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Original Article

Safety and efficacy of Ahmed glaucoma valve implantation in refractory glaucomas in Northern Indian eyes

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Abstract

Purpose: To evaluate the safety and efficacy of Ahmed glaucoma valve (AGV) implantation in refractory glaucoma in Northern Indian eyes.
Background: The success rate of trabeculectomy remains low in cases of refractory glaucoma even with the use of antifibrotics. Glaucoma drainage devices have proven to be more efficacious in reducing intraocular pressure (IOP) in these glaucomas.
Methods: Retrospective records of 55 consecutive patients who underwent AGV implantation at Dr. Shroff's Charity Eye Hospital, New Delhi, India from January 2003 to December 2012 were reviewed. Pre-operative data included age, gender, eye laterality, specific diagnosis, number of anti-glaucoma medications, number of prior incisional surgeries, visual acuity and IOP on medical treatment. Postoperative data included visual acuity and IOP on day one, 1 week, 1 month, 3 months, 6 months, 1 year and yearly thereafter, number of anti-glaucoma medications, any complication or additional surgical intervention required. Success was defined as IOP >5 and <22 mmHg with or without treatment.
Results: Mean IOP decreased from 39.71 ± 8.99 pre-operatively to 17.52 ± 5.72 mmHg at last follow-up ($p < 0.001$) and number of medications reduced from 3.27 ± 0.84 to 1.25 ± 0.88 ($p < 0.001$). Visual acuity remained within one Snellen line or improved at last follow-up in 47 cases (85.4%). The cumulative probability of success was 85.45% at 1 year and 79.63% at 3 years. The incidence of post-operative complications was 25.45%.
Conclusion: AGV implantation has proven to be safe and is effective in controlling IOP in refractory glaucoma in Northern Indian eyes.

Keywords: Refractory glaucoma, Ahmed glaucoma valve, Intraocular pressure

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Introduction

Glaucoma is one of the leading causes of blindness worldwide.[1] Refractory glaucoma is the term used to define any kind of glaucoma that does not respond to medical or conventional surgical treatment.[1–4] The most commonly performed surgical procedure for glaucoma is trabeculectomy with or without anti-fibrotic agents.[5–10] Various modifications have been tried to improve the success of trabeculectomy such as use of anti-fibrotic agents and mechanical barriers, but still the success rate remains low in cases of refractory glaucoma. Glaucoma drainage devices (GDDs) have proven to be more efficacious in reducing intraocular pressure (IOP) in refractory glaucomas.[11,12]

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In 1969, Molteno introduced the first drainage implant with a long silicone tube attached to a thin acrylic plate.[13,14] All currently available GDDs are based on the concept of the Molteno implant with various modifications such as introduction of a valve mechanism or variations in surface area of the end plate.

The Ahmed glaucoma valve® (AGV) (New World Medical Inc., Rancho Cucamonga, CA, USA) is a shunt device with a built-in Venturi valve which opens at a specific level of IOP, thus reducing the chances of hypotony in the early post-operative period.[15] The valve may act as a potential site for obstruction by inflammatory debris, especially in Asian eyes that are known to have more severe reactions.[16] The purpose of the present study is to evaluate the safety and efficacy of AGV implants in refractory glaucomas in a Northern Indian population.

Materials and methods

This is a retrospective cohort study of 55 patients with refractory glaucoma, who underwent AGV implantation at Dr. Shroff's Charity Eye Hospital, New Delhi, India from January 2003 to December 2012.

Patients of all ages and both genders with refractory glaucoma unresponsive to conventional medical and surgical therapy or significant conjunctival scarring or inflammation precluding trabeculectomy were included. Patients were excluded if they had irregular or inadequate (<3 months) follow up. Two patients were excluded because of irregular follow-up from a pool of 57 patients. The Institutional review board approval was obtained for this research. Further, written informed consent also was obtained from each participant.

Data collection

Pre-operative data were collected from patients' records including age at the time of surgery, gender, eye laterality, specific glaucoma diagnosis, number of anti-glaucoma medications used pre-operatively, number of prior incisional surgeries, visual acuity and pre-operative IOP on medical treatment. Postoperative data included visual acuity and IOP on day one, 1 month, 3 months, 6 months, 1 year and yearly thereafter, number of anti-glaucoma medications used post-operatively, any significant intra-operative or post-operative complications and any additional surgical intervention if required.

