Original Article

Combined Viscocanalostomy-Trabeculectomy for Management of Advanced Glaucoma – A Comparative Study of the Contralateral Eye: A Pilot Study

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ABSTRACT

Purpose: To compare combined viscocanalostomy-trabeculectomy (VISCO-TRAB) to trabeculectomy (TRAB) for the management of advanced glaucoma.

Materials and Methods: The study cohort comprised of 18 subjects with bilateral advanced glaucoma who underwent VISCO-TRAB surgery (VISCO-TRAB group) in the right eye and TRAB (TRAB group) in the left eye. VISCO-TRAB constituted lamellar scleral flap, deep scleral flap dissection with deroofing of Schlemm's canal (SC), viscodilation of SC, penetrating trabeculectomy, peripheral iridectomy, and tight flap closure. All eyes received subconjunctival mitomycin. Success criteria included intraocular pressure (IOP) < 14 mmHg or > 30% lowering of IOP with no devastating complications. A *P* value less than 0.05 was considered statistically significant.

Results: Mean IOP was significantly lower after VISCO-TRAB compared to TRAB at 1 week and 3 months postoperatively ($P<0.05$). No eyes lost more than two lines of Snellen acuity. There were more hypotony-related complications after TRAB than VISCO-TRAB surgery. Target IOP was achieved in 83.3% in the VISCO-TRAB group compared to 55.6% in the TRAB group.

Conclusion: Combined VISCO-TRAB is effective in reducing IOP to the target level for advanced glaucoma with lower postoperative complications.

Key words: Advanced Glaucoma, Trabeculectomy, Viscocanalostomy, Viscocanalostomy-Trabeculectomy

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INTRODUCTION

In advanced glaucoma, the severely compromised optic nerve requires low and stable intraocular pressure (IOP) to preserve the residual visual function.[1] Trabeculectomy (TRAB) with mitomycin C (MMC) is associated with a high incidence of hypotony-related complications or complications related to tight flap closure or early suture removal.[2-6]

During nonpenetrating glaucoma surgery, macroperforation of trabeculo-Descemet's membrane results in marked hypotony in 90% of cases.[7,8] This may be attributed to overdrainage due to the large scleral space that is cleared.[9] Combined viscocanalostomy—trabeculectomy (VISCO-TRAB) comprises dissection of a deep scleral flap, viscodilation of Schlemm's canal (SC), and intended macroperforation (penetrating sclerokeratectomy).[10] The technique is modified to control hypotony by enhancing internal flow via SC and a scleral lake and limiting external filtration with tight suturing of the scleral flap.

A previous study of VISCO-TRAB reported marked IOP reduction in the early postoperative period with fewer pressure spikes or complications related to excessive flow.[10] However, the results of this study[10] were compared to a historical group

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of patients with advanced glaucoma treated with TRAB in the preceding year. In this pilot study, we compared the results of VISCO-TRAB to TRAB in the contralateral eye of patients with bilateral advanced glaucoma.

MATERIALS AND METHODS

In this prospective contralateral eye study, the study cohort comprised subjects with bilateral advanced glaucoma scheduled for surgical treatment at the Glaucoma and Cataract Unit of the Magrabi Eye and Ear Center, Jeddah, Saudi Arabia, from January 2008 to December 2008. Advanced glaucoma in this study was defined as severe to total loss of neuroretinal rim in at least three quadrants of the optic disc, and severe visual field loss splitting fixation in at least one quadrant or a tubular field defect. In addition to the presence of advanced glaucoma, noncompliance to or the lack of achievement of target pressure with maximum medical therapy was considered as an indication for surgery. The study was randomized by selecting all right eyes of the subjects to undergo VISCO-TRAB surgery (VISCO-TRAB group) and all left eyes to undergo TRAB (TRAB group) regardless of which eye underwent surgery first or which eye had more advanced disease. When a subject met the inclusion criteria, the surgical plan was determined after discussion with the subjects regarding the type of the procedures to be performed. All subjects were masked to the type of surgery in each eye. Subjects with visually significant cataracts had separate-site phacoemulsification combined with the filtering procedure. The study was approved by the Institute's committee of ethics and the risk-benefit ratio was explained to the patient before signing a consent form.

