The clinical profile and operative outcomes of adult patients undergoing glaucoma surgery at Queen Elizabeth Central Hospital, Blantyre, Malawi

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ABSTRACT

Objective: This study was conducted to describe the characteristics and operative outcomes of adult patients undergoing glaucoma surgery at the Eye Department at Queen Elizabeth Central Hospital, Blantyre, Malawi.
Methods: This was a retrospective case series review of medical records. Case files of adult patients who underwent glaucoma surgeries between March 2019 and February 2020 were reviewed. The procedures of interest were trabeculectomy, Ahmed glaucoma valve surgery, and combined trabeculectomy and small incision cataract surgery. The primary outcome measure was the percentage post-Operative Intraocular Pressure (IOP) drop with a reduction of 30% or greater classified as a successful surgery. The pre-operative and post-operative median IOPs were compared using Wilcoxon's sign-ranked test. In addition, the Kruskal-Wallis test was used to compare the median IOPs of the three procedures. A multivariate binary logistic regression model was used to analyse possible factors associated with the surgical outcome.
Results: Sixty-two patient records fitting the inclusion criteria were found, reviewed, and analysed. There was a male to female ratio of 2:1. Two-thirds of the study population presented with blindness in one eye, and three quarters had advanced glaucoma. Successful IOP reduction was achieved in 70.9% and 91.9% of eyes on days one and seven post-operation, respectively. There were no statistically significant pre-operative or post-operative factors associated with the outcome identified in this study.
Conclusions: This study shows advanced disease, advanced age and male preponderance among the patients undergoing glaucoma surgery at a tertiary level eye unit in Malawi. Furthermore, the glaucoma surgeries achieved high rates of successful IOP lowering effects comparable to rates from similar studies in other parts of Africa.

Key words: Glaucoma surgery outcomes, Trabeculectomy, Glaucoma drainage device, Intraocular pressure

INTRODUCTION

Glaucoma is the second leading cause of blindness in the world[1]. The number of people with glaucoma is projected to increase to 111.8 million by 2040[1]. In 2020, a global analysis estimated the number of people aged 50 years and above who are blind from glaucoma to be 3.6 million[2].

Africa has the highest prevalence of blindness globally, with 15% attributed to glaucoma[3]. Similarly, local data from a Rapid Assessment of Avoidable Blindness (RAAB) survey in the Southern Region of Malawi reported that glaucoma accounts for 15.8% of blindness[4]. The burden of glaucoma is disproportionately higher in developing countries[5]. This problem is further exacerbated by a lack of disease awareness, poor access to eye care, sub-optimal diagnostic and management tools, as well as socio-economic deprivation.

Patients who suffer from glaucoma experience profound changes in their everyday lives due to functional visual loss, inconvenience, cost of treatment, as well as the side effects of treatment. The absence of symptoms during the early stages is challenging for those affected because they tend to be unaware of any visual impairment until the disease is advanced[1]. This has led to glaucoma being described as the "silent thief of sight"[1].

The main goal of glaucoma management is lowering intraocular pressure (IOP), as this is recognised as the only modifiable risk factor for the development and progression of the condition[6]. Early detection and intervention are crucial in preserving vision[6]. Surgery is usually the preferred form of treatment in Africa, as maintaining lifelong medical therapy is often unachievable[6]. The treatment's success depends on the sustained lowering of IOP and a decrease in the progression of visual loss.

We conducted a retrospective case series review of medical records to describe the clinical profile and operative outcomes of adults undergoing glaucoma surgeries at Queen Elizabeth Central Hospital (QECH) in Blantyre, Malawi. The outcome of interest that determined the success of the procedure was post-operative IOP.

Currently, the success rate of adult glaucoma surgery in Malawi is unknown; hence filling this knowledge gap is crucial in optimising the approach to glaucoma management.

MATERIALS AND METHODS

Setting: This was a retrospective case series review of medical records at the Eye Department of QECH in Blantyre, Malawi, a major referral eye care centre in the southern region of Malawi and one of five units conducting glaucoma surgeries in the country.

Study population: The operating theatre register was used to identify adult patients who underwent surgical treatment for glaucoma from March 2019 to February 2020. The procedures of interest were trabeculectomy, combined manual small incision cataract surgery and trabeculectomy and Ahmed Glaucoma Valve (AGV) implantation. The AGV surgeries were performed without an anti-metabolite agent, while the other procedures of trabeculectomy and combined cataract and trabeculectomy were done using Mitomycin-C (MMC) and 5-Flourauracil (5FU).

