

Clinical outcome of a nonvalved Aurolab aqueous drainage implant in posterior segment versus anterior chamber

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Purpose: To evaluate the outcome of a nonvalved Aurolab aqueous drainage implant (AADI) in the management of refractory glaucoma. **Methods:** Retrospective case series of patients with refractory glaucoma underwent AADI implantation in posterior segment (PS group) or anterior chamber (AC group) with minimum follow-up of 1 year. Primary outcome criterion was success, defined as intraocular pressure (IOP) <18 or >6 mm Hg or IOP reduced to <20% from baseline, for two consecutive visits after 3 months. Failure was defined as inability to meet IOP criteria, any additional glaucoma surgery, loss of light perception, and implant explantation. Secondary outcome criteria compared groups based on mean IOP, mean glaucoma medication use, best-corrected visual acuity, and complications at each postoperative visit. **Results:** In the AC and PS group of 64 patients, 32 tubes each were placed. Preoperative mean IOP was 37.41 ± 8.6 and 43.38 ± 10.3 mm Hg in AC and PS, respectively. Postoperatively IOP reduced to 14.22 ± 4.9 and 15.21 ± 8.1 mm Hg in AC and PS groups, respectively ($P < 0.001$). Preoperative mean antiglaucoma medication changed from 2.56 ± 0.9 and 3.44 ± 0.5 to 1.03 ± 0.9 and 1.67 ± 0.5 in AC and PS, respectively, postoperatively ($P < 0.001$). No significant change in VA was noted in either group. At 12 months, success rate was 84% in AC group and 72% in PS group, with PS group having 2.63 times higher hazard (risk) of failure than AC group. **Conclusion:** AADI implantation in PS or AC is a safe and effective method for IOP control in refractory glaucoma with its low cost being of significance in developing countries.

Key words: Aurolab aqueous drainage implant, intraocular pressure, nonvalved glaucoma drainage implant, refractory glaucoma

Glaucoma drainage devices (GDDs) have been conventionally used for the treatment of refractory glaucoma and are found to be beneficial in eyes that have had prior unsuccessful filtration surgeries.^[1-3] The majority of patients included in previous reports underwent anterior chamber (AC) tube insertion. The major disadvantage of AC tube insertion, especially in young patients, results from the potential for anterior rotation of an initially well-positioned tube leading to corneal endothelial contact and corneal decompensation. The insertion of the drainage tube into the AC is contraindicated in certain cases because of a shallow or distorted AC, presence of vitreous prolapse, presence of peripheral anterior synechiae, or in cases of preexisting corneal diseases. In such cases, the drainage tube can be inserted through the pars plana or posterior chamber with a simultaneous pars plana vitrectomy (PPV) to prevent tube occlusion with vitreous.^[4-7] Pars plana insertion of the tube can also be considered in cases where simultaneous vitrectomy is needed as in cases of coexisting retinal disorders such as retinal detachment, retained lens fragments, proliferative diabetic retinopathy, media opacities, neovascularization, or epiretinal membrane or eyes which have undergone previous PPV.^[8-12]

Various studies in the past have evaluated the results of GDDs with tube placed in the posterior segment (PS). Very

few studies have compared the AC versus PS placement of the tube.^[13,14] Baerveldt or Ahmed implant has been most commonly used in earlier studies. In developing countries such as India, the high cost required for procuring drainage implants, such as Ahmed and Baerveldt, limits its use. The Aurolab aqueous drainage implant (AADI, Aravind Laboratories, Madurai, India) is based on the design of the Baerveldt 350 implant. It is available at a cost of approximately US\$ 50 in India, thus enabling the use of GDD among patients for whom the conventional GDD is beyond the reach.

In our study, we investigated the clinical outcome of AADI inserted in eyes undergoing concurrent PPV in the PS group compared with tube placement in nonvitrectomized eyes in the AC group.

Methods

After getting approval from the Institutional Review Board and ethical clearance from the Ethics Committee, a retrospective review was performed on all medical records of patients

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Cite this article as: Maheshwari D, Dabke S, Rajagopal S, Kadar MA, Ramakrishnan R. Clinical outcome of a nonvalved Aurolab aqueous drainage implant in posterior segment versus anterior chamber. Indian J Ophthalmol 2019;67:1303-8.

