Intermediate-term outcomes of pars plana tube insertion of Aurolab aqueous drainage implant for refractory glaucoma

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ABSTRACT

Purpose To report the safety and efficacy of parsplana tube insertion of Aurolab aqueous drainage implant(AADI) in patients with refractory glaucoma.

Methods Charts of patients with refractory glaucoma who underwent AADI via the parsplana route between June 2014 and June 2018with a minimum follow-up of 6 months were retrospectively reviewed. Success was defined as complete when the intraocular pressure (IOP) was ≥5 and18 mmHg or IOP reduction was ≥30%from baseline without antiglaucoma medication (AGM) andas qualified if requiring additional AGMs.

Results The study included 63 eyes of 63 patients with a mean age of 36.1±20.6 years and a mean follow-up of 19.7±15.7 months. Glaucoma postvitreoretinal surgery was the the most common aetiology (22 eyes, 35%). The mean IOP reduced from 36.6±10.7 mmHg to15.7±8.2 (57.1%), 15.02±7.3 (60%) and 17.2±8.5 mmHg (53%) at 6 months and 1 and 2 years, respectively. Kaplan-Meier estimates showed that the cumulative probabilities of failure were 8% (95% CI4.3% to 22.4%) at 6 months, 23% (95%CI12.8% to 38.6%) at 1 year, 30% (95%CI17.4% to 45.9%) at 18 months and 47% (95% CI13.4% to 64.9%) at the 2 years time points.Vitreous blocking tube tip was noted up to 8% of eyes on follow-up.

Conclusion Pars plana AADI insertion is a useful procedure for the control of IOP in patients with refractory glaucoma.

INTRODUCTION

Glaucoma drainage devices (GDDs), are an increasingly popular surgical option in the management of complex glaucoma, which cannot be managed by medical treatment and/or conventional surgical treatments with adjunctive antifibrotic agents.[1 2] GDDs are of two types: non-valved (Molteno, Baerveldt glaucoma implant(BGI)) and valved (Ahmed glaucoma valve (AGV)),both of which share a common design of a tube that shunts aqueous humour from the anterior chamber to an endplate located at the equatorial region of the globe, thereby reducing intraocular pressure(IOP).[3] Pars plana insertion of GDD into the vitreous cavity is regarded as a treatment option when anterior chamber complications are anticipated based on anatomical considerations, such as a shallow anterior chamber with compromised endothelial cell function as in iridocorneal endothelial syndrome, aphakia, penetrating keratoplasty, vitreous in the anterior chamber, concomitant need for retinal surgery or an extensive anterior staphyloma with scarring.[4–7]

The Aurolab aqueous drainage implant (AADI; Aurolab, Madurai, India) is a relatively new, non-valved, low-cost GDD, similar in design to the BGI, that has been in use for refractory glaucomas over the past few years.Though there have been evolving literature on the safety and efficacy of the AADI in controlling refractory glaucomas,[8–13] all studies report on the outcomes following insertion of the AADI tube into the anterior chamber. The purpose of this study was to evaluatethe effectiveness of AADI when implanted in the pars plana in terms of IOP control, reduction in the antiglaucoma medications (AGMs) and the associated complications and resurgeries.

METHODS

Case records of patients who underwent AADI tube insertion via the parsplana route into the vitreous cavity between June 2014 and June 2018 for glaucoma refractory to maximal tolerated medical therapy, failed trabeculectomy or secondary glaucomas identified as high risk for trabeculectomy failure were collected from a computerised database, and data of those patients with a minimum of 6 months' follow-up were included in the analysis. Patients with either prior vitrectomy or combined AADI with vitrectomy or silicone oil removal were all included in the study. The combined surgeries were all performed by a senior vitreoretinal surgeon(NB) and a senior glaucoma surgeon(GVP). Our earlier publication on outcomes of AADI surgery in adult refractory glaucoma had included only patients with tube placement in the anterior chamber.[8]

Baseline demographic and clinical information were collected from the selected patients' case-sheets. The IOP, number of AGMs, BCVA, complications and resurgery, if any, were recorded at months 1, 3, 6, 12 and 6 monthly thereafter.