Data collection: A total of 76 adult patient case files were identified from the operating theatre register. Of these, 62 (81.6%) paper patient record files were retrieved from the patient records office and analysed in this study. The patient data were extracted using a structured data collection tool from the patient record files. All records belonged to Malawian residents of African origin.

Demographic information was collected from the patient records files. Details on pre-operative assessment such as visual acuity, IOP, CDR, type of glaucoma, previous incisional surgery in the eye to undergo surgery, which eye was operated on and whether the contralateral eye was blind were also recorded. In addition, details on intraoperative findings and post-operative clinical features were recorded. Visual acuity was converted to and graded according to the WHO classification of visual impairment (Appendix 1). The glaucoma was categorised as advanced of the CDR was 0.8 or greater, or they had one eye already blind from glaucoma. The visual acuity had three categories: unchanged, better, or worse. The visual acuity was graded as unchanged if it remained in the same WHO visual impairment category before and after surgery. The visual acuity was graded as worse if it changed to a category with a higher degree of visual impairment after surgery.

Data analysis: Patient data collected was coded, entered, and managed using Microsoft excel. The cleaned data was exported to STATA version 14 for analysis. The primary outcome measure was post-operative IOP reduction at one week. The post-operative IOP reduction was categorised into 'successful' and 'not successful', where success was defined as a percentage IOP reduction of 30% or more. In addition, intra-operative and post-operative complications were recorded and evaluated for association with the success or failure of the glaucoma surgeries. We carried out a bivariate analysis of each predictor variable against the surgical outcome and entered all variables with a p-value <0.25 into the multivariable logistic regression model. We presented results as crude adjusted Odds Ratios (OR), with corresponding 95% Confidence Intervals (CI) and p-values. We used a two-tailed $p<0.05$ to indicate statistical significance. All statistical analyses were conducted using STATA version 14.

Ethical clearance: The study protocol adhered to the tenets of the Declaration of Helsinki and was granted ethical approval by the College of Medicine Research and Ethics Committee (ethics approval certificate number P.11/20/3189). Confidentiality and anonymity of participants were maintained by removing patient identifying markers and collecting data anonymously by providing each participant with a unique study identification number.

RESULTS

Characteristics of the study population: The mean age of the patients was 59.1 years (95% CI: 54.8-63.4) SD ±2.2. The ages of the study patients ranged from 19 to 91 years, and 43 (69.3%) were male.

In the study population, 38 (61.3%) of the 62 eyes had some level of visual impairment prior to surgery. Furthermore, 41 (66.1% 95% CI: 54.0- 78.2) patients had unilateral blindness, that is, having a visual acuity less than 3/60 in the fellow eye, which is graded as blindness according to the WHO criteria for visual impairment (Appendix 1). Three-quarters of the study population had advanced glaucoma, with a CDR of 0.8 or greater. The median (IQR) of the CDR was 0.9 (0.8-1.0). The rest of the population characteristics are shown in Table 1.

Appendix 1: WHO classification of visual impairment

Category	Presenting distance Visual acuity	
	Worse than	beter or equal to
0- mild or no impairment		6/18
1- moderate visual impairment	6/18	6/60
2- severe visual impairment	6/60	3/30
3- blindness	3/60	1/60 or CF at 1m
4- blindness	1/60	PL
5- blindness	NPL	

Copied from the WHO International Statistical Classification of Diseases and Related Health Problems. 10th revision 2016 Chapter VII H54 Blindness and low vision.
CF: Counting fingers
WHO: World Health Organisation
PL: Perception of Light
NPL: No Perception of Light

Table 1: Characteristics of the study population

Variable	Mean age	Median age	IQR
Age	59.1	60.5	50-71
Variable	Frequency	Percentage	95% CI:
Sex			
Male	43	69.4	(57.6- 81.2)
Female	19	30.6	(18.8- 42.4)
Comorbidities			
Diabetes	3	4.8	(0.1- 10.3)
Pre-op vision impairment in operated eye			
Normal to mild visual impairment (6/6 -6/18)	24	38.7	(26.2- 51.2)
Moderate visual impairment (6/24 -6/60)	18	29	(17.4- 40.6)
Severe visual impairment (5/60 -3/60)	10	16.1	(6.7- 25.5)
Blindness (2/60 -1/60)	8	12.9	(4.3- 21.5)
Blindness (HM-LP)	2	3.3	(1.2- 7.7)
Blindness (NLP)	0	0	
Laterality of vision			
Blindness in the fellow eye	41	66.1	(54.0- 78.2)
No blindness in the fellow eye	21	33.9	(21.8- 45.9)
CDR in operated eye (N=55)			
1.0	23	41.8	(28.4- 55.3)
0.8-0.9	19	34.6	(21.6- 47.5)
0.6-0.7	8	14.5	(4.9- 24.2)
<0.6	5	9.1	(1.2- 16.9)
Prior incisional surgery in operated eye			
Yes	14	22.3	(11.9- 32.6)
No	48	77.7	(67.3- 88.1)
Type of glaucoma			
POAG	53	87.1	(78.5- 95.7)
JOAG	7	11.3	(3.2- 19.4)
PACG	1	1.6	(0.6- 4.8)
Operated eye			
Right eye	41	66.1%	(54.0- 78.2)
Left eye	21	33.9%	(21.8- 45.9)

