Jimma University Institute of Health, Faculty of Medical Science, Department of Ophthalmology

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Trabeculectomy outcomes among patients with Glaucoma at Jimma university medical center department of ophthalmology from 2020 to 2023 in Jimma, Ethiopia

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Research Thesis To Be Submitted To Department Of Ophthalmology, Faculty Of Medical Science, Institute Of Health, Jimma University In Partial Fulfillment Of The Requirements For The Specialization Degree In Ophthalmology

Trabeculectomy outcome at Jimma university medical center department of ophthalmology 2020-2023.

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Abstract

Background

Glaucoma is the second most common cause of blindness and has been the burden of the health sector for the past few years with its vision- and life-related threats. The presentation can be different based on its stage, and the most common means of treatment is medical, though surgical treatment like trabeculectomy can also be the best alternative with different indications that lead to variable success rates.

Objectives

The purpose of the study is to present the outcome of trabeculectomy at Jimma University Medical Center and its intraoperative and postoperative complications.

Method

A hospital-based, retrospective analytic study was conducted among patients who had undergone trabeculectomy in 2020–2023. A structured questionnaire was used to collect data, which was coded and entered into epidata and then exported to SPSS version 27 for statistical analysis. A descriptive statistical analysis, cross tabulations, linear logistic regression, chi-square test, and Fisher exact test were performed. $P < 0.05$ is considered statistically significant.

Result

A total of 79 patients were studied, with a mean age of 54.2 years and a male-to-female ratio of nearly 4:1. In this study, 30 (38%) surgeries were done by glaucoma surgeons, 39 (49.4%) of them by general ophthalmologists, and 10 (12.7%) of them by residents. In all cases, MMC was used, and in 43 (54.4%) of cases, MMC was soaked in subconjunctiva space, and in 36 (45.6%) of cases, MMC was given a subconjunctiva injection. Preoperatively, the mean IOP was 30.72 ± 10.941 mmHg, and the mean postoperative IOP at least six months after surgery was reduced to 12.68 mmHg ± 5.360 mmHg, p =

0.001. The preoperative mean VA was 0.11 ± 0.165, and the mean VA postoperatively at six months was 0.103 ± 0.112, p = 0.048. Complete success was found to be 83.5%, qualified success was 3.8%, failure was seen in 11.4%, and hypotony in 1.3%. The overall success (both complete and qualified success) was 88.5% based on IOP.

Conclusion and Recommendation

Based on the IOP level, the success rate of trabeculectomy after six months of the surgery was 87.3%, which is good. The mean preoperative VA was dropped by one line, and there was a significant improvement in IOP six months after surgery. To explore predictors for surgical failure and increase efficacy, it is better to assess a long-term multicenter prospective follow-up study regarding the outcome of trabeculectomy

Key word

Glaucoma, Trabeculectomy, Intraocular pressure

Contents

Acknowledgment

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List of Abbreviations and Acronym's

AACG: Acute Angle Closure Glaucoma

AC: Anterior Chamber

AGM; Anti-Glaucoma Medications

CACG: Chronic Angle Closure Glaucoma

DM: Diabetes Mellitus

FDT: Frequency Doubling Technology

HTN: Hypertension

IOP: Intra Ocular Pressure

ISNT rule: Inferior rim > Superior rim > Nasal rim > Temporal rim

JOAG: Juvenile Open Angle Glaucoma

JUDO: Jimma University Department of Ophthalmology

KP`s: Keratic Precipitates

MMC: Mitomycin C

5-FU: 5-Fluorouracil

NRR: Neuro Retinal Rim

NTG: Normo Tensive Glaucoma

NVG: Neo Vascular Glaucoma

POAG: Primary Open Angle Glaucoma

PXG: Pseudoexfoliative Glaucoma

RBA: Retro Bulbar Anesthesia

RE: Refractive Error

RNFL: Retinal Nerve Fiber Layer

STA: Subtenon Anesthesia

V/A: Visual Acuity

V/F**:** Visual Field

VCDR: Vertical Cup to Disc Ratio

VH: Van Herick

ONE: INTRODUCTION

1.1.1 Background

Glaucoma is a group of diseases that have in common a characteristic optic neuropathy with associated visual function loss. Elevated intraocular pressure (IOP) is one of the primary risk factors (1). WHO estimated the global population of people with high IOP (>21 mm Hg) at 104.5 million. The incidence (newly identified cases) of primary open angle glaucoma (POAG) was estimated at 2.4 million people per year. Blindness prevalence for all types of glaucoma was estimated at more than 8 million people, with 4 million cases caused by POAG. The different types of glaucoma were theoretically calculated to be responsible for 15% of blindness, placing glaucoma as the second leading cause of blindness worldwide, following cataract (1).

Open angle glaucoma is usually insidious in onset, slowly progressive, and painless. Though usually bilateral it can be quite asymmetric. Because central visual acuity is relatively unaffected until late in the disease, visual field loss may be significant before symptoms are noted (2). There are five stages of glaucoma: stage one (initiating events), where chain of events that eventually may lead to optic nerve damage and visual loss, precede any pathologic alterations related to aqueous humor dynamics or optic nerve function. Stage two is stage of structural alterations and tissue changes which farther lead to stage three, functional alterations. This third stage is a stage of physiologic abnormalities that may lead to optic nerve damage and retinal ganglion cell loss that is stage four. Stage five is the end result of all the above stages, where progressive visual field loss occurs (2).

The pathophysiology of glaucomatous optic neuropathy is not well understood. Whether the site of primary damage is the ganglion cell body or their axons remains fiercely debatable. Irrespective of the initial site of neuronal injury and mechanisms involved, the terminal outcome is the death of RGCs and their axons leading to irreversible visual loss (18).

Glaucoma has different type classification; based on understanding of pathophysiology it is classified as primary, where there is no apparent contribution from other ocular or systemic disorders, and secondary, where there is a partial understanding of underlying predisposing ocular or systemic events. The first thought to has genetic basis and usually bilateral (2). Based

on mechanism of aqueous out flow obstruction, it is divided as open angle, in which AC angle structures are visible by gonioscopy, and closed angle, in which the peripheral iris is in apposition to trabecular meshwork or peripheral cornea. Closed angle glaucoma also classified as pulled mechanism (anterior contraction) and pushed mechanism (posterior mechanism, pressure behind the iris) (2).

Despite continued advances in laser and incisional surgery, medical therapy still appears to be the primary means by which intraocular pressure is controlled. Initial medical therapy has changed with the introduction of prostaglandin analogs, which are replacing β-antagonists as the drug of first choice. Laser trabeculoplasty, using either photocoagulative (argon and diode) or photodisruptive (frequency doubled Nd:YAG) lasers, is still reserved for patients who do not improve with medical therapy, although there is good evidence that initial laser trabeculoplasty is just as effective as initial medical therapy. Trabeculectomy with antifibrotic agents (5-fluorouracil or mitomycin C) is still the next step in intraocular pressure control, and glaucoma drainage implants are reserved for refractory cases. Cyclophotocoagulation is a last resort procedure because of poor visual outcomes and is reserved for patients with intractable pain and vision thought not to be useful (19).

1.1.2 Statement of the problem

Glaucoma is the second leading cause of blindness globally and most patients in Africa present with advanced stage of the disease or unilateral blindness with high intraocular pressure (IOP) (3, 4).The global prevalence of glaucoma for population aged 40-80 years is 3.54%. The prevalence of POAG is highest in Africa 4.20%, and the prevalence of PACG is highest in Asia 1.09%. In 2013, the number of people (aged 40-80 years) with glaucoma worldwide was estimated to be 64.3 million, increasing to 76.0 million in 2020 and 111.8 million in 2040(22). In 2005 in Ethiopia National Blindness and Low Vision Survey was conducted it shows glaucoma was found to be the fifth leading causes of blindness in Ethiopia contributing 5.2% to the total blindness (23) . The prevalence of glaucoma in Ethiopia was 7.9% (20), with these Magnitude patients have different means of management like Anti-Glaucoma Medication (AGM), LASER, Trabeculectomy, tube shunt and x-press shunt. Most common indication for trabeculectomy in developing country like Ethiopia is Disease progression, poor IOP control, and poor adherence, financial related problem and etc.

