

# Safety and efficacy of a low-cost glaucoma drainage device for refractory childhood glaucoma

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## ABSTRACT

**Background** To evaluate the safety and efficacy of a low-cost glaucoma drainage device (GDD), Aurolab aqueous drainage implant (AADI), similar in design to the Baerveldt glaucoma implant (BGI), in refractory childhood glaucoma.

**Methods** This prospective interventional study was conducted in a tertiary care postgraduate teaching institute. Children aged <16 years with uncontrolled intraocular pressure (IOP) refractory to medical treatment and considered at high risk of failure following trabeculectomy were recruited. Eligible children were implanted with the AADI. Those completing minimum 6-month follow-up were included. Main outcome measures were IOP reduction from preoperative values and postoperative complications.

**Results** 34 eyes of 31 patients were analysed. Average follow-up was 18.3±6.9 months. Mean IOP reduced from 27.4±7.5 mm Hg on maximum medication to 14.6±10.74 mm Hg, 13.8±7.5 mm Hg, 12.8±5.6 mm Hg and 14.7±5.8 mm Hg at 1 week, 6 months, 1 year (32 eyes of 29 children) and 2 years (25 eyes of 22 children) postoperatively, respectively ( $p<0.001$ ). The cumulative probability of success was 91.18% at 6 months and 81.7% at 18–24 months. Mean number of topical medications decreased from 3.1±0.6 to 1.8±1.3 at 6 months and 1.6±1.1 at 24 months ( $p<0.001$ ). Preoperatively, 25 patients required systemic acetazolamide, decreasing to three patients at 2 years. There was no tube erosion or infection. One eye developed retinal detachment.

**Conclusion** The AADI appears to be a viable low-cost GDD with effectiveness and safety profile comparable with published reports of the BGI and Ahmed glaucoma valve implant in children.

## INTRODUCTION

Childhood blindness is defined as best-corrected visual acuity (BCVA) <3/60 in a child aged <16 years old. The prevalence is estimated to be 0.1/1000 to 1.1/1000 children in different parts of the world<sup>1</sup> and 0.5/1000 children in India.<sup>2</sup> Childhood glaucoma is a potentially blinding condition and frequently remains undiagnosed and undertreated.<sup>3–4</sup> Despite its infrequent incidence, childhood glaucoma accounts for 7%–20% of childhood blindness.<sup>5–8</sup> This disproportionate share might be because even after diagnosis, childhood glaucoma is difficult to manage and often refractory to medical treatment and standard trabeculectomy surgery. Since approximately 40% of childhood blindness is avoidable, it becomes even more important to identify and treat it early.<sup>9</sup>

Glaucoma drainage devices (GDDs) have been reported to be beneficial in the treatment of refractory childhood glaucoma.<sup>10–16</sup> India has a large share of childhood glaucoma, of which many are refractory and would benefit from a GDD, but for the prohibitive cost. The Ahmed glaucoma valve (AGV) (New World Medical, Rancho Cucamonga, California, USA) at US\$ 260, the Baerveldt glaucoma implant (BGI) (Advanced Medical Optics, Santa Ana, California, USA) at US\$ 750 is simply beyond the reach of the majority of those who need it the most.

The Aurolab aqueous drainage implant (AADI) has been introduced recently for clinical use in India by Aurolab, a manufacturing division of Aravind Eye Institute, Madurai, India. This is a low-cost, non-valved, GDD (cost US\$ 50), designed like the BGI with a 350 mm<sup>2</sup> plate area. Professor George Baerveldt authorised the use of his very successful design, and the device was manufactured in collaboration with the Bascom Palmer Eye Institute, Miami, Florida. The AADI was made commercially available in India in June 2013. Our tertiary care Institution runs a busy Paediatric Glaucoma service, with a sizeable number of children with refractory glaucoma who are likely to benefit greatly from this device. We report our preliminary results of AADI implantation in children with refractory glaucoma.

