Long term results of glaucoma surgery among participants in an east African population survey

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Abstract

***Aim*—To evaluate the long term results of glaucoma surgery among people in East Africa.**

***Methods*—Participants in a population based survey of eye disease prevalence were offered glaucoma surgery using standardised criteria. Either surgical iridectomy or trabeculectomy was carried out as indicated by a medical officer or by one of two ophthalmologists. Trabeculectomy methods included releasable sutures and mitomycin C in the majority of eyes. Subjects were examined during the first week and 2 months after surgery. Nearly 3 years later, re-examination was carried out in those who were still resident in the region.**

***Results*—Among 46 people who were offered iridectomy, trabeculectomy, or combined cataract extraction/lens implant/trabeculectomy, 21 people underwent surgery (46%). Of the 21, 19 were re-examined at 3 years (90%), including 16/18 eyes after trabeculectomy. Among these, intraocular pressure (IOP) declined from 29.9 (SD 9.4) mm Hg to 14.7 (5.9) mm Hg, with 16 of 18 eyes (89%) achieving a reduction > 25%. Hypotony maculopathy, late bleb leak, and late endophthalmitis were not detected. Visually significant cataract developed in 5/15 re-examined eyes that underwent trabeculectomy alone (33%), possibly associated with pre-existing cataract and diagnosis of angle closure glaucoma, but not with mitomycin C use.**

***Conclusions*—Nearly half of those with glaucoma among residents of rural African villages accepted the offer of surgical therapy. While technical success was achieved at satisfactory levels, the development of cataract must be considered an important issue for application of glaucoma surgical therapy programmes.**

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While cataract remains the pre-eminent cause of vision loss worldwide, glaucoma and trachoma are the next most significant, blinding 5–6 million people each.[1 2] Major public health initiatives are proposed for reducing the morbidity from cataract, trachoma, nutritional blindness, and onchocerciasis, each of which has a therapeutic approach whose effectiveness has been proved.[3] Glaucoma has challenged the ingenuity of blindness prevention efforts by posing greater difficulties in diagnosis and treatment. The burden of glaucoma is greater in developing nations, owing to higher prevalence of the disease in important ethnic groups. Among Asians, particularly among Chinese, angle closure glaucoma (ACG) is dramatically more common, while open angle glaucoma (OAG) is similar in prevalence among Asian and European people. People of African origin have more glaucoma because they had four to five times higher rates of OAG compared with Europeans or Asians.[4–7] A recently completed survey of Hispanic Americans suggests that OAG is also more prevalent in this group than among white Americans (unpublished observations).

It was only recently that the benefit of intraocular pressure (IOP) lowering in preventing optic nerve deterioration was definitively shown.[8] The application of IOP reduction to large numbers of people in the developing world is an additional challenge. The cost of medical or surgical treatment appears to be beyond the resources of many countries. It is questioned whether chronic therapy with expensive medications and its monitoring cost are practical. Some have speculated that rural populations will be unwilling to undergo preventive surgical procedures that do not restore vision and that have risk. Trabeculectomy has been reported to have some benefit in black people in Africa and the Caribbean area.[9–16] However, the success rate as well as the complications may be different in developed and developing world settings.

In 1996, we conducted the Kongwa Eye Project, a survey of eye disease prevalence in Tanzania, documenting that 4.2% of adults over age 40 had glaucoma, with 3.1% affected by OAG. People whose glaucoma appeared to threaten serious loss of vision were offered surgical therapy at no cost. Three years later, we re-examined those who underwent surgery and present here the results and complications for their relevance to the issues of worldwide glaucoma management.

Methods

Detailed methodology of the Kongwa Eye Project has been given elsewhere.[7] Our subjects were African born residents of rural villages in Kongwa district, central Tanzania. Six villages were randomly selected, and after a house to house census for all people over 40 years of age was conducted, all eligible adult residents were offered eye examination. In each village, the programme was approved by elected officials and individual consent was obtained from each participant. The programme was approved by the Johns Hopkins University Joint Committee for Clinical Investigation and the National Blindness Prevention Committee of Tanzania. It followed the tenets of the Declaration of Helsinki.

