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ORIGINAL ARTICLE

Phacoemulsification with Goniotomy Using Kahook Dual Blade Versus Phacoemulsification with Subscleral Trabeculectomy in Management of Primary Open Angle Glaucoma

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Abstract

Background: Glaucoma surgeries result in substantial intraocular pressure (IOP) reductions but are associated with significant risks. Recently, new surgical techniques needed to achieve more IOP reduction with a satisfactory safety profile. *Aim*: Compare phacoemulsification and goniotomy with the Kahook Dual Blade (KDB) versus phacoemulsification

with subscleral trabeculectomy showing their impact on glaucoma surgery.

Methodology: This prospective, randomized, comparative study included 40 patients above age of 40 of both genders diagnosed as primary open-angle glaucoma. The patients were assigned into two equal groups: using the KDB and traditional subscleral trabeculectomy. Evaluation of visual acuity and measurement of IOP were the main outcomes.

Results: Traditional subscleral trabeculectomy group had showed statistically significant lower IOP at first week (P = 0.01) and at 6 month (P = 0.03 without statistical difference regarding medication requirements postoperative (P > 0.05) and in the success or failure rates (P > 0.05), in comparison to KDB group. However, both groups show significant differences compared with baseline values regarding IOP, medication requirements postoperative, and complications incidence (P < 0.001).

Conclusions: Phaco-Kahook goniotomy was proven to be effective in the treatment of glaucoma with high success rates as phaco-trabeculectomy and has potential advantages as like easy technique and it has excellent safety profile but without difference in reducing antiglaucoma medications and postoperative complication when compared with phaco-trabeculectomy. Also, Phaco-trabeculectomy has more effect on IOP reduction after 6 months.

Keywords: Glaucoma, Intraocular pressure, Kahook, Trabeculectomy

1. Introduction

G laucoma is a main etiology of irreversible blindness. The major risk factor for disease progression is high intraocular pressure (IOP).¹

Lowering IOP is the main aim of management for open-angle glaucoma (OAG) aiming to eliminate the injury of the optic nerve and keep the vision, and surgical intervention is often needed after failure of medical treatment.²

Traditional glaucoma surgeries such as trabeculectomy lead to IOP lowering but they are associated with significant risks.³ New surgical techniques needed to achieve more IOP reduction, a satisfactory safety profile, can be done with cataract surgery, and reduce the needs for glaucoma medications.⁴

The traditional goniotomy knife is used to split the trabecular meshwork (TM) beyond Schwalbe's line. Unfortunately, it had no significant long-term success in adults leading to elevated IOP.^{5,6}

The Kahook Dual Blade (KDB) is a recent Food and Drug Administration (FDA) approved ophthalmic knife prepared to carry out a goniotomy procedure by removing the TM in a more perfect pattern with little residual TM leaflets and minimal collateral injury.⁷

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It is intended with a taper tip permitting easy entry into the Schlemm canal and removes a section of TM.⁸

Goniotomy with the KDB may be done alone or associated with cataract procedure leading to significant IOP reduction postoperative.⁶

The aim of this study is to evaluate efficacy and safety of phacoemulsification and goniotomy using the KDB versus phacoemulsification with subscleral trabeculectomy in cases of primary OAG combined with visually significant cataract grade two or more on Lens Opacities Classification System.

2. Materials and methods

This prospective, randomized, comparative study was conducted from 2020 to 2022 after getting Institutional Review Board (IRB) consent, Faculty of Medicine, AL Azhar University. Informed written agreement was gained from all patients in the study after ensuring confidentiality and being informed of the risks, benefits, and alternatives of surgery.

The inclusion criteria were patients above age of 40 of both sexes diagnosed as primary OAG with visually significant cataract and with indication of glaucoma surgery. Exclusion criteria were other ocular diseases, corneal opacities that obstruct viewing of angle, previous ocular surgeries or trauma, other types of glaucoma.

The 40 patients were randomly divided into two similar groups (n = 20 in each group) according to computer-generated table of random numbers using the permuted block randomization method. A single investigator was evaluating the patients for eligibility, obtaining written informed consent and opening the sealed opaque envelopes containing group allocation. Group (1) (n = 20): was treated with phacoemulsification of the cataract in addition to goniotomy using the KDB. Group (2) (n = 20): was treated with phacoemulsification of the cataract in addition to traditional subscleral trabeculectomy.

All patients were subjected to preoperative assessment; history taking, full ophthalmic examination and laboratory investigations. Preoperative medications used were prophylactic topical antibiotic; mocifloxacin 0.3% eye drops four times daily, on the day before the operative day, topical steroid dexamethazone eye drops were used for 1 week before surgery, long-acting aqueous suppressants such as beta blockers which was stopped several days before surgery with outpatient monitoring of IOP and oral anticoagulants stopped 1 week preoperative.