Medical treatment is usually difficult due to the unavailability and cost of glaucoma medication, poor compliance as well as follow-up. Trabeculectomy is a well-recognized treatment option for the surgical management of glaucoma. It has been reported to be beneficial in terms of IOP lowering effect and slowing down of field loss (3, 4). However, the success rate as well as the complications may be different based on various factors- physician, age and race of the patient, type of glaucoma, use of ant scarring agents etc.

Wound healing modulating agents, usually anti- metabolites like 5-Fluorouracil and Mitomycin C (MMC) which inhibit the natural healing response and scar formation are used to reduce trabeculectomy failure (3). This was based on reports that success in trabeculectomy is lower in people from Africa or of African descent (3,4).

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 (3). Some studies have documented that mitomycin is associated with greater risks of thin, leaking blebs, hypotony with vision decrease, and late endophthalmitis (3), though other reports suggest that visually significant hypotony may be infrequent among black subjects treated with mitomycin (3). While the success of glaucoma surgery is important to its effective use in public health programs, its detrimental effects must also be considered.

Although MMC is a powerful antiproliferative, no best technique for its application or an optimal dosage has yet been defined. MMC is usually administered at the time of surgery using a sponge soaked in 0.2--0.5 mg/ml of this agent and placed between the sclera and conjunctival flap for 1-5 minutes (3). Applying the anti-metabolites over a wide area is believed to reduce the risk of a cystic bleb forming as well as avoiding increased risks of premature failure caused by scarring around the drainage site (5, 6, 7, 8,). Subconjunctival injection of MMC has been previously reported with various outcomes. It is thought a diffuse area of action would be obtained and direct toxicity to the conjunctiva reduced. While some reported scleral or corneal necrosis, others didn’t encounter any such complications attributable to the subconjunctival application of the MMC.A recent randomized clinical trial study comparing sub- conjunctival mitomycin C (0.02 mg) versus subconjunctival 5-fluorouracil (5mg) reported a similar efficacy between the techniques in lowering IOP (3).

It is therefore very important to study outcomes of trabeculectomy performed in a given setting, since most of Developing country, glaucoma patients have difficulty of getting medication due to availability and affordability in addition to poor IOP control and poor adherence where trabeculectomy can be an option for all the challenge we have.

1.1.3 Significance of the study

Trabeculectomy is a well-recognized treatment option for the surgical management of glaucoma. However, the success rate as well as the complications may be different based on various factors-physician, age and race of the patient, type of glaucoma, use of ant scarring agents etc. Wound healing modulating agents, usually anti- metabolites like 5-Fluorouracil and Mitomycin C which inhibit the natural healing response and scar formation are used to reduce trabeculectomy failure. Up to the knowledge (awareness) is concerned, there was no research done in South West Ethiopia concerning the outcome of trabeculectomy.

The Researches which were done in Ethiopia only asses the outcome based on IOP and VA. But in this research we also try to see it in terms of Intra operative and post-operative complications.

The findings of this study will assist to Understand the outcome of trabeculectomy with and without Mytomicin C will help to develop guidelines on how to manage glaucoma patients in our country. This study as it is a pioneer study in this region, it will help as a stepping stone for the future studies that will be conducted in this area, in addition understanding the outcome of trabeculectomy will help to forward policy makers in planning appropriate strategies as well as exploring the financial resources in the future.

CHAPTER TWO: LITERATURE REVIEW

Trabeculectomy is an incisional procedure in which a fistula is created between the anterior chamber and the subconjunctival space, bypassing the normal aqueous outflow pathway. The aqueous flows into the subconjunctival space, usually leading to an elevation of the conjunctiva, referred to as a filtering bleb. This procedure was initially performed as a full-thickness ("unguarded") procedure. High complication rates related to hypotony led to a major evolution in the surgical technique in that the fistula is now created under a partial-thickness flap of sclera ("guarding" the flow of aqueous) as a means of providing some resistance to aqueous flow through the fistula, thereby lowering the risk of postoperative hypotony(1,9).

There are different studies done on outcome of trabeculectomy worldwide. According to Retrospective cohort study with a total of 234 patients (330 procedures) who had undergone trabeculectomy surgery at Addenbrooke's Hospital, Cambridge, United Kingdom, between January 1988 and December 1990, Patients were identified through surgical logbooks. Surgical success was defined as "complete success" while intraocular pressure (IOP) remained 21 mm Hg with no additional medication and as "qualified success" if those requiring additional topical medication were included. Functional success was defined if patients did not progress to legal blindness (visual acuity 3/60 or visual field 10 degrees). After 20 years, 57% were classified as complete success, 88% were classified as qualified Success and 15% had become blind. Those at risk of trabeculectomy failure were younger or had uveitic Glaucoma. Those with pseudoexfoliation or aphakia were more likely to progress to blindness (10).

Another Retrospective study that evaluates medical charts of 547 patients undergoing glaucoma filtering surgery at the Department of Ophthalmology of the University of Cologne from 1987 to 1996 was reviewed. The status of the visual field, level of visual acuity, appearance of the bleb, cup/disc ratio and IOP were studied. Pre- and post-operative glaucoma medication was recorded. The eyes with congenital glaucoma and those treated with antimetabolites were excluded. The results are presented with particular emphasis being placed not only on intraocular pressure (IOP)

control but also on the progression of glaucomatous damage (deterioration of visual field or disc damage) and the decrease of visual acuity. The tonometric success rate of Trabeculectomy in controlling the IOP < 21 mmHg was 61%. Defining the rigid criteria for success of trabeculectomy as an IOP < 21 mmHg, no further visual field loss, no disc damage and no additionally required surgical intervention due to glaucoma, the success rate decreased to 44% (11).

A retrospective and noncomparative case series analysis was performed on data from Tri-Services General Hospital, Taiwan, from 2001 to 2004. The outcomes of trabeculectomy in eyes with acute primary angle closure glaucoma attack (AACG) and those with chronic primary angle-closure glaucoma (CACG) were assessed in terms of final intraocular pressure (IOP), changes to visual acuity, and the incidence of complications. A total of 52 eyes of 52 patients, 15 patients in AACG group and 37 patients in CACG group, were reviewed. The mean follow-up period was 32 months (range, 26-42 mo). Overall, no change in final visual acuity was found in 34 patients (65.4%), a loss of 1 line was found in 10 patients (19.2%), and a loss of 2 or more lines was found in 8 patients (15.4%). A complete success in final IOP was found in 34 patients (65.4%), and a qualified success was found in 9 patients (17.3%). The total trabeculectomy success rate in the study was 82.7% (12).

