Original Article

Midterm outcome of mitomycin C augmented trabeculectomy in open angle glaucoma versus angle closure glaucoma

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Purpose: The purpose of this study is to evaluate the efficacy and safety of Trabeculectomy with Mitomycin C in Open angle glaucoma versus Angle closure glaucoma. **Methods:** The medical records of patients who underwent Trabeculectomy with Mitomycin C were reviewed and followed for three years, divided into two groups: group 1: Open Angle Glaucoma (n = 41) and group 2: Angle Closure Glaucoma (n = 67). Success criterion was measured as Intraocular Pressure ≤21 mmHg with (qualified) or without (complete) use of Antiglaucoma medications. **Results:** A total number of 108 eyes of 137 patients were undertaken. Mean preoperative Intraocular pressure in group 1 was 31.4 ± 10.5 mmHg and in group 2 was 33.1 ± 9.4, which reduced to 10.5 ± 3.4, 10.5 ± 2.6, 11.6 ± 3.6, 11.0 ± 2.7, 11.0 ± 2.7 in group 1 and 10.9 ± 2.8, 12.0 ± 3.8, 12.8 ± 4.9, 12.4 ± 3.9, 12.4 ± 3.7 in group 2 with P value = 0.566, 0.032, 0.168, 0.049, 0.049 at three, six months, one, two, three years, respectively, with $P < 0.001$ at each visit. The number of Antiglaucoma medications was reduced from 0.75 ± 0.89 to 0.43 ± 0.55 at 3 yrs (P = 0.002). At 36 months follow-up, overall, 50.0% and 48.2% of eyes achieved complete and qualified success, respectively. Sub-group analysis showed that the success rate was higher in group 1 (68.3%) compared to group 2 (55.2%). Overall, complications such as hypotony (1.8%), choroidal detachment (2.8%), encapsulated bleb (2.8%), and bleb leakage (1.8%) were encountered. **Conclusion:** Primary Trabeculectomy with Mitomycin C is a safe and effective means of controlling Intraocular Pressure in both groups with good success and low rates of sight-threatening complications.

Access this article online

Website: www.ijo.in

DOI: 10.4103/ijo.IJO_1328_18

Quick Response Code:

Key words: Angle closure glaucoma, Mitomycin C, open angle glaucoma, trabeculectomy

Glaucoma is a multifactorial optic neuropathy with characteristic acquired atrophy of the optic nerve and loss of retinal ganglion cells and their axons, resulting in characteristic visual field abnormalities. Although many hemodynamic factors, such as ocular blood flow and perfusion pressure, have been reported to be associated with the development of glaucoma, intraocular pressure (IOP) remains, to date, the only factor modifiable through different treatment modalities, such as topical eye drops, laser procedure, and surgical intervention.[1-3] Surgery is conducted when maximum tolerated medications and laser therapy fail to control the progression of glaucomatous optic neuropathy.

Since the late 1960s, Trabeculectomy has been the surgery of choice for improving aqueous outflow in glaucomatous eyes; it is still regarded as the gold standard to which the newer surgeries are compared.[4,5] The long-term successful control of IOP in eyes that have undergone primary trabeculectomy has ranged from 48 to 98%, depending on follow-up time and the criteria used to define the successful outcome.[5-13] In most studies, complete success in terms of IOP has been described as an IOP of 21 mmHg or less, without medication.

The success of Trabeculectomy surgery depends on producing a controlled, scar-limited fistula stable enough to maintain adequate aqueous outflow. Factors associated with an increased risk of bleb failure include young age, aphakia, anterior segment neovascularization, inflammation, previously failed glaucoma filtering surgery, and prolonged exposure to ocular hypotensive agents.[14-17] Thus, to enhance surgical success, pharmacologic modulation of wound healing, such as treatment with 5-Fluorouracil and Mitomycin C (MMC) during and after Trabeculectomy, has been investigated since the early 1980s. Chen first applied MMC per-operatively during trabeculectomy for an eye with corneal leucoma and traumatic glaucoma, which had undergone penetrating keratoplasty and two antiglaucoma surgeries.[18] Several randomized controlled trials of intraoperative MMC compared to placebo in Trabeculectomy revealed a reduction of the relative risk of surgical failure.[19-22]

