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Phaco-Trabeculectomy Equals Trabeculectomy in Lowering IOP-A 4 Years Follow-Up Study

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Abstract

Objective: The aim of this study was to compare the long-term efficacy and safety of combined phaco-trabeculectomy (phaco-trab) and trabeculectomy (trab) alone.

Methods: Retrospective, non-randomized, interventional case series of phaco-trab and trab. Inclusion criteria were diagnosis of glaucoma for both plus vision impairing coexisting cataracts for phaco-trab. Primary outcome measures were change in intraocular pressure (IOP) and number of anti-glaucoma drugs (AGD) at 1 y and 4 ys after surgery, and postoperative interventions (i.e. laser suture lysis, 5-Fluorouracil injection, needling). Secondary outcome measures were visual acuity and complications. Success was defined based on the criteria from the tube-versus-trabeculectomy study.

Results: Mean age was 73.6 ± 8.7 years (28% males; 51% right eyes). Median preoperative IOP was reduced from 22.8 mmHg to postoperative 13.0 mmHg at 1 y and to 14.0 mmHg at 4 ys after phaco-trab (n=62), or in trab alone (n=72) from 21.8 mmHg to 12.0 mmHg at 1 y and 4 ys. AGD were reduced from 2.5 ± 0.8 to 0.1 ± 0.3 1 y and 0.2 ± 0.6 4 ys after phaco-trab, and from 2.6 ± 1.0 to 0.2 ± 0.5 AGD 1 y and 4 ys after trab alone. Both IOP and AGD reduction were statistically indifferent between the groups at all time points. Mean number of postoperative interventions was 2.1 for phaco-trab and 1.8 for trab (p=0.64). 75% of phaco-trab and 74% of trab eyes fulfilled the criteria for complete success after 4 ys (p=0.844).

Conclusion: Both procedures resulted in an equally successful and stable long-term reduction of IOP to the lower teens and AGD requirement, together with a good safety profile. The high number of postoperative interventions in both groups emphasizes the importance of a close follow-up. We therefore conclude that if a close and careful postoperative follow-up can be guaranteed, phaco-trabeculectomy should be the treatment of choice for patients with coexisting cataract and otherwise uncontrolled IOP.

Keywords: Glaucoma; Intraocular pressure; Phaco-trabeculectomy; Trabeculectomy

Introduction

Cataract and glaucoma are the leading causes of global blindness and a common finding mainly in an elderly population [1]. Yet, there is a lack of consensus regarding the surgical therapy of choice for patients with the concomitant diagnosis of cataract and uncontrolled IOP.

Combined extracapsular cataract extraction with phacoemulsification and intraocular lens implantation plus trabeculectomy (phaco-trab) is the current standard combined procedure for treating these coexisting conditions [1-5]. Phaco-trab has the advantage of early visual rehabilitation together with an efficient reduction of intraocular pressure (IOP) and anti-glaucoma drugs (AGD) [6]. The patient undergoes a single surgery and thus, is exposed to the perioperative risk only once. In addition, the combined approach may save healthcare costs. On the contrary, performing glaucoma and cataract surgery subsequently may have significant disadvantages. If cataract surgery is performed first, the glaucoma patient is at risk of a perioperative increase in IOP (IOP spike) and an elevated IOP postoperatively. This must be avoided because IOP elevation may further damage visual function, especially in patients with advanced stage glaucoma [7-9]. Vice versa, trabeculectomy (trab) has been shown to accelerate cataract progression, hence reducing vision furthermore [10,11]. Filtering bleb integrity and function may be compromised by a subsequent cataract surgery as well [12]. Thus, combined phaco-trab may be advantageous for patients with coexisting cataract and glaucoma. However, studies have reported a lower efficacy in intraocular pressure reduction and a higher perioperative risk for combined phaco-trab compared to trabeculectomy alone [13-18].