Patients were anesthetized using either Local anesthesia (peribulbar) or general anesthesia for

uncooperative patients and mentally challenged. Periocular skin was sterilized by povidone iodine (betadine) 10% then a drape was used after drying eyelid skin. Conjunctiva was sterilized using povidone iodine (betadine) 5%.

Postoperative treatment had included topical dexamethazone/tobramycin eye drops and ointment 4 times/day for a week with gradual withdrawal along the following 4–6 weeks.

During follow-up period complications were recorded and managed and success was assessed at 6-month postoperatively according to the following criteria: successful surgery was defined as IOP less than 18 mmHg or IOP lowered by greater than or equal to 20%, without antiglaucoma medications postoperatively (complete success) and with antiglaucoma medications postoperatively (Qualified success). Failure was defined as IOP greater than 18 mmHg inspite of medical therapy or IOP lowered less than 20% from initial baseline.

Postoperatively, the patients were evaluated at 1, 7 days, 1, 3, and 6 months. Examination included: Visual acuity using Landlot's broken rings chart then converted to logMAR. Measurement of IOP by Goldmann applanation tonometer. When IOP was more than 21 mmHg during the follow-up period additional antiglaucoma medication was added. A number of antiglaucoma medications were recorded.

The gathered data were tested using SPSS program (version 22). Tests applied: Kolmogorov–Smirnov test for normality of numerical data distribution, Student *t*-test for comparing 2 independent groups, repeated Measures ANOVA test for comparing more than 2 studied periods with post Hoc test and χ^2 test and Monte Carlo tests for Categorical data. Data presented as; mean ± standard deviation for normally distributed numerical data, median (range) for non-normally distributed numerical data. All data were assumed statistically significant if *P* value was less than or equal to 0.05.

A Priori G-power analysis was used to evaluate study sample size. Using α (type 1 error) = 0.05 and β (type 2 error) = 0.2 (power = 80%), 18 patients per group were enough to detect a 20% difference among the groups. To avoid potential errors and patients' loss during follow-up; 20 patients were needed in each group to find this difference.

3. Results

Fifty patients were involved in the present study; 10 patients were precluded and 40 patients were registered and analyzed. Fig. 1. Patients in the both groups were analogous regarding demographic data and side of the surgery (P > 0.05). Table 1, Figs. 2 and 3.

Regarding IOP, preoperative baseline values between two groups were not statistically significant (P = 0.88), whilst during the follow up period, statistically significant lower IOP values were detected in groups (II) in comparison to group (I) at 1st week (P = 0.01) and at sixth month (P = 0.03), while during first and third months there was no statistically variance among both groups (P > 0.05). However, IOP within both groups show significantly difference following surgery and during follow-up relative to baseline values (P < 0.001). Table 2 Fig. 4.

The preoperative number of antiglaucoma drugs and after 6 months follow-up had showed no

Table 1. Socio-demographic characteristics of the studied groups.

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	Group I (<i>N</i> = 20)	Group II ($N = 20$)	P value
Age (years)	58.2 ± 5.3	56.9 ± 7.07	0.51
Sex			
Male	9 (45%)	14 (70%)	0.11
Female	11 (55%)	6 (30%)	
Side			
Right	12 (60%)	10 (50%)	0.53
Left	8 (40%)	10 (50%)	

(Data were expressed as mean \pm standard deviation, or number (percentage)) I: Phaco-kahook group II: Phaco-trab group = (*P* value ≤ 0.05 was assumed statistically significant).

statistical variance among the two groups. But, both interventions had lowered drug requirements, and by 6 months postoperatively, there was a decrease of drugs within both groups with statistical significance



Fig. 1. Consort flow chart showing study design.



Fig. 2. Age of the studied cases.

(P < 0.001) in comparison to preoperative values. Table 3.

Success rates were calculated according to IOP values at 6 months postoperative. There was no statistically significant variance among the two groups in the success or failure rates (P > 0.05). Complete success was documented in 15 out of 20 eyes (75%) in1 group I and in 17 out of 20 eyes (80%) in group II. While qualified success was documented in 3 eyes (15%) in group I and 2 eyes (10%) in group II. The overall success rate (complete and qualified success) attained at the end of the follow-up period was 90% in group I and 95% in group II. The failure rate was 2 (10%) in group I and 1 (5%) in group II. Table 4.

Complications encountered in this study are displayed in Table 5. There was no significant variance seen among two groups (P > 0.05). No major adverse effects such as (persistent hypotony, choroidal detachment, and endophthalmitis) were documented in our study. No eyes required any additional glaucoma procedures during the observed follow-up.

Early hypotony was higher in phaco-trab group (10%) than phaco-kahook group (5%). The hypotony in all cases was transient and improved with conservative treatment (systemic steroids, cycloplegic eye drops and frequent topical prednisolone acetate 1% eye drops) despite one case in phaco-trab group who required conjunctival suturing for bleb leak.