This study was designed to evaluate the long-term outcome of trabeculectomy retrospectively in a series of consecutive cases of Open angle glaucoma (OAG) and Angle closure glaucoma (ACG) that had undergone Trabeculectomy with MMC. The aim was to obtain information on long-term IOP control, further progression of visual field defects, visual impairment and the need for cataract surgery after

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Manuscript received: 25.08.18; Revision accepted: 04.03.19

Cite this article as: Maheshwari D, Kanduri S, Kadar MA, Ramakrishnan R, Pillai MR. Midterm outcome of mitomycin C augmented trabeculectomy in open angle glaucoma versus angle closure glaucoma. Indian J Ophthalmol 2019;67:1080-4.

trabeculectomy, and to evaluate possible factors related to these outcome measures in patients with glaucoma. There are very few published studies in the literature comparing the long-term outcomes of Trabeculectomy with MMC in OAG and ACG. Therefore, it is with this background that this study was undertaken.

Methods

This study involved a retrospective analysis of 137 patients (108 eyes) who underwent MMC augmented Trabeculectomy in Aravind eye hospital, Tirunelveli between January 2013 to December 2013. The mean follow-up period of the final visit was 36 months. After obtaining institutional committee approval, records of patients were reviewed. Exclusion criteria included patients with a follow-up period of less than one year, insufficient hospital records, congenital glaucoma, significant ocular disease other than glaucoma or concurrent cataract surgery. Patients included in this study were OAG + ACG (Primary + secondary) glaucoma who underwent Trabeculectomy with MMC. In all cases, information for follow-up was obtained from the outpatient chart.

Preoperative data and Postoperative data (1, 3, 6, 12, 18, 24, 36 months) included patient's age, sex, type of glaucoma, number, type of Antiglaucoma medications (AGM), duration of medications, preoperative IOP with Goldmann applanation tonometer, cup/disc ratio, Best-corrected visual acuity (BCVA) using Snellens chart (Aurochart digital vision chart, version 2, Madurai, Tamilnadu, India), and visual fields (24-2, 10-2) using Humphrey Automated Perimetry (Zeiss model, Germany).

All surgeries were performed by using Conventional Trabeculectomy technique. A superior rectus bridle suture/corneal traction suture was applied. After a fornix-based conjunctival flap was created, the Tenon's capsule was dissected and adequate cautery applied. A sponge soaked in MMC (0.2 mg/ml) was placed under the conjunctival flap and removed after 2 minutes. The area was then irrigated copiously with 15-20 ml saline solution. A half-thickness, triangular scleral flap was dissected. Paracentesis was made with 15-degree blade. A viscoelastic agent was put. Anterior chamber (AC) entry was made with keratome. A block of sclera bed including trabecular meshwork was removed with a trabeculectomy punch (Kelly's punch). A broad-based Peripheral iridectomy was performed. The scleral flap was sutured with three 10-0 nylon, using the releasable suture method. The conjunctival flap was closed with 8-0 vicryl using either interrupted sutures/Wise technique. Watertight closure was performed with no leaks. AC was formed and Bleb raised.

Postoperatively, eye drops Dexoren S (Dexamethasone 0.1% + Chloramphenicol 0.5%, Indoco Remedies Ltd., Mumbai, Maharashtra, India) tapered from 8 times over a period of 12 weeks, eye drops Homide (Homatropine 2%, Aurolab, Madurai, Tamilnadu, India) 2 times, 1 time per day for 15 days, Injection Dexasone 2 ml (Dexamethasone sodium phosphate, Cadila Pharmaceuticals, Ahmadabad, Gujarat, India) stat were given. Any postoperative complications/procedures were recorded.

Complete success was defined as IOP ≤21 mmHg without any additional medication, whereas qualified success was defined as IOP ≤21 mmHg with or without medication. Failure was defined as uncontrolled IOP >21 mmHg despite medical treatment, or when an additional intervention (such as bleb revision, repeat trabeculectomy, or diode laser cyclodestruction, etc.) was required.

