RESEARCH ARTICLE

Efficacy of Endotrabeculectomy (Trabecula Ablation Ab Interno with the Forceps) for Open-angle Glaucoma

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Abstract

Aim: To investigate the efficacy of endotrabeculectomy (ETE) performed either alone or combined with phacoemulsification (phaco) in patients with primary open-angle glaucoma (POAG).

Materials and methods: Investigations were done in two groups. The first group (38 patients, 38 eyes) with POAG underwent ETE, and the second group of 126 patients (126 eyes) with POAG and cataracts underwent ETE and phaco. The hypotensive effect of the surgery was evaluated.

Results: In the ETE group, the mean intraocular pressure (IOP) was reduced from 20.25 ± 3.30 to 14.94 ± 1.95 mm Hg (26.2% reduction, $p < 0.001$) at 12 months. The number of medications was reduced from 2.8 ± 1.0 to 1.5 ± 1.0 ($p < 0.001$) at 12 months after the surgery. In the phaco-ETE group, the mean IOP was reduced from 18.24 ± 3.20 to 14.83 ± 1.71 mm Hg (18.7% reduction, $p < 0.001$) at 12 months. The mean number of medications was reduced from 2.2 ± 1.1 to 1.0 ± 1.0 ($p < 0.001$) at 12 months after the surgery. The success rate defined as a final IOP of <16 mm Hg using the Kaplan–Meier curve at 12 months was 73.8%. There were no complications that led to a constant visual decrease.

Clinical significance: Our study shows that ETE is technically simple, gives the ability to remove trabecula in any quadrant, and effectively reduces IOP in patients with POAG.

Conclusion: Endotrabeculectomy (ETE) is a safe and relatively simple procedure that significantly reduces IOP. The minimally invasive nature of the ETE allows expanding indications for combined treatment of glaucoma and cataract.

Keywords: Endotrabeculectomy, Intraocular pressure, Phacoemulsification, Primary open-angle glaucoma, Prospective non-randomized cohort study.

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Introduction

Trabeculectomy, introduced in the 1960s, is still called the standard of glaucoma surgery; it is frequently accompanied by short-term and long-term complications.[1–3] The major long-term disadvantage of glaucoma surgeries with filtering bleb formation involves the risk of the newly formed outflow pathway obliteration with the loss of the hypotensive effect.[4–6] According to the data, loss of the hypotensive effect in patients with OAG after trabeculectomy due to fibrosis of the filtration pathways is observed from 14.5 to 33.6%.[5,7–9]

The last decade has been characterized by the active development of minimally invasive surgeries for POAG with the approach through the chamber anterior angle—ab interno.[10,11] In OAG, the inner wall of Schlemm's canal and the juxtacanalicular trabecular meshwork show resistance to aqueous humor outflow.[12–14] The advantage of glaucoma surgeries with an approach through the angle of the anterior chamber and opening in Schlemm's canal consists of the restoration of the physiologic outflow pathway. Furthermore, the main area of aqueous humor resistance, namely, the trabecula, is also removed.

One of the most popular minimally invasive operations—trabectome, includes the electrosurgical ablation of trabecular meshwork and debris aspiration to improve aqueous access to collector channels. This surgical method can be performed after a corneal incision without damaging the conjunctiva.[15,16]

Since 2008 we have been developing a new surgery technique—ETE, namely, trabecula ablation through the angle of the chamber anterior with the means of the forceps.[17,18] The learning curve for performing ETE was 3–6 months, depending on the surgeon's surgical experience. A similar technique was proposed by Nakasato et al. in 2014.[19]

The purpose of this study was to investigate the efficacy of ETE performed either alone or combined with phaco in patients with OAG.

Materials and Methods

This prospective non-randomized cohort study was approved by the local ethics committee (Lviv National Medical University Ethics Committee No 4 from 28th April 2014) and followed the tenets of the Declaration of Helsinki.

After written informed consent, a total of 164 consecutive eyes of 164 Caucasian patients were included from June 2014 to June 2018.

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The inclusion criteria were age ≥50 years with POAG. The indication for ETE consisted of IOP above target on maximally tolerated medical therapy. The indication for phaco-ETE consisted of a visually significant cataract and no compensated IOP.

The exclusion criteria were corneal opacity or edema, neovascularization of the iris and anterior chamber angle, and intumescent cataract.