## METHODS

This was a prospective, non-comparative, interventional case series. Children aged <16 years with refractory glaucoma, presenting to the Paediatric Glaucoma Clinic of the Advanced Eye Centre, Postgraduate Institute of Medical Education and Research (a tertiary care referral postgraduate teaching institute), Chandigarh, India, scheduled for AADI implantation, were recruited for the study. Ethical clearance was obtained from the Institute Ethics Committee, and the study adhered to the principles of the Declaration of Helsinki. Informed consent was taken from the parents of all eligible participants.

All eligible patients underwent a comprehensive ophthalmological examination. Cooperative children had BCVA measured in LogMAR units, intraocular pressure (IOP) measured by Goldmann applanation tonometry (GAT), slit lamp biomicroscopy, gonioscopy and stereoscopic fundus evaluation on the slit lamp using a 90.0 D lens. Colour stereoscopic optic disc photographs and red-free nerve fibre layer photographs were taken on the Zeiss Fundus camera FF 450 with VISUPAC



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## Clinical science

System 451 (Carl Zeiss Ophthalmic Systems, Carl Zeiss Jena, Jena, Germany).

Younger children not cooperative for slit-lamp biomicroscopy underwent examination under anaesthesia (EUA) using sevoflurane. IOP was measured by Perkins hand-held tonometer, anterior chamber details were noted under the microscope and disc evaluation was done using a direct ophthalmoscope.

An average of three IOP measurements was computed for analysis; if they differed by more than 2.0 mm Hg, a fourth reading was taken, and the average of the three closest values was used for analysis.

### Inclusion criteria

- ▶ Age <16 years
- ▶ Eyes with uncontrolled IOP refractory to medical treatment
- ▶ Eyes considered at high risk of failure/complication following conventional filtering surgery such as those with excessive conjunctival scarring after prior ocular surgery or extremely thin sclera in buphthalmos
- ▶ Minimum 6 months postoperative follow-up

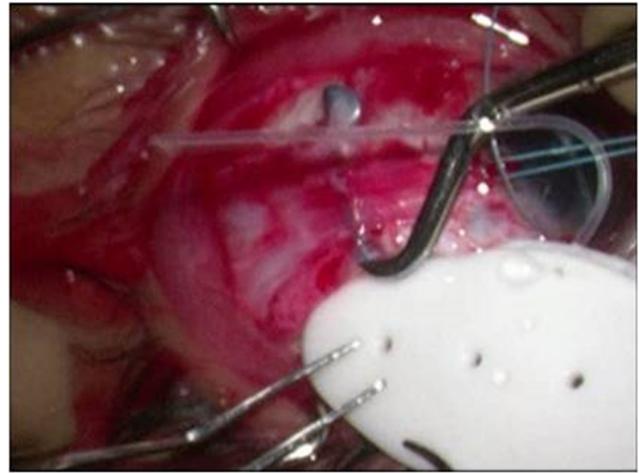
### Exclusion criteria

- ▶ Eyes with uncontrolled glaucoma which could be expected to have favourable postoperative outcome by conventional trabeculectomy, because of sufficient healthy conjunctiva:
  - ▶ Eyes with secondary uncontrolled glaucoma not operated previously
  - ▶ Postcataract surgery uncontrolled glaucoma with healthy conjunctiva
  - ▶ Uncontrolled glaucoma following pars plana vitrectomy or optical penetrating keratoplasty with moderate disc damage (Cup-disc ratio <0.8)
- ▶ Corneal abnormalities that would lead to erroneous IOP readings
- ▶ Uncontrolled systemic diseases such as congenital cardiac abnormalities, uncontrolled seizure disorders or any other condition not fit for general anaesthesia
- ▶ Any other active ocular disease (active uveitis, ocular infection)

### Surgical procedure

All procedures were performed by any one of the four glaucoma specialists (SK, PK, SR, SSP). The quadrant of choice for the implant was the superotemporal quadrant, followed by the inferior temporal, inferior nasal quadrants or superonasal quadrant, depending on the condition of the conjunctiva in that region. A 3-hour to 5-hour conjunctival peritomy was performed. The adjacent rectus muscles were hooked. The AADI tube was primed, and the plate was secured 8–10 mm posterior to the limbus, with the wings beneath the adjacent recti muscles, using two interrupted sutures 9–0 nylon (monofilament polyamide black, Ethilon; Ethicon, Johnson & Johnson, Himachal Pradesh, India) through the anterior fixation holes (figure 1). The tube was occluded completely with 6–0 Vicryl (Braided coated polyglactin 910 violet; Ethicon, Johnson & Johnson) near the tube-plate junction.