Access this article online

Website:

www.ijo.in

DOI:

10.4103/ijo.IJO_1341_18

Quick Response Code:



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Manuscript received: 21.09.18; Revision accepted: 03.04.19

who underwent AADI implant surgery between April 2014 and April 2016 for glaucoma services at Aravind Eye Care System, Tirunelveli, Tamil Nadu, India. The study adhered to the principles of the Declaration of Helsinki. Informed consent for surgery was obtained from all eligible participants. Patients with uncontrolled primary or secondary glaucoma on maximally tolerated medical therapy with high risk of trabeculectomy failure were included in this study. Patients with either previous GDD surgery in the operated eye or those who failed to or did not complete a minimum of 1-year follow-up were excluded from this study.

Data collected included age, sex, diagnosis, visual acuity, intraocular pressure (IOP), previous ocular surgeries, number of antiglaucoma medications (AGMs) used, tube location, complications, and period of follow-up. The preoperative IOP was determined as a mean of three measurements before the surgery. The site of placement of the tube was decided based on the clinical status of the patient's eye. The tube was placed in the vitreous cavity only in those cases where AC placement was contraindicated or if the patient required simultaneous vitreoretinal procedure. Postoperatively, the patients were reviewed at day 1, 1 week, 2 weeks, 1 month, 3 months, 6 months, and 1 year. IOP, visual acuity, and number of AGMs required were noted at each postoperative visit. Besides these visits, any patient who required to be seen depending on their ocular condition was followed up accordingly. Patients who did not report according to schedule were called telephonically and reminded about their appointment.

Aurolab aqueous drainage implant

Aurolab aqueous drainage implant (AADI), developed by Aurolab, a manufacturing division of Aravind Eye Care System, Madurai, India is a nonvalved aqueous shunt made up of nupil permanent implant silicone elastomer which has passed tissue culture cytotoxicity testing. Design of this implant is similar to the original Baerveldt glaucoma implant 350. The surface area of the end plate is 350 mm², and the silicon plate and tube length being 32 and 35 mm, respectively. The end plate of AADI has four fenestrations, which allows growth of fibrous bands enabling the formation of bleb. The device was manufactured in collaboration with the Bascom Palmer Eye Institute, Miami, Florida, USA. The device was made commercially available in India from June 2013. It is a low cost (US\$ 50) alternative for patients with refractory glaucoma in developing countries such as India.

Surgical technique

Surgery was done by two experienced surgeons. The surgical procedure consisted of a three-port vitrectomy performed by a PS surgeon in cases planned for PS tube insertion, followed by placement of GDD by anterior segment surgeon.

In all cases, a fornix-based conjunctival flap was taken and tenon's tissue was then dissected. The site of placement of the implant either supero-temporal or infero-nasal was decided by the operating surgeon based on the amount of preexisting conjunctival scarring if any. Adjacent recti muscles in the desired quadrant was isolated using muscle hooks. The AADI implant was then primed to check for any manufacturing defect. The end plate was then positioned between the adjacent recti muscles such that the anterior edge of the plate was around 8 mm from the limbus. The plate was then attached to

the underlying sclera with 9-0 nylon (monofilament polyamide black, Ethilon; Ethicon, Johnson and Johnson) sutures passed through the fixation holes of the implant. A noncompressing mattress suture (9-0 nylon, monofilament polyamide black, Ethilon; Ethicon, Johnson and Johnson) was applied to stabilize the tube to the sclera. Temporary tube occlusion was achieved by ligating it with 6-0 vicryl suture (braided-coated polyglactin 910 violet; Ethicon, Johnson and Johnson). Complete closure was then confirmed by attempting to irrigate balanced salt solution through the tube using a 27-gauge cannula. Scleral fistula was created at about 3 mm from the limbus using a 23-gauge needle. The tube was then trimmed with an anterior bevel up and inserted into the AC through scleral tract such that it would lie 1–2 mm past the surgical limbus. The position of the tube was confirmed by direct visualization by the operating surgeon. The limbal portion of the tube was covered with partial thickness corneal patch graft. Fenestrations in the tube were made in certain cases, which required short-term IOP control in immediate postoperative period until the vicryl suture lyses occurs. The conjunctiva and tenon's capsule were then closed using 8-0 vicryl sutures (braided-coated polyglactin 910 violet) using both interrupted and running techniques.

