



**ORIGINAL RESEARCH PAPER**

**Ophthalmology**

**“CLINICAL OUTCOMES OF VARIOUS SURGICAL MODALITIES IN CASES OF REFRACTORY GLAUCOMA”**

**KEY WORDS:**

Trabeculectomy, 5-FU, Glaucoma, Drainage Devices, 5-fluorouracil, Mitomycin C

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**ABSTRACT**

The study was conducted to evaluate the clinical outcomes of various glaucoma surgeries (trabeculectomy, trabeculectomy with mitomycin-C and glaucoma valve implantation) in cases of refractory glaucoma. When it becomes obvious that medication will not help then alternatives should be tried. These alternatives can be in form of:-

**Filtration Surgery** Termed as trabeculectomy allows drainage of aqueous humor from within the eye to underneath the conjunctiva where it is absorbed.

**Trabeculectomy with mitomycin C**-The use of antifibrotic agents such as mitomycin-C and 5-fluorouracil, along with releasable sutures or laser suture lysis, enhances the longevity of guarded procedures, Drainage Implants Glaucoma drainage devices are designed to divert aqueous humor from the anterior chamber to an external reservoir, where a fibrous capsule forms about 4-6 weeks after surgery and regulates flow.

**Aims of Study**

1. Study the clinical outcomes of trabeculectomy, trabeculectomy with mitomycin-C and glaucoma valve implantation in management of refractory glaucoma patients.
2. Evaluate the complications of glaucoma valve surgery.
3. Study the complications of trabeculectomy, trabeculectomy with mitomycin-C.

The proposed study was conducted in upgraded department of ophthalmology, LLRM Medical College, Meerut.

Population characteristics were number of eyes treated, diagnosed and follow up. The study was a prospective study with random selection of patients done from the OPD. The randomly selected patients were then divided into three groups, one group was subjected to trabeculectomy, second with trabeculectomy with mitomycin-C and the other group was subjected to glaucoma valve implantation.

**CRITERIA FOR FAILURE OF SURGERY:**

- IOP > 21 mm hg at end of 1 year or
- IOP not reduced by 20% from baseline at end of 1 year or
- IOP <=5 mm hg at end of 1 year

At 1 year postoperatively mean IOP for trabeculectomy, trabeculectomy with mitomycin-C and valve were 15.7±3.56 mmHg, 15.9±3.47 mmHg and 17.6±2.27 mmHg respectively. When comparing preoperative to 1 year post operative IOP, all the surgeries demonstrated statistically significant reductions in IOP although the magnitude of IOP reduction was greater for valve than trabeculectomy, trabeculectomy with mitomycin-C. Complication profiles differed for each type of glaucoma surgery. There were no intraoperative complications for all glaucoma surgeries. The immediate complication for both trabeculectomy.

Trabeculectomy with mitomycin-C was bleb leak (10%) and shallow anterior chamber (10%) while for valve implantation hyphema (20%) predominated.

Although complication profiles differ between procedures, all are safe and well tolerated. This study provides support that trabeculectomy, trabeculectomy with mitomycin-C and valve implantation are safe and effective glaucoma surgeries.

**CONCLUSION**

All the three surgeries ,glaucoma valve implantation, trabeculectomy, and trabeculectomy with mitomycin-C produce significant reductions in IOP. Although complication profiles differ between procedures, all are safe and well tolerated. This study provides support that trabeculectomy, glaucoma valve implantation and trabeculectomy with mitomycin-C are indeed safe and effective.

**INTRODUCTION**

Refractory glaucoma is defined as uncontrolled intraocular pressure with the evidence of optic nerve and/or visual field deterioration despite maximally tolerated anti-glaucoma medications (topical and or systemic), previously failed surgical treatment, or a combination of surgery and medicines or a high risk of failure of trabeculectomy.<sup>1</sup> Topical and oral medications help relieve intraocular pressure (IOP) through biological changes to the eye structures. They either increase drainage of aqueous fluid to release the pressure, or

they prevent additional production of aqueous humor. About one in ten people do not respond to traditional glaucoma treatment – in the form of topical and oral medications.<sup>2</sup>

When it becomes obvious that medication will not help then alternatives should be tried. These can be:

**Filtration surgery**

Termed as trabeculectomy allows drainage of aqueous humor from within the eye to underneath the conjunctiva where it is

absorbed. Trabeculectomy is a guarded partial-thickness filtering procedure performed by removal of a block of peripheral corneal tissue beneath a scleral flap.<sup>3</sup>

Successful trabeculectomy involves reduction of IOP and avoidance or management of complications.