The ligated tube was trimmed with bevel facing upwards and inserted into the anterior chamber parallel to the iris plane through a track created by a 23-gauge needle. The tube was secured to the episclera with 9–0 nylon suture, and two fenestrations were made in the tube with the needle of the 9–0



**Figure 1** Lateral end of Aurolab aqueous drainage implant plate being inserted beneath the lateral rectus muscle.

suture to facilitate early egress of aqueous and prevent high IOP spikes. It was covered with a partial thickness scleral patch graft. The Tenon's capsule and conjunctiva were sutured with 8–0 Vicryl (Braided coated polyglactin 910 violet).

Postoperative antibiotics were prescribed six times daily for 1 week, and topical corticosteroids were prescribed six to eight times daily for 6–8 weeks and tapered. Antiglaucoma medications were prescribed as required for the postoperative IOP status.

The main outcome measures were the postoperative IOP, requirement of antiglaucoma medications and any adverse effects. The younger children underwent EUA at regular intervals and their IOP was measured using the Perkins tonometer. The drugs required for IOP control and any complications were recorded on prospectively filled data sheets.

### Follow-up

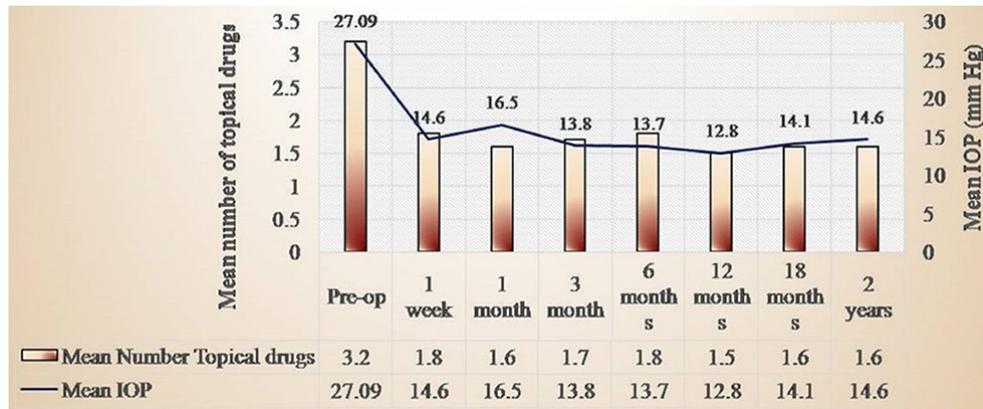
Patients were examined on the first postoperative day, first week and first month, 6 weeks and then on the third, sixth, 12th, 18th, 24th and 30th month, depending on when the surgery was done. In addition to these visits, any patient requiring to be seen depending on their ocular condition was followed up accordingly. IOP, visual acuity (where possible), corneal status, cellular reaction within the eye, status of the tube and the posterior segment were examined at each visit. Patients who did not report as per schedule were recalled telephonically and reminders were sent by post.

### Analysis

The difference between preoperative and postoperative IOP and antiglaucoma medications was analysed using the Wilcoxon signed rank test at each time point. Cumulative survival was determined using Kaplan-Meier survival analysis. The main subgroups in the cohort were children with primary congenital glaucoma (PCG) with failed initial surgery and secondary childhood glaucoma. Success in both groups was separately analysed.

