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Safety and efficacy of Aurolab aqueous drainage implant in refractory glaucoma: A prospective study

Jayasri P, Subashini Kaliaperumal, Geeta Behera, Mary Stephen

Purpose: This study was conducted to assess the intraocular pressure (IOP) control and postoperative complications following a non-valved glaucoma drainage device (GDD) surgery in refractory glaucoma. **Methods:** This was a prospective interventional study conducted on patients with glaucoma refractory to maximal medications or failed surgical treatment who underwent Aurolab aqueous drainage implant (AADI; Aurolabs, India) surgery. Primary outcome measures were IOP control, postoperative complications, and reduction in the number of antiglaucoma medications (AGM). **Results:** Thirty-four eyes were analyzed and the mean follow-up was 16.06 ± 5.63 months. The preoperative median (Q1, Q3) IOP was 31 mmHg (28, 36.5) which decreased to 12 mmHg (12, 14) at 6 months postoperatively. The median (Q1, Q3) number of AGMs decreased from 3 (3, 4) to 0 (0, 1). Significant complications like implant extrusion and tube exposure were noted in two eyes. The total success and failure rates at 6 months were 91.1% and 8.8%, respectively. **Conclusion:** AADI is effective in achieving target IOP and significantly reduces the use of AGMs with good safety in the short term. Long-term follow-up studies are needed to assess long-term IOP control and cost-effectiveness.

Key words: Aurolab aqueous drainage implant (AADI), glaucoma drainage device, glaucoma surgery, intraocular pressure (IOP), refractory glaucoma

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Glaucoma is the second most common cause of irreversible blindness worldwide. Refractory glaucoma is defined as uncontrolled intraocular pressure (IOP) with evidence of optic nerve and/or visual field deterioration despite maximally tolerated antiglaucoma medications, failed surgical treatment, or a combination of both, or a high risk of failure of trabeculectomy.[1]

Glaucoma drainage device (GDD) implantation was traditionally reserved for multiple failed trabeculectomies but is now evolving as the initial choice of surgery in refractory glaucoma.[2] These devices, which consist of a plate and a tube, create an alternate pathway by shunting aqueous to the equatorial plate through a tube inserted into the anterior chamber or vitreous cavity or the ciliary sulcus. A bleb forms around the plate which is sutured to the sclera posteriorly.

Cost is the main factor limiting the use of tube shunts in India. There are valved devices like Ahmed Glaucoma valve and non-valved ones like Molteno, Baerveldt, etc., which are useful when medications and conventional surgery fail to control the intraocular pressure. The popular valved device, Ahmed Glaucoma Valve (AGV) is used in refractory cases, but an encapsulation of bleb resulting in high IOP later is a major problem.[3] Aurolab aqueous drainage implant (AADI; Aurolab, India) is a low-cost non-valved drainage device designed on the principle of Baerveldt glaucoma implant with a large surface area of 350 mm^2. It has been commercially available for clinical use since June 2013.

Department of Ophthalmology, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, India

Correspondence to: Prof. Subashini Kaliaperumal, Department of Ophthalmology, JIPMER, Puducherry - 605 006, India. E-mail: subadoc@gmail.com

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There are a few Indian studies related to the use of AADI for refractory glaucoma but most of them are retrospective.[4-10] We report the results of a prospective study on the safety and efficacy of the AADI implant at our center. Its lower cost and easy availability were important considerations in our choice.

Methods

This was a prospective interventional study conducted between August 2019 and December 2021 after receiving approval from the Institutional Ethics Committee and the study adhered to the principles of the declaration of Helsinki. All participants were recruited after informed consent. Patients with refractory glaucoma such as multiple failed trabeculectomies, aphakic glaucoma, pseudophakic glaucoma, neovascular glaucoma, congenital glaucoma, post-traumatic glaucoma, post-penetrating keratoplasty glaucoma, post-vitreoretinal surgery glaucoma, uveitic glaucoma, extensive conjunctival scarring, and pseudo-exfoliation glaucoma were included in the study. Eyes, where applanation tonometry was not possible were excluded from the study.