Surgical technique

Most of the surgeries were performed under topical or peribulbar anesthesia. All surgeries were performed by the first author. The globe was rotated inferiorly with a 7/0 silk superior corneal traction suture. Combined VISCO-TRAB was performed in the superotemporal or superonasal quadrant trying to avoid sites of perforating scleral vessels. The surgical technique has been previously described.[10] Briefly, it comprises a fornix-based flap, light cautery, and subconjunctival application of MMC, 0.3 mg/ml for 3 min. A 4x4 mm rectangular lamellar scleral flap, one third of the thickness, is dissected to within 1 mm of clear cornea. A second deeper rectangular flap is dissected 0.5 mm inside the border of the first flap by dissecting a scleral pocket using a special dissecting microsurgery knife (Alcon/Grieshaber AG, Switzerland, Ref: 681.25), that left only a thin translucent layer of sclera overlying the choroid. Forward dissection of deep flap continues until SC is identified and deroofed. A specially designed viscocanalostomy cannula (Alcon/Grieshaber, Switzerland, Ref: 149.40), with an outer diameter of 165 μm is introduced into the ostia of SC, right and left, to inject sodium hyaluronate 1% (ProVisc, Alcon Inc., Fort Worth, TX, USA) into the canal. A small amount is injected and repeated a few times on each side. The floor of SC is incised transversely and a trabeculocorneal segment is excised for approximately 1.5 mm in length and 3 mm in width. A peripheral iridectomy is performed. The lamellar scleral flap is closed with watertight 4 10/0 nylon sutures. The AC is formed and the conjunctiva is closed with two corner sutures at the dissected edge and two central transverse mattress 10/0 nylon sutures.

The routine TRAB procedure comprised a fornix-based conjunctival flap, 0.3 mg/ml MMC for 3 min, a 2x3 mm lamellar sclera flap, a 1x2 mm penetrating sclerokeratectomy, and peripheral iridectomy. External filtration was titrated by the number of 10/0 sutures and suture tension at the lamellar flap. When the glaucoma procedure was combined with phacoemulsification, the surgeon switched his position temporally after outlining the deep flap. At the end of the phaco procedure, the AC was reformed and the corneal wound was secured by one 10/0 nylon suture and the filtering operation was completed.

Postoperatively subjects were prescribed combination antibiotic-corticosteroid eye drops every 2 h for 1 week and gradually tapered over the following 5 weeks. Cycloplegic-mydriatic eye drops were used when signs of early inflammation, shallow AC, hypotony were present or for an anticipated risk of aqueous misdirection. Postoperatively, subjects were examined at days 1 and 3 then at 1, 2, 4, and 8 weeks and every 3 months. Digital massage, focal compression, and laser suture lysis (LSL) were performed according to IOP level and degree of filtration. Success was defined as IOP less than or equal to 14 mmHg or the reduction of IOP by 30% or greater at last follow-up visit without devastating complications or loss of light perception. These cutoff values of target pressure were deemed suitable for severe optic nerve damage in subjects with advanced glaucoma. An absolute lower level of IOP was not defined as a very low IOP ($<$ 6 mmHg) may be beneficial if there was no associated visually disabling complications. Complete versus qualified success was considered when target IOP was achieved without or with added antiglaucoma medications.

Descriptive statistics for the comparison of both groups were performed using Pearson's chi-squared test for categorical variables and independent sample t-test for continuous variables with a significance level of $P \leq 0.05$. The two groups were compared in terms of early postoperative complications and surgical interventions, amount and percent of IOP reduction, and percentage of success or failure. The actuarial probability of failure over the follow-up length in each group was plotted using Kaplan--Meier survival analysis.