This study evaluated the safety of combined phaco-trabeculectomy in comparison to trabeculectomy alone, and the efficacy of lowering IOP and reducing AGD. The long-term success rate of both procedures over a period of 4 years was analyzed. The aim of this study was to demonstrate an adequate reduction of IOP and AGD with a good safety profile for combined phaco-trabeculectomy.

Methods

This retrospective interventional study was approved by the local ethics committee, and adhered to the principles of the Declaration of Helsinki and local law. The study included consecutive patients after combined phaco-trabeculectomy or trabeculectomy alone between January 2008 and December 2009. All surgical procedures, including primary operation and postoperative interventions, were performed by one surgeon (CK) at 2 affiliated centers (UniversityHospital Zurich and Talacker Eye Center Zurich, Switzerland). If a patient underwent surgery on both eyes, only the eye that was operated first was included in the study. The follow-up visits were conducted by the surgeon himself (CK) and took place on the 1st postoperative day, with subsequent postoperative visits as required in the postoperative phase, as well as 1 year (± 1 month) and 4 years (± 2 months) after surgery. All patients were followed up for a minimum of 48 months.

Primary study endpoints were IOP and AGD at 1- and 4-year follow-up, together with the requirements of postoperative interventions during the postoperative phase. These included laser suture lysis, subconjunctival application of 5-Fluorouracil (5-FU), and needling. Secondary outcome measures were visual acuity, and intra- and postoperative complications such as bleb leak, hemorrhage or hyphema. Furthermore, IOP spikes, defined as an IOP increase of equal or greater than 10 mmHg compared to baseline, and postoperative hypotony, defined as IOP of equal or smaller than 5 mmHg, were recorded as complication. The following main reasons for surgery were distinguished: cataract, drug intolerance, or uncontrolled IOP with or without progression of the disease.

Inclusion and exclusion criteria

Patients were neither randomized nor blinded due to the differing inclusion criteria of the procedures. Indications for both were medically uncontrolled IOP, local or systemic intolerance to glaucoma medication, or mal-compliance. If vision-impairing cataract (BCVA less than or equal to 0.8 Snellen) was present, patients were offered to be assigned to the phaco-trab group on their own decision. In the absence of vision impairing cataract, patients were assigned to the trab group. Exclusion criteria for both were previous ocular surgery except for cataract surgery, corneal diseases (e.g. keratoconus, corneal scars), ametropia and astigmatism (both >2 D).

Surgical procedures-trabeculectomy and phaco-trabeculectomy

A fornix based conjunctival flap and a 4 × 4 mm scleral flap barely into clear cornea was prepared with a 30° blade. Underneath the scleral flap, a short sclerocorneal tunnel, 2.2 mm in width, was formed to enter the anterior chamber above the trabecular meshwork. For phaco-trab, standard cataract extraction and implantation of a one-piece acrylic IOL (Acrysof, Alcon Inc., Hünenberg, Switzerland) was carried out through the sclerocorneal tunnel underneath the flap. The pupil was constricted with miochol E (Bausch & Lomb Swiss AG, Zug, Switzerland) for standard trabeculectomy with a pre-calibrated semicircular 0.6 mm Crozafon-de Laage punch (Moria SA, Antony, France) followed by iridectomy with Wecker scissors. The scleral flap was readapted with nylon 10-0 and the conjunctiva was sutured with vicryl 8-0 according to the surgeon's experience. Postoperative preservative free therapy included Atropine 1% once daily for 3 days, dexamethasone-natriumphosphat 1 mg/ml 8x/d, and ofloxacine 0.3% 4x/d. Ofloxacine was tapered off over 4 weeks, whereas steroids were adjusted to the postoperative healing and scarring process over 2 to 4 months.

