

Long-term outcome of low-cost glaucoma drainage device (Aurolab aqueous drainage implant) compared with Ahmed glaucoma valve

Surinder Singh Pandav,¹ Natasha Gautam Seth,² Faisal Thattaruthody,³ Manpreet Kaur,³ Madhuri Akella,³ Abhinav Vats,³ Sushmita Kaushik,³ Srishti Raj¹

¹Advanced Eye Centre, Postgraduate Institute of Medical Education and Research, Chandigarh, India

²Advanced Eye Centre, Postgraduate Institute of Medical Education and Research, Chandigarh, India

³Department of Ophthalmology, Post Graduate Institute of Medical Education and Research, Chandigarh, India

Correspondence to

Professor Surinder Singh Pandav, Advanced Eye Centre, Postgraduate Institute of Medical Education and Research, Chandigarh 160012, India; sspandav@yahoo.com

Received 21 January 2019

Revised 12 May 2019

Accepted 5 June 2019

ABSTRACT

Purpose To compare the long-term outcome of Aurolab aqueous drainage device (AADI) and Ahmed glaucoma valve (AGV).

Method Retrospective analysis of patients with refractory glaucoma who underwent AGV (AGV-FP7) and AADI (AADI Model 350) implantation. The outcome measures were intraocular pressure (IOP), requirement of antiglaucoma medications (AGMs) and re-surgery for IOP control. The postoperative complications were classified as early (≤ 3 months), intermediate (> 3 months to ≤ 1 year) or late (> 1 year).

Results 173 patients (189 eyes) underwent AGV implantation (AGV Group) while 201 patients (206 eyes) underwent AADI implantation (AADI group). The IOP in AADI group was significantly lower than AGV group at all time points till 2 years and comparable at 3 years. AADI group had significantly higher number of AGM in preoperative period and significantly lower number in postoperative period till 3 years compared with AGV group. AADI group had more hypotony-related complications but statistically insignificant ($p = 0.07$). The surgical interventions were significantly higher in AGV ($n = 18$) compared with AADI group ($n = 5$) in late postoperative period ($p = 0.01$). At 3 years, overall success was seen in 58.18% in AGV and 73.08% in AADI group ($p = 0.15$). Complete success was seen in 7.27% patients in AGV and 25.00% patients in AADI group ($p = 0.02$).

Conclusion Both AADI and AGV implant had comparable mean IOP at 3 years with lesser requirement of AGM in the AADI group. Both procedures appear to be safe with slight preponderance of hypotony-related complications in AADI group.

MANUSCRIPT

Glaucoma drainage devices (GDDs) are being increasingly used to manage patients with refractory glaucoma which require surgical intervention. They are employed more commonly as second line of management after failed glaucoma filtration surgery (GFS) that is, trabeculectomy with mitomycin C.^{1,2} More recently, they are increasingly being employed as a primary procedure in refractory glaucomas such as secondary to pars plana vitrectomy (PPV), penetrating keratoplasty, uveitis, neovascular glaucoma, etc.³ The rate of GDD implantation increased from 18% to 51%, whereas the rates of trabeculectomy decreased from 81% to 46% between 1996 and

2008, due to unpredictable wound healing and complications with trabeculectomy.³

The GDDs consist of a long tube which provides a channel for outflow of aqueous from the anterior chamber directly to equatorial plate which gets encapsulated later on and functions as a bleb.² The devices are classified as valved and non-valved devices. Ahmed glaucoma valve (AGV; New World Medical, Rancho Cucamonga, CA, USA) is a commonly employed GDD device for intraocular pressure (IOP) control. The reported success rate of AGV implant varies from 60% to 85% depending on the follow-up period. These devices suffer from the limitation of small surface area and hypertensive phase.⁴ The Baerveldt glaucoma implant (BGI; Advanced Medical Optics, Santa Ana, CA) is a commonly employed non-valved GDD. It has a large surface area which promotes diffuse bleb formation. The pooled results of ABC study showed that the Baerveldt group had lower IOP with requirement of lesser number of medications and a lower failure rate but was associated with increased number of hypotony-related complications.⁵

Aurolab aqueous drainage device (AADI; Aurolab, Madurai, India) is a newer non-valved GDD modelled on Baerveldt prototype. It became commercially available for use in India in June 2013. The major advantage of the device is its low cost (US\$50) compared with AGV implant (approximately US\$250). There are only two studies available in literature which have compared the efficacy and safety of this novel implant vis a vis the established AGV implant in adults and have demonstrated comparable outcome in the two devices.^{6,7} These studies suffer from limitation of small sample size and a short follow-up period.

Due to its low cost, AADI has a great potential to be used in developing nations in management of glaucoma. This study compares the long-term outcome of the AADI with AGV implant.