The indications for pars plana tube placement in our cohort were a shallow or non-existent anterior chamber to permit insertion of the tube between the iris and the cornea, or the concomitant need for vitreoretinal surgery, or where the corneal endothelium was compromised, or when there was extensive conjunctival scarring at the limbus due to multiple previous intraocular surgeries.

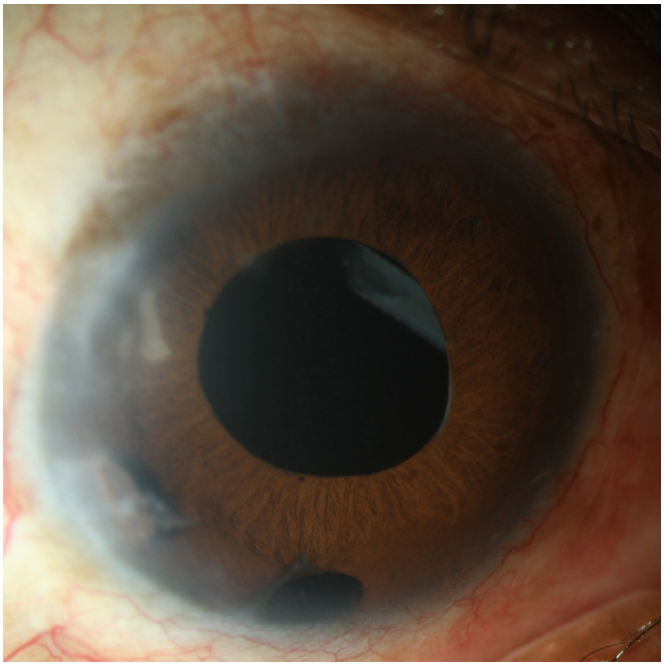

Figure 1 Postoperative slit-lamp photograph of a patient who underwent combined pars plana vitrectomy and pars plana implantation of Aurolab aqueous drainage implant. The tube was trimmed so that its tip is visible in the pupillary area.

SURGICAL METHOD

The technique of AADI surgery is already described elsewhere.[8] After securing the explant to the sclera and achieving watertight tube closure, the tube was trimmed 3.5 mm anterior to the limbus with the bevel facing up (figure 1 and online supplementary video).

Table 1 Baseline demographic and clinical characteristics

Number of eyes	N=63
Age (years), mean±SD	36.1+20.6
Gender,male:female	44:19
% males	–70%
Follow up (months), mean±SD	19.7±15.7
Median BCVA in logMAR units(Snellen equivalent)	0.78 (6/36) (IQR 0.48–1.48)
Median preoperative IOP (mm Hg)	38(IQR28–44)
Median number of AGM	3 (IQR 3–4)
Lens status,n (%)	
Phakic	12(19)
Pseudophakic	20 (32)
Aphakic	31 (49)
Previous intraocular surgery, n (%)	
Trabeculectomy	3 (5)
Postkeratoplasty	7 (11)
Pars plana vitrectomy	26 (41.3)
Cataract extraction	15 (24)
AADI	2 (3)
Corneal tear repair	1 (1.6)
None	9 (14)

AADI, Aurolab aqueous drainage implant; AGM, antiglaucoma medicine; BCVA, best-corrected visual acuity; IOP, intraocular pressure; logMAR, logarithm of minimum angle of resolution.