A Multicenter Analysis that evaluate the efficacy and safety of current trabeculectomy surgery in the United Kingdom which was Cross-sectional, multicenter, retrospective follow-up involving A total of 428 eyes of 395 patients which assed the outcome in terms of Surgical success, intraocular pressure (IOP), visual acuity, complications, and interventions. Success was stratified according to IOP, use of hypotensive medications, bleb needling, and resuturing/ revision for hypotony. Reoperation for glaucoma and loss of perception of light were classified as failures. Antifibrotics were used in 400 cases (93%): mitomycin C (MMC) in 271 (63%), 5-fluorouracil (5-FU) in 129 (30%), and no antifibrotic in 28 (7%). At 2 years, IOP (mean +/- standard deviation) was 12.4 +/- 4 mmHg, and 342 patients (80%) achieved an IOP </=21 mmHg and 20% reduction of preoperative IOP without IOP lowering medication, whereas 374 patients (87%) achieved an IOP </=21 mmHg and 20% reduction of preoperative IOP overall. An IOP </=18 mmHg and 20% reduction of preoperative IOP were achieved by 337 trabeculectomies

(78%) without IOP-lowering treatment and by 367 trabeculectomies (86%) including hypotensive medication. Postoperative treatments included suture manipulation in 184 patients (43%), resuturing or revision for hypotony in 30 patients (7%), bleb needling in 71 patients (17%), and cataract extraction in 111 of 363 patients (31%). Subconjunctival 5-FU injection was performed postoperatively in 119 patients (28%). Visual loss of >2 Snellen lines occurred in 24 of 428 patients (5.6%). A total of 31 of the 428 patients (7.2%) had late-onset hypotony (IOP <6 mmHg after 6 months). In 3 of these, visual acuity decreased by >2 Snellen lines. Bleb leaks were observed in 59 cases (14%), 56 (95%) of which occurred within 3 months. Two patients developed blebitis. Bleb-related endophthalmitis developed in 1 patient within 1 month postoperatively and in 1 patient at 3 years. There was an endophthalmitis associated with subsequent cataract surgery (13).

Studies done in African set up were very limited. One retrospective case-note search was carried out from operating theatre records in a private hospital at Lagos, Nigeria from 1989 to 1997. Patients undergoing primary trabeculectomy with a minimum follow-up of 6 months were included in the study. Visiting Consultants and registrars from the UK performed the surgery. Descriptive statistics And life-table analysis were applied to the data. Results 142 eyes of 100 patients were included in the study. When the criteria for success were an intraocular pressure (lOP) of less than 22 mmHg, 30% reduction from pre-operative levels and a decrease in visual acuity of less than 3 Snellen chart lines, then by life-table analysis success rates were 85%, 82% and 71% at the 1, 2 and 5 year postoperative intervals respectively. Success rates were lower if an lOP of less than 16 mmHg was taken as one of the criteria (65%, 61% and 46% at the 1, 2 and 5 year intervals, respectively) (14)

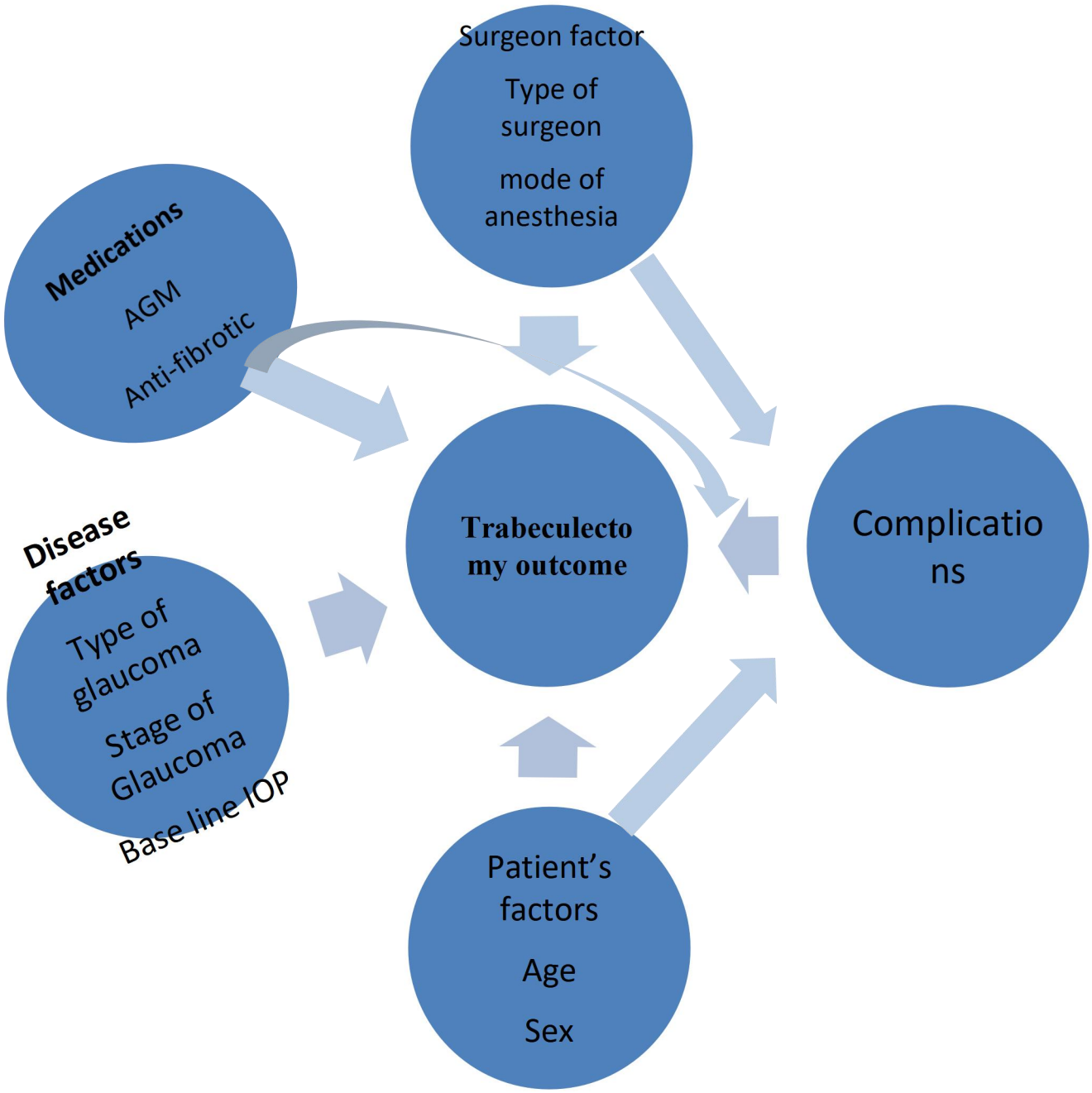
The review of literature done in African set up revealed the following: A total of 109 articles, published from 2000 to December 2012 were retrieved. Only 12 articles met inclusion criteria and were included in the study. The follow-up duration ranged from 6 months to 60 months. The post-trabeculectomy IOP range was 10 mmHg to 22 mmHg with rates varying from 61.8% to 90%. The visual acuity was unchanged among 19% to 30% of the participants in the last follow-up, and the improvement rate was 36% to 81.5% while those whose condition worsened ranged from 8.9% to 30.8%. The cup-disc ratio was ≤0.5 in 13% and ≥0.8 in 83% of the participants.

The failure rate of the c/d ratio was 0.9 and it increased by 0.027 units. There was a follow-up of only one study on the visual field. Trabeculectomy with or without application of antimetabolite appears to be a good way to lowering the IOP in Africa. In addition, the combined effect of trabeculectomy and cataract surgery produces visual benefits for the patients (15)

Retrospective Study done in Norththwest Ethiopia (Gonder) on a total of 69 eyes of 63 patients having post-operative follow up of six months was included in the study. The mean age at the presentation was 59.12 ± 12.64 years. On the last day before surgery, mean snellen VA was 0.28 (± 0.23) and it was changed to 0.24 (± 0.20) p=0.38, mean IOP was 31.87 mmHg (± 10.08) and it was reduced to 18.45 mmHg (± 6.12) p=0.001, mean CDR was 0.84 mm (± 0.13) and was changed to 0.85 mm (± 0.12), p= 0.009 at six months after surgery. Complete success and failure of trabeculectomy was 52 (75.4%) and 8 (11.6%), respectively. Based on IOP, the success rate of trabeculectomy was 75.4%. The mean preoperative VA was dropped by one line at six month after surgery and there was significant reduction of IOP from its base line. (16)

Retrospective Study done in Menelik II referral hospital, Addis Ababa, Ethiopia on a total of 166 charts of patients were reviewed; open angle glaucoma accounted for 86 (52.4%) and Pseudoexfoliative glaucoma for 79 (47.6%). 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. 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. (17)

CONCEPTUAL FRAMEWORK



CHAPTER THREE: OBJECTIVE OF THE STUDY

3.1 General objective

- To assess the outcome of trabeculectomy performed in Jimma university department of ophthalmology (JUDO) from 2020 –2023.

