

## ORIGINAL ARTICLE

## OUTCOMES OF COMBINED MANUAL SMALL INCISION CATARACT SURGERY AND TRABECULECTOMY

Abeba T. Giorgis, MD<sup>1\*</sup>, Addisu Worku, MD<sup>1</sup>

## ABSTRACT

**Background:** Within an aging population, coexistence of glaucoma and cataract is frequent. The treatment of either condition can influence the course of the other. Cataract extraction, glaucoma filtration surgery or combined procedures are the management options. The choice of procedures depends on the level of visual impairment, severity of glaucoma, level of intraocular pressure and other factors.

**Objective:** The study was aimed at assessing the outcomes of combined manual small incision cataract surgery and trabeculectomy in lowering intraocular pressure and restoration of vision.

**Methods:** A retrospective chart review of one-year follow-up of patients who underwent combined manual small incision cataract surgery and trabeculectomy at Menelik II referral hospital, Addis Ababa, Ethiopia.

**Results:** Operations performed on Forty-nine eyes of 43 patients were included in the study. Intraocular pressure decreased from mean 27.04 mmHg to 13.41 mmHg at 12 months postoperative follow-up, with mean reduction of 13.63 mmHg. Hypotensive medication was not required in 71.4% of the operated eyes. Visual acuity, which was less than 6/18 in all eyes on Snellen chart improved to greater than 6/18 (71.4%) in 35 eyes.

**Conclusion:** Combined manual small incision cataract surgery and trabeculectomy is effective in terms of IOP control and vision restoration in treating patients with coexisting cataract and glaucoma.

**Key words:** Cataract, Glaucoma, Manual small incision cataract surgery and trabeculectomy.

## INTRODUCTION

Coexistence of glaucoma and cataract is common among elderly individuals. The management decision to treat glaucoma varies between developed and developing countries based on the availability of hypotensive medications, laser therapy and surgical management. Phacoemulsification over the last 2 decades and the recently introduced femtosecond cataract surgery have been the standard for cataract extraction in the developed world (1,2), while manual small incision cataract surgery (MSICS), which is inexpensive procedure with comparable outcome, has remained the standard in many developing countries, including Ethiopia (3).

As far as glaucoma surgery is concerned, trabeculectomy has remained the gold standard filtration procedure since its introduction by Cairns and Watson in 1968 (4) while recently minimally invasive glaucoma surgery (MIGS) using new devices has been practiced mainly in the developed countries (5) and newer devices are also on the horizon (6).

However, the management decision has been challenging and remained debatable when cataract and glaucoma coexist. Bleb failure rate increases even after cataract surgery with a small incision size, and on the other hand cataract either develops or accelerates after filtration surgery (7,8,9). Therefore, managing the two coexisting eye diseases at the same time may be justified to avoid the shortcomings of two separate surgeries in addition to being more economical and time saving for both the patient and the health care team. It is less stressful to the patients.

Since the introduction of combined surgery for coexisting glaucoma and cataract, there has been number of available options of treatment. These include 1) Combined extracapsular cataract extraction - trabeculectomy (ECCE-Trab), 2) Manual small-incision cataract extraction - trabeculectomy (MSICS-Trab), 3) Phaco-trabeculectomy (Phaco-Trab) and 4) Phaco-minimally invasive glaucoma surgery (Phaco-MIGS), using the latest micro-invasive glaucoma devices. (10-14).

<sup>1</sup>Department of Ophthalmology, School of Medicine, College of Health Sciences, Addis Ababa University.

\*Corresponding author E-mail: abebatiorgis@yahoo.com

The main purpose of combining the procedures is to get the eye pressure controlled, preferable without hypotensive drug (s) while restoring vision of patients with surgery that has minimal surgery related complications.

Combined MSICS-Trab has been practiced in places where MSICS is a surgical procedure for cataract extraction. Comparable outcome of combined MSICS-Trab and Phaco-Trab in terms of intraocular pressure (IOP) control and visual improvement has been reported from studies in India (15, 16).