A simultaneous 25G pars plana vitrectomy was done(Constellation Vision System, Alcon Laboratories, Texas, USA) in all cases that did not have prior complete vitrectomy.Triamcinolone acetonide (4 mg/0.1 mL, Aurocort; Aurolab, Madurai, India) was used to create a posterior vitreous detachment to prevent postoperative tube occlusion by residual vitreous. Particular attention was given to vitreous base shaving in the area where the AADI tube was to be placed. In case of AADI placed in the superotemporal quadrant following vitrectomy,the superotemporal sclerotomy used for pars plana vitrectomy (PPV) was used to insert the tube into the vitreous cavity to have at least 4–6 mm of tube intravitreally. In case the AADI was placed in the inferonasal quadrant, a sclerotomy was created 3.5 mm behind the limbus for tube placement. Alternatively, in silicone oil-filled eyes,oil removal was done by active aspiration followed by multiple fluid air exchanges, and the retina was inspected at the end in all quadrants. At the end of the procedure, all ports were secured with 7–0 polyglactin suture (braided,coated polyglactin 910 violet; Ethicon,Johnson and Johnson, India).

The tissue patch graft over the tube entry site, the tube fenestrations and the conjunctival closure were done as described earlier.[8]

Postoperatively, topical steroids were given two hourly for a week and then tapered over 90 days; topical antibiotics were administered for a month with cycloplegic eye drops and and IOP-lowering medications as required.

Primary outcome measure

Failure of the AADI was 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. Complete success was defined as achieving these IOP levels without AGMs, and qualified success was considered when IOP control was achieved with AGMs. Cumulative rates of complete and qualified success were also calculated for IOP ranging between 6 and 15 mmHg and between 6 and 21 mmHg 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 losses in visual acuity for two consecutive visits were termed as vision threatening.

Statistical methodology

Continuous variables were described as mean with SD or median with IQR and categorical variables were expressed as proportions (n, %). Visual acuity was converted to logarithm of minimum angle of resolution (logMAR) for statistical analysis. Groupwise comparisons were made between continuous variables using the Student t-test or the Wilcoxon rank-sum test for non-parametric variables. The χ^2 test or Fisher's exact test was used to analyse group differences across categorical variables. 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 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. Differences between survival curves were determined using log-rank test.Data were entered into Microsoft

Table 2 Aetiology of glaucoma in eyes undergoing combined pars plana vitrectomy and AADI insertion

Aetiology	Eyes, n (%)
Post-VR surgery,SO induced	22 (35)
ICE syndrome	6 (9.5)
Glaucoma in aphakia	18 (28.5)
Traumatic glaucoma	3 (4.8)
Postkeratoplasty glaucoma	6 (9.5)
Aniridia	4 (6.3)
Neovascular glaucoma	4 (6.3)

AADI, Aurolab aqueous drainage implant; ICE, iridocorneal endothelial; SO, silicone oil; VR, vitreoretinal.

Excel and analysed using STATA V.14.0 statistical analysis software package, and p<0.05 was considered significant.

RESULTS

This study included 63 eyes of 63 patients with refractory glaucoma. The demographics and aetiology of refractory glaucomas in the study cohort are shown in table 1. The median age of the patients was 41 years (IQR=15–52 years, range1–72 years), and the median duration of follow-up period was 14 months (IQR=7–30, range6–58 months). The aetiology of refractory glaucoma in the study population is displayed in table 2.Silicone oil-induced secondary glaucoma postvitreoretinal surgery was the the most common glaucoma encountered (35%). Most eyes had undergone previous intraocular surgery (table 1), and 41% (n=26) had undergone previous pars plana vitrectomy with or without silicone oil injection.

All 31 aphakic eyes had either undergone prior PPV or had contraindications for tube placement in the anterior chamber. Fourteenhad undergone a prior vitrectomy and underwent AADI implantation at the time of silicone oil removal. Ten aphakic eyes had intractable glaucoma postcongenital cataract surgery and had shallow chambers due to extensive peripheral anterior synechiae(PAS), and three of these eyes also had epithelial ingrowth, further compromising the space in the anterior chamber. The remaining seven aphakic eyes who underwent pars plana tube insertion had a previouspenetrating keratoplasty; five of these eyes had 360 degrees anterior PAS where no space existed to permit anterior chamber tube insertion; one post-penetrating keratoplasty (PK) eye had early corneal decompensation with vitreous touching the endothelium; one post-PK eye had anterior staphyloma and extensive pre-existing conjunctival scarring at the limbus precluding safe translimbal tube insertion.

