Effect of Early Treatment with Aqueous Suppressants on Ahmed Glaucoma Valve Implantation Outcomes

Mohammad Pakravan, MD,[1] *Shahram Salehi Rad, MD,*[1] *Shahin Yazdani, MD,*[1] *Elaham Ghahari, MD,*[1] *Mehdi Yaseri, PhD*[2]

Objective: To evaluate the effect of early aqueous suppressant treatment on Ahmed glaucoma valve (AGV) surgery outcomes.

Design: Randomized clinical trial.

Participants: Ninety-four eyes of 94 patients with refractory glaucoma.

Methods: After AGV implantation, 47 cases (group 1) received topical timolol-dorzolamide fixed-combination drops twice daily when intraocular pressure (IOP) exceeded 10 mmHg, whereas 47 controls (group 2) received conventional stepwise treatment when IOP exceeded target pressure.

Main Outcome Measures: Main outcome measures included IOP and success rate (6 mmHg $<$ IOP $<$ 15 mmHg and IOP reduction of at least 30% from baseline). Other outcome measures included best-corrected visual acuity, complications, and hypertensive phase frequency.

Results: Groups 1 and 2 were both followed up for a mean of 45$\pm$11.6 and 47.2$\pm$7.4 weeks, respectively ($P = 0.74$). Mixed model analysis revealed a significantly greater IOP reduction in group 1 at all intervals ($P<0.001$). At 1 year, the cases exhibited a significantly higher success rate (63.2% vs. 33.3%; $P = 0.008$) and reduced hypertensive phase frequency (23.4% vs. 66.0%; $P<0.001$).

Conclusions: Early aqueous suppressant treatment may improve AGV implantation outcomes in terms of IOP reduction, success rate, and hypertensive phase frequency. *Ophthalmology 2014;■:1–6 © 2014 by the American Academy of Ophthalmology.*

Glaucoma drainage devices (GDD) have been used for decades for the management of refractory glaucomas.[1] After GDD implantation, intraocular pressure (IOP) normally goes through 2 phases: the hypotensive phase that occurs immediately after surgery and lasts for at least 1 week, followed by the hypertensive phase, which usually occurs 1 to 6 weeks after surgery, when congestion of the bleb wall is intense, and can last as long as 6 months.[2–5]

The Ahmed glaucoma valve (AGV) has a 1-way valve mechanism designed to open when IOP exceeds 8 to 10 mmHg; this arrangement tends to decrease the likelihood of early postoperative hypotony. However, the hypertensive phase seems to occur more frequently with AGVs (40%–80% of cases) when compared with nonvalved implants.[6–9]

A thicker and more congested capsule surrounding the AGV plate may contribute to the increased likelihood of the hypertensive phase, which may be the result of early contact of aqueous inflammatory mediators with overlying tissues.[2] Another possibility may be higher aqueous hydrostatic pressure within the bleb, which could compress, compact, and stiffen the capsule.

We speculated that the early initiation of aqueous suppressant treatment after AGV implantation may improve treatment outcomes by reducing the levels of aqueous humor inflammatory mediators surrounding the plate and diminishing hydrostatic pressure within the capsule. Both of these effects may lead to a thinner and more delicate capsular wall, and thus, better percolation of the aqueous and lower IOP levels. The current study was designed to assess the efficiency of this hypothesis.

Methods

This prospective, randomized clinical trial included 94 eyes of 94 patients with refractory glaucoma who underwent AGV implantation from December 2010 through October 2012. The study adhered to the Declaration of Helsinki, was approved by the ethics committee (equivalent to an institutional review board) of the Ophthalmic Research Center at Shahid Beheshti University of Medical Sciences, and was registered at http://www.clinicaltrials.gov (no. NCT01814514) on March 19, 2013, according to the standards set by the International Committee of Medical Journal Editors and the World Health Organization. After providing adequate explanations about the procedure, written informed consent was obtained from all patients before enrollment.

