

Long-term Outcomes of Combined Cataract Surgery and Trabeculotomy using Trabectome for Coexisting Cataract and Open-angle Glaucoma: A 5 Year Follow-Up

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Abstract

Purpose: To provide long term results of Trabectome combined with phacoemulsification in primary open-angle glaucoma.

Methods: In this interventional case series, 18 consecutive eyes that have had combined phacoemulsification with Trabectome were included. The main outcome measures were change in intraocular pressure (IOP), glaucoma medication use, and the rate of complications.

Results: Mean IOP was 17.67 ± 3.91 mmHg preoperatively which decreased to 13.87 ± 2.315 mmHg at 1 y. ($P < 0.05$) and 15.11 ± 3.22 at 5 y. There was a corresponding drop in glaucoma medications from 2.31 ± 0.60 at baseline to 1.00 ± 0.46 at 12 months and 1.17 ± 0.71 at 5 y ($P < 0.00$). The preoperative BCVA (Log Mar) was improved from 0.68 ± 0.26 pre-operatively to 0.08 ± 0.13 at 1 y and 0.11 ± 0.14 at 5 y respectively ($P < 0.00$). The only frequent complication was transient blood reflux resolving spontaneously within a few days. No vision threatening complication occurred.

Conclusion: Combined phacoemulsification and trabectome significantly lowered IOP and medication use in long term with early visual rehabilitation in the majority of patients.

Keywords: Glaucoma; Trabectome; Phaco

Introduction

Glaucoma and cataract are the leading causes of global visual impairment [1]. Cataract surgery and intraocular lens implantation can restore the vision, while blindness caused by glaucoma is irreversible.

Open-angle glaucoma and cataract often coexist in elderly population. The incidence and prevalence rates of both increases with age [2].

Glaucoma eye drops and elevated IOP, increase the risk of developing cataracts [3]. Cataract extraction can provide a modest decrease in IOP and has occasionally been recommended as an initial intervention for pressure control in glaucoma patients [4-6].

Considering the diseases severity and the necessity of IOP lowering, phacoemulsification can be combined with glaucoma surgery resulting in fewer procedures and better-cost effectiveness for the patient in comparison with long-term use of drops or two separate operating room procedures [7].

It is believed that the trabecular meshwork (TM) and inner wall of Schlemm's canal are the sites of greatest resistance to aqueous outflow in primary open-angle glaucoma. The conventional outflow pathway augmentation can lower IOP by facilitating physiologic outflow.

The latest method to assess conventional outflow pathway enhancement is through an internal approach to the TM and Schlemm's canal [8].

Contrary to external filtration surgeries, such as trabeculectomy and aqueous tube shunt, these procedures are categorized as internal filtration surgeries and are both performed from an internal approach under gonioscopic guidance. Published results suggest that these surgical procedures are safe and effective for the treatment of open-angle glaucoma [8].

The therapeutic goal of new glaucoma surgical procedures should be to equal or surpass the efficacy of the gold standard, trabeculectomy with anti-fibrotics, or decrease intraocular pressure (IOP) to a lesser degree but with significantly fewer complications [8].

Ab interno Schlemm's canal surgery seeks to treat glaucoma without the formation of an external filtering bleb, bypassing the resistance of the TM and inner wall of Schlemm's canal *via* an internal gonioscopic method.

The goal, therefore, is not equal to the efficacy of trabeculectomy but effectively lower IOP and glaucoma medications while eliminating complications associated with external filtration. These include hypotony, choroidal effusion or hemorrhage, a flat anterior chamber, cataract formation, corneal decompensation, or the long-term risk of bleb-related problems such as bleb infection, endophthalmitis and bleb dysesthesia.

The aim of this study is to report long-term results of trabectome surgery in combination with phacoemulsification in primary open-angle glaucoma over 5 y.

Methods

This study was an interventional case series of 15 patients (18 eyes) with uncontrolled open-angle glaucoma and cataract who had undergone trabectome combined with phacoemulsification by the internal approach at the Department of Ophthalmology at Iran University of Medical Sciences from April 2009 to April 2017. Inclusion criteria were patients who had cataract and mild to moderate primary open-angle glaucoma with uncontrolled IOP more than 21 mmHg while receiving maximum tolerable anti-glaucomatous treatments or those with controlled glaucoma (IOP less than 21 mmHg) and cataract who desired to decrease the number of medications.