Study examinations represent the preoperative data for the present study and were conducted by an ophthalmologist (RRB), three eye nurses, a refractionist, and study technicians. Visual acuity was measured at 4 metres using a tumbling E ETDRS chart (Lighthouse, New York, USA) in ambient illumination with presenting correction, if any. In people with presenting acuity <6/18 in either eye, retinoscopy and subjective refraction were carried out by an ophthalmic optician. Visual field testing was attempted when acuity was > 6/60, using the Dicon LD400 automated instrument. A threshold related, suprathreshold screening program (Dicon No 1) was administered with single stimulus presentations at 40 locations per eye in the central 25 degrees with best distance refraction and a +3 add. The first tested eye was selected randomly, and the subject underwent testing in this eye, the fellow eye, then the initial eye again. The first test was discarded to minimise the learning effect. If two or more adjacent points in the same hemifield were found abnormal in an eye, the full test was repeated in that eye. A probable visual field defect was defined as two contiguous, abnormal points in both field tests of that eye, with one of the abnormal points shared between the two field tests. A definite field defect was defined as three or more contiguous points abnormal in both tests of that eye, with at least two points of a cluster being the same in the two fields.

IOP was recorded as the median of three mean values (12 total measurements) with a calibrated TonoPen by an eye nurse or ophthalmologist with topical oxybuprocaine (proparacaine) hydrochloride 1% anaesthesia. Gonioscopy with a Posner, four mirror lens was performed before dilatation on eyes with shallow chambers by hand light evaluation or an IOP > 24 mm Hg and on a 20% subsample. All eyes with Shaffer grade I (narrow) or closed angles underwent indentation gonioscopy. The angle was graded as closed when the pigmented trabecular meshwork was obscured by iris apposition.

After dilatation of the pupil, the ophthalmologist graded nuclear, cortical, and posterior subcapsular cataract by comparison with standard photographs based on an adaptation of the LOCS III system.[17] He examined the optic disc with a hand held, 78 dioptre lens and 10× eye piece of the slit lamp. The vertical optic disc and cup diameter were measured stereoscopically with an eyepiece micrometre scale for calculation of vertical cup/disc ratio (c/d).

The definition of primary OAG (definition 3[7]) included those with an optic disc representing glaucoma damage, regardless of field defect, as well as those with reproducible field loss and a c/d >0.5. Glaucomatous disc damage was defined as: (1) c/d >0.9; or (2) c/d >0.7 with one or more of the following additional features: (a) a definitely abnormal nerve fibre layer, (b) at least 1 clock hour of complete rim loss (notch), or (c) c/d asymmetry between eyes of >0.3 in eyes that had less than a 0.2 unit difference in disc diameter. Non-glaucomatous causes of disc and field abnormality were excluded by detailed examination.

To define ACG, we denoted an occludable angle as present when 6 or more clock hours had no visible trabecular meshwork without indentation gonioscopy. Peripheral anterior synechiae were identified by indentation gonioscopy and were considered to be corroborating evidence for angle occlusion. Primary ACG was diagnosed in a person if one eye had primary occludable angle and also had one or more of the following criteria: (1) IOP > 24 mm Hg, (2) glaucomatous optic disc damage (see above), (3) definite, reliable visual field damage, or (4) a history compatible with an attack of acute angle closure or the development of an attack at examination. In addition, the fellow eye had to have an angle that was Shaffer grade 2 or less in at least 8 clock hours. People whose OAG or ACG was thought to have resulted from another ocular or systemic condition were labelled as having secondary glaucoma.