Patients with refractory glaucoma requiring AGV implantation were included. The exclusion criteria were age younger than 18 years, mental illness or dementia, history of glaucoma implants, known allergies to glaucoma medications, and known contraindications to the use of β-blockers. Eyes with fewer than 3 months of follow-up also were excluded from the analysis, but cases in which implantation was not successful were included.

All procedures were performed with use of the same technique by 1 of 2 glaucoma specialists (M.P. and S.Y.) or by a glaucoma fellow under their direct supervision. The procedures were performed as follows: a conjunctival incision was made 4 mm posterior to the

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Table 1. Demographic Characteristics of the Study Population

Parameter	Overall	Group 1	Group 2	P Value
Age (yrs), mean ± SD	44±19	47±18	41±19	0.195*
BCVA (logMAR), mean ± SD	1.2±0.77	1.32±0.8	1.1±0.74	0193†
VCDR, mean ± SD	0.83±0.19	0.82±0.21	0.84±0.17	0.559†
IOP (mmHg), mean ± SD	31.4±9.3	30.9±9.3	31.8±9.3	0.691*
Mean glaucoma medications ± SD	3.6±0.6	3.7±0.6	3.6±0.6	0.650*
History of intraocular surgery, no. (%)				
No surgery	34 (36.2)	16 (34.0)	18 (38.3)	0.688‡
Cataract	38 (40.4)	20 (42.6)	18 (38.3)	0.674‡
Trabeculectomy	21 (22.3)	10 (21.3)	11 (23.4)	0.804‡
Vitrectomy	3 (3.2)	2 (4.3)	1 (2.1)	>0.99§
Penetrating keratoplasty	2 (2.1)	2 (4.3)	0 (0.0)	0.495§
Glaucoma type, no. (%)				0.996§
Combined mechanism	17 (18.1)	9 (19.1)	8 (17.0)	
Aphakic	17 (18.1)	8 (17.0)	9 (19.1)	
NVG	14 (14.9)	8 (17.0)	6 (12.8)	
Pseudophakic	10 (10.6)	4 (8.5)	6 (12.8)	
Developmental	8 (8.5)	3 (6.4)	5 (10.6)	
PCG	7 (7.4)	4 (8.5)	3 (6.4)	
Inflammatory	6 (6.4)	3 (6.4)	3 (6.4)	
PACG	4 (4.3)	3 (6.4)	1 (2.1)	
Post traumatic	2 (2.1)	1 (2.1)	1 (2.1)	
JOAG	2 (2.1)	1 (2.1)	1 (2.1)	
POAG	2 (2.1)	1 (2.1)	1 (2.1)	
PXG	2 (2.1)	1 (2.1)	1 (2.1)	
Steroid-induced	1 (1.1)	0 (0.0)	1 (2.1)	
Ghost cell	1 (1.1)	0 (0.0)	1 (2.1)	

BCVA = best-corrected visual acuity; IOP = intraocular pressure; JOAG = juvenile open-angle glaucoma; logMAR = logarithm of the minimum angle of resolution; NVG = neovascular glaucoma; PACG = primary angle-closure glaucoma; PCG = primary congenital glaucoma; POAG = primary open-angle glaucoma; PXG = pseudoexfoliative glaucoma; SD = standard deviation; VCDR = vertical cup-to-disc ratio.
Group 1 comprised those who received early treatment with timolol plus dorzolamide. Group 2 comprised the controls.
*Mann–Whitney *U* test.
†Based on *t* test.
‡Chi-square test.
§Fisher exact test.

limbus at the superior temporal quadrant followed by adequate dissection. The AGV was primed, and its plate was secured to the sclera 8 to 10 mm posterior to the surgical limbus using 2 interrupted 7-0 silk sutures. After trimming the tube with the bevel facing anteriorly, it was inserted into the anterior chamber through a corneoscleral tract created using a 23-guage needle. A rectangular donor scleral patch graft (4×7 mm) was fashioned and secured over the tube using 8-0 Vicryl sutures (Ethicon, Inc., Bridgewater, NJ). The conjunctiva and Tenon capsule were repaired using 10-0 nylon sutures in a running fashion. Betamethasone (4 mg) and cefazolin (50 mg) were injected subconjunctivally upon completion of the surgery.

