Title page

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Title of the paper:

Glaucoma surgery outcome in Rwanda.

Abstract

Purpose:

To assess long term intraocular pressure (IOP) outcome after adult trabeculectomy surgery in Central Africa.

Patients and Methods:

All adult glaucoma patients who underwent trabeculectomy surgery in the Kabgayi Eye Unit, Rwanda between August 2003 and March 2008 were invited for a follow-up visit. Surgical and clinical data were collected from medical records. At the study visit best corrected visual acuity was measured and Goldmann applanation tonometry and biomicroscopy were done. Good IOP outcome was defined as both an intraocular pressure < 21mmHg and achieving ≥ 30% reduction from the preoperative IOP. Considering first operated eyes, univariate and multivariate logistic regression was used to investigate risk factors for failure.

Results:

Of 163 individuals operated 3 had died, 118 (74%) participated. Preoperatively, the mean IOP was 31mmHg (SD 11, range 12-60). At the time of the follow-up study visit the mean postoperative IOP was 13mmHg (SD= 5, range 4-35). Good IOP outcome was achieved in 132 eyes (84%). Univariate analysis suggested a protective effect against failure of use of anti-metabolites (OR=0.39, 95% CI 0.14- 1.11, P= 0.07) and a decrease in success with length of follow-up (OR=3.57, 95% CI 1.09-12.50, P= 0.03). The latter remained borderline significant with multivariate analysis. Seven eyes went from previously better vision (at least hand movements) down to perception of light or no perception of light after trabeculectomy. Particularly a flat anterior chamber in the first postoperative week (OR= 0.07, P< 0.001, 95% CI 0.01-

0.49) and late hypotony (OR= 0.04, P= 0.004, 95% CI 0.002- 0.99) were significant risk factors for severe visual loss.

Conclusions:

Trabeculectomy with anti-metabolites is one of the best available options for glaucoma management in Africa. However, the IOP control reduced at a follow-up duration beyond 2 years, highlighting the importance of regular long-term follow-up.

Key words: glaucoma surgery, Africa, outcome, anti-metabolites, follow-up

Introduction

Glaucoma is the leading cause of irreversible blindness worldwide.[1] The prevalence of primary open angle glaucoma (POAG) is highest in Africa.[2-4] The principal therapy for POAG remains reduction of intraocular pressure (IOP). Because lifelong anti-glaucoma drop application is usually not feasible nor reliable in Africa [4, 5] and since in this part of the world patients usually seek eye care when at least one eye has already been badly affected,[2, 4] glaucoma filtration surgery like trabeculectomy is often the preferred treatment option. Anti-metabolites like mitomycin-C (MMC) or 5-Flurouracil (5-FU) are applied to the surgical field during the operation in order to counter excessive scarring, which compromises the function of the filter and is frequently seen in patients of African origin.[4-8] There are conflicting results regarding the effect of anti-metabolites on IOP-control in African populations.[5, 9-11] Clinical trials that compared trabeculectomy with and without MMC have indicated a beneficial effect of the agent on IOP reduction among black people,[6, 12, 13] but most studies rarely extend beyond a follow-up of 2 years [4, 14-16] and suffer from heavy loss to follow-up.[5, 10, 14] A greater risk of thin, leaking blebs, hypotony with vision decrease, and late endophthalmitis have been reported with the use of MMC during trabeculectomy. In African studies, cataract formation induces visual loss in 25% to 50% of patients after glaucoma filtration surgery.[4, 5, 10, 16, 17] Although postoperative monitoring of the effect of pressure-lowering surgery and its potential complications is very important, compliance to regular follow-up visits is limited in Africa.[5] Few data on medium- to long- term prognosis of trabeculectomy are available, particularly from Central Africa.[4-6]

The primary aim of this cross-sectional review of operated patients, was to assess the long term outcome of trabeculectomy surgery among adult glaucoma patients in Rwanda, Central Africa. The objectives were to calculate the proportion of patients with good IOP-control over time after surgery, to document any complications and to identify predictors for good IOP-control. The study was undertaken in Kabgayi Eye Unit, which is a secondary as well as a tertiary eye center with over 20,000 annual outpatient attendances from all over Rwanda. This densely populated country with a reasonably good main infrastructure has a compulsory health insurance system, which facilitates health coverage even for the poor.[18]

Patients and Methods

Participants:

All adult patients (aged ≥ 18 year) with glaucoma who had undergone trabeculectomy surgery in the Eye Unit of the Kabgayi Hospital, Rwanda, between August 2003 and March 2008 were included in this study. A list of eligible patients was made by consulting the operating theatre records. Public announcements were made on the local radio for these patients to attend a free follow-up examination in Kabgayi Eye Unit in September-October 2008. Those patients who did not turn up, were visited by the social worker of our unit and invited to attend the eye clinic for examination.