Statistical analysis

Mean Standard deviation (SD) and Frequency (%) was used to describe summary information. Chi-square test or Fisher's exact test was used to assess the association between categorical variables. Group comparison for continuous variables was made by using Student's *t*-test or Mann – Whitney U test. *P* value of less than 0.05 was considered as statistically significant. Statistical analysis was done by STATA 11.1 (Texas, USA).

Results

A retrospective study comprising of a total number of 108 eyes of 137 patients is undertaken. Primary Trabeculectomies were performed with MMC during the period of the study; however, 14 patients had less than one year of follow-up and were excluded because of insufficient hospital records. In total, 41 eyes in the OAG group were compared to 67 eyes in the ACG group. Demographic data of the study population are presented in Table 1.

IOP

Mean preoperative IOP was 31.4 ± 10.5 mmHg in the OAG group and 33.1 ± 9.4 mmHg in the ACG group (*P* = 0.384).

Table 1: Demographic data of the study population

Characteristics	All patients	OAG	ACG	*P*
Age				0.566[t]
Mean (± SD)	56.27±8.9	56.90±10.2	55.88±8.1	
Range	32-77	32-77	39-76	
Gender (*n*)				0.007[c]
Male	64 (59.3)	31 (75.6)	33 (49.2)	
Female	44 (40.7)	10 (24.4)	34 (50.8)	
Visual acuity (log MAR)				0.382[m]
Mean (± SD)	0.32±0.28	0.30±0.30	0.34±0.28	
Range	0-1.08	0-1.08	0-1	
Preoperative IOP (mmHg)				0.384
Mean (± SD)	32.50±9.9	31.44±10.50	33.15±9.45	
Range	6-68	16-68	6-58	
Preoperative medications				0.046
Mean (± SD)	0.75±0.89	0.95±0.89	0.63±0.87	
Range	0-3	0-3	0-3	
Preoperative HFA MD				0.622[t]
Mean (± SD)	22.09±8.93	22.64±9.15	21.76±8.84	
Range	0.52-33.84	0.52-32.72	2.12-33.84	
Preoperative HFA PSD				0.257[t]
Mean (± SD)	7.39±3.25	6.93±3.27	7.67±3.23	
Range	1.32-14.44	1.32-14.44	1.56-14.26	

SD: standard deviation, MD: mean deviation, PSD: pattern standard deviation, OAG: open angle glaucoma, ACG: angle closure glaucoma, c-Chi Square Test, **P* < 0.05, *t* - paired *t* test, m - Mann Whitney

At the final follow-up, the OAG group had a greater mean total IOP reduction compared to the ACG group (11.0 ± 2.7 mmHg vs 12.4 ± 3.7; $P = 0.049$) which is of borderline statistical significance [Table 2].

Success and failure rate at follow-up visits

Overall, the success rates of complete and qualified success are 50% and 48.2%, respectively. Sub-group analysis showed that complete success was 68.3% in OAG and 55.2% in ACG at 36 months follow-up. The failure rate was 2 (3%) in the ACG group. The success rate was higher in the OAG group compared to the ACG group [Table 3].

Number of AGM

The number of AGM decreased from 0.9 ± 0.8 to 0.3 ± 0.5 ($P = 0.0003$) in the OAG group and from 0.6 ± 0.8 to 0.4 ± 0.5 ($P = 0.3157$) in the ACG group. However, the OAG group had a statistically significant reduction in AGM compared to the ACG group.

Postoperative complications

On intergroup comparison [Table 4], there is no significant difference between two groups ($P > 0.99$). In the immediate postoperative period (one month), there were a large proportion of cases (41.6%) with raised IOP (>21 mmHg). Among these patients, 3/4th of ACG and 1/4th of OAG underwent Argon laser suture lysis (ALS). In total, three in OAG and seven in ACG required Releasable suture removal. Also, digital message was performed in ten eyes with flat bleb in both groups.

