

ORIGINAL ARTICLE

SHORT TERM TONOMETRIC OUTCOME OF PRIMARY TRABECULECTOMY, MENELIK II REFERRAL HOSPITAL, ADDIS ABABA, ETHIOPIA

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ABSTRACT

Background: Trabeculectomy with Mitomycin-C is the standard surgical management of glaucoma. It has been performed in Menelik II Hospital for years but the outcome has never been evaluated.

Objective: To evaluate the tonometric outcome of primary trabeculectomy with Mitomycin-C in primary open angle glaucoma and pseudoexfoliative glaucoma patients at Menelik II Hospital, Ethiopia.

Methods: A retrospective chart audit of patients with primary open angle glaucoma and pseudoexfoliative glaucoma that underwent primary trabeculectomy with Mitomycin-C in 2014 was evaluated. The surgery was done by two glaucoma specialists. The tonometric outcome of trabeculectomy with Mitomycin-C was based on a set operational definition.

Results: A total of 166 charts of patients were reviewed; 98 (59%) were males and 68 (41%) were females. Primary open angle glaucoma accounted for 86 (52.4%) and Pseudoexfoliative glaucoma for 79 (47.6%). Majority of patients 150 (91%) were between 50-79 years of age. The mean (SD) intraocular pressure before surgery was 31.4 (± 8.4) mmHg and 11.8 (± 6.5) mmHg six months after surgery. At six months post-operative follow up, complete success was found in 60.2% and qualified success in 27.1%, failure 9.6%, and hypotony 3.0% of the patients. The overall success at six months post-operative follow up was 87.3%. It was 88.5% for primary open angle glaucoma and 86.1% for Pseudoexfoliative glaucoma patients. Complete success was found to be 52.8% and 48.0% for Primary open angle glaucoma and Pseudoexfoliative glaucoma patients respectively.

Conclusions: Primary trabeculectomy with Mitomycin-C is safe and has good short-term outcome among Ethiopian patients at Menelik II Hospital. The procedure has comparable success in patients with both Primary open angle glaucoma and Pseudoexfoliative glaucoma.

Key words: Primary open angle glaucoma, Pseudoexfoliative glaucoma, Mitomycin-C, Trabeculectomy, Intraocular pressure.

INTRODUCTION

Glaucoma is defined as a progressive loss of retinal ganglion cells and their axons, and this process is believed to be slowed down by lowering the Intraocular pressure (IOP) at all stages of the disease. It is one of the leading cause of irreversible blindness in Ethiopia and Primary open angle glaucoma and Pseudoexfoliative glaucoma are the most common sub-types (1-3).

Intraocular pressure is the only modifiable risk factors as demonstrated in studies reporting reduced visual field progression when IOP has been lowered. Therefore, the management of glaucoma is often emphasized on optimal IOP reduction in order to prevent or delay the disease progression (4-6). Lowering of IOP could be achieved with medical, laser or surgical treatment.

Partial thickness trabeculectomy remains the standard surgical procedure for glaucoma patients with uncontrolled IOP (6-8). The refinement of surgical technique and adjunctive usage of antimetabolites such as 5-Fluorouracil (5-FU) and Mitomycin C (MMC) further improved the success rate and survival of trabeculectomy over the past decades. It is believed that trabeculectomy has not only outperformed the medical treatment in lowering the magnitude of the IOP, but also the diurnal fluctuation of IOP. Nevertheless, the final outcome of this surgical therapy is variable in different age group, different types of glaucoma and different ethnicity (7, 9).

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Trabeculectomy even with MMC was considered a failure in African patients but studies are disproving the premise. MMC was found to be efficacious in African patients and increased the success rate of the procedure (10-12). Even though trabeculectomy with MMC has been performed for hundreds of glaucoma patients (majority of them being Primary open angle glaucoma (POAG) and Pseudoexfoliative glaucoma (PXG) annually at glaucoma unit, Menelik II Hospital, the outcomes of the procedure was not evaluated.

Among the challenges in the management of glaucoma patients in our setup are the cost and availability of medications. As many of our patients are poor and come from almost every corner of the country travelling long distances, having a successful surgical outcome not only delays the progression of the disease but also greatly reduces the financial burden per patient in particular and of the country in general. Therefore, the aim of this study was to evaluate the short-term tonometric outcome of primary trabeculectomy with MMC done with and without releasable stitches for POAG and PXG.

PATIENTS AND METHODS

It was a retrospective chart audit of all patients 40 years and above, who underwent primary trabeculectomy with MMC for PXG and POAG from January 1 to June 30, 2014 at Menelik II hospital. Patients who had no intraoperative complications during the procedure and with no previous or later intraocular surgery were included. The research and publication committee of the department of Ophthalmology, College of health sciences, Addis Ababa University approved the study.