The postoperative regimen included application of topical chloramphenicol 0.5% eye drops (Sina Darou Laboratories Co., Tehran, Iran) 4 times daily for 1 week and topical betamethasone 0.1% eye drops (Sina Darou Laboratories Co.) 6 times daily to be tapered gradually over 8 to 12 weeks depending on the degree of inflammation. Postoperative follow-up visits were scheduled on day 1 and weeks 1, 2, 3, 4, 6, 8, 12, 16, 24, and 54 after the operation and every 6 months thereafter. Considering the 30% or more reduction in IOP that can be achieved by dorzolamide hydrochloride plus timolol maleate fixed combination drops (Zilomole; Sina Darou Laboratories Co.) twice daily, and to prevent the risk of hypotony, we chose to initiate therapy when IOP reached 10 mmHg at any point during the follow-up point in group 1. After 3 months, the decision to continue or modify the treatment regimen of dorzolamide hydrochloride plus timolol maleate was made based on the target pressure. Group 2 (controls) received stepwise glaucoma treatment when IOP exceeded target pressure. The stepwise regimen included timolol maleate 0.5% (Sina Darou Laboratories Co.) twice daily, dorzolamide hydrochloride 2% (Sina Darou Laboratories Co.) twice daily, brimonidine tartrate 0.2% (Sina Darou Laboratories Co.) 3 times daily, and latanoprost 0.005% (Sina Darou Laboratories Co.) once daily.

The clinical data collected included age, sex, best-corrected visual acuity, and the type of glaucoma. The main outcome measures included IOP and success rate, which was defined as 6 mmHg < IOP < 15 mmHg and an IOP reduction of 30% or more from baseline. Because of the advanced glaucomatous damage in our patients, we considered a target pressure of 15 mmHg for all cases. Complete success was said to have been achieved when these criteria were met without medications and qualified when the same goals were met with maximum tolerated glaucoma medication. Other outcome measures included complications and the frequency of hypertensive phases (defined as an IOP increase to more than 21 mmHg in the first 3 months after surgery).

Based on our experience with the initial pilot study of 20 cases, we achieved standard deviations of 4 mmHg for IOP in both groups and estimated the required sample size to be able to detect a 3-mmHg difference in IOP with study power of 95% to be at least 47 patients in each study group. All data are represented as mean ± standard deviation, median (range), and frequency (percentage) values. To compare differences between the study groups we used the *t* test, the Mann–Whitney *U* test, the chi-square test, and the Fisher exact test. To adjust for baseline values, we used the analysis of covariance and ordinal logistic methods. To evaluate differences throughout the course of the study, we used linear and generalized mixed models. All statistical analyses were performed using SPSS software version 21.0 (IBM Corp., Armonk, NY). *P* values of less than 0.05 were considered to be statistically significant.

Results

This randomized clinical trial included 94 eyes of 94 patients with a mean age of 44±19 years; an equal number of eyes (47 cases) were assigned randomly to study groups 1 and 2 and were followed up for a mean of 45±11.6 and 47.2±7.4 weeks, respectively ($P = 0.74$). Table 1 summarizes the baseline and demographic characteristics of the study groups. No significant differences were observed between the 2 groups with regard to patient's age, best-corrected visual acuity, IOP, vertical cup-to-disc ratio, number of glaucoma medications, type of glaucoma, or history of intraocular surgeries.

Mixed-model analysis revealed that the IOP was reduced significantly from baseline values during the study period in both groups ($P<0.001$). IOP was consistently and significantly lower in group 1 at all follow-up intervals except on postoperative day 1 ($P<0.05$; Table 2; Fig 1).

Considering the timolol plus dorzolamide fixed combination as 2 drugs for generalized linear mixed-model analysis, the mean number of glaucoma medications was higher in group 1 from 2 to 12 weeks after the operation. However, the study groups were

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