Surgical procedures, complications, and post-operative interventions: All the trabeculectomy and combined cataract and trabeculectomy procedures were done with an anti-metabolite, the majority with MMC. There were seven (11.3%) eyes that experienced nine intra-operative complications.

There were 18 post-operative complications in 11 (17.7%) eyes. Hyphaema was the commonest post-operative complication. Three eyes experienced bleb leaks which required bleb resuturing in the operating theatre. Despite experiencing bleb leaks, these patients maintained a good IOP in the range of 6-10 mmHg. No eye developed post-operative endophthalmitis. The rest of the complications and interventions are shown in Table 2.

Comparison of pre-operative and post-operative vision: The WHO visual acuity grading of 29 (47.5%) of the 61 eyes remained unchanged, while 21 (34.4%) eyes experienced worsening after the glaucoma surgery. Of the 11 patients who experienced improved vision after surgery, six (54.5%) of them belonged to the combined cataract and trabeculectomy group. Figure 1 shows the comparison of pre-operative and post-operative visual outcomes.

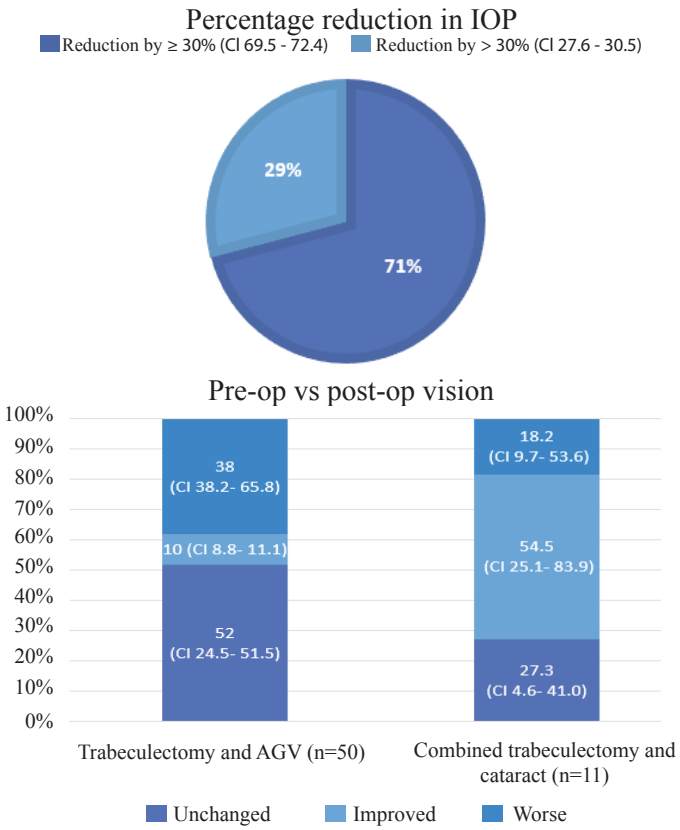

Figure 1: Comparison of pre-operative and post-operative vision andI OP in the study population

Table 2: Surgical procedures, complications and post-operative intervention

Variable	Frequency	Percentage
Procedure performed		
Trabeculectomy with MMC	36	58.1
Trabeculectomy with 5-FU	5	8.1
Ahmed glaucoma valve	10	16.1
Combined cataract and trabeculectomy	11	17.7
Intra-operative complications (n=10)		
Conjunctival buttonhole	3	30.0
Vitreous loss	1	10.0
Iris trauma	3	30.0
PI extension	3	30.0
Post-operative complications (n=18)		
Hyphaema	5	27.7
Hypotony	4	22.2
Flat anterior chamber	3	16.7
Bleb leak	3	16.7
Post-op interventions (n=37)		
Massage	16	43.3
Suture release	8	21.6
Double eye padding	4	10.8
Bleb resuturing	3	8.1
Oral acetazolamide	2	5.4
Intracameral OVD injection	1	2.7
OVD washout	1	2.7
Foreign body removal	1	2.7
Scleral flap revision	1	2.7

