

A comparative study of surgical outcome in patients with glaucoma treated with trabeculectomy done with and without the use of mitomycin C

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Abstract

Background: Recent population-based studies in southern India have reported various prevalence rates of primary open-angle glaucoma (POAG). The Vellore Eye Survey (VES) reported a prevalence of 0.41% for POAG in the 30-60 year age group whereas the Andhra Pradesh Eye Diseases Study (APEDS) estimated the prevalence of POAG in the urban population to be 2.56% in those aged 40 years and older. **Methodology:** All the patients attending the Out Patient Department of Upgraded Department of Ophthalmology in Medical College Hospital were evaluated and 60 cases of glaucoma were included in the study. **Results:** The nature of the bleb formation on last follow up period in the patients with the use of Mitomycin C and Trabeculectomy alone. Trabeculectomy with the use of Mitomycin C 1 patient each noticed Diffuse bleb + Cystic bleb, Encapsulated bleb, Cystic bleb alone and Most of the patient 37 eyes (92.5%) had diffuse bleb which was always associated with a well controlled intraocular pressure, and without the use of Mitomycin C 17 (42.5%) patients noticed with diffuse bleb and 20(50%) patients noticed with Flat bleb and only 3(7.5%) patients were noticed with Cystic bleb. **Conclusion:** There is significant difference in the two groups on outcome of IOP and percentage reduction($p < 0.0001$).

Key Words: POAG, Trabeculectomy, Mitomycin.

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INTRODUCTION

Glaucoma, one of the common disorders of the eye and it is the leading cause of irreversible blindness in the world. Primary Open Angle Glaucoma (POAG) is the most common cause and presentation of the disease and is estimated to have an incidence of 2.4 million new cases per

year.¹ POAG is recognized as chronic, progressive optic neuropathy that is associated with characteristic cupping and atrophy of the optic disc, Visual Field (VF) loss and open angles.² By appropriate screening and treatment, glaucoma usually can be identified and its progress arrested before significant effects on vision occur. Recorded worldwide 60.5 million people with glaucoma in 2010, and it is predicted that glaucoma will affect more than 79.0 million people by 2020. Glaucoma treatments, either pharmacologically or surgically, are directed toward reducing intraocular pressure (IOP). Since it was first introduced in 1968, trabeculectomy has been the most effective therapy in reducing IOP in patients with medically uncontrollable glaucoma.³ It is a simple economical and versatile technique. Although it has remained the gold standard for the surgical management for the last 30 years. It has a success rate between 67-94 % only in primary glaucoma and 80-90% only in primary

open angle glaucoma. Unlike most other surgical procedures, this filtering surgery can be successfully performed by inhibiting the wound healing process.⁴ Excessive postoperative scarring of the conjunctiva and Tenon's capsule, resulting in new water channels being blocked and poor postoperative control of IOP, has been reported to be the major reason for the failure of Trabeculectomy.⁵

Wound healing modulating agents usually antimetabolites, such as mitomycin C (MMC) and 5-fluorouracil (5-FU), which have been used in Trabeculectomy to delay the wound healing process, can improve the success rate of surgery by inhibiting both inflammation and fibroblastic activity. The antimetabolite, 5-FU best known as an antiproliferative agent in the palliative treatment of colonic and breast cancer, was first described to improve bleb formation after filtering surgery in an owl monkey model 1984. Mitomycin-C a recently discovered antimetabolite first described in a single intra operative application during filtering surgery by Chen in 1983 is an increasingly popular alternative to post-operative 5-FU in eyes with poor prognosis for filtering surgery.⁶ Recent population-based studies in southern India have reported various prevalence rates of primary open-angle glaucoma (POAG). The Vellore Eye Survey (VES) reported a prevalence of 0.41% for POAG in the 30-60 year age group whereas the Andhra Pradesh Eye Diseases Study (APEDS) estimated the prevalence of POAG in the urban population to be 2.56% in those aged 40 years and older. The prevalence of POAG in the Aravind Comprehensive Eye survey (ACES) was 1.2%. On the basis of the available data it is estimated that there are approximately 11.2 million persons aged 40 years and older with glaucoma in India. Primary open angle glaucoma is estimated to affect 6.48 million persons. Projected changes in world population will continue to increase the number and proportion of older people. The concomitant increases in those with cataract and glaucoma will increase the need for diagnostic and therapeutic services.⁷ POAG is a major worldwide health concern, because of its usually silent, progressive nature, and because it is one of the leading preventable causes of blindness in the world. With appropriate screening and treatment, glaucoma usually can be identified and its progress arrested before significant effects on vision occur. Examining and monitoring the optic nerve and the RNFL, structurally and functionally, is important for diagnosis and treatment. Functional loss recorded with automated static threshold perimetry is both sensitive and specific to early loss and provides quantitative data for the monitoring of change.⁸ Clinically, visual field loss often correlates with nerve fibre layer loss and optic nerve damage. The natural evolution of primary open angle glaucoma implies the loss of ganglion cells and their axons in the retina. It is