To our knowledge, there is no study that analyzed the efficacy of the combined procedure (manual small incision cataract surgery and trabeculectomy) among Ethiopia patients. Therefore, this retrospective study was designed to assess IOP lowering effect and vision restoration of the procedure.

## PATIENTS AND METHODS

The study was a one-year retrospective chart review of consecutive patients who underwent combined manual small incision cataract surgery and trabeculectomy at the Department of Ophthalmology, Menelik II tertiary referral hospital in 2016, Addis Ababa, Ethiopia.

Patients with a diagnosis of combined vision impairing cataract and preoperative glaucoma (including primary open-angle glaucoma (POAG), pseudo-exfoliative glaucoma (PXFG), chronic angle closure glaucoma, phacomorphic glaucoma, steroid induced glaucoma or ocular hypertension), and who had post-operative follow-up visits for a year and beyond were included in the study. Patients with previous failed filtration surgery, uveitic glaucoma and neovascular glaucoma were excluded. Accordingly, among 63 patients (75 eyes) that were operated during the year, 43 patients (49 eyes) were included in the study.

Glaucoma was diagnosed based on gonioscopy and the presence of characteristic optic disc changes (thinning, excavation or focal notch of the neurosensory rim, or asymmetrical cupping between the eyes of  $> 0.2$ ) and persistence high intraocular pressure (IOP) of 21 mmHg and above measured on more than one visit. In eye with dense cataract that did not allow examination of the funds, the diagnosis was based on previous record and presence of risk factors including persistently elevated IOP, glaucoma in the other eye, and presence of pseudo-exfoliative material either in the operated or the second eye.

Ocular hypertension was diagnosed based on the presence non-excavated optic nerve head, while IOP was persistently high and absence of other risk factors for glaucoma. Postoperative posterior segment examination was used to identify the status of the optic nerve head in eyes that had dense cataract.

The surgical steps were similar in all patients: it was performed under retrobulbar anesthesia and the conventional steps of MSICS were followed. Mitomycin C (MMC) 0.2mg/ml was the anti-fibrotic agent used and applied under the conjunctiva or Tenon's capsule for 2-3 minutes on the surgical area before half-thickness scleral tunnel construction. Can-opener or capsulorhexis technique through side port was the type of anterior capsulotomy done and PMMA IOL was used in all eyes. After completion of the cataract extraction and IOL implantation, posterior sclerostomy was performed at the middle of the floor of scleral tunnel by punching towards the limbal cornea-scleral junction using a Kelly's Descemet punch. The size of the sclerotomy was around 1.5 mm horizontally and 3 mm vertically, while the whole tunnel length vertically at the center was around 4 mm. Peripheral Iridectomy was not routinely done.

Two 9-0 or 10-0 nylon sutures, one noted as permanent and the other as releasable were applied to approximate the scleral tunnel close to the sclerostomy site. The conjunctival peritomy was repositioned back and sutured using the same suture material, two simple wing and one mattress at the middle of the limbal peritomy. Deeping of the anterior chamber and bleb formation with solution through side port was done routinely before completion of the procedure. Steroid and antibiotic were injected sub-conjunctively and applied topically before patching the eye overnight. Postoperative eye drops medications included antibiotic for 1-2 weeks and steroids 10-12 weeks.

The routine pattern of follow-up for patients with smooth post-operative course was at one day, one week, one month, three months and then every three to six months. During the postoperative visits, releasable suture removal was done under the slit-lamp microscope starting after the first week follow-up depending on IOP level and bleb formation.

**Data collection:** The surgical registration book of the hospital eye operation theater was used to generate the list of patients that underwent the procedure during the one year period and to retrieve their respective charts. After identifying the patients fulfilling the inclusion criteria, relevant data were reviewed and entered into a computer.

