supports the inner wall endothelium of Schlemm's canal, the stresses are tensionally integrated, which is essential in cellular response mechanisms.

Schlemm's canal:[8]

Schlemm's canal is a vascular sinus with a lumen that communicates around the entire globe.

Collector channels, aqueous veins and episcleral veins:[8]

Schlemm's canal is drained by a series of collector channels that in turn drain into a complex system of intrascleral, episcleral, and subconjunctival venous plexus.

The collector channels arise from the outer wall of Schlemm's canal at irregular intervals. A few (4–6) direct collector channels proceed directly from Schlemm's canal through the sclera thus communicating directly with aqueous veins on the surface of the eye

Aqueous veins empty into episcleral and conjunctival veins. Where aqueous and episcleral veins join, characteristic laminar flow of aqueous humor and blood is seen on slit-lamp examination at the limbus.

Aqueous outflow physiology

The aqueous outflow system as a passive filter:[8]

The traditional model of aqueous flow is that of a passive, nonenergy-dependent bulk fluid movement down a pressure gradient with aqueous leaving the eye primarily by the canalicular route.

The model is recognized as being somewhat oversimplified because of a component of uveoscleral flow. In the model, aqueous is forced through a syncytium

of extracellular matrix material in the juxtacanalicular space that acts as a passive resistance unit controlling pressure and flow. Evidence favoring the model is the finding of similar aqueous flow rates in living and enucleated eyes.

The aqueous outflow system as a dynamicmechanical pump:[8]

In this model, elastic and contractile tissues of the trabecular meshwork and valves within Schlemm's canal stretch in response to transient pressure increases.

The energy stored during distention is released when the pressure transients decay, causing the tissues to recoil to their prior configuration. Thepressure transients thus enable energy-dependent pulsatile fluid movement through the outflow system.

Uveoscleral flow:[8]

A lesser amount of the aqueous humor exits the eye by an alternate route through the ciliary muscle, the iris, the sclera, and other structures of the anterior segment . This alternate pathway is known by a number of terms, including *uveoscleral*, *unconventional*, *extracanalicular*, and *uveovortex flow*.

Aqueous humor enters the ciliary muscle through the uveal trabecular meshwork, the ciliary body face, and the iris root.

The fluid passes posteriorly between the bundles of the ciliary muscle until it reaches the supraciliary and suprachoroidal spaces.

Aqueous humor leaves the eye through the spaces around the penetrating nerves and blood vessels and through the sclera.

The net fluid flow into the uveal vascular system is quite low for a number of reasons:

1) the iris capillaries have thick walls that restrict movement of water and ions.

2) pressure in the uveal capillaries is higher than IOP. This pressure difference partially offsets the difference in oncotic pressure between the plasma and the tissue fluid of the uveal tract. Thus there is little driving force for fluid to cross the capillary walls.

In human eyes, the unconventional pathway is estimated to carry 5–25% of the total aqueous outflow. uveoscleral outflow increases up to four-fold when the anterior segment is inflammed.

Classification of glaucoma:[1]

Angle-closure glaucoma:

Primary angle-closure disease

Irido-trabecular contact is the final common pathway of angle closure disease, obstructing aqueous outflow; it can be conceptualized in two complimentary schemes:

Natural history

Primary angle closure *suspect*

Primary angle *closure*

Primary angle-closure *glaucoma*

Anterior segment mechanisms of closure

-Iris–pupil obstruction (e.g., 'pupillary block')

-Ciliary body anomalies (e.g., 'plateau iris syndrome')

-Lens–pupil block (e.g., 'phacomorphic block' (swollen lens or microspherophakia)

Secondary angle-closures

Anterior 'pulling mechanism':

The iris is pulled forward by some process in the angle, often by the contraction of a membrane or peripheral anterior synechiae.

-Neovascular glaucoma

-Iridocorneal endothelial syndromes (e.g., Chandler's syndrome)

-Epithelial downgrowth

-Fibrous ingrowth

-Flat anterior chamber

-Inflammation

-Penetrating keratoplasty

-Aniridia

Posterior 'pushing mechanism':

The iris is pushed forward by some condition in the posterior segment. Often the ciliary body is rotated anteriorly, allowing the lens to come forward also.

Ciliary block glaucoma (malignant glaucoma)

-Cysts of the iris and ciliary body

-Intraocular tumors

-Suprachoroidal haemorrhage

-Intravitreal air injection (e.g., retinal pneumopexy)

-Ciliochoroidal effusions (e.g., panretinal photocoagulation)

-Inflammation (e.g., posterior scleritis)

-Central retinal vein occlusion

-Scleral buckling procedure

-Retrolental fibroplasias

Open-angle glaucoma

Primary open-angle glaucoma

-IOPs higher than 'normal range'

-IOPs within 'normal range' (low-tension glaucoma)

Secondary open-angle glaucoma

-Pigmentary glaucoma

-Pseudoexfoliation glaucoma

-Steroid glaucoma

-Lens-induced glaucoma

a) Phacolytic glaucoma

b) Lens-particle glaucoma

c) Phacoanaphylaxis

-Glaucoma after cataract surgery

-UGH syndrome (uveitis glaucoma hyphema)

-Glaucoma after neodymium:yttrium-aluminum garnet (Nd:YAG) laser posterior capsulotomy

-Glaucoma with vitreous in anterior chamber

-Glaucoma after trauma (Chemical burns, Electric shock, Radiation, Penetrating injury, Contusion injury)

-Glaucoma associated with intraocular haemorrhage

-Ghost cell glaucoma

-Hemolytic glaucoma

-Glaucoma associated with retinal detachment

-Glaucoma after vitrectomy (Intraocular gas, Intraocular silicone oil)

-Glaucoma with uveitis

a) Fuchs' heterochromic iridocyclitis

b) Glaucomatocyclitic crisis (Posner-Schlossman)

c) Precipitates on trabecular meshwork (trabeculitis)

-Herpes simplex

-Herpes zoster

-Sarcoidosis

-Juvenile rheumatoid arthritis

-Syphilis

-Human immunodeficiency virus (HIV) infection

-Glaucoma with intraocular tumors (Malignant melanoma, Metastatic lesions ,Leukemia and lymphoma)

-Benign lesions (e.g., juvenile xanthogranuloma , neurofibromatosis)

Amyloidosis

-Increased episcleral venous pressure

a) Obstruction of venous drainage (e.g., superior venacava obstruction)

b) Arteriovenous fistula (e.g., carotid cavernous)

c) Ocular episcleral venous anomalies (e.g., Sturge-Weber syndrome)

Developmental glaucoma

Anomalies of the anterior segment are present at birth. Glaucoma may be present at birth or may appear in the first decades of life

Primary congenital (infantile) glaucoma

-Congenital glaucoma

-Autosomal dominant juvenile glaucoma

-Glaucoma associated with systemic abnormalities

-Glaucoma associated with ocular abnormalities

Secondary glaucoma

-Traumatic glaucoma

-Glaucoma with intraocular neoplasm

-Uveitis glaucoma

-Lens-induced glaucoma

-Steroid-induced glaucoma

-Neovascular glaucoma

-Secondary angle-closure glaucoma

-Glaucoma with elevated episcleral venous pressure

-Glaucoma secondary to intraocular infection

Surgical anatomy for glaucoma surgery:[9]

The surgical limbus is a blue-grey transition zone between the parallel collagen fibers of the peripheral cornea and those of anterior sclera.

The anterior border is coincident with an imaginary vertical line between the peripheral edge of Bowman's and Descemet's membranes.

The posterior border ,covered by overlying conjunctiva & Tenon's capsule, is defined by transition between the white scleral tissue and the blue-grey zone.

The conjunctiva ,a mobile vascularized tissue with a surface epithelium,inserts in the peripheral corneal epithelium at the anterior limbal edge.

Tenon's capsule, a loose fibrovascular layer, attaches approximately 1.5to 2mm posterior to the conjunctival insertion.

In a limbal based conjunctival flap, the conjunctival insertion defines the anterior limit of the dissection. The posterior border incision of the scleral flap should begin peripheral to the gray-white scleral tissue.

With advance dissection, a relatively bright curvilinear white line parallel to the limbus is exposed that corresponds to the scleral spur.

Proceeding anterior to the scleral spur, the bed of the flap appears darker and more transparent . This zone, immediately anterior to scleral spur , corresponds to the underlying trabecular meshwork and Schlemm's canal. schlemm's canal is located in the most posterior area of the blue-gray limbus.

In dissecting forward, the angulation of the blade should be changed to follow the limbal curvature and to avoid premature entry into anterior chamber. The union between the sclera and cornea forms a visible change in the limbal curvature, the external scleral sulcus, which is the junction of the two different radii of curvature.

The internal scleral sulcus corresponds to the internal part of the limbus that holds the trabecular meshwork and in its posterior and lateral zone lays Schlemm's canal.

The dissection of the scleral flap should continue into clear cornea , anterior to Schwalbe's line. This is the point where entry is made into the entry chamber.

The oblique insertion of the peripheral corneal fibers into the sclera may creat the impression that the flap dissection was sufficiently anterior and led to premature entry into the anterior chamber .scleral flap dissection should be continued anteriorly until clear cornea is encountered.

The posterior or scleral border of the inner block should be placed anteriorly to the scleral spur. cutting or excising scleral tissue posterior to the scleral spur carries the risk of damaging the ciliary body and major circle of the iris and causing intraocular bleeding.

Underlying the sclera, posterior to the scleral spur, is the pars plicata of the ciliary body that terminates in the pars plana, approximately 2.5 to 3.5mm posterior to the limbus. Haemorrhage may occur if the ciliary body or major circle of the iris is injured when performing peripheral iridectomy.

Light cauterization to minimise haemorrhage should be applied only to the bleeding vessels, but the scleral flap should not be treated so as to avoid tissue shrinkage.

Trabeculectomy

The most commonly perform glaucoma filtering glaucoma procedure increase aqueous outflow through a surgical fistula into the subconjunctival space.

Indication:[10]

-Open angle glaucoma

-Closed angle glaucoma

- Childhood glaucoma

-Failed medical and laser therapy

Contraindications:[10]

-Cases likely to respond to less invasive treatements

-Eyes with previous failed trabeculectomy

- Eyes with severely scarred conjunctiva

- Neovascular glaucoma

-Uveitic glaucoma

Anesthesia:[9]

Retrobulbar

Peribulbar

Sub-tenon's

Topical

General anesthesia (children)

Pre-operative preparation:[9]

-topical antibiotics one day before surgery

-systemic antibiotics from the day of the surgery

-Intra ocular maintenance within normal limits

-miotic pupil by 2% Pilocarpin eye drops instilled for four times one hour before surgery

Surgical steps:[9]

Clear corneal traction suture:

To visualise the 12 o'clock limbal meridian which is, which is the preferred surgical site, the eye must be directed inferiorly.

It's usually preferred to place a clear cornea traction suture to maintain infraduction. After rotating eye inferiorly, the surgeon passes a 5-0 or 7-0 braided vicryl suture.

Conjunctival incision:

In standard trabeculectomy, either a limbal or fornix based conjunctival flap is taken to expose the corneoscleral junction.

Fornix based flaps are easier to develop and usually provide better exposure than limbus based flaps.

Water tight wound closure may be more difficult to achieve with fornix based flap particularly with the use of 5-FU and MMC.

The risk of intraoperative conjunctival button hole formation is higher with limbal based flaps and the procedure is more time consuming.

With the bleds of rounded tip Westcott scissors held perpendicular to the fold, ,2 to 3mm circuferinceal cut is made through the conjunctiva. without cutting tenon's capsule or injuring the underlying superior rectus muscle.

Through this opening, posterior tip of scissors blade is advanced approximately 4 to 5mm in each direction to make 8mm conjunctival incision. The surgen then graps tenon's capsule & cuts it with the same scissors.

Fornix based conjunctival peritomy:

While grasping the conjunctiva posterior to the limbus with non-toothed forceps, the surgeon makes 2mm wide incision through the limbal insertion with rounded tip westcott scissors.

The surgeon introduces the posterior scissor blade through the incision nd disinserts the conjunctiva for 3-4 clock hours.

After the conjunctival incision, the same scissors are used to free adhesions between tenon's capsule and episclera.

After cutting tenon's capsule, the tips of the scissors are used to develop a potential space between tenon's capsule and episclera .l

Light bipolar diathermy or cautery reduces episcleral bleeding.

Scleral flap:

The scleral flap width must extend beyond the edge of thinner block to produced aqueous humor out flow resistance.

Eequilateral triangular shape is preferred that is easier to dissect and close. The surgen outlines each scleral side of the triangle with the 15 or 45 degree disposable blade. The surgeon dissects 75% of dept of sclearal flap anteriorly into

peripheral clear cornea with a 15/45 degree sharp blade, a crescent knife or a bent round tipped blade.

The use of high magnification and flap bed haemostasis with dry cellulose sponges facilitates visualisation.

Paracentesis:

A self- celling paracentesis track should be made through the temporal clear cornea before entering the anterior chamber.

Through this site, the surgeon can reform the anterior chamber and tests for conjunctival wound leaks.

Removal of the inner block: sclerectomy (inner block removal with descemet's punch)

The surgeon first makes an incision to 90% corneal depth with the sharp blade held parallel to the optical axis. The incision should be as wide as the base of the sclearal flap to facilitate the punch insertion.

The incision is gradually deepen with multiple shallow cuts until aqueous humor is seen. Sudden decompression may cause excessive aqueous outflow and a flat or shallow anterior chamber that will complicate inner block removal.

with the scleral flap elevated, the surgeon introduces a kelley's descemet's membrane punch into the middle of the incision by placing the cutting edge facing posteriorly.

Closing the punch removes 0.75mm semi circular block of limbal tissue. Two or three punches are made to produce an opening approximately 2*1mm. Ieally only deep peripheral corneal stroma and descemet's membreane anterior to the sclearal spur should be removed.

Peripheral iridectomy:

After inner block removal the peripheral iris usually spontaneously bluges or protrudes into the filtering site.

The surgeon positions the vannus scissors parallel to the limbus , grasps the iris with 0.12mmtooth forceps slightly anterior to the centre of the inner block and retracts is posteriorly.

The open scissors are closed to complete the iridectomy. If the surgeon encounters excessive iris prolapse and if iridectomy does not permit repositioning of iris, gentle pressure over the peripheral cornea and scleral flap applied with a cotton tipped applicator.

Scleral flap closure:

Three interrupted 10-0 nylon sutures close the triangular flap. It should not be tied too tightly. The two side sutures placed near the anterior the anterior limbal base of the triangular flap serve to direct aqueous humor flow posteriorly.

Suture tension should be adjusted to achieve visible aqueous out flow,normal anterior chamber depth and intra ocular pressure between 10 an 15mmhg.

Conjunctival closure:

Limbal based flap:

A single continuous running 10-0 nylon suture on a tapered point needle closes the conjunctiva and tenon's capsule.

Fornix based flap:

Interrupted 10-0 nylon horizontal matress sutures are used to close fornix base conjunctival flaps.

10-0 nylon is preferred because wound healing may be altered by post operative injections of 5-FU.

When the suture is tied, the knot lies buried under the conjunctiva.

To check for wound leaks and button holes ,the conjunctival incision site is wiped with the collagen sponge while injecting balanced salt solution into the a.c through the paracentesis site.

End of the procedure:

Topical 1% atropine sulphate is instilled to minimise patients' discomfort and to deepen the a.c by providing cycloplegia.

Broad spectrum antibiotic such as gentamycin sulphate (20mg) and dexamethasone sodium phosphate (2mg) are usually injected subconjunctivally.

Post – operative treatment:[9]

-Patched eye for 24hrs.