Study design:

Basic demographic, surgical, pre-, and postoperative data were collected from patient clinical records. At the study follow-up visit best corrected visual acuity (BCVA) was measured using Snellen charts. Biomicroscopy, intraocular pressure by Goldmann

applanation tonometry and eye fundus examination at the slit lamp using a hand held 90 diopter lens were done by the study ophthalmologist (SDS). The preoperative IOP was taken as the value recorded in the notes immediately prior to surgery and the postoperative IOP as measured at the follow-up study visit.

Outcome variables:

The main outcome variable was IOP. Success was defined as an intraocular pressure < 21mmHg and achieving ≥ 30% reduction from the preoperative IOP at the follow-up study visit. An additional IOP target of ≤ 15mmHg was investigated. A secondary outcome variable of severe visual loss was defined as a drop in visual acuity from hand movements (HM) or better to perception of light (PL) or no perception of light (NPL). As in a majority of other eye centers in Africa, visual field testing is not routinely practiced in our clinic hence this was not included in our outcomes. Visual status was classified according to the World Health Organization (WHO) acuity definitions.[19]

Analysis:

All study data were collected in a standardized manner and entered in a Microsoft Access database. STATA-software 9.2 was used for analysis. Descriptive statistics were used for contingency tables and continuous variables on all operated eyes. Univariate and multivariate logistic regression was used to investigate risk factors for failure. Where individuals had surgery on two eyes, the results of the first operated eye were taken for inclusion in these regression analyses. Kaplan–Meier survival curve analysis was also undertaken.

Ethics:

This study was conducted in accordance with the Declaration of Helsinki and approved by the Rwandan National Ethics Committee and the London School of Hygiene and Tropical Medicine Ethics Committee. Free and informed consent to participation was obtained. Participants were reimbursed their transport and where accommodation or additional therapy was necessary, this was provided at no cost.

Results

Participation:

Of the 163 eligible patients, 3 had passed away, 118 (74%) participated, the remaining 42 could not be found. There were 70 (59%) male patients. The average age at the time of operation was 60 years (range 18-88, SD 15). Forty-three of the participating patients underwent trabeculectomy on both eyes, resulting in 161 eyes with surgery.

Baseline data from the clinical records:

Table 1 presents the characteristics of the study eyes. Preoperatively, the mean IOP was 31mmHg (SD 11, range 12-60, 3 missing data).The conjunctival blebs were mostly fornix-based (94%) with two thirds being done by one surgeon (SDS). The size and shape of scleral flaps and the methods for suture placement varied between surgeons. Anti-metabolites (MMC or 5-FU) were applied during the operation in almost 90% of eyes. Mitomycin C was almost always used in 0.5mg/ml concentration and 5-FU in 50mg/ml, applied on a soaked surgical sponge wedged between the trabeculectomy flap and the conjunctiva for 2-3 minutes. After removal of the sponge,

the site was irrigated copiously with balanced saline solution. Post-operatively, eyes were treated with combined antibiotic and steroid drops administered by the patients or their families over a 6 week tapering course. Patients were typically discharged from hospital 3-7 days after their trabeculectomy. Figure 1 shows complications and re-interventions encountered in the study eyes. Early complications (within 1 week) happened in 27 (17%) eyes. There was no difference in early complications between those with and without antimetabolite use (p=0.56). Late complications developed in 21 (13%) eyes. The most common late complication was failure to reduce the IOP (n=12). Three patients (4 (2.7%) eyes) developed blebitis. All eyes with blebitis had anti-metabolites, 3 had MMC at the time of surgery and the other received 5-FU at the time of subsequent needling. One eye with blebitis went on to develop a corneal ulcer and underwent evisceration one year after trabeculectomy with MMC. A total of 21 (13%) eyes needed re-intervention following initial surgery (Figure 1).

Clinical data at the follow-up study visit:

The clinical findings at the follow-up study visit are shown in table 2.

The mean follow-up after the operation was 27 months (SD= 15, range 7- 83). At the time of the follow-up study visit the mean postoperative IOP was 13mmHg (SD= 5, range 4-35). Seven eyes had an IOP < 5mmHg, of which one had a flat anterior chamber at the time of the study visit. A good IOP outcome (IOP < 21mmHg and ≥ 30% reduction from the preoperative IOP-value) was achieved in 132 (84%) eyes. The target of an IOP ≤ 15mmHg was met in over two thirds of eyes (70.6%). 134 (84.8%) of eyes remained phakic and 9 had cataract surgery at the same time as the trabeculectomy. Thus 15 (9.5%) had cataract surgery at some stage following the trabeculectomy. Seven severely diseased eyes with vision counting fingers 2 meter

or worse prior to surgery went from previously better vision (hand movements n= 3, counting fingers at 1 meter n=3, counting fingers at 2 meters n=1).down to perception of light or no perception of light after the trabeculectomy. The eye pathologies responsible for this adverse visual outcome seen at the study follow up visit were evisceration (n=1), significant cataract (n=1), posterior capsule opacification (n=1), corneal opacification (n=1) and uveitis with extensive posterior synechiae (n=1). For the remaining 2 eyes no other obvious cause than end stage glaucoma could be found.

