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Comparison of the New Low-Cost Nonvalved Glaucoma Drainage Device with Ahmed Glaucoma Valve in Refractory Pediatric Glaucoma in Indian Eyes

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Purpose: To compare outcomes of a nonvalved glaucoma drainage device (the Aurolab aqueous drainage device [AADI] with a valved glaucoma drainage device (the Ahmed glaucoma valve [AGV]) in refractory pediatric glaucoma.

Design: Retrospective interventional case series.

Participants: One hundred sixteen eyes of 97 children with refractory pediatric glaucoma.

Methods: Children (≤16 years) treated with drainage implants from January 2007 through December 2016 with a minimum follow-up of 6 months (operated by a single surgeon) were included. Success was defined as intraocular pressure (IOP) ≥6 mmHg or ≤21 mmHg (complete without antiglaucoma medications [AGMs] and qualified with AGM); repeat glaucoma surgery or loss of light perception was failure.

Main Outcome Measures: Comparison of success rates and complications with AADI (350 mm^2) and silicone AGV (models FP7 [182-mm^2 surface area] and FP8 [102-mm^2 surface area]) implantation.

Results: Outcomes of 116 eyes of 97 children (AADI, 36 eyes; AGV, 85 eyes; FP7, n = 14; FP8, n = 72) were analyzed. Median follow-up for AADI was 16.8 months (interquartile range [IQR], 11.7−24.5 months) and for AGV was 27 months (IQR, 15.3−52.3 months). Preoperative parameters (age, IOP, number of AGMs) were similar in both groups except number of previous nonglaucoma surgeries, which were significantly more in AADI ($P = 0.05$). Qualified success was similar ($P = 0.81$) in both groups, 91% and 88% at 1 year and 81% and 84% at 3 years with AADI and AGV, respectively. With AADI, the complete success was significantly more (41.8% vs.13.7%; $P < 0.005$). The postoperative mean IOP (12.6±5.5 mmHg vs. 17.6±6.8 mmHg; $P = 0.001$), median number of AGMs (1 [IQR, 0−2] vs. 2 [IQR, 1−3]; $P < 0.001$), and hypertensive phase (16.5% [n = 7] vs. 40% [n = 34]; $P = 0.02$) were significantly less in AADI compared with AGV. Transient complications (AADI, 30.5% [n = 11/36] vs. AGV, 21.1% [n = 18/85]; $P = 0.26$), sight-threatening complications (AADI, 13.9% [n = 5/36) vs. AGV, 7% [n = 6/85]; $P = 0.22$), and complications needing intervention (AADI, 19.4% [n = 7/36] vs. AGV, 14.1% [n = 12/85]; $P = 0.46$) were similar in both groups.

Conclusions: In refractory pediatric glaucoma, both AGV and AADI showed similar qualified success and complication rates at 1 and 3 years. However, the AADI showed greater complete success, better IOP control, less need for AGM, and lesser incidence of an hypertensive phase. *Ophthalmology Glaucoma 2018;1:167-174 © 2018 by the American Academy of Ophthalmology*

Managing childhood glaucoma is a challenge and surgery is the mainstay of treatment.[1] In southern India, the prevalence of primary congenital glaucoma is high (1 in 3300 live births). Combined trabeculotomy and trabeculectomy is the procedure of choice in the management of primary congenital glaucoma and also for most glaucomas associated with ocular anomalies.[2,3]

Glaucoma surgery in children has higher risk of failure and a greater complication rate compared with surgery in adult eyes.[4] Although the surgical success is as high as 85% in the first year of life with combined trabeculotomy and trabeculectomy, success decreases with time to almost 58% by 6 years of age.[5] Added to this, delayed presentation and severe disease phenotype results in lower long-term success rates for primary surgery in certain types of pediatric glaucoma.[6,7]

Glaucoma drainage devices are indicated in refractory glaucomas with failed filtering surgery or as a primary procedure in certain complicated secondary glaucomas. The most commonly used glaucoma drainage devices worldwide are the flow-restricted Ahmed glaucoma valve (AGV) implant and the non−flow-restricted Baerveldt implant. The use of implants in developing countries is restricted by the high cost of these devices and their availability. The Baerveldt implant is not available in India; however, Aurolab (Madurai, India) has designed a low-cost non−flow-restricted device

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similar to the Baerveldt implant known as the Aurolab aqueous drainage device (AADI) available in India since 2014.

The reported success rates of the AGV in various types of childhood glaucoma range from 60% to 90% at 1 year and 30% to 50% at 5 years,[8,9] and with the Baerveldt implant, these are 80% to 90% at 1 year and 50% to 60% at 5 years.[10,11] Very few studies have compared the outcomes of flow-restricted and non−flow-restricted implants in pediatric glaucoma.[12,13] Those that have are limited further by small sample sizes, and there are no reports comparing the AGV with the newly available AADI implant. We aimed to examine the surgical outcomes and complications of AGV and AADI implants in the management of refractory childhood glaucomas.

