"A RANDOMIZED CLINICAL TRIAL OF COMPARISON OF MICROTRABECULECTOMY VERSUS CONVENTIONAL TRABECULECTOMY IN PRIMARY OPEN ANGLE GLAUCOMA AT KLE'S DR. PRABHAKAR KORE HOSPITAL AND MRC, BELGAUM."

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Endorsement By The Hod, Principal / Head Of The Institution

This is to certify that the dissertation entitled **"A RANDOMIZED CLINICAL TRIAL OF COMPARISON OF MICROTRABECULECTOMY VERSUS CONVENTIONAL TRABECULECTOMY IN PRIMARY OPEN ANGLE GLAUCOMA AT KLE'S DR. PRABHAKAR KORE HOSPITAL AND MRC, BELGAUM."** is a bonafide research work done by **Registration No.BK0108004**.

Dr. R. K. DANDUR MS,DOMS
Professor and Head,
Department of Ophthalmology
J. N. Medical College,
Nehru Nagar,
Belgaum-590 010

Date :

Place : **Belgaum**

Dr. V. D. PATIL MD, DCH
Principal,
J. N. Medical College,
Nehru Nagar,
Belgaum-590 010

Date :

Place : **Belgaum**

LIST OF ABBREVIATIONS USED

AC	**–**	Anterior chamber
AG	**–**	Antiglaucoma
BCVA	**-**	Best corrected visual acuity
IOP	**-**	Intra ocular pressure
mm Hg	**-**	Milimeter of mercury
PL	**-**	Perception of light
POAG	**-**	Primary open angle glaucoma
PR	**-**	Projection of ray
SFT	**-**	Small flap trabeculectomy

ABSTRACT

Background and objectives

Currently trabeculectomy is the most popular filtering procedure for glaucoma. Although it has remained the gold standard for the surgical management for more than 30 years, it has a success rate between 67-94% only in primary glaucomas. Several serious postoperative complications are not infrequently associated with trabeculectomy.

A recent technique of creating a fistula into the subconjunctival space with minimal disruption of conjunctiva in the form of small flap trabeculectomy known as microtrabeculectomy has been described. It is a much scaled down modification of "full size" procedure and is claimed to be less disruptive to ocular tissues.

The purpose of this study is to compare the IOP control in microtrabeculectomy with conventional trabeculectomy and to compare the safety of microtrabeculectomy with conventional trabeculectomy in post operative complications of primary open angle glaucoma.

Method

The present one year comparative study was conducted in the Department of ophthalmology, KLE Dr.Prabhakar Kore Hospital and MRC Belgaum on 16 patients divided in two groups, Patients in group I underwent the procedure of microtrabeculectomy and patients in group II underwent conventional trabeculectomy. The procedure of microtrabeculectomy included limbal based conjunctival flap 4mm from limbus at superior quadrant. A square shaped lamellar sclera flap of 2x2 mm (1/2 to 1/3rd thickness of sclera) hinged at limbus, dissected until at least 1mm of bluish grey zone was exposed. Anterior chamber was entered at the anterior end. Kelly's punch was used to remove 1.0. x 1.0 mm of trabecular

meshwork. Tip of scleral flap was approximated with single 10-0 monofilament suture, after performing peripheral iridectomy.Conjunctival flap was sutured with 10-0 monofilament (continuous sutures).

The procedure of conventional trabeculectomy included, a limbal based conjunctivo-tenon flap at 12 O'clock position at least 8-10mm from the limbus. A partial thickness, limbal based, lamellar, square shape scleral flap of 5x5 mm (1/2 to 1/3 thickness of sclera). The flap was extended well past the limbus into the clear cornea, until 1mm of bluish grey zone was exposed and a 1 x 4mm block of tissue anterior to scleral spur was excised manually. A broad based, peripheral iridectomy was performed and the scleral flap was reapproximated to the scleral bed with three to five monofilament sutures. Conjunctival flap closure was done meticulously with 10-0 monofilament continuous sutures. All patients were followed up for a minimum period of 3 months.

Results

Mean pre operative IOP in SFT (microtrabeculectomy) i.e. Group I was 30.75± 6.04 mm of Hg and mean post operative IOP was 13.87 ± 2.80 mm of Hg at the end of 3rd month (P value < 0.0001) which is both statistically and clinically significant. All patients had IOP ≤ 21 mm of Hg without medication with low lying and shallow diffuse blebs i.e. 100% completed success and with fewer intra and early post operative complications as compared with conventional trabeculectomy i.e. Group II in which the mean pre operative IOP was 30.0± 7.27 mm of Hg and mean post operative IOP was 14.12 ± 2.80 mm of Hg at the end of 3rd month with 100% completed success.

Conclusions

SFT (microtrabeculectomy) is a safe procedure that effectively reduces IOP and produces good filtering blebs with fewer complications which is comparable in terms of IOP reduction in the procedure of conventional trabeculectomy and better in terms of safety with no use of pharmacological wound modulators. More studies are needed to ascertain it as an alternative to the conventional trabeculectomy glaucoma surgery.

Key words

Conventional trabeculectomy, Small flap trabeculectomy, microtrabeculectomy, POAG

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INTRODUCTION

In the present scenario the term “glaucoma” is reserved for those people with established, visually significant, end organ damage. In the public health context, glaucoma can be seen as an optic neuropathy associated with characteristic structural damage to the optic nerve and associated visual dysfunction that may be caused by various pathological processes. [1]

Glaucoma is defined as a disturbance of the structural or functional integrity of the optic nerve that can usually be arrested or diminished by adequate lowering of IOP. An important distinction must be noted in the criteria currently used to define primary open-angle glaucoma (POAG), in contrast to all other forms of glaucoma.

Primary open-angle glaucoma is explicitly characterized as a multi factorial optic neuropathy with a characteristic acquired atrophy of the optic nerve and loss of retinal ganglion cells and their axons developing in the presence of open anterior chamber angles, and manifesting characteristic visual field abnormalities. [2]

Glaucoma is the second leading cause of blindness worldwide. The number of people with primary glaucoma in the world in the year 2000 is estimated at nearly 66.8 million, with 6.7 million suffering from bilateral blindness.

In developed countries, fewer than 50% of those with glaucoma are aware of their disease. In the developing world, the rate of known disease is even lower. [3]

There will be 60.5 million people with OAG and ACG in 2010, increasing to 79.6 million by 2020, and of these, 74% will have OAG. Women will comprise 55% of OAG in 2010. Asians will represent 47% of those with glaucoma . Bilateral blindness will be present in 4.5 million people with OAG and in 2010, rising to 5.9 million people in 2020. [4]

In a study in 2001 in rural south Indian population the prevalence of POAG in this population was 1.62%. The prevalence increased with age, and 98.5% were not aware of the disease.[5]

The common denominator of the glaucomas is a characteristic optic neuropathy, which derives from various risk factors including increased intraocular pressure (IOP) . Although elevated IOP is clearly the most frequent causative risk factor for glaucomatous optic atrophy, it is not the only factor, and attempts to define glaucoma on the basis of ocular tension are no longer advised.

Nevertheless, IOP and aqueous humor dynamics, which regulate the pressure, are critical to our understanding of glaucoma, not only because they are the most common and best understood of the causative risk factors for glaucoma, but also because they are presently the only factors that can be controlled to prevent progressive optic neuropathy. [6]

Currently trabeculectomy is the most popular filtering procedure for glaucoma. Although it has remained the gold standard for the surgical management for more than 30 years, it has a success rate between 67-94% only in primary glaucomas. [7]

Several serious postoperative complications are not infrequently associated with trabeculectomy , including early postoperative aqueous leak with moderately shallow anterior chamber (21%), postoperative hyphema (18-38%), progression or initiation of cataractogenesis (10-20%) and failing bleb due to scarring within the conjunctiva, episclera and surrounding tissues. [8]

A recent technique of creating a fistula into the subconjunctival space with minimal disruption of conjunctiva in the form of small flap trabeculectomy known as

microtrabeculectomy has been described. It is a much scaled down modification of "full size" procedure and is claimed to be less disruptive to ocular tissues. [9]

So this study had been undertaken to compare the efficacy and safety in microtrabeculectomy with conventional trabeculectomy in cases of primary open angle glaucoma.

OBJECTIVES

1. To evaluate the intra ocular pressure control in microtrabeculectomy compared with conventional trabeculectomy.

2. To evaluate the safety of microtrabeculectomy in comparison with conventional trabeculectomy in post operative complications in patients of primary open angle glaucoma.

REVIEW OF LITERATURE

Historical perspective

The concepts and definitions of glaucoma have evolved in the past 100 years, and still they remain imprecise and subject to technical qualifications. The word *glaucoma* originally meant 'clouded' in Greek; as such, it may have referred either to a mature cataract or to corneal oedema that might result from chronic elevated pressure. [2]

The advent of modern glaucoma surgery

Trabeculectomy, introduced by Cairns in 1968, has become the gold standard filtering procedure for many eyes with glaucoma.[9,29] A number of variations on the original technique have been described. These have included changing the size,[10] shape, and position of the sclerostomy and trapdoor, limbal, or fornix based conjunctival incisions, and altering the method of performing the sclerostomy by trephination, sclerectomy, and the use of a scleral punch. That no one simple procedure has been universally accepted implies that, in terms of IOP control none has a significant advantage over any of the others. It is generally accepted that preoperative risk factors are the most important determinants of surgical success, and the use of adjective antimetabolite treatment in high risk cases has gained popularity over the last decade.

Early postoperative pressure control following small flap Trabeculectomy (microutrabeculectomy) has been shown to be comparable with published series for conventional trabeculectomy. [9-11]

GLAUCOMA

Glaucoma is defined as optic neuropathy characterized by optic disc cup changes with progressive loss of visual filed with or without increased intraocular pressure.

Elevated IOP is clearly the most frequent causative risk factor for glaucomatous optic neuropathy. However it is not the only risk factor, other factors include IOP and aqueous humor dynamics, which regulate the pressure are critical to our understanding of glaucoma. They are presently the only risk factors that can be controlled to prevent progressive optic neuropathy. [12] Hence glaucoma had been defined "disturbance of structural or functional integrity of eye that can be arrested or diminished by adequate lowering of intra ocular pressure (IOP) [13].

Glaucoma is not a single disease process rather, it embraces a composite of pathological conditions which have the common feature, that their clinical manifestations are to a greater or lessor extent dominated by height of intra ocular pressure which the tissues of the particular eye in question, are unable to withstand without damage to their structure or impairment of their function. The clinical and pathological diversity in this disease process in intriguing but yet certain common denominators, underlying the cloud of diversity exist, namely IOP rise, optic nerve head damage and visual filed loss.[13]

The term glaucoma refers to a group of diseases that have in common a characteristic optic neuropathy with associated visual filed loss for which elevated intraocular pressure (IOP) is one of the primary risk factors, of these cardinal signs, visual filed loss is diagnostically the most specific, since both cupping and intraocular pressure exhibit physiological variation in a given population. [14]

Glaucoma can be diagnosed according to three levels of evidence. The highest level of certainty requires optic disc abnormalities (Vertical Cup Disc Ratio > 97.5 percentile of the normal population) and visual filed defect compatible with glaucoma. In the second, if a visual filed test could not be performed satisfactorily. A severely damaged optic disc (Vertical Cup Disc Ratio > 995 percentile of the normal population) would be sufficient to make the diagnosis. Lastly if the optic disc could not be examined because of media opacity (and, hence, no filed test also possible), an IOP exceeding the 99.5^{th} percentile of the normal population, or evidence of previous glaucoma filtering surgery, may be taken as sufficient of a diagnosis of glaucoma.[1]

Three factors determine the IOP:

a. The rate of aqueous humor production by the ciliary body.

b. Restance to aqueous outflow across the trabecular meshwork Schlemm's canal system.

c. The level of episcleral venous pressure.

In most cases increased IOP is caused by increased resistance to aqueous humor outflow.[14]

Classification and staging of glaucomas

Glaucomas can be considered to consist of five stages.

Stage 1 - Initiating events

Stage 2 - Structural alterations

Stage 3 - Functional alterations

Stage 4 - Optic nerve damage

Stage 5 - Visual loss

CLASSIFICATION OF THE GLAUCOMAS BASED ON INITIAL EVENTS [6]

A. Open-angle glaucomas without other known ocular or sustemic disorders.

   i. Chronic open-angle glaucoma (POAG)

   ii. Normal-tension glaucoma

B. Angle-closure glaucomas without other known ocular or systemic disorders

   i. Pupillary block glaucomas

   ii. Combined mechanism glaucoma

C. Developmental glaucomas

   i. Congential glaucoma

   ii. Juvenile open-angle glaucoma

   iii. Axenfeld - Rieger syndrome

   iv. Peters anomaly

   v. Aniridia

   vi. Other developmental anomalies.

D. Glaucomas associated with other ocular and systemic disorders

   i. Glaucomas associated with disorders of the corneal endothelium.

      1. Iridocorneal endothelial syndrome

      2. Posterior polymorphous dystrophy

      3. Fuch's endothelial dystrophy

ii. Glaucomas associated with disorders of the iris and ciliary body.

1. Pig mentary glaucoma
2. Iridoschisis
3. Plateau iris
4. Iris and ciliary body cysts.

iii. Glaucoma associated with disorders of teh lens

1. Pseudoexfoliation syndrome
2. Glaucomas associated with cataracts
3. Glaucomas associated with lens dislocation.

iv. Glaucomas associated with disorders of the retina, choroid and vitreous.

1. Neovascular glaucoma
2. Glaucomas associated with retinal detachment and vitreoretinal abnormalities.

v. Glaucomas associated with intraocular tumors.

1. Malignant melanoma
2. Retinoblastoma
3. Metastatic carcinoma
4. Leukaemias and lymphomas
5. Benign tumors

vi. Glaucomas associated with elevated episcleral venous pressure.

vii. Glaucomas associated with inflammation.

1. Glaucomas associated with uveitis.
2. Glaucomas associated with keratitis. episcleritis, and scleritis.

viii. Steroid - induced glaucoma.

ix. Glaucomas associated with ocular trauma.

x. Glaucomas following intraocular surgery.

1. Ciliary block (malignant) glaucoma
2. Glaucomas in pseudophakia and aphakia
3. Epithelial , fibrous, and endothelial proliferation
4. Glaucomas associated with corneal surgery
5. Glaucomas associated with vitreoretinal surgery.

