



Research Article

A STUDY ON EFFICACY OF TRABECULECTOMY AND TRABECULECTOMY
WITH MITOMYCIN C ON GLAUCOMA MANAGEMENT

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ABSTRACT

Background: Glaucoma is a chronic, progressive optic neuropathy caused by a group of ocular conditions which lead to damage to optic nerve with loss of visual function. It is the third leading cause of blindness worldwide. The common risk factor known is a raised intraocular pressure. It's prevalence in India is between 2.2%-5.8%. Trabeculectomy is the surgical treatment for glaucoma. The surgery forms a filtering channel to the subconjunctival space and its efficacy depends upon two routes of drainage of the aqueous-through the canal of schlemm and by trans scleral route to the subconjunctival space. Mitomycin C is an anti fibroblastic agent used intraoperatively. It slows down the healing process resulting in bleb that exhibit greater filtration. It thus increases the outcome of trabeculectomy procedure. It is administered intraoperatively as a topical application as 0.01%-0.05% for 1-5 minutes.

Objective: To study the efficacy of trabeculectomy and trabeculectomy with Mitomycin C in Primary open angle glaucoma and Primary narrow angle glaucoma.

Materials and Methods: This prospective interventional clinical study was conducted between October 2018 to September 2020 at Rajah Muthiah medical college and hospital, Annamalai University, Annamalai Nagar, Tamil Nadu. Patients attending OPD of the Ophthalmology department diagnosed as a case of glaucoma were included in the study. 15 patients underwent trabeculectomy and 15 patients underwent trabeculectomy with Mitomycin C. They were examined at discharge, 1 week, 1 month and 3 months. Visual acuity, IOP, Indirect ophthalmoscopy examination were done at every visit.

Results: Out of 30 patients around 10(33.33%) were males and 20(66.66%) were females. 40% males and 60% females underwent trabeculectomy surgery. 26.7% males and 73.3% females underwent trabeculectomy with Mitomycin C. With both the surgeries, the mean IOP of both eyes showed significant drop immediately after surgery. From then there was a mild increase at 1 week, 1 month and 3 months but stayed well below the preop IOP. The drop in IOP was more in the trabeculectomy with Mitomycin C group than the trabeculectomy group.

Majority of the patient had stable IOP control and did not need adjuvant medication. Only few patients developed postop complications.

Conclusion: The study concluded that trabeculectomy was successful in arresting the progression of the disease by decreasing and controlling the intraocular pressure within the normal range, along with stabilization of visual acuity. Adjuvant treatment with MMC increases the outcome of trabeculectomy.

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INTRODUCTION

Glaucoma is the third leading cause of blindness worldwide¹. Its prevalence in India is between 2.2%-5.8%. Glaucoma is a chronic, progressive optic neuropathy caused by a group of ocular conditions which lead to damage to optic nerve with loss of visual function. The common risk factor known is a raised intraocular pressure. A sustained IOP may be due to increased formation of aqueous humour, difficulty in its exit, or a raised pressure in its episcleral veins². The two main influences for the pathogenesis of glaucoma are 1. mechanical

changes due to increased intraocular pressure. 2. vascular perfusion of optic nerve head. The diagnosis of glaucoma is made after looking for combination of clinical signs-characteristic changes in optic nerve head, abnormalities in visual field and a raised intraocular pressure. IOP is the key risk factor for development and progression of glaucoma. Decrease in IOP delays onset and progression of glaucoma. The ultimate goal of treatment is to preserve vision to meet the patients need. Treatment should delay or stop the damage to optic nerve and ganglion cell layer. The only way to delay or

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stop damage is to lower IOP to the level below which there will not be continued damage to the optic nerve. It can be done using anti glaucoma drugs or surgery.

Trabeculectomy is the surgical treatment for glaucoma. It involves the creation of a lamellar scleral flap. Under this flap, a piece of sclera which includes a short length of the canal of schlemm is excised, thus producing two new entrances in to the canal and forms a filtering channel to the subconjunctival space and its efficacy depends upon two routes of drainage of the aqueous-through the canal of Schlemm and by trans scleral route to the subconjunctival spaces. Mitomycin C is an antifibroblastic agent used intraoperatively. It inhibits DNA synthesis. It is a potent DNA cross linker. It forms crosslinks between the complimentary strands of DNA preventing separation of the strands inhibiting DNA replication³.It slows down the healing process resulting in bleb that exhibit greater filtration. It thus increases the outcome of trabeculectomy procedure. It is administered intraoperatively as a topical application as 0.01%-0.05% for 1-5 minutes. Dosage of 0.02% Mitomycin C used for 2 minutes was useful in lowering IOP in glaucoma patients at risk of bleb failure.