MATERIALS AND METHODS

This was a retrospective analysis of patients with refractory glaucoma, requiring surgical intervention for the management of glaucoma. They presented to the tertiary care institute from June 2013 to January 2018. The study adhered to tenets of Declaration of Helsinki. The study was approved by Institute Ethics Committee and informed consent was obtained from all the participants before surgery. The records of patients were reviewed for various



© Author(s) (or their employer(s)) 2019. No commercial re-use. See rights and permissions. Published by BMJ.

To cite: Pandav SS, Seth NG, Thattaruthody F, et al. *Br J Ophthalmol* Epub ahead of print: [please include Day Month Year]. doi:10.1136/bjophthalmol-2019-313942

parameters like demography (age, sex and laterality), diagnosis/indication of surgery, history of failed filtration surgery, visual acuity, IOP, the number of antiglaucoma medication (AGM) before surgery, lens status and type of GDD. The patients were divided into two groups: the AGV group—patients undergoing AGV (AGV-FP7) implantation and the AADI group—patients undergoing AADI (AADI Model 350) implantation.

The patients younger than 18 years, patients with no perception of light or with previous cyclodestructive procedure/previous GDDs were excluded. The postoperative visual acuity and IOP were analysed at day 1, 1 week, 1 month, 3 months, 6 months, 12 months, 18 months, 2 years, 3 years and 4 years along with requirement of AGM/ additional surgery.

Surgical technique

Localised conjunctival peritomy was done, most commonly in superotemporal quadrant. The tenon was bluntly dissected till the equator. The implant (AGV/AADI) was inserted into the subtenon space. The two adjacent muscle bellies (most commonly superior and lateral rectus) were hooked and the lateral expansions of AADI plate were fashioned beneath them. The plate was fixed to sclera around 10 mm from limbus using 5–0 Dacron suture (Polyester, Green Braided, Alcon Laboratories, Fort worth, TX, USA). The tube of AADI was occluded tightly near tube plate junction using 6–0 vicryl suture (Braided-coated polyglactin 910 violet, Ethicon, Johnson & Johnson, India). The AGV implant tube was not occluded; it was primed using balanced salt solution to check for the patency of valve. A partial thickness track was created in the sclera by 23 G needle and entry was made into anterior chamber. The tube was trimmed to required length and was fashioned in the track to anterior chamber. The exposed part of tube was covered using sclera patch graft. The conjunctival peritomy was closed with 8–0 vicryl suture (Braided-coated polyglactin 910 violet, Ethicon, Johnson & Johnson).

The patients were prescribed topical antibiotics and steroids in tapering doses for 4–6 weeks. The AGMs were continued in the postoperative period in the AADI group for 3–6 weeks, when they were gradually tapered. In AGV group, all AGMs were stopped on first postoperative day and reintroduced as and when required.

Outcome measures

The success of GDD was defined as complete success if the IOP was >5 or ≤ 21 mm Hg without requirement of AGM or if there was reduction of IOP by $\geq 20\%$ from baseline without the use of AGM, qualified success if the above-mentioned IOP criteria was met with ≤ 2 topical AGM. The failure was labelled if the IOP criteria required >3 AGM/use of systemic AGM, loss of perception of light or requirement of further surgical intervention for IOP control. The complications in the postoperative period were noted and classified as early (≤ 3 months), intermediate (>3 months to ≤ 1 year) or late (>1 year). Any episode of hypotony (≤ 5 mm Hg on a single visit) was noted. Persistent hypotony was defined as IOP ≤ 5 mm Hg on two consecutive visits after 3 months. The hypertensive phase was defined as IOP > 21 mm Hg during the first 3 months after surgery (with or without AGM) after reduction of IOP to less than 22 mm Hg during the first postoperative week and not caused by tube obstruction, retraction or valve malfunction.⁸ Prophylactic AGM was introduced in AGV group in first 2 weeks if IOP was > 12 mm Hg, to blunt the usual hypertensive phase.

Statistical analysis

The Statistical Package for the Social Sciences programme (IBM SPSS V.21.0 for windows, Chicago, IL, USA) was used for statistical analysis. Descriptive statistics were presented by mean \pm SD. The normality of the data was checked using Shapiro-Wilk test. Wilcoxon signed rank test was used to compare the baseline and final parameters within the group while Mann-Whitney U-test was employed to compute significance between baseline and final follow-up parameters between the two groups. The qualitative variables were analysed using Fisher's exact test and Pearson's χ^2 test. 'P value' of <0.05 was considered significant. Kaplan-Meier survival analysis was performed to compare times to failure.

Sample size: Since it was a retrospective analysis, sample size was not calculated. The studies published in literature has shown 50% lesser requirement of medication in AADI group compared with AGV.⁷ Going by this and assuming 80% power, the sample size was calculated to be 15 eyes in each group.⁹

RESULTS

In all, 173 patients (189 eyes) underwent AGV implantation (AGV group) while 201 patients (206 eyes) underwent AADI implantation (AADI group). All these patients completed 6-month follow-up. The baseline characteristics are highlighted in [table 1](#).