Methods

A retrospective review of the records of consecutive children (age <16 years) who underwent either AGV or AADI implantation from January 2007 through December 2016 with a minimum follow-up of 6 months was performed. Figure 1 shows a flow chart with details of the number of patients and eyes included in the study. The institutional review board of L. V. Prasad Eye Institute approved the study. Informed consent was obtained, and the study adhered to the tenets of the Declaration of Helsinki. All children had medically uncontrolled glaucoma and many had undergone previous failed filtering surgeries, other nonglaucoma intraocular surgeries, or both. Primary glaucoma included children with primary congenital glaucoma, infantile glaucoma, and juvenile open-angle glaucoma, and secondary glaucoma included children with secondary developmental or acquired glaucomas.

Demographic and preoperative data included age at the time of surgery, previous surgical procedures, number and type of glaucoma medications, intraocular pressure (IOP), and visual acuity (VA). Intraocular pressure was measured with Perkin's applanation tonometer within 5 minutes of induction of general anesthesia to minimize the effect of anesthesia on IOP (the inhalational anesthetic Sevoflurane [Baxter India Private Limited, Waulj, Aurangabad] was used) or with Goldmann's applanation tonometer in the clinic depending on the child's age. Visual acuity was measured by fixing and following light and Teller acuity charts whenever possible for nonverbal children and using Lea symbols, Kay pictures, or the logarithm of the minimum angle of resolution (logMAR) chart for verbal children.

Surgical Procedures

All procedures were performed by a single surgeon (S.S.). The choice of the device was based on the diagnosis, severity of glaucoma, size of the eyeball, time required or allowed for IOP control, and commitment to postoperative follow-up. We implanted the AGV in eyes that needed immediate IOP control and in children for whom frequent follow-up was not possible. Most AGV implants (New World Medical, Inc., Rancho Cucamonga, CA) used were model FP8 (102-mm^2 surface area) and the FP7 (184-mm^2 surface area) in children older than 10 to 12 years. The AADI (Aurolabs, Madurai, India) is available in a single size of 350 mm^2; hence, the single size was used for all AADI cases. In India, the AGV implant is available at a cost of $350 US dollars and the AADI is available at a cost of $75 US dollars. The surgical

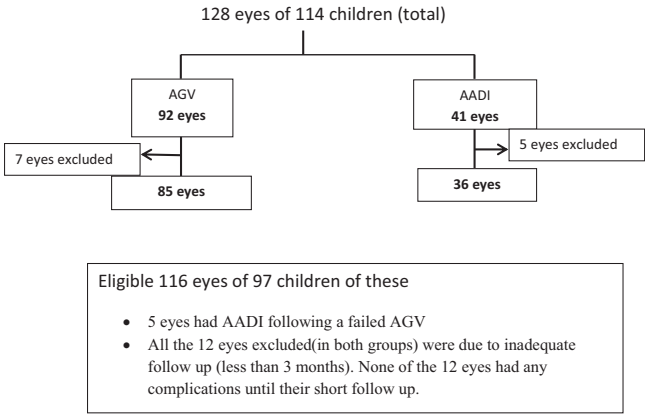

Figure 1. Flowchart showing the details of patient inclusion and exclusion. AADI = Aurolab aqueous drainage device; AGV = Ahmed glaucoma valve.

technique was similar for both the implants except for a few steps. We preferred the superotemporal quadrant for implantation, unless scarred as a result of previous surgeries. Surgical technique included a corneal traction suture and a 6- to 7-mm limbal-based conjunctival incision placed 6 mm behind the limbus. Posterior dissection between the recti muscles was carried out to create a sub-Tenon pocket for implant placement. The implant was primed, and the plate secured to the sclera with 2 10-0 polypropelene sutures (Ethicon, Johnson & Johnson, Delhi, India) 8 mm behind the limbus. A bevel-up tube of adequate length was trimmed and inserted into the anterior chamber and sulcus through a 3- to 4-mm scleral tunnel made with a 24-gauge needle. The tube was anchored in place with 10-0 nylon sutures and was covered with a scleral or corneal patch graft with fibrin glue and supplemented with 10-0 nylon sutures. The conjunctival closure was performed with 8-0 polyglactin sutures (Ethicon) in a continuous fashion, ensuring watertight closure. A subconjunctival injection of dexamethasone and lidocaine, 0.1 ml each, was injected at the conclusion of the surgery. The surgical steps that were different for the AADI were as follows: identification and isolation of the adjacent rectus muscles in the chosen quadrant and placing the plate under the muscles before anchoring the implant to the sclera using 10-0 Prolene sutures. Complete flow restriction was achieved by ligating the tube with 6-0 Vicryl sutures. Two ligatures were used in all the eyes.