Aims

To study the outcome of Trabeculectomy and Trabeculectomy with Mitomycin C in glaucoma patients.

Objectives

1. To study the clinical outcomes of patients who underwent trabeculectomy and trabeculectomy with Mitomycin C
2. To study the efficacy of trabeculectomy and trabeculectomy with Mitomycin C

MATERIALS

Study Design Prospective interventional study

Study Place Department of Ophthalmology, Rajah Muthiah Medical College and Hospital, Annamalai Nagar, Chidambaram– 608002

Study Duration 2 years (October 2018 to September 2020)

Target Population Glaucoma patients attending Ophthalmology Department at Rajah Muthiah Medical College and Hospital.

Study Population Subjects diagnosed to have Glaucoma who underwent trabeculectomy and trabeculectomy with mitomycin C in the Ophthalmology Department at Rajah Muthiah Medical College and Hospital.

Inclusion criteria

- ✓ Eyes with advanced glaucomatous damage due to open angle or angle-closure glaucoma.
- ✓ Patient refractory to medical therapy
- ✓ Those with advanced visual field defect
- ✓ High intraocular pressure at presentation
- ✓ Inability to afford the cost of anti glaucoma medication
- ✓ Poor compliance

Exclusion criteria

- ✓ All cases of secondary open or angle-closure glaucoma
- ✓ Congenital glaucoma

- ✓ Absolute glaucoma

METHODOLOGY

Selection and Allocation method

Patients with glaucoma attending Raja Muthiah Medical College and Hospital were the target population. Based on the inclusion criteria study population were selected and their details of personal information, history, examination and investigations were entered in the case performa. Visual acuity, slit lamp examination, Gonioscopy were done. IOP was measured using Non contact tonometry. Fundus examination was done with Indirect Ophthalmoscope.15 patients each were selected and Trabeculectomy and trabeculectomy with Mitomycin C was done. It was carried out by making a fornix based conjunctival peritomy. Thereafter, a 3x3 mm triangular limbus-based scleral incision was fashioned in both groups. A triangular partial thickness scleral flap is raised and 2x2 mm of deep sclera, Schlemm's canal and the trabecular meshwork was removed using Kelly's punch. Because of the fluid in the iris will partially prolapse through the sclerotomy and is therefore grasped to perform peripheral iridectomy. This iridectomy will prevent future blockage of the sclerotomy. The scleral flap was replaced and secured in place by two interrupted 10-0 polyamide sutures. For the trabeculectomy with mitomycin C group a sponge soaked in 0.2mg/ml mitomycin C was applied on the sub tenon space for three minutes and the area was washed with balanced salt solution. However, the conjunctiva was secured to be watertight. Patients were examined at discharge, 1st week, 1st month, 3rd month. Visual acuity, IOP, Indirect ophthalmoscopy examination were done at every visit.

Statistical analysis

All the data were entered in the case proforma for each patient and the data collected was entered in to Microsoft Excel Sheet and statistical analysis was arrived using IBM SPSS software. Statistical methods like frequencies in number and percentage, Mean ±SD, P value were used wherever applicable.

RESULTS

Demography

Total Study Population:30;

Age groups present in the study:40-70 years.

Table 1 Distribution of age between the two groups.

Age group (in years)	Trabeculectomy		Trabeculectomy with mitomycin C	
	N	%	N	%
40-44	2	13.3	1	6.7
45-49	1	6.7	1	6.7
50-54	3	20.0	2	13.3
55-59	4	26.7	6	40.0
60-64	3	20.0	2	13.33
65-69	2	13.3	3	20.0

X² - 1.333 d.f – 5 P-value – 0.931

Table 1: 7 (46.7%) of the study participants in the trabeculectomy group belonged to the 50 – 59 years age group and 8 (53.3%) in the trabeculectomy with mitomycin C group also belonged to 50-59 years of age. Both the groups were similar concerning age as indicated by a value of more than 0.05

Table 2 Distribution of sex between the two groups.