In the PS group, the glaucoma surgeon first fixes the end plate in the same manner as mentioned earlier. The vitreoretinal surgeon then performed a three-port PPV and any additional vitreoretinal procedure if required. A thorough vitrectomy was done including removal of the vitreous base in order to prevent the tube end being blocked by vitreous. Once vitrectomy was completed, the superior two sclerostomies were closed with 8-0 vicryl (braided-coated polyglactin 910 violet) and infusion line was kept on to maintain the globe pressure. Using a 23-gauge trocar cannula, entry was made 3 mm posterior to the limbus and the tube end was trimmed and inserted into the vitreous cavity and scleral portion of the tube was covered with partial thickness corneal patch graft. The conjunctival and tenon closure was done similar to AC group. The traditional Hoffmann elbow, however, was not used.

The initial postoperative regimen included topical fluoroquinolone, antibiotic, topical steroids, and AGMs. The steroids were tapered depending on the degree of postoperative inflammation. Continuation and the number of AGMs was decided based on the IOP once the tube opened the following spontaneous lysis of the ligating vicryl suture.

The primary outcome criterion for both groups was success, defined as: (1) IOP <18 mm Hg or IOP >6 mm Hg or IOP reduced to <20% from baseline, for two consecutive visits after 3 months. Failure was defined as inability to meet IOP criteria, *de novo* glaucoma procedure (e.g., cyclodestruction, additional tube shunt), loss of light perception, and removal of the implant. Secondary outcome criteria compared groups based on mean IOP, mean glaucoma medication use, best-corrected visual acuity, and complications at each postoperative visit.

Statistical analysis

Categorical variables were analyzed using Chi-square test or Fisher's exact test. Two sample continuous variables were analyzed with Student's *t*-test or Mann-Whitney *U*-test. Pre and post comparisons were done using paired *t*-test or Wilcoxon sign-rank test. Treatment failure was analyzed with Kaplan-Meier curve using log-rank test, and hazard ratios were calculated using a Cox proportional hazard model.

P value <0.05 is considered as statistically significant. All statistical analyses were done using a statistical software STATA 11.1 (Texas, USA).

Results

Baseline characteristics

A total of 80 patients underwent AADI implantation during the study period, of which 64 eyes of 64 patients were included for analysis as remaining patients failed to or did not complete a minimum of 1 year follow-up after surgery.

Out of 64 eyes, 32 eyes had drainage tube implanted in the AC and remaining 32 eyes had the tube implanted in the PS. The baseline demographic characteristics of study group are shown in Table 1.

Treatment outcomes

At 12 months, the success rate was 84% in the AC group and 72% in the PS group [Table 2]. PS group had 2.63 times higher hazard (risk) of failure than AC group with 95% confidence interval (CI: 0.87–7.94) and the *P* value (>0.05) [Fig. 1].

The most common reason for failure was high IOP in both groups which accounted for 3 (9.4%) failure in the AC group and 4 (12.5%) failure in the PS group. None of the patients in either group required *de novo* glaucoma surgery.

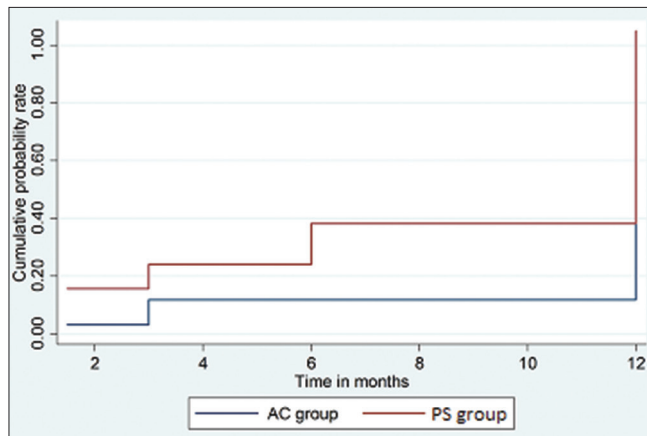


Figure 1: Kaplan–Meier analysis using the log-rank test

Intraocular pressure

AADI implanted at either of the site was effective in reducing IOP [Fig. 2 and Table 3]. The mean IOP in the AC group decreased from 37.41 ± 8.6 mm Hg preoperatively to 14.22 ± 4.9 mm Hg at 1 year (38% reduction, *P* < 0.001). The mean IOP in the PS group decreased from 43.38 ± 10.3 mm Hg preoperatively to 15.21 ± 8.1 mm Hg at 1 year (35% reduction, *P* < 0.001). When comparing the two groups, it is the AC group that had a uniform and persistent decrease in IOP through 1 year postsurgery (*P* > 0.05).

