

Intraocular Pressure Control and Post Operative Complications with Mitomycin-C Augmented Trabeculectomy in Primary Open Angle and Primary Angle-Closure Glaucoma

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Purpose: To compare intraocular pressure (IOP) control and post operative complications after trabeculectomy with Mitomycin-C (MMC) in patients with primary open angle glaucoma (POAG) and primary angle-closure glaucoma (PACG).

Material and Methods: Sixty patients of both genders with age range of 40 to 70 years, fulfilling the inclusion criteria were planned for trabeculectomy. The patients were selected from glaucoma clinic who were diagnosed as having POAG or PACG with uncontrolled IOP (more than 22mmHg) with topical anti glaucoma medication. Thirty patients (30 eyes) were randomly enrolled in each group. The patient's IOP was assessed at all post operative follow up visits i.e. at day 1, 1 week, 1 month, 6 months and 1 year with record of post operative complications.

Results: The mean IOP in POAG patients, preoperatively was measured at 22.93 ± 3.9 mmHg. There was a mean drop of 10.63 ± 3.2 mm Hg at 12 months post operatively. The mean IOP in PACG group, registered at $22.13 \text{ SD} \pm 7.44$ mmHg preoperatively. After surgery, mean IOP dropped to 9.42 ± 2.1 mm Hg (Please check this figure) at 12 months follow up. There was insignificant difference between post operative IOPs at different follow ups in both POAG and PACG patients with p-value = 0.092 and 0.34 respectively.

In early post operative phase, out of 30 patients, 18 (60%) had complications in PACG group and 9 (30%) patients had complications in POAG group (p-value= 0.0379).

In late post operative phase, 8 patients (26.6%) had complications with PACG and only 1 (3.3%) patient showed complication in POAG group (p-value=0.0301).

Conclusion: MMC augmented trabeculectomy was beneficial in patients with POAG and PACG with similar control of IOP, although range of complications were on the high side in PACG group but statistically this was found insignificant (p-value=0.0301)

Cairns was the first to describe the partial thickness trabeculectomy in 1967, and it still remains the standard procedure for patients who have failed on maximal medical therapy with uncontrolled intraocular pressure (IOP)¹. The use of intraoperative mitomycin-C (MMC) as an adjunct to standard trabeculectomy has increased the success rate of this procedure over the last couple of decades²⁻⁴.

The final outcome of IOP after trabeculectomy has been variable in different types of glaucoma, different age groups and different races. For example success rate is good in patients with POAG than neovascular type of glaucoma⁵. People over the age of 40 years do well than the patients under 40 years, due to early fibrosis with failure of drainage procedure⁶. From the studies conducted on overseas Asians, the success rate of trabeculectomy in this community appears to be

lower than in Caucasian^{7,8}. African descendents in USA and Europe have poor outcome to surgery with increased failure rate than their white counterparts^{9,10}.

The purpose of our study was to carry out trabeculectomy with MMC on our endogenous population over 40 years of age, either with primary open angle glaucoma (POAG) or primary angle closure glaucoma (PACG), who showed high IOP (>25mmHg) with maximal medical therapy and monitor their IOP control and rate of complications over a period of one year.

MATERIALS AND METHODS

This prospective, comparative case series was carried out at Isra Postgraduate Institute of Ophthalmology, Al-Ibrahim eye hospital, Karachi from January 2005 to January 2006. The permission for the study was granted by institute's ethics committee.

Sixty patients of both genders were recruited from the glaucoma clinic, with 30 patients having POAG and 30 patients with the diagnosis of PACG (mentioning the criteria for diagnosis of POAG and PACG). All these patients were using topical anti-glaucoma medication with their IOP still remaining uncontrolled over 25 mmHg. Patients with diagnosis of PACG had already laser peripheral iridotomy (LPI) carried out. The patients with acute attack of angle-closure glaucoma, secondary glaucoma, pseudopahkic glaucoma and previous history of drainage surgery or tube-shunt procedure were excluded from the study.

The pre-operative work up included a detailed ocular and medical history with slit-lamp biomicroscopic examination of anterior segment, Goldman applanation tonometry, gonioscopy using Goldman 2 mirror lens and dilated fundus examination with plus 90D lens.

Base line IOP measurement was taken with mean of 2 highest values measured at 9:00 am and 4:00pm by Goldman applanation tonometer (GAT). All patients had their optic disc photographs taken and visual fields examined by Humphrey automated perimeter.