-Steroid-antibiotic eye drops6 times/day tapered over one and half months

-Homatropine eye drops two times/day

-Anti-glaucoma medication if post operatively raised IOP

Intraoperative Complications of Trabeculectomy:[11]

Traction suture

-Hematoma in superior rectus muscle

- Severing of superior rectus tendon

- Coeal perforation

- Conjunctival flap

-Mishandling of conjunctiva

- Conjunctival buttonhole/tear

- Subconjuctival/episcleral bleeding

- Mitomycin sponge application

- Retained mitomycin sponge after surgery

- Conjunctival buttonhole/tear by sponge

Scleral flap dissection

- Improper thickness of superficial flap

- Disinsertion of the superficial flap

- Inadvertent early entry into anterior chamber

- Incomplete removal of Descemet's membrane

Sclerostomy

- Inadequate/incomplete fistula formation

- Iris/corneal/lens injury

Corneal injury

- Abrasion and epithelial defect

- Descemet's membrane detachment

Iridectomy related

- Incomplete iridectomy

- Large iridectomy

- Iris incarceration/prolapse

- Iris bleeding/anterior chamber bleeding (hyphema)

- Iridodialysis

Others

- Lens injury

- Ciliary body injury

- Cyclodialysis

- Vitreous loss

- Shallow anterior chamber

- Conjunctival wound leak

- Serous choroidal detachment

-hyphema

Early and late post operative complications of trabeculectomy:[11]

Early complications

Hyphaema : Common causes of bleeding are iris and ciliary body trauma during the iridectomy portion, especially in patients with active tissue neovascularization. Other sources of bleeding are from cut ends of Schlemm's canal and the corneoscleral wound.[11]

Shallow/flat anterior chamber : shallow anterior chamber occurred in both eyes of one patient due to aqueous misdirection.

A persistent shallow or flat anterior chamber can lead to lenticulo corneal touch, corneal oedema, cataract, hypotony and its related complications like maculopathy and choroidal detachment.[12]

Hypotony: 20% of cases of glaucoma-filtering surgery are associated with hypotony[13]

Bleak leak: An inadvertent buttonhole or tear in the conjunctiva during a filtering procedure or a wound leak through the conjunctival incision can be responsible for an early leaking bleb. Late bleb leaks are more frequently encountered in thin, avascular blebs that were exposed to antifibrotic agents at the time of surgery.[14]

Choroidal detachment: Choroidal detachment due to serous effusions in the suprachoroidal space frequently occurs due to hypotony in the postoperative period following glaucoma drainage surgery.[11]

Endophthalmitis: Leakage of filtering bleb can cause endophthalmitis.[14]

Late complications

Cataract: Direct lens injuries during surgery are rare but the anterior capsule can be torn by sharp instrumentation, leading to cataract formation. This complication can happen during creation of a paracentesis, excision of the internal block, and while performing the iridectomy. Excessive fluid irrigation into the anterior chamber can also lead to cataract formation.[11]

Decreased visual acuity: hypotonous maculopathy and cataract formation/progression are the common causes of reduced visual acuity.[15,16]

Encapsulated bleb: Encapsulation of the filtering bleb occurs in approximately 13% of eyes following trabeculectomy and is increasing in incidence, partly due to the detrimental effect of topical therapy on conjunctival and episcleral Fibroblasts. Encapsulation occurs in the early post-operative period, when adhesions form between the episcleral tissues and Tenon's capsule creating a fibrous, vascular cyst that entraps aqueous and creates a localised, domeshaped bleb. The associated intraocular pressure (lOP) rise peaks in the first 6 weeks post-operatively and may cause additional optic nerve head damage in vulnerable eyes.[17]

Endophthalmitis

Wound Healing in Glaucoma Filtering Surgery:[18]

Successful glaucoma filtering surgery is characterized by the passage of aqueous humor from the anterior chamber to the subconjunctival space, which results in the formation of a filtering bleb.

I) Clinical and Histopathologic Findings After Glaucoma filtering Surgery:

A) Bleb formation, failure and encapsulation:

Formation of a filtering bleb, which is a subconjunctival accumulation of aqueous. Functioning blebs may be thin and polycystic with transconjunctival flow of fluid.

Other flatter, thicker, and more diffuse blebs with a relatively avascular appearance in comparison to the surrounding conjunctiva may also successfully lower intraocular pressure.

In failed blebs, the scarred conjunctiva firmly adheres to the underlying episcleral tissue.

The encapsulated bleb also known as a "Tenon's capsule cyst." This localized, dome-shaped, cyst-like cavity of hypertrophied Tenon's capsule forms over the filtering site, usually by the third postoperative week, and entraps aqueous, resulting in increased intraocular pressure.

B)Histopathologic findings:

Addicks et al' have described a histopathologic appearance of loosely arranged connective tissue beneath the conjunctival epithelium in functioning blebs.

At the light microscopic level, subepithehal clear spaces corresponded to conjunctival microcysts, which are seen clinically and indicate a functional filtering bleb.

With electron microscopy the loose connective tissue was observed to contain scattered but otherwise normal collagen fibrils with 50 to 200 micron channel-like spaces throughout the stroma.

Both light and electron microscopy showed normal conjunctival epithelium with no junctions between the cells that would limit fluid flow.

Failed blebs demonstrated abnormally thickened, dense collagenous connective tissue beneath the conjunctival epithelium, which appeared normal . Fibroblasts and blood vessels were were also seen within the connective tissue of failed blebs.

Histopathoiogically, the walls of encapsulated blebs were thin, almost avascular membranes which consisted of sheets of fibrous connective tissue with areas of active proliferation of fibroblasts.

The cyst-like spaces of encapsulated blebs were lined by acellular material, which was probably fibrin, and not by surface epithelium, which lines true cysts.

II) Wound healing:[18]

In the first six days after surgery **(early healing**), the limbal fistulas generally remained open, although by day six, fibroblasts had begun to proliferate along the walls of the opening.

Fibrinous material at the limbal fistula was seen in at least one eye early in the postoperative period.

During the **intermediate healing** phase (days 7-9), continued proliferation and migration of fibroblasts, which were presumably derived from the adjacent episclera and subconjunctival tissue, were observed. Fibroblasts during the intermediate stage were predominantly oriented perpendicular to the corneoscleral lamellae.

In the **late healing** phase (days 1O-14), the limbal fistulas, with one exception, were completely closed by granulation tissue.

The fibroblasts were oriented in a plane parallel to the cornea, a finding consistent with early wound remodelling and maturation.

During days 7-14, ingrowth of episcleral fibroblasts, migration of macrophages, blood vessel formation, and deposition of collagen were noted.

Sequence of Events in Wound Healing:[18]

After surgical trauma to the conjunctiva, episclera, and iris, blood vessels constrict, and leakage of plasma proteins (including fibrinogen, fibronectin, and plasminogen) and blood cells occurs.

When exposed to tissue factors, plasma, or blood, or both clot to form a gel-like fibrin-fibronectin matrix, into which inflammatory cells (including monocytes and macrophages), new capillaries and fibroblasts migrate.

The fibrin-fibronectin matrix is eventually degraded by inflammatory cells and fibroblasts subsequently synthesize fibronectin, interstitial collagens and glycosaminoglycans to form young fibrovascular connective tissue, also known as granulation tissue.

Blood vessels are reabsorbed over time and fibroblasts largely disappear as the tissue is remodeled to form a dense collagenous subconjunctival scar with scattered fibroblasts and blood vessels.

Fibroblast proliferation and migration play prominent roles in GFS wound healing. Large number of factors appear to be chemotactic for fibroblasts in general. These include lymphokines, complement, collagens of types I to V, fibronectin, some proteolytic digestion fragments of collagen and fibronectin,and platelet-derived growth factor.

III)Anatomical and Physiological Factors Related to Bleb Failure:[18]

A. External factors:

External factors at the episceral-conjunctival interface are responsible for most cases of GFS failure. Fibroblast proliferation, synthesis of the extracellular matrix (collagen and glycosaminoglycans), and subsequent development of subconjunctival fibrosis play prominent roles in external failure.

B. Intraocular and scleral factors:

Intraocular complications can lead to blockage of the filtration site by prolapse of lens, iris, vitreous, or ciliary body.

An inadequate opening into the anterior chamber due to scleral remnants or Descemet's membrane in the fistula may also lead to primary failure.

C. Inflammation and blood:

Intense preoperative and postoperative inflammation is undesirable because of the associated fibrinous and cellular responses and accelerated wound healing.

Clinical observations suggest that the presence of blood beneath the conjunctival flap postoperatively may also increase the probability of bleb failure.

serum derivatives including fibronectin and platelet-derived growth factor may stimulate fibroblast migration and proliferation.

In addition, macrophages, which may be activated, by blood, appear to play a key role in inducing the fibroproliferative response in epiretinal membrane formation and wound repair in general.

V) Clinical Factors Associated with Bleb Failure:[18]

-aphakia

- active anterior segment neovascularization

- previously failed GFS

- race

Different changing doses of Mitomycin–c:

Robert C. et al found that *0.02%* MMC applied for 2 minutes between the sclera and Tenon's capsule of patients at risk for failure is associated with few serious

complications. They demonstrated the long term efficacy and safety of low doseMMC (0.02% for 2min.)[19]

Stone *et al* and Shields *et al* , in two separate studies, titrated the exposure times of MMC to the number of risk factors for failure and reported similar surgical success rates in the different exposure time subgroups. They noted that all cases of hypotony related maculopathy occurred in those patients with the lowest risk for failure.[19]

Vital P et al found that in their study is the use of intraoperative mitomycin C (0.4 mg/ml) in relatively uncomplicated cases may be associated with unacceptable risks & its consequences.[16]

Jae L. et al found that from their study is the mean post operative intra ocular pressure with 0.4mg/ml MMC after 3 months was singificantly lower than with 0.2mg/ml and 0.1mg/ml dose ofMMC. There was no statistical difference among the three groups in the success rate regardless of medication and the size & longevity of the filtrating bleb. Post operative hypotony was noted with 0.4mg/ml MMC which was unacceptable.[6]

Manners T et al found that with 0.02% MMC, applied between the sclera and the conjunctiva for 1–5 minutes ,visual aquity was better, i.o.p was controlled post operatively. Hypotonous maculopathy occurred in one patient and no cases of late bleb infection were found**.** [20]

ShigeedaT et al found bleb leak, bleb related hypotony and bleb related infections in with POAG who underwent initial trabeculectomy with MMC 0.04mg/ml.[21]

Even though many long term studies are required, trabeculectomy with low risk as initial surgery should be performed with low doe MMC is a better alternative to prevent long term failure and complications.

Mitomycin-c replacing 5-FU:

Liu W. et al found that subconjunctival injection of MMC (0.1mL of 0.2mg/mL) were more effective than subconjunctival 5-FU injection (0.1mL of 50mg/mL) for early dysfunctional filtration blebs after trabeculectomies.[22]

Gregory L.et al found that drug-induced corneal epithelial defects were seen in 5-FU-treated eyes and not in MMC-treated eyes.[23]

Antonio p et al found that hypotony, loss of visual acuity, choroidal effusion, shallow anterior chamber, cataract progression,hyphema were equivalent between 5-FU and MMC treated groups. But corneal epithelial toxicity is noted in only 5-FU treated group.[15]

Mitomycin-C[24,5]

Mitomycin-C (MMC) is an anti-neoplastic/ antibiotic agent isolated from soil bacterium Streptomyces caespitosus. It is used intravenously to treat upper gastro-intestinal tumors, anal cancer, breast cancer and bladder tumors.Mitomycin C has also been used topically rather than intravenously in several areas like bladder cancers and intra-peritoneal tumors.

In eye surgery, it is applied topically to prevent recurrence in pterygium surgery, to prevent scarring during glaucoma filtering surgery and haze after Photorefractive keratectomy (PRK) or lasik.

MMC was first used in ophthalmology in 1969 in Japan, where recurrent pterygium were successfully treated with the drug . Its use and application in ophthalmology has been increasing in recent years because of its modulatory effects on wound healing.

Pharmacology and mechanism of action:

It is an anti-metabolite with anti-proliferative effect on cells showing the highest rate of mitosis by inhibiting DNA synthesis and interferes with RNA transcription and protein synthesis. DNA is inhibited by cross linking at the N position of Adenine and at 06 and N position of Guanine. The cell cycle is most affected during the late G-I and early S-phase. The chemical formula is C15H18N4O5.

Drug Reconstitution And Pharmacokinetics:

Mitomycin is delivered to the eye in a complete solubilized form, often in the presence of conjunctival and corneal epithelial defects, the drug is highly bioavailable to the target tissue.

Its hydrophobic character favors its penetration into the epithelially denuded cornea and conjunctiva, while deterring its movements into or through the intact epithelium.

The use of Mitomycin eye drops, even at the highest dose used, does not result in any detectable levels of Mitomycin in the blood.

The drug is available in a vial (2mg/ml). It is further reconstituted with normal saline (5ml) to make 0.4mg/ml or in 10ml to make 0.2mg/ml. the drug should be stored under refrigeration after reconstitution to preserve its potency and under these conditions; it is potent for a period of two weeks only.

Clinical uses of Mitomycin C in Ophthalmology:

-Pterygium surgery

-Glaucoma filtering surgery

-Refractive surgeries

-Ocular surface tumors

-Squint surgeries

-Dacryocystorhinostomy (DCR)

-Allergic conjunctivitis.

1)Pterygium Surgery :

The pterygium is a horizontally oriented, triangular growth of abnormal tissue that invades the cornea from a base in the canthal region of the bulbar conjunctiva.

Dose: 0.2-0.4 mg/ml applied intra-operatively over bare sclera for 1-5 minutes. Among the most impressive results with pterygium were double masked,

prospective trial using doses of 0.4mg/ml (0.04%) and 1mg/ml four times daily for two weeks has been proven most efficacious.

Other reports also describe good results with no serious complications using 0.2mg/ml of Mitomycin-C

Complications: Secondary glaucoma, corneal melting and perforation corneal edema, scleral calcification. Other complications of MMC in pterygium surgery include pain, excessive tearing, prolonged hyperemia, late haemorrhage, chemosis, lid edema, ptosis, wound dehiscence, photopobia, corneal blood staining, pigment accumulation, superficial punctate keratitis and delayed wound healing.

2) Glaucoma filtering surgery:

The high failure rate of trabeculectomy surgery is partly due to subconjunctival or scleral scarring at bleb. MMC inhibits the fibroblasts proliferation and subsequent scarring of filtration bleb.

Intraoperative MMC applied at concentration of 0.2mg/ml controlled post-operative intra-ocular pressure (IOP) as effectively as a 0.4mg/ml concentration in high risk cases of congenital glaucoma, but with lower incidence of complications and thin walled blebs [5].No significant difference was seen in overall success or complication between subconjunctival and intra-scleral application of MMC augmented trabeculectomies in glaucomatous eyes at high risk of surgical failure. In selected pediatric cases of primary or secondary glaucoma in which visualization of the trabecular meshwork is poor trabeculectomy augmented with MMC and 5-FU is a good treatment option.

Dose: 0.02-0.04% concentration is kept for 1-5 minutes generally subconjunctival and sometimes subscleral.

Complications: Development of thin walled cystic blebs, late bleb leaks, bleb infections, endophthalmitis, chronic hypotony, hypotonic maculopathy and corneal epithelial toxicity.

Indications of MMC in glaucoma:

-aphakic/pseudophakic glaucoma

-post traumatic glaucoma

-previous failed filtering surgery

-glaucoma secondary to uveitis and inflammation

-congenital/developmental/juvenile glaucoma

-patients using long term antiglaucoma medications

3) Refractive Surgeries:

Haze formation with loss of corneal transparency and surface irregularities and myopic regression are the major complications after corneal refractive surface surgery.

The use of Mitomycin-C with its antibiotic and anti-neoplastic properties is intended to inhibit wound healing mechanisms leading to sub-epithelial fibrosis.

Using mitomycin-C in PRK for myopia greater than - 5.00 D seems safe and effective, and can reduce haze formation after surgery; therefore, it can be considered a suitable alternative for patients with myopia greater than - 5.00 D, whose corneas lackan appropriate thickness to perform LASIK, with a desirable optical zone. With this method, vision can be corrected with a better quality of vision regarding contras sensitivity.

It is usually applied at a concentration of 0.2mg/ml (0.02%) for 12 to 120 seconds over the ablated stroma, although some studies suggest that lower concentrations (0.01%, 0.002%) could also be effective in preventing haze when treating low to moderate myopia. This dose of MMC has not been associated with any clinically relevant epithelial corneal toxicity.