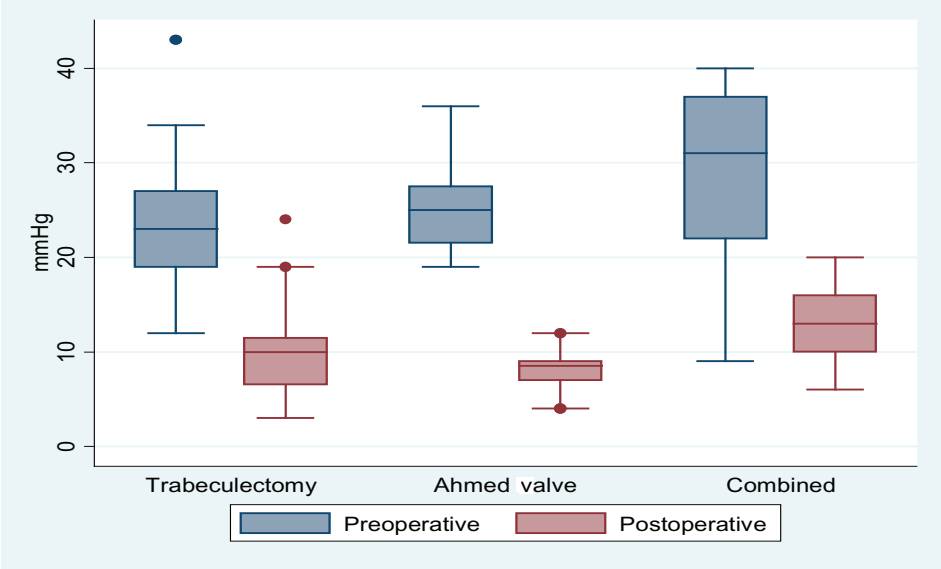

Figure 2: Comparison of pre-operative and post-operative IOP by surgical procedure

Comparison of median IOP: The three surgical procedures resulted in a 60% mean IOP reduction post-operatively. The median pre-operative IOP was 24 (IQR 20-29). The post-operative median IOP was ten on both day one (IQR 8-18) and week one (IQR 7-12.5) post-operatively. The collective pre-operative and post-operative median IOPs were compared using Wilcoxon's sign ranked test. The pre-operative IOP was 25 (CI 23.0-27.0) and the post-operative IOP was 15 (CI 12.0-18.0). A statistically significant IOP reduction was detected between pre-operative and post-operative measurements (mean difference 10.0 CI 6.8-13.3), with a P-value of <0.001.

Comparison of IOP by procedure: Of the three procedures, AGV implantation resulted in the lowest median IOP. Eyes that underwent combined trabeculectomy and cataract surgery had the highest pre-operative IOP with the widest distribution compared to AGV or trabeculectomy surgeries. In addition, AGV produced the narrowest range of post-operative IOPs. This is shown in Figure 2.

A Kruskal-Wallis test was used to compare the median IOPs of the three procedures. The median pre-operative IOP for the trabeculectomy, Ahmed valve and combined cataract and trabeculectomy were 23.9 (21.6- 26.2), 25.4 (20.9- 29.9) and 28.9 (21.9- 35.9) while the post-operative IOP were 10.0 (8.4- 11.6), 7.9 (6.1- 9.7) and 12.5 (9.9-15.2) respectively. There was a statistically significant difference in the population median IOPs between the three procedures with a P-value of 0.045.

Factors affecting the surgical outcome: A multivariate binary logistic regression model was used to identify possible factors associated with the outcome of the glaucoma surgeries. There were no statistically significant factors that affected the surgical outcome identified in this study.

DISCUSSION

The mean age of the study population was 59.1 years, with the majority (88.7%) of patients being above 40 years of age. Other African studies that analysed glaucoma surgery outcomes have reported mean age in the range of 56-67 years[7–10].

There was a gender disparity among the patients who underwent surgery in our study with 69.4% of the population being male. This is similar to a previous study done at the same study location[11], and is also similar to studies from Nigeria, Ghana, and Tanzania where men comprised 74%, 65% and 72%, respectively[12–14] of POAG patients presenting at eye care facilities. One possible reason for the lack of equity is the interplay of cultural factors in low-income countries like Malawi[15]. For example, women are less likely to be educated and access information regarding health care services. The males are usually the breadwinner and women do not have control over the household income or any influence over decision making in the home[16].