In order to investigate risk factors for failure only one eye per patient was included in the analysis below. Where two eyes had surgery the first to receive surgery was included in the data-set. Table 3 shows the results of the analysis. Univariate analysis suggested a protective effect against failure of use of cytotoxic and a decrease in success proportion with length of follow-up. These effects were similar but slightly less marked with multivariate analysis. When the analysis was repeated using failure defined as IOP > 15mmHg length of follow-up remained a significant risk factor (p= 0.001), even after multivariate analysis (p=0.005). Age (OR 0.76 p=0.6), gender (OR 0.98 p=0.96) and antimetabolite use (OR 1.14 p=0.84) remained non-significant. Using Kaplan–Meier survival curve analysis figure 2 shows that the cumulative probability to maintain good IOP outcome (< 21mmHg and at least 30% reduction) for first eyes reduces from over 90% at a follow-up of 2 years to 60% after 5 years of follow-up. Logistic regression for failure defined as visual decrease from HM or better to PL or NPL showed that early operative complications (OR= 0.20, p=0.04, 95% CI 0.03-1.11), particularly a flat anterior chamber in the first postoperative week (OR= 0.07, p< 0.001, 95% CI 0.01-0.49) and late complications

(OR= 0.10, P=0.005, 95% CI 0.01-0.74), especially late hypotony (OR= 0.04, p= 0.004, 95% CI 0.002- 0.99) were significant risk factors for such severe visual loss.

Discussion

There have been quite a few retrospective reports of trabeculectomy from the African continent. A large range of success has been reported using varying outcomes and with varying periods of follow-up. As a general rule the follow-up has been poor hence the studies are prone to large bias. Our finding of a success proportion of 84% (IOP < 21 mmHg and ≥30% drop) and 71% (IOP ≤15 mmHg) with a mean follow-up period of 27 months is comparable both with Tanzania (73% patients IOP ≤ 15mmHg, mean follow-up 8 months) and Nigeria (82% IOP ≤ 22mmHg. 61% IOP ≤ 15mmHg, 2 years follow-up). [5, 14] These results are also similar to the national audit of trabeculectomy surgery in the UK (84% IOP ≤ 21mmHg at one year).[20]

The role of anti-metabolites:

Trabeculectomies without anti-metabolite use were effective in lowering the IOP to < 22mmHg but not to < 16mmHg in Nigeria.[14] Meta-analysis on reported trials demonstrated a significant protection against failed IOP control for both MMC and 5-FU compared to placebo.(Wilkins et al. 2005, Green et al. 2014) Clinical trials comparing trabeculectomy with and without MMC have indicated a beneficial effect of the agent on IOP reduction among black people.[6, 12] Although in our study the use of anti-metabolites increased the proportion of eyes achieving an IOP < 21mmHg and an IOP ≤ 15mmHg, their effect did not come out that strongly. In the literature there are conflicting results regarding the effect of 5-FU on IOP-control in Africa. Some studies found that the application of 5-FU during surgery improved IOP control [10, 21], while others failed to demonstrate a difference.[5, 11] Whether the anti-

metabolite MMC controls IOP better than 5-FU is unclear.[22, 23] A retrospective study from West Africa, comparing MMC and 5-FU over a long follow-up time found the use of intra-operative MMC to be associated with a lower likelihood of requiring postoperative medications and a greater likelihood of achieving IOP lowering (IOP <21mmHg) without medications relative to the use of 5-FU.[16]

Long-term prognosis of glaucoma surgery:

In our study IOP control reduces over time beyond 2 years of follow-up. The few available long-term follow-up data after glaucoma filtration surgery from Africa confirm this finding. In a West African study (follow-up ≥ 6.5 years) the target of IOP of < 15mmHg without medical therapy was met in 13.5 to 17.6%, depending on the anti-metabolite used.[16] Especially after trabeculectomy without the use of anti-metabolites, the proportion of eyes with good IOP-control (< 21mmHg) reduced over time from 70% immediately after the initial trabeculectomy to 21% 4 years later.[15] In a Nigerian study the success rates of trabeculectomy without anti-metabolites (IOP < 16mmHg) were 65%, 61% and 46% at the 1, 2 and 5 year intervals respectively.[14]

Most studies report outcome documented at single point assessment, while cumulative survival analysis data might provide a more realistic picture.