Sex	Trabeculectomy		Trabeculectomy with mitomycin C	
	N	%	N	%
Male	6	40	4	26.7
Female	9	60	11	73.3

$X^2 - 0.600$ d.f - 1 P value - 0.439

Table 2: 9 (60%) among those receiving trabeculectomy alone were females and 11 (73.3%) among those receiving trabeculectomy with mitomycin C were females. Both the groups were similar concerning the distribution of sex as indicated by a P-value of more than 0.05.

Table 3 Distribution of diagnosis between the groups.

Diagnosis	Trabeculectomy		Trabeculectomy with mitomycin C	
	N	%	N	%
Both eye Primary narrow-angle glaucoma	3	20	2	13.3
Both eye Primary open-angle glaucoma	12	80	12	80
Right eye primary narrow angle glaucoma	0	0	1	6.7

$X^2 - 3.200$ d.f - 2 P-value - 0.989

Table 3: Among the study participants who had received trabeculectomy, 3 (20%) had both eye primary narrow-angle glaucoma and 12 (80%) had both eyes primary open-angle glaucoma. Among those who received trabeculectomy with mitomycin C, 2 (13.3%) had both eye primary narrow-angle glaucoma, 12 (80%) had both eyes primary open-angle glaucoma and 1 (6.7%) had right eye primary narrow-angle glaucoma. The distribution of diagnosis was found to be similar in both the groups with a P-value of more than 0.05.

Table 4 Distribution of visual acuity in the right eye before surgery.

Visual acuity right eye	Trabeculectomy		Trabeculectomy with mitomycin C	
	N	%	N	%
6/24	5	33.3	5	33.3
6/36	5	33.3	5	33.3
6/60	4	26.7	3	20.0
4/60	1	6.7	1	6.7
1/60	0	0	1	6.7

$X^2 - 1.143$ d.f - 4 p value - 0.887

Table 4: Among the study participants who had received trabeculectomy, 5 (33.3%) had visual acuity of 6/24, and 5 (33.3%) had visual acuity of 6/36. A similar distribution was found among those who had received trabeculectomy with mitomycin C. The visual acuity of both groups was found to be similar to a P-value of more than 0.05.

Table 5 Distribution of visual acuity in the left eye before surgery.

Visual acuity left eye	Trabeculectomy		Trabeculectomy with mitomycin C	
	N	%	N	%
6/12	4	26.7	2	13.3
6/18	1	6.7	2	13.3
6/24	1	6.7	1	6.7
6/36	4	26.7	4	26.7
6/60	3	20.0	4	26.7
5/60	1	6.7	1	6.7
2/60	1	6.7	1	6.7

$X^2 - 1.143$ d.f - 6 p value - 0.980

Table 5: Among the study participants who had received trabeculectomy, 4 (26.7%) had a visual acuity of 6/12, and 4 (26.7%) had visual acuity of 6/36. Among those who had received trabeculectomy with mitomycin C, 4 (26.7%) had visual acuity of 6/36 and 4 (26.7%) had visual acuity of 6/60. Both the groups were found to be similar concerning visual acuity in the left eye with a P-value of more than 0.05

Table 6 Distribution of visual acuity in right eye between the groups immediately after surgery.

Visual acuity right eye	Trabeculectomy		Trabeculectomy with mitomycin C	
	N	%	N	%
6/24	5	33.3	5	33.3
6/36	5	33.3	5	33.3
6/60	4	26.7	3	20.0
4/60	1	6.7	1	6.7

$X^2 - 1.143$ d.f - 4 P value 0.887

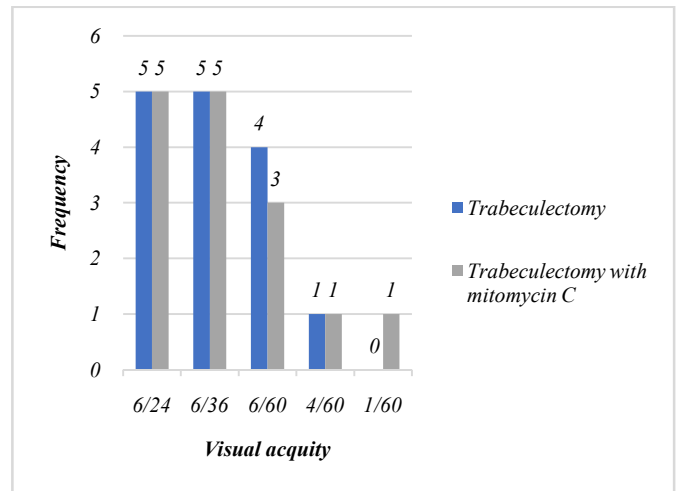


Fig. 1 bar chart showing distribution of visual acuity in the right eye immediately after surgery.