In total, 3% of ACG developed Hypotony who experienced spontaneous recovery. Choroidal detachment (CD) developed in two (3%) of ACG and one (2.4%) of OAG, which subsided after oral steroids in ACG and OAG without any treatment. Bleb leakage developed in two eyes of ACG, which was managed medically. In total, 3% of ACG and 2.4% of OAG had encapsulated bleb. These eyes received bleb needling.

Intraocular lens implantation (IOL) was performed in 24.4% of OAG and 37.3% in ACG within one year after primary Trabeculectomy. There is a significant ($P = 0.003$) improvement in Best corrected visual acuity (BCVA) in the ACG group compared to the OAG group at the final visit.

Table 2: Comparison of intraocular pressure in open angle glaucoma vs angle closure glaucoma

Visits	OAG (n=41)		ACG (n=67)		P*
	Mean (SD)	Range	Mean (SD)	Range	
Preoperative	31.44 (10.50)	16-68	33.15 (9.45)	6-58	0.384
One month	17.02 (9.79)	2-36	15.13 (7.18)	4-38	0.251
Three month	10.58 (3.49)	5-24	10.94 (2.86)	2-22	0.566
Six month	10.58 (2.68)	7-16	12.07 (3.84)	7-26	0.032
First year	11.63 (3.66)	5-26	12.88 (4.98)	6-40	0.168
Second year	11.05 (2.77)	5-19	12.46 (3.99)	7-28	0.049
Third year	11.05 (2.75)	5-18	12.40 (3.79)	6-28	0.049
P#	<0.001		<0.001		-

OAG: open angle glaucoma, ACG: angle closure glaucoma, SD: standard deviation, *$P < 0.05$, #Mann Whitney

Discussion

The principal aim of this study was to determine the success rates for long-term IOP control after primary conventional Trabeculectomy with MMC in OAG vs ACG and the need for further treatment either medical or surgical. Based on clinical experience and the literature, in the high-risk cases including young patients, black patients, eyes with failed trabeculectomy, trauma, aphakia, active uveitis or neovascular glaucoma, the routine filtration surgery will often fail.[23]

The goal of filtering surgery is to reduce and maintain the IOP at a level that will prevent further optic nerve damage and visual field loss. The most common cause of failure after filtering surgery is scarring at the filtration site due to excessive fibrosis.[24] Various anti-fibrotic agents have been used to increase the success rates of glaucoma filtration surgery, particularly in these high-risk cases.[24]

Since medical therapy was equally as effective as surgical therapy in preventing glaucomatous visual field progression according to Collaborative Initial Glaucoma Treatment Study, patients requiring surgery have usually received AGM for a long time.[25] Aggressive medical therapy increases the number of inflammatory cells and enhances the risk of external bleb scarring and filtration surgery failure. That is the reason, almost all types of glaucoma patients in our practice, including primary and secondary, received concurrent MMC application during trabeculectomy.[25]

We found the three-year success rates for IOP control after primary Trabeculectomy in the OAG (68.3%) group were higher compared to the ACG (55.2%) group. This could be attributed to more postoperative complications in the PACG Group, and particularly more number of cataract extraction in the PACG group, which eventually led to poor IOP control. Cataract extraction has been reported elevated IOP in post-trabeculectomy ACG eyes which could be applicable in our study also. Moreover, in PACG eyes, anatomical arrangements risk the eye to shallow/flat AC, aqueous misdirection, and cilochoroidal effusion.

In contrast, a study conducted by Sihota *et al.* showed ten-year success rates for IOP control in Primary Angle Closure Glaucoma (PACG) comparable to those in Primary Open Angle Glaucoma (POAG) eyes.[26] Overall, the percentage of eyes

Table 3: Success and failure rate at follow-up visits

Outcome	OAG (n=41)			ACG (n=67)		
	First year	Second year	Third year	First year	Second year	3rd year
Complete	32 (78.1%)	28 (68.3%)	28 (68.3%)	42 (62.7%)	37 (55.2%)	37 (55.2%)
Qualified	8 (19.5%)	13 (31.7%)	13 (31.7%)	20 (29.9%)	26 (38.8%)	28 (41.8%)
Failure	1 (2.4%)	-	-	5 (7.4%)	4 (6.0%)	2 (3.0%)