well established that significant amount of ganglion cell death 25-30% occurs before any visual field defect is produced, thus giving rise to the concept of pre-perimetric glaucoma.⁹ Optical Coherence Tomography is newer non invasive, non-contact technique of measuring thickness of retinal nerve fibre layer. It provides potential means for quantification of RNFL thickness and also for detection and documenting progression of RNFL loss. Careful evaluation of the optic nerve head and RNFL is crucial in glaucoma, not only for diagnosis, but also for providing information about the location and severity of visual field damage. OCT may be useful in glaucoma screening in high risk group.¹⁰

METHODOLOGY

All the patients attending the Out Patient Department of Upgraded Department of Ophthalmology in Medical College Hospital were evaluated and 60 cases of glaucoma were included in the study.

Study design: Prospective study.

Sample size: 80

Mitomycin C: The drug is available in a vial(2mg/ml).It was also obtained from same source as 5-FU.It is further reconstituted with normal saline (5ml)to make 0.4mg/ml or in 10ml to make 0.2mg/ml. The drug should be stored under refrigeration after reconstitution to preserve its potency and under these conditions; it is potent for a period of two weeks only. MMC used as surgical sponge soaked the antimetabolite 2mm x 2mm size of the sponge was used to swell it to 4mm x 4mm with 0.1 ml of MMC. it was stored in refrigerator, and if precipitates were formed, they were dissolved by first warming the drug to room temperature before use.

Inclusion Criteria:

Patients with Primary open angle glaucoma. Patients with Primary angle closure glaucoma. Elevated IOP above the level of 21 mmHg without treatment. Glaucomatous optic disc appearance. Glaucomatous visual field damage. Wide and open angle on gonioscopy. Narrow and closed angle on gonioscopy.

Exclusion Criteria:

Patients who have undergone prior ocular surgery. Normotensive glaucoma. Secondary glaucomas like lens related glaucoma, iris neovascularisation, trauma. Macular degenerations/ maculopathies. Optic neuritis. Chorioretinal degeneration. Arteritic ischemic optic neuropathy. OCT image with signal strength of <4/10 was excluded.

Informed consent was obtained from all the patients. Detailed history was taken from all the patients. All the patients were subjected to detailed history taking regarding following points.

RESULTS

Table 1: Age and gender distribution of cases of PACG

Age Group		Sex		Total
		Female	Male	
31-40 years	N	0	0	0
	%	0	0	0
41-50 years	N	8	6	14
	%	40.0%	30.0%	35.0%
51-60 years	N	9	11	20
	%	45.0%	55.0%	50.0%
61-70 years	N	3	3	6
	%	15.0%	15.0%	15.0%
Total	N	20	20	40
	%	100.0%	100.0%	100.0%

The above table and below graph showing the age and sex wise distribution of patients in our study in PACG patients age range was 31-70 years out of which 20 patients were females and 20 patients were males the most frequent age group age was more than 50.

Table 2: Age and gender distribution of cases of POAG

Age Group		Sex		Total
		Female	Male	
30-40 yrs	N	0	0	0
	%	0	0	0
41-50 yrs	N	7	6	13
	%	36.8%	28.6%	32.5%
51-60 yrs	N	6	10	16
	%	31.6%	47.6%	40.0%
61-70 yrs	N	6	5	11
	%	31.6%	23.8%	27.5%
Total	N	19	21	40
	%	100.0%	100.0%	100.0%

The above table and below graph showing the age and sex wise distribution of patients in our study in POAG patients age range was 31-70 years out of which 19 patients were females and 21 patients were males the most frequent age group age was more than 50.

