Intermediate-term outcomes of Aurolab aqueous drainage implant in refractory paediatric glaucoma

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ABSTRACT

Aim To report the intermediate-term outcomes of Aurolab aqueous drainage implant (AADI) surgery in paediatric eyes with refractory glaucoma.

Methods Case records of patients below 18 years, who underwent AADI surgery between 2012 and 2015 with ≥2 years follow-up, were analysed. The intraocular pressure (IOP), visual acuity, number of antiglaucoma medications, complications and resurgery if any were recorded at baseline, day 1and then at months 1, 3, 6, 9, 12, 18, 24 and at the last visit. Failure was defined as IOP >18 mm Hg or not reduced by at least 30% below baseline, IOP ≤5 mm Hg on two consecutive follow-up visits after 3 months, reoperation for a complication or loss of light perception vision.

Results 101 eyes of 101 patients were included with a mean age of 10.4±4.7 years at the time of surgery and a mean follow-up of 40.9±15.1 months. Glaucoma following cataract surgery was the most common type of glaucoma (n=31, 30%), followed by primary congenital glaucoma (n=29, 29%). The cumulative probability of failure was 15.8% (95% CI 10.1% to 24.5%) at 1 year, 22.7% (95% CI 15.7% to 32.2%) at 2 years, 42.5% (95% CI 32.6% to 53.9%) at 3 years and 62.1% (95% CI 49.5% to 74.8%) at the 4 years time point.

Conclusion The AADI showed excellent success until 2 years after surgery in paediatric eyes after which failure rates increased. Further prospective studies with longer follow-up are required to evaluate the long-term success of the AADI for paediatric glaucomas.

INTRODUCTION

Glaucoma in paediatric eyes is more challenging to manage compared with adult eyes.[1–3] The developmental defects in the trabecular meshwork make these eyes less amenable to intraocular pressure (IOP) control with topical antiglaucoma medications (AGMs) and surgical intervention is likely to be needed at an earlier stage of the disease.[1 4 5]

Goniotomy, trabeculotomy, trabeculectomy with mitomycin C and trabeculectomy with trabeculotomy have been the mainstay of glaucoma filtration surgery in paediatric glaucomas over the past few decades.[4 5] However, an aggressive healing response in children often leads to fibrosis of the conjunctival bleb in a few years, mandating either repeat trabeculectomy or a glaucoma drainage device.[3] The use of glaucoma drainage devices, such as the Ahmed and Baerveldt glaucoma implants (BGIs), has been reported to have moderate long-term success rates in paediatric glaucomas.[6–10] However, the Baerveldt implant is not readily available in the developing world and its use is cost prohibitive for the majority, thereby creating a need for lower cost implants.

The Aurolab aqueous drainage implant (AADI, Aurolab, Madurai, India) is a relatively new, non-valved, low cost, glaucoma drainage device, similar in design to the BGI, which has been in use for refractory glaucomas over the past few years. Short and intermediate-term outcomes in adult eyes have shown the AADI to have a good safety and efficacy profile.[11–14] In a study on refractory paediatric glaucomas, Kaushik *et al* report excellent outcomes using the AADI from a small cohort of eyes with a mean follow-up of less than 2 years.[15] However, longer follow-up studies with a larger number of patients are required to establish the safety and efficacy of the AADI for paediatric glaucomas. In this paper, we report longer outcomes from the use of the AADI in a large cohort of paediatric eyes with refractory glaucoma.

METHODS

Informed consent was obtained from the parents of all patients before undertaking surgery and the study was conducted as per the tenets of the Declaration of Helsinki. Case records of patients below 18 years of age, who underwent the AADI surgery between January 2012 and December 2015 for uncontrolled glaucoma despite maximal tolerated medical therapy or previous failed angle surgery/trabeculectomy or secondary glaucomas deemed as high risk for failure of trabeculectomy, were identified from a computerised database. We included data from those patients who followed up for a minimum period of 2 years. In patients who underwent bilateral surgery, the eye operated first was considered for analysis.