In our study, three-quarters of the patients had advanced glaucoma, with two-thirds of the operated eyes having some degree of visual impairment prior to surgery and 16.2% being blind. Most patients with glaucoma in low-income countries present with advanced disease due to late presentation[12,13]. One reason for late presentation with glaucoma is a low socio-economic status[17]. Other barriers to accessing eye care services in Africa in general include lack of awareness about glaucoma, cultural belief and misconceptions about the cause of blindness, shortage of ophthalmologists, lack of functional referral systems, and inadequate access to eye care facilities[1,3,18,19]. All these factors culminate in an increased burden of avoidable blindness.

Regarding surgical outcomes, 70.9% of eyes that underwent glaucoma surgery achieved a successful IOP reduction one day post-operatively, rising to 91.9% at one week. In comparison, a review article on the success rates of glaucoma surgeries in Africa reported a range from 61.8% to 90%[20]. It is worth noting that these studies had varying follow-up times, with the final follow-up time ranging from 6 to 60 months. Although a longer follow-up time allows for a comprehensive understanding of the success rate of glaucoma surgeries, it is essential to study immediate post-operative outcomes as they are a proxy indicator of the long-term success of the surgical treatment [21,22]. Literature shows that early post-operative IOP reduction is linked to the long-term success of glaucoma surgery[21,22].

The IOP was lower in the trabeculectomy group compared to the combined cataract surgery and trabeculectomy group, similar to other research on combined surgery in managing eyes with cataracts and POAG[23]. However, in the latter, the procedure performed was the phacotrabeculectomy which is considered the "treatment of choice" in glaucoma patients with coexisting cataracts[24]. In contrast, the combined procedure performed in this study population was trabeculectomy and manual small-incision extracapsular cataract extraction.

The AGV surgery produced the lowest mean post-operative IOP. This finding is similar to that reported in the landmark Tube Versus Trabeculectomy (TVT) study. It was found that both trabeculectomy with anti-metabolite and tube surgery resulted in a significant and sustained reduction of IOP, with the latter having a higher success rate. However, at the end of the follow-up period of 5 years, both procedures had similar IOP reduction[25].

In addition, the AGV resulted in a lower range of post-operative IOPs compared to the trabeculectomy and combined cataract and trabeculectomy procedures. While the efficacy of a trabeculectomy can be influenced by a surgeon's experience[26], the AGV contains a standard filtration route with a valve mechanism primed to open and close so that aqueous humour flow is maintained in the range of 8–12 mmHg[27]. This suggests that the AGV may result in more predictable post-operative IOP levels compared to trabeculectomy and combined cataract and trabeculectomy. The AGV devices are not readily available at our hospital, and as such, their use is limited to patients with failed trabeculectomy or secondary glaucomas.

In the trabeculectomy and AGV group 38% of eyes had worsening of visual acuity. This occurrence in the early post-operative period has been reported in other studies[28,29], with some improvement to baseline vision seen on follow up. In addition, 52.0% of the operated eyes had the same level of visual acuity before and after surgery which is a favourable outcome since the primary goal of surgery is to stabilise visual acuity and disease progression by lowering IOP. It is imperative that the patient, through careful counselling understands expected outcome, minor risk of post-operative visual decline and the high risk of blindness without surgery[6].

An improvement in visual acuity was seen in six (54.5%) of eyes that underwent the combined cataract and trabeculectomy procedure. Similar findings were reported in a study done in Eastern Africa that assessed the visual and IOP outcomes in combined cataract and trabeculectomy surgery[7]. Visual outcomes were encouraging, considering the advanced glaucomatous optic neuropathy. At discharge, there was an improvement in visual acuity in 58 (41%) of 142 eyes compared with the pre-operative measurement; on the other hand, the vision was unchanged in 43 (30%) eyes and was worse in 20 (29%) of eyes.

One limitation of the study was that due to the Covid-19 pandemic, the number of patients that presented at QECH with glaucoma during the last quarter of the study time period was very low. This resulted in having a small sample of patients with this condition, which may have influenced the non-significant findings obtained in the study. Another limitation is the retrospective nature of the study. QECH uses paper-based system of records, which only contains post-operative data up to 10 days. Our recommendation is that a large-scale prospective study should be carried out to provide a complete understanding of the post-operative outcomes.

CONCLUSIONS

This study found that most patients undergoing glaucoma surgeries at QECH were males and had advanced disease. In addition, this study showed that approximately two-thirds of the glaucoma surgeries performed at the Eye Department of QECH achieve a successful IOP reduction comparable to rates seen in studies published in other parts of Africa. The Ahmed valve glaucoma surgery was the most successful surgical procedure for lowering IOP.

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Availability of data and materials: The datasets used during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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