Single application of diluted MMC 0.02% solution following scraping of the corneal surface was effective and safe in treating haze and regression after PRK for myopia.

4) Ocular surface tumors:

Ocular surface tumors include a variety of neoplasms originating from squamous epithelium, melanocytes, and lymphocytic resident cells of the conjunctival stroma.

MMC selectively inhibits DNA synthesis. Topical MMC can treat satellite and multifocal lesions and the entire ocular surface. Topical MMC 0.4mg/ml (0.04%) is administered four times a day for three weeks. It has been used successfully as

adjunctive therapy for controlling conjunctival and corneal squamous cell carcinoma even in extensive recurrent disease.

5) Squint surgeries:

Topical Mitomycin-C may enhance the success rate of strabismus surgery with delayed adjustment and reduce post-operative adhesions. Intra-operative application of MMC is reported in cases of restrictive squints. It helps to reduce fibrosis and scarring under the tenons layer.

Dose: 0.2mg/ml for 5 minutes between the conjunctiva and the sclera after adhesion release.

6) Dacryocystorhinostomy:

The most important cause of failure of DCR surgery is fibrosis occurring under the flaps near the osteotomy sites. MMC in these cases tends to suppress fibrous proliferation and scar formation.

Intra-operative MMC application is effective in increasing the success rate of DCR surgery and no significant complications resulted from its use.

Dose: 0.02 to 0.04% for 5-30 minutes to the osteotomy site.

7) Allergic conjunctivitis :

In a study topical MMC (0.2mg/10ml) was applied four times a day for 3 months and was found to be safe and effective alternative to topical azelastine, in treating allergic conjunctivitis.

Ocular complications of topical Mitomycin C:

Minor complications :

ocular pain

photophobia,

lacrimation

lid edema

foreign body sensation (secondary to superficial punctate keratitis)

wound leak

hypotony maculopathy

hyphema

encapsulated bleb

choroidal detachment

branch vein obstruction

shallow AC

Major complications :

scleral ulceration

necrotizing scleritis

perforation

uveitis

cataract

glaucoma

symblepharon formation

Contraindications for topical use:

• One-eyed patients

• Very old patients

• Pregnant women

• Those with predisposing condition to corneal ulceration or poor healing such as immunocompromised patients or patients with Sjogren's syndrome, atopic keratoconjunctivitis , acne rosacea or herpetic keratitis.

METHODOLOGY

The present one year longitudinal study was conducted in the Department of Ophthalmology, KLES Dr. Prabhakar Kore hospital and Medical Research Centre, Belagavi on patients undergoing glaucoma filtering surgery during the period of 1st January 2015-31st December 2015 including 30 eyes of 30 patients.

Sample size calculation:

$$n = \frac{[(z\alpha + z\beta)\,\delta]^2}{\sigma}$$

$= 5.6^2 =$ **App. 31.36**

$\alpha = .05$, $z\alpha = 1.96$, $\beta = .2$, $z\beta = .84$ -80%,

$= \delta$ =SD. 12, σ = Effect size 6

This calculation's value has been considered.

Selection Criteria

Inclusion Criteria:

1. Patients who are diagnose of glaucoma and IOP >21mmhg.
2. Follow up patients who's intra ocular pressure doesn't come under control with medical management.
3. Patients diagnosed of cataract and glaucoma both.

Exclusion criteria:

1. Patients who do not consent to be part of the study
2. Participants in whom ocular fundus cannot be made out due to very hazy media.
3. Patients with ocular anomalies.
4. Patients with systemic anomalies.
5. Dense corneal opacity not allowing to view anterior chamber for trabeculectomy.

The patients were evaluated as follows:

Pre-operative:

1) Detailed systemic and ocular history
2) Detailed general examination
3) Visual acuity without/with glasses
4) Refraction
5) Slit lamp examination
6) Fundus examination
7) IOP measurement
8) Gonioscopy
9) Visual fields
10) Fundus photos
11) Anterior segment photos

Once diagnosed as glaucoma, the patients were started on a medical line of treatment with one or more of the following drungs.

- Carbonic anhydrase inhibitors.
- Beta blockers.
- Alfa adrenergics
- Hyperosmotic agents.

Following criteria were then used to decide if the patient required anti-glaucoma surgery.

1) Patient with uncontrolled IOP

2) Patient with progressive field defects.

3) Patient not compliant to medical therapy and not able to follow up regularly.

4) Patient not affording long term medical treatment.

Trabeculectomy with intraoperative 0.1mg/ml MMC:

Surgical steps:

Pre-operative:

1) All patients underwent IOP measurement with schiotz tonometer and NLD petency test.

2) All patients were given Tablete Ciprofloxacin500mg two times per day along with IOP lowering eye and/or Tablet Acetazolamide 250mg two times per day.

3) On the day of the surgery, all the patients were given Injection Mannitol 20mg- 200ml over 20 minutes intravenously.

4) Pre Mannitol and post Mannitol IOP was measured.

5) If there is only trabeculectomy, Pilocarpine 2% eye drops wes instilled 4 times before surgery.and if it's trabeculectomy with SICS with PCIOL , Tropicamide along with Phenylephrine eye drops was instilled 4 times before surgery.

Anaesthesia:

All patients were given peribulbar anaesthesia consisting of 7-8cc 2% Xylocaine with 1:1,00,000 unit adrenaline and 1500 unit Hyaluronidase.

Surgery:

1) Universal eye spectulum put.

2) Superior rectus bridle sutures was taken.

3) A limbal based/fornix based conjunctival flap taken.

4) cauterization done with wet field electric cautery.

5) Patients underwent guarded filtering procedure with limbal based partial thickness scleral flap measuring 4.5x4.5 mm. in size.

6) A 4.5mmx4.5mm geletin sponge soaked in 0.1mg/ml of mitomycin -C was applied under the partial thickness scleral flap for two min.

After 2minutes the sponge was removed and discarded. Next copious irrigation of surgical area (50ml) was done to wash out any MMC, lest it enters the anterior chamber.

Then trabeculectomy was performed in a routine manner.

7) This was followed by a peripheral iridectomy.

8) In all cases, the partial thickness flap was closed with 8-0 monofilament polymide non-absorbable suture with 2 sutures at ends of the scleral flap.

9) In all patiens conjuctival flap was closed with 8-0 monofilament polyglactin absorbable suture either continuous or interrupted.

10) All patients received subconjuctival injection of 20mg of gentamycin and 2mg of dexamethasone along with antibiotic eye ointment.

Postoperative:

1) All patients were given systemic antibiotics and analgesics for 5 days.

2) Topical antibiotic and steroid combination was instilled 6 times a day for 2 weeks and then tapered over 6-8 weeks.

3) Topical cycloplegic two times per day for four weeks.

Follow up:

Detailed examination of the patients was done on follow ups (1day, 1 week, 1month, 3months) with special importance given to

1) Visual Acuity: It was considered improved or worsened if changes in VA by 2 lines or more and low vision category were also observed (i.e. HM close to face to PL, was observed).

2) Conjunctival wound: look for the wound leak.

3) Bleb: its size, shape, height, vascularity, any areas of thinning, any leakage, infection.

4) Cornea: epithelial erosions, striate keratopathy, bullae etc.

5) Anterior chamber: depth and contents.

6) Iris: any evidence if iritis and patencyof PI.

7) Pupil: any pupillary membrane, pupillary reactions

8) Lens: Any cataractous changes in phakic eyes and position of PCIOL in pseodophakic eyes.

9) Fundoscopy.

10) Intraocular pressure measurement (with NCT)

11) Other MMC related or surgical or post surgical complications like hyphema,bleb leak,blebitis,choroidal detachment,hypotony,shallow AC .

Hypotony was defined as : IOP <5 mm Hg on two visits.

And additional medical management was done in patients with IOP >21mmhg.

The patients were followed up, after discharge, on 1 day, 1 week, 1 month and 3 months after discharge.

Outcome (IOP)was defined as follows:

A “complete success” when the IOP was less than 21mmHg without glaucoma medication,

A “qualified success” when the IOP was less than 21 mm Hg with or without glaucoma medication, and a “failure” when the IOP was greater than or equal to 21 mm Hg with medical treatment or when repeat surgery was required.

OBSERVATION AND RESULTS

Age Distribution of the patients

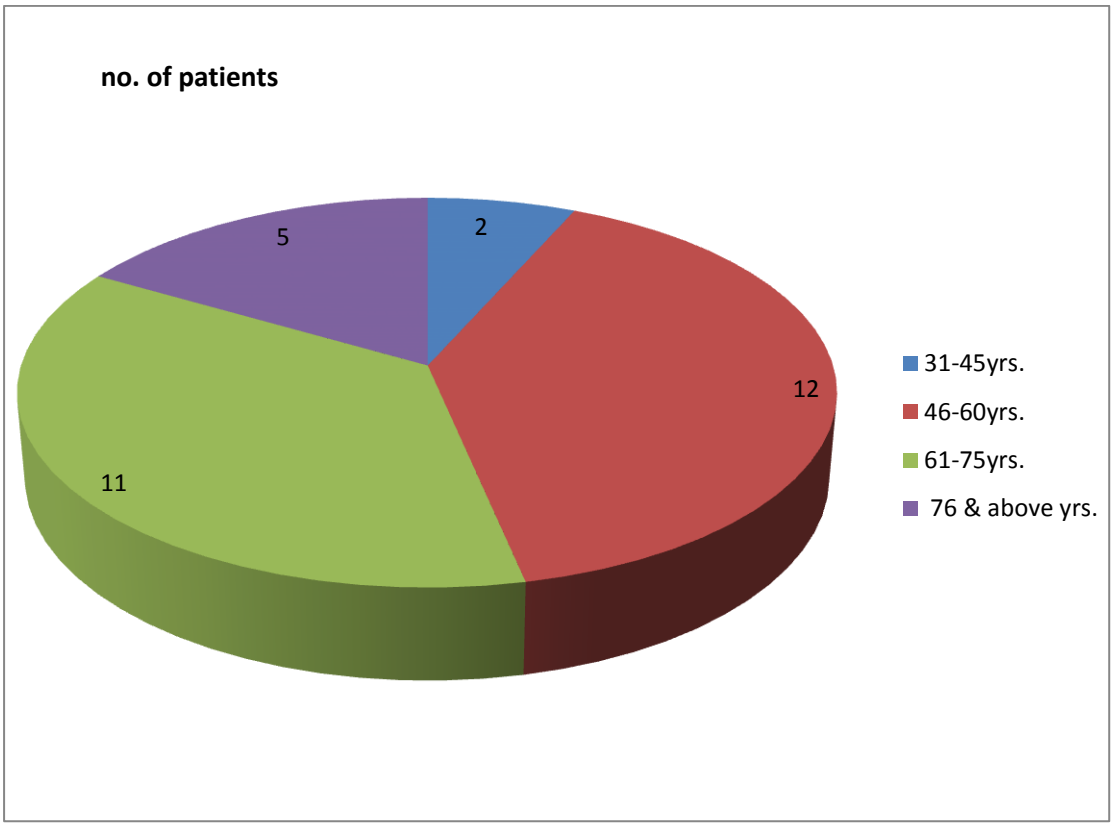
Table I shows the age distribution of patients.

Thirty eyes of thirty patients was included in this study. Out of thirty patients, maximum number of patients (twelve patients) were between 46-60 years age group, two patients belonged to 31-45 years age group, eleven patients belonged to 61-75 years age group and five patients were above 76 years.

Table I: Age distribution

Age in years	Number of patients with %
31-45	2 (6.6 %)
46-60	12 (40 %)
61-75	11 (36.6 %)
76 & above	5 (16.6 %)

Graph I: Age distribution



Gender distribution of patients

Table II shows the sex distribution of patients in this study

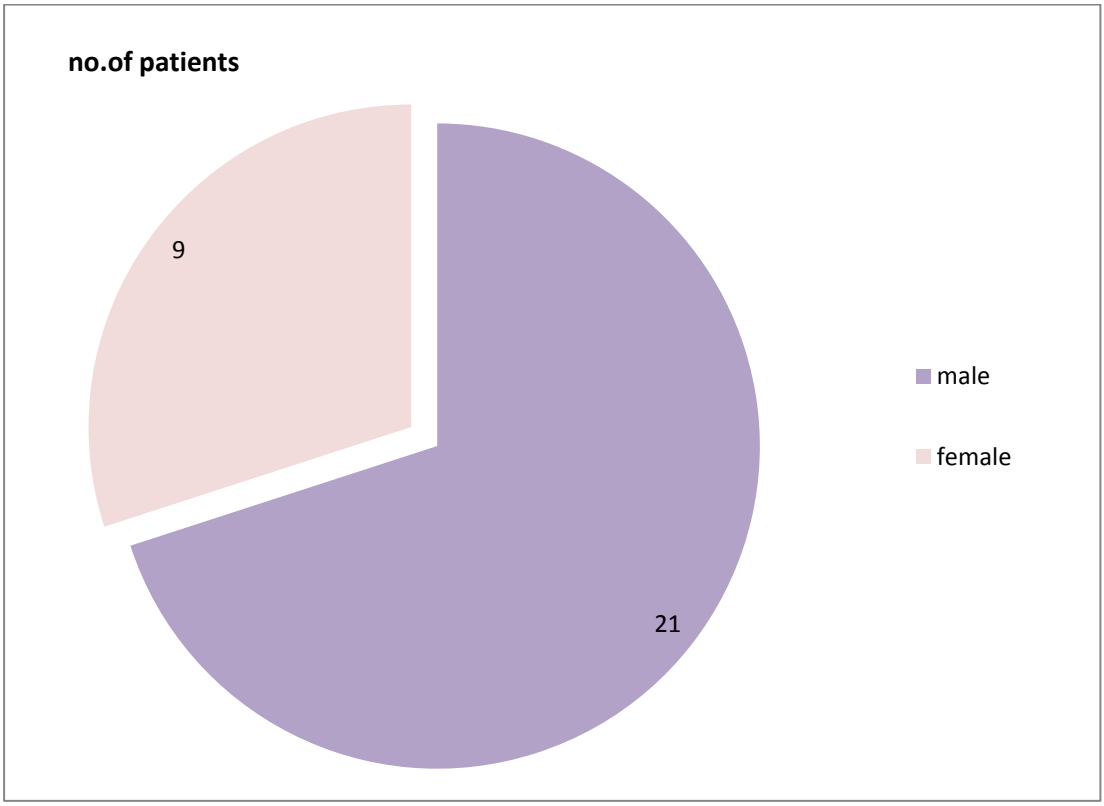
There were 21 (70%) male patients & 9 (30%) female patients in this study.

M: F :-2:1

Table II: Gender distribution

Sex	Number of patients (%)
M:F	2:1
Male	21 (70%)
Female	9 (30%)

Graph II: Gender distribution



Etiological Distribution of cases

• 15 patients (50 %) were diagnosed as primary open angle glaucoma.