There were two glaucoma surgeons who did the procedures. Both surgeons did fornix based trabeculectomy with MMC 0.04% applied for 2-3 minutes and washed with copious amount of normal saline. The sclera flaps were rectangular and peripheral iridectomy was performed. In patients with high intraocular pressure, trabeculectomy was done after slowly lowering IOP through paracentesis. The scleral flaps were approximated and conjunctiva was closed water tight conjunctival using 9/0 nylon.

For all patients, Gentamycin and Dexamethasone were injected sub-conjunctival at the end of the surgery. Ciprofloxacin 0.3% eye drops and 0.1% Dexamethasone eye drops were applied post operatively.

There were few surgical differences between the two glaucoma surgeons. Based on the two techniques, patients were categorized as group A and group B.

In group A, the surgeon applied MMC under scleral flap, sclerostomy was made by using Kelly punch and all stitches were permanent. In group B, MMC was applied under the conjunctiva before scleral flap was made; sclerostomy was cut by blade and venues scissors, scleral flaps closed by two releasable and one permanent suture.

The outcome measure was IOP control with or without anti-glaucoma medication at six months post operatively. The tonometric outcome of trabeculectomy with MMC was assessed based on the following operational definition: Complete success: if the mean IOP was ≤ 21 and > 5 mmHg without anti-glaucoma medications, qualified success: if the mean IOP was ≤ 21 and > 5 mmHg with anti-glaucoma medication, failure: if mean IOP was > 21 mmHg with anti-glaucoma medication and hypotony: if IOP was ≤ 5 mmHg. Stages of glaucoma was decided based on vertical cup-to-disc ratio (VCDR). Early if VCDR was ≤ 0.65 , moderate if VCD R was 0.7 to 0.85 and advanced if VCDR was > 0.85 . Data were coded, entered onto and analyzed using SPSS version 21.0. We used Chi square test and binary logistic regression to see association.

RESULTS

A total of 166 charts of patients which fulfilled the inclusion criteria were analyzed. All the 166 patients had follow up at six months post operation. Among the 166 patients 98 (59%) were males and 68 (41%) were females. Majority of the patients (91%) were in the age range between 50 to 79 years. Those between 40 to 49 years were 7.8% and above 80 years were only 1.2% (Table 1).

Table 1: Age and Sex distribution of the study population. Menelik II Hospital, Addis Ababa, Ethiopia. 2014.

Age (in years)	Male	Female	Total
40-49	9	4	13 (7.8%)
50-59	34	21	55 (33.1%)
60-69	42	28	70 (42.2%)
70-79	13	13	26 (15.7%)
≥ 80	0	2	2 (1.2%)
Total	98 (59%)	68 (41%)	166 (100%)

Majority of the patients were from Addis Ababa and Oromia Regional state accounting for 48.8% and 35.5%, respectively and together they constituted 84.3%. The rest were shared among the other regional states.

The types of glaucoma were fairly close; POAG accounting for 52.4% and PXG for 47.6% cases. The pre-surgery IOP documented on the 166 patient charts ranged from 21 to above 50mmHg taken with I care for all patients. Majority of the patients, 136 (81.9%) had IOP between 21 and 40 mmHg. The IOP record of the patients could be before or after the initiation of anti-glaucoma medications (**Table 2**).

The mean IOP before surgery was 31.4 ± 8.4 mmHg. Before surgery, except one patient, all patients were applying either 0.5%Timolol alone or 0.5%Timolol with 4% Pilocarpine (99.4%). Fifty seven (34.3%) of the patients were given Acetazolamide tablets before surgery. By the time the patients were operated, 58.4% had advanced, 31.3% had moderate and 10.2% had early stage of glaucoma.

Table 2: Pre operation Intra ocular pressure in different age group of the study population, Menelik II Hospital, Addis Ababa, Ethiopia. 2014.

Intraocular pressure before surgery, (mmHg)	Age					Total
	40-49	50-59	60-69	70-79	>80	
21-30	5	22	34	16	2	79 (47.6%)
31-40	6	20	24	7	0	57 (34.3%)
41-50	2	12	11	3	0	28 (16.9%)
>50	0	1	1	0	0	2 (1.2%)
Total	13 (7.8%)	55 (33.1%)	70 (42.2%)	26 (15.7%)	2 (1.2%)	166 (100%)

At six-month post operation follow up, complete success was found to be 60.2% and qualified success was 27.1%. Failure was seen in 9.6% and Hypotony in 3.0%. The overall success (both complete and qualified success) was 87.3%. The mean (SD) IOP at six month was 11.8 (± 6.5) mmHg (Table 3). The

Among the failure group, 11 (11.2%) were males and five (7.3%) were females and hypotony was three in males and two in females. Complete success was 60.2% and 60.3% in male and female patients, respectively, at six months. There was no statistically significant difference between the males and females

Table 3: The level of Intra ocular pressure at six months post operation. Menelik II Hospital, Addis Ababa Ethiopia 2014.