Postoperative interventions

Postoperative care included the following interventions: laser suture lysis, subconjunctival injection of 5-Fluorouracil (5-FU) and needling. All were performed by one surgeon (CK). The postoperative interventions were usually standardized by the following algorithm: (1) local massage of the bleb, (2) removal of releasable sutures or laser suture lysis, (3) subconjuntival 5-FU injections, and (4) bleb needling in the operating room.

Definition of success and failure

Success was defined on the basis of the Tube Versus Trabeculectomy study (TVT study) criteria [19]. Postoperative IOP equal to or less than 21 mmHg and IOP reduction of at least 20% compared to baseline and no use of AGD was required for complete success. Qualified success was reached with the above criteria for IOP, but AGD requirement equal to or less than baseline [19]. Glaucoma surgery during the follow-up period was classified as treatment failure.

Statistical methods

Data were coded in Excel and analyzed in SPSS version 22 (IBM Corporation, New York, NY, USA). Descriptive statistics such as median and interquartile range (IQR) were computed. Assumption of normality was evaluated with the Kolmogorov-Smirnov Test. Associations between two discrete variables were analyzed with the Chi^2 test. Differences in continuous variables with respect to two groups were tested with the non-parametric Mann-Whitney test. Differences in continuous variables with respect to a factor with three levels were tested with the non-parametric Kruskal-Wallis test. Kaplan-Meyer analysis combined with the log-rank test was applied to "time to event" and "complete failure" and "qualified failure" outcomes. Cox regression was computed to evaluate the influence of operation method on survival, adjusted for diagnosis, age, and gender. Results of statistical analysis with a p-value smaller than 0.05 were interpreted as statistically significant.

Results

A total of 134 eyes of 134 subjects were included in this study. The phaco-trab group comprised 62 patients (74% females) with a mean age of 76 (± 7.0) years, while the trab group included 72 patients (71% females) with a mean age of 71 (± 9.5) years. On average, phaco-trab patients were significantly older than trab patients ($p<0.001$). This is associated with the fact that cataracts are predominantly age related. Regarding the distribution of gender and eyes (53% right eyes for phaco-trab and 50% for trab) there was no statistically significant difference between the intervention groups. Overall, 51% of patients were diagnosed with primary open-angle glaucoma, 42% had pseudoexfoliation glaucoma and 7% another form of glaucoma ($p=0.830$) or ocular hypertension. Due to differing indications for surgery, the primary reason for the intervention varied between the two groups ($p<0.001$). Phaco-trab patients underwent surgery due to cataract in 21%, intolerance to eye drops in 21%, and uncontrolled IOP in 58% of cases. Trab patients underwent surgery due to drug intolerance in 21%, and uncontrolled IOP in 79% of cases. 10 trab and 5 phaco-trab eyes were excluded before statistical analysis because the contralateral eye was already included in the study. In the phaco-trab

group one patient was lost to follow-up due to death. Patient demographics are summarized in Table 1.

	Phaco-Trab	Trabeculectomy	p-value
Patients [n]	62	72	
Mean age [y] (±SD)	76 (± 7.0)	71 (± 9.5)	<0.001[1]
Gender [n] (%)			0.702[2]
Male	16 (26%)	21 (29%)	
Female	46 (74%)	51 (71%)	
Eye [n] (%)			0.732[2]
Right eye	33 (53%)	36 (50%)	
Left eye	29 (47%)	36 (50%)	
Type of glaucoma [n] (%)			0.830[3]
PEX glaucoma	25 (40%)	31 (43%)	
POAG	32 (52%)	37 (51%)	
Other glaucoma	5 (8%)	4 (6%)	
Reason for surgery [n] (%)			<0.001[3]
Cataract	13 (21%)	-	
Drug intolerance	13 (21%)	15 (21%)	
Uncontrolled IOP	36 (58%)	57 (79%)	
LENS [n] (%)			
Phacic	-	45 (62%)	
Pseudophacic	-	27 (38%)	
Cataract surgery during follow-up	-	15 (21%)	

Table 1: Demographic characteristics.[1]Mann–Whitney U test; [2]Fisher's exact test; [3]Pearson's chi-squared test; PEX glaucoma: Pseudoexfoliation glaucoma; POAG: Primary Open-angle Glaucoma.