Surgical technique

The surgical procedure consisted of AGV implantation (models S2, S3, FP7, FP8) using a standardized surgical technique by a single experienced surgeon (SD). Surgery was done after obtaining informed written consent under peribulbar or general anesthesia. After applying a superior rectus bridle suture or corneal traction suture, a fornix-based conjunctival flap and tenon's capsule were dissected to allow insertion of the plate of the implant into sub-tenon's space 8 mm behind the corneal limbus. Before insertion of the plate, the valve of the implant was primed with balanced salt solution (BSS®, Alcon, Fort Worth, TX, USA). The plate was fixed to the sclera with 9–0 black nylon sutures (Ethicon®, Alcon, Fort Worth, TX, USA). The tube was shortened to the desired length with its sharp bevel facing anteriorly to allow 2–3 mm of tube in anterior chamber. An anterior chamber (AC) paracentesis wound was created at the peripheral cornea and sodium hyaluronate 1% (Healon®, Abbott Medical Optics) was injected to prevent collapse of the AC after sclerostomy was made. To prevent tube movement, a radial groove was made in the sclera at the proposed site & the edges of the groove were retracted using mild cautery. The tube of the implant entered the AC parallel to the iris plane through the sclerostomy made with a 23 gauge syringe needle. For ease of entry, the needle was bent in a Z-shaped manner. In pseudophakic patients with post-penetrating keratoplasty (post-PK) glaucoma and peripheral anterior synechiae, the tube was placed in the ciliary sulcus. Concurrent anterior or pars plana vitrectomy was performed in aphakic patients and in patients in whom pars plana insertion of tube was planned. The tube was fixed to the sclera with 9–0 black nylon (Ethicon, Ethilon) suture. The anterior part of the tube was covered with a donor scleral patch graft, which was then fixed to the sclera with 9–0 black nylon sutures. The conjunctiva was closed with 8–0 polyglactin suture (Vicryl®; Ethicon, Inc., Somerville, NJ, USA). The sodium hyaluronate in the AC was removed as much as possible through the paracentesis site. No adjunctive antimetabolite was used in any of the cases. Patients with neovascular glaucoma were treated with panretinal photocoagulation and/or intravitreal bevacizumab (Avastin®, Genentech, South San Francisco, CA, USA) before the AGV was implanted.

Postoperatively, all patients received intensive steroid, antibiotic and cycloplegic drops daily. The antibiotic drops were stopped at 2 weeks postoperatively, and steroid drops were tapered gradually over 4–8 weeks.

All the parameters studied for the postoperative evaluation were documented on each follow-up wherever possible and decisions to start antiglaucoma medications or to perform other surgeries were taken accordingly.

Success criteria

Success was defined as IOP >5 and <22 mmHg with or without anti-glaucoma treatment. Failure was defined as IOP <5 or >22 mmHg using every available glaucoma medication that the patient could topically or systemically tolerate[17] (maximal medical therapy or MMT), need for additional glaucoma surgery or loss of light perception. Results of the most recent examination were used to record the final IOP for classification as a success or failure. Preoperative IOP was recorded on the most recent visit prior to surgery. IOP was measured with a Goldmann applanation tonometer, a handheld applanation tonometer (Kowa®, Kowa Optimet Inc., Torrance, CA, or Perkins®, Clement Clarke, Columbus, OH) or a Tono-pen® (Mentor O & O, Norwell, MA).

Statistics

Statistical analysis was done using the SPSS software® (Chicago, Illinois). The Kolmogorov–Smirnov test was used to test for normality of numeric variables. For comparisons of two normally distributed numerical variables, we used paired Student's *t* tests to determine any significant changes

in various quantitative parameters preoperatively and postoperatively. The cumulative success probability was determined using the Kaplan–Meier survival analysis based on the aforementioned criteria. *P* values less than 0.05 were considered statistically significant.

Results

The baseline characteristics of the study sample are summarized in Table 1. The mean age was 41.16 ± 19.41 years (range 9–77 years). Forty-one patients (74.54%) were male and 14 (25.46%) were female. The mean follow-up period was 619 ± 384 days (range 90 days to 3 years). Before implantation, eyes had been treated with an average of 1.58 ± 0.65 ocular procedures (Table 1). Of the three eyes with neovascular glaucoma, two had proliferative diabetic retinopathy and one had central retinal vein occlusion. Three patients presented with congenital glaucoma with associated aniridia and cataractous lens in one. Twenty-three patients had undergone previous filtering surgery and 32 patients had AGV implantation as a primary procedure. The tube was positioned in AC in 39 eyes, pars plana in 2, and ciliary sulcus in 14 eyes.