Patients' demographics (age in months and gender), baseline best-corrected visual acuity (BCVA), baseline IOP, number of AGMs, cup to disc ratio, previous surgical history and the date of AADI surgery were recorded from the case records. 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. The IOP was recorded using the Goldmann applanation tonometry in older children. Younger children underwent examination under anaesthesia with portable slit lamp biomicroscopy, Perkins

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Table 1 Baseline demographics and clinical characteristics of patients

Variable	Mean/N	SD (95% CI) or %
Age (years)	10.4	4.7 (9.5 to 11.4)
Gender (n, % boys)	118	75
Preoperative IOP (mm Hg)	34.2	9.9 (32.4 to 36.1)
Preoperative AGM	2.8	0.7 (2.7 to 3.1)
Preoperative BCVA (LogMAR)	0.81	0.5 (0.68 to 0.92)
Cupto disc ratio	0.82	0.1 (0.79 to 0.84)

AGM, antiglaucoma medication; BCVA, best-corrected visual acuity; IOP, intraocular pressure; LogMAR, logarithm of minimum angle of resolution.

tonometry and disc evaluation with direct ophthalmoscopy. IOP was measured with Perkin's applanation tonometer within 5 min of induction of general anaesthesia with inhalational Sevoflurane (Baxter India, Waulj, Aurangabad, India) to minimise the effect of anaesthesia on IOP. Gonioscopy was also done for all children, either in the outpatient clinic or under general anaesthesia when indicated. Glaucoma was classified as primary congenital glaucoma if no other ocular or systemic comorbidities were noted. Additionally, eyes with glaucoma following cataract surgery, and those associated with ocular and systemic co morbidities were also recorded. The IOP, number of AGMs, BCVA, complications and resurgery if any were recorded at day 1, and then at months 1, 3, 6, 9, 12, 18, 24 and the last visit after 24 months if any from the case files.

Surgical technique was similar to that described previously.[14] All surgeries were done by a single surgeon (GVP) under general anaesthesia and a 350 mm^2 AADI was used in all eyes. Superotemporal quadrant was the most preferred location for placement of the AADI. The inferonasal quadrant was chosen in eyes with pre-existing dense subconjunctival scarring in the superotemporal quadrant with inadequate tissue plane at sub-Tenon's space in which to implant the plate of the aqueous shunt.[16] The physical dimensions of AADI are the same as the BGI. The AADI like BGI has a lesser anterior–posterior diameter than the AGV. The issue addressing the proximity of the posterior edge of an inferonasal BGI to the optic nerve has been published.[17]

Postoperatively topical antibiotics were used four times a day for1 month, topical steroid drops for 3 months in tapering dose and topical cycloplegic eye-drops once at night for 2 months were prescribed. Topical aqueous suppressants (0.5% timolol maleate or fixed combination 0.5% timolol maleate and 2% dorzolamide) were continued till ligature suture dissolution (approximately 5–6 weeks), depending on postoperative IOP levels. Thereafter, topical aqueous suppressant use was titrated to ensure IOP in the low teens. Oral acetazolamide was reserved for use only in the immediate postoperative phase for eyes with IOP >30 mm Hg despite the use of topical aqueous suppressants.

Primary outcome measure was the cumulative failure rate of the AADI at 2 years defined as IOP >18 mm Hg or not reduced by at least 30% below baseline on two consecutive follow-up visits after 3 months, IOP ≤5 mm Hg on two consecutive follow-up visits after 3 months, reoperation for glaucoma or a complication, or loss of light perception vision.[14] Complete success was defined as achieving these IOP levels without AGMs and qualified success was considered when IOP control was achieved with AGMs.[14] Cumulative rates of complete and qualified success were also calculated for IOP ranging between 6–15 mm Hg and 6–21 mm Hg for the purpose of comparison with other studies. Reoperation for glaucoma or a complication was defined as additional surgery requiring a return to the operating room including cyclodestruction surgery. Complications leading to more than two line loss in visual acuity for two consecutive visits were termed as vision threatening.[14]

Statistical analysis

All continuous variables were described as mean with SD or median and IQR and categorical variables were described as proportions (n, %). Visual acuity was converted to the logMAR for statistical analysis. Comparison of IOP between pre-AADI and post-AADI at different time intervals was carried out using one-way analysis of variance with Bonferroni adjustments.