Surgery was performed at Mvumi Mission Hospital, where subjects were offered care free of charge, including transport, food, and lodging for the postoperative 5–7 days. They were fully informed of the risks and benefits of surgery before giving consent. All surgery was performed by experienced surgeons. Fifteen of 26 operations (56%) were carried out by an assistant medical officer-ophthalmology (AMO Ophth), while the remaining 11 procedures were performed by one of two North American trained ophthalmologists. The training for an AMO Ophth involves 1 year of specialised practical instruction in ocular surgery following a 2 year, practical medical curriculum.

Since lasers were not available, surgical iridectomy was offered to those with primary ACG whose disc and field were normal. Trabeculectomy was offered to those with definite OAG and IOP > 24 mm Hg, to those with ACG associated with disc or field damage, and to those with secondary glaucoma and IOP > 24 mm Hg. Explanations of the disease and its treatment were given by trained Tanzanian team members in appropriate languages.

Trabeculectomy was performed under either the operating microscope or with loupes. A limbus based conjunctival flap was used and mitomycin C at 0.4 mg/ml was applied (16/20 eyes, 80%) to the sclera for 5 minutes, then washed off with saline. The square scleral flap was closed with two releasable or nonreleasable 10-0 nylon sutures that were subsequently removed as appropriate (for releasable sutures). Conjunctiva was closed with 9-0 Vicryl suture. One eye underwent a combined extracapsular lens extraction, lens implant and trabeculectomy procedure.

Eyes were treated with topical steroids administered by the patients or their families over a 4 week tapering course and a topical antibiotic for 1 week. Patients were typically discharged from hospital 5–7 days after their last surgery. A 6 week postoperative evaluation was performed by the ophthalmologist or an eye nurse in the village. Three years later, an ophthalmologist re-examined each operated subject, evaluating visual acuity, slit lamp examination, IOP (TonoPen), gonioscopy, and retina and optic disc after dilatation. Visual fields were not repeated. Subjects who required further treatment or surgery were again offered care at no cost.

All study data were recorded on standard forms, checked for completeness, and entered into a database using customised software with range and value checks. Entered data were checked against original data forms for accuracy. Data analysis was carried out with SAS statistical software for univariate and multivariate regression analysis.

Results

Forty six people were offered glaucoma surgery and 21 accepted (46%). These included acceptance rates of 5/11 (45%) for iridectomy, 15/31 (48%) for trabeculectomy alone, and 1/4 (25%) for combined cataract extraction, lens implant, and trabeculectomy. We compared the known features of 31 people who did or did not accept trabeculectomy (without lens implant; Table 1). The accepters and the refusers were not significantly different in any measured variable and were nearly identical in mean age, sex, diagnosis, preoperative IOP, visual field abnormality, and rate of legal blindness in one eye. Acceptance was very similar among the six villages in the study. Those who agreed to surgery had slightly worse acuity in the better eye (p = 0.18) and somewhat more normal c/d ratio in the better eye (p = 0.06).

At the 1 week evaluation, four eyes had positive Seidel tests at the conjunctival closure, but all healed without therapy. One eye was noted to have new iridocorneal adhesion.

Examination at 3 years was carried out on 90% of people and 88% of eyes (23/26) which underwent glaucoma surgery, including 5/6 eyes after iridectomy and 18/20 trabeculectomies (including the one combined trabeculectomy/lens implant operation). Among eyes that underwent iridectomy, all iris holes were open, the gonioscopic grade was more open, and visual acuity was the same or better in 4/5 eyes. The fifth eye had declined from 20/20 to 20/25. IOP ranged from 16 to 27 mm Hg in these eyes (without any therapy) and there had been no substantial change in the optic disc evaluation. One subject who had initially allowed iridectomy to be performed in only one eye now requested it in the fellow eye.

After trabeculectomy, mean IOP decreased from 29.9 (SD 9.4) mm Hg preoperatively to 14.7 (5.9) mm Hg at 3 years (18 eyes of 14 people; individual data given in Table 2). A reduction of 25% or more in untreated baseline IOP was achieved in 16 of 18 eyes. The mean c/d ratio increased by only 0.027 units (0.66 (0.25) to 0.69 (0.22), p = 0.8, n = 13 eyes). The c/d ratio worsened by 0.05 units or more in four eyes, improved by 0.05 or more in three eyes, and was unchanged in the remainder.