All patients had a comprehensive slit lamp and ophthalmoscopy exam before surgery.

Visual acuity, IOP, and a number of medications were recorded at the time of the pre and postoperative visits. The preoperative (baseline) IOP was the mean of the IOPs recorded at two visits while on preoperative treatment. IOP measurements were recorded after 1 week, 1 month, and every 3 months thereafter. The IOP was measured using a Goldmann applanation tonometer and was recorded by independent persons who were not aware of previous surgeries. Each type of medication was counted as one, and each fixed combination was counted as two.

Absolute success was defined as a postoperative IOP of ≤16 mm Hg and a ≥20% reduction from baseline without the need for additional medication. Qualified success was a postoperative IOP of ≤16 mm Hg and a ≥20% reduction from baseline with or without the need for topical glaucoma medication. The absolute and qualified success was recorded at 1, 3, 6, 9, and 12 months after operations.

Cases were considered treatment failures if the success criterion was not met at two consecutive visits after 3 postoperative months. Treatment failure also included an increase in glaucoma medications from baseline at two consecutive visits after 3 postoperative months and the need for additional glaucoma surgery.

To account for censoring, we estimated the cumulative percentages of absolute and qualified success as well as the failure rates over time with the Kaplan–Meier method.

The obtained data were presented as M ± SD (M—mean average and SD—standard deviation). The data difference between the groups was analyzed using a two-tailed *t*-test (for two independent groups) and analysis of variance—one-way analysis of variance for more than two groups. Statistical significance was assumed for $p \leq 0.05$.

Secondary outcome measures included: complications from the ETE procedure (intraoperative and postoperative) as well as the number of glaucoma medications at baseline as well as 3, 6, 9, and 12 months postoperatively.

The baseline characteristics of patients are presented in Table 1. The subjects comprised 164 Caucasian patients (164 eyes) with uncontrolled POAG. Among them, there were 79 males (79 eyes) and 85 females (85 eyes). The patients were analyzed in two groups. In the first group, stand-alone ETE was performed, and in the second group, combined surgery ETE and phaco were performed. The minimum follow-up for all patients was 12 months.

Table 1: Baseline characteristics of patients

	ETE *(n = 38 patients, 38 eyes)*	*ETE-Phaco* *(n = 126 patients, 126 eyes)*
Age mean ± SD	68.39 ± 7.78	71.02 ± 8.34
Range	51–79	50–84
Gender, *n* (%)		
Female	20	65
Male	18	61
Lens status		
Phakic, *n* (%)	21	126
Pseudophakic, *n* (%)	17	
Mean IOP preop	20.25 ± 3.30	18.29 ± 3.25
Mean medication preop	2.78 ± 1.01	2.24 ± 1.09
Mild stage	5	39
Moderate stage	16	53
Severe stage	15	32
Indeterminate stage	2	2

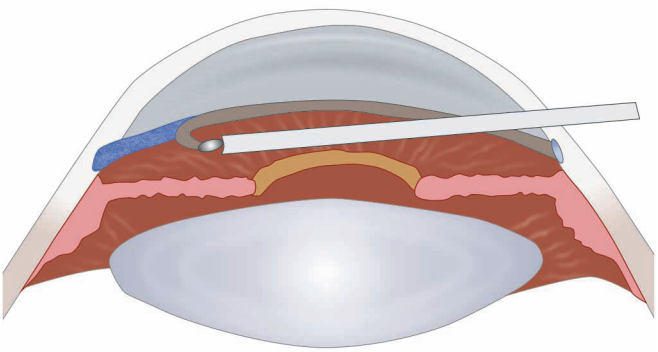

Fig. 1: Scheme of endotrabeculectomy

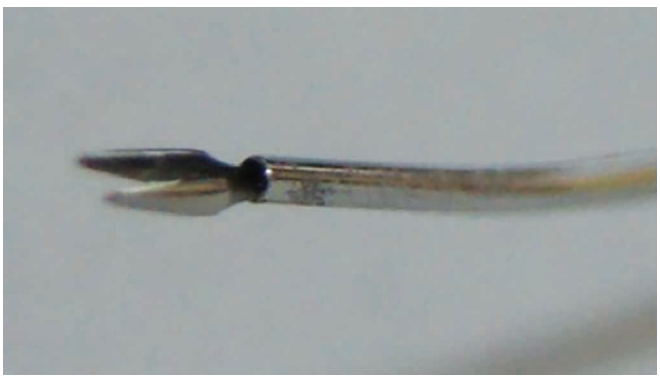

Fig. 2: The tip of the forceps for endotrabeculectomy

Endotrabeculectomy Technique (Fig. 1)

