Outcomes of trabeculectomy among glaucoma patients in Uganda: A 4-year hospital based audit

Mbumba FB[1], Hirnschall N[2], Arunga S[1,3], Kwaga T[1], Onyango J[1], Rigal K[2]

[1]Ophthalmology Department, Faculty of Medicine, Mbarara University of Science and Technology, Uganda
[2]Vienna Institute for Research in Ocular Surgery (VIROS), a Karl Landsteiner Institute, Hanusch Krankenhaus, Vienna, Austria
[3]International Centre for Eye Health, London School of Hygiene & Tropical Medicine, UK

Corresponding author: Dr Simon Arunga, Mbarara University of Science and Technology, Mbarara, Uganda.
Email: sarunga@must.ac.ug

ABSTRACT

Objective: To determine the outcomes of trabeculectomy surgery and predictors of post-operative Intra Ocular Pressure (IOP) among glaucoma patients attending Ruharo Eye Centre.
Materials and Methods: In a clinical audit conducted from January to June 2016, we reviewed records of all patients who had undergone trabeculectomy at Ruharo Eye Centre (REC), at least in one eye prior to recruitment. We made phone calls to patients inviting them for a clinical examination. For the patients who turned up, we recorded their Best Corrected Visual Acuity (BCVA), Visual Fields (VFs), Intra Ocular Pressure (IOP), Cup-Disc Ratio (CDR), and any post-operative complications. We also asked patients about their general satisfaction with both the operation and vision. We did a before and after comparison analysis on several outcome measures using STATA v14. These included: visual acuity, intra ocular pressure, cup disc ratio and visual field. We defined treatment success as a post-operative IOP reduction of 40% from baseline and analyzed for its predictors in a multivariate regression model.
Results: Sixty-two eyes of 38 patients were included in this study. Median age was 66 years (range 24 to 91 years). Median observation time was 2.8 years (range 0.2-4.6 years). Overall treatment success rate was 95%. Mean IOP pre-and post-operatively was 32 mmHg (95% CI 29.3-34.7) and 12.9 mmHg (11.7-14.2) respectively, P=0.001; there was no significant worsening of visual acuity and visual field loss. Mean visual acuity Log MAR pre and post-operatively was 0.58 (95% CI 0.48-0.68) and 0.65 (95% CI 0.52-0.78), P=0.21. Mean visual field defect was 23.4 (95% CI 21.4-25.5) and 22.9 (95% CI 20-9-25.0), P=0.44.
Conclusion: Trabeculectomy in our setting seemed to have a good success rate and provided good IOP control, preservation of vision and visual fields.

Key words: Glaucoma, Trabeculectomy, Intraocular pressure, Uganda

INTRODUCTION

Glaucoma has been reported as the second leading cause of global blindness after cataract and furthermore as the leading cause of irreversible blindness largely due to primary open angle glaucoma[1]. Bilateral blindness from glaucoma is projected to have affected 11 million individuals worldwide by 2020[1-3].

Based on randomized controlled trials, the only reliable treatment for glaucoma is to decrease intraocular pressure. The therapeutic options in glaucoma include drugs, laser and surgical treatments. The appropriate glaucoma therapy must be considered according to the individual patient, the type of glaucoma, and the stage of the disease [4-6].

In developing countries, especially among blacks, surgical treatment of glaucoma is assumed to be preferable to medical treatment[7]. Although the Advanced Glaucoma Intervention Study (AGIS) stated that Argon Laser Trabeculoplasty (ALTP) may provide better outcomes than trabeculectomy in African patients; this method is not available in most eye units in Africa including Ruharo Eye Centre (REC) in Mbarara, South Western Uganda.

In Uganda, Primary Open Angle Glaucoma (POAG) is the commonest type accounting for almost 65%[8,7]. Trabeculectomy is the most common surgical procedure performed for POAG at REC[9,8]. This study sought to evaluate the long-term outcome of trabeculectomies performed at REC with the aim of determining the effectiveness of the procedure in relation with IOP control, visual acuity and visual field preservation.

MATERIALS AND METHODS

In a retrospective audit conducted from January to June 2016, we reviewed records of all adult glaucoma patients

who underwent trabeculectomy at Ruharo Eye Centre from January 2011 to December 2014. Ruharo Eye Centre (REC) is a tertiary eye hospital, located in Mbarara Municipality, South Western Uganda. The eye hospital receives patients mainly from South Western Uganda, Tanzania, Rwanda and Congo. It serves a population of about 5 million people.