**Preoperative data:** Patients' age, sex, number of hypotensive medications that had been used, Snellen visual acuity (best corrected distance vision, i.e., taken either with eye glasses or pinhole), intraocular pressure, (measured with either Goldmann or I-care tonometer at the time of surgery decision) and the type of glaucoma diagnosis were included.

**Postoperative data:** Visual acuity, IOP, prescribed number of hypotensive medications and complications were documented at first week, and at 1, 3, 6 and 12 months.

**Data Analysis:** The data was analyzed using Statistical Package for Social Sciences (SPSS) version 20. Data of intraocular pressure and number of hypotensive medications used are presented in mean with standard deviation. Paired Student's t-test was used to compare mean preoperative and postoperative intraocular pressure change and independent Student t-test was used to compare subgroups. Chi-squared test was used to test associations between categorical variables. Statistical significance P- values of <0.05 were considered significant.

**Outcome Measures:** success rate of IOP control, visual acuity, number of hypotensive drugs used and complications.

Success of intraocular pressure control was graded as follows:

I. Complete success: IOP in the range of 5 to 20 mm Hg without hypotensive medication.

II. Qualified success: IOP in the range of 5 to 20 mm Hg with hypotensive medication(s).

III. Failure: IOP > 21 mm Hg with hypotensive medication(s) at the end of follow up.

Good vision: Snellen Visual acuity 6/18 and above.

**Ethical clearance:** The study was approved by the research and publication committee of the Department of ophthalmology and the institutional review board of the College of Health Sciences, Addis Ababa University.

## RESULTS

Forty-three patients were included in the study. Females were larger in number, 25 (58.2%), than males, 18 (41.9%). Their age ranged from 48-82 years while the mean age was  $66.10 \pm 9.87$  years. Majority of the patients, 30 (69.8%), were age above 60 years (See Table 1). Eighteen patients were residents of Addis Ababa, while the rest live in the different regions.

**Table 1:** Age and sex distribution of patients underwent Manual Small Incision Cataract Surgery Combined with Trabeculectomy, January – December 2016.

Age	Sex		Total
	Female	Male	
40 -50	3	1	4
51 - 60	7	2	9
61 - 70	11	7	18
> 70	4	8	12
<b>Total</b>	<b>25</b>	<b>18</b>	<b>43</b>

The preoperative ocular characteristics of the operated 49 eyes are depicted in Table 2. The Snellen visual acuity was less than 6/18 in all eyes, and 36 (73.5%) eyes had vision 6/60 and below. Pseudoexfoliative glaucoma and Primary open-angle glaucoma were the common diagnosis made in 22 (44.9%) and 12 (24.5%) eyes, respectively. Cataract that was dense enough not to allow assessment of the optic nerve head was found in 25 eyes (51%).

Advanced stage glaucoma diagnosis was made based on glaucomatous optic neuropathy (vertical cup-disc ratio 0.9 and above) in 16 (32.7%) and 5 (10.2%) eyes preoperative and postoperative, respectively. The median duration of glaucoma diagnosis was 14 months ranging 1 to 36 months. The mean number of hypotensive medications used (39 eyes) was  $2.65 \pm 0.63$ , while 24 (49%) had two drops and 15 patients were taking additional oral acetazolamide tablets.

**Table 2:** Preoperative ocular characteristics of eyes underwent Manual Small Incision Cataract Surgery Combined with Trabeculectomy, January – December 2016

Preoperative ocular characteristics of patients	No of eyes (%)
<b>Laterality</b>	
Right eye	29 (59.2)
Left eye	20 (40.8)
<b>Visual acuity</b>	
<6/18 – 6/60	13 (26.5)
<6/60	36 (73.5)
<b>Diagnosis</b>	
Pseudoexfoliative glaucoma	22 (44.9)
Primary open angle glaucoma	12 (24.5)
Ocular hypertension	7 (14.2)
Angle closure glaucoma	4 (8.2)
Phacomorphic glaucoma	2 (4.1)
Steroid induced glaucoma	2 (4.1)
<b>Glaucomatous optic neuropathy</b>	
Non glaucomatous (CDR: 0, 0.1, 0.2 and 0.3)	5 (10.2)
Early (CDR: 0.4 and 0.65)	1 (2.0)
Moderate (CDR: 0.7, 0.8 and 0.85)	2 (4.1)
Severe (CDR: > 0.9)	16 (32.7)
Opaque media	25 (51.0)

Age related macular degeneration, high myopia and diabetic retinopathy were the co-existing ocular pathology in 8 (16.3%), 6 (12.2%) and 2 (4.1%) eyes respectively.