• The next common group was pseudo- exfoliative glaucoma which

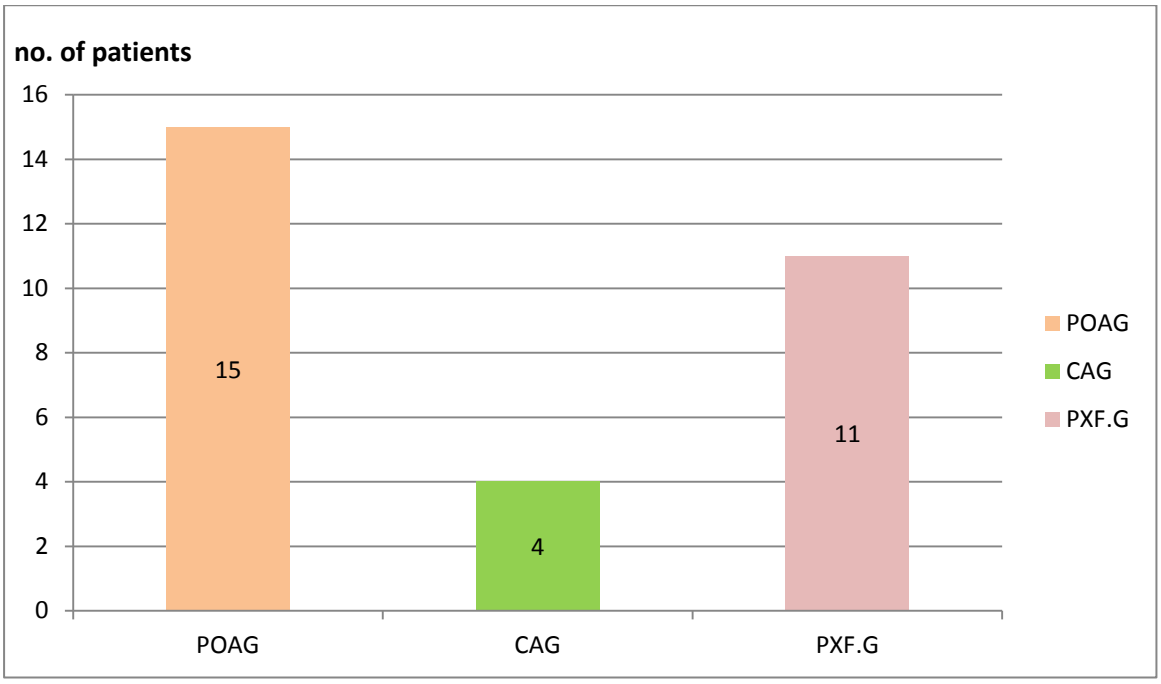
Constituted 11 patients (36.6%)

• There were 4 patients (13.3%) with chronic angle closure glaucoma

Table III: Types of glaucoma

Diagnosis	Number of patients (%)
Primary Open Angle Glaucoma	15(50%)
Chronic Angle Closure Glaucoma	4(13.3%)
Pseudo exfoliative glaucoma	11(36.6%)

Graph III :Types of glaucoma



Number of eyes:

Table IV shows that were operated.

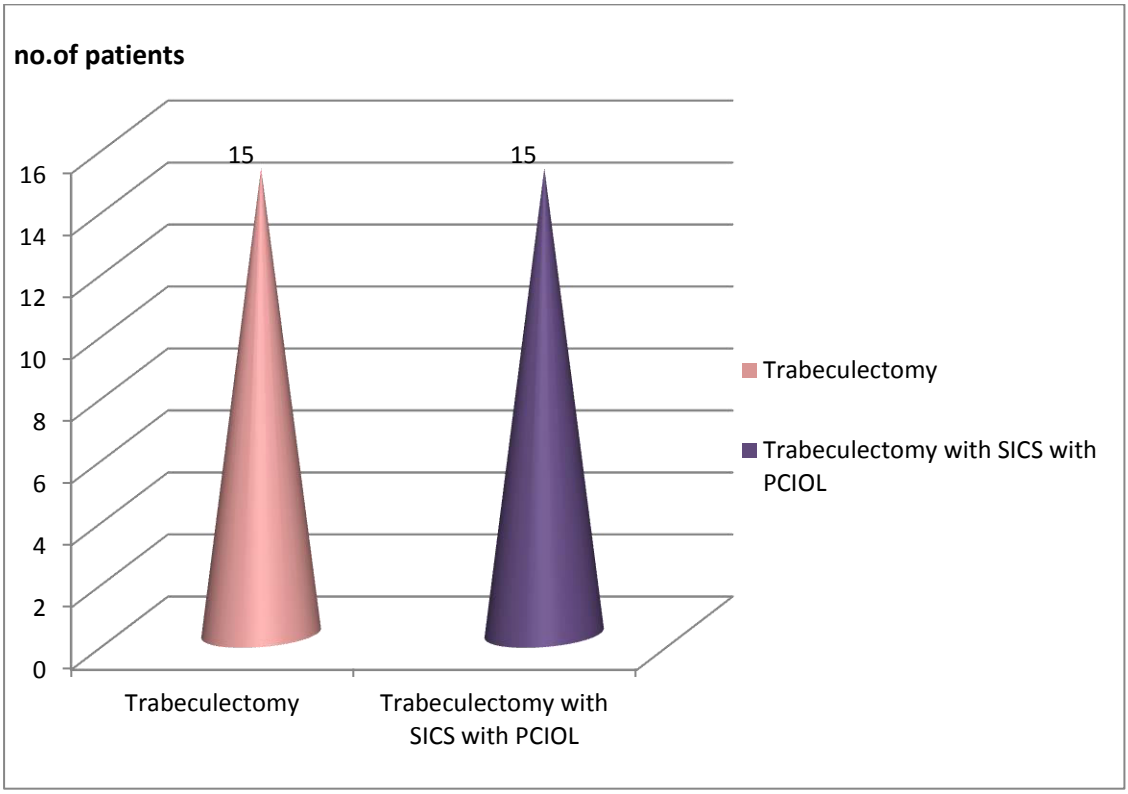
• I- Plain trabeculectomy with MMC (0.1mg /ml x 2 minute)

• II-Trabeculectomy with MMC (0.1mg /ml x 2 minute) with SICS with PCIOL

Table IV: Aditional surgery with trabeculectomy

Type of surgery	Number of patients
Trabeculectomy	**15**
Trabeculectomy with SICS with PCIOL	**15**

Graph IV: Aditional surgery with trabeculectomy



Intraocular pressure.

Table V (b) shows shift of IOP from initial levels to those at the 1st day, 1St week, 1st month, 3 months, post operatively.

• The initial IOP of 21 patients was between 2 1-30 mm Hg and of 9 patients between 31-55 mm Hg.

Table V (a): pre-op IOP

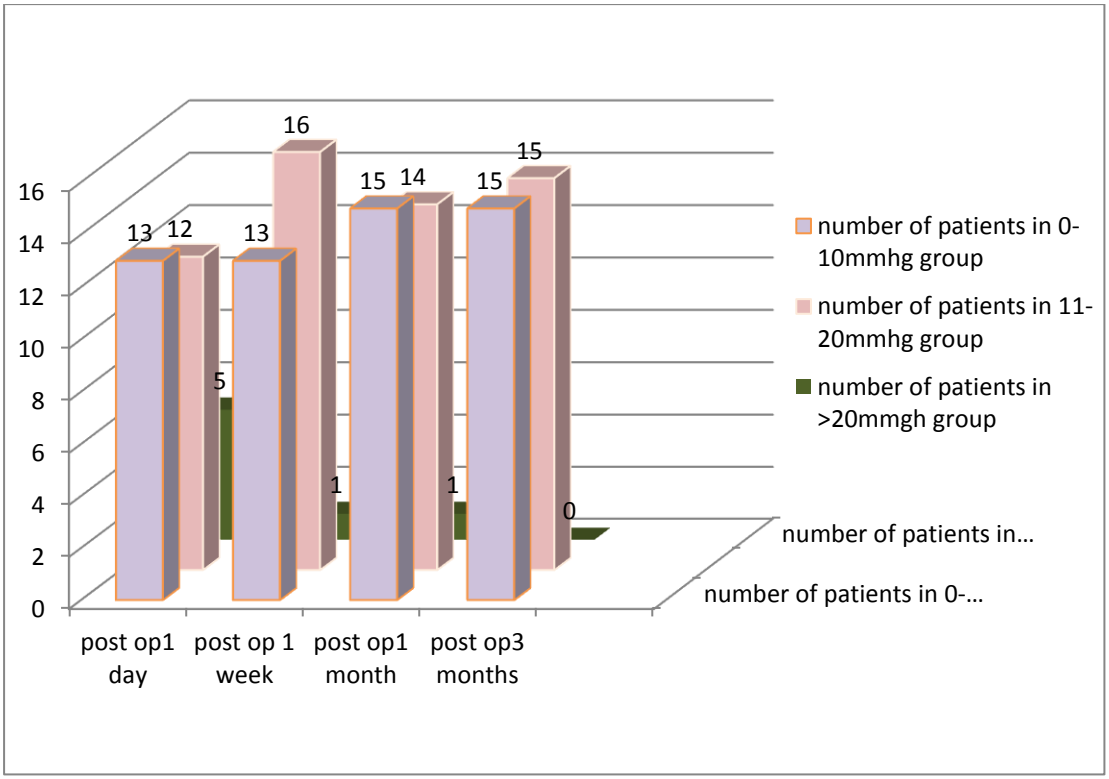
Number of patients	Pre-op IOP(mmhg)
21(70%)	21-30
9(30%)	31-55

- At 1st day post-op, 13 patients had IOP between 0-10 mm Hg and 12 patients Between 11-20 Hg and 5 patients had IOP between 21-30 mm Hg
- At end of 1 week post-op the IOP of 13 patients was between 0-10 mm Hg, IOP of 16 patient between 11-20 mm Hg, and one patient with IOP >20 mm Hg.
- At end of 1 month post-op, IOP of 15 patients was between 0- 10 mm Hg, 14 Patients between 11-20 mm Hg and IOP of 1 patients was >20 mmhg
- At end of 3 months post-op, IOP of 15 patients was between 0- 10 mm Hg, 15 Patients between 11-20 mm Hg.

Table V (b): Intra ocular pressure (post-operative no. of patients in each group of IOP)

Period	Number of patients in each group of pressure (mmhg)		
IOP range	0-10	10-20	>20
1 day	13(43.3%)	12(40%)	5(16.6%)
1 week	13(43.3%)	16(53.3%)	1(3.33%)
1 month	15(50%)	14(46.6%)	1(3.33%)
3 months	15(50%)	15(50%)	0

Graph: V: Intra ocular pressure (post-operative no. of patients in each group of IOP)



The mean IOP and mean fall in IOP.

Table VI shows the mean IOP of the patients.

The mean pre-op IOP was 30.18± 9.68 mm Hg. The mean IOP at the end of 1 day,1 week, 1 month, 3 months post-op was 11.65± 5.24; 11.64 ± 5.46;11.95 ± 4.84 and 10.97 ± 3.84 mm Hg respectively.

The mean fall of IOP from pre-op levels to those at end of 3rd post-op month was 11.55 ± 0.41mmhg.

- On application of student paired t test, t P value is (<0.001) which was highly significant (P<0.005).

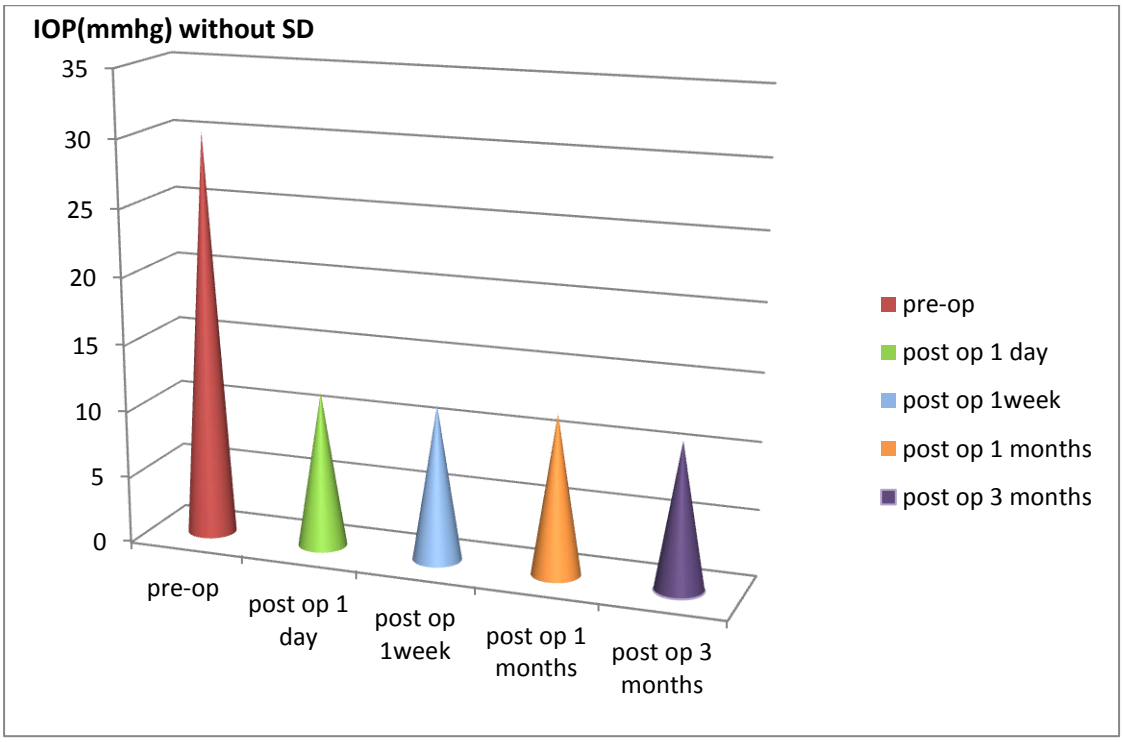
Table VI (a): mean IOP

Time period	Mean IOP(mmhg)
Pre-op	30.18± 9.68
Post op 1 day	11.65± 5.24
Post op 1 week	11.64 ± 5.46
Post op 1 month	11.95 ± 4.48
Post op 3 months	10.97 ± 3.84

Table VI (b): P and t values

Time	Mean IOP with SD	values
Pre op	30.18± 9.68	
Post op(3 months)	10.97 ± 3.84	***P=<0.001***

Graph VI: Mean IOP without SD.



Gradings of blebs according to Moorfield's classification

Table VII explains the gradings of blebs after three months:

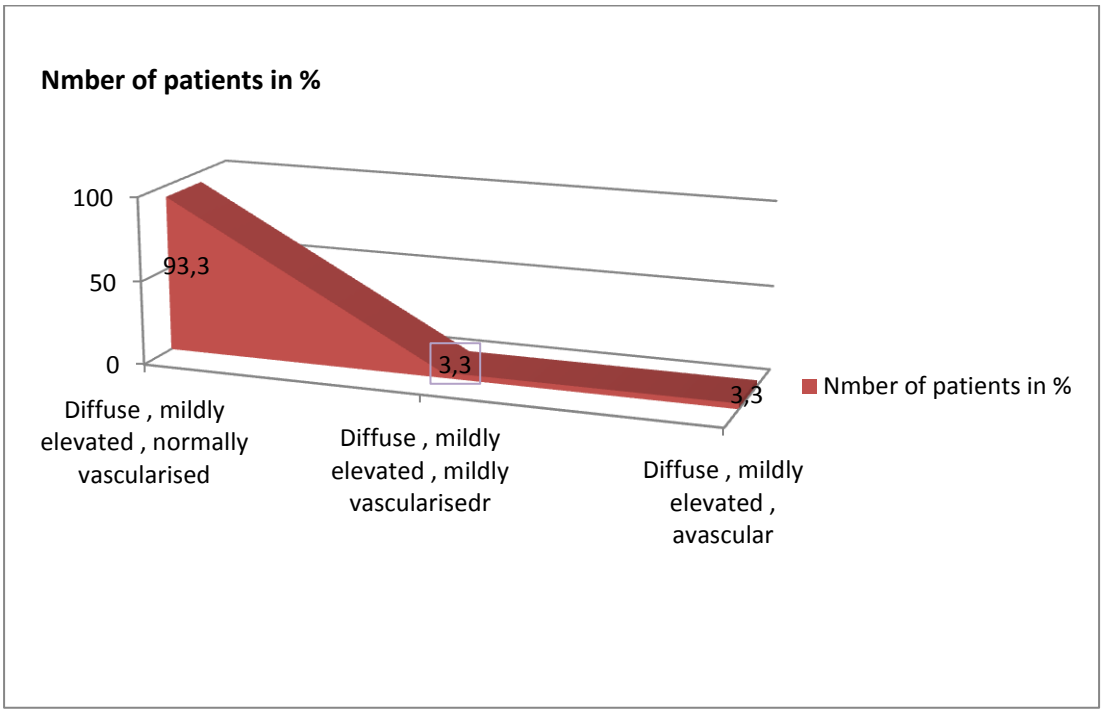
- The most common variety of bleb encountered was grade II or diffuse, mildly elevated and normally vascularised filtering bleb (according to Moorfie ld's classification) seen in 28 patients (93.3%),in the last follow up.