Postoperative Regimen

The postoperative regimen included topical antibiotics and cycloplegics for 1 to 2 weeks and topical steroids in tapering doses over 2 months. Additionally, aqueous suppressants were continued for children with AADIs in the early postoperative period until dissolution of the ligature (approximately 5−6 weeks), and aqueous suppressants were started in children with AGV implants when a hypertensive phase (HP) was detected. Topical steroids and cycloplegics were stepped up and continued in AADI eyes after the dissolution of ligature and slowly tapered over 2 to 3 months. The children were examined on day 1, week 1, week 3 or 4, every month for 3 months, and every 3 to 4 months thereafter. Additional visits were needed in case of any postoperative complication. Apart from clinical examination, B-scan ultrasonography was an important part of postoperative follow-up to assess posterior segment complications and the bleb characteristics in young children.

Outcome Measures

Primary outcome measures were IOP control and requirement and number of antiglaucoma medications (AGMs). The secondary outcome measures were VA, presence or absence of an HP, and postoperative complications. Complete success was defined as IOP of 6 mmHg or more and 21 mmHg or less without AGMs and qualified success was defined as IOP of 6 mmHg or more and 21 mmHg or less with AGMs. Eyes requiring surgical intervention for IOP control or those with vision-threatening complications with loss of light perception were considered failures. An HP was defined as IOP of more than 21 mmHg after an initial low or normal IOP with cystic and tense bleb in the absence of a tube block. Resolution of the HP was defined as IOP of 21 mmHg or less and reduction in the number of AGMs started during the HP with a less-tense bleb. Hypotony was defined as IOP of less than 6 mmHg recorded at least on 2 consecutive postoperative visits 1 week apart.

Statistical Analysis

Descriptive statistics included means and standard deviations for parametric variables and medians and interquartile ranges (IQRs) for nonparametric variables. The chi-square test was used to compare the proportions between the 2 groups. Kaplan-Meier analysis was used to assess cumulative probability of success and the chi-square test was used to compare the survival between the 2 groups. In this study, 1 eye of 80 children and both eyes of 17 children were included. To account for intereye correlation, we used a mixed-effects model to compare the preoperative and postoperative characteristics in the AADI versus the AGV groups and in the FP7 model versus FP8 model groups. A P value of 0.05 or less was considered statistically significant. Statistical analyses were performed using R software (version 3.3.2) and e1071 package (Vienna, Austria).

Results

Demographic Features

A total of 116 eyes of 97 patients met the eligibility criteria, of which 36 eyes of 31 patients received the AADI and 85 eyes of 73 patients received the AGV implant. Two eyes in the AGV group and 5 eyes in the AADI group had undergone a previously failed AGV implantation.

The baseline characteristics and demographic details for both the groups are summarized in Table 1. The median age of the child at drainage device implantation was similar in both groups ($P = 0.74$): 4 years for the AGV group and 4.5 years for the AADI group. The median number of glaucoma surgeries before tube implantation were similar in both the groups. Twenty-six eyes (30%) in the AGV group and 9 eyes (25%) in the AADI group did not undergo any kind of filtering surgery before receiving a glaucoma implant. No significant difference was noted in baseline characteristics between the 2 groups; however, the number of other intraocular surgeries (nonglaucoma surgery) was significantly more ($P = 0.05$) and the number of preoperative AGMs were significantly more ($P = 0.05$) in the AADI group. The details of diagnosis for which children underwent implant surgery and the type of GDD used are given in Table 2, and details of previous nonglaucoma intraocular surgeries are given in Table 3.

Among the eyes that received an AGV, the FP7 implant was used in 14 eyes, and the remaining 72 eyes received the FP8 implant. Age at surgery ($P < 0.001$) and mean preoperative IOP ($P = 0.02$) were significantly higher in the FP7 group. The postoperative IOP and number of AGMs were similar in eyes with the FP7 and FP8 implants (Table 4). The AADI was available only after 2014, resulting in a significantly shorter follow-up of 16.8 months (IQR, 11.7−24.5 months) compared with the AGV group (median follow-up, 27 months; IQR, 15.3−52.3 months; $P < 0.05$).

Intraocular Pressure Reduction

Mean preoperative IOP in the AADI group was 34.6±8.2 mmHg and in the AGV group was 31.7±7.7 mmHg ($P = 0.19$). One eye in the AGV group was excluded for preoperative IOP assessment because the IOP was measured digitally. The number of eyes that were excluded at the last follow-up from IOP analysis (because of digital IOP measurement) were 3 in the AADI group and 4 in the AGV group; however, all 7 eyes showed digitally normal IOP and no complications. Mean IOP at last follow-up in the AADI group was 12.6±5.5 mmHg, significantly lower compared with the mean of 17.6±6.8mmHg in the AGV group ($P < 0.001$).