CLASSIFICATION OF GLAUCOMAS BASED ON MECHANISMS OF OUTFLOW OBSTRUCTION [6]

1. Open angle glaucoma mechanisms

A. Pretrabecular (Membrane overgrowth)

I. Fibrovascular membrane (neovascular glaucoma)

II. Endothelial layer, often with descement-like membrane

i. Iridocorneal endothelial syndrome

ii. Posterior polymorphous dystrophy

iii. Penetrating and non penetrating trauma

III. Epithelial down growth

IV. Fibrous in growth

V. Inflammatory membrane

i. Fuch's heterochromic iridocyclitis.

ii. Leutic interstitial keratitis.

B. Trabecular (Occlusion of intertrabecular spaces)

I. Idiopathic

i. Chronic open angle glaucoma

ii. Steroid induced glaucoma

II. Clogging of the trabecular meshwork

i. Red blood cells

a. Hemorrhagic glaucoma

b. Ghost cell glaucoma

ii. Macrophages

a. Hemolytic glaucoma

b. Phacolytic glaucoma

c. Melanomalytic glaucoma

iii. Neoplastic cells

a. Malignant tumors

b. Neurofibromatosis

c. Nevus of Ota

d. Juvenile xanthogranuloma

iv. Pigment particles

a. Pigmentary glaucoma

b. Pseudoexfoliation syndrome (Glaucoma capsulare)

c. Uveitis

d. Malignant melanoma

v. Protein

a. Uveitis

b. Lens induced glaucoma

vi. Viscoelastic agents

vii. α-chymotrypsin induced glaucoma

viii. Vitreous

III Alterations of the trabecular meshwork

i. Edema

a. Uveitis (trabeculitis)

b. Scleritis and episcleritis

c. Alkali burns

ii. Trauma (angle recession)

iii. Intraocular foreign bodies (hemosiderosis , chalcosis)

C. Posttrabecular

I. Obstruction of Schlemm's canal

i. Collapse of canal

ii. Clogging of canal (e.g sickled red blood cells)

II. Elevated episcleral venous pressure

i. Carotico cavernous fistula

ii. Cavernous sinus thrombosis

iii. Retrobulbar tumors.

iv. Thyrotropic exophthalmos

v. Superior vena cava obstruction

vi. Mediastinal tumors

vii. Sturge -Weber syndrome

viii. Familial episcleral venous pressure elevation.

AQUEOUS HUMOR DYNAMICS

Aqueous production

Aqueous is produced in the non pigmented epithelium of the ciliary body process; the bases of the pigmented epithelial cells face the ciliary body stroma, which contains a rich vascular supply. The vessels of the ciliary body processes are relatively leaky providing adequate water and ions for the production of aqueous.

Aqueous is produced by three primary methods active transport, ultra filtration and diffusion.

Active transport (secretion) is the primary means of aqueous production, Active transport involves use of the ATP as a carbonic anhydrase. Over 70% of the sodium that reaches the aqueous is pumped by active transport. The sodium gradient created by active transport is responsible for the majority of the water that enters the aqueous following this osmotic gradient.

Ultra filtration is the passage of materials from a region of higher pressure to a region of lower pressure. This system is pressure dependent; water and small water soluble molecules that are not highly charged enter the aqueous through this mechanisms.

Diffusion allows lipid soluble molecule to pass across the lipid portion of the cell membrane into the posterior chamber.

The normal rate of aqueous productions is about 2µl/min (range 1.8 to 4.3µl/min). This rate decreases with age (about 2% decade) and during sleep (by 45% as average)

Aqueous outflow

There are number of potential pathways for aqueous humor to leave the eye including the trabaculocanalicular, uveoscleral, transcorneal and post iridial routes. The trabaculocanalicular and uveoscleral routes account for most of the aqueous elimination. The volume of aqueous humor that flows through the angle of anterior chamber is approximately equal to the volume of fluid that flows through the pupil.

Trabaculocanalicular (Conventional) outflow; approximately 90% of aqueous leaves through the trabecular meshwork; this is considered as conventional outflow pathway. Trabecular outflow is pressure dependent, increasing as intraocular pressure increase.

The trabecular meshwork consist of three layers: the uveal meshwork, the conrneoscleral meshwork and juxtacanalicular tissue. Aqueous humor flowing through the trabecular meshwork enters Schlemm's canal and from there it flows into the scleral, episcleral and conjunctival venous system. To exit the eye via this route, intraocular pressure must be higher than episcleral venous pressure. When pressure is below episcleral venous pressure (8 to 12 mm Hg) all aqueous must pass through non conventional routes.

Unveosleral (non-conventional) outflow: approximately 10% of aqueous tumor leaves through the cilary body face and its route. This alternative pathway is called by a number of terms including uveoscleral, non conventional, extracanalicular, secondary and uveovertex outflow. Aqueous humor enters the ciliary muscle through the uveal trabecular meshowork, ciliary body face and iris route into the suprachoroidal space. This uvesocleral outflow is pressure independent. The main rsistance to uveosceral flow is the tone of the ciliary muscle. Factors that contract ciliary muscle, such cholinergic agents e.g. (pilocarpine) lowers uveoscleral outflow, where as factors that relax ciliary muscle, such as atropine raises the uveoscleral outflow.

Basics of primary open angle glaucoma

Glaucoma is defined as optic neuropathy characterized by optic disc cup changes with progressive loss of visual field with or without increased intraocular pressure.

Basic science and pathogenesis

Glaucoma preferentially damages axons at the vertical poles of the optic disc and is influenced to a variable extent by the level of IOP. Although the actual death

of retinal ganglion cells occurs by apoptosis, the vents leading upto this event are poorly understood.

Conventionally underlying mechanisms have been grouped into those that cause axon damages through direct mechanical effects within the lamina cribrosa and those mediated by ischemia. These factors act synergistically.

Mechanical theory

The mechanical theory was proposed by Von Graefe. This theory hypothesizes that, as the plates of the lamina rotates posteriorly with elevated IOP and the pores are increasingly misaligned, axon bundles passing through these pores are damaged, either directly through compression or indirectly through disruption of axoplasmic transport. Retrograde axoplasmic transport is essential for the delivery of many substances. Including neurotrophic factors, to the retinal ganglion cell body necessary for its survival. Interruption of this process could trigger pathways that lead to ganglion cell death.

Vascular theory

This theory was given by Von Jager. The optic nerve head blood flow is dependent or resistance to blood flow, blood pressure, intraocular pressure and viscosity of blood.

Ocular blood flow = Perfusion pressure / Resistance to flow

Perfusion pressure = Mean arterial BP- IOP

Mean arterial BP p= Diastolic BP + 1/3 (Systolic BP-Diastolic BP)

So decrease BP or increase resistance to blood flow or increase in IOP due to any underlying cause results in decrease in blood flow to the axons resulting in ischemia of axons, which in turn result in deceased metabolic activity and accumulation of extracellular exotoxins such as glutamate. Ischemia also results in deprivation of neurotrophins and retinal ganglion cell death due to disruption of axonal transport.

Excitotoxicity theory

Glutamate an amino acid is an excitatory neurotransmitter in CNS and retina. At low levels it acts as a neurotransmitter and at high levels, it is neurotoxic. High level of glutamate may occur due to neurotrophin deprivation, neuronal vascular compromise, and/or improper Muller cell metabolism secondary to elevated IOP. Glutamate acts on glutamate receptors (N-methyI-D-asparatete) in the neurons, which opens sodium channels, which increases the intra cellular calcium levels to toxic levels by opening calcium channels in cell membrane. This activates the enzyme nitric oxide synthatase, which leads increase in nitric oxide and to the formation of destructive free radicals. This results in retinal ganglion cell death.

ANATOMICAL ASPECTS

The limbus and the filtration angle are two structures of the eye which are of importance in the consideration of physiological and pathological mechanisms of gluacoma. [15]

External Layers [16]

Overlying the sclera are two distinct tissue layers, the conjunctiva and tenon's capsule. There are two potential spaces, subtenon's and subconjunctival. The conjunctiva, a mucous membrane, is lined with non-keratinized stratified squamous

epithelium with a delicate underlying substantia propria. The next enveloping coat is the relatively avascular , fibroelastic tenon's capsule. The sclera in composed of three layers: the episclera ; a fine superficial, vascular connective tissue; the stroma, an avasular dense array of randomly oriented collagen lamellae and the lamina fusca, a thin layer bordering the uvea.

LIMBUS

It is the transition zone between conjunctiva and sclera on one side and the cornea on the other. It is a bluish grey translucent area with a well defined corneal edge and merging inconspicuously into the sclera. The transparent corneal tissue behind a line which joins the ends of the Bowman and Descemet's membrane is 1 mm shorter than Descemet's membrane. This overlap is the greatest along the superior margin and the least at the sides, giving an elliptical appearance to the cornea. Thus the limbus is broadest superiorly being about 1.2 to 1.5mm vide whereas 0.8 mm inferiorly and 0.4 mm to the to the sides.

The external landmarks to the surgical limbus are;

a. Anterior limbal border / corneo-limbal junction.

b. Posterior limbal border / sclero-limbal junction.

c. Mid limbal zone, in between.

a. Corneo-limbal junction

Conjunctiva is a fibrous membrane surfaced with epithelium which is loosely attached to the sclera by a tenous subconjunctival connective tissue, the insertion of the conjunctiva on to the cornea corresponds to the termination of the Bowman's membrane. Only the epithelium extends forwards on to the surface the cornea forming corneo-limbal junction.

b. Sclero-limbal junction

It corresponds to the scleral spur internally and is best appreciated by the scleral scatter method of illumination during slit lamp biomicroscopic examination.

c. Midlimbal zone.

Widest superiorly and is most commonly used as an incisional site to enter the anterior chamber. The line is formed by the intersection of the blue zone with the white tissue posteriorly corresponding to the Schwalbe's line internally i.e., the termination of the Descemet's membrane.

GONIOSCOPIC APPEARANCE OF THE NORMAL FILTERATION ANGLE:

For viewing the angle of anterior chamber, sincere efforts were made by numerous ophthalmologists. Koeppe, Tronsco. Barkan made their contribution to gonioscopy by developing various gonioscopes. Goldman in 1938 made a great improvement in the technique of gonioscopy by introducing his three-mirror contact lens.[17,18] Flowing anatomical structures are visible in a normal filtration angle as viewed through a Goldman Gonioscopic mirror.

- Root of the Iris
- Ciliary body band
- Scleral spur
- Trabecular meshwork
- Schwalbe's line

Grading of Angle Structures

The grading of angel width is an essential part of the assessment of the glaucomatous or potentially glaucomatous eyes. Its main aim is to evaluate the functional status of the angle, its degree of the closure and the risk of future closure.[19] Presently Shaffer's, Schie's and the clinically relevant spaeths are in use.

Shaffer's Grading System.

In the Shaffer grading system, an estimation of the angle width is achieved by observing the amount of separation between two imaginary tangential lines, constructed to the inner surface of the trabeculum and the anterior iris surface, respectively. This grading system also provides a method of comparing the widths of different anterior chamber angles. The system assigns a numerical grade (0 to 4) to each with associated anatomical description, the angle width in degrees and implied clinical interpretation. [20]

1. Grade 4(35^o to 45^o) is the widest angle, characteristic of myopia and in aphakia, in which the ciliary body can be visualized with ease. It is incapable of closure.
2. Grade 3(20^o-35^o) is an open angle in which at least the scleral spur can be identified. It is incapable of closure.
3. Grade 2(20^o) is a moderately narrow angle in which only the trabeculum can be identified. Angle closure is possible but unlikely.
4. Grade 1(10^o) is a very narrow angle in which only Schwalbe's line, and perhaps also the top of the trabeculum, can be identified. Angle closure is not inevitable, although the risk is high.

5. A Slit Angle is one in which there is obvious iridocorneal contact but no angle structures can be identified. This angle has the highest danger of imminent closure.

6. Grade $0(0^o)$ is a closed angle resulting from iridocorneal contact; it is recognized by the inability to identity the apex of the corneal wedge.

MICROSCOPIC STRUCTURE OF THE TRABECULAR MESHWORK

On meridional section, the trabecular meshwork is triangular. The apex is attached to the posterior layers of the cornea and the Schwalbe's ring. The inner side of the triangle lies in the anterior chamber. The outer side is in contact anteriorly with the sclera and further back, it is in relation to Schlemm's canal. The trabecular meshwork has 2 parts: non-filtering and filtering.

a) Non-filtering part: This lies just posterior to the Shwalbe's line and consists of three to five trabecular beams covered by small trabecular cells that often form elongated bands of rows.

b) Filtering part: This is divided into three parts.

a. Uveal meshwork :- The portion adjacent to the aqueos in the anterior chamber is arranged in bands a rope like trabecular that extend from the iris root and ciliary body tot he peripheral cornea in a lattice like pattern.

b. Corneoscleral meshwork:- This portion extends from the scleral spur to the anterior wall of the scleral sulcus and consists of flattened sheets of trabeculae that are perforated by elliptical openings. These holes become progressively smaller as the trabecular sheets approach Schemm's canal with a diameter range of 5 to 50 microns. The spaces of fontana are spaces in between like holes in the sponge which communicate with the anterior chamber on inner

side and lie near the canal of Schlemm on the outer side. According to Salzmann, each trabecular beam consists of four layers namely-

i. Endothelial lining

ii. Hyaline layer

iii. Elastic tissue

iv. Collagenous tissue

The elastic and collagenous tissue form the inner core which makes up for more than 1/3rd the thickness.

c. Juxtacanalicular meshwork:- The outermost portion of the meshwork (adjacent to Schlemm's canal) consists of a layer of connective tissue lined on either side by endothelium. The outer endothelial layer comprises the inner wall of Schelmm's canal while the inner layer is continuous with the remainder of the trabecular endothelium. Pinocytic vesicles are seen on either endothelial surfaces. Holmsberg believed them to the be intra-endothelial channels connecting the trabecular spaces to Schlemm's canal. The ultimate pore size in fixed tissue was found measure 0.5 to 1.5 microns.

Basic trabecular structure

Each trabecular beam has a -

a. Covering of trabecular cells

b. Subcellular cortex (earlier called as glass membrane) and

c. An inner collagenous core.

The trabecular cells are about 120 μm long cells arranged in the long axis of the trabecular sheet.

Functions

1. Produces glycosaminoglycans, extracellular glycoproteins and fibrillar material.
2. Phagocytosis – Helps in keeping the trabecular filter clean.
3. Contains cytoskeletal filamentous proteins which may pay a role in altering the meshwork configuration.
4. Provides a lining for the inter and intratrabecular spaces.

Three types of cells are seen, namely

a. Trabecular cells- predominantly involved in phagocytosis, fibrillogenesis and tissue repair.
b. Cribriform cells- responsible for the production of the extracellular substances and fibrillar structures of the cribriform layer and their outflow channels.
c. Endothelial lining of Schlemm's canal- capable of developing pores, vacuoles and transcellular minor channels through which aqueous fluid, parties and even RBCs can pass.