- In 1 patient (3.3%) we encountered grade I or diffuse, avascular, mildly elevated filtering bleb and in 1 patient grade III or diffuse, mildly elevated and mildly vascularised bleb was encountered.

Table VII: Gradings of bleb at final follow up

Type of bleb	Number of patients in %
Diffuse , mildly elevated , avascular	3.3
Diffuse , mildly elevated , normally vascularised	93.3
Diffuse , mildly elevated , mildly vascularised	3.3

Graph VII: Gradings of bleb at final follow up



Change in visual Acuity.

Table VIII shows the change in visual acuity from pre-op levels compared to those at the last follow up.

• 7 patients (23.3%) had stable visual acuity on last follow up.

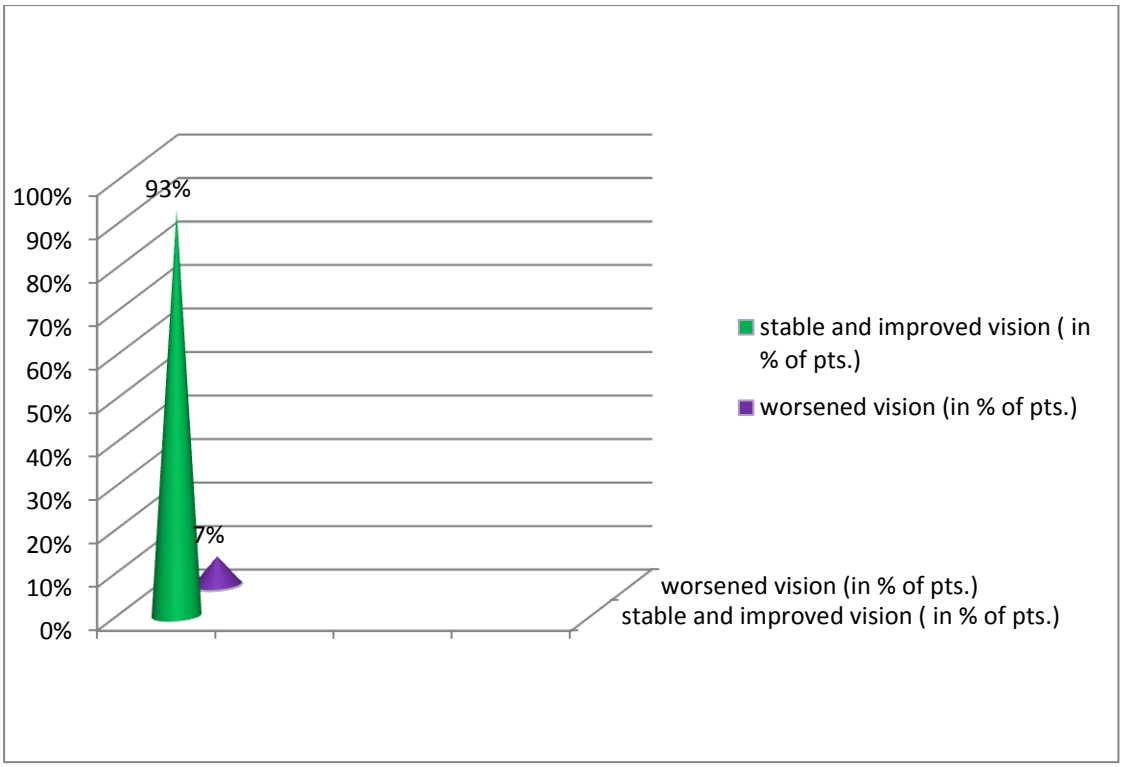
• In 2 patients (6.6%) showed worsening of the visual acuity.

• In 21 eyes (70%) the visual acuity improved.

Table VIII: Change in visual acuity in last follow up

	No of eyes	Stable and improved	Worsened
Present study (2014)	30	28 (93.3 %)	2 (6.6 %)

Graph VIII: Change in visual acuity in last follow up



Causes of decreased visual acuity:

Table IX shows the causes of decreased visual acuity.

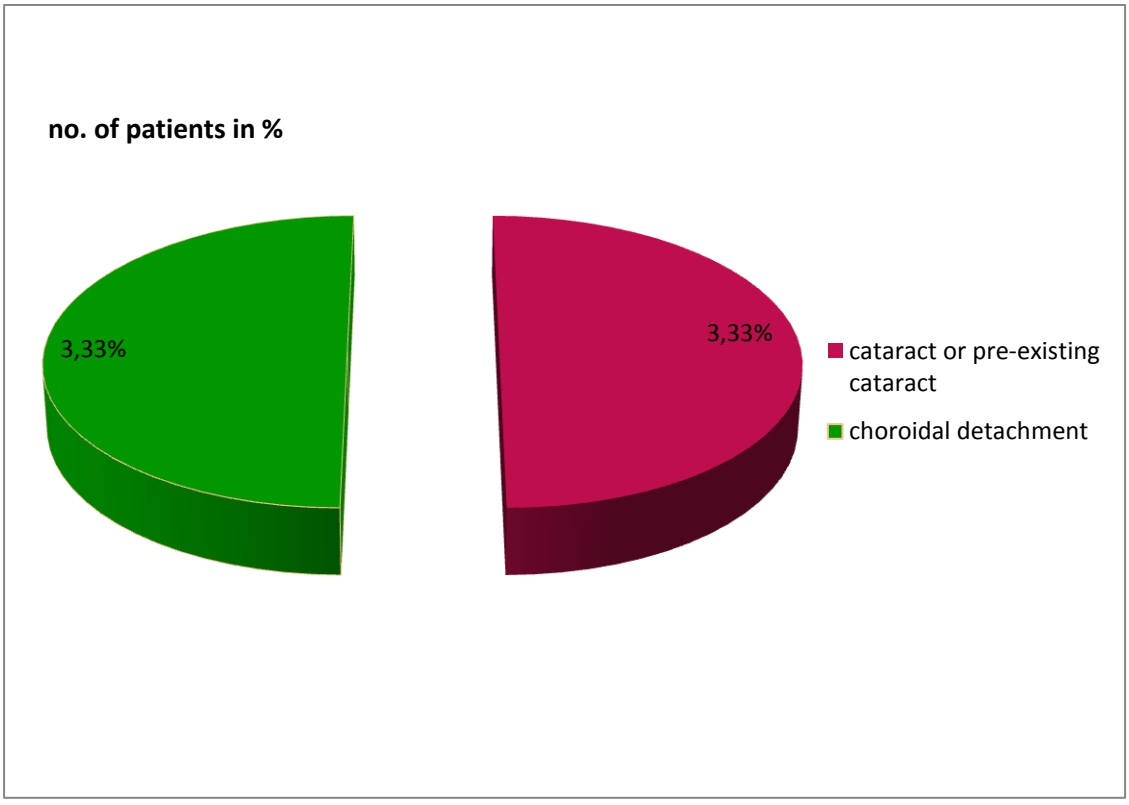
• 1 patient (3.33%) had decreased visual acuity due to cataract formation or Progression of a pre-existing cataract.

1 patient (3.33%) had decreased visual acuity due to choroidal detachment.

Table IX: Causes of decreased visual acuity

Causes	Number of patients in %
Cataract or pre-existing cataract	3.33% (1 pt.)
Choroidal detachment	3.33% (1 pt.)

Graph IX: Causes of decreased visual acuity



Success Rates:

Table X shows the success rates observed with trabeculectomy with MMC and trabeculectomy with MMC with SICS with PCIOL:

• 27 patients (90%) had complete success.

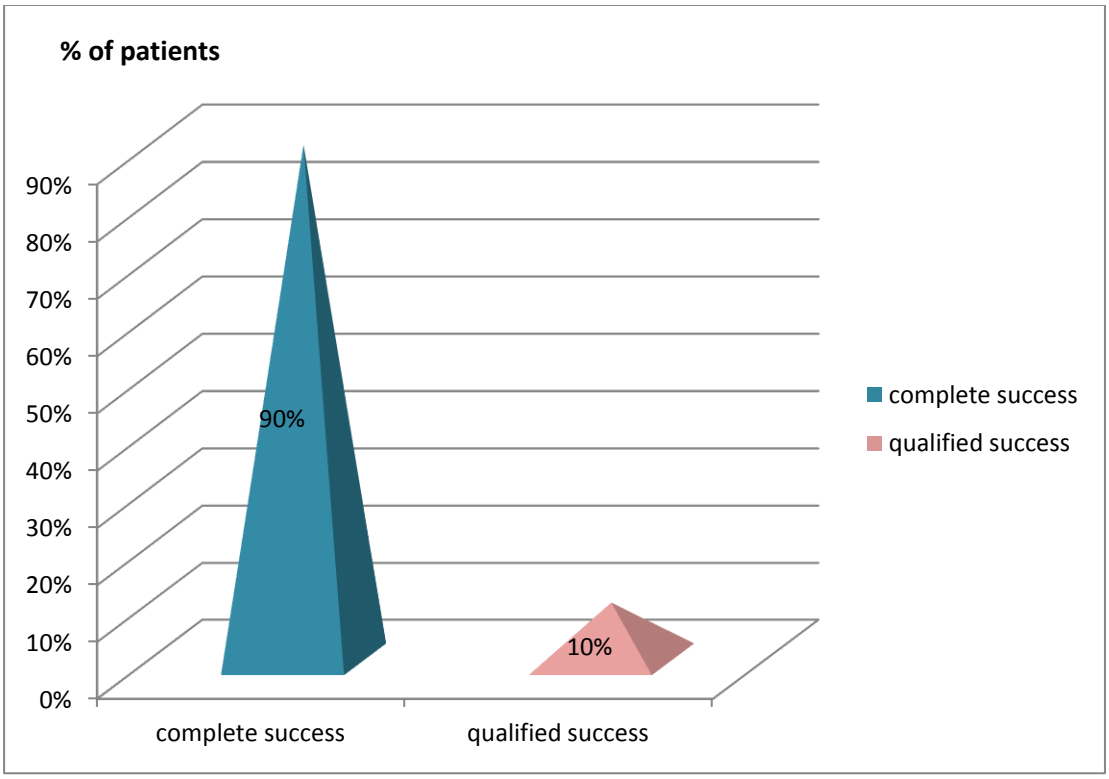
• 3 patients (10%) had qualified success

No failure Rate (0%)

Table X: Success rate

	Complete success	Qualified success	Over all success
Our study (2014)	27 (90 %)	3(10 %)	30 (100 %)

Graph X: Success rate



Complications:

Table XI shows the complications

Early complications

We encountered one patient (3.33%) with shallow AC & one patient (3.33%) with choroidal detachment during one week follow up.

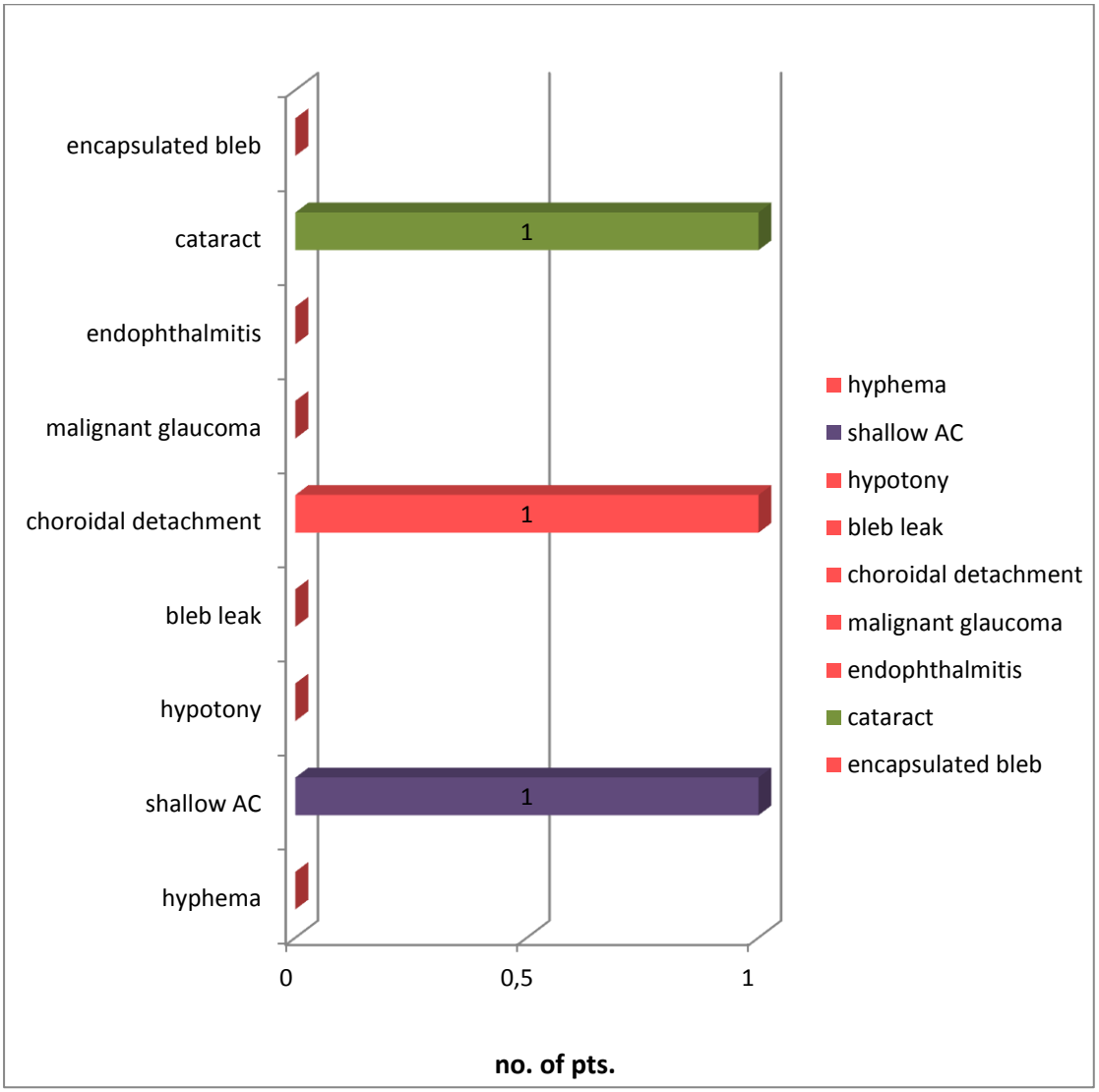
Late complications:

One (3.33%) patient developed cataract or progression of pre-existing cataract.

Table XI: Complications

Complications	Number of patients
Early	
Hyphema	**-**
Shallow AC	**1(3.33%)**
Hypotony	**-**
Bleb leak	**-**
Choroidal detachment	**1(3.33%)**
Malignant glaucoma	**-**
Endophthalmitis	**-**
Late	
Cataract	**1(3.33%)**
Encapsulated bleb	**-**

Graph X: Complications



DISCUSSION

This study included 30 eyes of 30 patients with glaucoma selected from the out patient department of the K.L.E. Society's Hospital and Medical Research Centre Belgaum.

All cases had at least 3 months follow up.

Age Distribution

Age constitutes an important factor in determining the success rate of trabeculectomy because patients younger than 50yrs. Old,wound may heal more vigorously after filtering surgery than older patients and have poor prognosis unless medications that modify wound healing such as MMC are used.[9]

In a view of their longer life expectancy, younger patients are also at greater risk of visual loss.[9]

Out of thirty patients, maximum number of patients(12 patients) were between 46-60 years age group, 2 patients belonged to 31-45 years age group, 11 patients belonged to 61-75 years age group and 5 patients were above 76 years.

This compares with study done by Palmer S who had maximum number of patients in 61-75 years age group, five patients belonged to 31-45 years age group, three patients belonged to 46-50years age group and six patients were above 76 years of age.[25]

Palmer S had three patients below 30 years of age. Where as in our study,none of the patients was below 30 years of age.

The number of patients < 50 years of age in our study was 2(6.66%) and they have achieved successful outcome post surgically without any complications.

Gender distribution.

In the present study 21 (70.6%) patients were males and 9 (30.3%) cases were females.

Comparison of gender distribution with other study.