Fig. 3. Sex of the studied cases.

IOP	Group I (<i>N</i> = 20)	Group II ($N = 20$)	P value
Preoperative	21.4 ± 1.9	22.1 ± 1.6	0.21
1 week	16.7 ± 2.2^{b}	14.3 ± 3.4^{b}	0.01 ^a
1 month	15.8 ± 1.9^{b}	15.2 ± 2.1^{b}	0.36
3 months	15.5 ± 1.8^{b}	14.7 ± 1.8^{b}	0.16
6 months	$15.6 + 2.01^{b}$	$14.3 + 1.5^{b}$	0.03 ^a

Table 2. Pre and postoperative IOP (mmHg) in both groups.

(Data were expressed as mean \pm standard deviation)I: Phacokahook group. II: Phaco-trab group. (*P* value ≤ 0.05 was assumed statistically significant).

^a Significance relative to group 1.

^b Significance relative to preoperative value.

Figs. 5 and 6 In phaco-kahook group, 3 (15%) patients had an IOP spike with an associated hyphaema which respond to medical treatment. One patient only in each group had shallow AC. Fig. 7.

4. Discussion

Glaucoma filtration surgery is done to decrease IOP when maximal tolerable antiglaucoma medications and/or laser surgery fail to reach the target IOP Shaarawy⁹

Trabeculectomy is considered the conventional glaucoma surgery with well-established success and complication rates Wang.¹⁰ But, because of high rates of postoperative complications, there was a need for safer alternatives. Goniotomy using KDB is one of these alternatives Tojo.¹¹ Therefore, this study was conducted to evaluate efficacy and safety of both interventions and their impact on IOP, need of antiglaucoma medications postoperative, success rate and postoperative complications.

In the present study, the results have showed that both interventions achieved better values of IOP and lesser needs for antiglaucoma medications comparing with preoperative values with no difference between them regarding the need of antiglaucoma medications postoperative, success rate and postoperative complications but Phaco-Trab group had better values of IOP at 1 week and 6 months follow-up as compared with Phaco-Kahook group.

According to the current study, Phaco-Trab group had showed better reduction of IOP at first week postoperative and at 6 months in comparison to Phaco-Kahook group.

Our results as regard IOP reduction were similar to the result shown by Francis and Winarko¹² who compare phaco-Trabectome and Phaco-Trabeculectomy in OAG and had detected a significant variance in IOP lowering in Phaco-Trabeculectomy group. Furthermore, in a study comparing Trabeculotome versus Trabeculectomy alone, there was also a significant IOP lowering in Trabeculectomy group Jea.¹³

On the other hand, Jessica and colleagues conducted a study that compare phaco-trabectome versus phaco-trabeculectomy in patients with OAG and show no significant difference in IOP reduction between the two surgeries at 6 months, this variance may be due to lower number of patient involved in their study and early end of the trial before achieving the intended sample size Ting.¹⁴

In contrast to our results, another study comparing Phaco-trab versus phaco-ExPRESS in primary OAG documented statistically reduced IOP in Phaco-ExPRESS than Phaco-Trab at 2 weeks and 1 month. However, no statistical variance was found at 3, 6, and 12 months postoperatively. This may be



Fig. 4. Mean values of IOP among studied groups.

Table 3. Number of anti-glaucoma medications in both groups.

Medication	Group I (<i>N</i> = 20)	Group II ($N = 20$)	P value
Preoperative 6 months	$\begin{array}{c} 2.4 \pm 0.59 \\ 0.75 \pm 1.1^{\rm a} \end{array}$	$\begin{array}{c} 2.3 \pm 0.47 \\ 0.40 \pm 0.69^{\rm a} \end{array}$	0.73 0.54

(Data were expressed as mean \pm standard deviation) I: Phacokahook group II: Phaco-trab group. (*P* value \leq 0.05 was assumed statistically significant).

^a Significance relative to preoperative value.

Table 4. Success rate after 6 months in both groups.

	Group I (<i>N</i> = 20)	Group II $(N = 20)$	P value
Complete success	15 (75%)	17 (85%)	0.42
Qualified success	3 (15%)	2 (10%)	1
Total (complete + Qualified) success	18 (90%)	19 (95%)	1
Failure	2 (10%)	1 (5%)	1

(Data were expressed as number (percentage))I: Phaco-kahook group. II: Phaco-trab group. (P value ≤ 0.05 was assumed statistically significant).

explained by larger number of patients conducted in their study as long as longer duration of follow-up Zhang.¹⁵

Regarding IOP reduction in group I, there was a significant reduction from mean baseline IOP at 6 months which is similar to studies that evaluate results of phacoemulsification combined with goniotomy using the Kahook in glaucoma patients and revealed significant reduction of IOP from baseline to 6 months after operation Ibrahim, Hirabayashi.^{16,17}

While in group II, IOP reduction was also significant from mean baseline at 6 months. This was matching with Zhang and colleagues¹⁸ who reported significant decrease in IOP from baseline in phaco-trab group and also with the result by Tham¹⁹ who reported a significant decrease of IOP from baseline following Phaco-trab in treatment of primary open-angle glaucoma.