The demographic features such as age, sex, laterality were comparable in both the groups. The patients with previous history of failed GFS and cataract surgery were also comparable in both the groups ([table 1](#)). The mean follow-up was 27.41 ± 18.81 months and 24.62 ± 18.14 months in AGV and AADI groups, respectively. In all, 157 in AGV group and 151 eyes in AADI group completed 1-year follow-up. In total, 55 eyes in AGV group and 52 eyes in AADI group completed 3 years of follow-up ([table 2](#)).

The indication of surgery was comparable in both the groups except that higher number of patients with primary open-angle glaucoma and patients with post-PPV underwent AGV implantation, whereas AADI was put in higher number in patients who developed glaucoma secondary to trauma ([table 1](#)).

Visual acuity

The mean best corrected visual acuity (logarithm of the minimum angle of resolution) was better in AGV group versus AADI group at baseline (0.62 ± 0.26 vs 0.68 ± 0.22 , $p=0.03$) and at final follow-up (0.60 ± 0.27 vs 0.66 ± 0.24 , $p=0.02$). There was no significant difference in the visual acuity in the two groups at baseline and final follow-up ($p=0.25$ in both groups). Two patients in each group lost perception of light at final follow-up.

IOP and AGM

There was significant reduction in IOP and AGM at all follow-up visits compared with baseline ($p<0.01$) in both the groups ([figure 1](#)). In AGV group, there was 50.38% reduction in IOP and 53.69% reduction in AGM at 1-year follow-up and 51.21% reduction in IOP and 47.54% reduction in AGM at 3-year follow-up. In AADI group, there was 59.31% reduction in IOP and 72.57% reduction in AGM at 1 year and 57.44% reduction in IOP and 68.14% reduction in AGM at 3-year follow-up.

The IOP in AADI group was significantly lower than AGV group at 3 months, 6 months, 12 months, 18 months, 2 years and 4 years. AADI group had significantly higher number of AGM in preoperative period but it was significantly lower in postoperative period at all time points till 3 years and comparable

Table 1 Demographic profile and baseline characteristics of two groups

	AGV n (%)	AAI n (%)	P value
Number of patients	173	201	
Number of eyes	189	206	
Age	52.68±16.84	47.82±16.79	<0.01
Sex (male:female)	135:54	145:61	0.83
Laterality (right:left)	95:94	98:108	0.62
Mean cup disc ratio	0.76±0.19	0.76±0.15	0.18
Mean visual acuity (logMar)	0.62±0.26	0.68±0.22	0.03
Mean IOP	30.15±11.31	29.97±11.03	0.85
Preoperative AGM			
Mean combined AGM	4.06±1.21	4.52±0.99	<0.01
Mean topical AGM	3.12±1.09	3.38±0.85	0.02
Mean oral AGM	0.94±0.39	1.17±0.56	<0.01
Failed GFS	42	57	0.58
Lens status			
Phakic	70 (37.04)	85 (41.26)	0.41
Pseudophakic	101 (53.44)	99 (48.06)	0.31
Aphakic	18 (9.52)	22 (10.68)	0.74
Aetiology			
Secondary glaucoma			
Post-penetrating keratoplasty	18 (9.52%)	32 (15.53%)	0.09
NVG	20 (10.58%)	31 (15.05%)	0.23
Trauma	12 (6.35%)	27 (13.11%)	0.03
Post-PPV	40 (21.16%)	21 (10.19%)	<0.01
Uveitic	8 (4.23%)	16 (7.77%)	0.21
Pseudophakic glaucoma	7 (3.70%)	8 (3.88%)	1.00
ICE	6 (3.17%)	6 (2.91%)	1.00
PBK	5 (2.65%)	6 (2.91%)	1.00
Lens induced	2 (1.06%)	4 (1.94%)	0.69
Steroid	6 (3.17%)	2 (0.97%)	0.16
Malignant	1 (0.53%)	1 (0.49%)	1.00
Primary glaucoma			
POAG	44 (23.28%)	30 (14.56%)	0.03
PACG	18 (9.52%)	11 (5.34%)	0.13
Childhood glaucoma			
JOAG	1 (0.53%)	6 (2.91%)	0.12
PCG/developmental	1 (0.53%)	5 (2.43%)	0.22

AAI, aurolab aqueous drainage implant; AGM, antiglaucoma medication; AGV, Ahmed glaucoma valve; GFS, glaucoma filtration surgery; ICE, iridocorneal endothelial syndrome; IOP, intraocular pressure; JOAG, juvenile open-angle glaucoma; NVG, neovascular glaucoma; PACG, primary angle-closure glaucoma; PBK, pseudophakic bullous keratopathy; PCG, primary congenital glaucoma; POAG, primary open-angle glaucoma; PPV, pars plana vitrectomy; logMar, logarithm of the minimum angle of resolution.