Table 6: & graph 1: Among the study participants who had received trabeculectomy, 5 (33.3%) had visual acuity of 6/24, and 5 (33.3%) had visual acuity of 6/36. A similar distribution was found among those who had received trabeculectomy with mitomycin C. The visual acuity of both groups was found to be similar to a P-value of more than 0.05.

Table 7 Distribution of visual acuity in the left eye between the groups immediately after surgery.

Visual acuity left eye	Trabeculectomy		Trabeculectomy with mitomycin C	
	N	%	N	%
6/12	4	26.7	2	13.3
6/18	1	6.7	2	13.3
6/24	1	6.7	1	6.7
6/36	4	26.7	4	26.7
6/60	3	20.0	4	26.7
5/60	1	6.7	1	6.7
2/60	1	6.7	1	6.7

$X^2 - 1.643$ d.f - 6 P value - 0.949

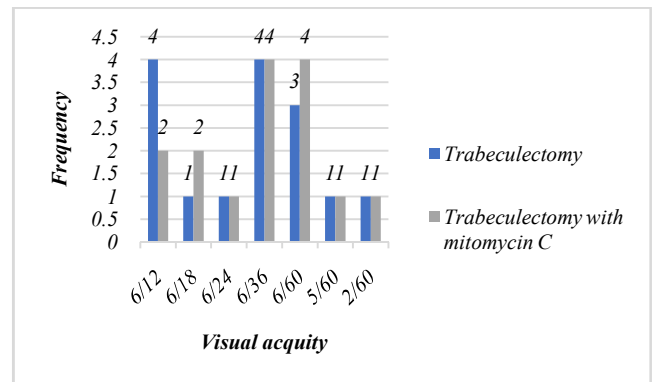


Fig.2 bar chart showing distribution of visual acuity of the left eye immediately after surgery.

Table 7 & graph 2: Among the study participants who had received trabeculectomy, 4 (26.7%) had a visual acuity of 6/12, and 4 (26.7%) had visual acuity of 6/36. Among those who had received trabeculectomy with mitomycin C, 4 (26.7%) had visual acuity of 6/36 and 4 (26.7%) had visual acuity of 6/60. Both the groups were found to be similar concerning visual acuity in the left eye with a P-value of more than 0.05.

Table 8 Distribution of visual acuity in right eye between the groups 3 months after surgery.

Visual acuity right eye	Trabeculectomy		Trabeculectomy with mitomycin C	
	N	%	N	%
6/24	5	33.3	5	33.3
6/36	5	33.3	5	33.3
6/60	4	26.7	3	20.0
4/60	1	6.7	1	6.7

6/24	5	33.3	5	33.3
6/36	5	33.3	5	33.3
6/60	4	26.7	3	20.0
4/60	1	6.7	1	6.7
1/60	0	0	1	6.7

$\chi^2 - 1.143$ d.f - 4 P value 0.887

Table 8: Among the study participants who had received trabeculectomy, 5 (33.3%) had visual acuity of 6/24, and 5 (33.3%) had visual acuity of 6/36. A similar distribution was found among those who had received trabeculectomy with mitomycin C. The visual acuity of both groups was found to be similar to a P-value of more than 0.05.

Table 9 Distribution of visual acuity in the left eye between the groups 3 months after surgery.

Visual acuity left eye	Trabeculectomy		Trabeculectomy with mitomycin C	
	N	%	N	%
6/12	4	26.7	2	13.3
6/18	1	6.7	2	13.3
6/24	1	6.7	1	6.7
6/36	4	26.7	4	26.7
6/60	3	20.0	4	26.7
5/60	1	6.7	1	6.7
2/60	1	6.7	1	6.7

$\chi^2 - 1.643$ d.f - 6 P value - 0.949

Table 9 : Among the study participants who had received trabeculectomy, 4 (26.7%) had a visual acuity of 6/12, and 4 (26.7%) had visual acuity of 6/36. Among those who had received trabeculectomy with mitomycin C, 4 (26.7%) had visual acuity of 6/36 and 4 (26.7%) had visual acuity of 6/60. Both the groups were found to be similar concerning visual acuity in the left eye with a P-value of more than 0.05. There is no change in visual acuity before and after the surgery and during follow-up.