After treatment, the preoperative visual acuity that was less than 6/18 in all the eyes improved to 6/18 and above in 28 (57.1%), 38 (77.6%), 37 (75.5%) and 35 (71.4%) eyes at first week and 3, 6 and 12 months, respectively (Table 3).

Advanced stage glaucoma, age related macular degeneration, posterior capsular opacity, de-centered intraocular lens, and corneal opacity were the causes documented for eyes with low visual acuity, less than 6/18.

**Table 3:** Preoperative and post-operative visual acuity of eyes underwent Manual Small Incision Cataract Surgery Combined with Trabeculectomy, n = 49.

Time	Number of eyes (%)		
	>6/18	<6/18 – 6/60	<6/60
<b>Preoperative</b>	-	13 (26.5)	36 (73.5)
<b>In the first week</b>	28 (57.1)	9 (18.4)	12 (24.5%)
<b>3 months</b>	38 (77.6)	3 (6.1)	8 (16.3)
<b>6 months</b>	37 (75.5)	6 (12.2)	6 (12.2)
<b>1 year</b>	35 (71.4)	5 (10.2)	9 (18.4)

Postoperatively, the preoperative mean intraocular pressure, 27.04 mmHg, decreased statistically significantly ( $P < 0.0001$ ) to 13.00, 13.10, 14.38 and 13.41 mmHg at one week, 3, 6 and 12 months, respectively (Table 4).

**Table 4:** Intra-ocular pressure of preoperative and during postoperative follow-up visits, n= 49 eyes.

Visit	Mean IOP	SD	P-value
<b>Preoperative</b>	27.04	1.08	-
<b>1 week</b>	14.40	0.42	< 0.001
<b>3 months</b>	12.29	1.07	< 0.001
<b>6 months</b>	13.01	1.76	< 0.001
<b>12 months</b>	14.32	1.17	< 0.001

Comparing the different types of glaucoma and ocular hypertension, there was no statistically significant difference in mean baseline and postoperative IOP reduction. POAG, PXFG, and angle closure glaucoma had mean IOP less than 15 mm Hg throughout the year follow-up, and at 12 months, all the types of glaucoma and OHT had mean IOP below 15 mm Hg as well (Table 5).

**Table 5:** Comparison of preoperative and postoperative mean intraocular pressure among the different types of glaucoma, n=49 eyes.

Time	Intraocular pressure (SD) in mm Hg among types of glaucoma						P-value
	POAG	PXFG	OHT	CACG	Phacomorphic Glaucoma	Steroid induced G	
<b>Preoperative</b>	26.95 (5.40)	27.64 (8.10)	24.94 (3.12)	26.00 (9.63)	44.00 (21.28)	24.00 (4.41)	0.10
<b>Postoperative</b>							
<b>1 week</b>	12.17 (6.13)	12.73 (7.12)	14.14 (5.73)	7.75 (6.55)	25.15 (3.04)	15.00 (4.24)	0.093
<b>3 months</b>	15.58 (6.04)	14.94 (7.72)	15.57 (4.35)	11.75 (8.73)	10.50 (2.12)	23.50 (12.02)	0.663
<b>6 months</b>	13.18 (5.03)	13.87 (6.12)	19.43 (7.83)	13.03 (8.10)	11.00 (4.24)	15.50 (3.53)	0.319
<b>12 months</b>	12.83 (6.06)	13.60 (6.05)	14.51 (7.03)	13.60 (6.36)	12.00 (2.82)	12.00 (1.41)	0.988