Sex	**Present study (2014)**	**Palmer S. (1991)**
Male	21 (70.00%)	17 (51.5)
Female	9 (30.00%)	16 (48.48)

The greater percentage of male patients could be attributed to a 70.00% of cases in our study were primary open angle glaucoma which is more common in males than females [26]

Because of social reasons, females can not visit the hospitals from rural side and most of our cases are from rural side.

Type of Glaucoma

It's an important factor determining the ultimate outcome of filtering surgery is the type of glaucoma.

Comparison of type of glaucomas with other study.

Diagnosis	Present study (2014)	P.Steven (1991)
Primary Open Angle Glaucoma	15(50%)	15(45.45 %)
Chronic Angle Closure Glaucoma	4(13.3%)	1(3.03 %)
Pseudo exfoliative glaucoma	11(36.6%)	-
Pigmentary recession glaucoma	-	-
Juvenile glaucoma	-	3(9.09%)
Angle recession glaucoma	-	2(6.06%)
Others	-	12(36.3%)

Our study had 15 patients (50 %) of primary open angle glaucoma (POAG) and 4 patients (13.3%) of chronic angle closure glaucoma (CACG).This is more or less comparable to the study by Palmer S. – 45.45% POAG and 3.03% CACG.[25]

In the study done by Palmer S. et al, trabeculectomy was performed with adjuvant MMC on low as well as high risk cases.[25]Though our study has included the low risk cases only.

[High risk cases include congenital glaucoma, neovascular glaucoma, aphakic and pseudophakia glaucoma, patients with failed filtering surgery, glaucoma secondary to uveitis]. [27]

Lee J. et al also had maximum number of patients with POAG (83.2%) underwent trabeculectomy, 5.8% patients with pseudoexfoliative glaucoma and 5.2% patients with CACG .Though our study had 36.6% patients with pseudoexfoliative glaucoma.[28]

Lee J.et al had also included high risk cases while in our study, there are low risk cases only.

Application of 0.1mg/ml MMC for two min. in surgical procedures:

In our study, out of thirty patients, 15 patients underwent trabeculectomy with 0.1mg/ml MMC (for 2 min.) and 15 patients underwent trabeculectomy with MMC (0.1mg/ml for 2min.) with SICS with PCIOL which is similar to the study done by Hah MH. Et al who also had performed trabeculectomy with MMC and trabeculectomy with cataract surgery in his study.[29]

Many investigators have studied the effects of intraoperative MMC application during trabeculectomy using different concentrations and exposure time to determine the minimum effective dose and application time of MMC.

Kim YY et al pointed out that occurrence of hypotony significantly increased with longer duration of intraoperative MMC use.[30] Chen et al reported success rates of 76% using a mitomycin concentration of0.1 mg/ml, 100% using a concentration of 0.2 mg/ml, and 100% using a concentration of 0.4 mg/ml.[25]

Lower concentrations of MMC that are prepared and applied in a standardized fashion during trabeculectomy, could potentially provide trabeculectomy success rates similar to that reported with off-label preparations, and that such a treatment regime could result in in lower complication rates than higher doses of MMC.[31]

The dose of 0.1 mg/ml for 2 minutes used in our study was based on the above findings. The dose 0.1mg/ml for 1min exposure time was decided in our study because even with the dose of 0.2mg/ml (for 5min) ,complications like chronic bleb leak and hypotonus maculopathy had been reported.[32]

The goal of glaucoma filtering surgery is to slow or eliminate the pressure dependant retinal ganglion cell loss during the life time of a patient. Unfortunately, the usual trabeculectomy without an anti-fibroproliferative agent, yields pressure control in upper normal range at which 1/3rd to 1/2 patients suffer additional visual loss in 5 years. Further more, 1/2 of these cases require additional medical therapy to achieve even that. [33]

Hence, the lower pressures with shorter exposure time which are associated with MMC trabeculectomy may be more beneficial to prevent further visual loss. [5]

The other variable factor in the intraoperative MMC application is the method of application.

Two techniques are used:

a) **Episcieral** (Costa VP et al) : application of MMC over scleral bed before scleral dissection and then draping conjunctiva and Tenon's layer over it.[16]

b) **Sub-scleral application** (J.Singh et al): application of MMC

under the partial thickness scleral flap and then draping conjunctiva and Tenon's capsule over it.[32] We did not come across any study in literature that compares the two modes of application.

In favour of one mode of application is,

Within 1 month of trabeculectomy, eyes are still early in the wound healing processes. Fibroblast proliferation and early scar formation, which heavily influence filtering bleb morphology and function, are still occurring. Shortly after trabeculectomy, bleb cavities still exist, but the increase in fiber proliferation increases the aqueous flow resistance and can lead to filtering bleb failure. Ren and Qiao proposed that the increased resistance to aqueous flow that results in filtering bleb failure is divided into two parts: those that resist flow upstream from the scleral flap and those that resist flow downstream from the scleral flap. More specifically, shortly after trabeculectomy, there is no resistance to flow upstream to the scleral flap because it is open. subconjunctival fibrovascular tissue proliferates early in the healing process, creating flow resistance. So sub scleral application of MMC appears to be logical.[24]

In our study, in all cases MMC has been applied sub-scleraly only and noticed benifical effect which is similar success rate as kyprianou et al.[34]

Intraocular pressure

The initial IOP of 21 patients was between 2 1-30 mm Hg and of 9 patients between 31-55 mm Hg.

At 1st day post-op, 13 patients had IOP between 0-10 mm Hg and 12 patients Between 11-20 Hg and 5 patients had IOP between 21-30 mm Hg,At end of 1 week post-op the IOP of 13 patients was between 0-10 mmhg, IOP of 16 patient between 11-20 mm Hg, and one patient with IOP >20 mm Hg.,At end of 1 month post-op, IOP of 15 patients was between 0- 10 mm Hg, 14 , Patients between 11-20 mm Hg and IOP of 1 patients was >20 mmhg.

At end of 3 months post-op, IOP of 15 patients was between 0- 10 mm Hg, 15 Patients between 11-20 mm Hg. Which Is more or less similar to study done by Lee J et al who had also used 0.1mg/ml MMC for 5min,intraoperatively to rule out the efect of low and high dose of MMC and he noted IOP less than 21mmhg for 70% of his cases at the end of three months. [23]

The mean IOP and mean fall in IOP.

The mean pre-op IOP was 30.18± 9.68 mm Hg. The mean IOP at the end of 1 day,1 week, 1 month, 3 months post-op was 11.65± 5.24; 11.64 ± 5.46;11.95 ± 4.84 and 10.97 ± 3.84 mm Hg respectively.

The mean fall of IOP from pre-op levels to those at end of 3rd post-op month was 11.55 ± 0.41mmhg.

• On application of student paired t test, P value is (<0.001) which was highly significant (P<0.005).

Lee S had use different concentrations of MMC (0.2-0.4mg/ml for 1-5min.) in his study in which mean pre-op IOP was 24.02± 8.98mmgh which is almost similar to our study and at the end of six months,mean post -op IOP was 12.6±6.1 for all the patients which is also matching with our study. This shows that with the doses higher than 0.1mg/ml (for 2min), value of mean post-op IOP doesn't differs.[28]

Lee J et al also had used 0.1mg/ml MMC for 5min in his study to rule out the effect of low and high dose of MMC in which mean pre-op IOP was 27.9±10.0 and mean post –op IOP was 16.5±6.4 noted which matches with our study.[23]

Type of Bleb at final follow up.

The most common variety of bleb encountered was grade II or diffuse, mildly elevated and normally vascularised filtering bleb (according to Moorfield's classification) seen in 28 patients (93.3%),in the last follow up. In 1 patient (3.3%) we encountered grade I or diffuse, avascular, mildly elevated filtering bleb and in 1 patient grade III or diffuse, mildly elevated and mildly vascularised bleb was encountered. (3.3%)

Palmer S had characteristic bleb formation present in the successful eyes, typically appearing as a large, elevated, avascular bleb in 93.9% cases where as failed bleb was noted in 6.06% cases in his study (0.2mg/ml MMC for 5min). This more or less matches with our study.[30]

Costa VP et al had 98.9% well functioning bleb with 0.4%MMC applied for 1.5-2-5min in trabeculectomy and 73.3% well functioning bleb with 0.4mg/ml MMC applied for 3.5min intrabeculectomy with placoemulsification with PCIOL which is similar to our study.[16]

Prata J et al studied post op complications and short term outcome of MMC with 0.5mg/ml for 3-5min and noted encapsulated bleb in 10.2% cases around 56th day.[15] This shows that bleb failure rate is less with the low doses of MMC and we have achieved higher rate of well functioning bleb with 0.1mg/ml MMC applied for two min.

Blebs in our study were well formed and there was no bleb related complications noted (i.e. blebitis, bleb leak) and this we attribute to the low dose of MMC in our study.

Visual Acuity

` `7 patients (23.3%) had stable visual acuity on last follow up and 2 patients (6.66%) showed worsening of the visual acuity.

• In 21 eyes (70%) the visual acuity improved and one patient (3.33%) had decreased visual acuity due to cataract formation and progression of a pre-existing cataract. One patient (3.33%) had decreased visual acuity due to choroidal detachment.

Beatty S et al studies trabeculectomy with MMC (0.2mg/ml for 5min) and had 91.6% improved or stable visual acuity which excellently matches with our study.

None of the patients with decreased acuity was observed to have had prolonged hypotony which matches with our study.[36]

Prata J et al noted that cataract progression was the most frequent reason for visual loss (12.2%) and Shigeeda et al also noted 39% patients with decreased VA post operatively and the cataract was the most common cause for that which is similar to our study.[15,33]

Success rate:

We had complete success in 27 cases (90%) and qualified success in 3 cases (10%).

The complete success rate encountered in our study is 90% matched with that Costa VP et al with complete success rate was 95% and Palmer S et al with complete success rate of 84%. [25,16]

Lee J et al studied the effect of low and high dose MMC in trabeculectomy-0.2mg/ml and 0.4mg/ml and achieved complete success with both the doses which matches with our study.[23] While the success rates in the above studies was encouraging, it was the complications associated with high doses which was worrisome.

Complications

The early complications encountered were one case each of shallow AC (3.33%) (grade I) and choroidal detachment(3.33%) and 2(6.66%) patients developed cataract or progression of pre-existing cataract.

• Shallow AC: one patient (3.33%)

Shallow AC was noted in one patient (3.33%)in our study. This correlated well with study by Costa VP et al who found 7cases (13.7%) and J. Singh et al -2 cases (10%)[16,30] and Mochizuki K.et al (17.3%)[36] Shallow AC after trabeculectomy with MMC is due to over filteration and wound leak.[9]

• Progressive Cataract: one patient (3.33%)

The one case (3.33%) in our study had pre-operative cataract which progressed after surgery.

Prata J et al noted 12.2% cataract progression in their study [15] and Baig M et al had 44.2% cases with reduced visual acuity and among this in 40.4% cases, visual deterioration was due to cataract.[37] In our study also, we found cataract was the reason for the low vision post operatively.

• Choroidal detachment: One case (3.33%)

One case (3.33%) in our study developed choroidal detachment after surgery within one week.However Costa VP et al (0.4mg/mi x 3mm) also had encountered 11 cases (21.5%) of choroidal detachment.

Cheung J. et al used the concentration of mitomycin C varied from 0.2 to 0.5 mg/ml and was applied for 30 seconds to 5 minutes for uncontrolled glaucoma & said lOP reduction after mitomycin C filtering surgery is sustained in the intermediate-term & noted cataract formation-progression, hyphema , choroidal detachment , hypotony maculopathy and endophthalmitis.[4]

• Other complications:

There were no cases of scleral thinning or necrosis in our series as compared to 2 cases (10%) in study by J. Singh et al. Though he used the dose 0.2mg/ml and sub scleral technique.[30] the application time (5 minutes) was longer than our series (2minutes) and this may have increased the risk of thinning and necrosis of sclera.

Our study did not have any cases of endophthalmitis in the MMC group which matched with the findings of J. Singh et al, Costa VP et al.

CONCLUSION

Intraoperative application of MMC in low doses (0.1mg/ml x 2 minutes) was associated with better control of IOP, stabilization of visual acuity, well functioning normally vascularised blebs, with minimal acceptable complications and can be used as a safe and efficacious adjuvant in primary filtering surgeries in low risk cases.

SUMMARY

Trabeculectomy provides consistentlylower intraocular pressures (IOPs) than medical therapy. [38]In manycountries prolonged medical therapy and close supervision are impossible, and surgeons already practiseearly trabeculectomy.[39]The success rate of trabeculectomy has been limited by post operative fibrosis at the surgical site leading to bleb failure after month or years. To increase the success rate of glaucoma filtering surgery antifibrotic agents have been used to modulate wound healing.[37] It is known that this anti-pro- liferative agent acts in a dose and time dependent way.[41] So this study examines the role of low dose (0.1mg/ml for 2 min) MMC as an antifibroblastic adjuvant to trabeculectomy, in low risk cases.

- Thirty eyes of 30 patients has been undergone trabeculectomy with MMC or trabeculectomy with MMC with SICS with PCIOL.
- Out of thirty patients, maximum number of patients(12 patients) were between 46-60 years age group and minimum number of patients were above 76 years.
- M:F is 2:1
- Fifteen patients with POAG, 4 patients with CACG, 11 patients with pseudoexfoliative glaucoma underwent glaucoma filteration surgery.
- Fifteen patients underwent trabeculectomy with MMC and 15 patients underwent SICS with PCIOL with trabeculectomy with MMC.
- The initial IOP of 21 patients was between 21-30mmhg and IOP of 9 patients was between 31-55mmhg.
- The mean pre-op IOP was 30.18± 9.68 and mean IOP at the end of one day, one week, one month and three months was 11.65 ±m

5.24,11.64±5.46,11.95±4.48 and 10.97±3.84 respectively. So on application of student "t" test it was statistically significant. (P<0.001).

- Complete success (IOP was less than 21 mm Hg without glaucoma medication) was observed in 90 % of cases and qualified success (IOP was less than 21 mm Hg with or without glaucoma medication) was noted in 10% of cases. VA was stable or improved in 93.3%.
- In 6.6% patients (2 patients), VA was reduced because of cataract or pre-existing cataract (one patient- 3.33%) and choroidal detachment(one patient-3.33%)
- The most common variety of bleb encountered was grade II or diffuse, mildly elevated and normally vascularised filtering bleb (according to Moorfield's classification) seen in 28cases (93.3%),in the last follow up.
- Analysis of the complications encountered in present study in which we used a very low dose (0.1 mg/ml x 2 minutes), shows shallow AC (3.33% %) and choroidal detachment (3.33%) and these can be attributed to the toxic side effects of MMC.

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ANNEXURE I – CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

ID NO. | | | |

Mr/Mrs/Ms_____

You are invited to participate in our research study titled **"**ONE YEAR HOSPITAL BASED LONGITUDINAL STUDY TO KNOW THE SAFTY AND EFFICACY OF MINIMAL DOSE OF MITOMYCIN –C IN TRABECULECTOMY." Conducted by Dr. _____ , Post Graduate in M.S. Ophthalmology under the guidance of Dr _____ , M.S., PhD PROFESSOR, DEPT. OF OPHTHALMOLOGY, J .N.MEDICAL COLLEGE, K.L.E. UNIVERSITY , BELGAUM-590010

Respected Sir/Madam we request you to enroll yourself to participate in our study as you are eligible for doing so.Your participation in the study is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N. Medical College. If u decide to participate you are free to withdraw at any time.

Purpose of the study: - The purpose of the research is to evaluate the the benefit of minimal concentration and exposure time of mitomycin-c as an adjunct to trabeculectomy, & to evaluate the complications of minimal dose of mitomycin-c in trabeculectomy

Procedure Involved: - If you agree to enroll yourself in this study, you will be asked to give detailed history. Then you will be clinically examined in detail by slit-lamp

examination, fundoscopy, tonometry for measurement of intraocular pressure. Syringing for patency of the lacrimal sac, gonioscopy, visual fields measurement and investigations like Blood Pressure measurement, Random Blood sugar will be done. Then you will be undergoing trabeculectomy (with mitomycin c) surgery. You will be asked to follow up on specified dates when your progress would be monitored and documented.