Patients with corneal opacity which impaired angle visualization or history of previous ocular surgery and angle closure were excluded. Written informed consent was obtained from all participants. The current study adhered to the tenets of the Declaration of Helsinki. 15 patients including 9 male and 6 female entered the study and before surgical intervention, for all patients best-corrected visual acuity was checked and complete slit exam including Goldmann applanation tonometry and gonioscopy was done. Two experienced surgeons performed all operations.

Surgical technique

The ab-interno approach of the Trabectome (NeoMedix Corp., Tustin, CA) was first performed in all cases, followed by cataract extraction.

After the area was prepped and draped, topical anesthesia was administered and a 1.6 or 1.7 mm keratome was used to make a near-limbal temporal clear corneal incision.

Preservative-free lidocaine 2% was injected into the anterior chamber.

The microscope and head were tilted for optimal gonioscopic view of the angle.

The Trabectome goniosurgical lens (a modified Swann-Jacobs lens) was placed on the cornea to verify the angle landmarks. The Trabectome hand piece was inserted and advanced nasally across the anterior chamber with the infusion on. The pointed tip of the footplate was inserted through the trabecular meshwork into Schlemm's canal. Using an initial power setting of 0.7-0.8 W, the surgeon slowly advanced the instrument along the meshwork first in a counter clockwise, then in a clockwise, direction using the limbal corneal incision as a fulcrum, ablating and removing a strip of trabecular meshwork un-roofing the canal of Schlemm.

The power was titrated up or down depending on the desire to ablate a wider strip of trabecular meshwork or to minimize charring of tissue, respectively. Verification of the cleft was performed, as the hand piece was removed, and the angle was viewed for evidence of blood reflux from the newly exposed collector channels. After filling the anterior chamber with an OVD, phacoemulsification and IOL implantation were then performed using the surgeon's preferred technique. At the end of the surgery acetylcholine chloride (Miochol) was instilled for pupils more than 6 mm, to prevent further peripheral

anterior synechiae. The corneal incision was then hydrated and checked for leakage.

Postoperative care varied according to clinical presentation but usually included topical steroids (Fluorometholone) 8 times a day tapered over 6 weeks and topical antibiotics 4 times daily for 5 days. Intraocular pressures checked with Goldmann applanation tonometry and Snellen visual acuities were measured before and after surgery at each visit. Complications were charted, and numbers of pre and post-operative adjunctive medications were compared.

Statistical analysis

Success was defined as final IOP \leq 21 mmHg and one of the following: \geq 20% reduction of IOP or a reduction of 1 glaucoma medications with final IOP \leq baseline IOP if baseline IOP \leq 21 mmHg.

Failure was defined as a less than 20% decrease in IOP from baseline, no decrease in medications or additional need to medications or glaucoma surgery.

For statistical analysis, analysis of variance (ANOVA) was used to compare changes in IOP and medications across different baseline IOP subgroups. Paired sample t-test was performed on the pre- and postoperative data.

Results

18 eyes of 15 patients underwent phaco-trabectome and completed 5 y of follow up. Table 1 shows baseline demographic data. There were 6 female and 9 male who entered the study. Mean age was 65.87 ± 8.14 (54-77) y.

Parameters	Value
Patients/eyes	15/18
Age	
Mean \pm SD	65.87 ± 8.14
Range	54-77
Sex	
Male	0.6
Female	0.4
Cup to disc ratio	
Mean \pm SD	0.49 ± 0.18
Range	0.2-0.8
CCT	
Mean \pm SD	553 ± 31.97
Range	490-590
MD	
Mean \pm SD	-6.1 ± 5.65
PSD	

Mean ± SD	3.83 ± 2.16
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Table 1: Patient’s demographics.

The mean preoperative IOP was 17.67 ± 3.91 (12-25) y. The mean baseline MD was -6.1 ± 5.65 and mean PSD was 3.83 ± 2.2.