Of the 55 patients, 49 (89.09%) were considered successful at the most recent follow-up as per the defined criteria (Table 2). The mean pre-operative IOP was 39.71 ± 8.99 mmHg and 74.54% patients were on three or more anti-glaucoma drugs. Post-operatively, the mean IOP and number of medications used, at different time points are described in Figs. 1 and 2, respectively. After the initial postoperative reduction in medications, the mean number of medications gradually increased over a period of time. However, at any point of time it was less than the preoperative requirement.

Of the 49 successful eyes, 95% required one or more anti-glaucoma medications and 5% were not treated postoperatively. The cumulative probability of success was 85.45% at 1 year and 79.63% at 3 years (Figs. 3 and 4).

Table 1. Characteristics of patient population studied (*n* = 55).

Age in years (mean ± SD)	41.37 ± 22.88
Gender	
Male (%)	41 (74.54)
Female (%)	14 (25.46)
Specific glaucoma diagnosis	
Post-penetrating keratoplasty glaucoma	19 (34.55%)
Glaucoma post VR surgery	8 (14.55%)
Traumatic glaucoma	6 (10.91%)
Neovascular glaucoma	3 (5.45%)
Uveitic glaucoma	3 (5.45%)
Aphakic glaucoma	3 (5.45%)
ACIOL with secondary glaucoma	3 (5.45%)
Congenital glaucoma	3 (5.45%)
Advanced POAG	3 5.45%)
Advanced CACG	2 (3.64%)
Microphthalmos	1 (1.82%)
Malignant glaucoma	1 (1.82%)
Frequency of type of previous glaucoma surgery	
Trabeculectomy ± Mitomycin C	18 (32.7%)
Trabeculotomy	3 (5.45%)
Combined cataract and trabeculectomy	2 (3.64%)
Lens status	
Phakic	20 (36.36%)
Pseudophakic	24 (43.64%)
Aphakic	11 (20%)

Of the six eyes that had failed based on IOP criteria, there was one each in neovascular, congenital, post-VR surgery and malignant group while two in the post-PK category. However, subgroups were small and asymmetrical precluding statistical comparisons. The eyes that had failed underwent a mean of 1.83 ± 0.40 prior incisional surgeries as compared to 1.55 ± 0.67 in successful eyes. However, the difference was not statistically significant ($p = 0.30$).

The mean IOP in eyes that had AGV implantation as the primary procedure and prior failed filtering surgery was 16.59 ± 6.12 and 18.82 ± 4.97 mmHg respectively. The difference although clinically significant, was not statistically significant ($p = 0.15$).

Among the failed eyes, two eyes suffered loss of light perception; one developed retinal detachment, whereas three required additional glaucoma surgery. However, the loss of light perception in both the patients was determined to be not directly related to AGV implantation.

The case of malignant glaucoma had a past history of combined phacotrabeculectomy. Following AGV implantation, the patient developed a shallow AC requiring IOL explantation and re-vitrectomy. However, during insertion of infusion cannula, the surgery was complicated with suprachoroidal hemorrhage and retinal detachment.

The patient with neovascular glaucoma was primarily a case of central retinal vein occlusion. Tube implantation was performed after failure of conventional filtering procedure. Later, this patient developed progressive proliferative vitreoretinopathy with loss of IOP control and light perception.

One patient with congenital glaucoma with aniridia and subluxated lens with a history of lens aspiration with vitrectomy underwent trabeculotomy and trabeculectomy as a primary surgery. AGV implantation was performed in view of uncontrolled IOP after failed filtering surgery in this patient. The patient subsequently required trans-scleral photoablation for the control of IOP.

A hypertensive phase (HP) was defined as a rise in IOP to >21 mm of Hg within 3 months of AGV implantation, after reduction of IOP to <22 mmHg during the first postoperative week and not caused by tube obstruction, tube retraction, or malfunctioning of the valve.[18] Resolution of the HP was defined as an IOP <22 mmHg along with (1) a reduction of the IOP by 3 mmHg or more with the same number of medications or less or (2) reduction of at least one medication with a change of IOP <3 mmHg. This phase was observed between 1 and 3 months in 15/55 (27.27%) patients in our study (Fig. 1). The peak mean IOP at 3 months postoperatively was significantly higher than that at 6 months ($P = 0.008$). There was resolution of HP in 12 (80.0%) patients in our series. No patient considered as successful, required systemic antiglaucoma medication after the HP was over. Moreover, none of our patients required secondary surgical intervention to control the HP.