Epibulbar anesthesia is followed by two limbal paracenteses of 1.2 mm. After intracameral anesthesia of 1% lidocaine, the anterior chamber is filled and deepened with viscoelastic. Specially designed forceps (Fig. 2) are inserted into the anterior chamber through one of the paracentesis. Under direct gonioscopic control with the means of Swan Jacobs or Mori surgical goniolenses, the trabecula is captured from the side of the anterior chamber and removed within the targeted area (Fig. 3). Sometimes, it is possible to remove detached trabecula in the chamber anterior (Fig. 4).

Having been captured with the forceps, the trabecula detaches from the scleral spur and Schwalbe's line relatively easily. Trabecula ablation is controllable, which allows it to perform within the target area.

In all cases, the trabecula was ablated within 120–150° in the lower nasal and lower temporal quadrants.

During trabecula ablation, a white strip of Schlemm's canal outer wall becomes visible.

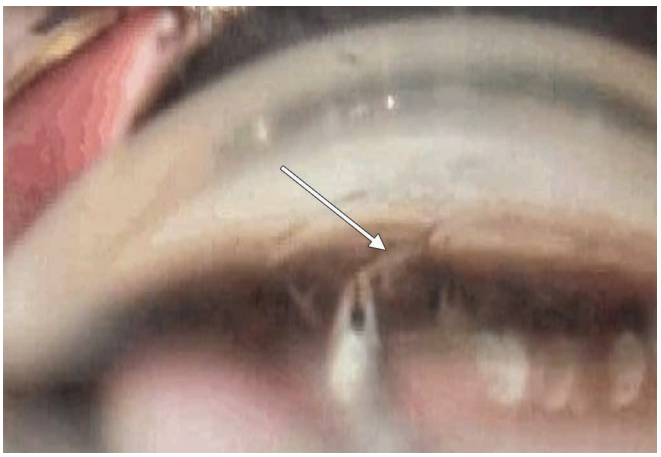

Fig. 3: Capturing and beginning of the trabecula ablation. The arrow shows the ablated trabecula meshwork

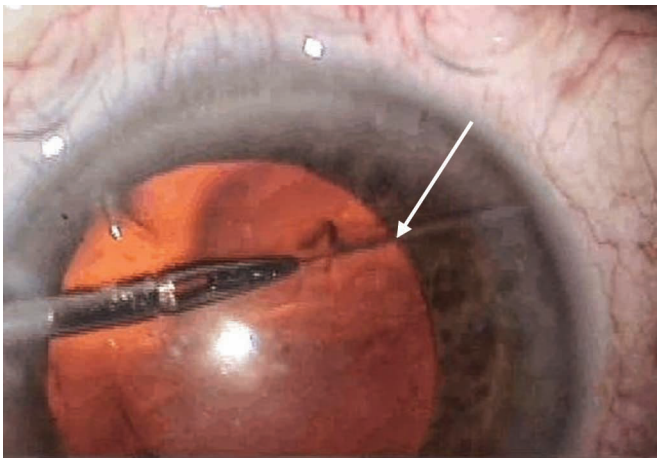

Fig. 4: A strip of the ablated trabecula in the chamber anterior

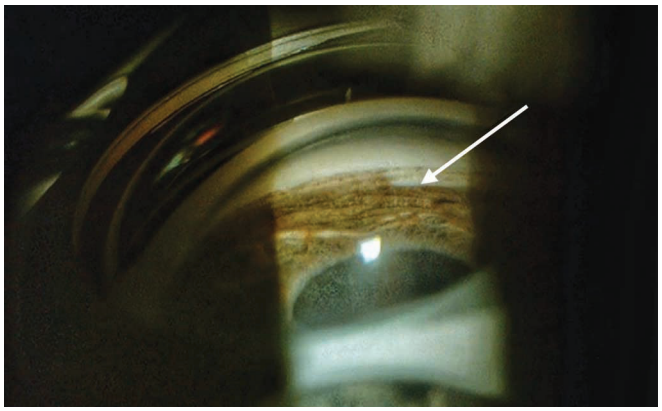

Fig. 5: The angle of the chamber anterior after endotrabeculectomy. The arrow shows Schlemm's canal outer wall

After trabecula ablation and viscoelastic aspiration, blood reflux into the anterior chamber in the area of ablated trabecula was observed in all cases, which was considered a positive prognostic of the surgery.