The mean of postoperative IOP and mean percent reduction of IOP at each time point, are shown in Table 2.

Time	Mean IOP ± SD	Reduction in IOP% (N)		Number of eyes
		<20%	≥ 20%	
Pre-OP	17.67 ± 3.91	NA	NA	18
2 month	14.5 ± 2.455	55.6	44.4	18
6 month	14.11 ± 2.083	61.1	38.9	18
1 y	13.87 ± 2.315	44.4	55.6	18
2 y	14.88 ± 2.419	56.3	43.8	16
5 y	15.11 ± 3.216	61.1	38.9	18

Table 2: Intraocular pressure preoperatively and postoperatively.

Table 3 shows the mean number of glaucoma medications preoperatively was 2.3 ± 0.6 (1-3) y in 16 patients.

	Mean ± SD	Range	Number of eyes

Reduction in medication % (n)	No change	Reduction one drug	Reduction two drugs
2 nd month	18.8% (3)	56.3% (9)	25% (4)
6 th month	12.5% (2)	50% (8)	37.5% (6)
1 y	6.3% (1)	62.5% (10)	31.3% (5)
2 y	21.4% (3)	50% (7)	28.6% (4)
5 y	25% (4)	43.8% (7)	31.3% (5)

Table 4: Change in medications during follow up.

The mean preoperative BCVA (logMar) was 0.60 ± 0.2 and was improved to 0.11 and 0.11 at 2 and 5 y follow up respectively, which was statistically significant (P-value=0.000) (Table 5).

The mean preoperative cup/disc ratio was 0.48 ± 0.19 in 15 cases and after 5 y follow up it was 0.50 ± 0.24. The difference between means was not statistically significant (P-value=0.34).

The mean MD after 5 y was -5.71 ± 5.34 which has no significant difference with baseline (P<0.49).

The mean PSD after 5 y was 3.09 ± 2.22 with significant difference with baseline (p<0.04).

Parameters	Mean ± SD	Range	Number of eyes
Log BCVA			
Pre-OP	0.60 ± 0.20	0.4-1.3	15

Pre-OP	2.31 ± 0.602	1-3	16
1 st d	0.00 ± 0.00	0	18
5 th d	0.56 ± 0.616	0-2	18
2 nd month	1.22 ± 0.428	1-2	18
6 th month	1.06 ± 0.236	1-2	18
1 y	1.00 ± 0.458	0-2	18
2 y	1.13 ± 0.62	0-2	16
5 y	1.17 ± 0.71	0-3	18

Table 3: Number of pre-and postoperative glaucoma medications.

Table 4 shows the number of glaucoma medications and percentage reduction at each time point. Decrease in number of medication is significant between before operation and 2, 6 months, 1, 2 and 5 y after operation (P value=0.00).

Success (defined by more than 20% drop in IOP) was achieved in 44.4% (8), 38.9% (7), 55.6% (10), 43.8% (7), 38.9% (7) at 2, 6 months, 1, 2 and 5 y respectively.

Success (defined by reduction of 1 glaucoma medication) was achieved in 50% (7) in 2 y and 43.7% (7) in 5 y of follow up (Table 4).

Reduction of 2 glaucoma medication occurred in 31.3% (5) at 2 and 5 y follow up (Table 4).

6 th month	0.11 ± 0.13	0-0.4	18
1 y	0.08 ± 0.13	0-0.48	18
2 y	0.12 ± 0.14	0-0.48	16
5 y	0.11 ± 0.14	0-0.48	18

Table 5: Visual acuity pre-operation and post-operation.

Discussion

MIGS (micro-invasive glaucoma surgery) including different glaucoma devices such as Trabectome offers a micro-invasive approach and a better safety profile for the management of different glaucoma subtypes.

Trabectome surgery can be most effectively applied in mild to moderate glaucoma where a postoperative IOP above episcleral venous pressure is sufficient to prevent glaucoma progression. The surgical management of glaucoma involves mainly the treatment of patients with uncontrolled IOP under glaucoma therapy, patients with allergies or handling difficulties or patients demanding a daily life without any medication. MIGS can be offered as first-step procedure, stand-alone surgery or combined technique, and also as rescue strategy in failed invasive surgeries trabeculectomy or tube-shunt procedures [9-14].