After recording basic demographic details of the patients, all patients underwent a comprehensive ophthalmological examination including best-corrected visual acuity (BCVA), slit-lamp examination of the anterior segment, and intraocular

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pressure (IOP) by applanation tonometry, and fundus for optic disc evaluation. These patients underwent AADI implantation. All surgeries were performed by a single fellowship-trained glaucoma surgeon with more than 15 years of experience in the use of various implants (Ahmed, Baerveldt and Molteno implants). All surgeries were performed under a peribulbar block.

Surgical technique

A silk traction suture was passed through the superior and lateral recti muscles to expose the scleral bed in the superior-temporal quadrant of the eye after conjunctival peritomy. Priming of the AADI implant was done using a 30-G cannula to check the patency of the tube. The external plate was tucked posteriorly into the sub-tenon space and sutured to the sclera with 8-0 nylon suture through the anterior positional holes of the plate 8 mm behind the limbus [Fig. 1]. The tube was ligated with a 7-0 or 6-0 polyglactin (vicryl) suture near the tube-plate junction. The polyglactin suture reliably lyses 4–6 weeks postoperatively, causing the spontaneous opening of the tube. Venting of the tube was done with 2–4 cuts by a spatulated needle of 10-0 nylon suture to prevent the initial hypertensive phase. The tube was cut and bevel-up to permit its extension 2–3 mm into the anterior chamber. The tube was inserted through the needle track created using a 23-G bent needle 3 mm from the limbus. It was ensured that the tip of the tube was not touching the cornea or the iris. The tube was anchored to the sclera with an 8-0 nylon suture and then covered with a scleral patch graft measuring approximately 4 × 4 mm sutured with interrupted vicryl sutures. The conjunctiva was re-approximated to the limbus with vicryl sutures.

All patients were scheduled for postoperative follow-ups on day 1, and 1 week, 1 month, 3 months, 6 months, 9 months, and 12 months after surgery. Common postoperative complications like choroidal detachment, corneal decompensation, macular edema, aqueous misdirection, anterior uveitis, ocular hypotony, tube exposure, tube retraction, tube occlusion, retinal detachment, and failure of procedure were assessed.

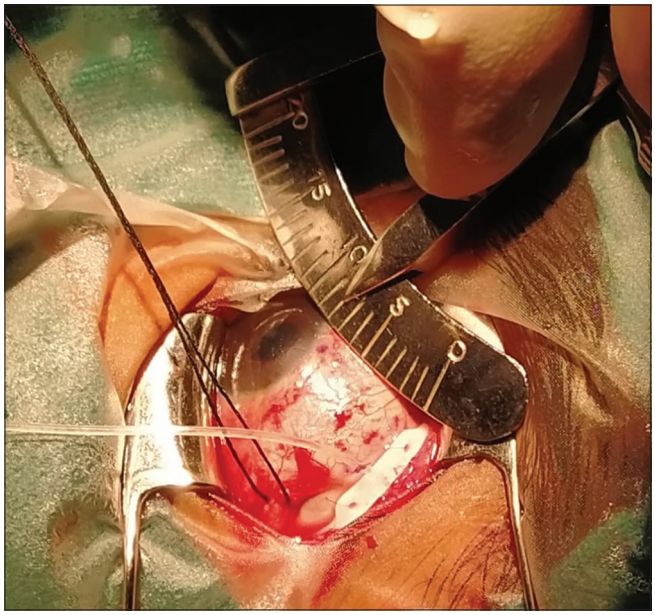

Figure 1: Intraoperative image of AADI implantation

Complete success was defined as IOP of ≥5 mmHg and ≤18 mmHg without any AGM, without any sight-threatening complications, or additional glaucoma procedure (surgery/laser) at the 6-month follow-up visit. Qualified success was achieved if similar IOP control was attained with 1 or 2 topical AGM, without any sight-threatening complications or no additional glaucoma procedure (surgery/laser) and vision loss not progressing to nil perception of light; Treatment failure was when IOP was <5 mmHg or >18 mmHg and required 3 or more topical or systemic AGM, presence of sight-threatening complications, or additional glaucoma procedure, or vision loss progressed to nil perception of light.