The core is formed by collagen types I, II and IV, fibronectin, thrombospondin, chondroitin sulphate, dermatan sulphate and "curly' collagen which play an important role in outflow resistance.

Connection of TM with ciliary muscle system.

The overall form of ciliary body consists of flat bundles of non-striated fibres, the most external being longitudinal or meridional, the intermediate radial or oblique and the most internal circular or sphincteric.

The outer longitudinal muscle bundles end posteriorly in the supraciliary lamina and suprachorodiea in so called epichoroidal muscle stars while anteriorly they taper off forming 3 types of tendons namely;

a. **Type A** tendons which affix the outermost fibre bundles to the scleral spur/sclera.

b. **Type B** tendons which pass through the entire TM without a major connection with the trabecular lamellae, they are anchored within the posterior corneal stromal layers.

c. **Type C** tendons form brush like terminations of elastic like fibres that bend into the fibre system of the outermost corneoscleral meshwork and cribriform layer, thereby changing their course by about 90 deg. A "cribriform plexus' is formed by the delicate network of elastic like fibres of cribriform layer to which the type C tendons form inter digitating connections and hence modify the diameter of cribriform layer and hencer regul at the outflow resistance. Thus contraction of the longitudinal ciliary muscle would open up the anterior portion of the trabecular meshwork mainly and increase aqueous outflow.

SCHLEMM'S CANAL

This is a cirular channel which indents the deeper / inner surface of the sclera at the sclerolimbal junction. It may be oval / triangular with the apex towards Descemet's membrane and the scleral spur forming the posterior boundary. It occupies half the distance between the scleral spur and the Schwalbe's line being about 0.5 mm in length on cross section. It has a diameter of 190 to 370 microns. In contains aqueous and blood in varying proportions, but normally almost entirely aqueous. It is lined by endothelial cells whose nuclei project towards the lumen. Villi

like projections may be seen on the inner wall. The vacuolar configuration of the endothelium provides a mechanism for direct communication between the extracellular spaces of the trabecular zone and canal of Schlemm and are probably the major route for entry of aqueous into the canal.

Intrascleral aqueous vessels, the aqueous veins of Ascher have been defined as originating from the outer wall of Schlemm's canal and terminating in episcleral and conjunctival veins in a lamination of aqueous and blood referred to as the laminated vein of Goldmann. The episcleral veins drain into the cavernous veins drain into superior ophthalmic of facial via the palpebral and angular veins.

The milestone in the history or glaucoma surgery was laid down by Mackenzie who performed scleral puncture. Von Graefe was first to advocate iridectomy as surgical procedure of glaucoma. Heine introduced cyclodialysis. Holths was the pioneer of iridenclesis. Langrange designed the first filteration operation of sclereto iridectomy. [21,22] Elliot proposed corneoscleral trephining which consists of making a large limal based conjunctival flap and cutting a small trephine hole in the corneoscleral margin Barkan practiced goniotomy as procedure of choice in buphthalmos.[23] Scheie introduced iridectomy with scleral cautery in 1958 Chandler described the basic technique of doing peripheral iridectomy incases of glaucoma.[24] But there are complications due to this technique such as hemorrhage, injury to lens, incomplete iridectomy, cataract formation and endophthalmitis.[25,26]

However, in the standard full thickness filtering procedures filtering blebs often become very thin an may rupture creating the danger of endophthalmitis. These procedures also may be complicated by excessive aqueous filtration, which can lead to a prolonged flat anterior chamber, associated with corneal decompensation, synechiae formation, and cataract formation. Various implant (seton) proedures have

also been attempted to maintain patency of the drainage fistula but have been uniformly unsuccessful over the years.[27]

In an attempt to minimize the complications of full thickness filtering procedures, partial thickness filtering operation was introduced. The concept of partial thickness scleral flap surgery first suggested by Sugar as an 'Experimental trabeculectomy in 1961.[28]

Trabeculectomy was popularized by Cairns in his report in 1968. By reflecting a Corneoscleral flap and excision of short length of canal of Schlemm's with its trabecular adenexae. [9,29]

The bleb classification is desribed is as follows.[30]

- Good filtration characterized by low IOP and a bleb which is thin polycystic that is type 1.
- Good filtration characterized by low IOP and bleb which is thin walled and shallow diffuse that is type 2.
- Poor filtration with increasing IOP and bleb which is flat due to episcleral fibrosis that is type 3.
- Poor filtration with increasing IOP which is encapsulated bleb i.e., type 4.

Vernon S.A et.al described small flap trabeculectomy (microtrabeculectomy) a much scaled down modificationof the “full size” procedure, with the intention being to perform a filtering operation that is less disruptive to ocular tissues.

In this study small flap trabeculectomy procedure was performed on 36 eyes from 36 patients with a minimum follow up of 24 months (mean 50.8).

The Results are as follows—The mean (SD) intraocular pressures at presentation and preoperatively were 33.7 (7.5) and 24.6 (4.5) mm Hg respectively.

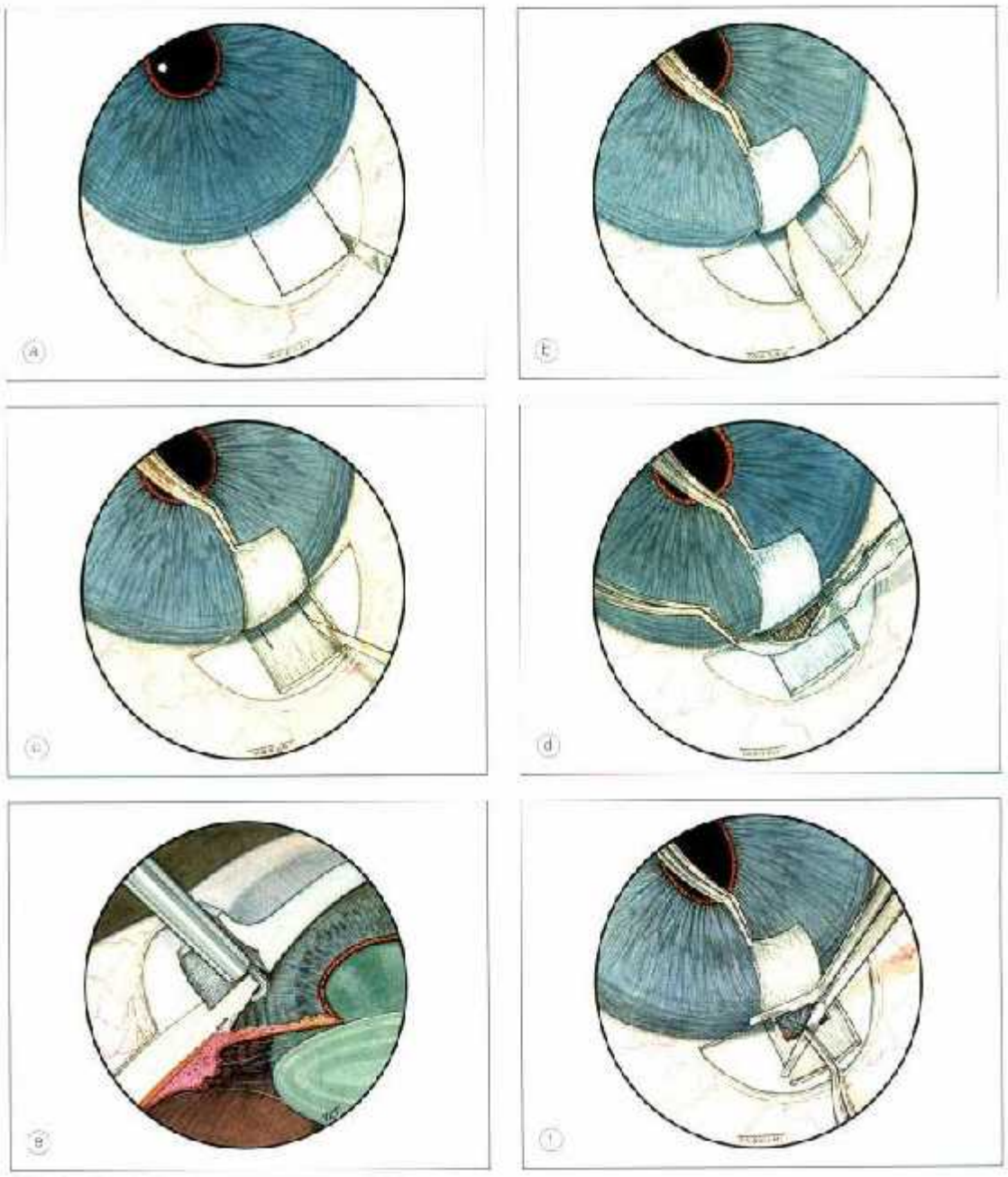
At 6 months, 1, 2, 3, 4, 5, and 6 years the mean (n, SD) IOPs (mm Hg) of those eyes followed to each time point were 11.9(36, 4.6), 12.6 (36, 4.7), 13.2 (36, 4.6), 13.7 (29, 4.1), 13.2 (22, 4.0), 12.7 (15, 4.8), and 12.3 (8, 4.7) respectively. [9]

The conclusion was that the small flap trabeculectomy (microtrabeculectomy) is effective at reducing IOP in low risk glaucoma eyes with IOP control similar to previous reports of filtering surgery utilising larger sclera trapdoors. [9]

The procedure is as follows:

A limbus based conjunctival flap is fashioned commencing 4 mm from and exposing the limbus. A 2 mm×2 mm scleral trap door is constructed and an anteriorly sited 0.75 mm diameter internal sclerostomy is achieved with a Kelly punch (Storz). A small basal peripheral iridectomy is followed by two 10/0 nylon scleral trapdoor sutures and a running 10/0 gauge suture of choice to the conjunctiva. [9]

TRABECULECTOMY (CT) AND MICROTRABECULECTOMY (SFT)



a) Outline of superficial scleral flap (2 x 2mm in SFT & 5 x 5mm in CT)

b) Dissection of superficial scleral flap (2 x 2mm in SFT & 5 x 5mm in CT)

c) Incision of deep sclerotomy flap

d) Excision of deep scleral flap with Vannas Scissors (in CT)

e) Excision of deep scleral Tissue with Kelly's Descemet's membrane punch (in SFT)

f) Peripheral iridectomy

METHODOLOGY

The present study was conducted on sixteen patients of POAG , half of the patients underwent small flap trabeculectomy (microtrabeculectomy) and on the other half procedure of conventional trabeculectomy was performed during the study period of one year from January 2009 to December 2009 at KLE Dr.Prabhakar Kore Hospital and M.R.C Belgaum.

Study design

One year randomized clinical trial.

Study period

The present study was conducted during January 2009 to December 2009.

Source of Data

Patients undergoing small flap trabeculectomy (microtrabeculectomy) and conventional trabeculectomy at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

Sample size

A sample size of 16 cases (08 in each group).

Sampling procedure

A sample size of 16 cases was calculated considering Using the formula;

$$n = \frac{2 \times (Z_{\alpha} + Z_{\beta})^2 \quad pq}{(P_1 - P_2)^2}$$

Selection criteria

Inclusion Criteria

1. The patients undergoing Glaucoma filtering Surgery at KLES Dr.Prabhakar Kore Hospital and M R C, Belgaum.
2. Age between 40 yrs to 80 yrs.
3. Increase in IOP above the level known to cause optic nerve damage.
4. Patients willing to give consent.

Exclusion Criteria

1. Age below 40 yrs or above 80 yrs.
2. Secondary glaucoma cases.
3. Congenital glaucomas, Angle closure glaucomas.
4. Patients not willing to give consent.

Procedure

The study is conducted in Department of Ophthalmology at KLE Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during one year duration. Patients with POAG were enrolled. The study was approved by the Ethical and Research Committee of Jawaharlal Nehru Medical College, Belgaum.

After finding the suitability as per inclusion and exclusion criteria patients were selected for the study and briefed about the nature of the study, the interventions used and written informed consent was obtained (Annexure–I). Further, descriptive data of the participants like name, age, sex, detailed history, were obtained by interviewing the participants and clinical examination and necessary investigations

were recorded on predesigned and pretested proforma (Annexure-II). The patients were assigned randomly into two groups according to the type of procedure by computer generated table of two.

- Group I-Patients undergoing small flap trabeculectomy (microtrabeculectomy).
- Group II - Patients undergoing conventional trabeculectomy.

Preoperatively all the below mentioned investigations were done. All patients were operated using peribulbar anaesthesia. The postoperative IOP was evaluated on 1st week, 6th week and 3rd month.

Preoperative evaluation

History

Detailed history was recorded in all the cases in both the groups. Headache or eye ache, diminution of vision, coloured halos , any family history of glaucoma was recorded. Any history of drug intake was also taken. Past history in relation to any previous ocular medication or treatment was noted.

Local examination

Detailed local examination of the eyes was carried out starting with:

- Determination of visual acuity was done by Snellen's chart and near vision chart.
- External ocular examination was done.
- Detailed anterior segment examination with slit lamp biomicroscopy was done which included papillary reaction in both the eyes and depth of

peripheral anterior chamber by comparing it with peripheral corneal thickness.

Gonioscopy

In all patients gonioscopy was performed by using Goldman three mirror lens and grading of angle width was done according to the Shaffer's grading.

IOP measurement

Intra ocular pressure measurement was done with Goldman's applanation tonometer.

Visual field

Central 30˚ visual field was done with Bjerrum target screen.

Constriction of field was graded according to Kanski's classification.

+1	Early visual field defect
+2	Arcuate scotoma
+3	Severe damage with extensive visual field loss to small residual field

Fundus examination

For dilatation of pupil a combination of 10% phenylephrine and tropicamide 0.8% drops were instilled once in 15 minutes for three times.

This was followed by optic nerve head evaluation by direct ophthalmoscopy and 90 D lens on slit lamp in particular reference to vertical and horizontal cup : disc ratio, neuroretinal rim, any optic disc hemorrhage, blood vessels and macula.

Laboratory investigation

- Haemoglobin
- B.T , C.T
- Urine examination for albumin and sugar

All cases were put on oral acetazolamide 250 mg b.d on the day prior to surgery along with pilocarpine nitrate 2 % eye drops 4 times a day in the eye to be operated and all cases received 1.5 gm / kg body weight of 20% mannitol intravenous1-2 hours prior to surgery.

Surgical procedure

All the surgeries of group I and group II were performed at KLE Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum

Group I: Small flap trabeculectomy (microtrabeculectomy)

All cases were done under local peribulbar anesthesia. Under all aseptic precautions the eye to be operated was painted with 5% povidone iodine and spirit and was draped.