Glaucoma medication

Both devices were effective in reducing the need for glaucoma medications [Fig. 3 and Table 3]. The mean number of glaucoma medications required in the AC group decreased from 2.56 ± 0.9 preoperatively to 1.03 ± 0.9 at 1 year (40% reduction, *P* < 0.001). The mean number of glaucoma medications required in the PS group decreased from 3.44 ± 0.5 preoperatively to 1.67 ± 0.5 at 1 year (49% reduction, *P* < 0.001). When comparing the two groups, the AC group required fewer glaucoma medications at all postoperative visits through 1 year (*P* = 0.014).

Visual outcomes

AC group had no significant change in visual acuity, whereas PS group had a moderate improvement in visual acuity, which was not statistically significant [Table 4].

Complications

After 1 year of follow-up, 19% of patients in the AC group and 28% patients in the PS group experience complications, though not statistically significant [Table 5].

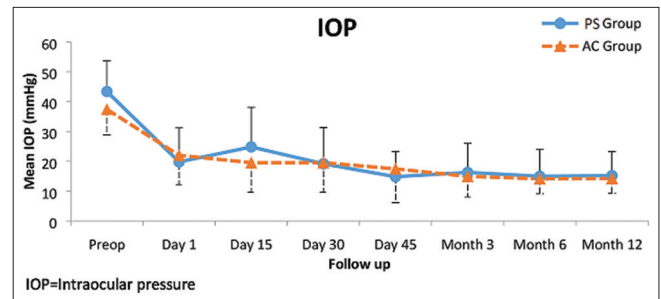


Figure 2: Intraocular pressure

Table 1: Baseline patient characteristics

	AC group	PS group	Overall	<i>P</i>
Age mean (SD)	51.69 (19.2)	46.19 (17.5)	48.94 (18.4)	0.235 [†]
Sex [<i>n</i> (%)]				0.048 [°]
Male	20 (62.5)	27 (84.4)	47 (73.4)	
Female	12 (37.5)	5 (15.6)	17 (26.6)	
Glaucoma subtype				
Traumatic	7 (22%)	14 (44%)	21 (32%)	
NVG	7 (22%)	8 (24%)	15 (23%)	
POAG	10 (31%)	-	10 (16%)	
Pseudophakic glaucoma	5 (16%)	5 (16%)	10 (16%)	
SACG	3 (9%)	5 (16%)	8 (13%)	
Prior trabeculectomy	9 (28%)	4 (13%)	13 (20%)	

NVG=Neovascular glaucoma; POAG=Primary open angle glaucoma; SACG=Secondary angle closure glaucoma, [†]Two-sample *t*-test, [°]Chi-squared test

Table 2: Treatment outcome

	AC group (%)	PS group (%)	P
Overall outcome			
Success	27 (84.4%)	23 (71.9%)	0.226 ^C
Failure	5 (15.6%)	9 (28.1%)	
Reasons for failure			
Tube explantation	1 (3.1%)	3 (9.4%)	0.613 ^F
Hypotony	-	1 (3.1%)	>0.999 ^F
High IOP	3 (9.4%)	4 (12.5%)	>0.999 ^F
High IOP and vision loss	1 (3.1%)	-	>0.999 ^F
Vision loss	-	1 (3.1%)	>0.999 ^F