### RESULTS

A total of 34 eyes of 31 children (21 boys and 11 girls) were analysed. The mean age at surgery was  $8.2 \pm 3.6$  years (range 1–14 years). A total of 19 eyes (16 children; 58.8%) had PCG, and 15 eyes of 15 children (44.2%) had secondary glaucomas including glaucoma following cataract surgery, pars plana vitrectomy,



**Figure 2** Graph showing mean number of antiglaucoma drug requirement (left: y-axis) and mean intraocular pressure (IOP) reduction (right: y-axis) over time (x-axis).

uveitis, Sturge Weber syndrome and Axenfeld Reiger syndrome. AADI was implanted as the primary glaucoma procedure in 12 eyes (11 children), where the conjunctiva was too scarred after previous surgery and trabeculectomy was likely to fail and subsequent to previous glaucoma surgery in 22 eyes.

The average follow-up was  $18.3 \pm 6.9$  months (9–36 months). A total of 29 children (32 eyes) completed 1 year follow-up; 22 (25 eyes) completed 2-year follow-up. The three children who underwent surgery in both eyes received the second AADI 7 months, 8 months and 11 months following the first surgery, respectively. All except three children (<3 years age) were cooperative for slit lamp evaluation and GAT.

### Primary outcome measures

IOP reduced from preoperative mean  $27.4 \pm 7.5$  mm Hg on maximum medication (including systemic acetazolamide) to  $14.6 \pm 10.74$  mm Hg,  $13.8 \pm 7.5$  mm Hg,  $12.8 \pm 5.6$  mm Hg and  $14.7 \pm 5.8$  mm Hg at 1 week, 6 months, 1 year and 2 years postoperatively, respectively (Wilcoxon signed rank test  $p < 0.001$  at every postoperative time point) (figure 2). Requirement of topical medications decreased from mean  $3.1 \pm 0.6$  medications preoperatively to  $1.8 \pm 1.3$  at 6 months and  $1.6 \pm 1.1$  at 24 months ( $p < 0.001$  at every time point) (figure 2). Preoperatively, 25 patients were on systemic acetazolamide and three patients were on acetazolamide and glycerol in addition to four topical antiglaucoma medication. At the end of 2 years, three patients were on systemic treatment for glaucoma.

Of the 12 eyes of 11 children who were implanted with the AADI as primary glaucoma procedure, nine eyes had secondary glaucoma. There was no difference in the IOP at baseline or at any time point in this subset of patients compared with those who had had a failed glaucoma surgery previously (table 1). The child who lost vision due to retinal detachment

had previously undergone PPV for traumatic retinal detachment and had a primary AADI. The two children who required tube trimming had PCG and had received AADI after failed trabeculectomy.

Using Kaplan-Meier survival analysis, the cumulative probability of success was 91.18% at 6 months and 81.7% at 18–24 months (figure 3). In the PCG group, cumulative success rate was 100% at 6 months, 85.7% at 12–24 months. In the secondary glaucoma group, cumulative success rates were 83% at 6 months and 78% at 12–24 months (figure 4). Log-rank test comparing survival curves by diagnostic group showed no statistically significant difference in survival between primary and secondary glaucomas ( $p = 0.46$ ).

The reasons for failure were high IOP in five eyes (necessitating cyclophotocoagulation in four eyes and a second AADI in one eye) and retinal detachment in one eye. The mean BCVA did not show any statistically significant change at final follow-up visit from preoperative levels.

### Secondary outcome measures

The safety profile of the AADI was excellent. One patient lost vision after he developed retinal detachment, which progressed on to PVR and phthisis bulbi. Other complications were not sight threatening and could be managed successfully. In the first week, four patients had hyphaemia and two had transient hypotony, all of which resolved with conventional treatment. At 3 months, two children required trimming of the tube of the AADI which had pushed into the anterior chamber towards the pupillary margin. One child required tube repositioning due to tube-corneal touch. One child had conjunctival retraction requiring resuturing. By 6 months, three children developed a cataract and underwent cataract extraction.