- Figure 5 shows a gonioscopic view of the anterior chamber angle after ETE.
- Viscoelastic is washed out using aspiration-irrigation, and hydroadaptation of the paracenteses is performed.
- In the case of combined surgery, clear corneal incision phaco and IOL implantation followed by viscoelastic aspiration.
- In the postoperative period, installations of antibiotics for 7 days and corticosteroids for 1 month were prescribed.

Results

Table 2 shows the preoperative and postoperative IOP measurements, and Table 3 shows the change in glaucoma medications over time in ETE and phaco-ETE groups, respectively. Both the IOP and number of medications were significantly reduced at all time intervals following the ETE alone as well as phaco-ETE surgeries. In the ETE group, the mean IOP was reduced from 20.25 ± 3.30 to 14.48 ± 1.41 mm Hg (28.5% from the initial, $p < 0.001$) at 6 months after the surgery and from 20.25 ± 3.30 to 14.94 ± 1.95 mm Hg (26.2% reduction, $p < 0.001$) at 12 months. The number of medications was reduced from 2.8 ± 1.0 to 1.3 ± 1.2 at 6 months after the surgery and to 1.5 ± 1.0 at 12 months after the surgery ($p < 0.001$).

In the phaco-ETE group, the mean IOP was reduced from 18.24 ± 3.20 to 14.67 ± 1.53 mm Hg (19.6% from the initial, $p < 0.001$) at 6 months and from 18.24 ± 3.20 to 14.83 ± 1.71 mm Hg (18.7% reduction, $p < 0.001$) at 12 months. The mean number of medications was reduced from 2.2 ± 1.1 to 0.8 ± 0.9 at 6 months after the surgery and to 1.0 ± 1.0 at 12 months after the surgery ($p < 0.001$).

Around 12 months after surgery, the IOP in both groups did not differ significantly, although, in the group where the stand-alone ETE was performed, the preoperative pressure was higher than in the group where the combined operation was performed (Table 2).

Figure 6 shows the dynamic of IOP changes after stand-alone ETE and combined surgery.

The success rate defined as a final IOP of <16 mm Hg and reduction of ≥ 20% from baseline with or without glaucoma medication (qualified success) calculated using the Kaplan–Meier curve at 6 months was 76.6% after ETE, 78.4% after phaco-ETE surgeries, and 77.5% for all cases. The success rate at 12 months was 65.7% after ETE, 76.4% after phaco-ETE surgeries, and 73.8% for all cases (Table 4).

There were no intraoperative complications. In the early postoperative period, hyphema was observed in nine cases. In all cases except one, hyphema disappeared without any special management within 2–3 days after surgery. One subject had persistent hyphema and required anterior chamber washout. At the time of the final examination, visual acuity decreased by more than two lines when compared with preoperative visual acuity in one eye (0.6%) because of cataract progression. No cases of postoperative endophthalmitis or choroidal hemorrhage have been reported. Six patients (six eyes) among 164 had undergone second surgery (trabeculectomy) due to uncontrolled IOP in the time between 3 and 12 months. Table 5 shows the types of postoperative complications and secondary surgeries following endotrabeculectomy surgery.

Discussion

The most similar to the ETE by technique is the operation of trabecula ablation ab interno with internal limiting membrane forceps.[19] The hypotensive effect obtained by the authors was higher than the hypotensive effect of ETE—12 months after surgery,

Table 2: Intraocular pressure (IOP) (mean mm Hg ± SD) before and after endotrabeculectomy