Survival analysis was performed using the failure of the AADI as the censoring variable and Kaplan-Meier (K-M) curves were plotted to depict cumulative survival rates at various time points. Time for failure was defined as the interval between the time of surgery and failure.[14] Differences between survival curves for different mechanisms of glaucoma were determined using the log-rank test. The survival probability for each outcome was assessed using the Cox proportional hazards models and displayed using HRs with 95% CI. Covariates used for adjusting HRs were those with a $p<0.1$ in univariate models and those that have been shown to influence failure rates in the previous studies.

Data were entered into Microsoft Excel and analysed using STATA (V.12.1, I/C) statistical analysis software package and $p<0.05$ was considered statistically significant.

RESULTS

A total of 136 eyes underwent AADI during the study period of which, 101 eyes of 101 patients with a minimum of 2 years were included in the analysis. The average follow-up was 40.9±15.1 months (24–84 months). The baseline demographic and clinical features of the study population are shown in table 1.

The different aetiologies of glaucoma included in the study along with their mean IOP and the number of AGMs at the time of AADI is presented in table 2. The most common type of glaucoma in our patient cohort was glaucoma following congenital cataract surgery (n=31, 30%) of which 29 eyes (94%) were with

Table 2 Distribution and clinical characteristics of different glaucoma aetiologies in the study

Type of glaucoma	N	Mean IOP at baseline (mm Hg)	No of AGM	Previous filtering surgery/GDD (n, %)
Primary congenital glaucoma	29	35.18 (8.5)	2.5 (0.7)	29 (100)
Glaucoma after cataract surgery	31	34.2 (9.4)	2.9 (0.6)	10 (32)
Glaucoma associated with congenital eye and systemic anomalies	10	28.2 (6.9)	3.2 (0.4)	6 (60)
Glaucoma associated with congenital eye anomalies alone	8	38.4 (10.8)	3.3 (0.5)	4 (50)
Glaucoma with acquired conditions	18	35.8 (8.6)	3.8 (0.8)	4 (22)
Juvenile open angle glaucoma	5	28.4 (11.1)	2.8 (0.8)	5 (100)

AGM, antiglaucoma medications; GDD, glaucoma drainage device; IOP, intraocular pressure.

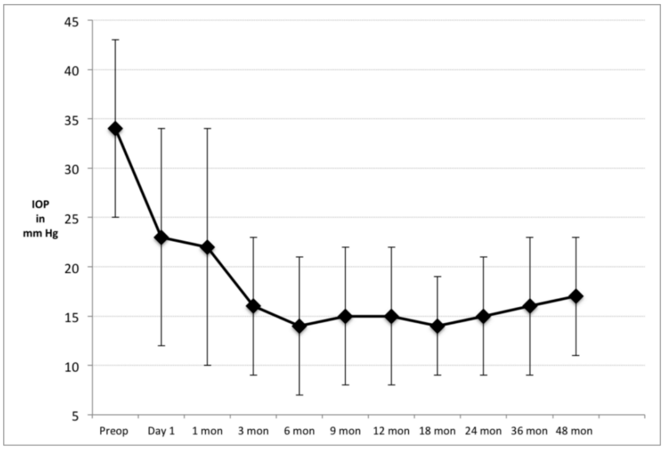

Figure 1 IOP trend following Aurolab aqueous drainage implant surgery. IOP, intraocular pressure.