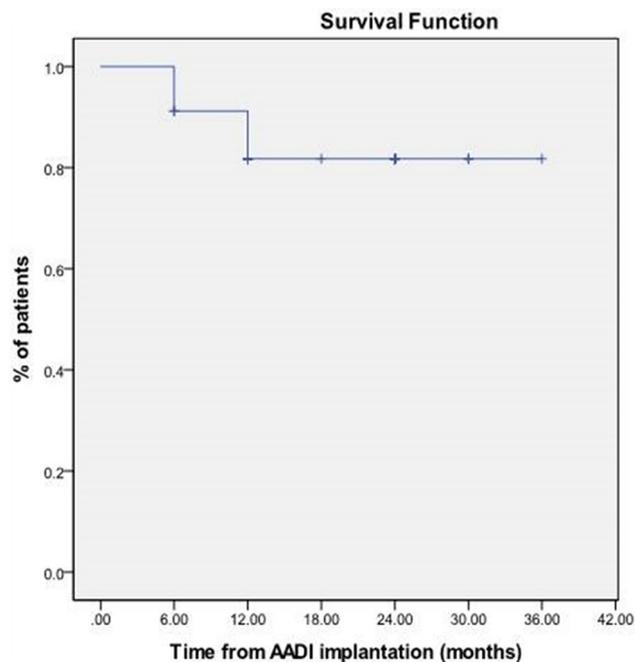
There was no tube erosion or infection in any patient.

**Table 1** IOP over time in patients implanted with AADI as primary glaucoma surgery compared with those where it was after previously failed glaucoma surgery

|   | Baseline IOP (mm Hg), mean $\pm$ SD | IOP 3 months (mm Hg), mean $\pm$ SD | IOP 6 months (mm Hg), mean $\pm$ SD | IOP 1 year (mm Hg), mean $\pm$ SD | IOP 2 years (mm Hg), mean $\pm$ SD |
|---|-------------------------------------|-------------------------------------|-------------------------------------|-----------------------------------|------------------------------------|
| Primary AADI (n=12)                         | 25.7 $\pm$ 8.8                      | 13.6 $\pm$ 10.1                     | 11.0 $\pm$ 4.7                      | 12.6 $\pm$ 4.9                    | 15.0 $\pm$ 4.8                     |
| AADI after previous glaucoma surgery (n=22) | 27.8 $\pm$ 6.5                      | 13.9 $\pm$ 6.1                      | 15.3 $\pm$ 7.7                      | 12.9 $\pm$ 6.0                    | 14.5 $\pm$ 6.3                     |
| p*  | 0.261                               | 0.488                               | 0.102                               | 0.951                             | 0.447                              |

\*Mann-Whitney U test.

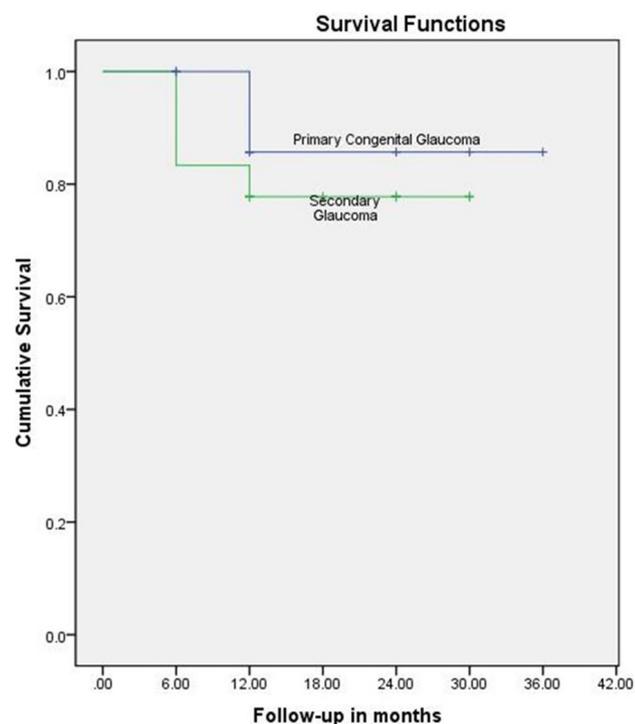
AADI, Aulrolab aqueous drainage implant; IOP, uncontrolled intraocular pressure.



**Figure 3** Cumulative probability of success over time for all patients with paediatric glaucoma who received the AADI (Kaplan-Meier life table analysis). AADI, Aurolab aqueous drainage implant.