at 4 years (table 2). Hypertensive phase was seen in 79 eyes (41.79%) in AGV group. Prophylactic AGM was started in 103 eyes (54.45%) in AGV group in first 2 weeks when IOP was >12 mmHg. Out of these 103 eyes, 21 eyes (20.39%) developed hypertensive phase. Hypertensive phase was seen in 58 out of 86 eyes (67.44%) in which no AGM prophylaxis was started. The early, intermediate and late complications in both the groups were comparable and are tabulated in table 3.

In all, 38 eyes in AGV group and 40 eyes in AAI group developed hypotony in the early postoperative period. In all, 15 eyes in AGV group and 24 eyes in AAI group developed serous choroidal effusion in early postoperative period. Two

Table 2 Mean intraocular pressure and antiglaucoma medication (oral+topical) requirement in both groups at baseline and during follow-up

	AGV	AAI	P value
Baseline			
Mean IOP (mm Hg) ±SD	30.15±11.31	29.96±11.03	0.85
Mean glaucoma medications±SD	4.06±1.12	4.52±0.99	<0.01
Number (N)	189	206	
Day 1			
Mean IOP (mm Hg) ±SD	8.59±7.36	18.38±13.05	<0.01
Mean Glaucoma Medications±SD	0.00	1±0.00	<0.01
Number (N)	189	206	
1 month			
Mean IOP (mm Hg) ±SD	18.57±8.08	17.96±9.27	0.19
Mean glaucoma medications±SD	0.73±0.93	2.48±1.63	<0.01
Number (N)	189	206	
3 months			
Mean IOP (mm Hg) ±SD	16.43±5.84	13.43±5.96	<0.01
Mean glaucoma medications±SD	1.55±1.14	1.01±1.24	<0.01
Number (N)	189	206	
6 months			
Mean IOP (mm Hg) ±SD	15.50±5.01	13.21±5.72	<0.01
Mean glaucoma medications±SD	1.68±1.15	1.06±1.15	<0.01
Number (N)	189	206	
12 months			
Mean IOP (mm Hg) ±SD	15.06±4.94	12.19±4.22	<0.01
Mean glaucoma medications±SD	1.88±1.27	1.24±1.47	<0.01
Number (N)	157	151	
18 months			
Mean IOP (mm Hg) ±SD	14.96±5.51	11.99±3.57	<0.01
Mean glaucoma medications±SD	2.08±1.23	1.18±1.12	<0.01
Number (N)	128	115	
2 years			
Mean IOP (mm Hg) ±SD	14.50±5.49	12.28±3.83	<0.01
Mean glaucoma medications±SD	2.19±1.30	1.24±1.10	<0.01
Number (N)	101	92	
3 years			
Mean IOP (mm Hg) ±SD	14.71±6.19	12.75±4.78	0.09
Mean glaucoma medications±SD	2.13±1.42	1.44±1.21	0.02
Number (N)	55	52	
4 years			
Mean IOP (mm Hg) ±SD	14.91±6.43	12.83±5.05	0.05
Mean glaucoma medications±SD	1.76±1.35	1.58±1.48	0.47
Number (N)	36	33	

AAI, Aurolab aqueous drainage implant; AGV, Ahmed glaucoma valve; IOP, intraocular pressure.

eyes in AAI group developed serous choroidal effusion after 3 months. The serous choroidal effusion resolved with conservative management in all the patients except one which required choroidal drainage. Two patients in AAI group developed

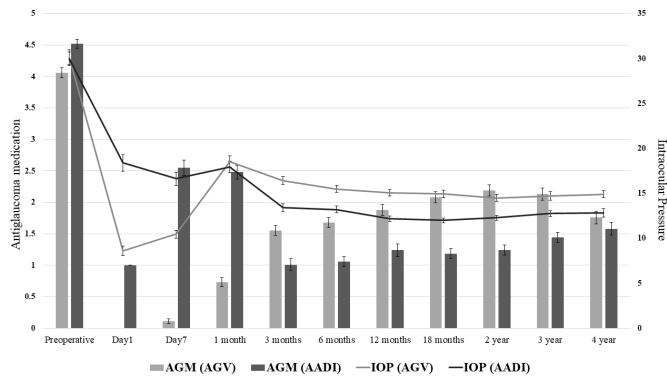


Figure 1 The trend of intraocular pressure and AGM in postoperative period in both the groups (error bars: SE of mean). AGM, antiglaucoma medication.

haemorrhagic choroidals which were drained surgically. Seven patients in AADI group developed persistent hypotony compared with one patient in AGV group ($p=0.07$). The AGV group required significantly higher number of surgical interventions for IOP control (14 diode laser cyclophotocoagulation (DLCP), 2 GDD capsule excision and two re-AGV) compared with AADI group (5 DLCP) in late postoperative period ($p=0.01$). The various other surgical interventions in both the groups were comparable and are tabulated in table 3.