		Subgroups		
Time interval	*All cases*	*ETE*	*phaco-ETE*	*p-value**
Baseline	18.79 ± 3.33	20.25 ± 3.30	18.24 ± 3.20	0.01
Day 7	15.55 ± 2.68	15.48 ± 2.60	15.58 ± 2.73	0.88
1 month	14.80 ± 1.89	15.10 ± 2.53	14.71 ± 1.65	0.42
3 months	14.75 ± 1.56	14.89 ± 1.37	14.69 ± 1.64	0.58
6 months	14.61 ± 1.49	14.48 ± 1.41	14.67 ± 1.53	0.61
9 months	14.82 ± 1.60	14.62 ± 1.12	14.91 ± 1.78	0.49
12 months	14.86 ± 1.76	14.94 ± 1.95	14.83 ± 1.71	0.84
p-value**	<0.0001	<0.0001	<0.0001	

*p**, reliability indicators between results in two subgroups; *p***, reliability indicators between results before and after operation

Table 3: Number of glaucoma medications (mean ± SD) before and after ETE

		Subgroups		
Time interval	*All cases*	*ETE*	*Phaco-ETE*	*p-value**
Baseline	2.4 ± 1.1	2.8 ± 1.0	2.2 ± 1.1	0.01
1 month	0.5 ± 0.9	0.4 ± 1.0	0.6 ± 0.9	0.61
3 months	0.9 ± 1.0	0.9 ± 1.1	0.8 ± 0.9	0.93
6 months	0.9 ± 1.0	1.3 ± 1.2	0.8 ± 0.9	0.09
9 months	0.9 ± 1.1	1.4 ± 1.1	0.7 ± 1.0	0.04
12 months	1.2 ± 1.1	1.5 ± 1.0	1.0 ± 1.0	0.10
p-value**	<0.0001	<0.0001	<0.0001	

*p**, reliability indicators between results in two subgroups; *p***, reliability indicators between results before and after operation

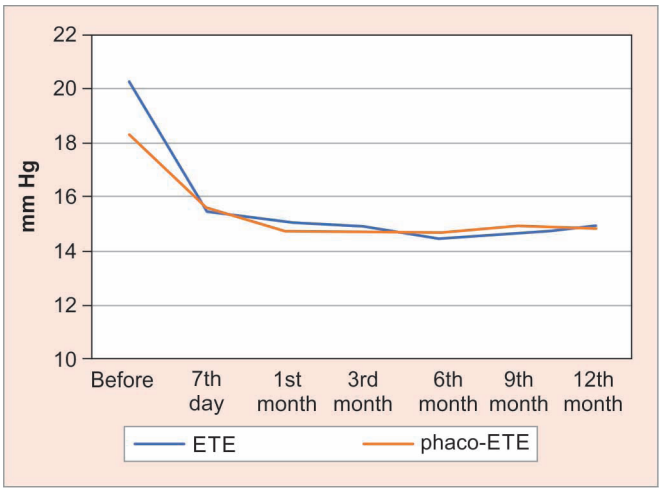

Fig. 6: Dynamic of IOP before and after operation endotrabeculectomy in two groups

the IOP decreased from 20.0 ± 6.8 to 10.4 ± 3.2 mm Hg. The number of antiglaucoma medications decreased from 2.7 ± 1.3 to 1.2 ± 1.2, which was similar to our results (from 2.8 ± 1.0 to 1.5 ± 1.0 in the ETE group). The investigation conducted by Nakasato et al.[19] was limited by a comparatively small number of cases (26 eyes of 23 patients).

The most common operation for trabecula ablation is trabectome, developed by Minckler et al. in 2005.[15] Its effectiveness has been confirmed by many studies. However, the hypotensive effect in these studies differs significantly, probably depending on the level of preoperative IOP. The higher the preoperative IOP, the more pronounced the hypotensive effect of surgery. Thus, in the study provided by Bendel and Patterson,[20] preoperative pressure was 18 mm Hg, and the reduction of IOP was 19.62%. In the study provided by Lee et al.[21], preoperative pressure was 24.4 mm Hg, and the reduction of IOP was 34.8%. Akil et al.[22] investigated the effectiveness of trabectome for the surgical treatment of patients with high IOP. In the trabectome-alone group, IOP decreased from 37.6 ± 6.6 to 19.9 ± 7.8 mm Hg (47.1% reduction). In the combined trabectome group, IOP decreased from 33.0 ± 4.9 to 18.5 ± 6.4 mm Hg (44.2% reduction). In our study, the preoperative IOP in the ETE group was 20.25 mm Hg, which is somewhat lower than in most studies, and the reduction of IOP in the ETE group was 26.2%.