POAG: primary open angle glaucoma, PXFG: psuedoexfolation glaucoma, OHT: ocular hypertension, CACG: chronic angle closure glaucoma, IOP: intraocular pressure

The overall success rate of IOP control at the completion of 12 months follow-up was 87.7% (43 eyes), Complete 71.4% (35 eyes) and qualified 16.3% (8 eyes). The pressure remained above 21 mm Hg in six eyes while they were on hypotensive medications. The analysis of success rate showed no statistically significant difference either in complete or qualified success rate, or in failure among the different types of glaucoma.

In the first three months of postoperative period, 43 (87.3%) of the operated eyes were without hypotensive medication. And at one-year follow-up, 35 (71.4%) of the eyes were free of medication. The mean number of hypotensive medication lowered from  $2.65 \pm 0.63$  preoperative to  $1.49 \pm 0.82$  at 12 months follow up (Table 6).

**Table 6:** Preoperative and postoperative number of anti glaucoma medications used to control intraocular pressure.

Visit	Mean number of medications	Standard deviation	P- value
<b>Preoperative</b>	2.65	0.63	-
<b>3 months</b>	1.10	0.05	<0.001
<b>6 months</b>	1.16	0.75	<0.001
<b>12 months</b>	1.49	0.82	<0.001

Zonular dehiscence, posterior capsule tear and vitreous loss were the types of intra-operative complications recorded in 6 eyes, among them 5 eyes were with pseudoexfoliative glaucoma. The types of post-operative complications recorded in the first one month follow-up period were hyphema (1 eye), pupillary inflammatory membrane (2 eyes), shallow anterior chamber (2 eyes) and choroidal effusion with hypotony, i.e. IOP < 5 mm Hg, (1 eye).

At the last visit, filtering bleb was present in 75.5% and flat bleb was recorded in 12 (24.5%) eyes.

## DISCUSSION

The study has assessed the outcome of combined cataract extraction with glaucoma surgery in terms of vision restoration, intraocular pressure control, need of hypotensive drug to control the IOP and complications. Cataract and glaucoma are the two common eye diseases that occur among the elderly population. This was the fact in this study that has identified mean age 66.10 years and the majority to be age above 60 (69.8%). Other studies have also reported similar mean age (61.3, 64.13, and 66.20, years) among patients underwent combined procedure either Phaco-Trab or MSICS-Trab (15, 17, 18). Our result also also shown a similar finding with a mean age of 66.10 years and the majority to our patients were aged above 60 (69.8%).

Pseudoexfoliative glaucoma was the commonest type of glaucoma diagnosis in this study, 22 eyes (44.9%). And this can be explained by the fact that pseudoexfoliation and pseudoexfoliative glaucoma are common conditions among Ethiopians (19-21). The high and fluctuating nature of IOP in pseudoexfoliative glaucoma requires keeping the IOP at low and stable level, which achievable with filtering surgery as was indicated in this study.

The visual acuity of our patients improved to  $\geq 6/18$  in 28 eyes (57.1%) and 35 eyes (71.4%) in the first one week and at 12 month follow-up. The number of eye with visual acuity  $\geq 6/18$  during the first one week postoperative follow-up was less as compared the subsequent visits. This can be explained by the presence of wound inflammatory reaction of the anterior segment and wound healing process. The visual acuity of  $\geq 6/18$  that was achieved at the last follow-up is lower when compared to  $\geq 6/12$  in 43 eyes (78.2%) at 3 years in India (15). On the other hand, visual acuity  $\geq 6/18$  that was achieved in 38 eyes (77.8%) at 3 months, is better as compared to other study report at 8 weeks that achieved the same level of vision improvement in 23 eye (65.7%), (3). Fourteen eyes (28.6%) remained visual impaired, less than 6/18 visual acuity; which can be explained by the glaucomatous optic nerve head damage and other preexisting ocular pathology documented in their charts.