3.2 Specific objectives

- To identify the outcome of trabeculectomy performed in JUDO during the study period based on IOP change.
- To identify VA change for patients who had trabeculectomy surgery performed in JUDO during the study period
- To identify the intraoperative complications of trabeculectomy.
- To identify the post-operative complications of trabeculectomy.

CHAPTER FOUR: METHOD AND MATERIALS

4.1 Study area and period

4.1.1 Study Area

Jimma town is the administrative center of Jimma Zone, and is located in the Oromia region of Ethiopia, 352 km southwest of the capital Addis Ababa. The town has a city administration, municipality, and 17 Kebeles

JUDO was founded in 1980s by the Ethio-Italian cooperation as part of the prevention of blindness activity all over the country. It was renovated in 2006. The department's main objective is training undergraduate and post graduate students, provision of total tertiary eye care at the static and comprehensive eye care at outreach sites & conducting problem solving researches. Being under Jimma University, it also runs both undergraduate and postgraduate studies. JUDO is tertiary eye centre, carrying out multifaceted ophthalmic training and eye care service. It serves a total population of 20 million people in southwest Ethiopia and it is the only tertiary eye care center in the region. It has bed capacity of 48, 7 outpatient clinics, 3 subspecialist ophthalmologist, 10 ophthalmologist, 24 Residents, 3 optometrist, 3 ophthalmic nurses, 12 Operation Room (OR) nurses and 18 General Nurses. Glaucoma clinic is one of the specialty clinics found in JUDO.

4.1.2 Study Period:

The study was conducted on Glaucoma patients operated from March, 2020 – February, 2023 G.C.

4.2 Study design:

Hospital based, retrospective study was employed on candidate patients who had undergone Trabeculectomy at JUMC department of Ophthalmology from January, 2020 – January, 2023 G.C.

4.3 Populations

4.3.1 Source population

All patients who have Trabeculectomy surgery at JUDO.

4.3.2 Study population

All patients who have undergone Trabeculectomy at JUDO in the study period

4.3.3 Sample size and sampling procedures

4.3.3.1 Sample size calculation:

All study subjects who met the inclusion criteria included.

4.3.3.2 Sampling procedures

All medical charts of patients, who underwent Trabeculectomy surgery, fulfilled the inclusion criteria included in the study.

4.4. Inclusion and exclusion criteria

4.4.1 Inclusion criteria

Medical records of patients, who underwent trabeculectomy from 2020 - 2023 with or without mitomycin C by the Glaucoma surgeon, General Ophthalmologist and Ophthalmology Residents in the Department of Ophthalmology, and medical records of Patients who had completed 6 months of postoperative follow-up and for whom IOP was taken during the follow up period were included in this study.

4.4.2. Exclusion criteria

- Medical records of patients who did not complete 6 months of postoperative follow-up and for whom IOP was not taken during the follow up period excluded.
- Those who had additional laser therapy and/or tube shunt
- Incomplete or lost medical records excluded.

4.5 Study variables

4.5.1 Dependent variables

- Trabeculectomy outcome

4.5.2 Independent variables

- Age, sex, type of glaucoma, stage of glaucoma, systemic disease and Ocular morbidity, vertical CD ratio, Baseline IOP, aneasthesia, Releasable suture, Surgeon type, Anti-fibrotic,AGM)

4.6. Data collection procedure

Medical record number (identification number) of patients who have undergone trabeculectomy surgery from March 2020 – February 2023 G.C was collected from Major operation theatre registration log book and /or out patients Glaucoma clinic follow up registration logbook and then the charts of the patients collected from medical records room. The medical records (charts) were made available to data collectors on weekends and returned to medical records room on working days. Data collection tool; questions & tables were used to guide extraction of data from the individual medical records (chart).

A predesigned format used to retrieve important clinical information from the medical record which includes, age and sex of the patient, type of glaucoma, baseline as well as postoperative visual acuity (VA), baseline and postoperative IOP, preoperative and postoperative glaucoma medication, Postoperative VA and IOP, Any intraoperative complication, any postoperative complication and secondary intervention.

Materials needed**:** medical records of patients, pen, pencils, and paper were used to collect the data.

Data collectors: The clinical data collected by trained ophthalmic nurse.

4.7 Data analysis

The data was collected and exported to SPSS version 27 after entering into Epi data version 3.1. We cleaned and coded using SPSS version 27.0 for analysis. Descriptive statistics (frequencies and percentages) were computed to show the picture of the data. “Chi square and Fisher exact tests were used to determine the association between dependent and independent variables. Paired samples t-test was performed to compare thecorrespondent preoperative and postoperative IOP, VA. P- value <0.05 was considered significant

4.8 Data quality control

Trained ophthalmic nurses collected data. Half day training were given for data collectors regarding study objective, data collection and measurements ethical issues during data collection and how to fill the predesigned format properly. The format was always filled by trained data collectors. Pretest was done for about 10 patients from total study population a day before the actual data collection time in order to assess its clarity, length, completeness and consistency. Data collection tool was checked daily for accuracy, consistency, and completeness. Data was cleared, cleaned by principal investigator.

4.9 Ethical consideration

Before starting the research, as per the basic principles of World Medical Association Declaration of Helsinki, ethical review committee of Jimma University College of Health Sciences approved the proposal and provided us support letter. This support letter was given to the head of Jimma Medical Center.

4.10 Operational definition of terms

Staging of glaucoma based on the ONH features is adapted from Damji et al (17, 21):

- Early glaucoma - Early glaucomatous disc features C/D <0.65
- Moderate glaucoma - Moderate glaucomatous disc features (e.g. vertical C/D 0.7–0.85
- Advanced glaucoma - Advanced glaucomatous disc features (e.g. C/D >=0.9)
- Baseline IOP**:** IOP taken during trabeculectomy surgery decision.
- Normal Vision: presenting VA ≥ 6/12 (0.5) in the of operated eye

- Visual impairment/ low vision: visual acuity of less than 6/12 (0.5), but equal to or better than 6/60 (0.1), or corresponding visual field loss to less than 20 degrees, in the better eye with best possible correction.
- severe visual impairment - visual acuity of 6/75 (0.08) to 6/120 (.05)
- Blindness: Presenting visual acuity of less than 6/120 (0.05), or corresponding visual field loss to less than 10 degrees, in the better eye.
- Complete success: if the mean IOP was ≤21 and >5 mmHg or 30 % reduction from the base line without anti-glaucoma medications,
- Qualified success: if the mean IOP was ≤21 and >5 mmHg or 30 % reduction from the base line with one anti-glaucoma medication,
- Failure: if mean IOP was >21mmHg with anti-glaucoma medication
- Hypotony: if IOP was ≤5mmHg (10,17).

4.11 Plan for dissemination of results

Findings of this research will be distributed to Jimma University postgraduate and research study office. It will be presented on a national ophthalmic association meeting. It will also be made available for a publication on international journals. Further, it will be uploaded and made available on the Website of Jimma University.

Chapter 5: Results

This retrospective review identified a total of 148 medical records of trabeculectomy procedures that were performed from March 2020 to February 2023. Of these, 79 charts with Trabeculectoy surgeries met the inclusion criteria.