Our results show a significant reduction of the postoperative IOP after ETE. The IOP reduction of 26.2% at 12 months after ETE as a stand-alone procedure was comparable to the 19–40% reductions reported in the literature for trabectome as a stand-alone procedure in POAG.[14,18,19,21–24] Medication reduction of 46.4% after a stand-alone ETE also falls within the range as reported after trabectome from the literature.[21,23–27]

There are not many comparative studies of the effectiveness of trabecula ablation ab interno as a single procedure and as a combined operation with phaco. Our study has found a less pronounced hypotensive effect of combined ETE + phaco (from 18.24 ± 3.20 to 14.83 ± 1.71 mm Hg, 18.7% reduction of IOP at 12 months after operation) compared to the hypotensive effect in the ETE group (from 20.25 ± 3.30 to 14.94 ± 1.95 mm Hg, 26.2% reduction of IOP at 12 months after operation). We believe that it was due to the lower preoperative IOP in this group compared to ETE stand-alone group. We found that the less invasive nature of ETE made it possible to perform combined phaco-ETE surgery even in patients with compensated IOP who used two or more antiglaucoma drops, which reduced the number of glaucoma

Table 4: Kaplan–Meier survival plots (%) for the IOP of ≤16 mm Hg and a ≥20% IOP reduction

		Subgroups		
Time interval	*All cases*	*ETE*	*phaco-ETE*	*p-value*
1 month	87.0	90.6	85.5	
3 months	81.4	80.6	81.5	
6 months	77.5	76.6	78.4	
9 months	76.5	76.6	76.4	
12 months	73.8	65.7	76.4	0.84

Table 5: Secondary surgeries and postoperative complications

	All cases (eyes)	*Subgroups (eyes)*	
	n (%)	*ETE n (%)*	*Phaco-ETE n (%)*
Failures requiring further glaucoma surgery			
Trabeculectomy	6 (3.7%)	4 (10.5%)	2 (1.6%)
Aqueous shunt	–	–	–
Repeat AIT	–	–	–
Total secondary surgery	6 (3.7%)	4 (10.5%)	2 (1.6%)
Complications			
Hyphema	9 (5.5%)	2 (5.3%)	7 (5.6%)
Transient hypotony (IOP of <7 mm Hg)	–	–	–
Spike of IOP (IOP of >10 mm Hg from baseline)	–	–	–
Aqueous misdirection	–	–	–
Choroidal effusion	–	–	–
Choroidal hemorrhage	–	–	–
Endophthalmitis	–	–	–
Cataract progression requiring phaco	1	1 (4.8%)	–
Visual acuity decrease >2 lines	1 (0.6%)	1 (4.8%)	–

medications. That is why preoperative IOP in this group was lower than in the ETE group, and the hypotensive effect of the surgery was less evident, but the amount of glaucoma medication was reduced. A similar result was obtained by Bussel et al.[26]: in the group where ab interno trabeculectomy (AIT) was performed, the reduction of IOP was 28% (from 23.7 ± 5.5 to 16.2 ± 3.9 mm Hg), and in the group of combined operation AIT and phaco, the reduction of IOP was 19% (from 20.0 ± 5.9 to 15.6 ± 5.1 mm Hg). Minckler et al.[16] evaluated the outcomes of trabectome-alone vs combined trabectome with phaco. At 24 months, IOP decreased from 25.7 ± 7.7 to 16.6 ± 4.0 mm Hg (40% reduction) in the trabectome-alone group compared to decreasing of IOP from 20.0 ± 6.2 to 14.9 ± 3.1 mm Hg (30% reduction) in the combined group. Parikh et al.[28] also found out that phaco has not contributed significantly to IOP reduction combined with trabectome. Kaplowitz et al.,[25] in the meta-analysis of AIT outcomes, showed that stand-alone trabectome decreased IOP by 39%, and combined phaco-trabectome–for 27%.[29]

Most authors define the success of the operations as the final IOP < 21 mm Hg. We believe that the pressure of 21 mm Hg is insufficient to stabilize the glaucoma process. Therefore, we defined success as a postoperative IOP of ≤16 mm Hg and a ≥20% reduction from baseline and no need for secondary surgeries. Thus, our results of the cumulative probability of success are slightly lower than those of other authors. So Akil et al.[22] found a 1-year success rate of 80%, Esfandiari et al.[30]—82.6%, and Bendel and Patterson[20]—85%. Okeke et al.[27] reported that the trabectome + phaco and trabectome alone groups had a 94 and 79% survival rate at 12 months, respectively. Bussel et al.[26] showed a survival rate in the phaco-AIT group 92% and in the AIT group 94%. But in the same groups, if the definition of success of the operations was IOP of <15 mm Hg or 20%, IOP reduction results would be 77 and 70%, respectively. In that case, such results would have been very similar to ours (76.4% after phaco-ETE and 65.7% after ETE).