OAG: open angle glaucoma, ACG: angle closure glaucoma

Table 4: Comparison of postoperative complications in open angle glaucoma vs angle closure glaucoma

Postoperative complications	OAG (%)	ACG (%)	Total	*P*
Hypotony	0	2 (3.0)	2 (1.8)	>0.99[1]
CD	1 (2.4)	2 (3.0)	3 (2.8)	
Encapsulated bleb	1 (2.4)	2 (3.0)	3 (2.8)	
Bleb leakage	0	2 (3.0)	2 (1.8)	

OAG: open angle glaucoma, ACG: angle closure glaucoma, CD: Choroidal detachment, [1]Fisher's exact test

receiving AGM was reduced for both groups in our study, which varies in different studies, ranging from 1% to 49%.[8,27-29]

Progressive visual field loss after trabeculectomy was documented to be insignificant at final visit in this study, whereas there has been visual field loss which was reported to be 50-60% after 10-22 years in a study conducted by Sihota *et al*.[26] However, our follow-up lasted only for three years.

In our practice, 62 eyes (57.4%) developed complications such as hypotony, CD, bleb leak, encapsulated bleb, cataract, etc., which is comparable to the study conducted by Ching *et al.*, in which 86 eyes (58.5%) encountered complications.[25]

In this study, the overall incidences of postoperative complications till final visit were insignificant between two groups. However, results were comparable between PACG and POAG groups in the study conducted by Tan, Fang *et al*.[30]

In our study, two eyes (1.8%) developed hypotony, CD and three (2.8%) eyes developed encapsulated bleb, which is similar to another study conducted by Cheung *et al*.[24] This may be related to MMC application during filtering surgery which often leads to the formation of thin-walled, avascular blebs leading to low outflow resistance, overfiltration, and finally causing hypotony.[31] Also, these thin-walled blebs are prone to leakage subsequently leading to the development of blebitis or endophthalmitis. In a retrospective study of trabeculectomy with MMC, only one eye (0.7%) developed bleb leakage which is comparable to our case series in which two eyes (1.8%) developed bleb leakage.[32]

In this study, cataract progression developed in 48.1%; out of which, 32.4% underwent extraction. In a similar study conducted by Rajiv *et al*., 55.3% underwent subsequent cataract surgery after trabeculectomy.[33] Cataract progression or formation may be possibly related to the surgery/aging/caused or accelerated by MMC. The exact etiology is unknown.

In the present study, ALS was performed in 35 (32.4%) eyes and releasable sutures were put in 10 (9.3%) eyes. In a study conducted by Bindlish *et al.*, ALS was performed in 35.7% of eyes in Whites.[33] A proper technique must be adopted to control filtration (either releasable suture or ALS) or to prevent over-filtration in the early postoperative period.

In our current study, there is a significant improvement in BCVA in the ACG group compared to the OAG group. This can be attributed to a higher number of cataract surgeries performed in the ACG group.

There are certain limitations in our study which include its retrospective design, intermediate term follow-up, and loss of follow-up. Different experienced surgeons were involved in the management, so there can be a difference because of the surgeon's factor. All these could have been causes for bias in our study.

Previous studies have shown successful long-term outcomes and IOP reduction after Trabeculectomy in the setting of OAG.[34] As a result of the anatomic abnormalities that accompany ACG, there is an increased risk of severe postoperative complications, such as aqueous misdirection, following filtration surgery in these patients.[34] However, very few studies in the literature compared long-term outcomes of trabeculectomy with MMC in ACG vs OAG.

Conclusion

In conclusion, our study suggests that anti-fibrotic agent assisted Trabeculectomy achieves a favorable midterm successful outcomes in IOP control in patients with OAG when compared to ACG. However, a long-term follow-up is required to evaluate the tonometric outcomes. In spite of Trabeculectomy related complications, if managed effectively with a tailored regimen, surgical outcome is as good as a normal eye.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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