Original Article

Intermediate-term outcome of Aurolab aqueous drainage implant in refractory glaucoma

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Abstract:

PURPOSE: The purpose of the study was to evaluate the intermediate-term outcomes of Aurolab aqueous drainage implant (AADI) in terms of intraocular pressure (IOP) lowering from baseline levels, the number antiglaucoma medications (AGMs) in the postoperative phase, and the rate of complications.

METHODS: It was a retrospective interventional case series. All patients who underwent AADI surgeries with sulcus fixation from March 2018 to September 2018 at a tertiary eye care hospital in North India with a minimum follow-up of 1 year were recruited for the study. A standard AADI technique was employed. The primary outcome measures were the postoperative IOP, the requirement of AGMs, and early and late postoperative complications.

RESULTS: A total of 20 patients were recruited in the study. The mean follow-up period was 25.25 ± 3.76 months. The mean IOP reduced from 33.20 ± 7.95 mmHg to 19.45 ± 9.19 mmHg at day 1, 13.62 ± 3.92 mmHg at 6 months, 12.78 ± 3.36 mmHg at 1 year, and 13.0 ± 2.53 mmHg at 2 years postoperatively ($P < 0.001$). The mean number of AGMs also reduced from 3.7 ± 0.97 to 0.35 ± 0.81 at 6 months, 0.42 ± 0.83 at 1 year, and 0.26 ± 0.73 at 2 years postoperatively ($P < 0.001$). Early postoperative complications, such as hypotony and hyphema, were seen in 5 (25%) patients, although none of them was sight-threatening. Late postoperative complications, such as hypertensive phase and persistent fibrinous membrane, were also seen in five eyes.

CONCLUSION: The study assessed the clinical outcomes, safety profile, and long-term AGM requirement with AADI and found it to be a good viable surgical option in refractory glaucoma.

Keywords:

Aurolab aqueous drainage implant, glaucoma drainage device, refractory glaucoma

Introduction

Glaucoma drainage devices (GDD) are indicated in refractory glaucomas with failed filtering surgery or as a primary procedure in certain complicated secondary glaucomas. Recently, there has been a paradigm shift from filtering surgery to drainage implant surgery as a primary procedure in glaucoma in the Western world. The reasons for the increased popularity of glaucoma drainage implants are better clinical experience with time and refinement of surgical techniques. The ratio of trabeculectomy to glaucoma drainage implants decreased from 27:1 in 1994 to 3:2 in 2012 in the United States.[1] The two most commonly used GDD worldwide are the Ahmed glaucoma valve (AGV) implant, which has a flow-restrictive valve that results in a unidirectional flow of aqueous and the valve-less Baerveldt glaucoma implant (BGI), which is nonflow restricted.[2] BGI is not commercially available in India and AGV, which was the only glaucoma implant available in India until recently, is still beyond the reach of the majority of those who need it the most due to its high cost. The Aurolab aqueous drainage implant (AADI), a nonvalved glaucoma implant, was introduced for clinical use in India in 2013 by Aurolab, a manufacturing division of Aravind Eye Institute, Madurai, India, and has been designed on the same principle as Baerveldt implant. These devices are cost-effective and made of NuSil permanent implant silicone elastomer, which has passed tissue culture cytotoxicity testing.[3] Their inception has revolutionized the surgical management of refractory glaucoma in the

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developing world, where earlier cyclodestructive procedures had to be done due to cost barriers.

The device has a plate area of 350 mm^2, which is approximately double that of AGV and has the potential to lower intraocular pressure (IOP) in low teens. The 32 mm long end plate extends beyond 2 clock h of circumference on the equatorial sclera. While the AGV implants start to work immediately, these devices usually start functioning at around 6 weeks when the ligature opens up. As the eye with increased IOP has increased inflammatory mediators in their aqueous, any method that restricts its flow to the desired site in the initial few weeks would theoretically reduce the formation of angry-looking blebs and decrease the hypertensive phase (HTP). In the case of AGV, which starts to function almost immediately after implantation, the high concentration of inflammatory mediators may cause a more intense reaction at the plate site, leading to an increased HTP. Furthermore, because of the unrestricted nature of aqueous outflow in AADI, there are more chances of hypotony and its related complications as compared to valved aqueous outflow in AGV. Another benefit of AGV is that the IOP lowering results are obtained almost immediately, unlike in AADI, where it requires the continuation of preoperative antiglaucoma medications (AGMs) till the ligature opens. Sulcus fixation of the tube prevents the dreaded corneal complications in the postoperative period and is usually preferred unless the patient is phakic.