RESULTS

The study included 18 patients aged 64.0 $\pm$ 14.7 years. The

majority of the eyes (15 eyes, 83.3%) had open-angle glaucoma [Table 1]. Two thirds of eyes in each group were using three or more glaucoma medications. The mean cup-disc-area ratio was 0.92 in both groups and the average visual field mean deviation was 20.9±6.0 dB in the VISCO-TRAB group and 20.8±8.4 dB in the TRAB group ($P = 0.9$). Operative data and postoperative complications were summarized in Table 2. The glaucoma procedure was combined with cataract removal (clear-cornea phacoemulsification and in-the-bag foldable lens implantation) in six eyes in the VISCO-TRAB group and seven eyes in the TRAB group ($P = 0.7$). During the first postoperative month, four eyes required LSL in the VISCO-TRAB group compared to seven in the TRAB group ($P = 0.2$). Postoperative hypotony-related complications were reported more commonly after TRAB than after VISCO-TRAB surgery [Table 2]. Four eyes in the TRAB group required postoperative surgical interventions (anterior chamber reformation: two eyes; choroidal drainage: one eye; and conjunctival suturing for leakage: one eye) compared to one eye in the VISCO-TRAB group that required intraocular lens repositioning. The mean follow-up duration was 14.9±4.1 months in the VISCO-TRAB group and 13.7±4.5 months in the TRAB group ($P = 0.7$). Mean postoperative IOP was significantly lower in the VISCO-TRAB group after 1 week and after 3 months ($P = 0.05$) [Table 3, Figure 1]. Amount and percent of IOP reduction at the last follow-up were greater in the VISCO-TRAB group than in the TRAB group, but did not reach a statistical significance ($P = 0.4$ and 0.3, respectively). The number of eyes with an IOP of 14 mmHg or less with or without glaucoma medications at the last follow-up was comparable between the two groups (17 eyes (94.4%) in the VISCO-TRAB group and 16 eyes (88.9%) in the TRAB group, Table 4). On the other hand, 15 eyes in the VISCO-TRAB group had ≥ 30% IOP lowering compared to 13 in the TRAB group ($P = 0.4$). On the other hand, complete success of IOP control ≤ 14 mmHg without medications at the last follow-up was seen in 15 (83.3%) eyes in the VISCO-TRAB group compared to 10 (55.6%) eyes in the TRAB group. None of the eyes lost more than two lines of Snellen acuity. The cumulative probability of failure did not reveal a significant difference between both groups as shown in the Kaplan--Meier survival analysis chart (Figure 2, log rank test, $P = 0.8$)). The mean survival time for the VISCO-TRAB group was 8.1 months (standard error 1.0, 95% confidence interval 6.15 and 10.05 months) and for the TRAB group 8.26 months (standard error 1.09, 95% confidence interval 6.12 and 10.39 months).

Table 1: Preoperative parameters of eyes of subjects who underwent viscocanalostomy–trabeculectomy in the right eye and trabeculectomy in the left eye

Variable	VISCO-TRAB group N= 18		TRAB group N = 18	
	Count	%	Count	%
Glaucoma diagnosis				
Primary open-angle	13	72.2	13	72.2
Primary angle-closure	3	16.7	3	16.7
Low-tension glaucoma	1	5.6	1	5.6
Juvenile glaucoma	1	5.6	1	5.6
Preoperative IOP (mmHg)				
</= 25	10	55.6	9	50.0
> 25	8	44.4	9	50.0
Preoperative Snellen's visual acuity				
20/20: 20/40	6	33.3	5	27.8
20/50: 20/200	9	50.0	8	44.4
< 20/200	3	16.7	5	27.8
Previous glaucoma treatment				
None	1	5.6	1	5.6
Medicinal	13	72.2	14	77.8
Previous Trabeculectomy	4	22.2	3	16.7
Lens status				
Clear	8	44.4	9	50.0
Cataract	7	38.9	7	38.9
Pseudophakia	3	16.7	2	11.1

Table 2: Operative data, complications and postoperative outcomes of subjects who underwent viscocanalostomy–trabeculectomy in the right eye and trabeculectomy in the left eye