IOP=Intraocular pressure, ^CChi-square test, ^FFisher's exact test

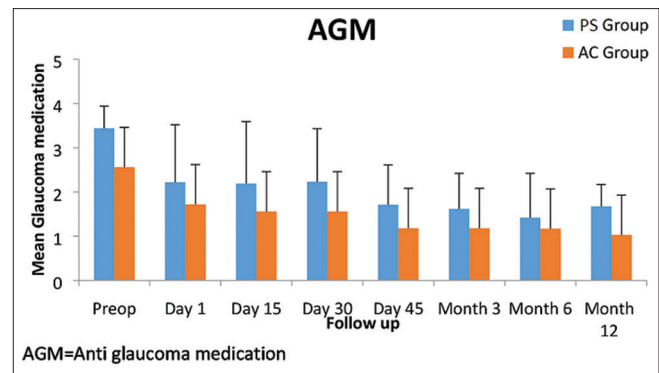
Table 3: Mean IOP and mean AGM use

Visits	AC group mean (SD)	PS group mean (SD)	P ^m
Preop			
Mean IOP	37.41 (8.6)	43.38 (10.3)	0.023
Mean AGM	2.56 (0.9)	3.44 (0.5)	0.018
Day 1			
Mean IOP	22.00 (9.8)	19.80 (11.4)	>0.05
Mean AGM	1.72 (0.9)	2.22 (1.3)	>0.05
Day 15			
Mean IOP	19.53 (9.9)	24.81 (13.3)	>0.05
Mean AGM	1.56 (0.9)	2.19 (1.4)	>0.05
Day 30			
Mean IOP	19.53 (9.9)	19.17 (12.1)	>0.05
Mean AGM	1.56 (0.9)	2.23 (1.2)	>0.05
Day 45			
Mean IOP	17.47 (11.3)	14.83 (8.4)	>0.05
Mean AGM	1.18 (0.9)	1.71 (0.9)	>0.05
Month 3			
Mean IOP	14.94 (6.9)	16.28 (9.7)	>0.05
Mean AGM	1.18 (0.9)	1.62 (0.8)	>0.05
Month 6			
Mean IOP	14.13 (5.0)	14.97 (9.1)	>0.05
Mean AGM	1.17 (0.9)	1.42 (1.0)	>0.05
Month 12			
Mean IOP	14.22 (4.9)	15.21 (8.1)	>0.05
Mean AGM	1.03 (0.9)	1.67 (0.5)	>0.05
P ⁿ			
Mean IOP	<0.001	<0.001	
Mean AGM	<0.001	<0.001	

IOP=Intraocular pressure; AGM=Antiglaucoma medication; ^mMann-Whitney test (group-wise comparison), ⁿWilcoxon signed-rank test (comparing last visit with preop)

Discussion

In this study, we retrospectively examined the clinical outcome of AADI tube placement in the AC in nonvitrectomized eye versus PS placement after complete PPV. Literature review shows very few studies having been done comparing the clinical outcomes of drainage tube placement in AC versus

**Figure 3: Mean AGM**

PS.^[13,14] The authors found that only limited studies have been published regarding the outcomes of AADI in adult refractory glaucoma, especially using the PS approach.

In our study, the mean IOP reduction was almost similar in both the groups, which correlates well with previous similar study done with Baerveldt and Ahmed glaucoma valve implant.^[13,14] The percentage drop in IOP at the end of 12 months was 38% in the AC group and 35% in the PS group. In a systematic literature review of GDDs, the percentage change in IOP in Baerveldt and Ahmed implant was found to be around 54 and 51%, respectively.^[15] However, in tube versus trabeculectomy (TVT) study the average reduction in IOP was 49.9% at 1 year.^[16]

In addition to tube ligation technique, in certain cases venting slits were performed and we were able to lower IOP particularly in the first week postoperation. Later, the IOP became relatively high in certain cases and was sustained until the ligating material degraded, which usually occurred 3–4 weeks after surgery. This hypertensive phase was controlled by AGM, which was tailed off thereafter in most patients.

In our study, the success rate was 84% in the AC group and 72% in the PS group at last follow-up examination. Previous study done by Maris *et al.* in 2013 using Ahmed valve showed success rates of 90 and 86.6% at 12 months in the AC and PS groups, respectively.^[14] Similarly in a study done by Rososinski *et al.*, the qualified success rates were around 90% in both the groups.^[13] Chian-huey hon *et al.* did a systematic review of GDDs and found the success rates to be varying from 75 to 85% for Ahmed and Baerveldt implant.^[15] Thus the success rates of our study correlate well with other intermediate term studies done using conventional drainage implants.