At 1-year follow-up, complete success was seen in 11.46% and qualified success in 54.70% patients in AGV group (overall success 66.24%) while complete success was seen in 38.00% and qualified success in 45.33% patients (overall success 83.33%) in AADI group. The rate of overall success and complete success was significantly higher in AADI group ($p<0.001$). At 3-year follow-up, complete success was seen in 7.27% and qualified success in 50.91% (total success 58.18%) in AGV group while

Table 3 Complications and surgical interventions in both the groups in the postoperative period

Complications	AGV n (%)	AADI n (%)	P value	Surgical intervention	AGV n (%)	AADI n (%)	P value
Early							
HypHEMA	25 (13.23)	29 (14.08)	0.88	HypHEMA drainage	0 (0)	3 (1.46)	0.25
Hypotony (total)	38 (20.11)	40 (19.42)	<0.01	AC reformation	2 (1.06)	1 (0.49)	0.61
1 week	23 (12.17)	7 (3.40%)	<0.01				
1–3 months	0 (0)	9 (4.37)		Choroidal drainage	0 (0)	1 (0.49)	1.00
Serous Cchoroidals	15 (7.94)	24 (11.65)	0.24				
Conjunctival retraction	1 (0.53)	3 (1.46)	0.62	Conjunctival resuturing	0 (0)	2 (0.97)	0.50
Haemorrhagic choroidals	0 (0)	2 (0.97)	0.50	Choroidal drainage	0 (0)	2 (0.97)	0.50
Tube block	2 (1.06)	0 (0)	0.23				
Vitreous haemorrhage	2 (1.06)	1 (0.49)	0.61				
Orbital haematoma	0 (0)	1 (0.49)	1.00				
Tube cornea touch	1 (0.53)	0 (0)	0.48	Tube reposition	1 (0.53)	1 (0.49)	1.00
Tube invisible	1 (0.53)	1 (0.49)	1.00	Tube reposition	1 (0.53)	1 (0.49)	1.00
Malignant glaucoma	1 (0.53)	0 (0)	0.48	Anterior vitrectomy	1 (0.53)	0 (0)	0.48
Intermediate							
Hypotony	0 (0)	5 (2.43)	0.06	Tube ligation	0 (0)	1 (0.49)	1.00
Serous choroidals	0 (0)	2 (0.97)	0.50				
Tube exposure	0 (0)	5 (2.43)	0.06	Resuturing	0 (0)	4 (2.12)	0.12
Corneal decompensation	1 (0.53)	3 (1.46)	0.62				
Flat AC	0 (0)	1 (0.49)	1.00	AC reformation	0 (0)	1 (0.49)	1.00
Exudative RD	0 (0)	1 (0.49)	1.00	Oral propranolol	0 (0)	1 (0.49)	1.00
Tube touch to cornea	2 (1.06)	5 (2.43)	0.45	Tube reposition/tube trim	2 (1.06)	3 (1.46)	1.00
ReRD	1 (0.53)	0 (0)	0.48				
				DLCP	5 (2.65)	4 (2.12)	0.74
Late							
Hypotony	1 (0.53)	7 (3.40)	0.07	Tube ligation	0 (0)	1 (0.49)	1.00
Graft failure	1 (0.53)	1 (0.49)	1.00				
Tube retraction	1 (0.53)	1 (0.49)	1.00	Tube reposition	0 (0)	1 (0.49)	1.00
Tube cornea touch	2 (1.06)	3 (1.46)	1.00	Tube reposition/trim	2 (1.06)	2 (0.97)	1.00
Tube exposure	0 (0)	2 (0.97)	0.50	Conjunctival resuturing	0 (0)	2 (0.97)	0.50
Vitreous block	0 (0)	1 (0.49)	1.00	Anterior vitrectomy	0 (0)	1 (0.49)	1.00
Corneal decompensation	2 (1.06)	1 (0.49)	0.61	OPK	2 (1.06)	1 (0.49)	0.61
				GDD explant	1 (0.53)	0 (0)	0.48
				Intervention for IOP control	Re-AGV-2 (1.06), DLCP-12 (6.35), capsule excision:2 (1.06)	DLCP-5 (2.43)	0.01

AADI, AuroLab aqueous drainage implant; AC, anterior chamber; AGV, Ahmed glaucoma valve; DLCP, diode laser cyclophotocoagulation; GDD, glaucoma drainage devices; IOP, intraocular pressure; OPK, optical penetrating keratoplasty; RD, retinal detachment; Re-AGV, Ahmed Glaucoma valve implanted again as second procedure; ReRD, retinal re-detachment.