- A wire speculum was placed and a superior rectus bridle suture was placed and secured.
- A limbal based conjunctival flap 4mm from limbus at superior quadrant was made.
- A square shaped lamellar scleral flap of 2x2 mm (1/2 to 1/3rd thickness of sclera) hinged at limbus was made and dissected until at least 1mm of bluish grey zone was exposed.
- Anterior chamber was entered at the anterior end with vannas scissors.

- Kelly's Descemets membrane punch was used to remove 1.0. x 1.0 mm of trabecular meshwork.
- Tip of scleral flap was approximated with single 10-0 monofilament suture, after performing peripheral iridectomy.
- Conjunctival flap was water tight sutured with 10-0 monofilament (continuous sutures).

Group II: Conventional trabeculectomy

Initial steps are similar to Group I till placement of superior rectus bridle suture.

- A limbal based conjunctivo-tenon flap at 12 O'clock position at least 8-10mm from the limbus was made.
- A partial thickness, limbal based, lamellar, square shape scleral flap of 5x5 mm (1/2 to 1/3 thickness of sclera) was made.
- The flap was extended well past the limbus into the clear cornea, until 1mm of bluish grey zone was exposed.
- A 1 x 4mm block of tissue anterior to scleral spur was excised manually.
- A broad based, peripheral iridectomy was performed .
- The scleral flap was reapproximated to the scleral bed with three to five monofilament sutures.
- Conjunctival flap closure was done meticulously with 10-0 monofilament continuous water tight sutures.

Post operative course

In all patients Antibiotic steroid eye drops were administered six times per day and gradually tapered over six weeks.

A detailed postoperative examination of the patients was done on 1st day, first week, sixth week and three months. Patients were evaluated on 1st postoperative day as follows:

- Conjunctival inflammation
- Condition of the bleb
- Corneal haze
- Anterior chamber formation
- Hyphema

In subsequent follow ups IOP (Goldman's applanation tonometer) recording along with the above mentioned criterias were thoroughly evaluated.

Criteria used in the study

No standard definition exists for the success of glaucoma surgery with regard to IOP; because no single target pressure can be regarded as a safe limit for disease control in all individual eyes. [31] In our study we used the limit of 21 mm of Hg because it makes this study comparable with the other study on the similar problem. [9]

Definition of outcome

A complete success was defined as an IOP less than 21 mm of Hg without medication and an qualified success required antiglaucoma medication to achieve this pressure. A qualified failure was defined as an IOP greater than 21 mm of Hg on maximum medication and a complete failure where further glaucoma surgery was done or recommended, if there was hypotony with overt maculopathy or loss of light perception. [32-33]

Statistical analysis

Unpaired 't' test was used to compare mean IOP attained by the two groups at each follow up.

RESULTS

TABLE NO.1: AGE DISTRIBUTION AMONG PATIENTS IN GROUP I & II

Age in years	No. of cases		Percentage	
	Group I	Group II	Group I	Group II
40-50	03	01	37.5%	12.5%
51-60	00	02	00%	25.0%
61-70	04	05	50%	62.5%
71-80	01	00	12.5%	00%
Total	08	08	100%	100%

In this study the age range of the patients was 45 to 74 years in group I with a mean age of 59.75±11.34 years. In group II the age range of the patients was 50 to70 years with a mean age of 62.62±7.30 years.

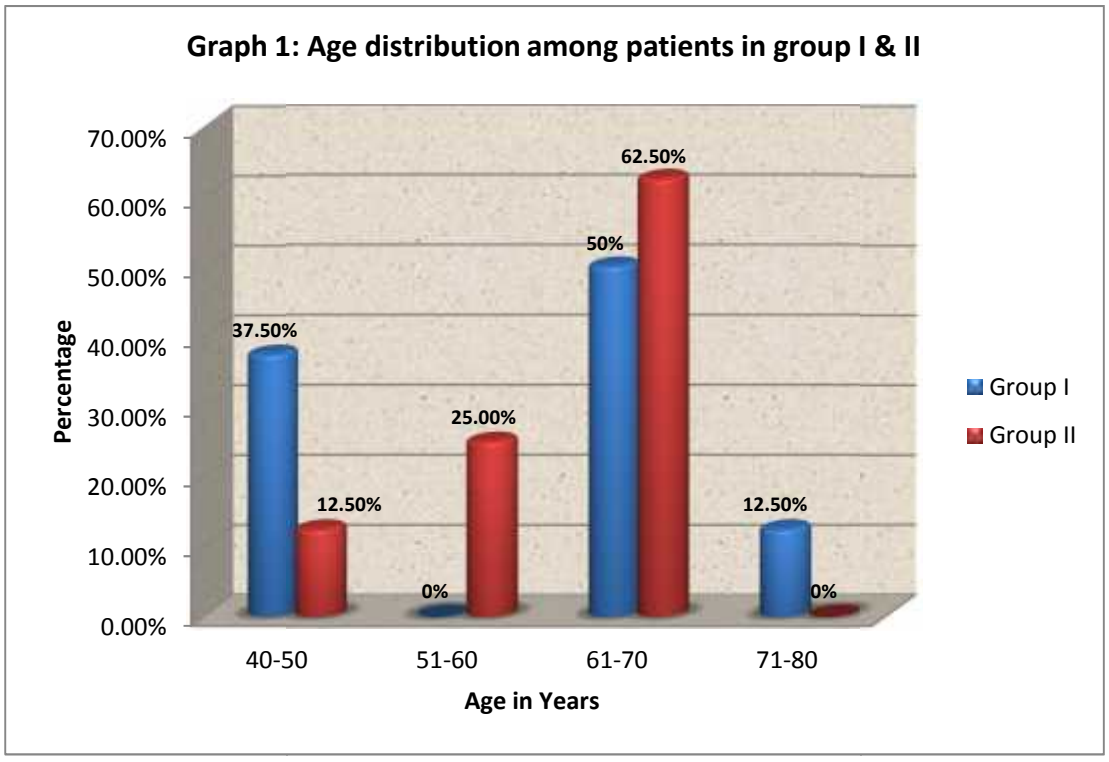


TABLE NO.2: GENDER DISTRIBUTION AMONG PATIENTS IN GROUP I & II

Gender	No. of cases		Percentage	
	Group I	Group II	Group I	Group II
Male	05	06	62.5%	75.0%
Female	03	02	37.5%	25.0%
Total	08	08	100%	100%

In this study the female to male ratio was 3:5 in group I and 1:3 in group II.

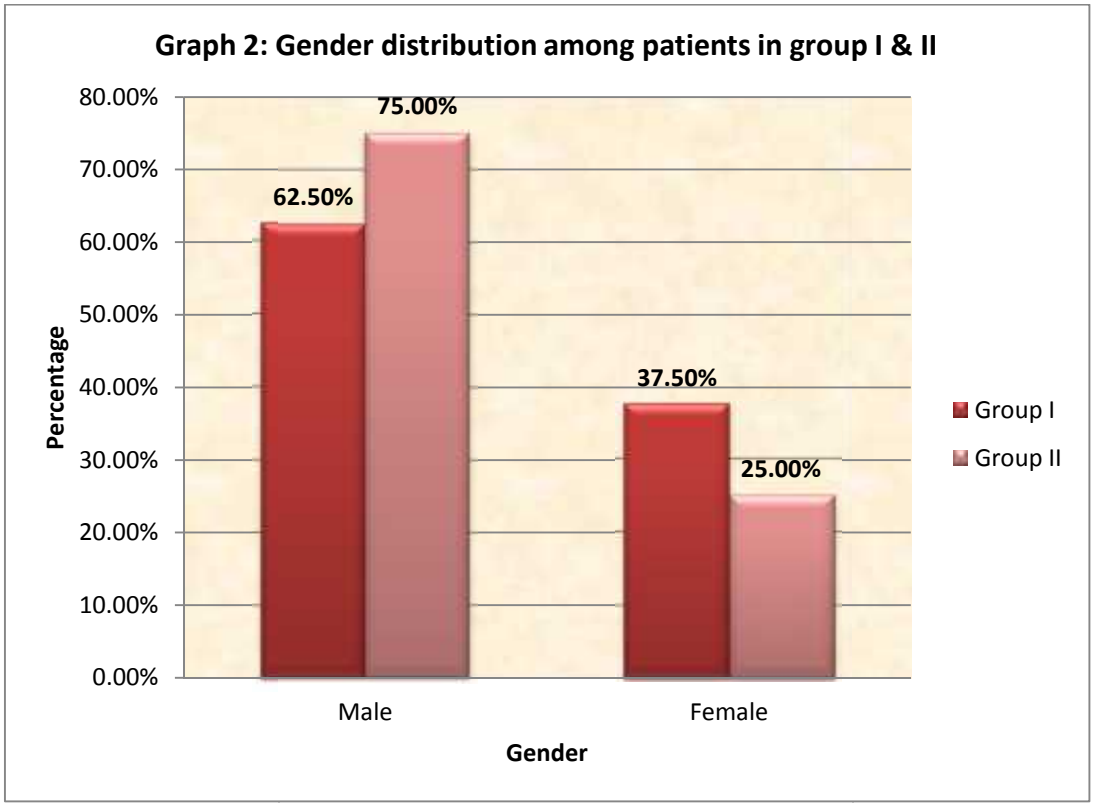


TABLE NO.3: FAMILY HISTORY OF GLAUCOMA AMONG PATIENTS IN GROUP I & II

Family history	No. of cases		Percentage	
	Group I	Group II	Group I	Group II
Present	01	00	12.5%	00%
Absent	07	08	87.5%	100%
Total	08	08	100%	100%

As shown in table 3, one patient in group- I had first degree relative with POAG.

TABLE NO.4: ANTIGLAUCOMA DRUGS AMONG PATIENTS IN GROUP I AND GROUP II

Antiglaucoma drugs	No. of cases		Percentage	
	Group I	Group II	Group I	Group II
Present	02	01	25.0%	12.5%
Absent	06	07	75.0%	87.5%
Total	08	08	100%	100%

As shown in table 4, two patients in group- I were on previous antiglaucoma medication and one patients in group- II was on previous antiglaucoma medication. In total 13 patients were newly diagnosed.

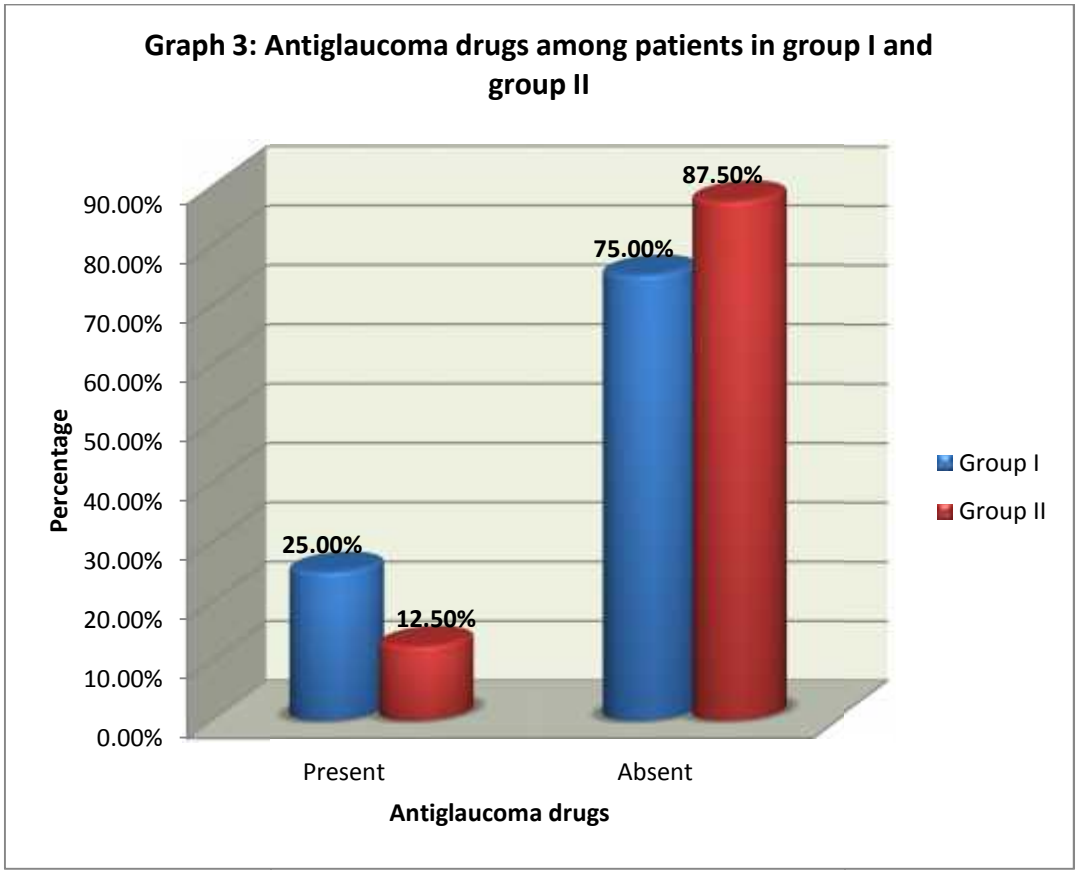


TABLE NO.5: ASSOCIATED SYSTEMIC DISEASE AMONG PATIENTS IN GROUP I AND GROUP II

Systemic disease	No. of cases		Percentage	
	Group 1	Group 2	Group 1	Group 2
Hypertension	01	01	12.5%	12.5%
Diabetes mellitus	01	01	12.5%	12.5%
Hypertension with diabetes	00	00	00%	00%
Asthma	00	00	00%	00%
No systemic disease	06	06	75.0%	75.0%
Total	08	08	100%	100%

As shown in table 5, one case (12.5%) was hypertensive in both of the groups and another one case (12.5%) of was diabetic in both of the groups.