However, the most important determinant of the function of the implant would be the long-term IOP lowering efficacy and safety. This study is designed to evaluate the intermediate-term outcomes of AADI in terms of IOP lowering from baseline levels, the number of AGMs in the postoperative phase, and the rate of complications.

Methods

It is a retrospective interventional case series. All patients who underwent AADI surgeries with sulcus fixation from March 2018 to September 2018 at a tertiary eye care hospital in North India with a minimum follow-up of 1 year 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 patients/parents of all eligible participants.

Patient demographics, detailed slit-lamp examination, and intraoperative details were collected for every patient. Postoperatively, best-corrected visual acuity (BCVA), IOP, number of AGM, and postoperative complications (early/late) were noted.

Eyes that underwent AADI with the tube in sulcus for refractory glaucoma with uncontrolled IOP on maximal tolerated medical therapy and with prior failed trabeculectomy or high risk of failure following conventional filtering surgery such as those with excessive conjunctival scarring after prior ocular surgery such as prior keratoplasty or vitreoretinal surgery were included in the study. A minimum of 12-month follow-up was required.

Surgical procedure

All surgeries were performed by a single surgeon (JP) so as to eliminate the surgeon's bias in the outcomes. A standard AADI technique was employed wherein a 3- to 5-clock-h conjunctival peritomy was performed. The adjacent rectus muscles were hooked. The AADI tube was primed, and the plate was secured in the superotemporal quadrant in all patients; 9 mm posterior to the limbus, using two interrupted sutures 10–0 nylon (monofilament polyamide black) through the anterior fixation holes, with the wings beneath the adjacent recti muscles. The tube was occluded completely with 8–0 Vicryl (braided-coated polyglactin 910 violet) near the tube – plate junction.

The ligated tube was trimmed with bevel facing upward and inserted into the sulcus through a track created by a 23-gauge needle. The tube was secured to the episclera with a 10–0 nylon suture, and three to four fenestrations were made in the tube with the needle of the suture to facilitate early egress of aqueous and prevent high IOP spikes. The tube was covered with a scleral patch graft. The Tenon's capsule and conjunctiva were sutured with 8–0 Vicryl.

Postoperative antibiotics were prescribed four times daily for 1 week, and topical corticosteroids were prescribed for 6 weeks in tapering doses starting eight times a day. AGMs were prescribed as required for the postoperative IOP status.

Analysis

The primary outcome measures were the postoperative IOP, the requirement of AGMs, and early and late postoperative complications. Complete success was defined as IOP ≤21 mmHg without AGM, whereas qualified success was termed when IOP ≤21 mmHg with AGM(s) after 2 weeks of opening of ligature. The surgical procedure was termed as a failure when IOP >21 mmHg with AGM or with any sight-threatening complication or loss of more than two-line vision in the postoperative phase or when another glaucoma surgery was performed. The secondary outcome was any change in LogMAR visual acuity.

Statistical analysis included mean and standard deviation (SD) for continuous variables. The difference between preoperative and postoperative IOP, AGMs, and LogMAR visual acuity was analyzed using the Wilcoxon *t*-test at each time point. Any $P < 0.05$ was considered statistically significant.