Visual acuity remained stable (within one Snellen line of preoperative levels in cases wherever quantitative visual acuity measurement was possible) or improved at last follow-up in 47 cases (85.4%). Of the 8 patients, who had worse visual acuity compared with the preoperative level, two actually lost light perception, one developed retinal detachment, two had cataract progression, and one suffered graft failure whereas

Table 2. Preoperative and postoperative (last follow-up) comparisons.

	Preoperative	Postoperative	
IOP (mean ± SD mmHg)	39.71 ± 8.99	17.52 ± 5.72	$P < 0.001$
Antiglaucoma medication (mean ± SD)	3.27 ± 0.84	1.25 ± 0.88	$P < 0.001$
Visual acuity (logMAR units)	1.36 ± 0.55	1.37 ± 0.68	$P = 0.919$

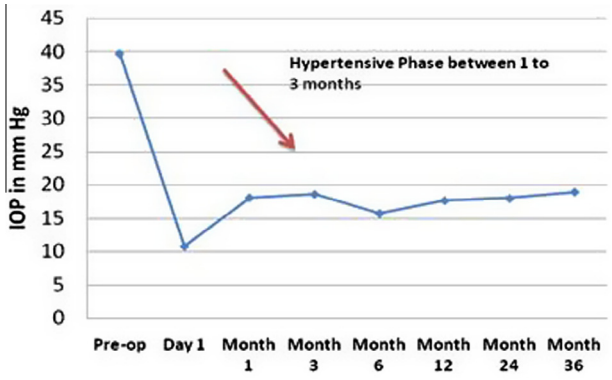

Figure 1. Mean intraocular pressure after Ahmed glaucoma valve implantation. The preoperative intraocular pressure of 39.71 ± 8.99 mmHg decreased to 10.80 ± 4.57 mmHg at 1 day, 18.6 ± 4.56 mmHg at 3 months ($N = 55$, $P < 0.001$), 15.74 ± 4.12 mmHg ($N = 55$, $P < 0.001$) at 6 months, 17.67 ± 6.45 mmHg ($N = 38$, $P < 0.001$) at 1 year and 18.94 ± 3.55 mmHg at 3 years ($N = 19$, $P < 0.001$) after surgery.

two had progression of glaucoma. The mean (±SD) visual acuity at baseline was 1.36 ± 0.55 logarithm of the minimum angle of resolution (logMAR) units and at the last follow-up was 1.37 ± 0.68 logMAR units ($P = 0.919$) (Table 2).

Complications

No major intra-operative complications occurred in any of the patients. Fourteen (25.45%) patients developed post-operative complications of which, seven (50%) required surgical intervention (Table 3). The most common post-operative complication was hypotony i.e. IOP of 5 mm of Hg or less that occurred in 6/55 (10.90%) patients. Two of these patients presented with bullous choroidal detachment with shallow AC requiring reformation.

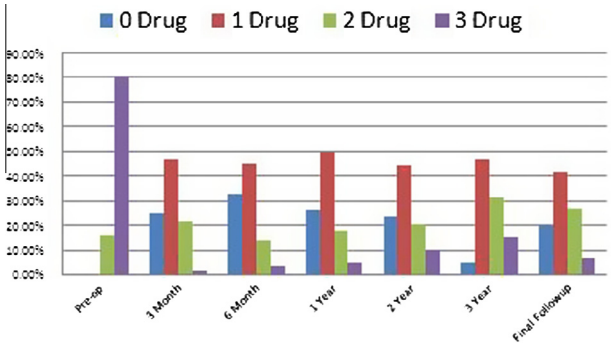

Figure 2. Number of drugs used at different time points. Number of medications was reduced from 3.27 ± 0.84 in pre-operative period to 1.01 ± 0.75 ($N = 55$, $P < 0.001$) at 3 months, 0.92 ± 0.83 ($N = 55$, $P < 0.001$) at 6 months, 1.02 ± 0.83 ($N = 38$, $P < 0.001$) at 1 year, 1.17 ± 0.92 at 2 years ($N = 29$, $P < 0.001$) and 1.57 ± 0.83 ($N = 19$, $P < 0.001$) at 3 years.