Medical Therapy

The median number of preoperative AGMs was higher in the AADI group ($P = 0.05$). Table 1 shows the number of glaucoma medications in both groups at baseline and at last follow-up. Patients in the AADI group required significantly fewer medications (median, 1; IQR, 0−2) compared with the AGV group (median, 2; IQR, 1−3; $P \leq 0.001$) after implant surgery. After surgery, 17 of 36 eyes (47%) in the AADI group did not require any AGMs, whereas only 10 of 85 eyes (11%) in the AGV group demonstrated IOP control without medications. Hence, the number of eyes demonstrating IOP control without AGM were significantly more in the AADI group ($P < 0.001$).

Treatment Outcomes: Survival Analysis

The cumulative probability of qualified success was similar for both the groups, which was 91.6% (95% confidence interval [CI], 83%−100%) for the AADI group at 12 months and 81% at 36 months, and 88.1% (95% CI, 81%−95.7%) for the AGV group at 12 months ($P = 0.9$) and 85% at 36 months (Fig 2A). The rates of complete success were low in both the groups but were significantly higher ($P < 0.005$) in the AADI group with 41.8% (95% CI, 23.7%−73.8%) compared with the AGV group at 13.7% (95% CI, 7.6%−24.5%; Fig 2B).

The most common cause for failure in the AGV group was high IOP, and 7 eyes underwent repeat glaucoma surgery for IOP control. Only 1 eye in the AADI group showed failure because of high IOP. Failure because of sight-threatening complications (suprachoroidal hemorrhage, retinal detachment, endophthalmitis, hypotony causing cataract) occurred in 5 eyes (13.8%) in the AADI group and in 6 eyes (7%) in the AGV group. The eye with retinal detachment in the AADI group was a redetachment in an eye with Stickler's syndrome.

Three of 85 eyes (3.5%) in the AGV group and 8 of 36 eyes (22.2%) in the AADI group had undergone prior transscleral cyclophotocoagulation plus endocyclophotocoagulation. We excluded eyes with prior cyclophotocoagulation and reanalyzed the survival probability; the complete success was 35% in the AADI group and 7% in the AGV group ($P < 0.001$). Previous AGV

Table 1. Showing the Demographic, Preoperative, and Postoperative Characteristics in the Aurolab Aqueous Drainage Device and Ahmed Glaucoma Valve Groups

Parameter	Aurolab Aqueous Drainage Device (n = 36)	Ahmed Glaucoma Valve (n = 85)	P Value
Preoperative parameters			
Age (yrs), median (IQR)	4.5 (1.5–9)	4 (2–11)	0.74
Gender (male:female)	25:11	50:35	
Eyes (right:left)	20:16	45:40	
Preoperative visual acuity (logMAR), median (IQR)	1.1 (0.8–1.4)*	1.15 (0.75–1.6)*	0.97
Preoperative IOP (mmHg), mean ± SD	34.5±8.23	31.7±7.6	0.19
No. of other intraocular surgeries, median (IQR)	2 (1–2.5)*	1 (1–2)*	**0.05**
Previous glaucoma procedures, median (IQR)	1 (0.5–1)*	1 (0–2)*	0.71
Preoperative AGM, median (IQR)	4 (3–5)*	3.5 (3–4)*	**0.05**
Follow-up (mos), median (IQR)	16.8 (11.7–24.5)*	27 (15.3–52.3)*	**<0.05**
Postoperative parameters			
Postoperative IOP (mmHg), mean ± SD	12.6±5.5	17.6±6.8	**<0.001**
VA at last follow-up (logMAR), median (IQR)	1.4 (1–1.85)*	1.4 (0.8–2.1)*	0.76
Postoperative AGMs, median (IQR)	1 (0–2)*	2 (1–3)*	**<0.001**
No. of eyes without AGMs	17/36	10/85	**<0.001**
% (95% CI)	47 (31–62)	11 (6–20)	
No. of eyes in hypertensive phase	6/36	34/85	**0.02**
% (95% CI)	16 (7–31)	40 (30–50)	

AADI = Aurolab aqueous drainage device; AGM = antiglaucoma medication; AGV = Ahmed glaucoma valve; CI = confidence interval; IOP = intraocular pressure; IQR = interquartile range; logMAR = logarithm of minimum angle of resolution; SD = standard deviation; VA = visual acuity.
Boldface indicates statistically significant values.
*Median (IQR).

implantation in 5 of 36 eyes in the AADI group and in 2 of 85 eyes in the AGV group could be a confounder. We excluded these 7 eyes and reanalyzed the data. Even on repeat analysis, the IOP control and the survival probabilities were better with the AADI (27% in the AADI group and 7% in the AGV group; $P = 0.002$).