Results

A total of 20 patients were recruited for the study. The mean age ± SD of the study cohort was 45.55 ± 22.33 years (range: 10, 80); 14 (70%) patients were males and 6 (30%) were females. The mean follow-up period was 25.25 ± 3.76 months. Glaucoma diagnosis in the study population was primary open-angle glaucoma (one eye), primary angle-closure glaucoma (one eye), glaucoma in pseudophakia (two

eyes), postvitreoretinal surgery (three eyes), iridocorneal endothelial syndrome (one eye), postkeratoplasty (seven eyes), congenital glaucoma (one eye), neovascular glaucoma (two eyes), traumatic glaucoma (one eye), and steroid-induced glaucoma (one eye) [Table 1]. Of 20 eyes included in the cohort, 12 underwent AADI as primary glaucoma surgery, 6 patients already had 1 glaucoma procedure, and 2 patients had 2 glaucoma proceduresprior to AADI. Core vitrectomy was done along with AADI in two of the patients, whereas one patient underwent phacoemulsification along with AADI. All the patients had sulcus placement of the tube.

The mean IOP reduced from 33.20 ± 7.95 mmHg to 19.45 ± 9.19 mmHg at day 1, 13.62 ± 3.92 mmHg at 6 months, 12.78 ± 3.36 mmHg at 1 year, and 13.0 ± 2.53 mmHg at 2 years postoperatively [$P < 0.001$ Table 2 and Figure 1]. The mean number of AGMs also reduced from 3.7 ± 0.97 to 0.35 ± 0.81 at 6 months, 0.42 ± 0.83 at 1 year, and 0.26 ± 0.73 at 2 years postoperatively [$P < 0.001$ Table 3 and Figure 2]. The mean LogMAR BCVA at the time of surgery was 1.81 ± 1.58, and it improved to 1.41 ± 1.03 ($P = 0.05$) at 3 months postoperatively. Further, at 6 months, the mean BCVA was 1.47 ± 1.08 ($P = 0.73$). It then came down to 1.85 ± 1.41 ($P = 0.85$) at 12 months and 1.91 ± 1.45 ($P = 0.73$) at 24 months postoperatively [Table 4].

Of 20 patients, 5 (25%) developed early postoperative complications (within 6 weeks), although none of them was sight-threatening. There were two patients who developed hypotony; one of them was managed conservatively, whereas the other underwent tube stenting for maintaining the optimum IOP. Both of them were of the adult age group. One of the patients who underwent prior penetrating keratoplasty had vitreous blocking the tube after AADI, for which laser vitreolysis was performed. Hyphema was seen in the rest two patients, which cleared eventually on conservative treatment. Late postoperative complications were also seen in five eyes. Intense inflammatory reactions leading to the formation of persistent membranes were seen in three patients; one of them was managed by YAG membranectomy, and rest were managed conservatively. The HTP was seen in three patients (one of them also had inflammatory membranes). Overall, none of the patients developed any serious complications. Only one patient had to undergo stenting for management, and the rest were managed in the outpatient department (OPD).

At 6 months, 16 (80%) of the patients did not require any AGM, and 2 (10%) patients needed AGMs to control IOP. Further 2 (10%) of the patients from the cohort had IOP <21 mmHg (22 mmHg) even with AGMs. At 2 years, none of the patients had IOP >21 mmHg.

Overtime, the success rate was 80% (complete – 65% and Qualified – 15%) at 3 months, 90% (complete – 80% and qualified – 10%) at 6 months, 100% (complete – 74% and

Table 1: Preoperative demographic details of patients

Variable	Number
Number of eyes (patients)	20
Mean age (years)	45.55±22.33
Males, *n* (%)	14 (70)
Females, *n* (%)	6 (30)
Mean follow-up (months)	25.25±3.76
Mean IOP preoperatively (mmHg)	33.20±7.95
Mean BCVA	1.81±1.58
AGMs	3.70±0.97
Diagnosis, *n*	
POAG	1
PACG	1
Post-PK glaucoma	7
NVG	2
Congenital glaucoma	1
Post-VR surgery glaucoma	3
Steroid-induced glaucoma	1
ICE syndrome	1
Glaucoma in pseudophakia	2
Traumatic glaucoma	1

IOP: Intraocular pressure, BCVA: Best-corrected visual acuity, AGMs: Antiglaucoma medications, POAG: Primary open-angle glaucoma, PACG: Primary angle-closure glaucoma, PK: Postkeratoplasty, VR: Vitreoretinal, ICE: Iridocorneal endothelial, NVG: Neovascular glaucoma