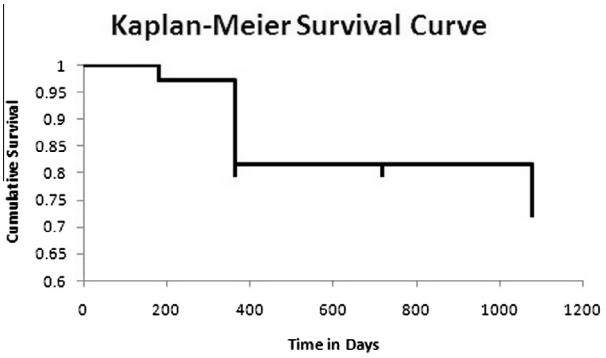

Figure 3. Kaplan–Meier life-table analysis. Cumulative probability of success following AGV implantation was 85.45% at 1 year and 79.63% at 3 years.

Two patients developed obstruction of the tube (one by a vitreous tag and another by cortical matter) that required anterior vitrectomy and cortical washout, respectively. One patient with tube extrusion and conjunctival erosion required tube repositioning and reinforcement with a scleral patch. Another patient had conjunctival erosion and exposure of sclera patch graft which responded to conservative treatment with oral doxycycline, corticosteroids, and tear substitutes.[19] Two post-PK patients had tube-corneal touch in the early postoperative period. One of these eyes subsequently developed corneal decompensation requiring repeat keratoplasty. Other complications included, one eye with corneal graft infiltrates unrelated to surgery and another with a retinal detachment. None of our patients developed motility disorder, wound leak, bleb related infections or encapsulation.

Discussion

AGV is a shunt device with a flow restriction mechanism that is used in difficult glaucomas either as a primary surgical option or after failure of conventional filtration procedures.[20–26] Most case series have reported success rates

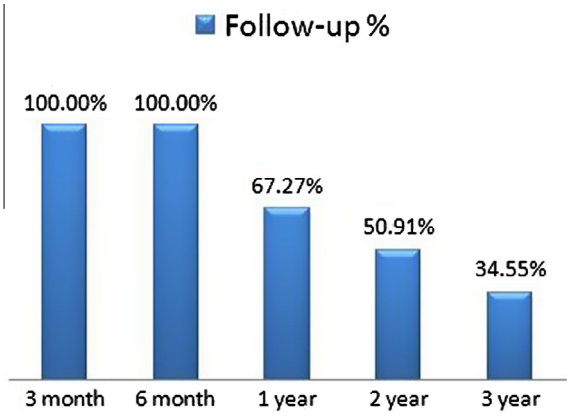

Figure 4. Follow-up percentage at different time points.

Table 3. Post-operative complications.

Complication	No. of patients	Surgical intervention
Post-operative hypotony ± choroidal effusion	6	2
Graft failure[a]	1	1
Tube obstruction	2	2
Tube erosion	1	1
Tube corneal touch[a]	2	
Phthisis bulbi	1	
Retinal detachment[b]	1	
Suprachoroidal hemorrhage[b]	1	
Conjunctival erosion	1	
Motility disorder	0	
Bleb related infections	0	
Wound leak	0	
Loss of light perception[a]	2	
Malignant Glaucoma[a]	1	1

[a] More than one complication may have occurred in an eye.
[b] Complication was unrelated to surgery.

between 67% and 94% depending on the criteria used to define success and lengths of follow-up.[18,21] Our study reported the success rate of AGV implantation to be 89.1% which is comparable to the published data.[27]

In our study, AGV implant reduced the pre-operative mean IOP of 39.71 ± 8.99 mmHg to 17.52 ± 5.72 ($p < 0.001$) and dependency on anti-glaucoma medications from 3.27 ± 0.84 pre-operatively to 1.25 ± 0.88 ($p < 0.001$) at final follow up visit which is comparable to other studies.[2,3] (Table 2).

The cumulative probability of success was 85.45% at 1 year and 79.63% at 3 years which is comparable to various published case series. A North Indian study reported a success rate of 86.91% at 12 months and 83.76% at 24 months.[2] Huang et al.[27] reported a success rate of 88% and Lima et al.[3] reported it to be 70.5%.