Risks and Benefits :- Rare complications of trabeculecomy surgery includes globe perforation, retro bulbar hemorrhage, expulsive choroidal hemorrhage, early hypo tonicity , late hypo tonicity , hypotonic maculopathy ,choroids, flat bleb, shallow anterior chamber. for which all necessary precautions will be taken.

Your participation may benefit you and others and others suffering from same ailment in future, by helping us learn more about the disease process and better treatment modalities.

Alternatives: - If you are not willing to participate you will be treated according to the existing protocol & it will not affect your relationship with this hospital.

Costs for participating in this research: - There will not be any extra cost incurred by the participant. The participant will however have to pay for the investigations which are the part of the existing management protocol for this ailment. There is no commitment for any reimbursement or any other compensation for the participant.

Privacy and Confidentiality:- The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to others without your written permission.

Authorization to Publish Results: - When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Compensation: - In the event of injury related to the study, treatment will be made available through KLES Dr. Prabhakar Kore Hospital & MRC, Belgaum. There is no compensation or payment for such medical treatment by law. The doctors and the staff will provide facilities and medical attention to you.

Questions: - If you have any questions about the research you may please contact:

1) Chief Investigator, Dr._____, P.G, Department of Ophthalmology, JNMC, Belgaum. Contact No._____ .

2 Under the guidance of Dr._____ . M.B.B.S, DOMS, M.S., PhD PROFESSOR, DEPT. OF OPHTHALMOLOGY, J .N.MEDICAL COLLEGE, K.L.E. UNIVERSITY , BELGAUM-590010.

If you need any further information regarding your rights as a study participant contact

3) Dr._____ , CHAIRPERSON, JNMC, Belgaum and chairman of Institutional Ethics Committee. Contact No. _____

Consent for participation in research trial

I, Mr./Ms./Mrs _____ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up ant of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name: _____

Signature or the Left Thumb Print of Subject: _____

Witness Name: _____

Signature of Witness: _____

Investigators Name: _____

Signature of Investigator: _____

Date: _____

ANNEXURE I – CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

ID NO. | | | |

Mr/Mrs/Ms_____

You are invited to participate in our research study titled **"**ONE YEAR HOSPITAL BASED LONGITUDINAL STUDY TO KNOW THE SAFTY AND EFFICACY OF MINIMAL DOSE OF MITOMYCIN –C IN TRABECULECTOMY." Conducted by Dr.DHARA SHAH, Post Graduate in M.S. Ophthalmology under the guidance of Dr REKHA B.K. M.B.B.S, DOMS, M.S., PhD PROFESSOR, DEPT. OF OPHTHALMOLOGY, J .N.MEDICAL COLLEGE, K.L.E. UNIVERSITY , BELGAUM-590010

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Procedure Involved: - If you agree to enroll yourself in this study, you will be asked to give detailed history. Then you will be clinically examined in detail by slit-lamp examination, fundoscopy, tonometry for measurement of intraocular pressure. Syringing for patency of the lacrimal sac, gonioscopy ,visual fields measurement and investigations like Blood Pressure measurement, Random Blood sugar will be done. Then you will be undergoing trabeculectomy (with mitomycin c) surgery. You will be asked to follow up on specified dates when your progress would be monitored and documented.

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Your participation may benefit you and others and others suffering from same ailment in future, by helping us learn more about the disease process and better treatment modalities.

Alternatives :- If you are not willing to participate you will be treated according to the existing protocol & it will not affect your relationship with this hospital.

Costs for participating in this research :- There will not be any extra cost incurred by the participant. The participant will however have to pay for the investigations which are the part of the existing management protocol for this ailment. There is no commitment for any reimbursement or any other compensation for the participant.

Privacy and Confidentiality:- The only people to know that you are a research subject are members of the research team. No information about you or information

provided by you during the research will be disclosed to others without your written permission.

Authorization to Publish Results :- When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Compensation :- In the event of injury related to the study, treatment will be made available through KLES Dr. Prabhakar Kore Hospital & MRC, Belgaum. There is no compensation or payment for such medical treatment by law. The doctors and the staff will provide facilities and medical attention to you.

Questions :- If you have any questions about the research you may please contact:

1) Chief Investigator, Dr. Dhara Shah, P.G, Department of Ophthalmology, JNMC, Belgaum. Contact No. 09724307949.

2 Under the guidance of Dr REKHA B.K. M.B.B.S, DOMS, M.S., PhD PROFESSOR, DEPT. OF OPHTHALMOLOGY, J .N.MEDICAL COLLEGE, K.L.E. UNIVERSITY , BELGAUM-590010.

If you need any further information regarding your rights as a study participant contact

3) Dr. GANGA S. PILLI, CHAIRPERSON, JNMC, Belgaum and chairman of Institutional Ethics Committee. Contact No. 08312471350

Consent for participation in research trial

I, Mr./Ms./Mrs _____ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up ant of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name: _____

Signature or the Left Thumb Print of Subject: _____

Witness Name: _____

Signature of Witness: _____

Investigators Name: _____

Signature of Investigator: _____

Date: _____

ANNEXURE II – PROFORMA

PATIENTS ID NO: | | |

NAME: | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | |

AGE: | | | Years

SEX: | | (1-Male; 2-Female)

ADDRESS: | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | |

CONTACT NUMBER :- | | | | | | | | | | |

OP NUMBER: | | | | | | | | |

IP NUMBER: | | | | | | | | |

DATE OF ADMISSION: | | | | | | | | | |

DATE OF DISCHARGE: | | | | | | | | | |

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

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

FINAL RESULT INFORMATION | |

1- INELIGIBLE
2- ELIGIBLE- REFUSAL
3- ELIGIBLE- PARTICIPATING

SURGEON'S NAME: | | | | | | | | | | | | | | | | | | |

SURGEON'S SIGNATURE: _____

DATE: | | | | | | | | |

CHIEF COMPLAINTS:

DIMINUTION OF VISION ☐

Duration: _____ days/ months/years

LE ☐

Duration: _____ days/ months/years

HISTORY OF PRESENT ILLNESS:

1 .DIMINUTION OF VISION	1- Gradual; 2- Sudden	☐
	1- Progressive; 2- Static	☐
	1- Painless; 2- Painful	☐
	1- For distance; 2- For near	☐
2. DIPLOPIA/POLYOPIA	1- Present; 2- Absent	☐
3. COLOURED HALOS	1- Present; 2- Absent	☐
4. BLACK SPOTS BEFORE THE EYES	1- Present; 2 - Absent	☐
5. WATERING	1- Present; 2 - Absent	☐
6. REDNESS	1- Present; 2 - Absent	☐
7. DISCHARGE	1- Present; 2 - Absent	☐
8. H/O WEARING GLASSES	(1-Distance; 2-Near; 3-Both)	☐

Duration: ☐☐ months/years

PAST HISTORY:

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

OCULAR SURGERY: 1- Present; 2- Absent ☐

Type of surgery: _____

Duration: ☐☐ months/years

DIABETES: 1- Present 2- Absent ☐

Duration: ☐☐ months/years

HYPERTENSION: 1- Present 2- Absent ☐

Duration: ☐☐ months/years

ANY OTHER MEDICAL DISORDERS: _____

PERSONAL HISTORY:

SMOKING: 1- Present; 2- Absent ☐

Duration: ☐☐ months/years

ALCOHOLISM: 1- Present; 2- Absent ☐

Duration: ☐☐ months/years

ANY OTHER ADDICTIONS: _____ ☐

Duration: ☐☐ months/years

GENERAL PHYSICAL EXAMINATION:

General Appearance:

1- Well built ,2- Moderately built, 3- Poorly built, 4- emaciated ☐

Pallor: 1- Present 2- Absent ☐

If present 1- Mild 2- Moderate 3- Severe ☐

Pulse: ☐☐☐ /minute

BP:- ☐☐☐ ☐☐☐ mm of hg

Temperature: ☐☐☐ degree Fahrenheit

Respiratory rate: ☐☐ /minute

SYSTEMIC EXAMINATION:

CVS: 1- Normal 2- Abnormal ☐
if 2, specify :_____

RS: 1- Normal 2- Abnormal ☐
if 2, specify: _____

CNS: 1- Normal 2- Abnormal ☐
if 2, specify :_____

Per Abdomen: 1- Normal 2- Abnormal ☐
if 2, specify :_____

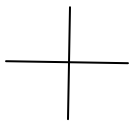
OCULAR EXAMINATION:

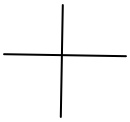
Head posture: 1- Erect ,2- Tilted ☐

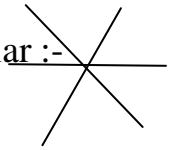
Visual Axis: 1- Parallel, 2- Deviated ☐

Facial Symmetry: 1- Symmetrical, 2- Asymmetrical ☐

Extraocular movements:

RE- 

LE- 

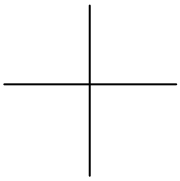
Binocular :- 

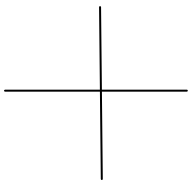
(N- Normal, R- Restricted) ☐

1) Visual Acuity:

	RE	LE
DISTANT		
PINHOLE		
NEAR		
AIDED		

REFRACTION/RETINOSCOPY:





Prescription	Spherical	Cylindrical	Axis	BCVA
RE				
LE				

2. Adnexa (1- Normal; 2-Abnormal)	☐	☐

3. Sclera (1- Normal; 2- Congested)	☐	☐
4. Conjunctiva (1-normal; 2-conjunctival congestion; 3-ciliary congestion; 4-chemosis)	☐	☐
5. Cornea (1- normal; 2-opacity; 3-vascularisation)	☐	☐
6. Anterior chamber (1- normal depth; 2-shallow; 3-deep)	☐	☐
7. Iris (1-normal colour & pattern; 2-Abnormal)	☐	☐
8. Pupil: Size- ____ in mm Shape- 1- Round & Regular; 2-Abnormal Reaction: Direct (1. Present, 2. Absent) Indirect (1. Present, 2. Absent) Near reflex (1. Preset, 2. Absent)	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐
9. Lens Clarity- 1. Clear, 2. Opaque Cataract - (1) , PCIOL - (2) Cataract if present- 1.immature 2.mature 3. hyper mature A) CORTICAL- (1.Present, 2. Absent)	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐
B) NUCLEAR SCLEROSIS- 1. PRESENT, 2- ABSENT If present- 1. Grade-1	☐ ☐	☐ ☐

2. Grade-2 3.Grade- 3 4. Grade-4		
(C) POSTERIOR SUBCAPSULAR CATARACT PRESENT, 2. ABSENT	☐	☐

FUNDUS	RE	LE
GLOW		
MEDIA		
DISC Size Shape Color Nasalization Bayonetting Lamellar dot sign Haemorrhages Others:		
C:D RATIO		
BLOODVESSELS		
BACKGROUND		
MACULA		

DIAGNOSIS:-

IMPRESSION:-

INVESTIGATIONS:

1. Ocular

A) Lacrimal patency

(1-PATENT;2- regurgitation: 2A- Clear fluid, 2B- Mucopurulent ; 3-BLOCKED) ☐

RE

LE ☐

B) IOP: (with Schiotz tonometer)

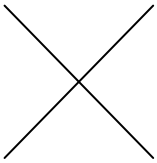
RE: ☐ mm of hg

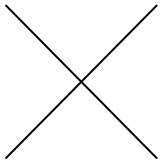
LE : ☐ mm of hg

C) Blood sugar: _____mg%

D) Blood Pressure :_____mm of hg

E) Gonioscopy:





OPERATIVE PROCEDURE: 1) TRABECULECTOMY WITH MINIMAL DOSE OF MITOMYCIN C.(0.1MG/ML FOR 2 MINUTES)

2) TRABECULECTOMY WITH MINIMAL DOSE OF MITOMYCIN C(0.1MG/ML FOR 2 MINUTES) with SICS with PCIOL

DATE:_____/_____/_____

OPERATING EYE : _____

ANAESTHESIA: PERIBULBAR BLOCK/ TOPICAL

INCISION: 1. Superior ☐

2.Temporal ☐

3. Superior temporal ☐

4. Inferior temporal ☐

Operative Complications: 1. Present, 2. Absent ☐

If present- specify

Post- operative complications: 1. Present, 2. Absent ☐

If present- specify

FOLLOW UP PLAN: 1 DAY post-operatively

1. Conjunctiva (1-normal; 2-conjunctival congestion; 3-ciliary congestion; 4-chemosis)	☐
2.Section/suture site (1-edges opposed; 2- edges gaping)	☐
3.Cornea (1-clear; 2-hazy/descemets fold)	☐
4. Anterior chamber (1- normal depth; 2-shallow; 3-deep)	☐
5. Iris (1-normal colour & pattern; 2-Abnormal)	☐
6. Pupil: Size- ____ in mm Shape- 1- Round & Regular; 2-Abnormal IF 2 (Specify) :	☐
7.Intraocular Lens (1-in situ, 2-decentred)	☐

VISUAL ACUITY	RE	LE
DISTANT		
PINHOLE		

IOP: (with non contact tonometer)

RE: ☐ mm of hg
LE : ☐ mm of hg

CONDITIONOF BLEB:

COMPLICTIONS (IF ANY OTHER):

FOLLOW UP PLAN: 1 WEEK post-operatively

1. Conjunctiva (1-normal; 2-conjunctival congestion; 3-ciliary congestion; 4-chemosis)	☐
2.Section/suture site (1-edges opposed; 2- edges gaping)	☐
3.Cornea (1-clear; 2-hazy/descemets fold)	☐
4. Anterior chamber (1- normal depth; 2-shallow; 3-deep)	☐
5. Iris (1-normal colour & pattern; 2-Abnormal)	☐
6. Pupil: Size- ____ in mm Shape- 1- Round & Regular; 2-Abnormal IF 2 (Specify) :	☐

7.Intraocular Lens (1-in situ, 2-decentred)	☐

VISUAL ACUITY	RE	LE
DISTANT		
PINHOLE		

IOP: (with non contact tonometer)

RE: ☐ mm of hg
LE : ☐ mm of hg

CONDITIONOF BLEB:

COMPLICTIONS (IF ANY OTHER):

FOLLOW UP PLAN: 1 MONTH post-operatively

1. Conjunctiva (1-normal; 2-conjunctival congestion; 3-ciliary congestion; 4-chemosis)	☐
2.Section/suture site (1-edges opposed; 2- edges gaping)	☐
3.Cornea (1-clear; 2-hazy/descemets fold)	☐

4. Anterior chamber (1- normal depth; 2-shallow; 3-deep)	☐
5. Iris (1-normal colour & pattern; 2-Abnormal)	☐
6. Pupil: Size- ____ in mm Shape- 1- Round & Regular; 2-Abnormal IF 2 (Specify) :	☐
7.Intraocular Lens (1-in situ, 2-decentred)	☐

VISUAL ACUITY	RE	LE
DISTANT		
PINHOLE		

IOP: (with non contact tonometer)

RE: ☐ mm of hg
LE : ☐ mm of hg

CONDITIONOF BLEB:

COMPLICTIONS (IF ANY OTHER):

FOLLOW UP PLAN: 3 MONTHS post-operatively

1. Conjunctiva (1-normal; 2-conjunctival congestion; 3-ciliary congestion; 4-chemosis)	☐
2.Section/suture site (1-edges opposed; 2- edges gaping)	☐
3.Cornea (1-clear; 2-hazy/descemets fold)	☐
4. Anterior chamber (1- normal depth; 2-shallow; 3-deep)	☐
5. Iris (1-normal colour & pattern; 2-Abnormal)	☐
6. Pupil: Size- ____ in mm Shape- 1- Round & Regular; 2-Abnormal IF 2(Specify) :	☐
7.Intraocular Lens (1-in situ, 2-decentred)	☐

VISUAL ACUITY	RE	LE
DISTANT		
PINHOLE		

IOP: (with non contact tonometer)