Among eyes with trabeculectomy alone, visual acuity was essentially unchanged in five eyes, improved by one or more line in four eyes, and was worse in eight eyes (Fig 1). In five eyes, the optical media were substantially worse at the 3 year examination, in two eyes

Table 1 Comparison of people who refused with those who agreed to have trabeculectomy

	Refused surgery	*Agreed to surgery*	
Number of people	16	15	
Number of eyes	5 bilateral, 11 unilateral	4 bilateral, 11 unilateral	
Sex	9 female, 7 male	9 female, 6 male	
Mean age (SD)	56.73 (9.35)	56.33 (7.61)	ns
Diagnosis	10 OAG, 6 ACG	8 OAG, 6 ACG, 1 trauma	
Preoperative visual acuity (SD)			
Worse eye	0.36 (0.30)	0.23 (0.25)	p=0.20
Better eye	0.64 (0.32)	0.49 (0.28)	p=0.18
Preop IOP, right (SD)	28.0 (8.0)	29.0 (10.7)	ns
Preop IOP, left (SD)	25.1 (9.8)	27.1 (10.6)	ns
Cup/disc ratio, worse eye	0.80 + 0.11	0.81 + 0.19	ns
Cup/disc ratio, better eye	0.70 + 0.11	0.57 + 0.25	p=0.06
Field loss one or both eyes (or blind one eye)	9/16	10/15	ns

ACG = angle closure glaucoma; OAG = open angle glaucoma.

Table 2 Preoperative and postoperative data on trabeculectomy eyes evaluated

Eye No	*Diagnosis*	*IOP pre*	*IOP post*	*C/D pre*	*C/D post*	*Mitomycin used*
1 R	ACG	41	14	0.9	no view	yes
1 L	ACG	20	15	0.3	0.3	yes
2 R	ACG	46	4	0.7	0.4	yes
2 L	ACG	13	8	0.3	no view	yes
3 R	ACG	23	7	0.8	0.7	yes
3 L	ACG	24	13	0.9	0.9	yes
4	OAG	28	25	0.7	0.8	yes
5 R	OAG	27	20	0.2	0.5	yes
5 L	OAG	33	22	0.3	0.6	yes
6	OAG	25	19	0.9	no view	no
7	OAG	33	8	0.6	0.6	yes
8	trauma	34	22	0.7	0.8	yes
9	OAG	28	no data	0.9	no data	yes
10	ACG	48	14	0.9	no view	no
11	OAG	23	13	0.8	0.8	yes
12	OAG	26	10	0.7	0.7	yes
13	OAG	20	13	0.8	no view	yes
14	ACG	43	18	1.0	1.0	yes
15	ACG	26	no data	0.8	no data	no
16	OAG (IOL)	33	19	0.9	0.9	no

Eye No = number for eye; where bilateral surgery performed; R = right; L = left; ACG = angle closure glaucoma; OAG = open angle glaucoma; IOL = combined trabeculectomy and intraocular lens implant surgery; IOP = intraocular pressure; C/D = cup/disc ratio; No data = no examination was performed at 3 years after surgery; No view = cup/disc ratio could not be estimated due to media opacity.