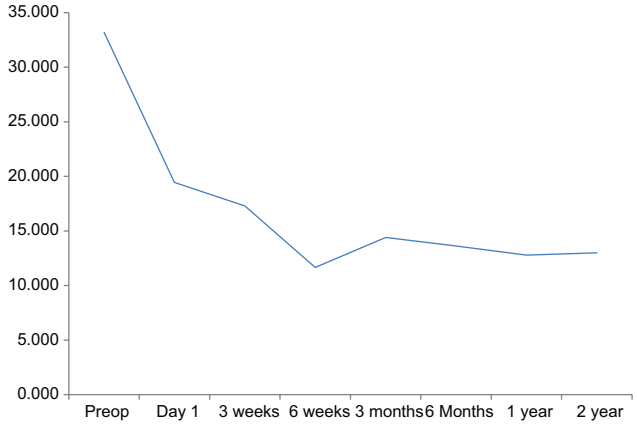

Figure 1: Intraocular pressure trends after Aurolab aqueous drainage implant

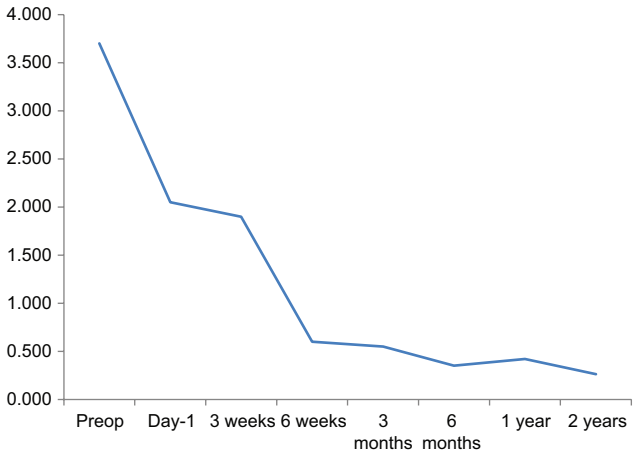

Figure 2: Mean antiglaucoma medications after Aurolab aqueous drainage implant

Table 2: Intraocular pressure changes after Aurolab aqueous drainage implant

IOP at different follow-up visits					
IOP follow-ups	**Mean±SD**	**Mean different from preoperative**	**SD of mean different from preoperative**	***P****	***n***
Preoperative	33.200±7.958				20
Day 1	19.450±9.197	13.750	9.952	0.000	20
3 weeks	17.300±7.753	15.900	9.330	0.000	20
6 weeks	11.650±4.368	21.550	7.380	0.000	20
3 months	14.400±6.762	18.800	9.747	0.000	20
6 months	13.625±3.923	19.575	9.732	0.000	20
1 year	12.789±3.360	20.411	8.931	0.000	20
2 years	13.000±2.539	20.200	8.220	0.000	20

*Wilcoxon *t*-test, mean compared with the mean of preoperative and other follow-ups. IOP: Intraocular pressure, SD: Standard deviation

Table 3: Number of antiglaucoma medications before and after Aurolab aqueous drainage implant

AGMs at different follow-up visits after AADI					
AGM follow-ups	**Mean±SD**	**Mean different from preoperative**	**SD of mean different from preoperative**	***P****	***n***
Preoperative	3.700±0.979				20
Day 1	2.050±1.605	1.650	1.348	0.000	20
3 weeks	1.900±1.210	1.800	1.056	0.000	20
6 weeks	0.600±1.095	3.100	1.334	0.000	20
3 months	0.550±0.887	3.150	1.226	0.000	20
6 months	0.350±0.813	3.350	1.268	0.000	20
1 year	0.421±0.838	3.279	1.204	0.000	20
2 years	0.263±0.733	3.437	1.124	0.000	20

*Wilcoxon *t*-test, mean compared with the mean of preoperative and other follow-ups. AGMs: Antiglaucoma medications, AADI: Aurolab aqueous drainage implant, SD: Standard deviation

Table 4: Best-corrected visual acuity before and after Aurolab aqueous drainage implant