surgical aphakia. Primary congenital glaucoma (n=29, 29%) was the second most common type of glaucoma included. Of the 10 eyes with systemic associations, five (50%) had Sturge-Weber syndrome, three (30%) had aniridia, two (20%) had Axenfeld-Rieger syndrome. Of the eight eyes with congenital eye anomalies alone, four (50%) had aniridia, two (25%) had ectopia lentis and and two (25%) had Axenfeld-Rieger anomaly. In the 18 eyes with coexistent acquired conditions, six eyes each had glaucoma following trauma, vitreoretinal surgery and long-term steroid application. A comparison of prior glaucoma filtration surgery across the different types of glaucoma is shown in online supplementary table 1. Eyes with primary congenital glaucoma and JOAG had conventional filtration surgery (ie, trabeculotomy or combined trabeculotomy-trabeculectomy or mitomycin C augmented trabeculectomy) as the primary surgery in most instances (>95% times) where as those with glaucoma following cataract surgery, and other forms of glaucoma associated with congenital eye disorders had AADI as the primary treatment without filtration surgery much more often (>60% times) ($p<0.001$). Eyes with glaucoma following cataract surgery (1.2±0.7 previous surgeries) and coexistent acquired conditions (2.1±2.0 previous surgeries)had significantly more intraocular procedures compared with primary congenital glaucoma (0.1±0.4 previous surgeries), glaucoma associated with congenital disorders (0.1±0.3 previous surgeries) and JOAG (0 prior surgeries) ($p<0.001$).

The median preoperative IOP was 34 mm Hg (IQR=28–40 mm Hg) and ranged from 10 to 54 mm Hg with a median of 3 AGMs (IQR=3–4 medicines). The episcleral plate of the AADI was placed in the superotemporal quadrant in 56 eyes (56%) and in the inferonasal quadrant in 45 eyes (44%). The median IOP values at different time points are shown in figure 1 and mean values are shown in table 3.

A comparison between other parameters of disease activity, that is, corneal diameter, axial length, spherical equivalent, Haab's striae and corneal oedema across various types of glaucoma is shown in online supplementary table 2. Eyes with primary congenital glaucoma had significantly larger corneal diameter and Haab's striae compared with other types of glaucoma.

The mean IOP reduced significantly at 1 month by 32% from baseline and by 55% at 1-year follow-up and the mean number of AGMs also reduced by 50% (table 3). The IOP reduced significantly on day 1 following surgery and there was a further drop at 3 months following which the IOP stabilised (figure 1).

Table 3 IOP comparisons at different time points in the study

IOP	Mean	SD (95% CI)	No of AGM	P value*
Baseline	34.23	9.2 (32.1 to 36.2)	2.8+0.7	
Day 1	23.36	11.1 (15.9 to 30.8)	2.0+0.9	0.03
1 month	22.70	12.5 (20 to 25.5)	1.6+0.9	0.74
3 months	16.20	7.9 (14.4 to 17.9)	1.3+0.9	<0.001
6 months	14.39	7.3 (12.7 to 16.1)	1.2+0.9	0.07
9 months	15.36	7.6 (13.5 to 17.2)	1.2+1.0	0.73
12 months	15.1	7.4 (1341 to 16.7)	1.2+1.0	0.46
18 months	14.94	5.9 (13.5 to 16.3)	1.2+1.0	0.82
24 months	15.84	6.9 (14.1 to 17.50)	1.2+1.0	0.28
36 months (n=42)	16.38	6.9 (14.2 to 18.5)	1.3+1.2	0.69
48 months (n=22)	17.27	6.5 (14.4 to 20.1)	1.3+0.9	0.63

*P value compared with the previous IOP .
. AGM, antiglaucoma medications; IOP, intraocular pressure.

The BCVA was available for 85 participants (85%) and it did not change significantly at the 1-year time point (preoperative mean BCVA=0.81±0.5 logMAR vs 0.89±0.7 logMAR at 1 year, p=0.11). Corneal endothelial touch was the most common complication (table 4), followed by tube retraction, exposure and anterior plate migration.