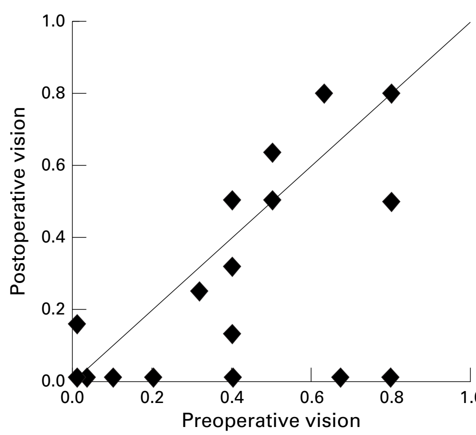

Figure 1 Comparison of preoperative and postoperative visual acuity in 17 eyes examined at 3 years after trabeculectomy (from a total of 20 trabeculectomy eyes; excluding one combined cataract/glaucoma case and two trabeculectomy eyes not examined at 3 years). Note five eyes with substantial decreases in acuity. For this figure, the value 0.01 was assigned for the seven eyes whose visual acuity consisted of the perception of hand movements.

because of significant posterior synechiae obscuring the view of the retina and in three eyes because of cataract that had become denser since surgery. Of these five eyes with media opacity, 4/5 had been graded as having media opacity preoperatively (LOCS III nuclear grade 1 in two eyes, grade 2 in one eye, and one eye had posterior synechiae precluding lens grading). Of 11 eyes that did not develop media opacity, only 3/11 had abnormal cataract grading preoperatively (nuclear grade 2 in one eye, grade 3 cortical in one eye, and one eye with posterior synechiae precluding grading). Eyes whose media and vision declined occurred in both ACG and OAG groups nearly equally (3/9 versus 2/10).

Overall, 16 of 20 eyes received mitomycin C, including 15/18 eyes that were examined at 3 years. Two of the 18 are non-informative for media opacity, as one was aphakic preoperatively and one was the combined lens implant/trabeculectomy procedure. Of the five eyes whose media worsened, three received mitomycin (60%), while 11/11 eyes with unchanged media received the drug.

IOP below 10 mm Hg was present 3 years after surgery in four eyes; the IOPs were 4, 7, 8, and 8 mm Hg, respectively. Each of these eyes had received mitomycin intraoperatively. In one eye of this group, acuity declined from 20/30 to 20/400 because of cataract. Another had a slight decrease from 20/25 to 20/40, one improved from 20/30 to 20/25, and one retained stable, severely depressed acuity. Hypotony maculopathy was not observed in any eye. There were no late bleb leaks, choroidal detachments, or signs of late endophthalmitis.

Discussion

While there are many reports of surgical evaluations of glaucoma operations in well designed studies, the strengths of the present report involve the patients and the setting in which surgery was performed. We carried out a disease prevalence survey among a rural African population, detecting 135 people with various forms of primary and secondary glaucoma. We offered surgery to those in whom we felt it might be beneficial and in whom the risk of progressive visual impairment was substantial. Eyedrop and laser treatment were unavailable. This situation faces many ophthalmic care centres in developing countries that screen for eye disease or have people who present themselves. Many such programmes presently fail to offer therapy for glaucoma, as it is considered impractical, too dangerous, or beyond the technical capability of the staff. Other eyecare centres have resources to carry out glaucoma therapy, but have no guidance as to which treatments are effective. This question is the basis for several ongoing, controlled clinical trials in the developed world.

We did not offer surgical treatment to every person defined as having OAG, though we did offer iridectomy or trabeculectomy to all those with ACG. The criteria for surgery in OAG included only those with (untreated) IOP of 24 mm Hg or greater and definite optic nerve damage in the visual field and/or optic disc. At Mvumi Mission Hospital, as in similar facilities in the developing world, patients overcome enormous obstacles simply to get to the hospital. Once discharged, they are unlikely to be seen again under typical circumstances. We felt it important to restrict the offer of surgery to those most likely to suffer significant vision loss from glaucoma. In 1996, we did not feel that aggressive surgical therapy should be applied to those with normal IOP levels, since its benefit was unknown at that time. The subsequently published data of the Normal Tension Glaucoma Study, showing treatment benefit in such people, should be considered in future studies.[8]