A HP is a frequent finding after placement of AGV.[28] In a report by Ayyala and associates, this 'hypertensive phase' (HP) occurred in 82% of the cases (70 of 85 patients).[28] Nouri-Mahdavi et al. reported the incidence of a HP to be 56.4% in their series.[18] Resolution of the HP occurred in 19 of 68 eyes (28%) in their study with available data. Panda et al. reported a HP in 80% of eyes between 1 and 3 months that was resolved with anti-glaucoma medications.[20] The incidence of a hypertensive phase with the silicone implant has been reportedly lower than with the polypropylene implant 36.4% versus 48.5%, respectively.[29] The HP (27.27%) in our study might have been minimized because of more frequent use of silicone implants and postoperative antiglaucoma medications in these eyes.

In the present study, the incidence of post-operative complications was 25.45%. Transient hypotony in the post-operative period is a common finding, more so with the non-valved implants. Valved implants open at a specific IOP level, thus having a lower chance of post-operative hypotony. The incidence of hypotony (10.90%) in our study compares favorably with other studies.[30] In our study, a total of 6 patients developed post-operative hypotony, of which 4 had spontaneous resolution. However, none of them had wound leaks as a cause.

One of the patients with post-PK glaucoma developed graft failure due to tube-corneal touch. The incidence of tube-corneal touch was much lower in our patients as compared to other studies.[2,31] The reason for this might be that most of the post-PK patients were pseudophakic with peripheral anterior synechiae, thereby prompting us to place the tube in the ciliary sulcus. This reduces the likelihood of tube-corneal touch.

Obstruction of the tube is a known complication following GDD surgery and occurred in 2 patients.[32] One of the patients, who developed obstruction of the tube due to a vitreous tag, was post-trauma and phakic with suspected inferior zonular dialysis. However, there was no vitreous in the AC at the time of implantation. On the fourth postoperative day, the vitreous tag advanced from the suspected zonular dialysis and blocked the tube. It was removed successfully by anterior vitrectomy. The other patient who developed blockade of the tube had undergone PK with ECCE/IOL 6 months prior to implantation and had no visible cortex at the time of surgery. Cortical material did appear post-operatively, which required removal to relieve the obstruction.

Tube erosion has been well reported in the literature.[33,34] A standard of care to prevent tube erosion is with the use of a patch graft. Common materials used include pericardium, sclera, fascia lata, and cornea.[35] Tube erosion occurred in one patient in our series, requiring repositioning with reinforcement. The lower incidence could be explained by the use of a scleral patch graft providing tectonic strength and protection against tube erosion.

Implant endplate size and its biomaterial have been considered to play a role in the final effect of GDDs on IOP control. Ishida et al. showed probabilities of success of 94.2% at 12 months and 82.4% at 24 months for the silicone plate group, and 83.2% at 12 months and 56. 7% at 24 months, for the polypropylene plate group.[29] In their series, Tenon's cysts that required needling or surgical excision were observed in 4.5% with silicon AGV implantation in comparison to 18.2% with polypropylene device. The polypropylene material may be the reason for the high risk of failure due to encapsulation in these cases.

We did not encounter any case of encapsulation in our study. This could possibly be explained due to less frequent use of polypropylene implants (20%) as compared to silicone AGV (80%).

Although formal motility testing was not performed, we did not encounter clinically-relevant motility disorders in any of our patients. The reason might be the placement of the implant in the superotemporal quadrant in most of our patients.[36,37]

The major limitation of our study is its retrospective design. Secondly, we had more patients in groups with post-PK glaucoma and glaucoma post-VR surgery as compared to other groups, so we could not compare the success rate of AGV implantation and risk factors for failure in various groups.

These series of patients are unique in that the patients were operated by a single surgeon, with a consistent technique. They were followed without significant secondary interventions such as needling or 5-fluorouracil injection. The results in terms of the IOP control, visual acuity and the complication rate in the series were satisfactory. The majority of the postoperative complications related to implant were resolved either spontaneously or with simple surgical procedures.

In conclusion, Ahmed glaucoma valve implantation has a good success rate in terms of IOP control and dependency over antiglaucoma medications and has low incidence of

complications. So, this surgery can be considered as a relatively safe and effective treatment modality for refractory glaucomas in Northern Indian Eyes.

Conflict of interest

The authors declared that there is no conflict of interest.

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