LogMar BCVA after AADI					
LogMar follow-ups	**Mean±SD**	**Mean different from preoperative**	**SD of mean different from preoperative**	***P****	***n***
Preoperative	1.811±1.589				20
Day 1	1.498±1.246	0.313	0.639	0.033	20
6 weeks	1.499±1.012	0.312	0.849	0.212	20
3 months	1.419±1.030	0.392	0.814	0.061	20
6 months	1.472±1.086	0.339	0.871	0.145	20
1 year	1.855±1.413	−0.044	1.268	0.798	20
2 years	1.913±1.452	−0.102	1.397	0.789	20

*Wilcoxon *t*-test, mean compared with the mean of preoperative and other follow-ups. BCVA: Best-corrected visual acuity, AADI: Aurolab aqueous drainage implant, SD: Standard deviation

qualified – 26%) at 1 year, and again 100% (complete – 84% and qualified – 16%) at 2 years [Figure 3].

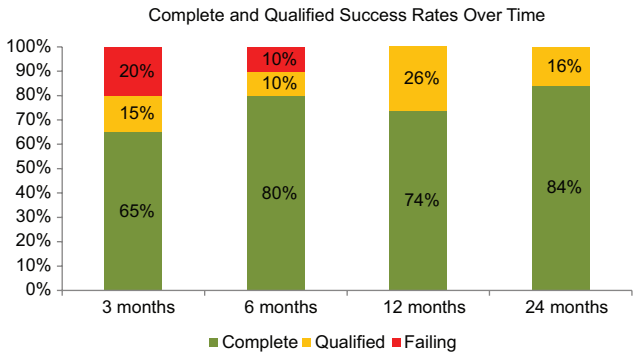

Figure 3: Postoperative outcome after Aurolab aqueous drainage implant

Discussion

Refractory glaucoma poses a unique challenge to treat as medical therapy is usually ineffective; furthermore, such cases either do not respond well to conventional filtering surgery or have a high failure rate.[4] GDD have been used widely in the treatment of refractory glaucoma, even as a primary glaucoma procedure. In the 1960s and 1970s, Dr. Anthony Molteno pioneered the development of a tube shunt implant, with a plate implanted posterior to the limbus and connected to the anterior chamber by a long silicone tube, thereby initiating the modern glaucoma drainage implant era.[1] Baerveldt implant was introduced in 1990, and it became the most preferred nonvalved implant due to its ease of implantation of large surface area implant in a single quadrant,[1] but still, the cost of these drainage implants has been the most important prohibitive factor in their wide use in a large section of the Indian population.

AADI developed by Aurolabs, Madurai, works on the same principle as BGI but at a very nominal fraction of the cost. It is Conformité Européenne approved and is available in the countries of Africa and South East Asia. This study was done to evaluate the intermediate-term outcomes of AADI in terms of IOP lowering from baseline levels, the number of AGMs in the postoperative phase, and the rate of complications.

In our study, the mean IOP reduced from 33.20 ± 7.95 mmHg preoperatively to 13.0 ± 2.53 mmHg at 2 years postoperatively. Hence, there was a 61% drop in the mean IOP at 2 years follow-up. In a recent study done by Philip *et al.* in 2019, evaluating the intermediate-term outcomes of AADI, the authors found a drop in the mean IOP to 55% at the end of 1 year.[5] Similarly, Kaushik *et al.* found a mean drop in IOP at the end of 2 years to be 47%, although the cohort they had taken was different from ours.[6] Nevertheless, the final IOP in these studies ranged between 12 and 14 mmHg only. It was the baseline IOP preoperatively which was higher in our cohort. The key to low IOP in GDDs lies in the thin encapsulation that happens around the plate.[4] Iwasaki *et al.*[7] studied the end-plate bleb morphology with magnetic resonance imaging, and they found that the formation of a bleb layer on both sides of the plate reduced IOP better than that in which it was formed only on one side. Furthermore, other studies on bleb characteristics in GDD showed a negative correlation of IOP control with bleb height and volume.[8] Increased bleb height and volume are actually a sign of HTP, the incidence of which is known to be more in valved implants. We experienced HTP in three of our patients but none of them went into failure and only one of them had to be put on long-term AGMs.