The study population of interest were participants who had undergone trabeculectomy surgery in at least one eye at REC from 2011 to 2014. The comparison of interest was a before and after mean IOP. The main outcome measure was a reduction in the mean IOP. This being an audit, we planned to include all participants who had undergone trabeculectomy during that period. However, using a paired means sample size calculation with STATA 14, a sample of 44 eyes would be adequately powered (90%) to detect a pre and post trabeculectomy difference of 5mmHg and a significance level set at 0.05.

We included patients who had undergone trabeculectomy surgery in at least one eye at REC from January 2011 to December 2014. Post trabeculectomy patients who had other comorbidities or had undergone another eye operation were excluded. Approval to conduct the study was obtained from the Ethics Committee of Ruharo Mission Hospital and Department of Ophthalmology of Mbarara University of Science and Technology as well as informed consent from each patient.

A list of all patients who had undergone trabeculectomy surgery at REC from January 2011 to December 2014 was obtained from the hospital theatre records. The patients whose phone numbers were registered were identified and a call made to them by the study nurse. For those whose phones were not reachable, the nurse made another attempt twice or thrice over the next few days and then recorded them as non-responsive. The patients who responded to their phones were invited to come for examination at REC. For those who accepted to return, we retrieved data from their case records on demographics, pre-operative vision, IOP, Visual Fields, Cup Disc ratio and surgical notes. They were then examined at REC by the study ophthalmologist and post-operative data recorded. This included Best Corrected Visual Acuity (BCVA) with Snellen charts, Visual Fields (VFs) with Henson automated perimeter, IOP with Goldman applanation tonometer, Cup-Disc Ratio (CDR) and any complications of surgery. Patients were then interviewed separately by the study nurse to ask about their general satisfaction with the surgery and their vision. These were simple 5-scale questions ranging from 5: Very satisfied, 4: Satisfied, 3: Neither satisfied nor unsatisfied, 2: Unsatisfied, 1: Very un-satisfied.

We conducted a before and after comparison analysis with STATA v14 on several outcome measures including: mean visual acuity (Log MAR), mean Intra Ocular Pressure, mean Cup Disc Ratio and mean Visual Field defect using matched pair student t-test. For purposes of analysis, we considered treatment success as having IOP reduction of 40% from baseline according to the preferred practice guidelines for target IOP [12,13]. We considered visual field progression as a change of 1.00dB/year from the mean baseline visual field[7,11]. We analyzed for predictors of final IOP in a multivariate regression model. The variables tested included: age, sex, distance from hospital, type of anti-metabolite used, education level, pre-operative IOP, visual acuity, VF defect and period after surgery.

RESULTS

Out of a total of 479 patients who were eligible for enrolment, 62 patients returned to the hospital out of which only 38 patients (62 eyes) were eventually enrolled. Twenty four patients were excluded as per the exclusion criteria. Figure 1 shows how the patients were enrolled.