Hypertensive Phase

In the AADI group, 7 of 36 eyes (16.5%) demonstrated an HP, which was significantly lower compared with 34 of 85 eyes (40%) in the AGV group ($P = 0.02$). The mean IOP after resolution of HP in the AADI group was 16.2±1.3 mmHg and required a median of 2 (IQR, 1–2) AGMs to maintain the IOP. In those patients who did not experience an HP, the mean IOP was 11.5±5.6 mmHg, requiring fewer AGMs (median, 0; IQR, 0–2). In AGV group, the mean IOP after resolution of HP was 18.1±5 mmHg, requiring a median of 2 (IQR, 2–3) AGMs at last follow-up, and was 17.2±7.5mmHg, requiring a median of 2 (IQR, 1–2) AGMs, in patients who did not experience an HP. In both groups, the mean IOP at the final visit in patients who experienced an HP was slightly higher, but not statistically significant, compared with those who did not experience an HP, but the number of glaucoma medications required at the final visit was higher in eyes that experienced an HP. The HP was short lived and resolved in all the eyes in the AADI group, and in the AGV group, the HP resolved in 30 eyes (88.2%) with the use of aqueous suppressants; 4 eyes (11.8%) in the AGV group with unresolved HP required additional glaucoma surgery to control the IOP.

Visual Acuity

Both groups showed an overall similar decrease in VA after implant surgery ($P = 0.76$). The mean VA decreased from 1.17±0.46 logMAR to 1.3±0.52 logMAR in the AADI group and

Table 2. Indications for Surgery in Both the Ahmed Glaucoma Valve and Aurolab Aqueous Drainage Device Groups

Indications for Surgery	Aurolab Aqueous Drainage Device (n = 36)	Ahmed Glaucoma Valve (n = 85)	Total (n = 121)
Congenital glaucoma	18 (50%; 33–67)	35 (41%; 30.6–52.4)	53
Secondary glaucoma	18 (50%; 33–67)	50 (59%; 47.6–69.4)	68
Various causes of secondary glaucomas			
Aniridia	0	7	7
Axenfeld-Rieger syndrome	0	1	1
Anterior segment dysgenesis	1	0	1
Glaucoma in aphakia	3	12	15
Glaucoma in pseudophakia	4	12	16
After keratoplasty	0	4	4
Steroid-induced glaucoma	0	3	3
After vitreoretinal surgery	6	9	15
Trauma	2	2	4
Ectopia lentis	2	0	2

Table 3. Details of Previous Intraocular Surgeries in Eyes That Received Implants

Previous Glaucoma Surgeries	Aurolab Aqueous Drainage Device (n = 36)	Ahmed Glaucoma Valve (n = 85)
Combined trabeculotomy + trabeculectomy	18	21
Trabeculectomy	5	6
Repeat trabeculectomy	1	3
TSCPC	7	3
AGV	5	2
ECP	1	0
Goniotomy	2	0
No previous glaucoma surgery	6	54
Other intraocular surgeries (nonglaucoma)		
Cataract surgery	7	24
Secondary IOL implantation	1	6
Vitreoretinal surgery	6	8
Penetrating keratoplasty	0	10

AGV = Ahmed glaucoma valve; ECP = endocyclophotocoagulation; IOL = intraocular lens; TSCPC = transscleral cyclophotocoagulation.

from 1.18±0.59 logMAR at baseline to 1.35±0.77 logMAR at last follow-up in the AGV group. In the AADI group, VA was same in 19 eyes (52.8%), improved in 11 eyes (30.6%), and decreased in 6 eyes (16.7%), and in the AGV group, VA remained same in 35 eyes (41.2%), improved in 30 eyes (35.3%), and decreased in 15 eyes (17.6%).

Complications

The details of complications, interventions, and outcomes are given in Table 5. Sixteen eyes in the AADI group (44.4%) and 24 eyes in the AGV group (28.2%) experienced complications. The rate of transient complications in the AADI group was slightly higher compared with that in the AGV group (AADI group, 11 eyes [30.5%]; AGV group, 18 eyes [21.1%]); however, this was not statistically significant ($P = 0.26$). In the AGV group, 7 of 85 eyes (8.2%) demonstrated hypotony (<6 mmHg) in the immediate postoperative period, and 2 eyes showed choroidal detachment. Hypotony was transient in 4 eyes and resolved with conservative management; choroidal detachment resolved in 1 eye with medical treatment, and 1 eye needed choroidal drainage. However, in the AADI group, 8 of 36 eyes (22.2%) demonstrated hypotony between the fifth and sixth week, corresponding to the period of ligature opening. Three eyes with hypotony demonstrated choroidal detachment; none required choroidal drainage. However, 3 eyes with prolonged hypotony and thickened choroid demonstrated total cataract and needed cataract extraction. This was considered a sight-threatening complication. The incidence of choroidal detachment (11.1% vs. 2.4%; $P = 0.04$) and cataract formation because of prolonged hypotony (8.3% vs. 0%; $P < 0.007$) were significantly greater in the AADI group compared with the AGV group.