Median preoperative IOP was 22.8 mmHg in the phaco-trab group and 21.8 mmHg in the trab group (p=0.04). On the first postoperative day median IOP was 10.5 mmHg after phaco-trab and 10.0 mmHg after trab (p=0.62), and at the end of the postoperative phase 12.0 mmHg and 11.0 mmHg (p=0.06), respectively. Median IOP was 13.0 mmHg and 12.0 mmHg after 1 year (p=0.02), and 14.0 mmHg respectively 12.0 mmHg 4 years after phaco-trab and trab (p=0.02). Reduction in IOP was statistically indifferent between the two intervention groups. A boxplot showing the development in IOP for both groups is given in Figure 1. Median IOP reduction from baseline in mmHg was -13.5 after phaco-trab and -11.75 after trab on the first postoperative day (p=0.28),-11.0 and -9.5 after 1 year (p=0.50), and -10.0 and -9.0 after 4 years (p=0.53). No IOP spikes occurred. Hypotony on the first postoperative day occurred in 13 (21%) phaco-trab eyes and in 14 (19%) trab eyes (p=0.35).

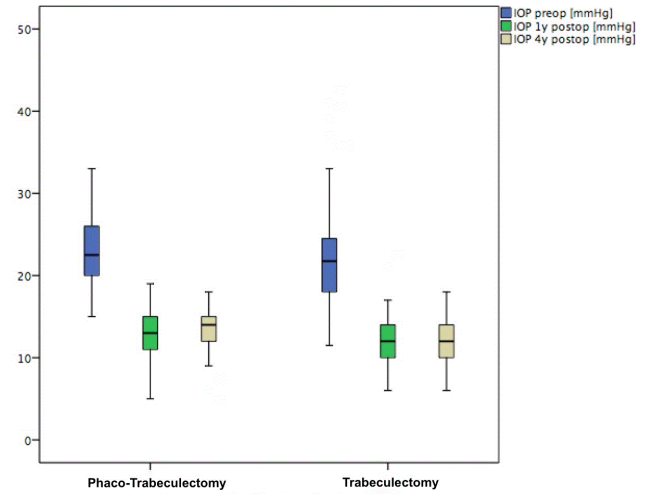

Figure 1: IOP development after Phaco-Trabeculectomy and Trabeculectomy. Boxplot of postoperative intraocular pressure (X-axis) per allocation group (Y-axis). IOP was measured preoperatively (IOP preop) as well as 1 year (IOP 1 y postop) and 4 years after surgery (IOP 4 y postop). The box represents the interquartile range, while the horizontal line in the box represents the median IOP. The whiskers represent the error bars and extend from the box to the highest and lowest IOP values. IOP: Intraocular Pressure [mmHg].

Four years after surgery patients of both groups required an average number of 0.2 AGD (p=0.80). AGD reduction was -2.4 AGD for both procedures after 1 year (p=0.56), and -2.2 for phaco-trab and -2.3 for trab after 4 years (p=0.41). Thus, both surgical procedures resulted in an equally successful and stable reduction of IOP and AGD. Table 2 summarizes IOP and AGD outcomes for all time points.

	Phaco-Trab	**Trabeculectomy**	**p-value***
Baseline			
IOP [mmHg]	22.8 (6.3, 15, 33)**	21.8 (6.5, 11.5, 41)	0.043
AGD [n]	2 (1, 1, 4)	3 (1, 0, 5)	0.273
1st Postoperative Day			
IOP [mmHg]	10.5 (7, 1, 25)	10.0 (4, 0, 18)	0.618
1 Year			
IOP [mmHg]	13.0 (4, 5, 19)	12.0 (4,6, 21)	0.017
AGD [n]	0 (0, 0, 2)	0 (0, 0, 3)	0.186
4 Years			
IOP [mmHg]	14.0 (3.5, 6, 18)	12.0 (4, 6, 18)	0.016
AGD [n]	0 (0, 0, 3)	0 (0, 0, 3)	0.798

Table 2: IOP and AGD outcomes 1 and 4 years after surgery. *Mann-Whitney U test, **Data are presented as median (interquartile range, minimum, maximum), IOP: Intraocular Pressure; AGD: Anti-glaucoma Drugs.