There were 62 males (78.5%) and 17 females (21.5%), with a male-to-female ratio of nearly 4:1. The mean age was 54.23 years (SD = 17.076, 14–99 years) **(Table 1).**

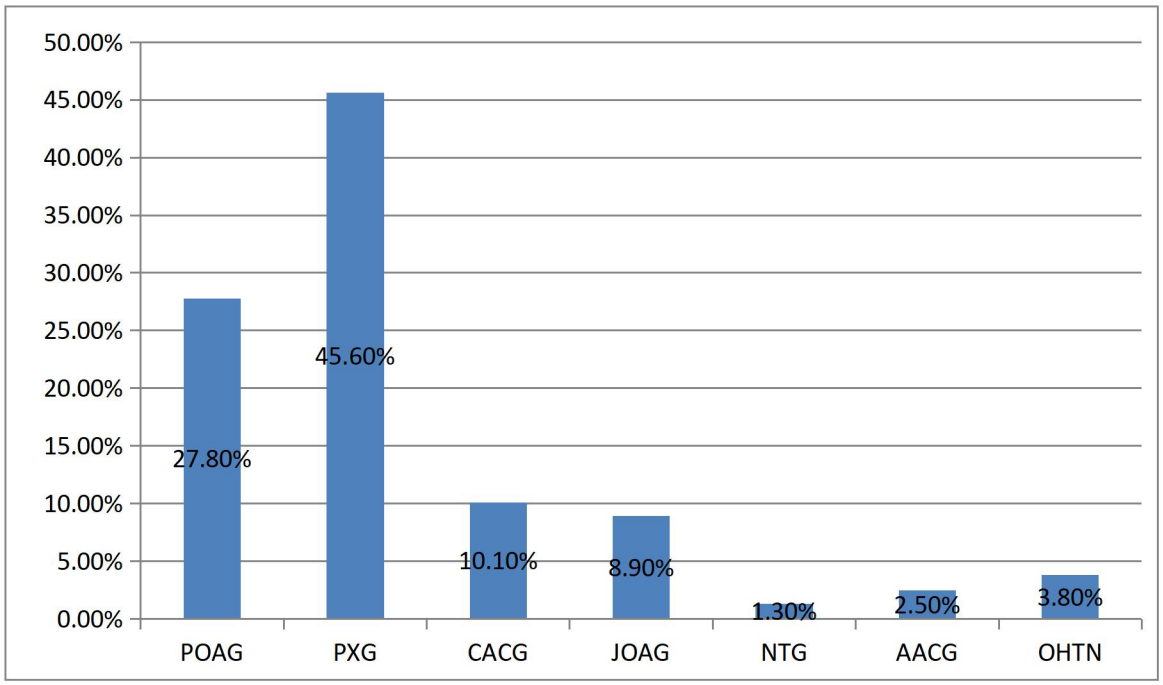
Table 1: Age sex distribution

Age catagory	Sex		
	Male	Female	Total
< 40 years	10(12.6%)	9(11.4%)	19(24%)
40-60 years	31(39.2%)	4(5.1%)	35(44.3%)
>60 years	21(26.6%)	4(5.1%)	25(31.6%)
Total	62(78.5%)	17(21.5%)	79(100%)

Preoperative data of the study population

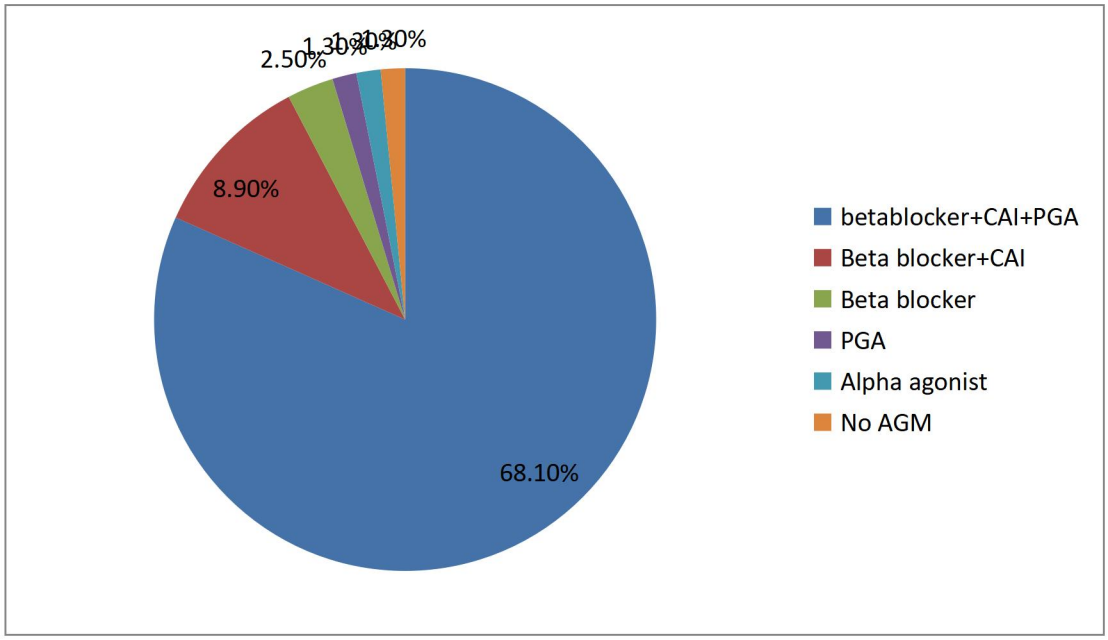
The types of glaucoma from trabeclectomy surgery Patient Pseudoexfolation glaucom (PXG) accounts for 36 (45.6%) cases,Primary Open angle glaucoma(POAG) 22 (27.8%), Chronic angle closure glaucoma (CACG) 8 (10.1%), and Juvenile open angle glaucoma (JOAG) 7 (8.9%) **(Figure 1)**. The mean IOP before surgery was 30.72 ±10.941 mmHg. The mean VA before surgery was 0.11008 ±0.1652

Figure1: Types of Glaucoma of study population



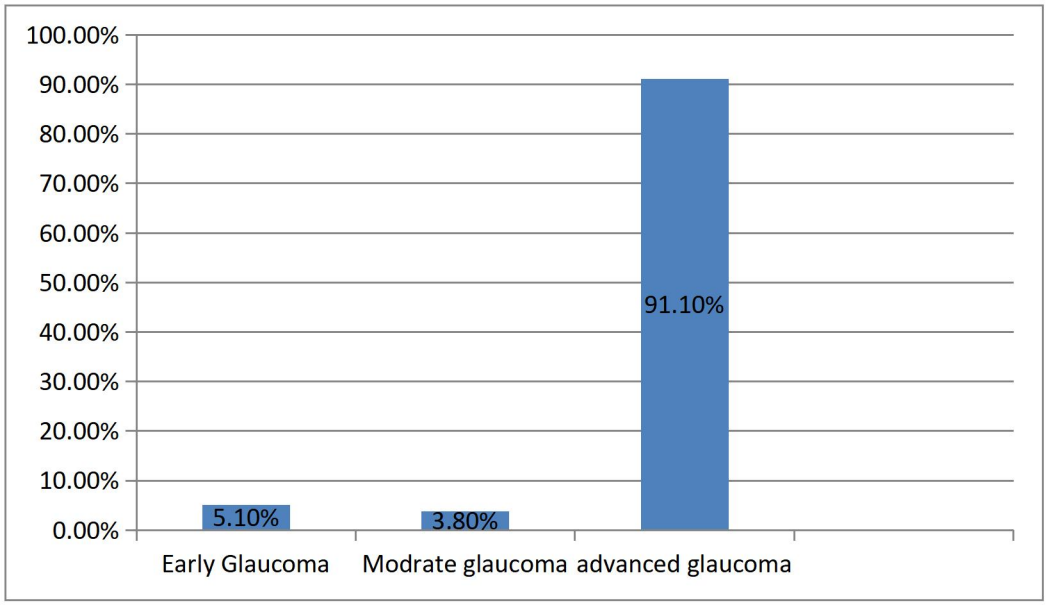
Except for one patient, all patients were applying topical anti glaucoma medication (AGM), of which beta-blocker + CAI (7.9%), beta-blocker + CAI with PGA analogue 67 (86.1%), beta-blocker alone (2.5%) **(Figure 2),** and there were no cases of miotic. Thirty-four (43% of the patients) were given PO AGM before surgery, and from this, diamox accounts for 32 (94.1%) and glycerol accounts for 2 (5.9%).