The rates of tube-related complications were similar in both the groups (11.1% in the AADI group and 11.7% in the AGV group; $P = 1.0$). Long-term complications like tube retraction and tube erosion were not seen in the AADI group. This could be the result of shorter follow-up in the AADI group. The incidence of sight-threatening complications like retinal detachment, suprachoroidal hemorrhage, endophthalmitis, and severe hypotony causing cataract was 13.9% in the AADI group and 7.0% in the AGV group ($P = 0.22$). Seven eyes in the AADI group (19.4%) and 12 eyes in the AGV group (14.1%) required interventions for complications ($P = 0.26$). The most common intervention was for tube-related problems in both the groups (5.5% in the AADI group and 5.8% in the AGV group).

Discussion

Childhood glaucomas are less common than adult glaucomas but are more difficult to manage. Glaucoma drainage devices are the mainstay of treatment in childhood refractory glaucoma. The 2 commonly used drainage implants are the AGV and Baerveldt. The Baerveldt is not available in India; however, Aurolab in Madurai, India, has introduced a nonvalved implant named the AADI that is similar in design to the Baerveldt implant with a plate area of 350 mm^2. Because it is manufactured locally, it is available at a low cost of approximately $75 US dollars compared with $350 US dollars for the Baerveldt implant. In a developing nation, this cost difference can make an enormous impact on the choice and frequency of use of the device.

Both valved and nonvalved implants have been used in the management of refractory pediatric glaucomas. Reports in adult patients showed valved devices to be associated with a lower incidence of hypotony and high rates of

Table 4. Comparison of 2 Implant Models, the FP7 and FP8, Used in the Ahmed Glaucoma Valve Group

	FP7 (n = 14)*	FP8 (n = 72)†	P Value
Age at surgery (yrs), median (IQR)	14.5 (9,15)	3 (2,7)	**<0.001**
Preoperative IOP (mmHg), mean ± SD	36.9±8.8	30.7±7	**0.02**
Preoperative AGM (no.), mean ± SD	3.79±0.7	3.33±1.03	0.15
Postoperative IOP (mmHg), mean ± SD	16.9±7.3	18±5.9	0.51
Postoperative AGM (no.), mean ± SD	1.86±1.35	2.01±1.11	0.08

AGM = antiglaucoma medication; IOP = intraocular pressure; IQR = interquartile range; SD = standard deviation.
Boldface indicates statistically significant values.
*Adult implant.
†Pediatric implant.