Antimetabolites are usually used during trabeculectomy surgery to prevent bleb failure due to scarring by the wound healing process. The most commonly used antimetabolites are 5-fluorouracil (5-FU) or mitomycin C (MMC).<sup>4</sup>

**5-FU**

**Advantages**

- Inexpensive
- No dilution or dosage calculations required
- Stable at room temperature
- Better safety margin than MMC

**Disadvantages**

- Less effective than MMC
- Multiple injections
- More potent than 5-FU
- Results in lower intraocular pressure
- Expensive Reconstituted from powder
- Not stable at room temperature
- Possibly more complications

Glaucoma drainage devices<sup>6</sup> are designed to divert aqueous humor from the anterior chamber to an external reservoir, where a fibrous capsule forms about 4-6 weeks after surgery and regulates flow. These devices have shown success in controlling intraocular pressure (IOP) in eyes with previously failed trabeculectomy and in eyes with insufficient conjunctiva because of scarring from prior surgical procedures or injuries. They also have demonstrated success in complicated glaucomas, such as uveitic glaucoma, neovascular glaucoma, and pediatric and developmental glaucomas, among others.<sup>7</sup>

The most commonly used valved implant is the Ahmed glaucoma valve, AGV.

**AIM AND OBJECTIVES**

1. Study the clinical outcomes of various surgical modalities such as trabeculectomy, trabeculectomy with mitomycin-C and glaucoma drainage devices for the management of refractory glaucoma.
2. Study the complications of trabeculectomy and trabeculectomy with mitomycin C.
3. Evaluate the complications of glaucoma valve surgery.

**MATERIALS AND METHODS**

A prospective study was conducted in June 2018-June 2019 at the OPD of upgraded Department of Ophthalmology at LLRM Medical College, Meerut.

In this study, random selection of patients was done from the OPD. Amongst these, the patients having intraocular pressure <30 mm Hg were subjected to either trabeculectomy or trabeculectomy with mitomycin-C and the patients having intraocular pressure >30 mmHg were subjected to glaucoma valve implantation surgery.

- Efficacy parameter was mean IOP before and after treatment
- Safety parameters were post operative complications, visual acuity, and subsequent interventions.

**Method Of Examination-**

IOP was measured by Goldmann applanation tonometer.

**Inclusion Criteria-**

Glaucomatous patients uncontrolled with maximum

medications.

**Exclusion Criteria-**

1. Any glaucomatous patient with IOP controlled with medications.
2. Any glaucomatous patient with bacterial, viral or fungal infection.
3. Any normotensive glaucomatous patient.
4. Non willing glaucomatous patient.
5. PL+ve but PR inaccurate or inconsistent patient.
6. Patient with corneal decompensation

**Criteria For Failure Of Surgery:**

1. IOP > 21 mm hg at end of 1 year or
2. IOP not reduced by 20% from baseline at end of 1 year or
3. IOP <= 5 mm hg at end of 1 year

**OBSERVATIONS & RESULTS**

A total of 30 eyes of 30 patients who fulfilled the inclusion criteria were included in the study who came to out patient department of ophthalmology of L.L.R.M Medical College, Meerut.

**Table 1: Selection Of Patients**

DIAGNOSIS	NO. OF PATIENTS	PERCENTAGE (%)
POAG	15	50%
NVG	6	20%
CHRONIC ANGLE CLOSURE	9	30%
TOTAL	30	100%

Table 1 shows the division of all patients in 3 groups. Maximum number of patients belong to the group of primary open angle glaucoma followed by chronic angle closure glaucoma and neovascular glaucoma.