Figure 2: Preopretive topical Anti-glaucoma medication



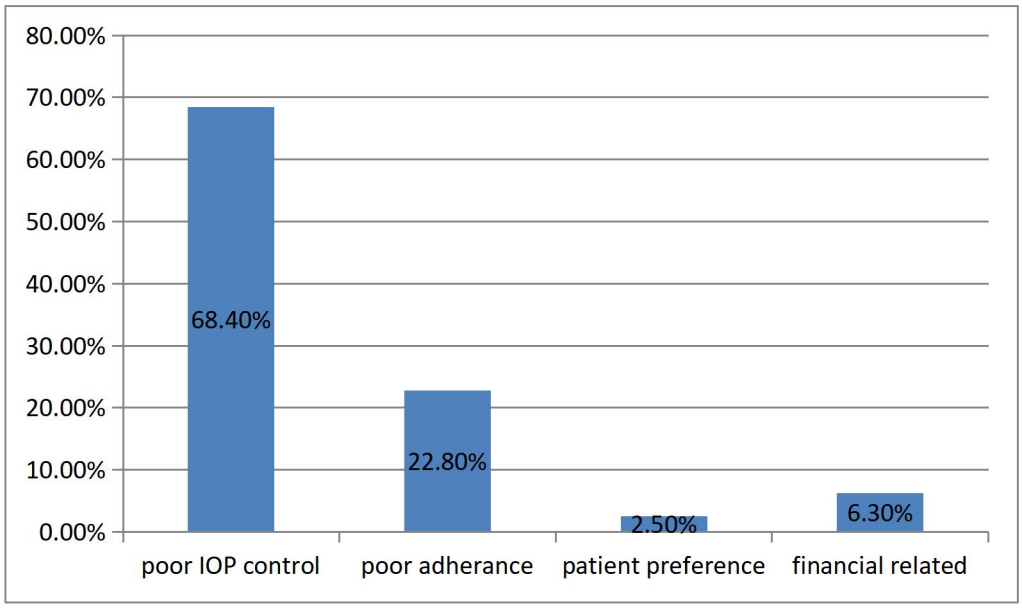
By the time the patients were operated 72 (91.1%) had advanced, 3 (3.8%) had moderate, and 4 (5.1%) had early stages of glaucoma **(Figure 3).**

Figure 3: Glaucoma stages of study population



The most common indication for trab surgery was poor IOP control 54, (68.4%) followed by poor adherance 18 (22.8%), financial issue 5 (6.3%) and patient preference 2(2.5%)(**Figure 4**)

Figure 4: Indication for trabeculectomy surgery



Intra oprative data of the study population

Surgery were done by glaucoma surgeons 30 (38%), general ophthalmologists 39 (49.4%), and residents 10 (12.7%). From the procedures, Trabeculectomy alone accounts for 68 (86.1%), and combined Trabeculectomy with small incision cataract surgery (SICS) and posterior capsule intraocular lens (PCIOL) accounts for 11 (13.9%). In all cases, Retrobulbar anesthesis(RB) was used. The globe was fixed by using a corneal traction suture and fornix-based trabeculectomy with MMC 0.2mg/ml either soaked sub conjuctival space or MMC 10 IU injected into subconjuctival space ,Washed with copious amounts of normal saline for 2-3 minutes. The sclera flaps were rectangular and trapezoid . In patients with high intraocular pressure, trabeculectomy was done after slowly lowering IOP through paracentesis. Osteotomy was done with side port knife AND peripheral iridectomy was performed, AC was maintained with BSS, and scleral flaps were approximated, and the conjunctiva was closed with a water-tight winged conjunctival using 9/0 or 10/0 nylon. At the end of the surgery, subconjuctival dexamethasone and gentamycine were given for all cases. From the cases, there are three (3) complications where there was one conjuctival button hole and two hyphema.

Post op data of study population

On the first post-operation day, the mean IOP was (14.57 ± 8.606) mmHg and VA was (0.070 ± 0.099) with complications of raised IOP in 33 cases, Bleb leak in 2 cases, and hypotony in 1 (one) case. For the complications Massaging and patching were done, respectively (**Table 2**). For 62 patients, post operation antibiotics and steroids eye drops were given; for the remaining 17 patients, cycoplegic was added.

Table 2: First post-operative day outcome

1st post op day IOP outcome	Frequency	Percentage
Raised IOP	33	41.8%
Bleb leak	2	2.5%
Hypotony	1	1.3%
Normal IOP	43	54.4%
Total	79	100%

On the first post-operative week, the mean IOP was (11.54 mmHg ± 5.866 mmHg) and the VA was (0.080 ± 0.124), with complications of raised IOP in 13 cases and hypotony in 2 cases where massaging and patching were done (**Table 3**). For all patients, post operation antibiotics and steroids eye drops were given.

Table 3: First post-operative week IOP result

1st post op week IOP outcome	Frequency	Percentage
Raised IOP	13	16.5%
Hypotony	2	2.5%
Normal IOP	64	81%
Total	79	100%

In the first post-op month, the mean IOP was (11.43 mmHg ± 4.703) mmHg and the VA was (0.093 ± 0.134), with complications of raised IOP in 7 cases (**Table 4**). From the 7 cases, AGM, which was combination of beta – blocker and Carbonic anhydrous inhibitor (CAI), started for 1 patient, massaging was done for 5 cases, and nothing was done for one patient.

On the second and third post-op months, the mean IOP was 12.05 mmHg ± 5.260 mmHg and the VA was 0.108 ± 0.147, with complications of failed trab in 9 cases and hypotony in 1 case (**Table 4**). In those cases, seven of them were on AGM; one patient had bleb revision, and one patient had needling. 53 patients were on dexamethasone and ciprofloxacilline eye drops at second and third post-operative months.

Table 4: Second and Third post-operative month result

2nd or 3rd post op month result	Frequency	Percentage
Failed trab	9	11.4%
Hypotony	1	1.3%
Normal IOP	69	87.3%
Total	79	100%

On six post-op months, the mean IOP was 12.68 mmHg ± 5.360 mmHg, which was a 58.7% reduction in IOP from the mean pre-op IOP (30.72 mmHg), and VA was 0.103 ± 0.112, with a complication of failed trab in 9 cases (**Table 5**). Eleven (11) cases were on AGM.