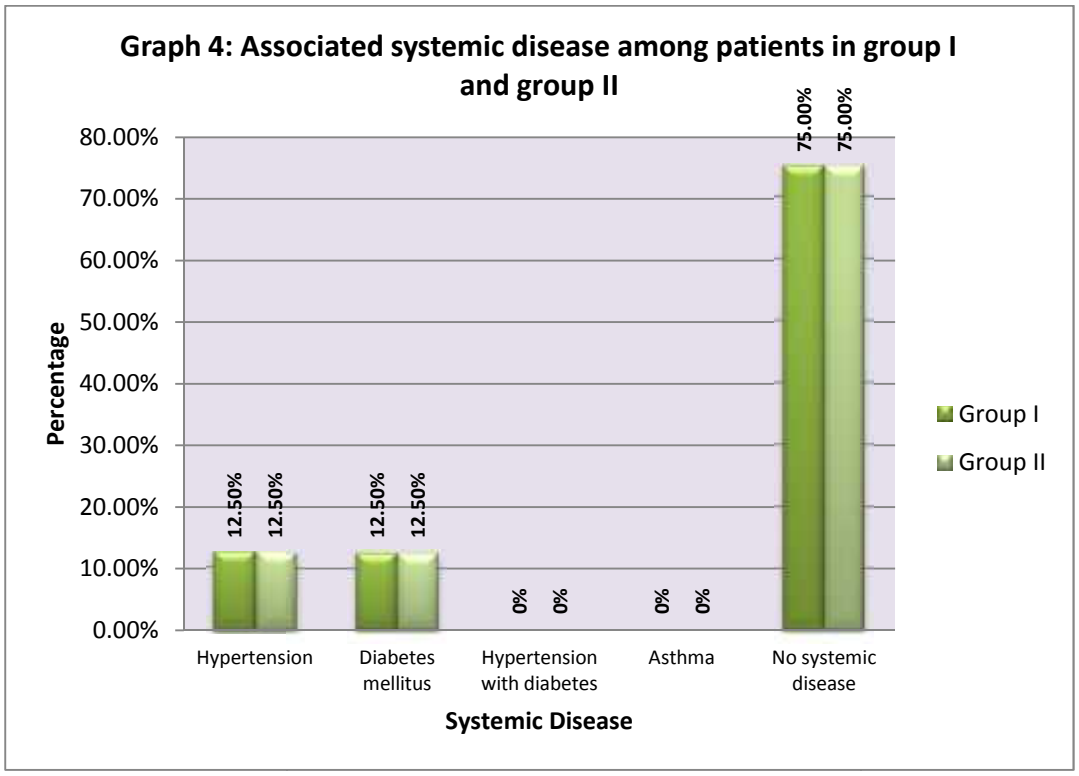


TABLE NO.6: PRE OPERATIVE BEST CORRECTED VISUAL ACUITY AMONG PATIENTS IN GROUP I AND GROUP II

BCVA	No. of cases		Percentage	
	Group 1	Group 2	Group 1	Group 2
≤6/60	01	02	12.5%	25.0%
6/60 – 6/24	04	02	50.0%	25.0%
6/24 – 6/18	00	03	00%	37.5%
6/18 – 6/6	03	01	37.5%	12.5%
Total	08	08	100%	100%

As shown in table 6 , the BCVA of one patients in Group –I and two patients in Group – II was ≤6/60 on Snellen's chart. All the remaining patients in both the groups had BCVA of ≥6/60.

TABLE NO.7: PRE-OPERATIVE CUP DISC RATIO IN GROUP I AND GROUP II

C:D Ratio	No. of cases		Percentage	
	Group 1	Group 2	Group 1	Group 2
≤0.5	00	00	00	00
0.6	00	00	00	00
0.7	04	01	50%	12.5%
0.8	01	05	12.5%	62.5%
0.9	03	02	37.5%	25.0%
Total	08	08	100%	100%

As shown in table 7, in group-I 50% cases had 0.7 cupping, in group-II 12.5% had 0.7 cupping

0.8 cupping in 12.5% in group-I and 62.5% in group-II.

0.9 cupping in 37.5% in group-I and 25.0% in group-II.

Note: One patient in each group had parapapillary atrophy with α and β zones.

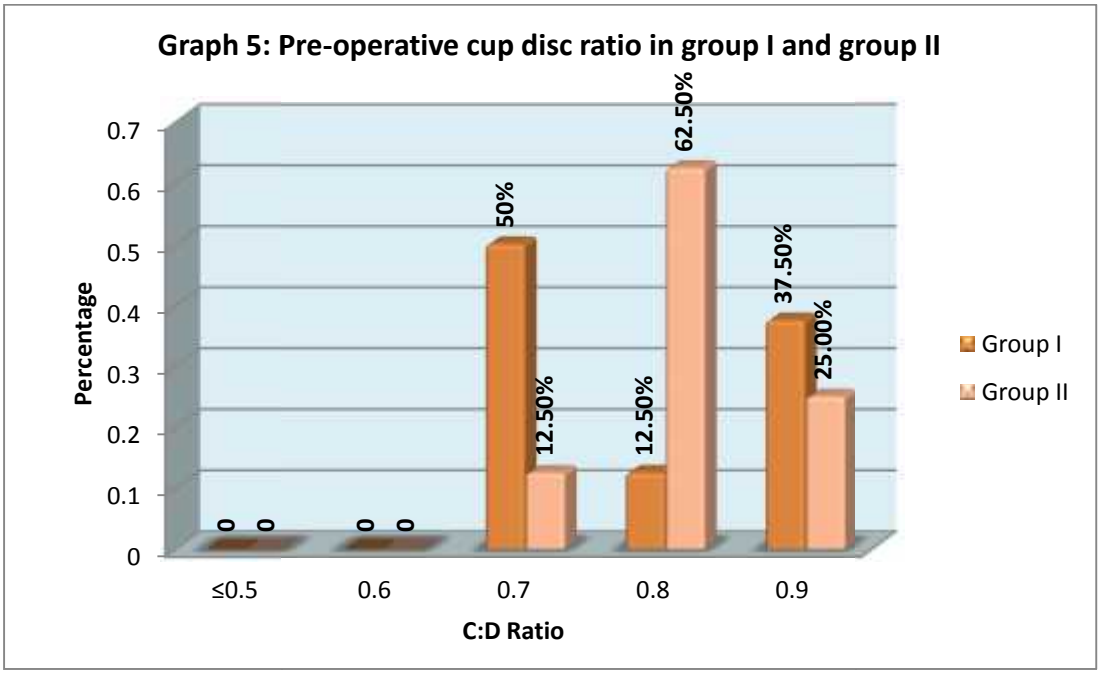


TABLE NO.8: PRE-OPERATIVE VISUAL FIELDS DEFECTS IN GROUP I AND GROUP II

Visual field defects	No. of cases		Percentage	
	Group 1	Group 2	Group 1	Group 2
Grade 1	00	00	00	00
Grade 2	03	03	37.5%	37.5%
Grade 3	04	05	50.0%	62.5%
Not recordable	01	00	12.5%	00%
Total	08	08	100%	100%

As shown in table 8, grade 2 field defect in 37.5% in both the groups. Grade 3 field defect in 50% cases in group-I and in group-II 62.5% cases.

In one patient of group-I fields were not interpreted due to low vision.

TABLE NO.9(A): COMPLICATIONS DURING INTRA OPERATIVE, EARLY POST OPERATIVE AND LATE IN GROUP I

Complications		Pr/Ab	No. of Cases
Intra operative	Button holing	-	00
	Sub conjunctival bleed	+	01
	Choroidal effusion	-	00
	Vitreous loss	-	00
	Stripping of descemets	-	00
Early post operative	Serous choroidal detachment	-	00
	Supra choroidal haemorrhage	-	00
	Uveitis	-	00
	Loss of central vision	-	00
	Decompression retinopathy	-	00
	Hyphaema	+	01
Late	Failure of filtration	-	00
	Leaking filtering Bleb	-	00
	Cataract progression	-	00
	Blebitis	-	00

As shown in table 9(a) one patient had intra operative sub conjunctival bleed and hyphema in early post operative period.

TABLE NO.9(B): COMPLICATIONS DURING INTRA OPERATIVE, EARLY POST OPERATIVE AND LATE IN GROUP II

Complications		Pr/Ab	No. of Cases
Intra operative	Button holing	-	00
	Sub conjunctival bleed	+	02
	Choroidal effusion	-	00
	Vitreous loss	-	00
	Stripping of descemets	-	00
Early post operative	Serous choroidal detachment	-	00
	Supra choroidal haemorrhage	-	00
	Uveitis	-	00
	Loss of central vision	-	00
	Decompression retinopathy	-	00
	Hyphaema	+	02
Late	Failure of filtration	-	00
	Leaking filtering Bleb	-	00
	Cataract progression	-	00
	Blebitis	-	00

As shown in table 9(b) two patients had intra operative sub conjunctival bleed and hyphema in early post operative period.

TABLE NO.10(A): IOP PROFILE IN PREOPERATIVE AND POST OPERATIVE PERIOD IN GROUP I

IOP mm Hg	No. of cases at each post operative period			
	Pre Op	Post Op 1st week	Post Op 6th week	Post Op 3rd month
0 – 10	00	03	02	01
11 – 20	00	05	06	07
21 – 30	04	00	00	00
31 – 40	03	00	00	00
≥ 41	01	00	00	00
Total	08	08	08	08

As shown in table10(a) preoperative IOP was with a maximum number of patients in the range of 21-30 mm of Hg. The post operative IOP at 3rd month follow up with a maximum number of patients in the range of 11-20 mm of Hg.

TABLE NO. 10(B) PERCENTAGE REDUCTION OF IOP IN PREOPERATIVE AND POST OPERATIVE PERIOD IN GROUP-I

Period	Mean IOP mmHg	p value	Mean percentage reduction
	Group I		
Pre operative	30.75±6.04		
Post operative 1st week	12.62±2.72	<0.0001	57.4±12.21
Post operative 6th week	13.5±2.97	<0.0001	54.4±13.47
Post operative 3rd month	13.87±2.80	<0.0001	53.2±12.61

As shown in table 10(b) there was a statistically significant difference noted in the group-I for post operative mean IOP levels percentage reduction.($p<0.0001$) in all the follow up periods.

TABLE NO.11(A): IOP PROFILE IN PREOPERATIVE AND POST OPERATIVE PERIOD IN GROUP II

IOP mm Hg	No. of cases at each post operative period			
	Pre Op	Post Op 1st week	Post Op 6th week	Post Op 3rd month
0 – 10	00	04	02	01
11 – 20	00	04	06	07
21 – 30	03	00	00	00
31 – 40	03	00	00	00
≥ 41	02	00	00	00
Total	08	08	08	08

As shown in table11(a) preoperative IOP was with a maximum number of patients in the range of 21-30 mm of Hg and 31-40 mm of Hg. The post operative IOP at 3rd month follow up with a maximum number of patients in the range of 11-20 mm of Hg.

TABLE NO.11(B)PERCENTAGE REDUCTION OF IOP IN PREOPERATIVE AND POST OPERATIVE PERIOD IN GROUP-II

Period	Mean IOP mmHg	p value	Mean percentage reduction
	Group II		
Pre operative	30.0±7.27		
Post operative 1st week	12.25±3.06	<0.0001	58.9±6.64
Post operative 6th week	13.5±3.02	<0.0001	54.4±7.97
Post operative 3rd month	14.12±2.80	<0.0001	52.2±6.95

As shown in table 11(b) there was a statistically significant difference noted in the group-II for post operative mean IOP levels percentage reduction.($p<0.0001$) in all the follow up periods.

TABLE NO. 12 : COMPARISON OF OUTCOME OF IOP AMONG GROUP I AND GROUP II

Period	Mean IOP mmHg		p value
	Group I	Group II	
Pre operative	30.75±6.04	30.0±7.27	0.826
Post operative 1st week	12.62±2.72	12.25±3.06	0.799
Post operative 6th week	13.5±2.97	13.5±3.02	1
Post operative 3rd month	13.87±2.80	14.12±2.80	0.861

As shown in table 12 there was no statistically significant difference noted when both the groups were compared for post operative mean IOP levels at different follow ups. P value for the third month post operative mean IOP levels (p = 0.861) suggests statistically insignificant.

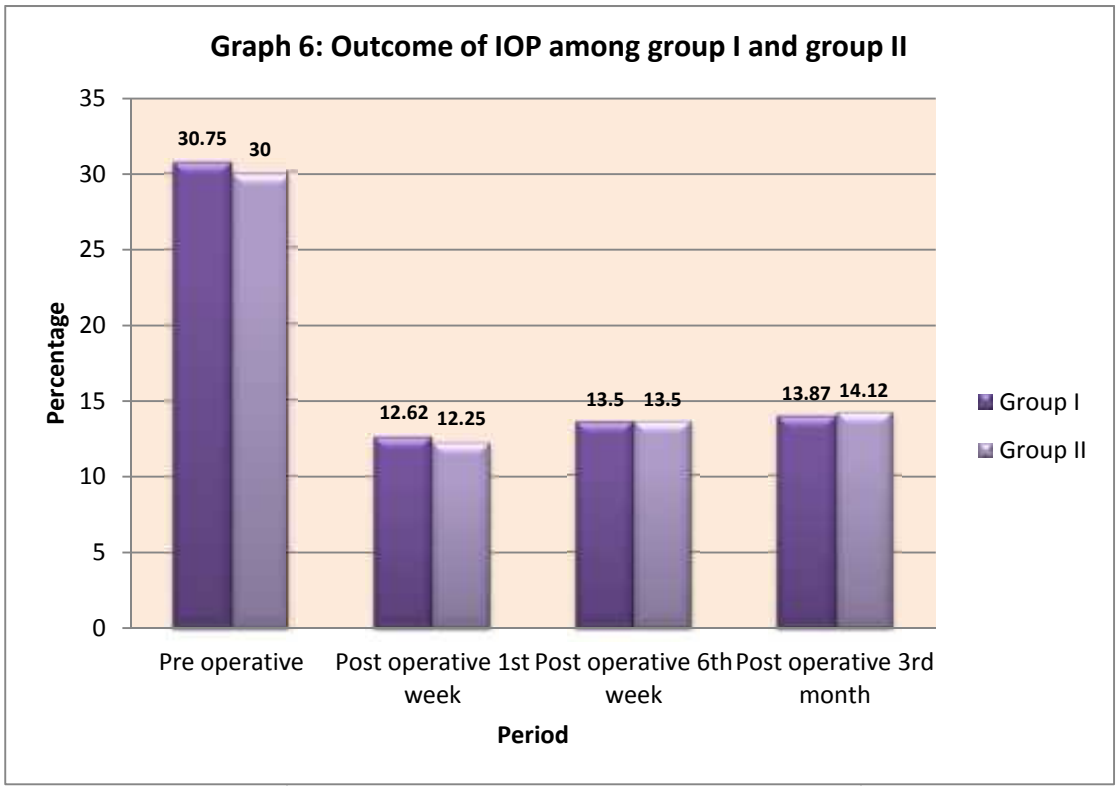


TABLE NO. 13 : PERCENTAGE REDUCTION COMPARISON OF IOP IN PREOPERATIVE AND POST OPERATIVE PERIOD GROUP I AND GROUP II

Period	Mean percentage reduction		p value
	Group I	Group II	
Post operative 1st week	57.4±12.21	58.9±6.64	0.775
Post operative 6th week	54.4±13.47	54.4±7.97	1
Post operative 3rd month	53.2±12.61	52.2±6.95	0.845

As shown in table 13 there was no statistically significant difference noted when both the groups were compared for post operative mean IOP levels percentage reduction. P value for the third month post operative mean IOP levels percentage reduction (p = 0.845) suggests statistically insignificant.