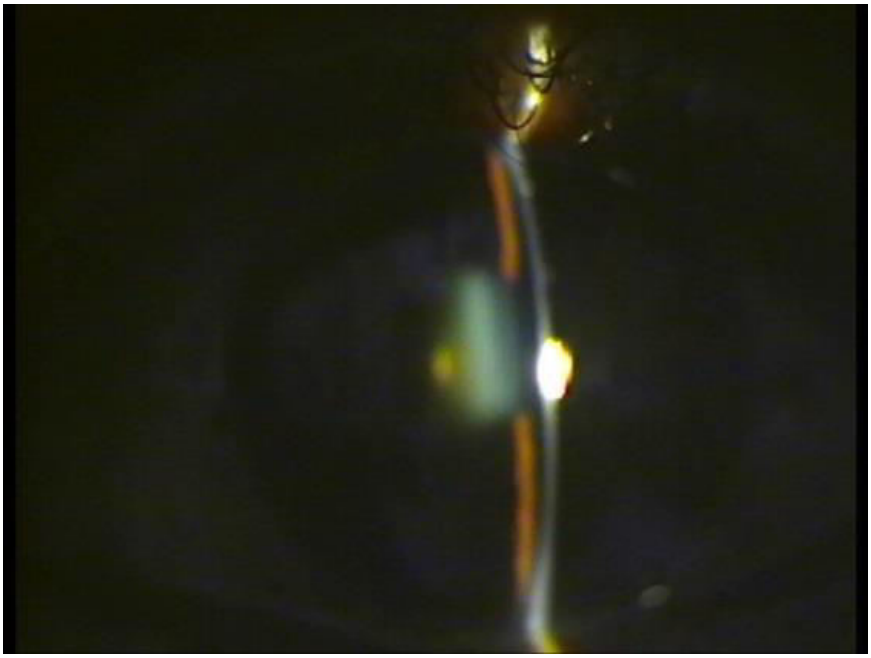
RE: ☐ mm of hg
LE : ☐ mm of hg

CONDITION OF BLEB :

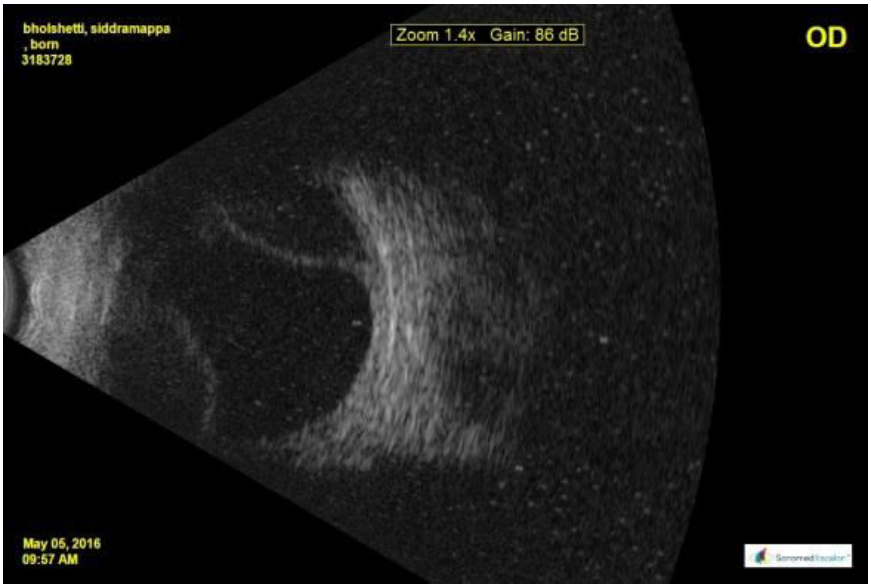
COMPLICATIONS (IF ANY OTHER):

ANNEXURE III – PHOTOGRAPHS

Complications:

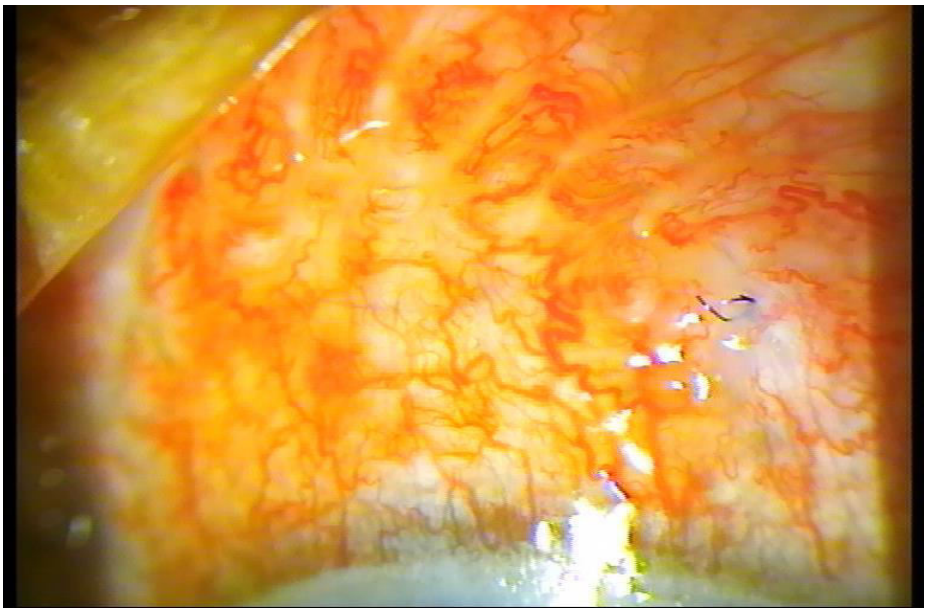


Shallow AC

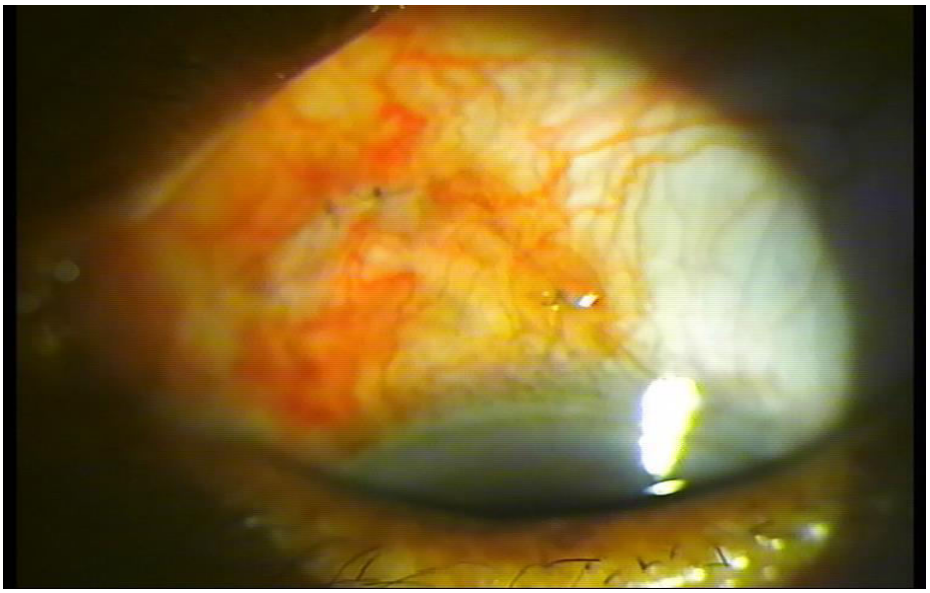


Choroidal Detachment

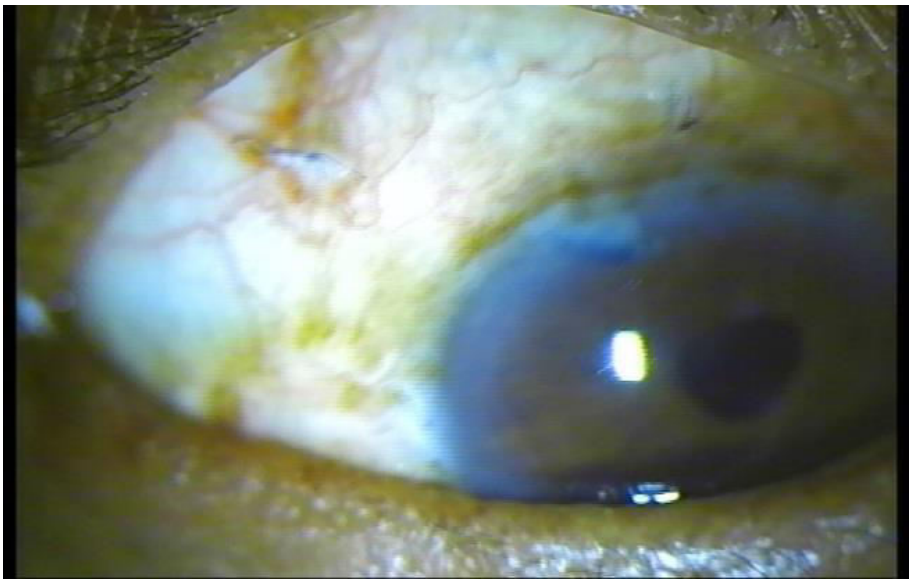
Moorfield's bleb grading:



Grade III bleb: mildly elevated, diffuse and mildly vascularised



Grade II bleb: mildly elevated, diffuse and normally vascularised



Grade I bleb: mildly elevated, diffuse and avascular

ANNEXURE IV – MASTER CHART

NAME		Pre-op																
	Age/Sex	Vision	IOP	Diagnosis	Procedure	Vision (1day)	Vision(1wk.)	Vision(1mnth)	Vision(3months)	IOP (1day)	IOP(1wk.)	IOP(1month)	IOP(3months)	Bleb (1day)	Bleb(1WK.)	Bleb(1month)	Bleb(3months)	Complications
patient 1	**70/M**	6\24	20.6)	**re g.a + simc**	**re combine**	HMCF	PR - A	6\12	6\12	10.6	18.1	7	12.4	II	II	II	II	
patient 2	**40/F**	CF-2M	51.7	**re a.c.g**	**re plain**	6\18	6\24	6\24	6\60	11.4	9.4	7.5	6.8	II & III	I &II	I & II	II	
patient 3	**72/F**	CF-3mt.	37.8	**le a.c.g + simc**	**le combine**	CF-0.5mt.	6\18	CF-2mt.	CF-3mt.	7.4	7.9	9.7	9.1	II	I &II	II	II	
patient 4	**60/M**	6\18	26.6	**re pxf.g + simc**	**re plain**	HMCF	6\24	6\24	6\18	21.9	6.1	7.8	8.7	II & III	II	I & II	II	
patient 5	**85/F**	CF-1mt.	22.4	**le a.c.g + simc**	**le combine**	CF-2mt.	6\24	6\18	6\36	9.3	6.3	11.4	7.3	II & III	II	II	II	
patient 6	**70/F**	6\36	50.6	**le pxf.g + simc**	**le plain**	6\36	6\18	6\12	6\12	16.4	15	13.1	11	II	II	II	I	
patient 7	**70/M**	CFCF	21.4	**le pxf.g**	**le plain**	CFCF	CFCF	6\36	CFCF	7	16.6	10	8.8	II	II	II	II	
patient 8	**65/M**	CF0.5mt.	34.4	**le pxf.g + simc**	**le combine**	CF-3mt.	6\18	6\36	6\24	11.3	11.8	15.3	18.6	II	II	II	II	
patient 9	**65/M**	CFCF	41.5	**le pxf.g**	**le plain**	CF-3mt.	CF- 5mt.	CF-2mt.	6\60	20.6	15.5	14.8	10.7	III	II	II	II	
patient 10	**77/M**	6\18	24.4	**le poag+simc**	**le combine**	6\36	6\24	6\24	6\12	17.3	29.1	8.4	15.7	II	II	II	II	
patient 11	**50/M**	6\60	20.6	**re poag + simc**	**re combine**	6\12	6\12	6\24	6\24	10.6	13.6	13.6	13.6	III	II	II	II	
patient 12	**50/M**	PR-IA	50.6	**le poag + simc**	**le combine**	PR-IA	PR-IA	CF-0.5mt.	CF-0.5mt.	39.4	8.8	10.1	7.3	III	II	II	II	
patient 13	**50/M**	6\12	24.4	**re a.c.g**	**re plain**	6\18	6\18	6\18	6\12	9.7	7.7	7.2	5.8	II	II	II	II	
patient 14	**74/M**	6\60	29	**le poag + simc**	**le plain**	6\24	6\24	6\36	6\24	12.3	18.4	11.1	11.2	II & III	III	II	II	
patient 15	**65/F**	6\24	31.1	**le a.c.g + simc**	**le plain**	CF-5mt.	6\18	6\12	6\12	10.9	11.8	14.6	18.1	II & III	II & III	II	II	
patient 16	**70/M**	PR-A	26.6	**le poag + simc**	**le combine**	CF-1mt.	PR-A	PR-A	PR-A	16.1	13.4	7.2	9.1	III	III	II	II	
patient 17	**60/M**	CF3mt.	22.4	**le poag + simc**	**le combine**	6\12	6\18	6\9	6\60	13.1	13.1	14.4	17.9	II	III & IV	III	II	
patient 18	**70/F**	6\24	24.4	**le pxf.g + simc**	**le plain**	6\24	6\12	6\36	6\12	8.6	7.1	14.1	8.3	III	III	II	II	
patient 19	**50/M**	HMCF	29	**re poag + smc**	**re combine**	6\36	6\24	6\18	6\12	7.2	13.6	7.8	10.8	III	II	II	II	
patient 20	**55/M**	6\18	24.4	**re pxf.g**	**re plain**	6\9	6\24	6\36	6\24	6.8	7.2	10.2	7.3	III	III	II	II	cataract(late),shallow AC(early)
patient 21	**50/F**	CF-1mt.	29	**le pxf.g + simc**	**le combine**	6\60	6\36	6\36(p)	6\24	25.1	18.4	12.1	10.1	III	II	II	II	
patient 22	**41/M**	6\18	24.4	**re poag**	**re plain**	6\18	6\36(p)	6\24	6\18	25.1	7.7	32.5	14.9	II	III	II	II	
patient 23	**60/M**	CFCF	23.8	**le poag + simc**	**le combine**	6\12	6\24	6\24	6\24	9.3	10.3	7.9	9.4	III	III	II	II	
patient 24	**50/M**	CF-2mt.	22.4	**le poag + simc**	**le combine**	CF-2mt.	CF- 2mt.	CF-3mt.	CF-5mt.	10.2	7.2	6.7	7.8	III	II	II	II	
patient 25	**64/M**	6\36	24.4	**re poag**	**re plain**	6\24	CF 4M	6\24	6\24	9.4	10.2	18.6	15.9	III	II	II	II	
patient 26	**55/M**	HMCF	26.6	**re pxf.g + simc**	**re plain**	CFCF	6\28	6\24	6\18	7.2	6.1	9.8	17.3	III	II	II	III	
patient 27	**80/M**	6\12	32.2	**re pxf.g**	**re plain**	6\24	6\36	6\18	6\12	10.2	10.2	7.2	6.8	III	III	II	II	
patient 28	**76/M**	CF-2mt.	24.4	**le poag + simc**	**le combine**	6\36	6\24	6\24	6\24	7.3	7.6	18.9	12.2	III	II	II	II	
patient 29	**62/M**	CF 2M	50.6	**re pxf.g**	**re plain**	CF 1M	CF- 0.5mt.	HMCF	CF-0.5mt.	4.4	5.1	6.4	6.8	III	III	III	II	Choroida ldetachment (early)
patient 30	**65/M**	CF1MT	24.4	**re poag + simc**	**re combine**	CF1MT	CF1MT	6\36	6\24	7.9	4.7	9.8	9.5	II	II	II	II	

ANNEXURE IV – MASTER CHART KEY

poag: primary open angle glaucoma

g.a: glaucomatous optic atrophy

pxf.g: pseudoexfoliative glaucoma

simc: senile immature cataract

smc: senile mature cataract

acg: angle closure glaucoma

plain: trabeculectomy with mmc

combine: trabeculectomy wit mmc with sics with pciol

mmc: mitomycin -c