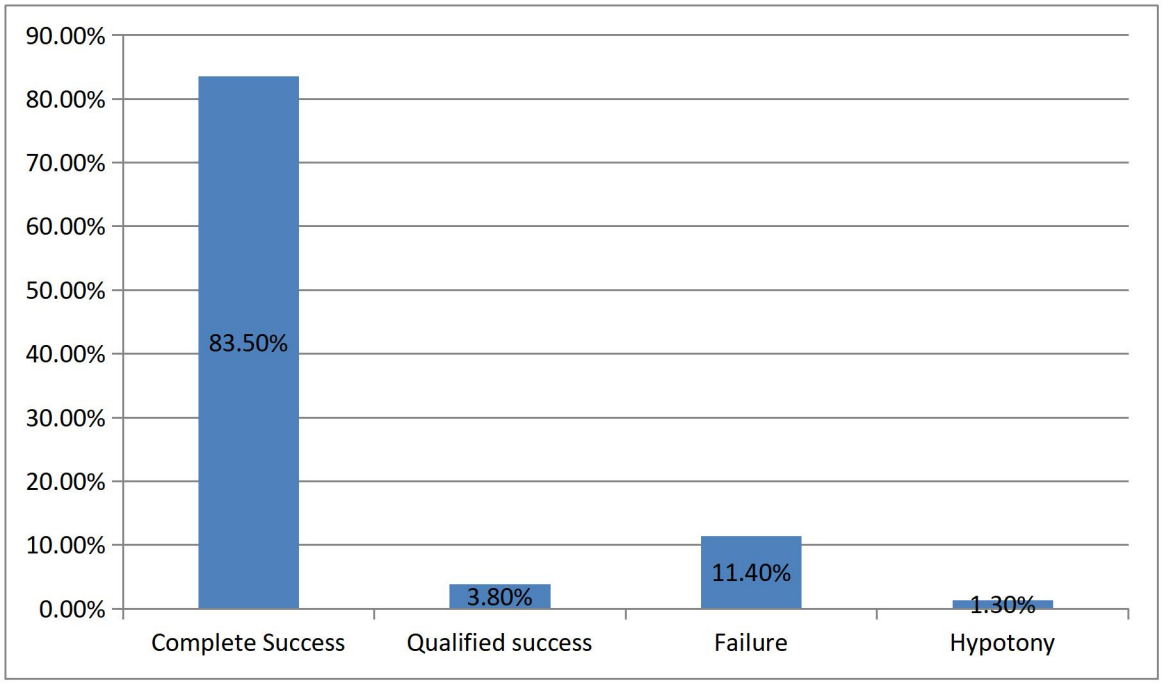
Table 5: Six post-operative month Result

6th Post op month result	Frequency	Percentage
Failed trab	9	11.4%
Hypotony	1	1.3%
Normal IOP	69	87.3%
Total	79	100%

Preoperatively, the mean IOP was 30.72 ± 10.941 mmHg, and the mean postoperative IOP at six months after surgery was reduced to 12.68 mmHg ± 5.360 mmHg, $p < 0.001$, which was a 58.7% IOP reduction from the mean pre-operation IOP. The mean VA before surgery was 0.110 ± 0.165, which changed to 0.103 ± 0.112, $p < .001$ at six months after surgery.

At six-month post-operation follow-up, complete success was found to be 66 (83.5%), qualified success was 3 (3.8%), failure was seen in 9 (11.4%), and hypotony in 1 (1.3%). The overall success (both complete and qualified success) was 87.3 %.(**Figure 5**)

Figure 5: Six month trabeculectomy outcome



The complete success of trabeculectomy with MMC at least six-month follow-up was 77.2% in POAG patients, 86.1% in PXG patients, 87.5% in CACG patients, and 85.7% in JOAG patients. The qualified success was 13.6% for POAG and 2.7% for PXG. Failure was 9.1% in POAG and 8.3% in PXG patients, and hypotony was seen in 2.7% of PXG patients only. The success and failure rates of the procedure were not significantly different between sub-types of glaucoma at six months (p = 0.976). (**Table 6**)

Table 6: Type of Glaucoma with their success

Type of glaucoma	Complete success	Qualified success	Failure	Hypotony
PXG	86.1%	2.7%	8.3%	2.7%
POAG	77.2%	13.6%	9.1%	-
CACG	87.5%	-	12.5%	-
JOAG	85.7%	-	14.28%	-
NTG	100%	-	-	-
AACG	100%	-	-	-
OHTN	100%	-	-	-

At the last visit, with mean follow up of 14.2 months (7 - 35 months), the mean IOP was (12.33 mmHg ± 5.303 mmHg) $p<0.001$, which was a 59.9% reduction in IOP from the mean pre-op IOP (30.72 mmHg), and VA was (0.110 ± 0.144), with a complication of failed trabeculectomy in 14 cases (**Table 7**). Eleven cases were on AGM, and for three patients, re-trabeculectomy was done, and for one patient, needling was done.

At the last visit, complete success was found to be 60 (75.9%), and qualified success was 4 (5.1%). Failure was seen in 14 (17.7%) and hypotony in 1 (1.3%). The overall success (both complete and qualified success) was 81.01%.

Table 7: Last visit outcome

Last post op visit outcome	Frequency	Percentage
Failed trab	14	17.6%
Hypotony	1	1.3%
Normal IOP	64	81.01%
Total	79	100%

Association and regression were done, and the six-month post-operative IOP and had no statistical association with age, sex, stage of glaucoma, pre-operation IOP, pre-operation medications, surgeon type, or type of surgery. (**Table 8**).

Table 8: Statistical analysis of factors influencing postoperative IOP outcome likelihood Pearson chi-square test $^{\beta}$, Fisher' exact test $^{\alpha}$, linear regression $^{¥}$

		Success N (%)	**Failure N (%)**	**P value**
Sex	Male	57(72.1%)	5(6.3%)	
	Female	16(20.2%)	1(1.3%)	0.617^{β}
Age				$0.568^{¥}$
Pre-op IOP				$0.493^{¥}$
Diagnosis	POAG	21(26.6%)	1(1.3%)	
	PXG	33(41.8%)	3(3.8%)	
	CACG	7(8.9%)	1(1.3%)	
	JOAG	6(7.6%)	1(1.3%)	0.764^{β}
Surgery	Trab alone	47(59.5%)	3(3.8%)	
	Combined trab	26(32.9%)	3(3.8%)	0.385^{α}
Surgeon	Glaucoma surgeon	28(35.4%)	2(2.5%)	
	General	36(45.6%)	3(3.8%)	
	ophthalmologist			0.741^{β}
	Resident	9(11.4%)	1(1.3%)	
Stage of	Early	4(5.1%)	0	
glaucoma	Moderate	2(2.5%)	1(1.3%)	0.884^{β}
	Severe	67(84.8%)	5(6.3%)	
Pre op	b-blocker+CAI	7(8.9)	0	
AGM (drop)	b-blocker+PGA+CAI	63(79.7%)	5(6.3%)	0.696^{β}

Chapter 6: Discussion

Different authors defined the success rate based on different criteria for various post-operative follow-up durations.

For the eyes in this study, complete success was found to be 66 (83.5%), qualified success was 3 (3.8%), failure was seen in 9 (11.4%), and hypotony in 1.3%. The overall success (both complete and qualified success) was 87.3% at six months after the surgery. In comparison with two different studies that used similar criteria with the present study which was done in Gonder, had a complete success rate of 52 (75.4%), a qualified success rate of 9 (13%), and a failure rate of 8 (11.6%). [16] And Addis Abeba Minilik II Hospital's complete success was found to be 60.2%, and its qualified success was 27.1%. Failure was seen in 9.6% and hypotony in 3.0% [17]. The overall success rate in the present study is better. However, in comparison to another study that was done in the UK, where 87% of operated patients maintained an IOP of ≤21 mmHg, or a 20% reduction in IOP without AGM [13], the current result is comparable. When it compares to one study that was done in Nigeria (Africa) with a cumulative success of 85% by 1 year [14], it is also comparable (87.3% vs. 85%).

The trabeculectomy failure rate in this study was 9 (11.4%), which is comparable to the tudy in Gonder, which was 11.6% [16], and slightly higher than that of Minilik II Hospital, which is 9.6% [17]. But statistically the difference in failure is not significant. In the present study, there was no significant difference in the outcome of trabeculectomy between eyes with PXG (86.1%) and POAG (77.2%), $p = 0.65$, which is comparable with studies that were done in Gonder with success rates of PXG (46.2%) and POAG (42.3%), $p = 0.34$ [16], and one that was done in Addis Abeba,Minilik II Hospital, with a complete success rate of POAG 52.8% versus PXG 48.0% [17]. but in the current study, it was PXG, which had better complete success than POAG (86.1% vs. 77.2%).