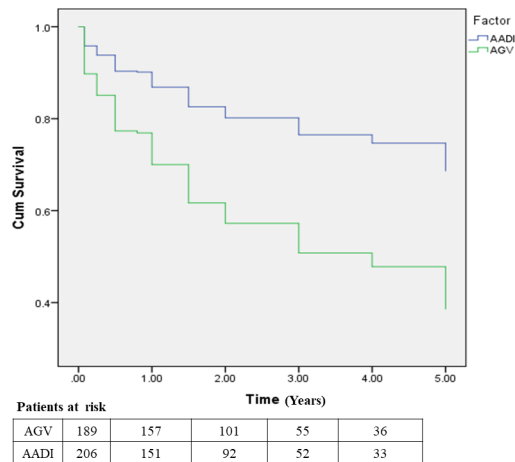


Figure 2 The Kaplan-Meier survival plots in AGV group and AADI group, the failure was taken as end point. AADI, Aurolab aqueous drainage device; AGV, Ahmed glaucoma valve.

complete success was seen in 25.00% and qualified success in 48.08% (overall success 73.08%) in AADI group. Only the rate of complete success was significantly higher in AADI group at 3 years of follow-up ($p=0.02$).

The survival probability of AGV group and AADI group at 1-year follow-up was 68.90% and 88.00%, respectively, and at 3-year follow-up was 50.40% and 77.00% respectively ($p<0.01$) (figure 2).

DISCUSSION

The management of glaucoma in developing nations poses a lot of challenges. The patients often present at advanced stage and are at increased risk of progression to blindness.^{10 11} Moreover, according to global projections, the number of people with glaucoma will increase by 74% from 2013 to 2040, with highest impact in Asia and Africa.¹² There is a need to develop comprehensive and cost-effective strategies to tackle the glaucoma burden, which is accessible and affordable to all sections of society in the developing nations. AADI is a novel, low cost indigenously built non-valved GDD, modelled on Baerveldt prototype (350 mm²).¹³ It is Conformité Européenne approved and is available in some countries of Africa and South East Asia. It has shown good results at short-term follow-up comparable to the commonly employed AGV implant, which is a valved device.^{6 7} Our study demonstrates that AADI has comparable outcomes with higher number of complete success at both 1-year and 3-years follow-up as compared with AGV implant.

The key difference between AGV implant and AADI is their mechanism of functioning. AGV implant, being a valved device, starts functioning immediately because the valve opens up when a certain pressure gradient builds up in anterior chamber. The valved GDDs provide immediate reduction of IOP and maintain the anterior chamber in early postoperative period. Its advantage is immediate control of IOP with lesser chances of hypotony-related complications.¹⁴ This immediate hypotensive phase is followed by hypertensive phase which usually starts after 3 weeks.¹⁵ The hypertensive phase was seen in 41.79% of our patients. Mahdavi *et al* have reported an incidence of hypertensive phase in 56% eyes.⁸ We found decreased incidence of hypertensive phase in the patients who were started on early aqueous suppressant therapy (20.39% vs 67.44%). It was comparable to the study by Pakravan *et al* in which early aqueous suppressant therapy following AGV implantation showed better IOP control

and lesser chances of hypertensive phase at 1-year follow-up (23.4% in treatment group vs 66% in no treatment group).¹⁶ It is suspected that since AGV implant allows immediate flow of aqueous from anterior chamber to subconjunctival equatorial plate, it also increases the exposure to inflammatory mediators which have been implicated in bleb encapsulation and long-term failure.^{17 18} Experimental data suggest that exposure to aqueous in the postoperative period leads to rapid decline in the porosity of bleb of glaucoma drainage implants.^{19 20} Since AADI is a non-valved implant, the tube is occluded at the time of implantation, with an absorbable suture; therefore, the flow of aqueous through the implant is delayed by 4–6 weeks, by that time implant is already encapsulated. The phenomenon of hypertensive phase is unusual after the non-valved implants owing to large surface area and presence of ligature which limit the flow in early postoperative period.^{8 21} The ligature degrades over a period of 4–6 weeks, a time when the capsule is formed around AADI. The downside of this is that immediate IOP reduction is not achieved in the postoperative period and the patients need antiglaucoma therapy for 4–6 weeks till the absorption of suture. The large surface area of the implant has been shown to be associated with better IOP control.^{22 23} AADI has a large surface area of 350 mm² compared with AGV implant which has a surface area of 184 mm². The IOP in AADI group was significantly lower with lesser requirement of AGM at all the time points from 3 months to 3 years. The AGV group underwent significantly higher number of surgical interventions for IOP control compared with AADI group (8.47% vs 2.43%, $p=0.01$). Five-year pooled analysis of Ahmed Baerveldt Comparison (ABC) and Ahmed Versus Baerveldt (AVB) studies also showed significantly higher requirement of number of glaucoma medications (AGV:2.3 vs BGI:1.2) and de novo glaucoma surgery in AGV group compared with Baerveldt group (AGV:19% vs BGI:6%).⁵