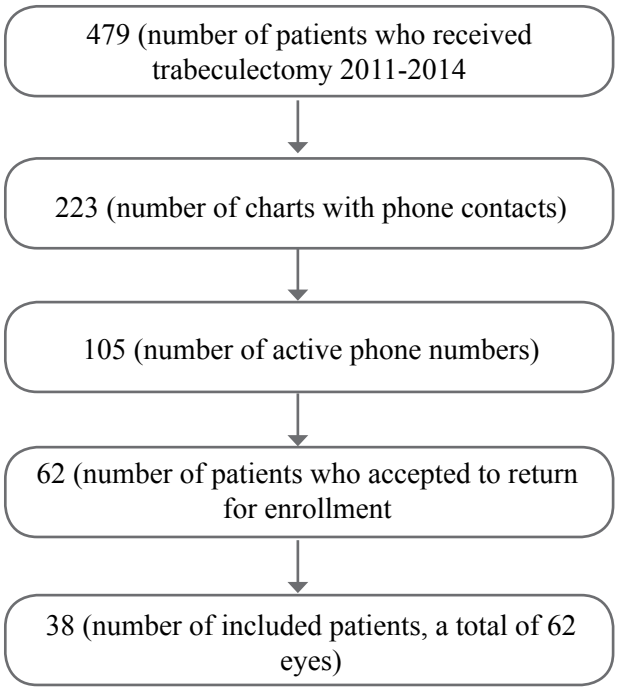

Figure 1: Flow diagram for participant enrolment

General characteristics: In total, 62 eyes of 38 patients were included in this study. Table one shows the general characteristics. About 2/3 of the participants were male; median age was 66 years (range 24-91 years). Their median follow-up period was 2.8 years (range 0.2-4.6 years). Out of the 62 patients, 24 had bilateral trabeculectomy. Two thirds of the trabeculectomies were with 5-FU (61%) and the commonest type of glaucoma was Primary Open Angle (POA) (84%).

Table 1: General descriptors of included participants (n=38 persons, 62 eyes)

Variable	Median	IQR	(Total Range)
Age	66	52-71	(24-91)
Distance from hospital in Kms	71	24-98	(2-525)
Period after surgery in years	2.8	1.8-3.6	(0.2-4.6)

Variable	Categories	N	(%)
Sex	Male	23	(61)
Education	No education	12	(32)
	Primary	8	(21)
	Secondary	15	(39)
	Tertiary	3	(8)
Type of glaucoma	Primary Open Angle	52	(84)
	Normal Tension	7	(11)
	Ocular Hypertension	1	(2)
	Angle Closure	2	(3)
Type of surgery	Trab + 5FU	38	(61)
	Trab + MMC	18	(29)
	Trab + no anti-metabolite	6	(10)

Key: Trab-Trabeculectomy, 5FU- Fluorouracil, MMC-Mitomycin C

Post-operative status versus pre-operative status: Table 2 shows a comparison of post-operative follow-up status versus pre-operative status on visual field type, mean visual field defect, vision, IOP and Cup Disc Ration (CDR). Mean post-operative IOP was almost 3 times less than the mean pre-operative IOP (12.9 Vs 32.0, P= 0.001). The 40% reduction target IOP was 19.2mmHg: this target IOP was achieved in 90% of the eyes. The mean visual acuity and visual field defect although higher post operatively were not statistically significant from pre-operative levels. Only 7 eyes had a post-operative mean visual field defect of more than 2DB with a median follow-up of 3.5 years (1 eye: 1.7 years, 1 eye: 2.2 years, 1 eye: 2.8 years, 4 eyes: >4 years). Paradoxically, the mean post-operative CDR was worse than the mean pre-operative CDR (0.89 Vs 0.83, P=0.001).

Table 2: Comparison of post-operative follow-up status versus pre-operative status

Variable	Pre-op		Post-op		P-value
	Mean	(95% CI)	Mean	(95% CI)	
Mean visual field defect	23.4	(21.4-25.5)	22.9	(20-9-25.0)	0.44
Mean maximum IOP	32.0	(29.3-34.7)	12.9	(11.7-14.2)	0.001
Mean Visual Acuity (LogMar)	0.58	(0.48-0.68)	0.65	(0.52-0.78)	0.21
Mean Cup Disc Ratio	0.83	(0.79-0.87)	0.89	(0.86-0.92)	0.001
Visual field defect					
Arcuate scotoma	14	(23)	12	(20)	
Atypical scotoma	4	(7)	4	(6)	
Loss of central vision	22	(36)	22	(36)	
Isolated scotoma	2	(3)	1	(2)	
Nasal step scotoma	4	(7)	3	(5)	
Paracentral scotoma	2	(3)	2	(3)	
Ring scotoma	13	(21)	17	(28)	
Vision category					
Normal/mild (6/6-6/18)	33	(53)	32	(52)	
Moderate (6/24-6/60)	22	(36)	21	(34)	
Severe (5/60-3/60)	2	(3)	4	(6)	
Blind (<3/60)	5	(8)	5	(8)	
IOP category					
<=10mmHg	0	(0)	21	(34)	
11-15mmHg	3	(5)	23	(37)	
16-20mmHg	5	(8)	15	(24)	
>20mmHg	54	(87)	3	(5)	

Predictors of achieving a target IOP: Table 3 shows a multivariate model of the factors which were associated with post -operative IOP. The variables tested included: age, sex, distance from hospital, type of surgery, education level, pre-operative IOP, visual acuity, VF defect and period after surgery. Out of these, education level, pre-operative IOP and period after surgery had a strong evidence of association.