We have not observed intraoperative complications. The main postoperative complication was hyphema (5.5%), which mostly reabsorbed spontaneously. It was necessary to perform a washout of hyphema in one case. This range of complications was similar to the range of hyphema after trabectome.[22,24,29] We have not observed early IOP spikes after ETE or phaco-ETE groups. In other studies, IOP spikes at 1 week after trabectome were observed in 4.9–26.3%,[16,20,24,29] which may be related to postoperative inflammation. Similar to data obtained in the literature, we have no complications which led to a permanent worsening of visual acuity.[16,20,24–26,29] Only in one patient from 21 phakic eyes (4.8%), cataract progression led to decreasing visual acuity and the necessity of cataract phaco. In this case, after the surgery, visual acuity recovered. This result was similar to data from other authors.[16,24,25]

Six patients (six eyes) among 164 (3.7%) have undergone second surgery (trabeculectomy) due to uncontrolled IOP in the time between 3 and 12 months. This result was better than the

results from other authors.[16,20,22,24,26] But counting the ETE group separately, the number of failed operations that needed further operations was four cases from 38 eyes (10.5%). These results are similar to results from other.[18,25]

Concerning the advantages of ETE. The main advantages of trabectome are that it only requires a small clear corneal incision that is smaller than that of a phaco wound with no conjunctival incision. However, the surgery requires the use of a complex device with constant irrigation for maintenance of the chamber's anterior depth and prevention of thermal tissue injury. The trabectome tip is inserted through a 1.6 mm wide incision, which, according to the authors, is usually sealed with a suture.[13] Also, it is possible to ablate trabecula meshwork with trabectome tip only up to 120° of the anterior chamber angle.

The surgery, suggested by us, is performed through small paracentesis that does not require suturing. The technical advantage of the surgery is the possibility to work in a stable anterior chamber due to its filling with viscoelastic. Besides, constant irrigation is not required. The specially designed forceps allow removing trabecula tissue in the target area. Due to two paracenteses in the opposite sites of the cornea, the trabecula can be ablated in any quadrant.

Another very similar procedure to endotrabeculectomy in the mining of technique and aim of the surgery is excisional goniotomy with the Kahook Dual Blade. The Kahook Dual Blade (KDB, New World Medical, Rancho Cucamonga, California, United States of America) is a novel single-use ophthalmic knife with two parallel blades designed to remove a strip of trabecula the purpose of restoring physiological outflow pathway.

Recent studies showed that excisional goniotomy with the Kahook Dual Blade lowered IOP by 10–22% and reduced medications by 12–35%.[31–33] The results of this study seem to be comparable to those of the endotrabeculectomy. The safety profile of the two procedures was also very similar.

The minimally invasive and atraumatic nature of endotrabeculectomy, as well as cataract phaco, promotes expanding indications of combined glaucoma and cataract surgery.

Our study has several limitations, which were short-term periods for follow-up. The number of patients was comparatively small. A larger prospective comparative study is needed to fully investigate the issues researched here. There was a possibility of bias in the selection of the Endotrabeculectomy vs other surgical techniques for glaucoma. Future studies involving randomization of treatment and comparison to other glaucoma surgeries need to be performed.

Clinical Significance

The ETE operation is technically simple and does not require expensive equipment. Our study demonstrates the efficacy of ETE in reducing IOP compared to trabecula ablation ab interno by trabectome. Other benefits of the surgery include the absence of thermal trauma and the ability to remove the trabecula in any quadrant.

Conclusion

The ETE is a safe and comparatively simple procedure that significantly reduces IOP (IOP reduction of 26.2% after ETE as a stand-alone procedure and 18.7% after combined phaco-ETE at 12 months after operation). The minimally invasive nature of the ETE allows expanding indications of combined treatment of glaucoma and cataract.

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