Variable	VISCO-TRAB group N= 18		TRAB group N = 18	
	Count	%	Count	%
Surgery type				
Glaucoma surgery only	12	66.7	11	61.1
Glaucoma and cat surgery	6	33.3	7	38.9
Anesthesia				
Topical	9	50.0	12	66.7
Peribulbar	8	44,4	5	27.8
General	1	5.6	1	5.6
Scleral flap closure				
2 corner sutures	0	00	4	22.2
2 corner and one limb sutures	0	00	8	44.4
2 corner and two limb sutures	14	77.8	4	22.2
More than 4 sutures	4	22.2	2	11.1
Operative complications	2	11.1	1	5.6
Laser suture lysis	4	22.2	7	38.9
Time of laser suture lysis				
During 1st 2 weeks	1	5.6	4	22.3
During 2nd 2 weeks	3	16.7	3	16.7
Postoperative complications				
Leaking bleb	0	00	2	11.1
Shallow/flat anterior chamber	2	16.7	3	16.7
Choroidal effusion	1	5.6	2	11.1
Hyphema	2	11.1	0	00
Tilted intraocular lens	1	5.6	0	00
Postoperative surgical intervention	1	5.6	4	16.7

VISCO-TRAB group denotes eyes that underwent viscocanalostomy–trabeculectomy, TRAB group denotes eyes that underwent trabeculectomy

DISCUSSION

Combined VISCO-TRAB starts as a viscocanalostomy procedure (large superficial lamellar flap, scleral lake formation, deroofing

Table 3: Mean intraocular pressure changes postoperatively in eyes of subjects who underwent viscocanalostomy-trabeculectomy in the right eye and trabeculectomy in the left eye

Variable	VISCO-TRAB group N = 18		TRAB group N = 18		*P* value
	Mean	SD	Mean	SD	
Preoperative IOP (mmHg)	26.3	9.8	25.4	9.9	0.8
IOP at first postoperative day	8.5	4.1	10.6	5.2	0.2
IOP at first postoperative week	7.2	2.9	9.8	5.4	0.04
IOP at first postoperative month	10.7	4.5	12.7	5.4	0.2
IOP at third postoperative month	10.5	3.9	13.6	5.0	0.05
IOP at last visit examination	10.8	3.5	12.7	3.7	0.1
Amount of IOP reduction (mmHg)	15.6	11.4	12.7	10.8	0.4
Percent reduction of IOP (%)	52.5	23.9	43.0	24.7	0.3
Preoperative glaucoma meds	2.7	1.2	2.8	1.2	0.8
Postoperative glaucoma meds	0.2	0.5	0.4	0.5	0.2
IOP before suture cutting (mmHg)	18.8	2.9	19.6	3.5	0.7
IOP after suture cutting (mmHg)	9.0	2.2	11.1	3.6	0.3

VISCO-TRAB group denotes eyes that underwent viscocanalostomy–trabeculectomy, TRAB group denotes eyes that underwent trabeculectomy

Table 4: Intraocular pressure and visual outcome at last visit of eyes of subjects who underwent viscocanalostomy–trabeculectomy in the right eye and trabeculectomy in the left eye

Variable	VISCO-TRAB group N = 18		TRAB group N = 18		*P* value
	Count	%	Count	%	
IOP category					0.5
≤14 mmHg	17	94.4	16	88.9	
>14 mmHg	1	5.6	2	11.1	
IOP Control ≤ 14 mmHg					0.2
Complete success	15	83.3	10	55.6	
Qualified success	2	11.1	6	33.3	
Failure	1	5.6	2	11.1	
30% lowering of IOP					0.7
≥30% drop of IOP	15	83.3	13	72.3	
<30% drop of IOP	3	16.7	5	27.7	
Visual outcome					0.4
Improved > one line	12	66.7	8	44.4	
Same (+ one line)	6	33.3	9	50.0	
Deteriorated > one line	0	00	1	5.6	