**Table 2: Types Of Glaucoma In Different Age Groups**

	POAG	NVG	Chronic Angle Closure
40-49yrs	5	2	2
50-59yrs	6	3	6
>60yrs	4	1	1

Maximum no. of patients belong to group POAG in age group 50-59 yrs

**Table 3: Mean IOP In The Three Groups Preoperatively**

	Trabeculectomy	Trabeculectomy With Mitomycin-C	Glaucoma Valve	PValue
PRE OP IOP	24.3±2.0575	24.7±2.7508	33.8±3.32	<0.001

Preoperatively, mean IOP was higher in eyes receiving a valve than trabeculectomy and trabeculectomy with mitomycin-C at 33.8±3.32, 24.3±2.0575 and 24.7±2.7508 mm Hg and respectively (p<0.001).

**Table 4: Type Of Glaucoma Surgery Done In Different Forms Of Glaucoma**

Diagnosis	Trabeculectomy	Trabeculectomy with mitomycin -C	Glaucoma valve implantation
POAG	5(16%)	7(23%)	3(6%)
NVG	0(0%)	1(3%)	5(17%)
CHRONIC ANGLE CLOSURE	5(13%)	2(6%)	2(7%)

Table shows that in this study, trabeculectomy with mitomycin-C (23%) was the major surgery done in POAG while glaucoma valve implantation was the major surgery done in both NVG (17%) and trabeculectomy was done in Chronic angle closure patients (13%).

**Table 5 : Mean IOP Measured In Subsequent Follow Up Till One Year**

No of days	Trabeculectomy	Trabeculectomy with mitomycin-C (mm Hg)	Glaucoma valve (mm Hg)
Pre op	24.3±2.0575	24.7±2.7508	33.8±3.32
Day 1	19.3±2.601	19.4±2.8	17.3±4.026
1 week	17.9±3.910	19.2±3.026	14.9±4.61
1 month	19.2±2.6	18.7±2.41	16.9±3.4419
3 month	17.8±2.925	17.6±3.261	17.4±3.35
6 month	17.6±3.49	17.3±3.56	17.6±3.49
1 year	15.7±3.56	15.9±3.47	17.6±2.27

All glaucoma surgeries- trabeculectomy, Trabeculectomy with mitomycin-C and Glaucoma Valve implantation demonstrated significant reductions in IOP although the magnitude was greater for valve than trabeculectomy and trabeculectomy with mitomycin-C.

**Table 6 : Preoperative And 1 Year Postoperative Metrics For Trabeculectomy, Trabeculectomy With Mitomycin-C And Glaucoma Valve**

No of days	Trabeculectomy	Trabeculectomy with mitomycin-C (mm Hg)	Glaucoma valve (mm Hg)
Pre op	24.3±2.0575	24.7±2.7508	33.8±3.32
Day 1	19.3±2.601	19.4±2.8	17.3±4.026
1 week	17.9±3.910	19.2±3.026	14.9±4.61
1 month	19.2±2.6	18.7±2.41	16.9±3.4419
3 month	17.8±2.925	17.6±3.261	17.4±3.35
6 month	17.6±3.49	17.3±3.56	17.6±3.49
1 year	15.7±3.56	15.9±3.47	17.6±2.27

At 1 year postoperatively mean IOP for trabeculectomy, trabeculectomy with mitomycin-C and valve were **15.7±3.56** mm hg, **15.9±3.47** mm hg and **17.6±2.27** mm hg. However, the mean log MAR visual acuity remained significantly poorer in the valve group (p=0.001). When comparing preoperative to 1 year post operative IOP, all surgeries demonstrated statistically significant reductions in IOP (the magnitude of IOP reduction was greater for valve than trabeculectomy, trabeculectomy with mitomycin-C at 17.6±2.27, 15.7±3.56mm Hg and 15.9±3.47mm Hg respectively (p<0.001).

All trabeculectomy, trabeculectomy with mitomycin-C and glaucoma valve implantation demonstrated statistically significant reductions in IOP (P<0.001) although the magnitude was greater for valve than trabeculectomy and trabeculectomy with mitomycin-C (mean decrease in IOP in trabeculectomy, trabeculectomy with mitomycin-C was 8.6 mmHg, 8.8mmHg and glaucoma valve group was 16.2 mmHg).