Intraocular pressure, in mmHg	Diagnosis		Total
	Primary open Angle Glaucoma	Pseudoexfoliative glaucoma	
>5 to ≤ 21	77	68	145 (87.3%)
>21	7	9	16 (9.6%)
≤ 5	3	2	5 (3.0%)
Total	87	79	166 (100%)

The overall success of trabeculectomy with MMC at six month follow up was 88.5% in POAG patients and 86.1% in PXG patients. Complete success was found to be 52.8% and 48.0% for POAG and PXG patients, respectively. The qualified success was 35.6% for POAG and 38.0% for PXG. Failure was 8.0% in POAG and 11.4% in PXG patients; and hypotony was seen in 3.4% and 2.5% for POAG and PXG respectively. The success and failure rate of the procedure was not significantly different between sub-types of glaucoma at the six month ($p=0.479$).

Comparison was made between group A and group B at six months. The overall success was 83.7% in group A and 91.2% in group B. Complete success in group A was 46.5% and 54.9% in group B; and the qualified success was 37.2% in group A and 36.3% in group B. Failure was 12.8% and 6.3% while hypotony was 3.5% and 2.5% in group A and B, respectively.

Binary logistic regression was used to test for association but there was no statistically significant difference between the groups at six months ($p=0.155$). The post-operative complications were hypotony and failing or failed bleb. Hypotony was seen in five patients (three males and two females) at six months follow up. One of the hypotony patients was a 65-year old male with choroidal effusion and drainage and anterior chamber reformation was done. Failing bleb or failed bleb was seen in nine patients (seven males and two females). These patients were managed with needling and MMC (two patients before six months).

The six month post operation IOP had no statistical association with age, stage of glaucoma, pre-operation IOP or pre-operation medications. But post operation anti-glaucoma drops had statistically significant association with IOP ($p<0.0001$) (Table 4).

Table 4: Number of anti -glaucoma drops at six-month post operation, Menelik II Hospital, Addis Ababa, Ethiopia 2014.

Number of anti-glaucoma drops	Diagnosis		Total
	POAG	PXG	
One	21	19	40 (24.0%)
Two	10	11	21 (12.7%)
No drop	56	49	105 (63.3%)
Total	87(52.4%)	79 (47.6%)	166 (100%)

DISCUSSION

Fibrosis of the sub conjunctival tissue may lead to bleb failure, decreasing the long-term success of trabeculectomy. The introduction of adjuvant antimetabolites such as MMC has improved the long-term success of trabeculectomy. Although subsequent studies have supported the beneficial effects of MMC on post-operative IOP reduction and filtration bleb survival, the benefits has been tempered by associated complications, including hypotony maculopathy (12-14).

The results in this study has shown that the overall success of primary trabeculectomy with MMC was 87.3% at six-month post operation. There was no published article on six-month post-operative IOP control; which made comparison difficult. Success rate of trabeculectomy with MMC was 81.8% in Congolese patients and the rate of complication was high (15). The success rate is comparable to our study results.

Our study showed that bleb failure was higher among younger age group; which is similar to other study done in black American glaucoma population (16). Complete success for men and women was the same. Studies done one-year post trabeculectomy showed an overall success rate of 92% in UK (a review of trabeculectomies done by different glaucoma surgeons with wide variability's of surgery) (17). Another study in USA showed an overall success rate of 85.4% (18).

At six months post operation, the overall success in POAG patients was 88.5%; with complete success of 52.8%. In one study done in Oman on 22 eyes of POAG patients, complete success was found in 48%, qualified success was 18% and failure was 36% in patients who had a minimum of six months follow up (19). As most literatures are on long term outcomes, there are few papers to compare our results with. In our study, hypotony was lower compared to some studies; 3% in 166 patients versus 8.5% in 47 eyes in African Caribbean patients (20).

POAG patients had a slightly better overall success compared to PXG patients between six and 12 months post operatively. On relative comparison, bleb failure was higher among PXG patients and hypotony in POAG patients. This could be due to more inflammatory response in PXG patients. Stage of glaucoma was not related to tonometric outcome. This could be because most of the patients had advanced glaucoma. The most important finding in this study was comparing a combination of trabeculectomy with MMC and releasable stitch with no releasable stitches. The success rate was higher among releasable stitch group.

Complete success was 60.2% and it is a very significant achievement for most of our patients with poor adherence. Thus, trabeculectomy with MMC is recommendable to patients with uncontrolled glaucoma in our population. The limitations of the study include absence of visual acuity and visual field evaluation. Generally being a retrospective study had its own shortcomings: but had shown the tonometric success in our setup.

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In conclusion, primary trabeculectomy with MMC is safe and has good short-term outcome in IOP control among Ethiopian patients at Menelik II hospital. The tonometric outcome is comparable in POAG and PXG patients. Any stage of glaucoma could achieve tonometric success if done by an experienced glaucoma surgeon. Further prospective study with long term follow-up that includes other parameters like visual field and Visual acuity evaluation is recommended.

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