Table 3: A multivariate analysis of predictors of post-operative IOP

Target IOP	Coefficient	P value	(95% Conf. Interval)
Period after surgery	1.07	0.026	(0.13-2.01))
Education	-1.47	0.009	(-2.58- -0.37)
Pre-operative IOP	0.13	0.011	(0.03-0.24)

DISCUSSION

The success rate of trabeculectomy is very dependent on the definition of success that is utilized, the duration of follow-up and the population studied. Thus, comparing results from different studies has to take multiple factors into account. In this study, we considered the following factors as indicators of a successful trabeculectomy. These included: reduction of IOP (IOP reduction of 40% compared to baseline), preservation of visual acuity, preservation of visual field and avoidance of further optic disc damage[7,12].

In terms of lowering IOP, our findings showed trabeculectomy was effective. The general IOP after surgery was almost 3 times less than pre-operative and 90% of the patients had a maximum post-operative IOP of less than 19.2mmHg. This was comparable to experiences

from a number of other studies where proportions ranged from 80-98%[13,14]. These older studies used a target IOP of less than 21mmHg.

Being able to predict which patients will benefit most is important to make a management and prognostic decision. Several factors come into play in securing a successful operation. These include: age, gender, type of surgery, indication, early post-operative IOP, duration after surgery and post-operative care[14-17]. Our study showed that post-operative IOP was strongly linked to duration after IOP with an increase of 1mmHg of IOP/ year after surgery. Considering that the mean post-operative IOP was 12.9mmHg, it would take about 7 years in our population to exceed the threshold target IOP of 19.2mmHg, assuming all factors remain constant. The Advanced Glaucoma Intervention Study (AGIS) also showed that a post-operative period of more than 7.7 years was more associated with deterioration[10]. Our follow-up was variable and ranged from 0.2-4.6 years. We intend to revisit this cohort after 7-10 years to evaluate their IOP.

Apart from duration after surgery, there was a very strong correlation between pre and post-operative IOP. A low pre-operative IOP was associated with a lower post-operative IOP. This might suggest the role of initial medical therapy to lower presenting IOP before doing a trabeculectomy. Lastly, similar to the AGIS, there was strong evidence of a better IOP control with increase in education with a reduction post-operative IOP of almost 1.5mmHg with every increase in the level of education.

Significant visual field deterioration is defined as a change in decibels of equal or more than 1.00/year[10]. Considering a median follow-up of 2.8 years, a significant visual field deterioration would have been 2.8dB. In our study, 7 eyes out of 62 (11.3%) had visual field defect progression between 3 and 5 dB from baseline. An 80 month trial at Moorfield's Eye Hospital showed that 20% of eyes had visual field progression 5 years after trabeculectomy[18]. In the CIGTS, perimetric progression was not significant for many years after trabeculectomy, but after 8 years the progression worsened by 3 dB in 21% of patients[11,19]. overall, our impression of our data is that visual fields were largely preserved: the mean pre and post-operative visual field defect was not statistically different. In fact, the post-operative mean score was better than the pre-operative. This could have been due to the learning curve effect. This correlated well with visual acuity which was also not different.

Interestingly, there was an observed increase of the CDR, however, although statistically significant, we felt it was not clinically important as the mean change of 0.06 was too small and did not affect visual field changes; it could be artefactual or age related.

LIMITATIONS

This study had a low enrolment rate. Out of the eligible 479 patients, we managed to enroll 38 (7.9%). Although his had sufficient power from our assumption to detect a difference in the pre and post trabeculectomy IOP, the sampling was not random. It is plausible that the patients who returned were the "happy patients". Therefore, this work provided some insight on the trend that needs to be confirmed in a carefully designed prospective study.

CONCLUSION

Trabeculectomy was an effective means of lowering the IOP with significantly high success rates, preservation of vision and prevention of further visual field loss. Presenting vision, duration after surgery and patients' education status were key predictors of post-operative IOP. We found trabeculectomy as a viable treatment option particularly in resource limited settings. A carefully designed prospective study is needed to provide stronger evidence of this effect.

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