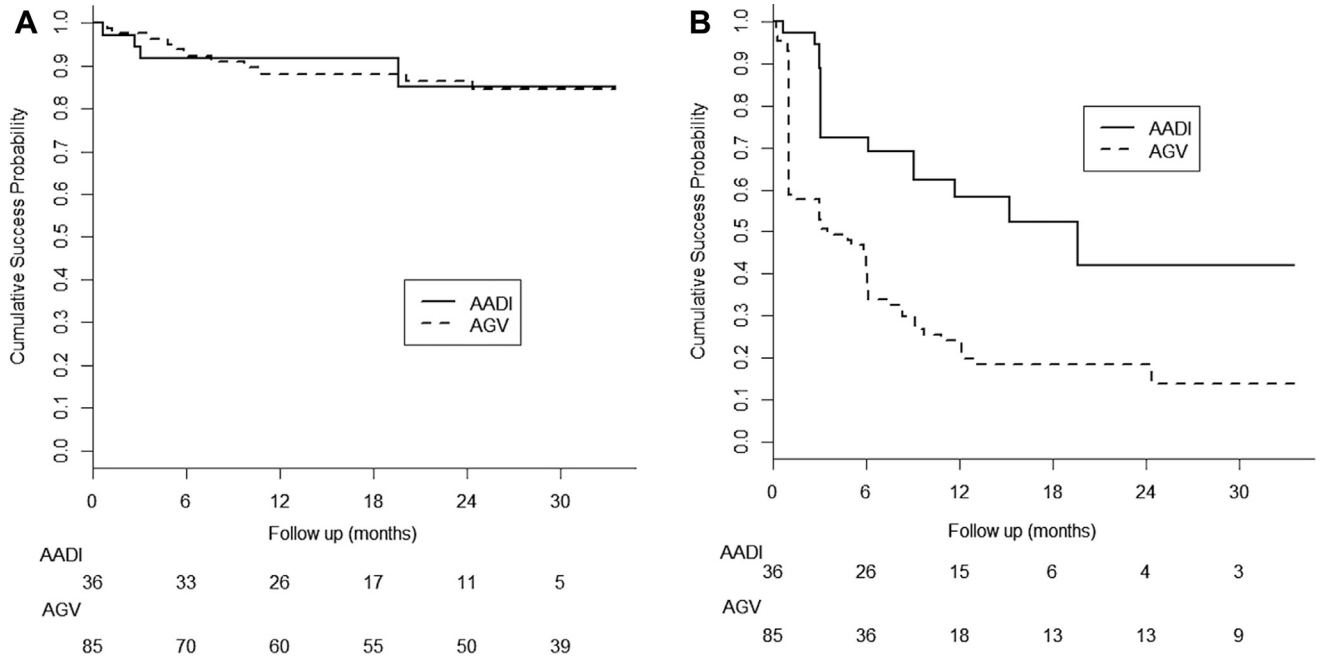

Figure 2. Kaplan-Meier survival analysis showing **A**, complete success and **B**, qualified success probability in eyes treated with the Aurolab aqueous drainage device (AADI; solid line) and the Ahmed glaucoma valve (AGV; dotted line) for refractory pediatric glaucoma.

encapsulation, with moderate IOP reduction often requiring postoperative glaucoma medications.[14,15] Nonvalved or non−flow-restricted devices are associated with better IOP control, fewer AGMs, and a higher risk of hypotony and its related complications.[16−18]

The only comparative study in literature is by El Gendy and Song,[19] who compared the BG 101-350 model of the Baerveldt implant with the S-2 model of the AGV implant in pediatric glaucoma. They reported a success rate of 80% in the Baerveldt group and 54.5% in the AGV group with a mean follow up was 2.7±2.5 years. The implants failed in 4 of 20 eyes in the Baerveldt group and 5 of 11 eyes in the AGV group. The model of the implant used (S-2, rigid polypropylene) and success criteria (defined as IOP <24 mmHg) used in their study were not similar to those used in ours; hence, it is difficult to draw direct

Table 5. Non−Sight-Threatening and Sight-Threatening Complications with in the Ahmed Glaucoma Valve and Aurolab Aqueous Drainage Device Groups

Complications	Aurolab Aqueous Drainage Device Group (n = 36)		Ahmed Glaucoma Valve Group (n = 85)		P Value
	No. of Eyes	%	*No. of Eyes*	%	
Non−sight-threatening complications					
Tube block by vitreous	1	2.8	2	2.4	0.89
Tube−corneal touch	3	8.3	4	4.7	0.43
Tube retraction	0	0	2	2.4	0.35
Others (hyphema, hypotony with no CD)	3	8.3	7	8.2	0.98
Choroidal detachment	4	11.1	2	2.4	**0.04**
Tube erosion	0	0	1	1.2	
Total	11	30.5 (95% CI, 15.4−45.5)	18	21.1 (95% CI, 12.4−29.8)	0.26
Sight-threatening complications					
Delayed hypotony with cataract	3	8.3	0	0	**0.007**
Endophthalmitis	1	2.8	3	3.5	0.5
Suprachoroidal hemorrhage	0	0	2	2.4	0.35
Retinal detachment	1	2.8	1	1.2	0.53
Total	5	13.9 (95% CI, 2.6−25.2)	6	7 (95% CI, 1.6−12.4)	0.22
No. of eyes needing interventions					
Total interventions	7	19.4 (95% CI, 6.5−32.3)	12	14.1 (95% CI, 6.7−21.5)	0.46

CD = choroidal detachment; CI = confidence interval.
Boldface indicates statistically significant values.

comparisons. However, our results with both the AGV and AADI are better than those reported by El Gendy and Song (85% success for the AGV group and 81% for the AADI group at 36 months). The silicone model of the AGV could have contributed to the improved success rate of the AGV in our study.

The success rate of the AGV in pediatric glaucoma using different definitions for success and with different models of implants range from 90% to 97% at 1 year to 54.8% to 80% at 2 years.[20–22] Al-Mobarak and Khan[21] reported their results with the AGV in primary and secondary pediatric glaucoma and found success rates of 54.8% at 2 years with the S-2 model versus 90.9% with the silicone AGV implant. Balekudaru et al[22] from India reported better outcomes with the AGV (both silicone and polymethyl methacrylate implants) in refractory pediatric glaucoma: 97% success at 1 year and 80% success at 2 years. Reoperations for tube-related complications were needed in 12.6% of eyes, and 13% of eyes needed repeat surgery for IOP control in their series. In their study, glaucoma occurring after keratoplasty was a significant risk factor for failure.