At the end of 12 months follow-up, the PS group showed a slight improvement in visual acuity, which was not statistically significant, whereas visual acuity in the AC group remained unchanged. The slight improvement noted in the PS group could be due to concomitant procedures done for associated vitreoretinal disorders in few cases. Previous studies done using Baerveldt and Ahmed valves showed either stable or improving visual acuity.^[2,3,13,14] However, in a study done by Harbick *et al.*, there was a significant net worsening of visual acuity at the end of 1 year, which was attributed to preexisting concomitant retinal and corneal problems.^[17]

At the end of 12 months follow-up, complication noted in the AC group was 19%, and in the PS group was 28%. The

Table 4: Visual outcomes

Visits	AC group Mean logMAR Snellen visual acuity (SD)	PS group Mean logMAR Snellen visual acuity (SD)	P ^m
Preop	1.09 (0.91)	1.69 (0.91)	0.009
Day 1	1.21 (0.94)	2.16 (0.83)	<0.001
Day 15	1.10 (0.91)	1.63 (0.96)	0.024
Day 30	1.10 (0.91)	1.43 (0.99)	0.192
Day 45	1.06 (0.89)	1.37 (1.01)	0.313
Month 3	1.08 (0.98)	1.19 (1.03)	0.622
Month 6	1.04 (1.00)	1.37 (1.10)	0.258
Month 12	1.08 (0.99)	1.32 (1.03)	0.425
P ⁿ	0.620	0.156	

^mMann-Whitney test (group-wise comparison), ⁿWilcoxon signed-rank test (comparing last visit with preoperative)

Table 5: Postoperative complications

	AC (n=32)	PS (n=32)	P ^f
Choroidal detachment	0	1	0.613
Tube complications	2	0	0.492
Tube iris touch	1	0	>0.999
Tube exposure	0	1	>0.999
Tube lens touch	1	2	>0.999
Vitreous hemorrhage	0	1	>0.999
Conjunctival retraction	1	2	>0.999
Endophthalmitis	0	2	0.492
Retinal detachment	1	0	>0.999
Hypotony	6	9	>0.999

^fFisher's exact test

most common complication noted in the AC group was tube related (9%) and in the PS group, two cases each of vitreous hemorrhage and endophthalmitis. We found choroidal effusion in 3% cases in the PS group, which when compared with previously done studies with Baerveldt implant 350 mm² had choroidal effusions ranging from 16 to 36.8%.^[3,18,19] One (3.1%) case had developed flat AC with corneal decompensation which required penetrating keratoplasty with reinsertion of tube into pars plana.

In the AC group one patient developed endophthalmitis secondary to tube exposure, while PS group had two patients (6%) who developed tractional retinal detachment with endophthalmitis. Three of the cases mentioned warranted explantation of the tube. One case in the PS group developed choroidal detachment with subsequent retinal detachment, which required vitreoretinal intervention with explantation of tube. In a study done by Scott *et al.*, one case of endophthalmitis and rhegmatogenous retinal detachment has been reported.^[20] Luttrull *et al.* reported four cases (8%) of rhegmatogenous retinal detachment in cases implanted with Baerveldt implant who had previously undergone repair of complicated retinal detachments.^[21] However, no PS complications such as retinal tears or detachments were reported in the study done by de Guzman *et al.*^[7] and Reichstein *et al.*^[22]

Two patients (6%) in the PS group had developed vitreous hemorrhage out of which one required vitreous lavage restoring the visual acuity. Though diplopia has been reported

with the use of conventional drainage devices such as Ahmed and Baerveldt in previous studies, we did not observe any patient reporting diplopia in this series.

The main limitation of our study is its retrospective nature with short duration of follow-up. Because the sample size is small with heterogeneity of baseline clinical characteristics of cases in the AC and PS group, direct comparison of the impact of the procedure alone could not be determined precisely. However, the intervention was beneficial to the patients in terms of IOP control and success rates in both the groups.

Owing to its recent release, not much published data are available with regards to efficacy and safety of AADI implant, with only two publications available, one by Kaushik *et al.* in refractory childhood glaucoma who found a success rate in excess of 90% at 1 year follow-up,^[23] and a more recent publication with AC or sulcus placement of AADI^[24] had a complete success of 66.6% and overall success of 92.6% in 54 eyes of 51 patients with a follow-up of 1 year.

Conclusion

In summary, we found that initial success of AADI was approximately 74%, whether the implant tube was placed in the AC of a nonvitrectomized eye or PS with PPV. Thus, the AADI is effective in controlling IOP in majority of cases with various subtypes of glaucoma. Furthermore, there was no much significant difference with regard to complications whether the tube was placed in the AC or PS, despite the need for additional vitreoretinal procedure in the latter. The decision to implant the tube into the AC versus PS needs to be individualized for each case. Further insight into this might be achieved with long-term prospective randomized clinical trials.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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