Preoperative IOP ranged from 10 to 58 mm Hg with a mean IOP of 36.68±10.75 mmHg with mean of 3.20±0.95 antiglaucoma medications (range 1–5). Compared with baseline, the mean IOP reduced by 50% at 1-month follow-up (p<0.001)

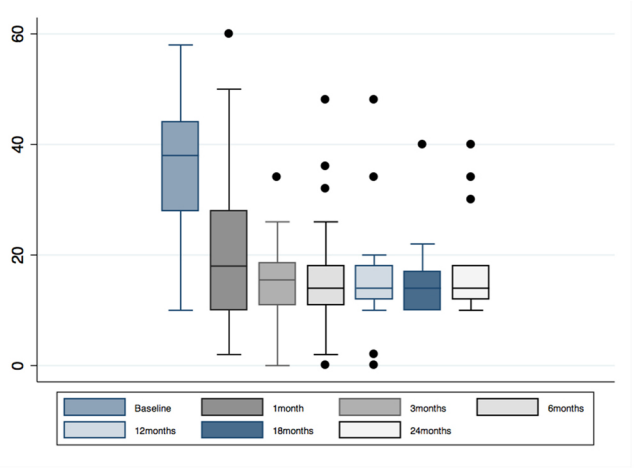

Figure 2 Intraocular pressure before and after Aurolab aqueous drainage implant into the pars plana. The box and whiskers represent the median±2 SD.

(figure 2). There was a significant drop again at 3 months' follow-up after which the IOP stabilised (table 3). Similarly, the number of medications also reduced significantly at 1 and 3 months and stabilised thereafter (table 3). The mean visual acuity was stable throughout the study period (table 3) and was around 6/36 Snellen's equivalent.

Twenty-four complications were seen in 19 eyes (30%) during the study period (table 4).Choroidal detachment, retinal detachment and vitreous blocking the tip of the AADI were the the most common complication seen in <10% eyes, while one eye developed phthisis following closed funnel retinal detachment. Cataract surgery and repeat vitrectomy were the the most common re-interventions required (table 4). Four out of five eyes with retinal detachment had poor visual outcome, while one maintained vision of 0.8 logMAR (6/36 Snellen's) at 18 months' follow-up.

Considering success as IOP between 6–18 mmHg or at least 30% reduction from baseline, failure was seen in 22 eyes (35%) at 2 years. Of these, 17 (77%) were due to inadequate IOP control, 4 (18%) were due to complications and 1 (5%) was due to resurgery alone. Table 5 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 8% (95% CI4.3% to 22.4%) at 6 months, 23% (95%CI12.8% to 38.6%) at 1 year, 30% (95%CI17.4% to 45.9%) at 18 months and 47% (95% CI13.4% to 64.9%) at the 2 years time points. The K-M plot for cumulative failure at various time points is shown in figure 3. There were no differences in the success rates based on the type of glaucoma (log-rank p=0.78)

Table 3 IOP trend and number of antiglaucoma medications required for control of IOP in the follow-up period

	Preoperative	1 month	3 months	6 months	12 months	24 months
IOP(mmHg), mean±SD	40.28±10.56	20.37±13.84	15.5±6.4	15.7±8.2	15.02±7.3	17.2±8.5
P value*		**<0.001**	**0.009**	0.94	0.97	0.38
Number of medications	3.20±0.95	1.84±1.15	1.45±1.0	1.46±1.17	1.5±1.2	1.6±1.1
P value*		**<0.001**	**0.003**	0.71	0.28	0.33
BCVA (logMAR)	0.94±0.73	0.93±0.74	0.94±0.73	0.89±0.79	0.85±0.77	0.99±0.85
P value*		0.71	0.61	0.28	0.50	0.33

*P value compared with previous visit, calculated using one-way analysis of variance with Bonferroni adjustments. Bold face values are statistically significant.
BCVA, best-corrected visual acuity; IOP, intraocular pressure;logMAR, logarithm of minimum angle of resolution.