The primary outcome measures were IOP, the number of antiglaucoma medications, and postoperative complications. Study participants were categorized into complete success/qualified success/treatment failure based on the above-mentioned criteria.

Sample size estimation

By comparing two dependent means and considering a minimum expected difference in IOP as 5 mmHg preoperatively and 3 months postoperatively with a standard deviation of 10 mmHg at a 95% level of confidence with a power of 80%, the sample size was calculated to be 31. Considering a 10% attrition rate, the required number of study participants was 34.

Statistical analysis

All statistical analyses were performed using the Statistical Package for the Social Sciences program (IBM SPSS version 28.0). The normality of the variables was tested using the Kolmogorov–Smirnov test and tests of significance were applied accordingly. Descriptive data were presented as median and quartiles (Q1 and Q3). Quantitative data at each time point of follow-up were compared using the Friedman ANOVA test. Pairwise comparison of quantitative variables between preoperative and 6 months postoperative visits was performed using the Wilcoxon signed-rank test. Survival analysis was performed for the failure of surgery as a censoring variable. The Kaplan–Meier curves were plotted to depict survival at different time points.

Results

Thirty-four eyes of 31 patients were assessed. The median age of study participants was 51.50 years (Q1, Q3; IQR: 40, 53; 13). Minimum age was 4 years and maximum age was 70 years. The average follow-up duration was 16.06 ± 5.63 (range: 8–24 months). The baseline characteristics of the study participants are given in Table 1. The etiologies of glaucoma preoperatively are shown in Table 2. The median preoperative IOP was 31 mmHg in 91% of the study participants requiring 3 or more AGMs. Around 76.5% had undergone previous glaucoma filtration surgery and 23.5% underwent AADI as the primary surgery.

The reduction in IOP and number of antiglaucoma medications between preoperative and 6 months postoperative period was statistically significant ($P < 0.001$) and is represented in Table 3. A significant reduction in IOP and AGM was noted at 1-month postoperatively, which is the time when the ligating suture lyses and the device becomes fully functional. The percentage of occurrence of early (<3 months) and late (>3 months) complications are represented in Table 4.

Hypotony was the most common complication noted in the early postoperative period. The choroidal detachment was noted in three eyes in the first 3 months. All cases were successfully managed medically with steroids. Extraocular motility restriction was noted in three eyes in the early postoperative period which was self-resolving. Tube erosion was noted in one eye which was treated with the placement of another scleral patch graft [Fig. 2a and 2b]. Tube repositioning and AC formation were done in one eye. Corneal decompensation was noted in two eyes leading to a significant decrease in vision.

Table 1: Preoperative (Pre-op) characteristics of participants

Variable	*n*=34
Pre-op IOP (mmHg) Median, (Q1, Q3)	31, (28,36.5)
Pre-op AGM, Median, (Q1, Q3)	3, (3,4)
Previous filtration surgery (Mean±SD)	1.15±0.92
Pre-op visual acuity (LogMAR) (Mean±SD)	1.49±1.25
Previous surgeries (*n*, %)	
Trabeculectomy with MMC	26, 76.5%
Laser iridotomy	3, 8.8%
Phacoemulsification with intraocular lens implantation	22, 64.7%
Pars plana vitrectomy	2, 5.9%
Penetrating keratoplasty	2, 5.9%

IOP: Intraocular pressure; AGM: Anti-glaucoma medications; SD: Standard deviation; MMC: Mitomycin C