Table 10 Change In Mean Intraocular Pressure Over Time In The Operated Eye

Intraocular pressure	Group	Mean	Std. Deviation	N
Before surgery	Trabeculectomy	30.133	2.9244	15
	Trabeculectomy with mitomycin C	27.800	2.9809	15
After surgery	Trabeculectomy	10.067	2.2824	15
	Trabeculectomy with mitomycin C	7.267	2.2824	15
1 week	Trabeculectomy	12.533	2.1668	15
	Trabeculectomy with mitomycin C	10.600	2.7980	15
1 month	Trabeculectomy	15.867	3.2264	15
	Trabeculectomy with mitomycin C	13.867	2.4456	15
3 months	Trabeculectomy	17.000	2.1712	15
	Trabeculectomy with mitomycin C	15.400	2.1974	15

*Greenhouse Geiser correction.
F value* - 0.346 P value - 0.731

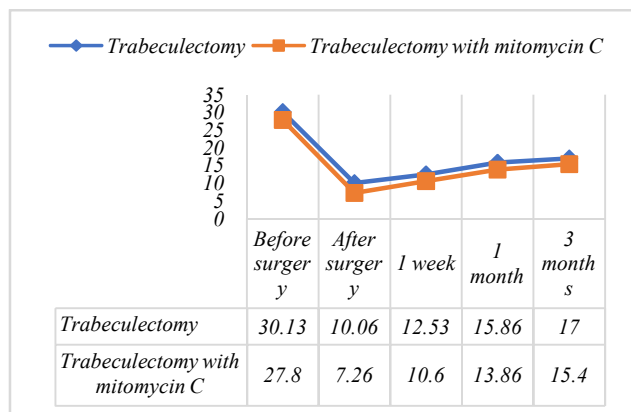


Fig.3 line diagram showing change in IOP over time.

Table 11 Difference in mean IOP between the groups over time.

IOP	Parameter	B	Std. Error	t	Sig.
Before surgery	Intercept	27.800	.762	36.463	.000
	Trabeculectomy	2.333	1.078	2.164	.039
	Trabeculectomy with mitomycin C	0 ^a	.	.	.
After surgery	Intercept	7.267	.589	12.331	.000
	Trabeculectomy	2.800	.833	3.360	.002
	Trabeculectomy with mitomycin C	0 ^a	.	.	.
1 week	Intercept	10.600	.646	16.406	.000
	Trabeculectomy	1.933	.914	2.116	.043
	Trabeculectomy with mitomycin C	0 ^a	.	.	.
1 month	Intercept	13.867	.739	18.760	.000
	Trabeculectomy	2.000	1.045	1.913	.066
	Trabeculectomy with mitomycin C	0 ^a	.	.	.
3 months	Intercept	15.400	.564	27.305	.000
	Trabeculectomy	1.600	.798	2.006	.055
	Trabeculectomy with mitomycin C	0 ^a	.	.	.

Table 11: The trend of intraocular pressure in both the groups was found to be similar to the F value of 0.346 and the P-value of 0.731. The IOP is decreasing in both groups immediately after surgery. With each follows up after the immediate measurement, IOP was found to be increasing. The decrease in the IOP immediately after surgery was found to be more in the trabeculectomy with mitomycin C group than when compared to trabeculectomy alone, similar pattern was also present in the 1st week follow up. But after that, both the group was found to have similar IOP during the 1st month, and 3rd-month follow-up.