In a nonrandomized, non-blinded, retrospective study by Ngai, 20 patients with steroid induced glaucoma had trabectome surgery alone [15]. The average preoperative IOP was 33.8 ± 6.9 mmHg and average preoperative glaucoma medication use was 3.85 ± 0.75 . At 12 months, the IOP was reduced to 15.00 ± 3.46 mmHg (P-value=0.03) and the medication use was also decreased to 2.3 ± 1.4 (P-value=0.01).

The survival rate at 12 months was 93%. At 12 months, 10 patients were continued on their preoperative steroid therapy, 5 were on tapered steroid treatments, and 5 had stopped the steroid use completely.

In another study by Francis, 304 eyes with POAG underwent combined phacoemulsification and trabeculotomy prospectively. The mean IOP was 20.0 mmHg \pm 6.3 (SD) preoperatively, 14.8 ± 3.5 mmHg at 6 months, and 15.5 ± 2.9 mmHg at 1 y. There was a corresponding drop in glaucoma medications from 2.65 ± 1.13 at baseline to 1.76 ± 1.25 at 6 months and 1.44 ± 1.29 at 1 y. Subsequent secondary glaucoma procedures were performed in 9 patients. Blood reflux in 239 patients (78.4%) was the only frequent complication, which resolved within a few days [16].

The main outcome measure in this study was the change of IOP after operation and preservation of decreased IOP after 5 y of follow-up. The mean preoperative IOP was 17.67 ± 3.91 and it was reduced to 14.88 ± 2.41 after 2 y and 15.11 ± 3.21 after 5 y. The difference between pre-op IOP and 2 y and 5 y post-operation was statistically significant.

In a retrospective multi-center study on 120 Chinese people, the trabectome reduced significantly the IOP from a baseline of 22.8 ± 1.34 mmHg to 17.6 ± 0.96 mmHg, and the use of glaucoma medications from 2.2 ± 0.17 mmHg to 1.4 ± 0.21 in a 2 y follow-up [17].

In our study number of medications reduced significantly from 2.31 ± 0.6 preoperatively to 1.13 ± 0.62 at 2 y and 1.17 ± 0.7 at 5 y. There was no significant difference in the number of medications between 2 and 5 y of follow-up.

Reduction of 2 medications was achieved in 28.6% (4) and 31.3% (5) of patients after 2 and 5 y respectively. Pahlitzsch in a 3 y study on 268 POAG patients and 98 PEX glaucoma patients showed 43.9% with reduction of one medication and 17.5% with reduction of two or more medications after trabectome surgery [18].

Mosaed et al. in a study of 538 patients who had trabectome surgery alone and 290 patients who underwent trabectome combined with phacoemulsification, reported a 31% reduction of IOP in the trabectome only group with a 28% drop in medication use at 1 y of follow-up. An 18% reduction in IOP and 33% drop in medication were reported in the combined group [19].

In our study BCVA was improved from 0.60 preoperatively to 0.12 at 6 months and remained stable at 0.13 until 5 y after operation (p-value=0.000).

Akil's study on 49 patients with phaco combined with trabectome surgery showed survival rate 80% and significant reduction of IOP and medications 1 y after surgery and Hashemian showed significant reduction of IOP and anti-glaucoma medication 1 y after combined surgery [20,21].

Medications have drawbacks such as cost, compliance and ocular surface problems. It is worth mentioning that combined surgery reduced at least one medication use by about 43.8% through 5 y of follow-up.

Transient complications such as hyphema were observed after surgery. We didn't observe hypotony and choroidal effusion in our patients.

This study was limited by small sample size and absence of a matched control group but the strength is long 5 y of follow up.

Based on the main goal of any glaucoma surgery, which is reduction of IOP with the lowest number of medications and minimal complications, our results indicated that combination of trabectome and phaco lead to early visual rehabilitation and considerably lowered IOP and medication use in long term.

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