The trabeculectomy was performed under peribulbar anaesthesia using fornix based conjunctival flap. Intra operative MMC was applied in concentration of 0.2 mg/ml (0.02%), for duration of 3 minutes in all patients to standardize the procedure. The details of the surgical procedure are described in the literature¹¹. All patients received topical

Moxifloxacin 0.5% (Vigamox-Alcon Belgium) for 4 weeks and Dexamethosone 0.1% (Maxidex-Alcon Belgium) for 8 weeks.

To achieve the target IOP (between 10-15 mmHg) in the early postoperative period, argon laser suture lysis was carried out according to the need in either group.

The intraocular pressure (IOP) was assessed at all postoperative follow up visits i.e. at day one, one week, one month, six months and one year in both groups.

Data analysis

Chi-square test of proportion was used to compare the complications in both groups at 5% level of significance. Mean and standard deviation was computed for age and IOP. Independent sample t-test was used to compare the mean age and IOP between each group. Paired sample t-test was used to compare mean IOP between pre and post operative follow up, while repeated measure ANOVA was used to compare mean IOP of different post operative follow up i.e. post-operative day 1, 1 week, 1 month, 6 months and 1 year.

RESULTS

Out of 30 POAG patients, 24 (80%) were male and 6 (20%) were female with male to female ratio of 4:1. In PACG group 13 (43.3%) patients were male and 17 (56.7%) were female with male to female ratio of 0.8 to 1%. The age range of participants was between 40-70 years with mean + SD 56.42 +11 years.

The mean preoperative IOP in POAG patients was measured at 22.93 ± 3.9 mmHg. The post operative IOP was found 13.23 SD ± 5.7 mmHg at day 1, 12.83 SD ± 5.71 mmHg at 1 month, 10.28 SD ± 4.27 mmHg at 6 months and 12.3 SD ± 4.81 mmHg at 12 months time. There was a mean drop of 10.63 ± 3.2 mmHg at 12 months postoperatively (Table-1).

The mean IOP in PACG group registered at 22.13 SD ± 7.44 mmHg preoperatively. After surgery, mean IOP measured 14.2 SD ± 5.79 mmHg at day 1, 12.17 SD ± 7.23 mmHg at 1 month, 12.13 SD ± 5.91 mmHg at 6 months and 12.71 SD ± 5.18 mmHg at 12 months time. This showed a mean drop of 9.42 ± 2.1 mmHg at 12 months postoperatively (Table 1). Comparison of preoperative and post operative IOP (final follow up after 1 year) is shown in (Fig. 1).

Early postoperative complications were significantly high in PACG patients. Out of 30 patients, 12 (40%) had complications in PACG group and 8 (30%) patients had complications in POAG group (p-Value =0.0379). Early complications noted in both POAG and PACG are shown in table 2. Similarly, Late postoperative complications were significantly high in PACG patients, out of 30 patients, 7 patients (23.3%) had complications, only 1 patient (3.3%) had complication in POAG group.

Four (13.3%) patients were lost in the follow up.

Comparison of late postoperative complications are shown in (Table 3).

Table 1: Comparison of intra ocular pressure (IOP) pre and post operatively in primary open angle glaucoma (poag) and primary angle closure glaucoma n = 60

	POAG Mean± SD mmHg	PACG Mean± SD mmHg
Pre-operative	22.93± 3.9	22.13± 7.44
Post Operative (After One Day)	13.23± 5.7 (p < 0.0001)	14.2± 5.79 (p < 0.0001)
Post Operative (After one Month)	12.83± 5.71 (p < 0.0001)	12.17± 7.23 (p < 0.0001)
Post Operative (After Six Months)	10.28± 4.27 (p < 0.0001)	12.13± 5.91 (p < 0.0001)
Post Operative (After One Year)	12.3± 4.81 (p < 0.0001)	12.71± 5.18 (p < 0.0001)

Table 2: Early postoperative complications

Complication	POAG (n=30)	PACG (n=30)
Flat bleb	4(13.3%)	6(20%)
Hypotony	1(3.3%)	2(6.7%)
Bleb leak	0 (%)	1(3.3%)
Shallow ant chamber	3(10%)	2(6.7%)
Raised IOP	0 (%)	1(3.3%)

Table 3: Late postoperative complications

Complication	POAG (n=30)	PACG (n=30)
Vascularized bleb	1(3.3%)	0 (%)
Flat bleb	0 (%)	2(6.7%)
Shallow ant chamber	0 (%)	1(3.3%)
Late hypotony	0 (%)	2(6.7%)
Tenon cyst	0 (%)	2(6.7%)