Table 4 Complications and resurgeries in the study cohort

Complications*	n (%)	Intervention*	n (%)
Choroidal detachment	5 (8)	PPV	3 (5)
Hypotony	4 (6)	PPV+SOI	2 (3)
Graft failure	2 (3)	PKP+SFIOL	1 (1.5)
Corneal decompensation	1 (1.5)	Tube repositioning	1 (1.5)
Vitreous blocking tube tip	5 (8)	Vitreous lavage	1 (1.5)
Retinal detachment	5 (8)	Repeat AADI	1 (1.5)
Vitreous haemorrhage	1 (1.5)	Anterior vitrectomy	2 (3)
Phthisis bulbi	1 (1.5)	Cataract surgery	3 (5)
Total	24 (38)	Total	14 (22)

*Interventions do not correspond to the complications provided in the same row of the table.
AADI, Aurolab aqueous drainage implant; PKP, penetrating keratoplasty; PPV, pars plana vitrectomy;SFIOL, sulcus fixated intraoculae lens; SOI, silicone oil injection.

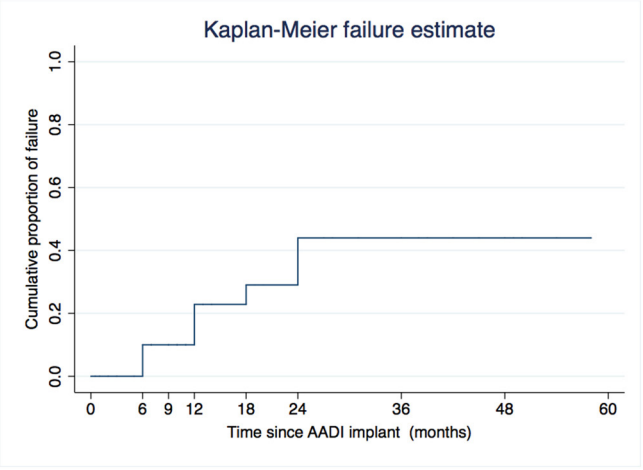

Figure 3 Kaplan-Meier plot for cumulative failure at various time points of follow-up. AADI, Aurolab aqueous drainage implant.

Discussion

In this study, we included eyes with predominantly aphakic glaucoma and refractory glaucoma following vitreoretinal surgery and found that the AADI with its tube placed in the parsplana region leads to a significant reduction in IOP at 1 month and that IOP continued to reduce further until 3 months following which it was maintained. Cumulative success rate ranged from 77%–84% at 1 year and between 42% and 61% at 2 years, based on different criteria used for success. Complications were seen in about a third of the eyes, with vitreous blockage of the tube and retinal detachment being the the most common complications seen in 8% of the operated eyes.

The use of GDDs, both the Ahmed valved implant and the Barveldt non-valved implant have significantly increased over the past decade, especially for refractory glaucomas.[1] The 5-year pooled results of the Ahmed Baerveldt Comparison Study and the Ahmed versus Baerveldt Study clearly show the clinical efficacy in controlling IOP in these difficult scenarios.[14] The tube versus trab study has also shown good IOP control with both-procedures, thoughtubes experienced slightly higher complication rates.[15] In view of this, an increasing number of surgeons are preferring tubes for surgical management of their patients with glaucoma.