## DISCUSSION

Medical therapy in refractory childhood glaucoma is difficult and IOP reduction is often sub-optimal. These children most commonly undergo trabeculectomy with antifibrotic agents such as mitomycin C (MMC) to counter the excessive healing



**Figure 4** Cumulative probability of success over time for patients with primary congenital glaucoma versus secondary childhood glaucoma who received the AADI (Kaplan-Meier life table analysis). AADI, Aurolab aqueous drainage implant.

response seen in young patients.<sup>17–19</sup> However, there is concern of a higher risk of complications with MMC in the paediatric age group<sup>20 21</sup> Beck *et al*,<sup>22</sup> on the other hand, compared the outcomes of children 24 months of age or younger, treated with aqueous shunt devices (AGV or BGI) or trabeculectomy with MMC. They found that GDD implantation resulted in greater IOP control but was also associated with a higher likelihood of postoperative complications requiring surgical revision, most commonly tube repositioning.

The cost of the GDDs available is prohibitive to large sections of the poor in the developing world. Professor George Baerveldt authorised the use of his highly successful design (350 mm<sup>2</sup> plate), for developing the AADI from Aurolabs, Madurai, India. The AADI is Conformité Européenne (CE) approved and is available in the countries of Africa and South East Asia at a fraction of the cost of the BGI. Our study indicates that the AADI appears to be an effective GDD with effectiveness and safety profile comparable with published reports of the Baerveldt and AGV implants for childhood glaucoma.<sup>10–16</sup> This is likely to be a boon for patients hitherto unable to afford a GDD.

A summary of published studies of the BGI in childhood glaucoma is shown in [table 2](#), with a comparison with our results. Our study compares favourably with these studies. All others were retrospective reviews of charts while we prospectively followed up all our patients. We found the efficacy at 1 year to be more than 90%, which dropped to 82% at 2 years. This is similar to that reported in previous studies using the BGI in children.<sup>10–16</sup>

The safety profile of the AADI was comparable with apparently lesser number of sight-threatening complications (one retinal detachment and no endophthalmitis or tube exposure), though that could be because of the comparatively shorter follow-up period.

Though a better study design to study non-inferiority would be a randomised controlled trial between the BGI and AADI, such a study was not possible because the BGI is not available for use in India. In addition, randomisation would have been difficult, since the BGI would be implanted in children whose parents could afford the device.

It is not clear whether a better surgical outcome is seen in congenital glaucoma compared with other childhood glaucoma diagnoses.<sup>23</sup> Because of possible increased infection risks associated with contact lens wear in patients after trabeculectomy, tube shunt surgery offers a viable alternative in patients with aphakia. We analysed our patients with primary glaucoma and secondary glaucoma. Though there appeared to be a better success rate for the refractory PCG group, the difference did not reach statistical significance.

Limitations of the study include the non-homogenous group with varied diagnoses and non-uniform earlier treatments. However, the numbers are too small to draw meaningful conclusions towards the reasons for failure of IOP control in five patients. Another drawback is the relatively short follow-up period. Considering that we are dealing with childhood glaucoma, with many children <5 years of age, a 2-year follow-up may mean very little in terms of visual preservation in their lifetime. More numbers with longer follow-ups are required to assess the true usefulness of the AADI in managing this difficult cohort of patients.

The patient population of this study was young children, who are notorious for failures of repeat trabeculectomy. Additionally, excessive use of antifibrotic agents like MMC is best avoided. The indications for GDD implantation cannot necessarily be extrapolated to an adult population where trabeculectomy