VISCO-TRAB group denotes eyes that underwent viscocanalostomy–trabeculectomy, TRAB group denotes eyes that underwent trabeculectomy

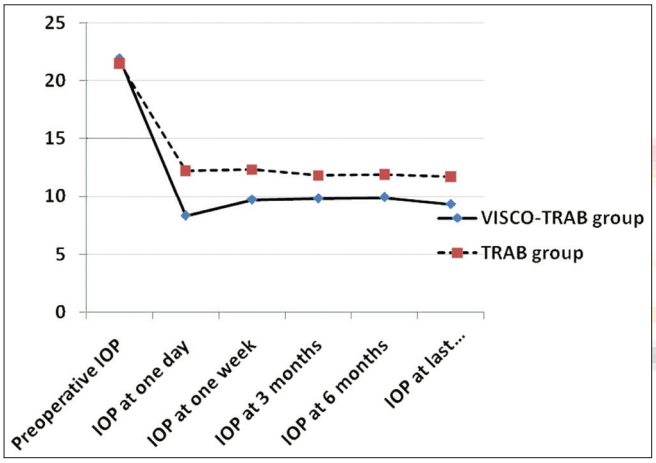

Figure 1: Comparison of intraocular pressure in eyes of subjects who underwent viscocanalostomy–trabeculectomy in the right eye and trabeculectomy in the left eye (mean follow-up = 14 months)

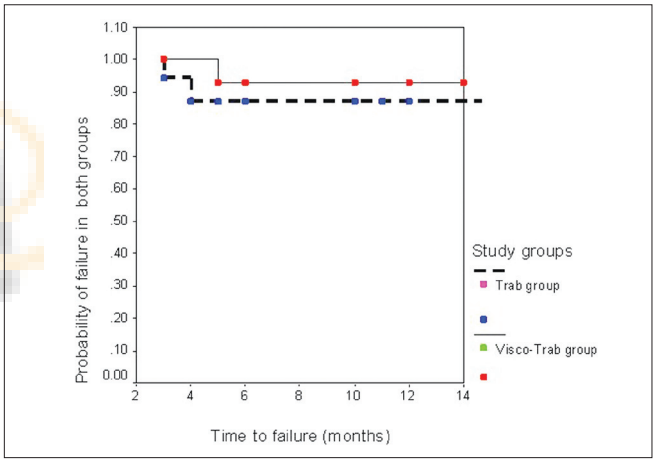

Figure 2: Kaplan –Meier survival analysis of probability of failure postoperatively in eyes of subjects who underwent viscocanalostomy–trabeculectomy in the right eye and trabeculectomy in the left eye

of SC, and viscoelastic expansion of the canal on either side) and ends up as a trabeculectomy (Mitomycin application, penetrating corneotrabeculectomy, and peripheral iridectomy), with tight closure of the lamellar flap. The rationale behind this combination is to achieve maximum IOP reduction for eyes with advanced glaucoma and to lower the early postoperative complications of both trabeculectomy and viscocanalostomy.

Surgeons familiar with trabeculectomy and nonpenetrating surgery will have no difficulty in performing VISCO-TRAB as the learning curve is not appreciable. In VISCO-TRAB, unlike viscocanalostomy, the technique is easier as dissection is not extending over the Descemet's membrane where the majority of macroperforations occur. Sanchez and associates[7] reported an iatrogenic perforation of the trabeculo-Descemet's membrane in 30% of the first 10 deep sclerectomies and in 3% of the subsequent 96 procedures. Operative complications of VISCO-TRAB in our study included choroidal exposure during dissection of second flap (one eye), and premature rupture of the Descemet's membrane before cannulation of SC (one eye).