Accordingly, success rates were similar for both groups at all-time points, with phaco-trab showing slightly better outcomes. 90% of phaco-trab patients and 82% of trab patients fulfilled the criteria for complete success 1 year after surgery (p=0.22), while 75% resp. 74% still reached complete success 4 years after surgery (p=0.84). Qualified success rates are summarized in Table 3.

	Phaco-Trab	Trabeculectomy	p-value*
1 Year			
No AGD	95 %	89 %	0.222
AGD ≤ baseline AGD	100 %	100 %	-
IOP ≤ 21 mmHg	100 %	100 %	-
20% IOP reduction from baseline	95 %	92 %	0.504
Complete Success	90 %	82 %	0.216
Qualified Success	95 %	92%	0.504
4 Years			
No AGD	85 %	83 %	0.815
AGD ≤ baseline AGD	100 %	99 %	1.000
IOP ≤ 21 mmHg	100 %	100 %	-
20% IOP reduction from baseline	89 %	86 %	0.797
Complete Success	75 %	74 %	0.844
Qualified Success	89 %	85 %	0.615

Table 3: Success rates 1 and 4 years after surgery. *Fisher's exact test; IOP: Intraocular Pressure; AGD: Anti-glaucoma Drugs.

Phaco-trab improved BCVA logMAR from 0.226 ± 0.121 preoperatively to 0.062 ± 0.074 after 1 year and 0.058 ± 0.084 after 4 years. This equals a median visual acuity of 1 for both postoperative follow-ups. In the trab group visual acuity remained 0.8 for all time points, pre- and postoperative. At the time of surgery, 62.5% of trab patients were still phacic, 55.6% of which had cataract surgery during the 4-year follow-up period. There was no difference in success rates between pseudophacic and phacic patients one (p=0.54) or four years (p=0.41) after trabeculectomy, nor between the pseudophacic patients and those who had cataract surgery during the 4-year follow-up period (p=0.46). Thus, we found no significant difference in outcomes whether trab was performed before, after or together with cataract surgery.

Postoperative care included the following interventions: laser suture lysis, subconjunctival application of 5-Fluorouracil (5-FU) and needling. Table 4 demonstrates postoperative interventions in each study group. Postoperative interventions were carried out in 74% of phaco-trab patients and 85% of trab patients. The mean number of interventions was 2.1 in the phaco-trab and 1.8 in the trab group (p=0.64). Thus, overall more trab patients needed a postoperative intervention, but in the phaco-trab group the number of interventions per person was higher.

Intervention		Phaco-Trab	Trabeculectomy	p-value*
Laser suture lysis	1x	12 (19%)	35 (49%)	0.001
	2x	21(34%)	14 (19%)	0.050
5-FU	1x	21 (34%)	29 (40%)	0.478
	2x	10 (16%)	10 (14%)	0.810
	3x	9 (15%)	6 (8%)	0.284
Needling	1x	4 (7%)	2 (3%)	0.415
Mean number (±SD)		2.1 (±1.8)	1.8 (±1.4)	0.637

Table 4: Postoperative Interventions after Phaco-Trab and Trabeculectomy. *Fisher's exact test; 5-FU: Subconjunctival application of 5-fluorouracil.