Tube trimming and repositioning were the most common forms of resurgery done (table 5).

Considering success as IOP between 6 and 18 mm Hg or at least 30% reduction from baseline, failure was seen in 53 eyes (53%) at 4 years of which 13 (25%) were due to complications and an additional 12 (23%) were due to resurgery. The remaining 52% were recorded as a failure due to uncontrolled IOP of which eight eyes (8%) underwent repeat AADI.

Table 6 shows the cumulative rates of complete and qualified success at various time points based on different outcome criteria.K-M estimates showed that the cumulative probability of failure was 15.8% (95% CI 10.1% to 24.5%) at 1 year, 22.7% (95% CI 15.7% to 32.2%) at 2 years, 42.5% (95% CI 32.6% to 53.9%) at 3 years and 62.1% (95% CI 49.5% to 74.8%) at 4 years time point. The K-M plot for cumulative failure at various time points is shown in figure 2. There were no differences in the cumulative failure rates between different subtypes of glaucoma (logrank=0.82). Similarly, Cox proportional hazards analysis did

Table 4 Complications at different time points during follow-up*

Complication	<3 months, (%)	3–12 months, (%)	>12 months	Total, (%)
Choroidal detachment	3 (3)	1 (1)	–	4 (4)
Endothelial touch	4 (4)	2 (2)	2 (2)	8 (8)
Tube retraction	1 (1)	2 (2)	1 (1)	4 (4)
Anterior plate displacement	1 (1)	3 (3)	–	4 (4)
Vitreous haemorrhage	1 (1)	–	–	1 (1)
Hypotony	1 (1)	–	1 (1)	2 (2)
Tube exposure	–	3 (3)	1 (1)	4 (4)
Patch graft melt	–	1 (1)	1 (1)	2 (2)
Retinal detachment	–	2 (2)	–	2 (2)
Cystoid macular oedema	–	1 (1)	–	1 (1)
Endophthalmitis	–	2 (2)	1 (1)	3 (3)
Total	11 (11)	17 (17)	7 (7)	35 (35)

*All % are out of total eyes (n=101), eyes with multiple complications have been attributed to the most severe complication.

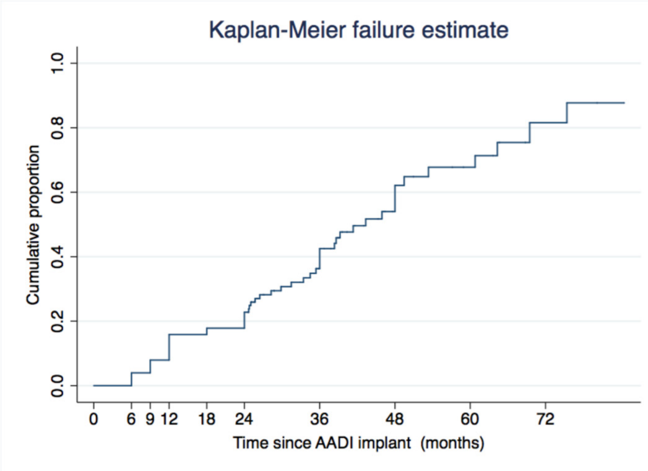

Figure 2 Kaplan-Meier analysis showing cumulative proportion of failure, with failure defined at IOP >18 mm Hg. AADI, Aurolab aqueous drainage implant.