Early postoperative complications such as anterior chamber shallowing and choroidal effusion were greater in severity after TRAB than after VISCO-TRAB. Additionally, patients required less postoperative surgical intervention in the VISCO-TRAB group (intraocular lens repositioning in one eye) than in the TRAB group (anterior chamber reformation in two eyes, choroidal drainage in one eye, and suturing a conjunctival buttonhole in one eye). In a previous study, three eyes after VISCO-TRAB required postoperative surgical intervention

compared to eight eyes after TRAB.[10] In another study on 60 eyes with advanced glaucoma that underwent trabeculectomy with mitomycin C, postoperative complication rate reached 35% of which 25% of the eyes had excessive filtration and shallow or flat AC and 15% had choroidal effusion.[11] Other studies reported a similar rate of postoperative complications after trabeculectomy with antifibrotic agents.[3,12,13] The enhanced internal filtration during the early postoperative period after VISCO-TRAB made LSL rare in the first 2 weeks after surgery despite tight closure of the lamellar scleral flap. This relatively long interval may limit excessive flow of aqueous into the subconjunctival space when LSL is performed, with subsequently lower adverse events. Morinelli and associates[14] reported that a longer time interval between surgery and LSL may result in both a lower degree of IOP reduction and a lower incidence of subsequent hypotony. In a previous study,[10] the complication rate after LSL in the VISCO-TRAB group was lower than the TRAB group both in incidence (2 of 15[13.4%] compared to 6 of 22 [27.3%]) and severity (one eye with grade 1 shallow AC compared to five eyes with grades 2 and 3 shallow AC, respectively).

The mean postoperative IOP was significantly lower in the VISCO-TRAB group than in the TRAB group ($P<0.05$) after 1 week and after 3 months. At the last follow-up, IOP was lower and more likely to be within the target range without added medications in the VISCO-TRAB group than in the TRAB group (but not statistically significant). Although filtration was titrated intraoperatively in the TRAB group, a single digit pressure reading was not achieved in many eyes early postoperatively. Early postoperative IOP reduction after VISCO-TRAB was partly attributed to improved internal flow mechanisms (dilation of SC and scleral lake formation) and partly to external filtration (many eyes had a low diffuse bleb immediately postoperatively in spite of tight flap closure). The "controlled" hypotony produced by enhancing internal filtration and limiting external filtration plays a major role in achieving a maximally low IOP during the early postoperative period without pressure spikes or severe complications related to excessive filtration. Although both types of procedures equally resulted in an IOP at last follow-up within the target range (89% in each group), complete success of achieving an IOP $\leq$ 14 mmHg without added medications was greater in the VISCO-TRAB group (83.3%) than in the TRAB group (55.6%).

Postoperatively, visual acuity was the same as preoperatively or improved by more than one line of Snellen acuity (due to optical correction, cataract surgery, or IOP reduction) for both groups. None of the eyes in either group had the "wipe-out" phenomenon after surgical treatment in this study nor in our previous report.[10] Costa and associates[15] reported that the risk of unexplained postoperative loss of the central visual field does exist but is lower than 1% and is more likely to occur in older patients with macular splitting in the preoperative visual field. In another study, Topouzis *et al.*,[16] reported no occurrences of the "wipe-out" phenomenon in their series of 21 patients end stage glaucoma after trabeculectomy with mitomycin. They concluded that this sudden, unexplained postoperative loss of central vision is, at most, a rare complication and early surgical intervention should be considered in these patients.

Combined VISCO-TRAB can be performed for all types of glaucoma regardless of the appearance of the angle. Disadvantages of this technique are that it requires a learning curve for surgeons not familiar with nonpenetrating glaucoma surgery, consumes more time than routine trabeculectomy, and there is the extra expense of viscoelastic and a special knife and cannula not routinely used with trabeculectomy. In this study, sodium hylauronate 1% was used instead of the high–molecular-weight Healon GV or Healon 5 which may have affected our results.[17] Tanito and coworkers[18] reported a comparable success rate using Healon 1% but they assumed that it may be related to the high incidence of postoperative hyphema.

In conclusion, combined VISCO-TRAB for the management of highly advanced glaucoma was efficacious in reducing IOP to a maximally low target level during the early postoperative period. Safety was indicated by the reduction the postoperative pressure spikes and the devastating complications related to excessive external filtration.

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