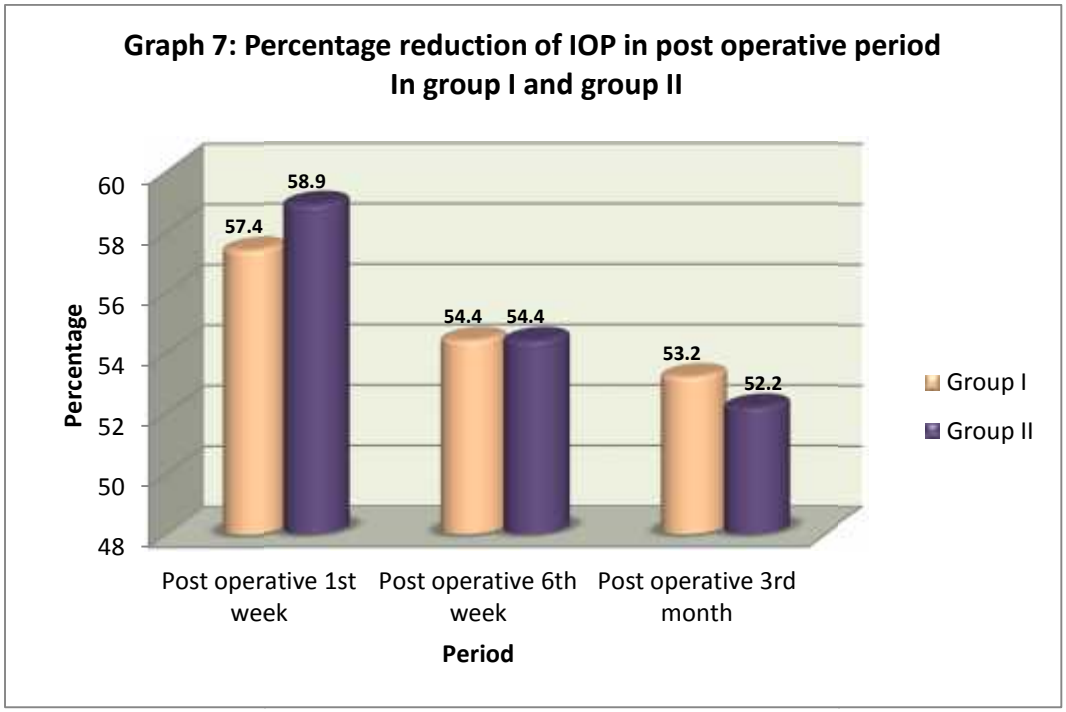


TABLE NO.14(A) : BLEB CHARACTERISTICS GROUP I

Type of Bleb	No. of cases	%
Type 1 thin polycystic filtering	00	00
Type 2 shallow diffuse filtering	08	100%
Type 3 vascularised non filtering	00	00
Type 4 encapsulated bleb	00	00
Total	08	100%

[According to Kanski classification]

As shown in table 14(a) All patients had type 2 shallow diffuse blebs.

TABLE NO.14(B) : BLEB CHARACTERISTICS GROUP II

Type of Bleb	No. of cases	%
Type 1 thin polycystic filtering	00	00
Type 2 shallow diffuse filtering	08	100%
Type 3 vascularised non filtering	00	00
Type 4 encapsulated bleb	00	00
Total	08	100%

As shown in table 14(b) All patients had type 2 shallow diffuse blebs.

TABLE NO. 15(A) : CHANGE IN BCVA ON LAST FOLLOW UP GROUP I

BCVA	No. of cases	%
Improved	00	00
Stable	08	100%
Worse	00	00
Total	08	100%

As shown in table 15(a) All patients had stable vision at the end of third month.

TABLE NO. 15(B) : CHANGE IN BCVA ON LAST FOLLOW UP GROUP II

BCVA	No. of cases	%
Improved	00	00
Stable	08	100%
Worse	00	00
Total	08	100%

As shown in table 15(b) All patients had stable vision at the end of third month.

TABLE NO. 16(A) : SUCCESS RATE GROUP I

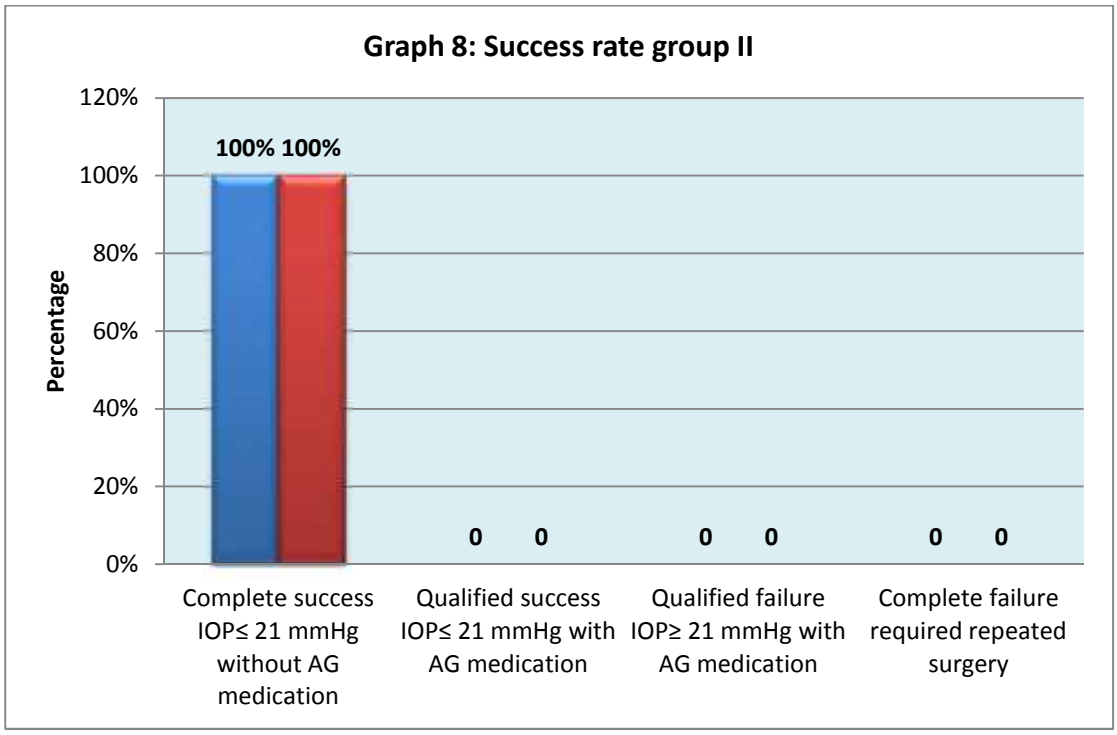
Success	No. of cases	%
Complete success IOP≤ 21 mmHg	08	100%
Qualified success IOP≤ 21 mmHg with AG medication	00	00
Qualified failure IOP≥ 21 mmHg with AG medication	00	00
Complete failure required repeated surgery	00	00
Total	08	100%

As shown in table 16(a) a 100% completed success was seen.

TABLE NO.16(B) : SUCCESS RATE GROUP II

Success	No. of cases	%
Complete success IOP≤ 21 mmHg	08	100%
Qualified success IOP≤ 21 mmHg with AG medication	00	00
Qualified failure IOP≥ 21 mmHg with AG medication	00	00
Complete failure required repeated surgery	00	00
Total	08	100%

As shown in table 16(b) a 100% completed success was seen.


Graph 8: Success rate group II
120%
100%
80%
60%
40%
20%
0%
Percentage
100% 100%
0 0
0 0
0 0
Complete success IOP≤ 21 mmHg without AG medication
Qualified success IOP≤ 21 mmHg with AG medication
Qualified failure IOP≥ 21 mmHg with AG medication
Complete failure required repeated surgery

DISCUSSION

Glaucoma is the leading cause of irreversible blindness in old and constitutes second only to cataract as the most common cause of blindness overall.

In the developing world the percentage increases in number of individuals with glaucoma which is more common in the age group of 60 years and above. Although medical treatment is used the cost and compliance to medical therapy with its side effects is a problem in developing countries. Hence an effective surgical procedure is needed which significantly curtails or slows the process of optic nerve damage and subsequent field loss.

In our study sixteen patients divided equally in two groups were enrolled with primary open angle glaucoma from our out patient and in patient department of KLE Dr.Prabhakar Kore Hospital and M.R.C Belgaum.

The one year randomized clinical trial was undertaken to evaluate the comparison of microtrabeculectomy versus conventional trabeculectomy in Primary open angle glaucoma.

a) Age distribution

Table1 depicts that majority of the patients were in the age group 61-70 years(50% patients of group-I and I group II 62.5% of patients). This shows that prevalence of POAG is more in the age > 60 years. Increasing age therefore becomes a significant risk factor which correlates with a study in which it was noted that 60 years and older population were at more risk.[34]

b) Sex distribution:

In table 2 among all the patients in both the groups together 5 were females and 11 were males. Though the number of patients considered in the study is not significant to comment on the prevalence of sex.

c) Family history:

In table 3 among all the patients in both the groups together one patient in group-I had first degree relative with POAG which is a known risk factor. In a study conducted on genetic risk in population based familial aggregation revealed study family history as significant risk factor.[35]

d) Systemic risk factors:

Table 5 depicts that in our study 12.5% of cases were hypertensive in both the groups and another 12.5% of cases were diabetic in both the groups. In studies on systemic blood pressure in POAG, revealed high blood pressure as a risk factor.[36-37]

In studies on patients with POAG with diabetes mellitus IOP was considered as a risk factor because persons with diabetes appear to have slightly higher IOP. [38-39]

e) Pre operative Best corrected visual acuity

In our study the BCVA of one patient in group-I and two patients in group-II was ≤6/60 on Snellen's chart. All the remaining patients in both the groups had BCVA of ≥ 6/60.

f) Pre operative cup disc ratio

In group-I 50% cases had 0.7 cupping, in group-II 12.5% had 0.7 cupping

0.8 cupping was seen in 12.5% in group-I and 62.5% in group-II.

0.9 cupping was seen in 37.5% in group-I and 25.0% in group-II.

There was increased vertical cup disc ratio compared to the horizontal. Increased vertical cup disc ratio is a risk factor for development of glaucomatous visual field loss. A study reported that increased cup disc ratio is a risk factor for prediction of visual field loss.[40]

One patient in each group had parapapillary atrophy with α and β zones. Zone beta is reported three times more common in patients with POAG than control subjects. [41]

All the findings are characteristic changes of POAG.

g) Visual field defects

In our study grade 2 visual field defect were present in 37.5% in both the groups. Grade 3 visual field defect were present in 50% cases in group-I and in group-II 62.5% cases.

In one patient of group-I fields were not interpreted due to low vision.

In a study conducted in 1999 noted visual field defects >15 decibles are always caused by ganglion cell loss of > 70%. [42]

h) Complications during intra operative, early post operative and late complications

As shown in table 9(a) and 9(b) in total three patient had intra operative sub conjunctival bleed during intra operative period. Two out of these three patients were on long term antiglaucoma medications, episcleral bleed is common in patients put on long term antiglaucoma medications. The same three patients mentioned above had hyphema which resolved spontaneously. There were no late complications noted in both the groups in either of the follow ups.

Outcome of IOP in group-I

As shown in table10(a) preoperative IOP was with a maximum number of patients in the range of 21-30 mm of Hg. The post operative IOP at 3rd month follow up with a maximum number of patients in the range of 11-20 mm of Hg.

As shown in table 10(b) there was a statistically significant difference noted in the group-I for post operative mean IOP levels percentage reduction.($p<0.0001$) in all the follow up periods.

Outcome of IOP in group-II

As shown in table11(a) preoperative IOP was with a maximum number of patients in the range of 21-30 mm of Hg and 31-40 mm of Hg. The post operative IOP at 3rd month follow up with a maximum number of patients in the range of 11-20 mm of Hg.

As shown in table 11(b) there was a statistically significant difference noted in the group-II for post operative mean IOP levels percentage reduction.($p<0.0001$) in all the follow up periods.

Comparison of IOP among group-I and group-II

As shown in table 12 there was no statistically significant difference noted when both the groups were compared for post operative mean IOP levels at different follow ups. P value for the third month post operative mean IOP levels ($p = 0.861$) suggests statistically insignificant.

Likewise as shown in table 13 there was no statistically significant difference noted when both the groups were compared for post operative mean IOP levels percentage reduction.

P value for the third month post operative mean IOP levels percentage reduction (p = 0.845) suggests statistically insignificant.

Bleb characteristics:

As shown in table 14(a) and 14(b) All patients in both the groups had type 2 shallow diffuse blebs suggesting the comparative efficacy of SFT in glaucoma filtering surgeries.

Change in BCVA on last follow up:

As shown in table 15(a) and 15(b) The post operative BCVA at third month remained the same in both the groups.

Success rate:

A complete success was defined as an IOP less than 21 mm of Hg without medication. Success rates in a previous study has ranged 80% and 75% depending on follow up time.

In our study Post operative IOP at third month follow up was < 21 mm of Hg in all the patients of both the groups indicating 100% success rate.

The mean IOP at presentation in **Group-I** was 30.75±6.04 mm of Hg and post operative mean IOP at third month follow up was 13.87±2.80 mm of Hg.

The mean percentage reduction of IOP preoperative to that of post operative third month follow up was 53.2±12.61 mm of Hg in **Group-I.**

The mean IOP at presentation in **Group-II** was 30.0±7.27 mm of Hg and post operative mean IOP at third month follow up was 14.12±2.80 mm of Hg.

The mean percentage reduction of IOP preoperative to that of post operative third month follow up was 52.2±6.95 mm of Hg in **Group-II**.

The target pressure of 30% reduction to that of preoperative IOP was also achieved.

Thus small flap trabeculectomy (microtrabeculectomy) is a safe procedure that effectively reduces IOP and produces good filtering blebs with fewer complications which is comparable in terms of IOP reduction in the procedure of conventional trabeculectomy and better in terms of safety with no use of pharmacological wound modulators

CONCLUSION

The glaucoma patients in developing countries are at more risk of visual loss due to economic constraints and compliance. Chronic use of topical medications have a high cost and economic burden to patients.