Table 2: Etiology of glaucoma in the study participants

Etiology of glaucoma	*n*, %
Refractory primary glaucoma	
Refractory primary open-angle glaucoma	10, 29.4%
Refractory primary angle-closure glaucoma	3, 8.8%
Primary congenital glaucoma	3, 8.8%
Developmental glaucoma	2, 5.9%
Refractory juvenile open-angle glaucoma	1, 2.9%
Refractory secondary glaucoma	
Neovascular glaucoma	6, 17.6%
Post-traumatic glaucoma	2, 5.9%
Post-penetrating keratoplasty glaucoma	2, 5.9%
Pseudophakic glaucoma	3, 8.8%
Aphakic glaucoma	1, 2.9%
Post-endophthalmitis glaucoma	1, 2.9%

Table 3: Comparison of baseline and follow-up in IOP and number of AGMs

	n at each visit	IOP in mmHg Median (Q1, Q3)	Number of AGM Median (Q1, Q3)
Pre-op	34	31 (28, 36.5)	3 (3, 4)
POD 1	34	28 (25.5, 30.5)	3 (3, 3.2)
POW 1	34	24 (21.5, 28)	3 (3, 2)
POM 1	34	20 (15.8, 24)	2 (1, 3)
POM 3	34	15.5 (12, 18)	1 (0,2)
POM 6	34	12 (12, 14)	0 (0, 1)
POM 9	34	14 (10, 15)	0 (0, 1)
POM 12	26	12 (10, 14)	0 (0, 1)
P value*		<0.001	<0.001

IOP: Intraocular pressure; AGM: Antiglaucoma medications; POD: Post-op day; POW: Post-op week; POM: Post-op month; *P* value of <0.05 was considered significant

The median LogMAR BCVA did not show any change postoperatively. None progressed to loss of light perception. The total success rate at the end of 6 months was 91.1% (complete success being 67.6% and qualified success being 23.5%). The failure rate at 6 months was 8.8%. Failure was due to loss of vision criterion. The Kaplan–Meier estimates show that the cumulative probability of failure was 8.8% (95% CI, 20–23.83). The Kaplan Meier survival plot for cumulative failure at various time points is shown in Fig. 3.

Discussion

Glaucoma is a chronic progressive disease of the optic nerve requiring life-long care. The cost of treatment, need for lifelong follow-up, and use of multiple topical and/or systemic antiglaucoma medications are cumbersome and affect the patient's quality of life. In cases of refractory glaucoma, particularly after failed trabeculectomy or extensive conjunctival scarring, and/or ongoing chronic inflammation, there is a high risk of repeat trabeculectomy failure. In these refractory cases, tube shunt surgery is the preferred modality of treatment as shown by the TVT study.[11–13]

In our prospective study, we found that AADI is effective in lowering IOP and reducing the need for AGM in refractory cases. We also found that the rate of significant complications is low in the short term. Most complications were transient and treated with medical management. We attained a complete success rate of 67.6% and a total success rate of 91.1% at the end of 6 months.

There are a few studies on the efficacy of AADI, only one of which is a prospective study comparing AADI and AGV with 19 patients in each group.[3] Being a cost-effective treatment for refractory glaucoma, AADI warrants prospective studies with longer follow-up. The IOP reduction of 12 mmHg (10,15) and reduction of AGMs to 0 (0, 2) at 6 months is comparable to the results published by Ray *et al*.[8] Our total success rate of 91.1% was slightly higher in comparison (87.5%), even with a more stringent cutoff of <18 mmHg as compared to theirs, which was <21 mmHg. However, 85% of their study participants had secondary glaucoma as compared to 44% in our report, which may be the reason for a lower success rate. Rathi *et al*.[3] published