Traditionally, the tube has been placed in the anterior chamber to shunt out the aqueous into the episcleral plateof the drainage device, which is located equatorially in the subconjunctival space, between the recti muscles. The potential risk of accelerated endothelial cell loss and cataract progression due to the tube in the anterior segment has prompted surgeons to place the tube in the pars plana with good success in most cases. Additionally, the pars plana route for tube placement is considered when the anterior chamber is too shallow or absent due to extensive PAS or aniridia. However, the benefit of placing the tube in pars plana should be weighed with the risks of retinal complications such as vitreous haemorrhage, retinal detachment and macular hole formation.There have been many previous studies comparing IOP and cumulative success rates following parsplana versus anterior tube placement, with most showing no differences in outcomes at intermediate time points (online supplementary table 1).[5 7 16] Our cumulative complete success of 77% at 1 year and 53% at 2 years was comparable to results from the study by Rososinksi *et al*,[16] who reported a complete success rate of 35% at 2 years and 78% at 1 year by Eslami *et al*.[17] Qin *et al* showed a 50% reduction in mean IOP in 57 eyesthat underwent parsplana tube implantation at a mean follow-up of 43.5 months, similar to our results.[7] In another study, Campagnoli *et al* showed a 50%–60% reduction in IOP at 1 year in 92 eyesand a cumulative success rate of 79% in eyes with non-NVG type of refractory glaucoma, very similar to our results.[4]

The AADI is a new, low-cost device intended for use in low-income countries, especially in resource-poor settings where there is no access to other implants. The AADI has been studied before with the tube placed in the anterior segment and has shown excellent IOP reduction. In a recent study, we have shown that AADI placed in the anterior chamber leads to a significant drop in IOP from 34.7±9.9 mmHg with 3.2±0.7 AGMs at baseline to 15.10±6.7 mmHg with 1.5±1.1 at 2 years' follow-up.[8] The success rate was 91% at 1 year and dropped to 50% at 4 years. Other authors have shown similar outcomes with the AADI, including eyes with congenital and other forms of paediatric glaucoma.[9 11 12] The AADI has also performed well compared with eyes receiving the AGV.[10]

Retinal detachment was the the most common vision-threatening complication and occurred in 8% of eyes receiving the AADI. Though this is a slightly higher proportion compared

Table 5 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)‡
6 months	92% (80%–97%)	92% (80%–97%)	92.0 %(79%–95%)	92.0 %(79%–95%)	92.0 %(79%–95%)	92.0 %(79%–95%)
12 months	84% (70%–92%)	87% (73%–93%)	77% (54%–82%)	81% (67%–82%)	77% (62%–87%)	79.5% (64%–88%)
18 months	75% (58%–86%)	80% (63%–89%)	70.1% (54%–83%)	77.1% (64%–88%)	64% (47%–76%)	68% (50%–80%)
24 months	61% (43%–75%)	68% (48%–82%)	53% (38%–71%)	63% (43%–78%)	42% (25%–57%)	46% (28%–63%)

*Success=IOP≤21 mmHg or 20% reduction from baseline.
†Success=IOP<18 mmHg or 30% reduction from baseline.
‡Success=IOP<15 mmHg or 40% reduction from baseline.

with other studies reporting on complications of pars plana drainage implants, it may be explained by the fact that almost half of the eyes had pre-existent vitreoretinal pathology and had required vitrectomy and silicone oil injection in the past. Indeed, three out of five eyes that developed RD after AADI had prior parsplana vitrectomy, including one for trauma and two for prior retinal detachment. Yet, it may be prudent to perform meticulous base dissection during vitrectomy, especially in the quadrant where the AADI tube is planned to be inserted, to reduce risk of future RD. Patients should be counselled regarding this increased risk and possibility of resurgery and potentially poor visual outcomes.

The drawbacks of the study are its retrospective nature and follow-up limited to 2 years after surgery. The strength of the study is the relatively good sample size. To the best of our knowledge, this is the first study showing outcomes of AADI with the tube placed in the pars plana.

In conclusion, the AADI with pars plana insertion of the tube is an effective way of controlling IOP in eyes with refractory glaucoma secondary to vitreoretinal pathologies and aphakia. Head-to-head comparison with anterior chamber insertion of the tube using a prospective study design is essential to understand whether the pars plana approach is preferable under certain conditions.

Contributors GVP: concept and design of the work, critical revision of content, final approval of the version to be published and accountable for all aspects of work in ensuring questions related to the accuracy or integrity of any part of work are appropriately investigated and resolved. NB: concept and design of work, critical revision of content and final approval of the version to be published. GB and HKW: data acquisition, analysis and preparation of the manuscript.

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