The mean number of AGMs reduced from 3.7 ± 0.97 to 0.26 ± 0.73 at 2 years postoperatively. There were only three patients who required long-term AGMs out of which one had HTP in the postoperative phase. The rest two patients maintained their IOP on a single AGM only. Unlike AGV, AADI is a valve-less implant with a large plate surface area. In general, AADI patients require fewer AGMs in the long run for IOP control when compared with valved implants like AGV.[2,9] This is particularly significant in the Indian subcontinent where cost happens to be a crucial factor in deciding long-term AGM compliance. Hence, AADI can be a game changer in glaucoma management in such financially deprived and under-resourced populations.

The complete success rate at the end of 2 years was 84% in our cohort, whereas the overall success rate was 100% at the end of 2 years, meaning that none of the patients landed into failure. This is actually a high overall success rate, as the other studies on AADI reported an overall success rate between 80% and 90%.[4-6] Even the complete success percentage was quite higher in our study. Now, the criteria defining complete and qualified success had been almost the same in most of the studies. One of the reasons for getting a higher success rate in our study can be a relatively smaller cohort size of 20 patients, but then, few of these studies were done on almost similar sample size for AADI. Nevertheless, there are some differences in patient profiles between cohorts of different studies such as mean age or prior surgery rate or types of secondary glaucoma, which might explain the difference in success rate. Overall, such a high success rate in the long term helps in establishing the clinical efficacy of this newly developed implant, which was designed to do a similar job as its valved counterpart but with only a fraction of its cost.

The mean LogMAR BCVA at the time of surgery was 1.81 ± 1.58, then dropping to 1.91 ± 1.45 at 24 months postoperatively. Although the difference was not statistically significant, there were multiple factors responsible for this drop, although none were surgery related. A majority of our patients had postpenetrating keratoplasty glaucoma. The status of the graft is an important deciding factor in terms of visual acuity. At the time of AADI surgery, few of them had decompensated grafts. This decompensation kept progressing after surgery, even with good IOP control, leading to a further drop in vision. Similarly, we operated on patients who had proliferative diabetic retinopathy, ocular ischemic syndrome, postvitreoretinal surgery, etc., Such retinal pathologies result in a compromise in the visual status of the patients. None of the patients experienced a drop in vision, which could be attributed to AADI surgery.

Early postoperative complications were reported in 5 (25%) eyes in our study. There were two patients in whom we experienced postoperative hypotony and only one of them required the surgical intervention of tube stenting. The literature states that hypotony is the most common and most anticipated complication of AADI surgery. Philip *et al.,*[5] in their study, found the overall percentage of hypotony to be 20%. Similarly, Senthil *et al.*[2] found hypotony in 8 of 36 (22.2%) eyes in their study group. The percentage of patients who experienced hypotony in our study is lesser, as reported by these authors, and it is also on par with the incidence reported with AGV. Late postoperative complications were also seen in five eyes. Overall, the complications were seen in 50% of the eyes, but all of them except one were managed in the OPD only without any surgical intervention. None of the eyes experienced any tube or plate exposure. There were no sight-threatening complications in our cohort such as endophthalmitis or retinal detachment or aqueous misdirection. A HTP was observed in three of our patients and only one of them needed long-term AGMs. Overall, the safety profile of AADI appears to be good, with no major complication reported in our study.

Limitations

There were a few limitations of our study. The retrospective nature of the study is one of them. A planned prospective study would have been a good choice in chronic and progressive diseases like glaucoma. Selection bias and heterogeneous samples are a few other limitations. A relatively small sample is also one of our limitations. However, there are only a few studies on AADI with an intermediate-term follow-up. Our study certainly adds to the literature. Furthermore, all the surgeries were

performed by a single surgeon which brings homogeneity to the outcome assessment. Further prospective studies with prolonged follow-ups are warranted to establish AADI as a cornerstone in glaucoma management, especially refractory glaucoma.

Conclusion

Our study assessed the clinical outcomes, safety profile, and long-term AGM requirement with AADI and found it to be a good viable surgical option in refractory glaucoma. It, thus, can provide an alternative option in surgical management, especially in patients with limited financial capacity. Further follow-up is required to determine its sustainability overtime.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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