**Table 2** Published studies of the Baerveldt glaucoma implant for refractory childhood glaucoma

| Parameters                           | Our study                                   | Mandalos <i>et al</i> <sup>15</sup><br><i>J Glaucoma</i> , 2016 | Tai <i>et al</i> <sup>14</sup><br><i>JAAPOS</i> , 2014 | Van Overdam <i>et al</i> <sup>12</sup><br><i>Br J Ophthalmol</i> , 2006 | de Moura <i>et al</i> <sup>13</sup><br><i>Am J Ophthalmol</i> , 2005 | Budenz <i>et al</i> <sup>11</sup><br><i>Ophthalmology</i> , 2004               |
|--------------------------------------|---|---|--|---|--|--|
| Study design                         | Prospective, non-comparative                | Retrospective, non-comparative                                  | Retrospective, non-comparative                         | Retrospective, non-comparative  | Retrospective, non-comparative                                       | Retrospective, non-comparative   |
| GDD used                             | AADI (ligature)<br>No stent/MMC             | BGI or Molteno stent; MMC                                       | BGI  | BGI   | BGI  | BGI (50–1 stage; 12–2 stage)   |
| Patients                             | <16 years<br>(31 eyes; 34)                  | <18 years<br>(69 eyes; 52)                                      | <19 years<br>(46 eyes; 35)                             | <16 years<br>(55 eyes; 40)  | <16 years<br>(48 eyes; 48)   | <18 years<br>(62 eyes; 62)   |
| Average age                          | 8.22 ± 3.61 years                           | 8.3 ± 5.1 years   | 5 months to 19 years                                   | 3.3 ± 3.6 years   | 4.1 ± 4.9 years  | 6.5 ± 5.2 years  |
| Study period                         | 2013–2015                                   | 2004–2011   | 2000–2010  | 1998–2003   | 1990–1999  | Not defined  |
| Minimum follow-up                    | 6 months                                    | 6 months  | 3 months   | 2 months  | 4 months   | 6 months   |
| Average follow-up                    | 18.3 ± 6.9 months                           | 45.7 ± 25.2 months  |  | 31.9 ± 18.9 months  | Median 21 months   | 24.8 ± 2.5 months  |
| Efficacy (success rates)             | 100%, 6 months<br>91.18%, 1 year            | 95.6%, 1 year<br>71.3%, 5 years                                 | 93.3%, 3–9 months<br>86.7%, 1 year                     | 94%, 1 year<br>94%, 2 years   | 95.0%, 6 months<br>90.5%, 1 year                                     | 87%, 6 months<br>82%, 1 year   |
| IOP 6–21 mm Hg)                      | 81.7%, 18 months<br>81.7% 2 years           | 39.7%, 8 years  | 86.7%, 2 years   | 85%, 3 years<br>78%, 4 years  | 87.2%, 18 months<br>83.7%, 2 years<br>74.4% 3 years                  | 68%, 2 years   |
| Complications requiring intervention | Cataract: 3 (8.8%)<br>Retinal detachment: 1 | Cataract: 23%<br>Encapsulation: 16.4%<br>Endophthalmitis: 5.8%  | BGI replacement: 2<br>No LP: 1                         | Cataract: 3<br>Phthisis: 2  | Cataract: 10%<br>Vitreous haemorrhage: 8.3%<br>Retinal detachment: 2 | Tube exposure: 1<br>Retinal detachment: 5<br>Endophthalmitis: 1<br>Phthisis: 1 |

AADI, AuroLab aqueous drainage implant; BDI, Baerveldt glaucoma implant; GDD, glaucoma drainage device; MMC, mitomycin C.

revisions or repeat trabeculectomy may be a viable option in many of the situations where we implanted the AADI. It must also be remembered that this study was carried out in a specialty paediatric glaucoma clinic. Examining children is a challenge and often requires general anaesthesia for meticulous postoperative follow-up, which may not be readily available in other settings.

Our study shows that the AADI appears to be an effective GDD with effectiveness and safety profile comparable with published reports of the BGI and AGV implant. It promises to be a viable low-cost solution for patients with refractory glaucoma.

**Contributors** All authors made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work. SK accepts full responsibility for the work and/or the conduct of the study, had access to the data and controlled the decision to publish. SK and PK: Drafting the work or revising it critically for important intellectual content. SK and SSP: Final approval of the version to be published. SK, PK, SR, JR: Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

**Competing interests** None declared.

**Ethics approval** Institute Ethics Committee, PGIMER, Chandigarh, India.

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