Regular follow-up is necessary to ascertain lasting control, but this is not easy to achieve in Africa, with only around 40% of patients attending eye clinics for more than 2 years.[15, 24] Despite its health insurance system compliance to regular follow-up remained low in Rwanda, suggesting that a network of health workers in community based rehabilitation programs needs to be reinforced to improve follow-up.

Visual outcome of glaucoma surgery:

Significant visual loss over time after glaucoma surgery has been reported in African studies in 25% to 50% of patients, usually attributed to cataract.[4, 10, 16, 25] We documented a lower percentage of significant visual loss and managed to reduce visual impairment, but this could be an underestimation since the visual acuity was not always measured with best correction before the operation. Nevertheless severe visual loss happened in our study population too. This was most frequently related to hypotony in the early and late postoperative phase. Postoperative hypotony and flat anterior chambers have been reported as a risk factor for cataract formation. Since vision rarely improves following simple trabeculectomy, offering systematically combined cataract and glaucoma surgery might be a useful option in motivating the patient to accept glaucoma surgery and to come back for regular eye check.[26] Whether combined cataract-glaucoma operation is as effective in lowering the IOP as a simple glaucoma intervention remains debated.[17]

The Tube vs. Trabeculectomy [TVT] study demonstrated a lower surgical failure requiring less re-operation in the Glaucoma Device Implant (GDI) group compared to the trabeculectomy group during five years of follow-up (29.8% failure rate in the GDI group versus 46.9% in the trabeculectomy group; $p = 0.002$).[27] GDI have been considered as an alternative surgical technique in Africa, but so far the follow-up is very limited.[28, 29] Furthermore, analysis of first eyes fulfilling the criteria of the Tube versus Trabeculectomy (TVT) study showed a failure rate of 32% (n=8/25), more nearly comparable to the GDI group. Our trabeculectomy success after 3 years (68%) is higher than reported in the TVT-study, so the debate remains open.

Complications of glaucoma surgery:

The overall early and late complication rates of respectively 17% and 13% found in our study were similar to that reported in other studies. In a Tanzanian study acute complications happened in 12%.[5] Shallow anterior chambers are relatively commonly reported in 6 to 23% of eyes.[5, 10, 14] The national audit on complications after trabeculectomy in the UK reported much higher early (46.6%) and late (42.3%) complications in 2002.[30] Surgical techniques have evolved since then. Some studies have documented an increased risk of thin, leaking blebs and hypotony with vision decrease for eyes operated with anti-metabolites 5-FU[10] and MMC[6, 12], while others suggested that visually significant hypotony may be infrequent among ‘black‘ subjects treated with MMC.[4, 13] Two long term case series from West Africa found a cumulative blebitis proportion of 2.5-3.3% depending on type of anti-metabolite used.[15, 16] The cumulative blebitis proportion in our study is within that range, but still higher than the 1% blebitis found in a recent multicenter study from the UK.[31] In order to avoid these bleb-related complications, bleb independent glaucoma surgery like canaloplasty has been proposed.[32]

Limitations of this study

Our study is a retrospective review with a relatively small number of participants.

Despite having one of the best follow-up proportions in the literature from an African context, our study results may be biased by loss to follow-up. Depending on the assumption that all who failed to attend for review failed or passed, the confidence intervals for good IOP outcome (IOP < 21 mmHg and ≥ 30% drop) may vary between 37 to 88%. A similar consideration can be made regarding the rate of complications.In addition there is the factor of missing data points as a result of historical retrieval of data from the notes. Furthermore, patients attending an eye

clinic are more health conscious, more likely to accept glaucoma surgery and more compliant to follow-up than the average Rwandan population, introducing selection bias and making the results nearer a best case scenario.

Conclusion:

We report longer term trabeculectomy outcomes in an African setting. The results are directly comparable with those published elsewhere and provide further support for this surgical approach being one of the best available for glaucoma management in this setting. The strongest risk factor for IOP failure was length of follow-up. The strongest risk factor for visual decrease was major post-operative hypotony.

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Legends of the tables and figures:

Legend of table 1
Table1: Pre, per and post-operative details of the study eyes (N=161). Percents given are out of the total for which records were available.

Legend of table 2
Table 2: Ophthalmic findings at the time of the study visit (N=161). Percents given are out of the total for which records were available.

Legend of table 3
Table 3: Univariate and multivariate analysis of potential predictors for IOP failure (> 20mmHg and < 30% reduction) in first operated eyes (n= 118 eyes), expressed in absolute and relative number of eyes, odds ratio (OR), 95% confidence intervals (CI) and p-value.

Legend of figure 1
Figure 1: Complications and re-interventions in the 161 study eyes.

Legend of figure 2
Figure 2: Cumulative probability to maintain good outcome (intraocular pressure IOP < 21mmHg and a 30% IOP reduction after trabeculectomy) for the first eyes only.