Preoperatively, the mean IOP was 30.72 ± 10.941 mmHg, and the mean postoperative IOP at six months after surgery was reduced to 12.68 mmHg ± 5.360 mmHg, $p = 0.001$. This result is comparable to the study done in Addis Abeba that changed the mean IOP before surgery from 31.4 ±8.4 mmHg to 11.8 (±6.5) mmHg at six months [17]. Gonder's mean IOP on the last day

before surgery was 31.87 mmHg (± 10.08) and it was reduced to 18.45 mmHg (± 6.12) with a p-value<0.001. University of Cologne, Germany The IOP decreased from a mean preoperative value of 28.5 mmHg (±9.8 mmHg) to 15.8 mmHg (±5.3 mmHg) at the last post-operative visit [11]. In the United Kingdom, the mean IOP decreased from 23 mmHg ± 5.5 mmHg at baseline to 12.44 mmHg at 2 years [13].

It is also comparable with the result reported by a study conducted in Nigeria, which indicated that there was a statistically significant difference between the mean pre-op and post-op IOP (p = 0.001) at the last examination at 12 months [14].

The preoperative mean VA was 0.11 ± 0.165, and the mean VA postoperatively at six months was 0.103 ± 0.112, p = 0.048, which is different with other study reports, which show reduction of VA. Which is a common event, usually after long-term trabeculectomy. This might be due to the development or progression of cataracts and/or the worsening of visual field loss [14].

There were no statistically significant differences with regard to sex, age, type of preoperative medications, IOP at diagnosis, stage of glaucoma or type of glaucoma. The above finding is comparable with the study that done in Addis Ababa (Minilik II Hospital) where the six month post operation IOP had no statistical association with age, stage of glaucoma, pre-operation IOP or pre-operation medications [17] and one study that was done in Addenbrooke's Hospital, Cambridge, United Kingdom with finding of no statistical significant with regard to sex, number of preoperative medications, medication at the time of surgery, IOP at diagnosis, or type of glaucoma [10].

CHAPTER 7: Conclusions and Recommendations

Conclusion

Trabeculectomy with MMC is safe and has a good short-term outcome in IOP control among Ethiopian patients at JUDO. Based on IOP level, the success rate of trabeculectomy after six months of the surgery was 87.3%, with complete success found to be 66 (83.5%) and qualified success being 3 (3.8%), failure seen in 9 (11.4%), and hypotony in 1 (1.3%). The IOP outcome is comparable in POAG and PXG patients and there is no VA change between pre-operative and postoperative.

Recommendations

We recommend trabeculectomy with MMC for our patients, specifically those with advanced stages of glaucoma, poor IOP control, poor adherence, and financial problems with medical treatment. Better to use glaucoma evaluation form appropriately so as to avoid miss documentation. Since majority of the patients who undergone trabeculectomy were at advanced stage, better to recommend those in need to do trabeculectomy before it end up with advanced or marginal stage. To explore predictors for surgical failure and increase efficacy, it is better to assess a long-term multicenter prospective follow-up study regarding the outcome of trabeculectomy.

Limitation of the study

Our study was limited to a retrospective design; patients were not randomized, and thus, demographic, behavioral, or clinical differences between the groups may confound the observed results. The use of secondary data sources from medical records had many blanks, and not all cards were accessible. In addition, the present study used secondary data from patient record chart which didn't have information about visual field and post-operative cup to disk ratio documentation. Complications were not fully documented. The small number of study participants is another limitation of this study.

Strength of the study

The strength of the study was the validation of the database done by completing fields before a record could be saved, which greatly reduced the problem of missing data. Double-entry of data increased the quality and reliability of the data. It is also the first study in this region.

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Data collection Tool

I. Pre – op data

1. Age……
2. Sex……
3. Duration of follow up……..
4. Date of Surgery……
5. Diagnosis A) POAG B) PXG C) CACG D) JOAG E) NTG F) OHTN G) AACG H) others……
6. Any ocular comorbidity A) Corneal disease B) Cataract C) Retinal disease D) no E) others……
7. Any systemic illness A) DM B) HTN C) Asthma D) Cardiac illness E) Others…..
8. Pre – OP VA OD…… OS……
9. Pre – OP IOP (a day before surgery) OD ….. OS…….
10. VCDR OD …….. OS ……
11. Stage of Glaucoma A) Early B) Moderate C) Advanced
12. Any Pre – OP AGM A) yes B) no
13. If yes for Q12 A. Timolol B) Latanoprost C) (beta blocker + CAI) D) Simbrinza E) Brimonidine F) Pilocarpine
14. Operated eye……
15. Any history of previous Ocular surgery on Operated eye A. YES B. NO
16. If yes for Q13 specify type of Surgery ……..

17. Indication for surgery A) Poor IOP control

B) Poor Adherence

C) Patient preference

D) Financial Issue

18. Any PO AGM before surgery A) Yes B) No

19. If yes for Q16 what was PO AGM A) Diamox B) Glycerol

II. Intra-operative data

1. Surgery done By A) Glaucoma Surgeon B) General Ophthalmologist C) Resident
2. Anesthesia type A) RB B) Peribulbar C) sub tenon D)GA
3. Surgical procedure A) Trab +SICS +IOL B) Trab alone C) . Trab + SICS without IOL
4. Traction Suture A) Corneal traction B) SR traction
5. Surgical Site A) Superior (12 O'clock) B) ST C) SN
6. Type Of Periotomy A) Fornix-Based Conjunctival Flap B)Limbus-Based Conjuctival Flap
7. Anti-metabolite A) NO B) 5-FU C)MMC
8. If anti fibrotic used Means of application A. Soaked B. injection
9. Ant – Fibrotic Concentration ……
10. Type of scleral flap A) Trapezoid B)Rectangular C)Square D)Triangular
11. Flap size……mm by ……mm
12. Surgical PI A) YES B) NO
13. Releasable stich A) YES B) NO

14. AC Reformation A) Air B) Visco C)BSS

15. Conjunctival suture A) Wing suture B) Continues C) Interrupted

16. Medication used at the end of surgery……..

17. Is there any Intra – OP complications A) Yes B) No

18. If yes for Q18 what is the complication

A) Sub conj.Hemorrhage

B) Conjunctival button hole

C) Severing of EOM tendon

D) Scleral perforation

E) AC bleeding (Hyphema)

F) Others ….

III. Post – OP Data

1. 1st post op day
    - VA----------
    - IOP……..
    - Complications (Wipe out, Hypotony, Raised IOP, AC reaction)…….
    - Intervention for complications …….
    - Medications……
2. 1st week of post op
    - VA----------
    - IOP……..

- Complications (Hypotony, raised IOP, endophthalmitis, cataract, uveitis)…….
- Intervention for complications …….
- Medications……

3. 1st month post op
    - VA----------
    - IOP……..
    - Complications (Hypotony, raised IOP, endophthalmitis, cataract, uveitis)…….
    - Intervention for complications …….
    - Medications……
4. 2nd or 3rd month post op
    - VA----------
    - IOP……..
    - Complications…….
    - Intervention for complications …….
    - Medications……
5. 6th month post op
    - VA----------
    - IOP……..
    - Complications…….

- Intervention for complications …….

- Medications……

6. Last Visit

    - VA----------

    - IOP……..

    - Complications…….

    - Intervention for complications …….

    - Medications……

7. Is there any surgical revision? A. Yes B. No

8. If Yes in above, what type of revision done? (Needling, stitch correction, re trab,…)

STATEMENT OF DECLARATION OF PRINCIPAL INVESTIGATOR

I the undersigned agree to accept responsibility for the scientific, ethical and technical conduct of the research project and provision of the required progress reports as per terms and conditions of the SRP in effect at time. Grant is forwarded as the result of this application.

Name of the student: Dr. Elias Tadesse (MD)

Signature ----------Date of submission----------

APPROVALS OF THE ADVISORS

1. Name of the advisor: ----------

   Signature_____

2. Name of the advisor: ----------

   Signature_____

3. Name of the advisor: ----------

   Signature_____