Kaushik et al[23] reported the results of AADI surgery in refractory pediatric glaucoma. The success probability was 91% at 6 months and 81.7% at 24 months. In their study, 14 of 34 eyes (41.1%) experienced complications, of which 1 eye experienced a sight-threatening complication (2.9%) and 4 eyes (11.7%) experienced complications needing intervention. Our success and complication rates in the AADI group are similar to those in the Kaushik et al study.

In our cohort, an HP was noted in 6 of 36 eyes (16.5%) in the AADI group and in 34 of 85 eyes (40%) in the AGV group. To our knowledge, no study on the Baerveldt implant or AADI implant in pediatric eyes has reported an HP. The HP evaluated in adult patients ranges from 30% to 80% with the AGV implant[22,24] and 48.6% with the Baerveldt implant.[25] Early initiation of aqueous suppression in eyes with an AGV shunt decreases the incidence and height of the HP.[26] Based on the results from this study, starting prophylactic aqueous suppression in children may help to reduce the incidence of an HP.

Incidence of cataract was higher in the AADI group. This complication was seen in eyes with hypotony that lasted for more than 1 to 2 months. The disruption of the blood–aqueous barrier, with chronic inflammation and hypotony, and prolonged steroid use could have contributed to cataract formation.

In our study, the complication rates after both types of implants were not significantly different. Tube-related complications like tube–cornea touch or tube migration were noted more with the AGV compared with the AADI, possibly because of the longer follow-up in children with the AGV and also modifications in the surgical techniques with experience in the AADI. Several factors may predispose young patients to tube–corneal touch. One of the main reasons is normalization of IOP or hypotony in the early postoperative period or during the time of ligature dissolution. Hypotony may shrink the elastic young eye, shifting the tube anteriorly and possibly causing tube migration and tube–cornea touch.

Elevated IOP with failure requiring repeat surgical intervention for IOP control was needed in eyes with the AGV, but in none of the eyes with the AADI. The incidence rates of choroidal detachment and hypotony were higher with the AADI compared with the AGV, likely because of its non–flow-restrictive nature and hypotony.

Five eyes in the AADI group and 6 eyes in the AGV group experienced sight-threatening complications. One eye in each group experienced a retinal detachment. The child with retinal detachment in the AADI group had Stickler's syndrome and already had undergone prior pars plana vitrectomy and endolaser treatment. Retinal detachment after implant surgery was noted when the ligature opened up. Retinal detachment in the AGV group was managed with appropriate surgical intervention. One eye in the AADI group and 3 eyes in the AGV group had endophthalmitis after undergoing penetrating keratoplasty. In these eyes, loose sutures and use of steroids would have contributed to graft infiltrate and endophthalmitis. One of the contributing factors also could be a decrease in IOP after glaucoma surgery with subsequent loosening of graft sutures, predisposing the patient to infection. Two eyes were identified with suprachoroidal hemorrhage on the first postoperative day. The likely reason for this complication may be highly myopic eyes and their response to sudden intraoperative or postoperative hypotony.

Detailed evaluation of visual outcomes was not possible because some of the children were unable to cooperate with subjective VA testing. The slight decrease in postoperative vision noted in our study may be the result of sight-threatening complications in few eyes in either group, which skewed the data. Motility disturbances have been described after implantation of drainage devices.[13,27] This complication may be the result of mechanical displacement of the implant, fibrotic bleb, or a fixation suture effect inducing scarring under the rectus muscle. We did not find any motility disturbances in our study in either group.

Limitations of this study include the flaws inherent in a retrospective study, including the nonrandomization of patients and nonhomogenous groups in terms of implant size, diagnosis, prior surgeries, and follow-up. Because the AADI implant was available beginning in 2014, the surgical techniques and postoperative management strategies may have changed during the study period (2007–2016). Eyes with previous implants and prior transscleral cyclophotocoagulation can confound the results. Hence, we excluded these eyes in the 2 groups and reanalyzed the data, which still showed significantly better success probability in the AADI group. Prospective studies with larger sample sizes and longer follow-up in uniform cohorts of patients with refractory pediatric glaucoma would be required to compare the outcomes of these 2 implants. In summary, we found that both the AADI and AGV implants effectively lowered IOP in difficult glaucomas in pediatric patients with similar numbers of complications. However, better IOP control with lesser need for AGMs was achieved by using the AADI. The cost of the AGV is prohibitive to large sections of the poor in the developing world, and the AADI can provide a safe, efficient, and cost-effective alternative to such patients.

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Abbreviations and Acronyms:
AADI = Aurolab aqueous drainage device; **AGM** = antiglaucoma medication; **AGV** = Ahmed glaucoma valve; **IOP** = intraocular pressure; **IQR** = interquartile range; **VA** = visual acuity.

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