No serious intra- or postoperative complications occurred, neither related to cataract surgery (e.g. Irvine-Gass syndrome, corneal decompensation) nor to trabeculectomy (e.g. persistent hypotony, bleb leak, blebitis with or without endophthalmitis). The similarity of outcomes was confirmed by Kaplan-Meyer survival analysis, which showed no significant difference in survival regarding surgical method and performance of postoperative interventions. Moreover, neither surgical method nor the performance or number of required interventions showed an influence on patient's survival in multiple regression analysis. Accordingly, success rates were the same with and without interventions.

Discussion

For patients with coexisting cataract and glaucoma a combined treatment addressing both conditions needs to be considered. Several studies have reported encouraging outcomes regarding IOP control and visual recovery after combined phaco-trab [2,5,6,17,20-22]. Kuroda et al. concluded that phaco-trab should be the treatment of choice in patients with mild and middle stage glaucoma [5]. This opinion is supported by several other studies [2,4,23]. Accordingly the European Glaucoma Society acknowledged in 2014 the combination of trabeculectomy plus small-incision phacoemulsification and cataract extraction as an effective and safe method in the treatment of concomitant cataract and glaucoma [24]. However, phaco-trab is usually not recommended in patients with severely uncontrolled glaucoma or patients with low target pressures, and trabeculectomy alone is generally considered more effective and safer than the combined procedure [13,14,18]. Rockwood et al. stated that combined phaco-trab is safe to perform and results in good visual acuity, but is associated with a higher complication rate and an increased risk of glaucoma reoperation [16].

With complete success rates of 75% and 74% four years after phaco-trab and trab alone, our results prove phaco-trab to be equally safe and effective in lowering intraocular pressure and AGD compared to trab alone. Both surgical procedures resulted in a stable and similar decrease of IOP and reduction in AGD. Unlike previous reports, both procedures reduced intraocular pressure long term to lower teens. In addition, we found no difference in outcome whether trab was performed before, after or together with cataract surgery.

Our analyses were very standardized as all surgeries were performed by the same surgeon as well as the close and practiced postoperative

follow-ups. The close postoperative follow-up allows early recognition of bleb dysfunction, increase in scaring and IOP. The large percentage of patients in need of postoperative interventions emphasizes its important role in the postoperative outcome. Only 26% of phaco-trab and 15% of trab patients did not require any postoperative interventions, but the necessary expenditure is rewarding. Immediate intervention can be the key to desirable success rates.

In our study population trab patients required significantly more laser suture lyses than phaco-trab patients. We believe that in phacic trab patients sutures at the flap are initially tightened firmer in order to better stabilize the anterior chamber in the early postoperative period and avoid anterior lens positioning with anterior chamber shallowing.

Surprisingly, absolute IOP reduction and success rates were slightly better after phaco-trab despite equal patient management and control. This may be due to the additional hypotensive effect of phaco, which is known to lower IOP by 2 mmHg on average [13,25-28]. This idea is supported by the fact that the difference in IOP balances out with time until it is the same for both groups at the 4-year follow-up. Furthermore, the phaco-trab group had a higher preoperative IOP, which may result in a slightly better IOP reduction as well [29,30].

Even though phaco-trab is generally expected to cause more intra- and postoperative complications, phaco-trab reached the same safety profile as trab alone with a potential vision increase if cataracts are concomitant. The amount of subsequent cataract surgeries after trab in the 4-year observation period was surprisingly high (55.6%). However, no serious complications occurred due to phaco-trab, trab or subsequent interventions in this study. Considering the fact that phaco-trab patients are spared from the perioperative risks and costs of a subsequent surgery, it is evident that the combined surgical approach should always be taken into consideration.

Our study showed that phaco-trab provides a long-term reduction of intraocular pressure to the lower teens together with a stable elimination of AGD requirement, with a good safety profile. We therefore conclude that if a close and careful postoperative follow-up can be guaranteed, phaco-trabeculectomy is the treatment of choice for patients with coexisting cataract and uncontrolled IOP.

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