Table 5 Resurgery at different time points during follow-up

Complication	<3 months, (%)	3–12 months, (%)	>12 months, (%)	Total, (%)
Tube ligation	1 (2)	–	1 (1)	2 (2)
Tube trimming	2 (2)	3 (3)	2 (2)	7 (7)
Tube repositioning	2 (2)	3 (3)	–	5 (5)
AADI explantation	–	–	1 (1)	1 (1)
PPV +SOI	1 (10)	2 (2)	–	3 (3)
CD Drainage	1 (1)	–	–	1 (1)
Scleral patch graft	–	1 (1)	2 (2)	3 (3)
Repeat AADI	–	3 (3)	5 (5)	8 (8)
Core vitrectomy		2 (2)	–	2 (2)
Cataract surgery	–	1 (1)	3 (3)	4 (4)
PK	–	1 (1)	–	1 (1)
Cyclophotocoagulation	–	1 (1)	–	1 (1)
Total	7 (7)	17 (17)	14 (13)	38 (38)

AADI, Aurolab aqueous drainage implant; CD, choroidal detachment; PK, penetrating keratoplasty; PPV, pars plana vitrectomy; SOI, silicone oil injection.

not yield any factors predicting greater failure rates, including age, type of glaucoma and type of prior surgery.

DISCUSSION

The AADI leads to a significant reduction in IOP by the third month after implantation and had a cumulative success rate of 84% at 1 year and 77% at 2 years follow-up. The success rate did not differ with the type of paediatric glaucoma. Complications and need for resurgery were seen in about one-third of the eyes.

In a previous study on AADI in paediatric glaucomas, Kaushik *et al* reported outcomes from 34 eyes of 31 patients with refractory paediatric glaucoma with a mean follow-up of 18 months.[15] Though authors did not specify criteria used to define success clearly, they report a cumulative success of 91% at 6 months and 82% at 18–24 months. We define success more rigidly, based on IOP and percentage reduction from baseline, and show that complete success ranges from 81% to 93% at 1 year and 69% to 89% at 2 years depending on the criteria used to define complete success. Our outcomes are similar to those reported by Kaushik *et al* till the 2-year time point. However, we notice a significant drop in the success rate with longer follow-up, with success ranging from 40% to 69% at 3 years and between 12% and 50% at 4 years. It is possible that greater conjunctival fibrosis around the episcleral plate of the AADI gradually leads to compromised access to the subconjunctival space which in turn leads to lower outflow and thus failure, though clinically the blebs observed following AADI implantation were diffuse and of low profile unlike the typical encapsulated blebs causing failure of IOP control in AGV. Indeed, the majority of the eyes that had repeat AADI did so after 2 years follow-up. In another recent retrospective study on AADI (n=36) versus Ahmed glaucoma valve (n=85) in paediatric eyes, Senthil *et al* reported a qualified success rate of 91% at 1 year and 81% at 3 years with the AADI, using IOP cut of 21 mm Hg or 20% reduction from baseline as success definition.[18] These are almost identical to our results using similar success criteria. However, they report a much lower complete success rate of 41% at 3 years, though this was significantly higher than the Ahmed valve (13.7%). Significantly, Senthil *et al* report that only one eye failed in the AADI group due to uncontrolled IOP, while other failures were due to complications. In our series, inadequate IOP control was the main cause of failure.

In other studies comparing IOP reduction using the Ahmed or Baerveldt implant for paediatric glaucoma show modest success rates. In a retrospective study on 119 eyes using the Ahmed device, Chen *et al* report an overall success rate of 55% (range 46%–70%) at 5 years, slightly better than our rate of 50% at 4 years.[7] However, these were eyes with medications, classified as qualified success in our series. In another retrospective study, Colás-Tomás *et al* report outcomes from 17 eyes that received either the Molteno or the Ahmed implant.[9] Considering the success criteria of IOP <21 mm Hg, they report success in 76%, 63% and 55% at the 6 months, 1–3 years and 4–8 years, respectively, very similar to our results. Mandalos *et al* retrospectively reported outcomes from 69 eyes of 52 patients with paediatric glaucoma that underwent surgery using the Baerveldt or Molteno implant with a mean follow-up of 45 months. Using success criteria of <22 mm Hg with medications, authors report a cumulative probability of qualified success of 95.6% at 1 year and this declined to 71.3% at 5 years and 39.7% at 8 years. These