DISCUSSION

In our study around 33.33% were males and 66.66% were females. 40% males and 60% females underwent trabeculectomy surgery. 26.7% males and 73.3% females underwent trabeculectomy with Mitomycin C. 46.7% and 53.3% patients in the trabeculectomy and trabeculectomy with mitomycin C respectively group belonged to the age group of 50-59 years. 80% and 20% patients had both eyes primary open angle glaucoma and both eyes primary narrow angle glaucoma in the trabeculectomy group respectively. 80%, 13.3% and 6.7% patients had both eyes primary open angle glaucoma, both eyes primary narrow angle glaucoma and right eye primary narrow angle glaucoma in the trabeculectomy with mitomycin C group respectively. Most patients included in the study had an uncontrolled IOP of >21 mm of Hg despite medical therapy. The ONH C/D ratio was estimated using indirect ophthalmoscope and it was seen that a majority of those needing surgery had advanced glaucomatous cupping. Preop mean IOP for trabeculectomy group was 30.13 mmHg and for mitomycin C group it was 27.8 mmHg. After trabeculectomy and trabeculectomy with mitomycin C, mean IOP of 10.06 mmHg and 7.26 mmHg was observed respectively during the immediate follow up. This was statistically significant with p value of 0.002. The mean IOP after 3 months surgery was 17mmHg and 15.4mmHg for trabeculectomy and trabeculectomy with mitomycin C group respectively. This reduction is consistent with the findings of Baig et al⁴. This was different from the range got by Aktas et al⁵. In that study the mean preop IOP for the trabeculectomy group was 40.2 mmHg and for the mitomycin C group was 29 mmHg. The mean post op IOP for the same was 14.4 mmHg and 10.1mmHg respectively. This difference can be due to their large number of patients and longer follow up.

The mean postop IOP with MMC can be compared to that of the study by Casson et al⁶ where the mean postop IOP was 20.05 mmHg. So the net result of trabeculectomy with MMC in terms of IOP was higher without MMC. Hence our study results were similar to theirs.

Ayala et al.⁷ reported that Mitomycin C add no benefits to IOP reduction after primary trabeculectomies in Swedish population. This is different from our study. It can be because the study they did was a retrospective study and the groups were taken from different time periods, surgeries were performed by multiple surgeons, majority were suffering from exfoliation glaucoma. Reibaldi et al⁸ did a nine year follow up of trabeculectomy and trabeculectomy with MMC in 114 POAG patients. He observed that MMC treated eyes had lower mean IOP of 13.33 mmHg vs 14.72 mmHg which is comparable to our study.

In our study, though visual acuity did change, the effect of surgery on this parameter did not show any difference between the two groups as can be seen from the p-value of 0.887 and 0.949 derived by the Chi-square test. Grading of the blebs by the Moorefields Bleb Grading System (MBGS) showed that when compared to the trabeculectomy group which had flat blebs, those in the trabeculectomy with mitomycin -c group had larger and more diffuse blebs. In terms of bleb and conjunctival vascularisation, both groups were similar. Applying the criteria for success, 93.3% of eyes (14 eyes) in the trabeculectomy group, and 100% of eyes (15 eyes) in the trabeculectomy with mitomycin -c group were deemed to have attained complete success. On looking into the complications encountered in the trabeculectomy with mitomycin C group, allergic reactions were most common .

Singh et al⁹ did study on consecutive series of 20 eyes from 18 patients undergoing trabeculectomy with MMC intraoperatively. He had a mean pre-operative IOP of 30.9 ± 10.9mmHg and a mean postoperative IOP of 15.3 ± 5.2 mmHg which is comparable with our study. He had a success rate of 85% which is different from our study may be because his follow up period was 1 year and the failed surgery patients had other associated eye complications. Rosentreter et al¹⁰ compared trabeculectomy with MMC (10 patients) and trabeculectomy with ologen (10 patients), absolute success at the end of year 1 was 100% in MMC group which is comparable to ours. Kitzawa et al¹¹ study on trabeculectomy with 0.2mg and 0.02mg Mitomycin C showed eleven (100%) eyes in the 0.2-mg group which is comparable to our study. Our success rate is also comparable to Ghazala et al¹² study on the effectiveness of trabeculectomy. Our results are also comparable to that of Baber et al. In their study, out of 46 eyes, the IOP was maintained at below 21 mmHg without medication in 42 eyes (91.3%).

CONCLUSION

Trabeculectomy has traditionally been considered the gold standard surgery for glaucoma. Any new modality is always compared to trabeculectomy in terms of efficacy and complications. Most surgeons find that trabeculectomy tends to fail over a course of time. This is primarily because of the scarring of the bleb and the adjacent conjunctiva. The anti fibrotic agent Mitomycin C regulates the process of bleb formation and ensures minimal scarring and bleb disorganization. It improves the prognosis of glaucoma patients by reducing the severity of progression thereby

preserving vision. It is a safe and effective procedure and has superior IOP lowering effects compared to trabeculectomy although long term IOP control is comparable between both the groups.

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