The review of recent literature highlights the usefulness and desirability of early trabeculectomy as the first line of therapy.

Surgical intervention for effective IOP control has been the goal of all the procedures. IOP is the only risk factor which is modifiable. Effective IOP control retards the glaucomatous changes and prevents the further visual deterioration by stabilizing the visual acuity.

Conventional trabeculectomy is being performed for effective control of IOP. The intraoperative , early post operative and late post operative complications are known in conventional trabeculectomy. The use of the pharmacological wound modulators causes corneal epithelial defects and hypotonic maculopathy in the early post operative period. Thus an alternative surgical procedure i.e. Small flap trabeculectomy (microtrabeculectomy) was compared with the conventional trabeculectomy.

In conclusion, our study revealed that small flap trabeculectomy is equally efficacious, safer and low cost with no use of pharmacological wound modulators in the effective control of IOP and good filtering shallow diffuse bleb in patients with POAG when compared to conventional trabeculectomy.

SUMMARY

Surgical intervention for glaucoma has gained popularity bu being effective, economical and compliant to the patient.

In order to outline the role of newer surgical procedures in reducing the IOP effectively and to know the bleb characteristics, small flap trabeculectomy was undertaken and compared with conventional trabeculectomy.

In our study we performed a one year randomized clinical trial on sixteen patients of POAG divided in two groups equally at KLE Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period January 2009 to December 2009.

Preoperative evaluation was done and small flap trabeculectomy was performed among the patients assigned in Group I and procedure of conventional trabeculectomy was performed among the patients assigned in Group II. Intra operative, early and late post operative complications were noted and compared among the two groups.

The age range of the patients was 45 to 74 years in group I with a mean age of 59.75±11.34 years. In group II the age range of the patients was 50 to70 years with a mean age of 62.62±7.30 years. Female to male ratio was 3:5 in group I and 1:3 in group II.

The BCVA of one patient in group-I and two patients in group- II was ≤6/60 on Snellen's chart. All the remaining patients in both the groups had BCVA of ≥6/60. The post operative BCVA at third month remained the same in both the groups.

The mean IOP at presentation in Group I was 30.75±6.04 mm of Hg and post operative mean IOP at third month follow up was 13.87±2.80 mm of Hg. This was statistically significant ($p < 0.0001$).

The mean IOP at presentation in Group II was 30.0±7.27 mm of Hg and post operative mean IOP at third month follow up was 14.12±2.80 mm of Hg. This was statistically significant ($p < 0.0001$).

However there was no statistically significant difference noted when both the groups were compared at third month post operative mean IOP levels ($p = 0.861$).

In our study 12.5% of cases were hypertensive in both the groups and another 12.5% of cases were diabetic in both the groups.

Post operative IOP at third month follow up was < 21 mm of Hg in all the patients of both the groups indicating 100% success rate.

The mean percentage reduction, preoperative to that of third month was 53.2±12.61 mm of Hg in Group I.

In Group II the mean percentage reduction, preoperative to that of third month was 52.2±6.95 mm of Hg .

However there was no statistically significant difference noted when both the groups were compared at third month post operative mean percentage reduction.

Intra operative and post operative complications were evaluated and managed without any deterioration in ocular condition in both the groups.

As seen in the literature of small flap trabeculectomy (microtrabeculectomy) in other studies, in our study also the surgical outcome in relation to effective IOP control and bleb charecteristics remained consistent.

Thus small flap trabeculectomy (microtrabeculectomy) is a safe procedure that effectively reduces IOP and produces good filtering blebs with fewer complications which is comparable in terms of IOP reduction in the procedure of conventional trabeculectomy and better in terms of safety with no use of pharmacological wound modulators.

SFT requires more number of studies to show it as an alternative effective glaucoma filtering surgical procedure than the conventional trabeculectomy with or without wound modulators.

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ANNEXURE - I

INFORMED CONSENT FORM

I.P. No. ☐ **I.D. No.** ☐☐☐

Mr. /Mrs./Ms_____

you are invited to participate in our research study titled **"A RANDOMISED, CLINICAL, TRIAL OF COMPARISON OF MICROTRABECULECTOMY VERSUS CONVENTIONAL TRABECULECTOMY IN PRIMARY OPEN ANGLE GLAUCOMA."** conducted by Dr. _____ Post-Graduate in M.S. Ophthalmology under the guidance of Dr. _____, M.S., D.O. Assistant Professor, Department of Ophthalmology, J N Medical College, Belgaum.

Respected sir/ madam, we request you to enroll yourself to participate in our study as, you are eligible for participating in this study. During the study you will be asked some questions in detail regarding your present complaint and you are supposed to answer to the best of your knowledge.

Your participation in research is voluntary, your decision whether or not to participate in the study will not affect your relationship with J N Medical college. If you decide to participate you are free to with draw at any time.

Purpose of the Study :

The purpose of research is to compare the efficacy and safety of microtrabeculectomy versus conventional trabeculectomy in primary open angle glaucoma.

Procedure Involved :

If you agree to participate in this study, you will be asked to give detailed history of the disease you have and you will have to undergo necessary investigations that may be required. You will then be allotted to one of the two groups by randomization and then subjected to surgical procedure depending on the group. Whichever group is allotted to you, You will have to agree upon it. You would be asked to follow up on specified dates when your progress would be monitored, documented and if necessary photographed.

Risks and Benefits :

As such there are no major risks involved, however some discomfort may occur during the process of investigations and the risks involved with the anaesthetic procedure and with microtrabeculectomy or trabeculectomy surgical procedure for which all precautions will be taken. As such minimal risk is involved in the operative procedure mentioned above. Your participation may benefit you and others suffering from same ailment in future, by helping us learn more about the disease process and better treatment modalities. No financial incentives are promised to you for being a part of study.

Alternatives :

Your decision whether or not to participate in this study will not affect the quality of treatment you receive and if you are not willing to participate, Further you may withdraw from the study at any time.

Costs for participating in this research :

There will not be any extra cost incurred by you. The participant will have to pay for the investigations which are the part of the existing management protocol for

this ailment. There is not 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, except :

1. In emergency to protect your rights and welfare.
2. If required by law

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 KLE Prabhakar Kore Hospital and M R C, 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 I have any questions about the research you may please contact :

1) Chief investigator ,

   Dr. _____P.G.

   Department of Ophthalmology,

   J N Medical College, Belgaum . .

2) Guide, Dr. _____

   Department of Ophthalmology,

   J N Medical College, Belgaum .

3) Principal, Dr. _____

   J N Medical College Belgaum and Chairman of

   Institutional Ethics Committee.

CONSENT STATEMENT

I.D. No : ☐ ☐ ☐

I Mr./Ms./Mrs._____Voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up any 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 :_____

Place :_____

ANNEXURE –II: PROFORMA

IP No : ☐☐☐☐☐☐☐☐☐☐ ID No. ☐☐☐

Name : ☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐

(First Name) (Middle Name) (Surname)

Age : ☐☐ Years

Sex : ☐ 1 – Male ; 2 – Female

Address : _____

Occupation : ☐☐☐☐☐☐☐☐☐☐

Religion : ☐ 1 1- Hindu 2 – Muslim 3 – Christian 4 – Sikh 5 Others(Specify)

Date of Admission: ☐☐ ☐☐ ☐☐☐☐

Date of Discharge : ☐☐ ☐☐ ☐☐☐☐

Diagnosis : _____

Proposed Surgery : _____

Is the patient eligible for Study ? ☐ 1 1– Yes 2 – No

Has informed consent been taken ? ☐ 1 1– Yes 2 – No

Final Result Information :

1. Ineligible
2. Eligible, Refusal
3. Eligible, Participating

☐

Date of surgery : ☐☐ ☐☐ ☐☐☐☐

I.D. No :- ☐ ☐ ☐

Chief complaints :

Diminution of vision Duration_____months / years

RE ☐ LE ☐

History of present illness :

1. Diminution of vision ☐ **Gradual** ☐ **Sudden**

☐ Progressive ☐ Static

☐ Painless ☐ Painful

☐ (1-Distance; 2 Near; 3 Both)

2. History of Diplopia / polypia ☐ 1 -Yes 2 - No

3. History of Coloured halos ☐ 1 - Yes 2 - No

4. History of Black spots infront of the eyes ☐ 1 - Yes 2 - No

5. History of watering / Discharge ☐ 1 - Yes 2 - No

6. History of Redness ☐ 1- Yes 2 - No

7. H/o wearing spectacles : ☐ 1- Distance ; 2 Near ; 3 Both)

Duration _____months / years

8. Any other complaints (if present, specify):

Past history

Diabetes : ☐ Duration :_____months / years

Hypertension : ☐ Duration :_____months / Years

Asthma: ☐ Duration :_____months / Years

Any other medical disorders :_____

Family history:

General physical examination

Vital signs :

Pallor: ☐ Pulse rate (Per minute): ☐☐☐

Oedema : ☐ Blood Pressure : ☐☐☐ / ☐☐☐

(mm of Hg)

Lymphadenopathy : ☐ Temperature : (^{0} F) ☐☐☐

Cardiovascular system : ☐ 1-Normal ; 2-Abnormal; If abnormal specify :_____

Respiratory system : ☐ 1-Normal ; 2-Abnormal; If abnormal specify :_____

Nervous System : ☐ 1-Normal ; 2-Abnormal; If abnormal specify :_____

Per abdomen : ☐ 1-Normal ; 2-Abnormal; If abnormal specify :_____

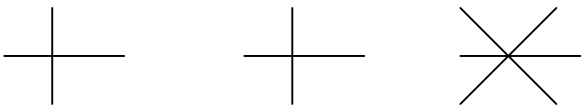
Ocular Examination :

Head Posture : ☐ (1- Errect ; 2 Tilted)

Facial Symmetry: ☐ (1-Symmetrical ; 2-Asymmetrical)

Visual Axes: ☐ (1-Parallel ; 2-Deviated)

Extra Ocular Movements: Right Eye Left Eye Binocular



Visual Acuity : Right Eye Left Eye

Distant :

Pinhole :

Near :

	(RIGHT EYE)	(LEFT EYE)
Adnexa		
Conjunctiva		
Cornea		
Sclera		
Anterior chamber		
Iris		
Pupil		
Lens		

FUNDUS : Right Eye Left Eye

GLOW:

MEDIA:

DISC:

SHAPE:

SIZE:

MARGIN:

COLOUR:

CUP:

SIZE:

DEPTH:

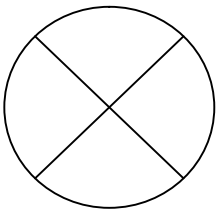
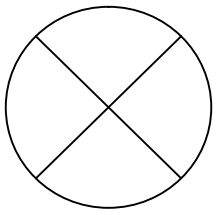
C-D RATIO:

NEURORETINAL RIM:

COLOUR:

NOTCHING:

WIDTH:

Gonioscopy: **Rt.**  **Lt.** 

Investigation :

1. Random Blood Sugar _____ mg%

2. Urine - Albumin ☐ (1-Present ; 2-Absent)

   - Sugar ☐ (1-Present ; 2-Absent)

   - Microscopy ☐ (1-Pus cells ; 2-No pus cells)

3. Lacrimal Sac patency : (1 – Patent ; 2 – Blocked)

   Right Eye ☐ Left Eye ☐

4. Intra Ocular Pressure : Right Eye ☐☐ Left Eye ☐☐

   (mm of Hg)

5. Any other:

TYPE OF SURGICAL PROCEDURE :

GROUP I – Microtrabeculectomy ☐

GROUP II – Conventional trabeculectomy ☐

INTRA OPERATIVE PROBLEMS : _____

POST OPERATIVE EVALUATION

Clinical features		**Follow up period**			
Date		**1st week**	**6th week**	**3rd Month**	**Remarks**
1.	**Visual Acutiy** DV: With PH Nv				
2.	**IOP (mm of Hg)**				
3.	**Anterior chamber**				
	Normal depth				
	Shallow (grade)				
	Deep				
4.	**Bleb**				
	thin polycystic filtering				
	shallow diffuse filtering				
	vascularised non filtering				
	encapsulated bleb				
5.	**Leakage**				
6.	**Fundus**				
Complications					
	Sub conjunctival bleed				
	Corneal edema				
	Shallow AC				
	Hyphema				
	Cataract progression				
	Choroidal detachment				
	Late bleb leakage				
	Blebitis				

ANNEXURE – III: PHOTOGRAPHS

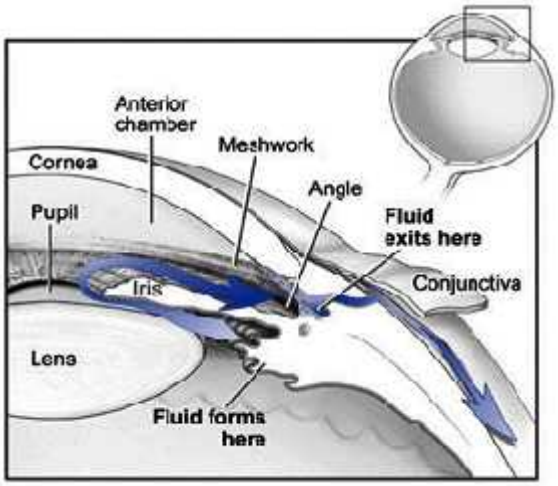


Fig. 1: Normal Aqueous flow

Fig. 2: Goldmann Three mirror lens

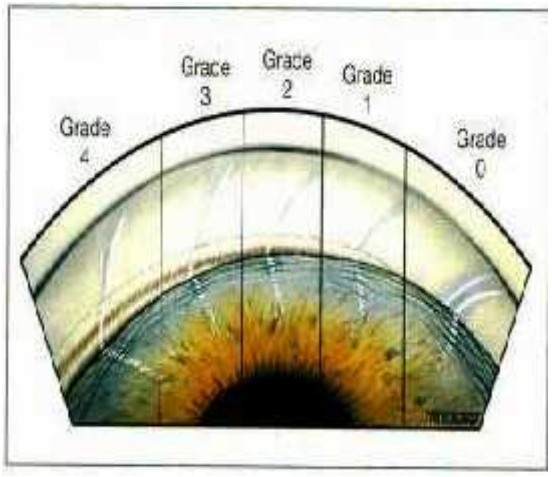


Fig. 3: Angle grading

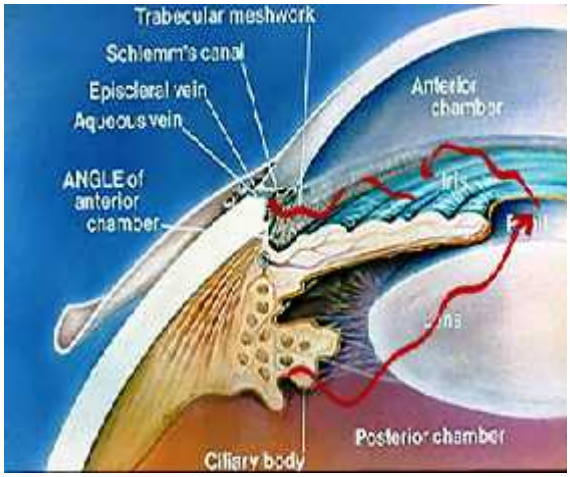


Fig. 4: Schematic view: Aangle of Anterior chamber

Fig. 5: Kelly's Descemet's Membrane Punch (1.0 x 1.0mm)