Complication profiles differed for each type of glaucoma surgery. There were no intraoperative complications for glaucoma surgeries. The immediate complication for both trabeculectomy and with trabeculectomy with mitomycin-C was bleb leak (10%) and shallow anterior chamber (10%) while for valve implantation hyphema (20%) predominated. From 1 week to 3 months 2 eye (20%) undergoing trabeculectomy and 1 eye (10%) with trabeculectomy with mitomycin-C developed encapsulated bleb. 1 eye undergoing valve implantation developed tube malposition (10%) and one eye developed conjunctival retraction (10%). Over 1 year 1 eye with trabeculectomy (10%), 2 eyes with trabeculectomy with mitomycin-C (20%) developed encapsulated bleb while 1 eye with valve implantation developed tube malposition (10%) and one developed tube occlusion (10%).

**DISCUSSION**

In this study the three groups were shown to be both safe and effective. All the surgical groups in this study had significant reductions in IOP over 1 year. The magnitude of reduction was greater for valves, but this was likely due to the higher mean

preoperative IOP in valve group. This is a prospective study of 30 patients, out of which 15 Patients was diagnosed with POAG, 6 with NVG and 9 with chronic angle closure glaucoma.

Out of 30 patients, 10 patients underwent trabeculectomy, 10 underwent trabeculectomy with mitomycin-C and remaining underwent glaucoma valve implantation.

Apart from IOP reduction, the type and rate of surgery, complications were also a primary focus of our study. There were no intraoperative complications in all 3 surgeries. Post operative complications were stratified into three groups based on postoperative time frame: Immediate (<1 week), Early (1 week to 3 months) and Late complications (3-12 months). Eyes receiving valve seemed to have more immediate post operative complications than trabeculectomy, trabeculectomy with mitomycin-C, mostly due to hyphema. One plausible explanation for the higher rate of hyphema is that more of the eyes receiving valve had neovascular glaucoma.

Bleb leak was seen in two patients which was treated by suture replacement. At the end of post operative one year, 2 patients who had undergone trabeculectomy and 1 patient of trabeculectomy with mitomycin-C developed encapsulated bleb while 2 patients who had undergone glaucoma valve implantation developed tube malposition and tube occlusion.

Mean visual acuity was significantly worse preoperatively for eyes in the valve group. This difference persisted at 1 year; however, the visual acuity in valve group did not worsen more on average than trabeculectomy, trabeculectomy with mitomycin-C over 1 year.

**CONCLUSION**

All the three surgeries, glaucoma valve implantation, trabeculectomy, and trabeculectomy with mitomycin-C produce significant reductions in IOP. Although complication profiles differ between procedures, all are safe and well tolerated. This study provides support that trabeculectomy, glaucoma valve implantation and trabeculectomy with mitomycin-C are indeed safe and effective.

**REFERENCES**

1. Comparison of outcomes of resident performed Ahmed valve implantation vs trabeculectomy: Journal of Current Glaucoma Practise 2016 May-August
2. Ted S Acott, Department of Ophthalmology, Renji Hospital Affiliated Medical School, Shanghai jiao tong University, Shanghai, China.
3. Tran DH, Souza C, Ang MJ, Loman J, Law SK, et al. (2009) Comparison of long-term surgical success of Ahmed Valve implant versus trabeculectomy in open-angle glaucoma. Br J Ophthalmol.
4. Michael S Kook, MD; Juntaek Yoon, MD; Jaeyong Kim, MD; Moo-Song Lee, PhD Ophthalmic Surgery, Lasers and Imaging Retina March/April 2000 - Volume 31
5. KB Mills - British Journal of Ophthalmology, 1981 - bjo.bmj.com
6. Joshi AB, Parrish RK II, Feuer WF. 2002 survey of the American Glaucoma Society: practice preferences for glaucoma surgery and antifibrotic use. J Glaucoma. 2005 Apr;14(2):172-174.
7. Topouzis F, Coleman AL, Choplin N, Bethlem MM, Hill R, Yu F, Panek WC, Wilson MR. Follow-up of the original cohort with the Ahmed glaucoma valve implant. Am J Ophthalmol. 1999 Aug;128(2):198-204.