Table 3: No. of cases of glaucoma filtering surgery with or without MMC

Surgery	No. of Cases	Percent
Trabeculectomy with MMC	40	50.0
Trabeculectomy alone	40	50.0
Total	80	100.0

Table number 3 shows, total number of cases (80) out of which we took 40 cases for trabeculectomy with MitomycinC and 40 cases for trabeculectomy alone.

Table 4: Last follow up bleb changes with the use of Mitomycin C and trabeculectomy alone

	Trabeculectomy +MMC		Trabeculectomy	
	N	%	N	%
D+C bleb	1	2.5	0	0
Diffuse bleb	37	92.5	17	42.5
Encapsulated bleb	1	2.5	0	0
Flat bleb	0	0	20	50
Cystic bleb	1	2.5	3	7.5

The above table shows the nature of the bleb formation on last follow up period in the patients with the use of Mitomycin C and Trabeculectomy alone. Trabeculectomy with the use of Mitomycin C 1 patient each noticed Diffuse bleb + Cystic bleb, Encapsulated bleb, Cystic bleb alone and Most of the patient 37 eyes (92.5%) had diffuse bleb which was always associated with a well controlled intraocular pressure, and without the use of Mitomycin C 17 (42.5%) patients noticed with diffuse bleb and 20(50%) patients noticed with Flat bleb and only 3(7.5%) patients were noticed with Cystic bleb.

Table 5: Outcome of IOP in MMC with trabeculectomy verses trabeculectomy alone

	Trab with MMC		Trab	
	Mean	Standard Deviation	Mean	Standard Deviation
Preopiop	30.30	3.55	33.08	3.29
Day1iop	12.85	1.49	19.65	2.02
Wk1iop	12.45	1.06	18.55	2.60
Wk2iop	12.55	0.90	18.65	2.28
Mth6iop	12.60	0.93	18.95	1.69

Table 5 showing there is significant difference in the two groups on outcome of IOP and percentage reduction.(p=<0.0001)

DISCUSSION

In our study 50% patients were in age group between 51-60 years and 35% patients were in age group 41-50 years and 15% patients were in age group above 60 years. This shows that prevalence of PACG is more above 50 years of age. Increasing age therefore becomes a significant risk factor. American Academy of ophthalmology said: In 2010, the worldwide estimated prevalence of angle-closure glaucoma was 15.7 million with bilateral blindness. Most cases of PACG occur in the sixth to seventh decade of life. It is thought to be explained by age-related growth. PACG is rare in patients younger than 40 years. In our study 40% patients were in age group between 51-60 years and 32.5% patients were in age group 41-50 years and 27.5% patients were in age group above 60 years. Our study shows that prevalence of POAG is more above 50 years of age. Increasing age therefore becomes a significant risk factor. In a study to measure the 4 years risk of open angle glaucoma found that, incidence rate of primary open angle glaucoma increased from 1.2% at age 40-49 years to 4.2% at age of 70 or more.¹¹ In another it was noted that one of the factors that predict the onset of primary open angle glaucoma is older age.¹² Last follow up bleb related changes was found in both the groups of trabeculectomy with MMC and trabeculectomy alone. Our study shows trabeculectomy with MMC groups 2.5% eyes have diffuse+ cystic blebs, 92.5% have diffuse bleb and 2.5% eyes have encapsulated bleb and 2.5% eyes have cystic bleb in trabeculectomy alone group 42.5% eyes have diffuse bleb 50% eyes have flat bleb and 7.5% eye have cystic bleb. On the other hand the preoperative IOP in trabeculectomy alone was (33.08± 3.29)mmHg, and post operative IOP at day1, week1, week2, and 6th month was (19.65 ± 2.02) mmHg, (18.55±2.60) mmHg, (18.65 ± 2.28) mmHg, (18.95 ± 1.69) mmHg respectively with a (p value <0.0001) at all occasion which is significant. An evidence based review of literature October 2002 also showed there was a weak evidence that combined procedure produce slightly worse long term IOP control than Trabeculectomy alone.¹³

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CONCLUSION

Successful management of complications of trabeculectomy with mitomycin C and trabeculectomy alone is anticipating and preventing complications whenever possible and early detection with timely appropriate intervention. However further work is required with a larger number of patients to reach a decisive conclusion.

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