In this study, the mean intraocular pressure was significantly reduced from the baseline mean level ( $27.04 \pm 6.04$ ) and remained below 15 mmHg throughout the year ( $P < 0.001$ ), with mean reduction 13.63 mmHg at last follow-up. This level of IOP is comparable to  $13.9 \pm 3.81$  mmHg reported at 3 years follow-up by Mittal S et al (15); and to an eight weeks mean IOP reduction of  $12.52 \pm 35$  mmHg reported by Khurana AK et al (17). And it is better than  $17.1 \pm 10$  mm Hg reported at 6 months follow-up by Thomas R et al (16). Singh P et al (18) reported mean IOP reduction from baseline  $23.93 \pm 0.75$  mm Hg to  $11.2 \pm 1.5$  mm Hg at 6 weeks post-operative follow-up in 45 patients, which is lower as compared to the 3 months mean IOP level of this study,  $12.29 \pm 1.07$  mmHg, but the time different should be taken in to consideration.

In the first postoperative week, the IOP remained low in all types of glaucoma and ocular hypertension, except in phacomorphic glaucoma, which can be explained by the presence of anterior chamber reaction before, during and after surgery, which is the nature of the disease.

Among the pseudoexfoliative glaucoma cases, the preoperative 27.64 mm Hg mean IOP remained less than 15 mm Hg during the one-year follow-up period, which is advantageous to keep the IOP low and stable to halt the damaging nature of fluctuating IOP in this form of glaucoma. Additionally, cataract extraction lowers IOP in all types of glaucoma due to widening of the anterior chamber angle and the possibility of remodeling of the trabecular meshwork (22,23).

The two patients with phacomorphic glaucoma underwent the surgery because of delayed presentation, more than a month, and consideration of the possibility of persistence angle closure; otherwise, they could have been managed by cataract extraction alone.

The 87.7% success of IOP control (IOP < 21 mmHg) with and without medication, at the last follow up, is comparable with that of retrospective comparative study of MSICS-Trab (a similar procedure with this study) and Phaco-Trab done in India, that achieved 89.0% and 92.3% success at 3 years follow-up, respectively. On the other hand, it is better than other study report from the same country with mean 6 months follow up that achieved IOP control in 73% MSICS-Trab group and in 75.6% Phaco-Trab group (15,16).

Forty-three (87.7%) and 35 (71.4%) eyes required no hypotensive drugs after the surgery during the first three months and the last follow up period, which is beneficial to the patients in terms of cost, being free of drug side effects and the physiological impact of having and applying medications. It is also beneficial and encouraging to the treating physician to have his/her patient being managed with less frequent follow-up visit.

The procedure enabled to reduce the number of hypotensive drugs that had been used prior to the surgery. The preoperative  $2.65 \pm 0.63$  mean number of hypotensive drugs reduced to  $1.49 \pm 0.82$  at one-year postoperative follow-up. The other studies, mentioned above, have also reported postoperative reduction of hypotensive drugs need (14,15).

The type and frequency of occurrence of both intra-operative and postoperative complications varies among studies reports, including this study (15,16, 18).

Pupillary fibrinous inflammatory membrane, the type of early postoperative complication, documented in three eyes, could be related to the surgical manipulation to the anterior chamber structures during the surgical procedure. Besides, two of the three eyes were with pseudoexfoliation, which by itself is associated with more wound reaction than the other types of glaucoma. Postoperative flat bleb was recorded in 6 (12.2%) eyes, which could be related to healing or fibrosis of the scleral tunnel.

The possibility of non-detailed documentation of clinical information during the preoperative, intra-operative and postoperative periods is believed to be the limitation of this retrospective study.

**Conclusion:** Combined manual small incision cataract surgery and trabeculectomy is effective in terms of IOP control and vision restoration in treating patients with coexisting cataract and glaucoma.

**Recommendation:** The procedure is doable and cost effective for eye care professionals who handle glaucoma patients and practicing manual small incision cataract surgery.

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