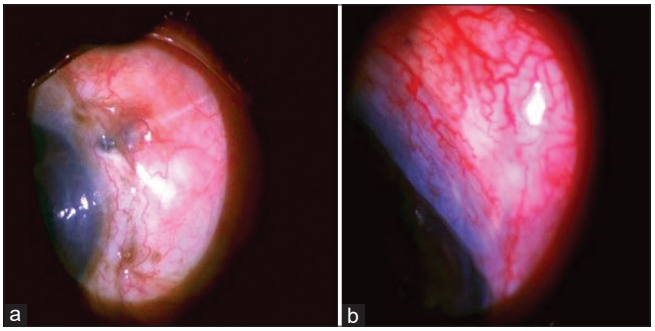

Figure 2: (a) Tube erosion and (b) surgical correction with scleral patch graft

Table 4: Summary of early and late complications

Complications	*n* (%)
Early Complications (< 3 months) *n*=34 eyes	
Transient hypotony	2 (5.8%)
Transient hypotony with choroidal detachment	3 (8.8%)
Extraocular motility restriction	3 (8.8%)
Anterior uveitis	3 (8.8%)
Choroidal detachment	3 (8.8%)
Corneal decompensation	2 (5.9%)
Tube exposure	1 (2.9%)
Late complications (>3 months)	
Corneal decompensation	1 (2.9%)
Plate extrusion	1 (2.9%)
Total	19 (56%)

A total of 19 events were noted in 10 eyes

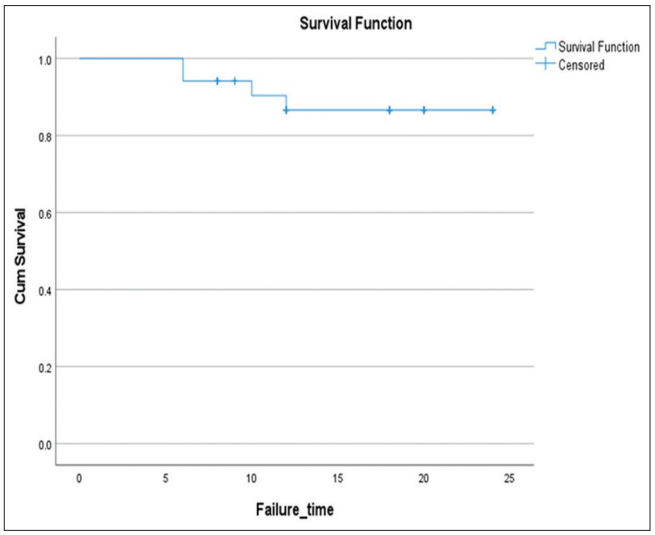

Figure 3: Kaplan–Meier survival plot for cumulative failure at various time points

a prospective RCT comparing AADI and AGV and reported complete success of 73.6% in the AADI group at 6 months. However, their sample size was lower with only 19 eyes in the AADI group. Puthuran *et al*.[4] showed similar IOP reduction in adult refractory glaucoma in their retrospective study. Their cumulative failure rate was 9.5% at 1 year and was found to increase in the long-term being 50.1% at 4 years. Our study showed a similar failure rate in the short term, but long-term follow-up results are awaited. Kaushik *et al*.[9] in 34 eyes of refractory childhood glaucoma reported IOP reduction similar to ours with a cumulative success rate of 91.18% at 6 months. However, they did not define the success criteria in their report.

Intraoperatively, no significant complications occurred. We noted 19 events of early and late complications in 10 eyes. Some eyes had more than one complication. All have been listed separately in Table 4. Thus, the total rate of complications was 56%. However, most were either transient or resolved on medical management, one of the 19 cases required repeated interventions and two were designated as failure.

In the early postoperative period (less than 3 months), transient hypotony was noted in two eyes (5.8%) and hypotony with serous choroidal detachment in three eyes (8.8%). However, both were resolved with medical management. These complications were noted during the one-month postoperative period which fairly corresponds to the time when the ligating suture is absorbed. Rathi *et al*.[3] reported ocular hypotony as the commonest complication in the early postoperative period (26.3%) which was higher than our study (14.7%). They also noted choroidal hemorrhage in two eyes which we did not encounter.