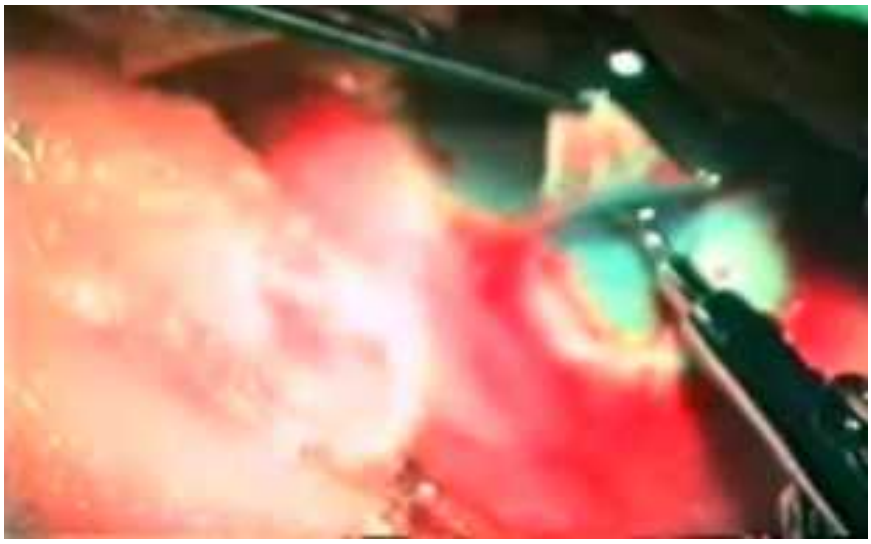


Fig. 6: Trabecular Meshwork removed using Kelly's Descemet's membrane punch in SFT

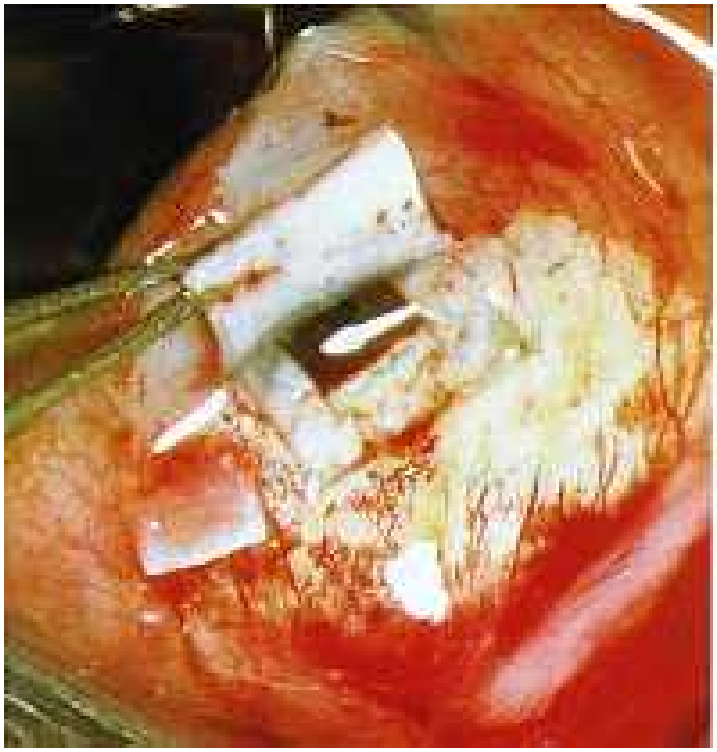


Fig. 7: Manual excision of 1 x 4mm block of tissue anterior to scleral spur in CT

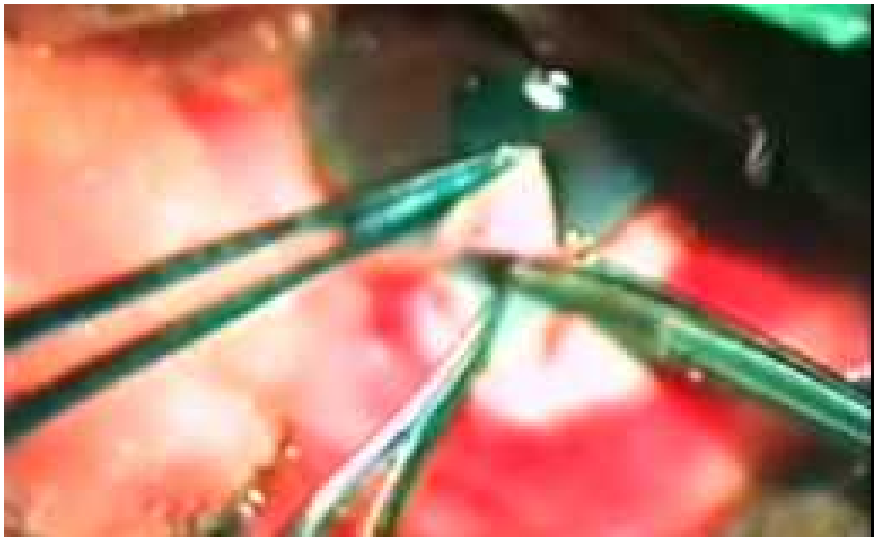


Fig. 8: Peripheral Iridectomy

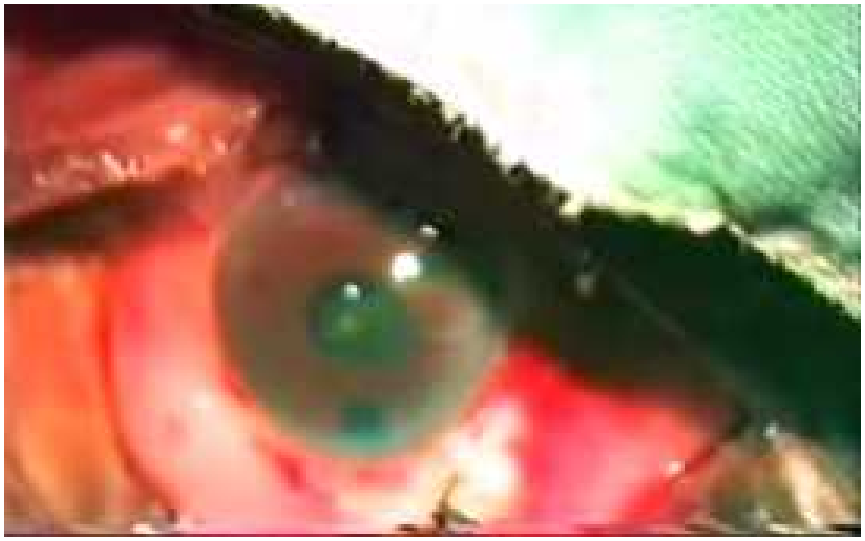


Fig.9: Water Tight Suture

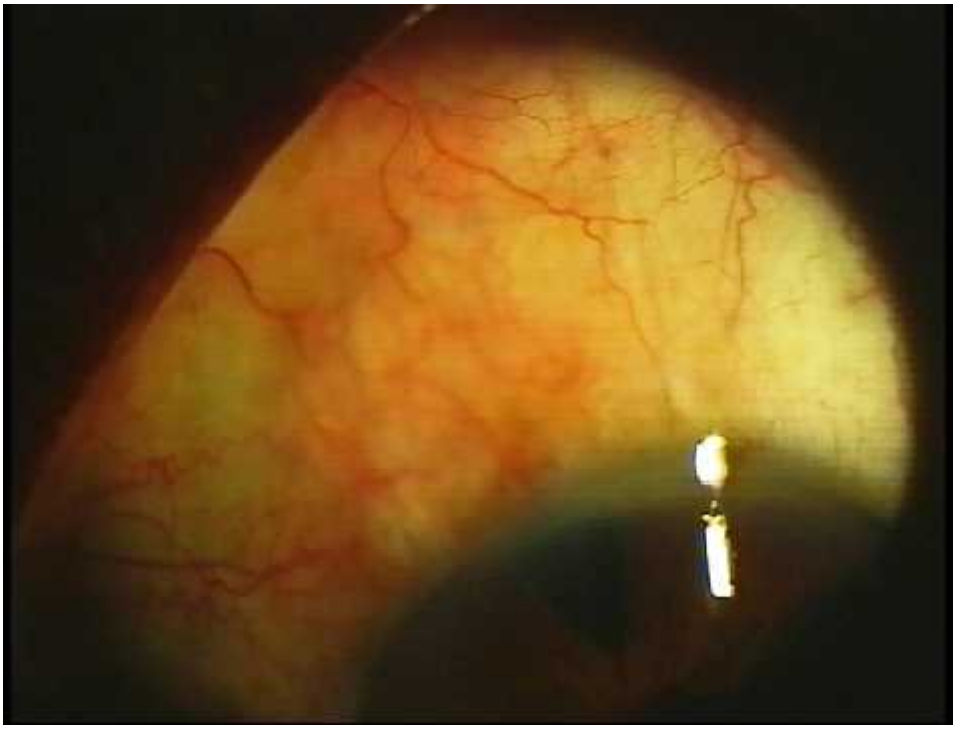


Fig. 10: Shallow Diffuse Bleb

Fig. 11: Slit bending at the Bleb

ANNEXURE – IV: MASTER CHART

KEY TO MASTER CHART

BCVA	**:**	Best corrected visual acuity
C:D	**:**	Cup – Disc ratio
CS	**:**	Completed success
CT	**:**	Conventional trabeculectomy
DM	**:**	Diabetes mellitus
F	**:**	Female
H	**:**	Hyphema
HMCF	**:**	Hand movements close to face.
HTN	**:**	Hypertension
Intra Op	**:**	Intra operative
IOP	**:**	Intra ocular pressure
I P No.	**:**	In Patient number
LE	**:**	Left eye
M	**:**	Male
MT	**:**	Microtrabeculectomy
NR	**:**	Not recordable
P	**:**	Primary open angle glaucoma
Post Op	**:**	Pre operative
Pre Op	**:**	Post operative
RE	**:**	Right eye
SD	**:**	Shallow diffuse
SH	**:**	Sub conjunctival haemorrhage

MASTER CHART

SL. No.	IP No.	Name	Age in years	Sex	Eye	Family history	Premedication	Systemic disease	Pre-OP BCVA	Angle grading	C:D Ratio	Visual Fields	Pre -OP IOP	Diagnosis	Type of Procedure	Complications			IOP			BLEB			BCVA at 3rd month	Success
																Intra Op.	Early Post Op.	Late	1st Week	6th Week	3rd Month	1st Week	6th Week	3rd Month		
1	303221	Bharmu	65	M	LE	-	-	-	6/12	4	0.7	2	24	P	MT	-	-	-	15	16	16	SD	SD	SD	6/12	CS
2	309404	Srinivas	66	M	RE	-	-	DM	6/60(P)	4	0.9	3	26	P	CT	-	-	-	10	10	12	SD	SD	SD	6/60(P)	CS
3	309387	Sonabai	60	F	LE	-	+	-	6/9(P)	3	0.7	2	24	P	CT	SH	H	-	10	13	13	SD	SD	SD	6/9(P)	CS
4	316816	Kashawa	50	F	RE	-	-	-	6/24	3	0.8	2	28	P	CT		-	-	14	14	15	SD	SD	SD	6/24	CS
5	316802	Keshav	69	M	RE	-	-	-	6/24(P)	3	0.7	2	26	P	MT	-	-	-	12	13	13	SD	SD	SD	6/24(P)	CS
6	323151	Shankar	70	M	RE	-	-	HTN	6/60	3	0.9	3	41	P	CT	SH	H	-	16	18	18	SD	SD	SD	6/60	CS
7	324265	Shivling	55	M	LE	-	-	-	6/24	4	0.8	2	24	P	CT	-	-	-	9	10	10	SD	SD	SD	6/24	CS
8	324290	Indirabai	74	F	LE	+	-	DM	6/24(P)	3	0.7	3	25	P	MT	-	-	-	10	11	11	SD	SD	SD	6/24(P)	CS
9	330667	Sadashiv	65	M	RE	-	-	-	6/36	3	0.9	3	29	P	MT	-	-	-	14	15	15	SD	SD	SD	6/36	CS
10	345498	Parshuram	70	M	LE	-	-	-	6/36(P)	3	0.8	3	42	P	CT	-	-	-	16	16	17	SD	SD	SD	6/36(P)	CS

SL. No.	IP No.	Name	Age in years	Sex	Eye	Family history	Premedication	Systemic disease	Pre-OP BCVA	Angle grading	C:D Ratio	Visual Fields	Pre -OP IOP	Diagnosis	Type of Procedure	Complications			IOP			BLEB			BCVA at 3rd month	Success
																Intra Op.	Early Post Op.	Late	1st Week	6th Week	3rd Month	1st Week	6th Week	3rd Month		
11	337474	Mallappa	68	M	LE	-	-	-	6/60(P)	3	0.8	3	28	P	CT	-	-	-	9	11	12	SD	SD	SD	6/60(P)	CS
12	342651	Hanumanth	62	M	RE	-	-	-	6/24	3	0.8	3	27	P	CT	-	-	-	14	16	16	SD	SD	SD	6/24	CS
13	344339	Tangewwa	65	F	RE	-	-	-	6/36	3	0.7	3	35	P	MT	-	-	-	15	15	16	SD	SD	SD	6/36	CS
14	360312	Somlingappa	45	M	RE	-	+	-	6/6(P)	3	0.9	3	32	P	MT	-	-	-	9	10	12	SD	SD	SD	6/6(P)	CS
15	361159	Harish	45	M	RE	-	-	-	HMCF	3	0.9	NR	42	P	MT	-	-	-	10	10	10	SD	SD	SD	HMCF	CS
16	363248	Rameeza	50	F	RE	-	+	HTN	6/9	3	0.8	2	33	P	MT	SH	H	-	16	18	18	SD	SD	SD	6/9	CS