We were pleased that 89% of those undergoing trabeculectomy achieved a target reduction of 25% in baseline IOP and that each iridectomy successfully led to a wider angle approach and no detectable side effects. Clearly, laser iridectomy would have potentially fewer side effects, though its practicality and long term success in this setting requires evaluation. Furthermore, the optic disc findings of both iridectomy and trabeculectomy eyes indicate overall stability. If it had been practical, we would have preferred to have multiple IOP measures to judge surgical success. Stability in visual field testing is a more definitive outcome measure, but we could not re-evaluate the visual fields of those seen at 3 years for logistical reasons. Even had we done so, we would have been comparing the results of one suprathreshold screening field test at each of two single points in time. Progression in field testing is difficult to judge without five or more serial threshold tests.[18]

The majority of operations were performed by an experienced assistant medical officer who had undergone a formal, 1 year training in eye surgery, but had not had formal ophthalmology residency training. It has been suggested that the lack of surgeons in developing countries should lead healthcare authorities to consider use of specifically trained technical personnel.[19] The care provided in our project supports this concept. It must be noted that the facility in which our medical officer works has modern equipment, operating microscope, reliable electricity, and the consultation of an ophthalmologist.

One might speculate that rural, uneducated people in developing countries would not agree to undergo glaucoma surgery, since vision is not improved and there is measurable risk. Nearly half of those offered surgery in this project did choose to undergo surgery with full informed consent. This is the first time, to our knowledge, that an estimate of acceptance of glaucoma surgery has been documented among subjects identified from screening a large community based population. All previous studies were carried out with people who had presented for care at a health facility and whose response to the offer of surgery might be expected to be different, since they had already shown the initiative to come for care. We did attempt to reduce the barriers to acceptance by providing care without cost and by providing transport, food, and lodging for the hospital stay of 1 week. The ongoing, public health programme of the Central Eye Health Foundation that served as partner to our project (supported by the Edna McConnell Clark Foundation and Helen Keller International) provided confidence among our subjects in the surgery that was offered. Not surprisingly, the acceptance of cataract surgery with lens implant (65/81, 80%) was higher than for glaucoma surgery (46%) (data to be presented in detail elsewhere). The barriers to acceptance of glaucoma surgery were not clarified by patient demographics or ocular findings, since accepters and refusers of surgery showed no significant differences with the sample studied. We have administered a questionnaire on attitudes towards health among the Kongwa Eye Project population. When these data are analysed, it may be possible to determine beliefs that affected the decisions of subjects.

While the success of glaucoma surgery is important to its effective use in public health programmes, its detrimental effects must also be considered. A substantial minority of those undergoing trabeculectomy developed cataract. Though the numbers are too small for detailed subgroup analysis, it did appear that progressive cataract was more common in those with mild or moderate lens opacity preoperatively. Interestingly, they were not more likely to have been treated with mitomycin. Other clinical trials have recently detected the development of cataract in 20% or more of those followed for 2 or more years after surgery.[8 20] It will be important to study methods to decrease this effect. In addition, programmes that are capable of operating for cataract and for glaucoma may choose to remove moderate or even early cataract at the time of glaucoma surgery in situations where access to patients will be limited to only a small number of encounters.

The use of mitomycin C has been associated with greater success in IOP lowering after glaucoma surgery in controlled trials,[21 22] as was another antifibrotic agent, 5-fluorouracil.[23 24] We chose to apply mitomycin to the majority of eyes in this study. This was based on reports that success in trabeculectomy is lower in people from Africa or of African descent.[20 25 26] Not all clinical trials have determined that African descent is a risk factor for trabeculectomy failure.[24] Clinical trials that compare trabeculectomy with and without mitomycin have indicated a beneficial effect on IOP success among black people with use of the agent.[22 27] Some studies have documented that mitomycin is associated with greater risks of thin, leaking blebs, hypotony with vision decrease, and late endophthalmitis[21 27] (H Jampel personal communication), though other reports suggest that visually significant hypotony may be infrequent among black subjects treated with mitomycin.[28] As a result, it will be important that those who undergo glaucoma surgery in the developing world have long term follow up for evaluation of these potential problems. None of these complications occurred in our patients, but this may be a result of the small number of people studied.

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