Irrespective of higher preoperative AGM, it was the AADI group which showed higher rate of complete success at 1-year and 3-year follow-up compared with AGV group (38.00% vs 11.46% at 1-year follow-up and 25.00% vs 7.27% at 3-year follow-up). The overall success was also better in AADI group than AGV group at 1-year follow-up (83.33% vs 66.24%) but was comparable to AGV group at 3-year follow-up (73.08 vs 58.18%). The other studies comparing the outcome of AADI and AGV implant in the first year have also shown higher rate of complete and overall success in AADI group.^{6 7} The overall success in the study by Pathak *et al* was 92.30% in AADI group versus 80.50% in AGV group at 1-year follow-up.⁷ AADI has also shown comparable outcomes with AGV implant in managing paediatric glaucoma at 1-year and 3-year follow-up.²⁴ Souza *et al* have also reported the success rate of AGV implant to be 80.00% and 49.00% at 1-year and 5-year follow-up.²⁵ Bouhenni *et al* found an overall success rates of 58.00% in Baerveldt implant at 5-year follow-up.²⁶

The visual acuity in both the groups was comparable. Two eyes in each group lost perception of light at final follow-up. Most of the complications in both the groups were transient and managed conservatively. Transient postoperative hypotony was seen in 12.17% eyes in AGV group. Lai *et al* also found the transient postoperative hypotony in 10.80% cases in AGV group.²⁷ The hypotony-related complications were higher in AADI group. Persistent hypotony was higher in AADI group (3.40%) compared with AGV group (0.53%) though this was statistically not significant. Two eyes (0.90%) in the AADI group developed haemorrhagic choroidals, which required choroidal drainage. Although statistically comparable, but AADI group developed more serous choroidal effusion (13.76%) than AGV

group (7.93%). Pathak *et al* reported serous choroidal effusions in 3.80% in AADI group and 5.60% in AGV group.⁷ Tube exposure was more common in AADI group (3.40%) while rest of the complications were comparable in the two groups. All the patients with tube exposure had scarred conjunctiva (three had pre-existing buckle, 1 each had scarring secondary to trauma and failed multiple glaucoma surgeries). So this increased incidence could be due to patient factors than implant per se. Two patients in AGV group required capsule excision compared with none in AADI group. In the pooled analysis by Christakis *et al*, AGV implant had a higher rate of bleb encapsulation (AGV 60%, BGI 27%; $p < 0.001$), whereas the Baerveldt group had higher rate of hypotony-related complications (AGV 4%, BGI 13%; $p < 0.05$).⁵

The survival probability was significantly higher for AADI group at all the time points. To summarise, AADI implant showed a higher rate of complete success at 1 and 3 years of follow-up with requirement of fewer AGM and less frequent surgical interventions for IOP control than AGV implant. The hypotony-related complications were higher in AADI group (though statistically insignificant). AADI is a low-cost GDD which is equally efficacious alternative to the commonly used AGV implant as a management option to deal with refractory glaucoma.

Contributors SSP: Concept and design of work, critical revision of content, final approval of version to be published, accountable for all aspects of work in ensuring questions related to accuracy or integrity of any part of work are appropriately investigated and resolved. NGS: Data acquisition, analysis, preparation of manuscript. FT and MK: Data acquisition, preparation of manuscript. MA and AV: Data acquisition and interpretation. SK and SR: Revision of manuscript for important intellectual content.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.