Table 6 Complete and qualified success based on different success criteria at different time points

	Complete success (<21)*	Qualified success (<21)*	Complete success (<18)†	Qualified success (<18)†	Complete success (<15)‡	Qualified success (<15)‡
12 months	93.1 (86–96.6)	93.1 (86–96.6)	84.2 (75.4–89.9)	84.2 (75.4–89.9)	81.2 (72.1–87.6)	81.2 (72.1–87.6)
24 months	89.1 (81.2–93.8)	89.1 (81.2–93.8)	77.2 (67.8–84.2)	79.4 (67.7–84.2)	69.3 (59.3–77.3)	69.3 (59.3–77.3)
36 months	68.6 (57.3–77.5)	81.7 (70.7–88.8)	57.5 (46.1–67.3)	69.7 (58.2–78.5)	39.8 (29.7–50.2)	50.2 (38.2–61.1)
48 months	50 (36.4–62.2)	73.9 (58.2–84.5)	37.9 (25.2–50.4)	57.4 (40.9–70.8)	11.7 (5–21.6)	21.5 (9.6–36.5)

*Success=IOP< 21 mm Hg and ≥5 mm Hg or 20% reduction from baseline.
†Success=IOP <18 mm Hg and ≥5 mm Hg or 30% reduction from baseline.
‡Success=IOP <15 mm Hg and ≥5 mm Hg or 40% reduction from baseline.

outcomes are almost identical to our results using the equivalent success criteria.

Paediatric eyes undergoing glaucoma drainage implants have been reported to experience greater adverse effects compared with adult eyes.[3] However, most complications can be managed successfully. O'Malley *et al* report complication rates of 35% and vision-threatening complications in 10% patients.[19] Similarly, Novak-Lauš *et al* report complications in 4 out of 10 eyes that underwent Ahmed valve for paediatric glaucoma.[20] Tube-cornea touch was the most common complication observed, similar to ours. The authors concluded that, though Ahmed valve implantation may be a viable option for the management of refractory paediatric glaucoma and shows success in IOP control, there was a relatively high complication rate limiting the overall success rate. In our cohort of the eight eyes with tube-cornea touch, five eyes were primary congenital glaucoma eyes, two had secondary glaucoma (one eye associated with Sturge Weber Syndrome, one eye with corticosteroid-induced glaucoma) and one had glaucoma following congenital cataract surgery.

We report endophthalmitis in three eyes, two eyes with patch graft melt with tube exposure, one eye with anterior migration of the plate and tube exposure. Additionally, tube retraction, tube exposure and anterior plate migration were seen in 12% eyes. We suspect that inherent high scleral elasticity in paediatric eyes results in shrinking of the eyeball after IOP normalisation or hypotony increasing the risk of endothelial touch. On further analysis, we observed that most of these cases occurred in the initial surgeries and may be considered as part of the surgeon's learning curve. Kaushik *et al* surprisingly report much lower complication rates, including no cases of tube erosion or infection.[15] The drawback of our study is its retrospective study design while its advantages are a large sample size with good follow-up.

In conclusion, we found a significant reduction in IOP starting at 3 months after AADI implantation in a diverse group of eyes with refractory paediatric glaucoma. Success rates were high up till 2 years follow-up, after which failure rates increased significantly every year. The risk of complications was also relatively high, comparable to those reported with other aqueous drainage implants in paediatric eyes and many required repeat AADI for IOP control. It will be prudent to maintain close follow-up for prolonged periods in these eyes with complex glaucomas. Longer follow-up studies are required to analyse success rates beyond the 4–5 years reported in this study.

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Contributors GVP: 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. PFP: drafting the work or revising it critically for important intellectual content and final approval of version to be published. HKW and SP: data acquisition, analysis, preparation of manuscript. SK and ALR: critical revision of content, final approval of version to be published.

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Patient consent for publication Not required.

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