Ray *et al*.[8] reported the most common early complication was a conjunctival retraction in 11.4% requiring additional surgery using conjunctival autograft. However, we did not encounter this. We noted extraocular motility restriction in three eyes in the early postoperative period which was transient and resolved over a few weeks. Extraocular motility restriction results because the wings of the 350 mm^2 AADI mechanically restricts the actions of the superior and lateral rectus when placed superotemporally. This can be avoided by tucking the wings under the muscle insertions. Motility disturbance was noted in one of 19 participants in the AADI group of Rathi *et al*.[3]

Anterior uveitis was observed in three eyes with fibrin reaction (two of the patients with hypotony), which subsided with steroids and cycloplegics. Steroids were continued for up to 3 months in these patients due to the higher inflammation. In all the other patients, topical steroids were tapered by 8 weeks.

Other complications noted were tube exposure in one eye (2.94%) at 3 months requiring repeat scleral patch graft placement. Corneal decompensation was noted in two eyes (7.14%), both designated as surgery failure due to eventual loss of vision. Of them, one was post-penetrating keratoplasty glaucoma who eventually had graft failure and IOP was controlled without medications. The other was a case of advanced diabetic eye disease with neovascular glaucoma who had early-onset hypotony (referred to earlier) and developed corneal decompensation at 6 months. This patient also had a plate extrusion (2.94%) and progressed to phthisis bulbi. Plate exposure was reported in two eyes in the study by Ray *et al*.[8] Tube exposure was reported in one eye by Rathi *et al*.[3] in the early postoperative period. They too reported graft failure in post-penetrating keratoplasty eyes in two cases, requiring repeat keratoplasty. However, they did not report any case of phthisis bulbi.

No other significant vision-threatening complications like retinal detachment, endophthalmitis, or aqueous misdirection syndrome were noted in our study. There was no requirement for additional glaucoma surgery/laser in our study. There was one case of repeat scleral patch graft done for tube exposure which was far lower than that of repeat procedures for complications reported previously (25%).[8]

In children with refractory glaucoma, pediatric-sized GDD is recommended. However, the failure rates are high due to encapsulated bleb following the use of valved GDD (Ahmed Glaucoma valve -FP 8, the surface area of 98 mm^2).[3] We performed AADI implantation in 5 (14.7%) pediatric eyes; all showed good IOP control with two of them requiring antiglaucoma medications, thus being as qualified successes. We implanted the same 350 mm^2 surface area plate as in adult eyes and did not find any difficulty. A prior study reported a

higher success rate with the AADI, compared to the AGV, and a higher occurrence of encapsulated blebs with AGV.[3]

Although the AADI is designed on the principle of Baerveldt glaucoma implant (BGI), no studies compare the BGI with AADI due to non-availability and cost. A retrospective review of the intermediate-term outcomes of BGI in Asian eyes by Seah *et al*.[14] had shown similar IOP reduction as ours, with a complete success of 54% and qualified success of 22%. Their failure rate was 24%, which is much higher compared to ours (8.8%) which may be due to a greater proportion of refractory secondary glaucoma.

The strengths of our study were its prospective study design and surgeries performed by a single glaucoma surgeon, thereby eliminating the differences in surgical methods.

The limitation of the study was the short-term follow-up. The indications were variable types of glaucoma which could be a confounding factor affecting results. We could not compare the results from differences in tube placement in different quadrants due to the small sample size. Also, we did not perform pars plana or sulcus insertion of a tube in any patients. We did not perform a cost–benefit analysis either.

Conclusion

The AADI is effective in achieving target IOP and significantly reduces the use of anti-glaucoma medications with a lesser occurrence of sight-threatening complications. Future research should aim at long-term follow-up and cost–benefit analysis with other procedures and devices.

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Conflicts of interest

There are no conflicts of interest.

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