REFERENCES

- Lim KS, Allan BDS, Lloyd AW, *et al*. Glaucoma drainage devices; past, present, and future. *British Journal of Ophthalmology* 1998;82:1083–9.
- Minckler DS, Francis BA, Hodapp EA, *et al*. Aqueous shunts in glaucoma: a report by the American Academy of ophthalmology. *Ophthalmology* 2008;115:1089–98.
- Desai MA, Gedde SJ, Feuer WJ, *et al*. Practice preferences for glaucoma surgery: a survey of the American glaucoma society in 2008. *Ophthalmic Surg Lasers Imaging* 2011;42:202–8.
- Riva I, Roberti G, Katsanos A, *et al*. A review of the Ahmed glaucoma valve implant and comparison with other surgical operations. *Advances in Therapy* 2017;34:834–47.
- Christakis PG, Zhang D, Budenz DL, *et al*. Five-year pooled data analysis of the Ahmed Baerveldt comparison study and the Ahmed versus Baerveldt study. *American Journal of Ophthalmology* 2017;176:118–26.
- Rathi SG, Seth NG, Kaur S, *et al*. A prospective randomized controlled study of Aurolab aqueous drainage implant versus Ahmed glaucoma valve in refractory glaucoma: a pilot study. *Indian J Ophthalmol* 2018;66:1580–5.
- Ray P V, Rao DP. Surgical outcomes of a new affordable non-valved glaucoma drainage device and Ahmed glaucoma valve: comparison in the first year. *Br J Ophthalmol* 2018.
- Nouri-Mahdavi K, Caprioli J. Evaluation of the hypertensive phase after insertion of the Ahmed glaucoma valve. *American Journal of Ophthalmology* 2003;136:1001–8.
- Raj S, Jurangal A, Gupta G, *et al*. Comparison of short-term outcomes of Aurolab aqueous drainage implant with Ahmed glaucoma valve in Post-Penetrating keratoplasty glaucoma; a retrospective follow-up study at a tertiary care center. *Ophthalmology Glaucoma* 2019.
- Omoti AE, Osahon AI, Waziri-Erameh MJM. Pattern of presentation of primary open-angle glaucoma in Benin City, Nigeria. *Trop Doct* 2006;36:97–100.
- Chen PP. Risk and risk factors for blindness from glaucoma. *Current Opinion in Ophthalmology* 2004;15:107–11.
- Tham YC, Li X, Wong TY, *et al*. Global prevalence of glaucoma and projections of glaucoma burden through 2040: a systematic review and meta-analysis. *Ophthalmology* 2014;121:2081–90.
- Kaushik S, Kataria P, Raj S, *et al*. Safety and efficacy of a low-cost glaucoma drainage device for refractory childhood glaucoma. *British Journal of Ophthalmology* 2017;101:1623–7.
- Coleman AL, Hill R, Wilson MROY, *et al*. Initial clinical experience with the Ahmed glaucoma valve implant. *American Journal of Ophthalmology* 1995;120:23–31.
- Molteno TE, Dempster AG. Methods of controlling bleb fibrosis around drainage implants. In: Mills KB, ed. *Fourth International symposium of the Northern eye Institute*. 1st edn. Manchester, UK: Pergamon Press, 1988: 192–211.
- Pakravan M, Rad SS, Yazdani S, *et al*. Effect of early treatment with aqueous suppressants on Ahmed glaucoma valve implantation outcomes. *Ophthalmology* 2014;121:1693–8.
- Molteno AC, Fucik M, Dempster AG, *et al*. "Otago Glaucoma Surgery Outcome Study: factors controlling capsule fibrosis around Molteno implants with histopathological correlation,". *Ophthalmology* 2003;110:2198–206.
- Choritz L, Koynov K, Renieri G, *et al*. Surface topographies of glaucoma drainage devices and their influence on human tenon fibroblast adhesion. *Invest. Ophthalmol. Vis. Sci.* 2010;51:4047–53.
- Pandav SS, Ross CM, Thattarathody F, *et al*. Porosity of bleb capsule declines rapidly with fluid challenge. *J Curr Glaucoma Pract* 2016;10:91–6.
- Prata JA, Santos RC, Labree L, *et al*. Surface area of glaucoma implants and perfusion flow rates in rabbit eyes. *J Glaucoma* 1995;4:274–280–80.
- Siegner SW, Netland PA, Urban RC, *et al*. Clinical experience with the Baerveldt glaucoma drainage implant. *Ophthalmology* 1995;102:1298–307.
- Heuer DK, Lloyd MA, Abrams DA, *et al*. Which is better? one or two? A randomized clinical trial of single-plate versus double-plate Molteno implantation for glaucomas in aphakia and pseudophakia. *Ophthalmology* 1992;99:1512–9.
- Prata JA, Mérmoud A, LaBree L, *et al*. In vitro and in vivo flow characteristics of glaucoma drainage implants. *Ophthalmology* 1995;102:894–904.
- Senthil S, Gollakota S, Ali MH, *et al*. Comparison of the new low-cost Nonvalved glaucoma drainage device with Ahmed glaucoma valve in refractory pediatric glaucoma in Indian eyes. *Ophthalmology Glaucoma* 2018;1:167–74.
- Souza C, Tran DH, Loman J, *et al*. Long-term outcomes of Ahmed glaucoma valve implantation in refractory glaucomas. *American Journal of Ophthalmology* 2007;144:893–900.
- Bouhenni R, Krasniqi M, Munire J, *et al*. Long-term outcomes of Baerveldt glaucoma implant shunts as a primary versus secondary procedure. *J Glaucoma* 2018;27:1169–74.
- Lai JSM, Poon AS, Chua JK. Efficacy and safety of the Ahmed glaucoma valve implant in Chinese eyes with complicated glaucoma. *Br J Ophthalmol* 2000;84:718–21.