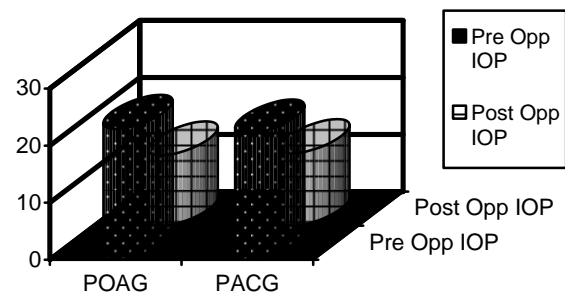


Fig. 1: Comparison between pre-operative and post operative intraocular pressure between poag and pacg groups

DISCUSSION

The large prospective studies such as Ocular Hypertension Treatment Study (OHTS)¹², Collaborative Normal Tension Glaucoma Study (CNTGS)¹³ and Early Manifest Glaucoma Treatment Study (EMGTS)¹⁴ have demonstrated that lower IOPs are associated with reduced risk for progression of visual field damage and visual loss. Despite the inception of multiple anti-glaucoma medications, trabeculectomy has still out performed the medical and laser treatment^{15,16}.

In this study, we performed trabeculectomy with MMC in two groups of patients, either with POAG or PACG, having uncontrolled IOP on anti-glaucoma therapy. We evaluated their IOP control at mean follow up of 12 months and also monitored any complication in early and late post operative period. There was a mean drop of 10.63 ± 3.2 mm Hg in POAG group compared to 9.42 ± 2.1 mm Hg in PACG patients.

Sihota and co-workers¹⁷ studied 64 eyes of 64 patients with POAG and PACG. The overall probability of success of trabeculectomy in controlling IOP to $<$ or $=$ 21 mm Hg with or without additional topical anti-glaucoma medication was 0.94 and 0.88 at 5 and 10 years respectively. There was no statistically significant difference in the qualified and absolute success rate for IOP control between POAG and PACG eyes. Akafo¹⁸ published his results of 81 eyes undergoing trabeculectomy. With 43 eyes having POAG, IOP control less than 21 mm Hg was witnessed in 29 (67%) eyes. On the other hand, 25 of 38 (65%) eyes with PACG required an average 1.5 different anti-glaucoma medications post op for the control of their IOP. In this series of patients, those having PACG though required additional topical anti-glaucoma medication for their IOP control, no adjunctive anti-metabolite was used, which can be one reason for majority of the eyes requiring extra medication. Palenga-Pydn et al¹⁹ reported 59 eyes of 51 patients with long term results of trabeculectomy with MMC. A successful IOP of 15 mm Hg was obtained in 91% in both POAG and PACG groups after 10 years follow up. Poor success rate were reported in Malaysia, where a study performed on 61 eyes of Chinese and Malay ethnicity, examined the results of un-augmented trabeculectomy at 2 years follow up²⁰. These workers found 62% success (IOP $<$ 21 mm Hg, no medications) for POAG and around 45% for PACG patients. Some of the poor results of trabeculectomy noted in literature can be due to un-augmented procedure performed without any use of anti-fibrotic agents. Wu and Yin²¹ randomly assign 40 eyes of 30 patients to receive un-augmented trabeculectomy or trabeculectomy augmented with 0.4 mg/ ml MMC. The MMC group had a 67 % drop in IOP at one year compared to 33% drop in the controlled group.

Although the early and late complications were slightly on high side in group of patients with PACG but this was not found statistically significant. In early postoperative phase, flat bleb was noticed in 13.3% of POAG patients and 20% PACG patients. While second most complication was hypotony seen in 3.3% of POAG patients and 6.7% PACG patients. In a study of 5-FU and MMC-augmented trabeculectomy in a West African population, Singh et al²² found no cases of hypotony maculopathy or choroidal detachment and only three cases of flat anterior chamber in 101 eyes. A report by Ramakrishnan et al²³ reported an incidence of only 0.7 % of hypotony in 778 Indian eyes, which had under gone trabeculectomy with MMC. The cause

for hypotony with anti-metabolite use is due to over filtration at the bleb site or under production of aqueous.

In summary MMC augmented trabeculectomy was found beneficial in lowering the IOP to similar level in patients with POAG and PACG. At the end of one year mean follow up, the difference of complication between two groups was statistically insignificant.

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