In our study, both interventions succeeded to lower the mean of antiglaucoma medications from baseline at the end of follow-up visits at 6 months. However, there were no statistical difference between the two groups in preoperative and at 6 month

Table 5. Postoperative complications in both groups.

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	Group I $(N = 20)$	Group II $(N = 20)$	P value
Shallow AC	1 (5%)	1 (5%)	1
Early hypotony	1 (5%)	2 (10%)	1
Bleb leak (conjunctival)	0	1 (5%)	1
Early hyphaema	3 (15%)	0	0.23
IOP spikes	3 (15%)	2 (10%)	1

(Data were expressed as number (percentage))I: Phaco-kahook group. II: Phaco-trab group. (*P* value \leq 0.05 was assumed statistically significant).

follow-up period. This was parallel with Ting¹⁴ who reported no significant difference between both groups as regard mean medications at 6 months.

As regard reduction of antiglaucoma medications in Phaco-kahook group, the mean was reduced from baseline at 6 months. Mean reduction of medications from baseline was also studied at 6 months by Hirabayashi, Ansari and Loganathan^{17,20} who reported a significant reduction from base line at 6 months.

Clement and his colleagues has reported significant reduction of antiglaucoma medications from base line at 6 months and 1 year after phaco-trab surgery which is matching with our results in group II where mean medications was significantly reduced at 6 months Tham.¹⁹

In our study, success rates were calculated according to IOP values at 6 months postoperatively. Complete success was achieved in 15 out of 20 eyes (75%) in 1 group I and in 17 out of 20 eyes (80%) in group II. Three patients (17.6%) in group I and two patients (10.5%) in group II were controlled with adjunctive topical medications to keep IOP below 18 mmHg. The total success rate attained at the end of the follow-up period 90% in group I and 95% in group II.

In our study, 2 (10%) cases in group I versus 1 (5%) case in group II experienced postoperative failure of IOP reduction despite using topical combination drops. Accordingly, there was no significant variance among the two procedures with respect to failure rates.

Jessica and her colleagues¹⁴ assess the success rates of Phaco-trabectome in comparison to Phaco-trabeculectomy. The success rate was not different significantly between both groups. In the same study, the failure rate was 1 of 8 eyes (12.5%) in the Phaco-Trabeculectomy group with no significance different in both groups regarding failure rate Ting.¹⁴

In parallel to our result, Ejaz Ansari and Loganathan²⁰ conducted a study for 12-month outcomes after Phaco-Kaook in primary OAG and reported complete success rate of 71.9% (vs 75% in our study).

Similarly, a study by Ibrahim¹⁶ and her colleagues was conducted to analysis the surgical outcomes and success predictors of Phaco-kahook in glaucoma patients and reported a 6-month total success rate of 86% (vs. 90% in our study).¹⁶

On other hand, a study by Linda and her colleagues to assess phaco-trab in POAG has reported a total success rate of 62% after 2 years (vs. 95% in our study), this may be due to longer duration of study and larger number of patients Poon.²¹

Complications encountered in this study did not show significant difference between both groups.



Fig. 5. Show photoslit of the right eye of the same patient from group II after phaco-trab. A. First day postoperative with shallow AC B. after 1 month with formed AC.



Fig. 6. Show photoslit of the left eye patient presented with bleb leak postoperative after phaco-trab. A. First day postoperative B. show diffuse bleb of the same eye after 3 months.

Early hypotony was higher in phaco-trab group (10%) than phaco-kahook group (5%). In phaco-kahook group, 3 patients (15%) had an IOP spike



Fig. 7. Show photoslit of the right eye patient presented with first day postoperative dispersed hyphaema and corneal edema after phacokahook goniotomy.

with an associated hyphaema which respond to medical treatment.

The limitations of our research may be the small sample size and shortened follow-up duration period so we recommend further evaluation of the phaco-kahook surgery in cases with other types of glaucoma for long term results.

4.1. Conclusion

Phaco-Kahook goniotomy was proved to be effective in treatment of OAG with high success rates as phaco-trabeculectomy and it may have potential advantages as has excellent safety profile. Phaco-trabeculectomy has more effect on IOP reduction after six months, though Phaco-kahook has a significant effect compared with baseline.

Disclosure

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Conflicts of interest

The authors declared that there were no conflicts of interest.

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