Original Research Article

Evaluation of the Efficacy and Safety of Affordable Glaucoma Drainage Device Implantation in Refractory Glaucomas: A Prospective Longitudinal Study

ABSTRACT

Aims: This study aimed to assess the efficacy and safety of implanting anaffordable glaucoma drainage device in patients with refractory glaucoma.

Methodology:A prospective longitudinal study was conducted involving 30 patients diagnosed with refractory glaucoma who underwent implantation of the Aurolab Aqueous Drainage Implant (AADI) between November 2021 and April 2022. All surgeries were performed by a single surgeon using a consistent technique. Patients were followed up for three months postoperatively. Outcome measures included postoperative intraocular pressure (IOP), best-corrected visual acuity (BCVA), the number of anti-glaucoma medications, and post-surgery complications. Complete success was defined as an IOP between ≥5 and ≤21 mm Hg, without the need for additional glaucoma medications.

Results: The majority of the patients were male (56.7%), while females comprised 43.3%. The mean age was 24.97 (±16.5). A significant decrease in the mean preoperative IOP from 31.67 (±9.8) mmHg to 12.7 (±4.0) mmHg was observed at the three-month follow-up, with a mean percentage reduction of 59.9% (P value <0.001). The mean number of preoperative topical anti-glaucoma medications (AGM) decreased from 3.17 (±0.59) to 0.17 (±0.53) at the three-month follow-up. Visual acuity remained stable in 10 (33.3%) eyes, improved in 9 (30%) eyes, and deteriorated in 11 (36.7%) eyes. Complications occurred in 4 patients (13.3%), including hyphema in 1 (3.3%) patient, choroidal detachment (CD) in 1 (3.3%) patient, and choroidal detachment with retinal detachment in 2 (6.6%) patients. The overall success rate was 96.6%.

Conclusion: The non-valved affordable glaucoma drainage device (AADI) demonstrated efficacy and safety in patients with refractory glaucoma, exhibiting good intraocular pressure control. Further follow-up is recommended to assess sustainability over time.

Keywords: Non valved Glaucoma Drainage Device (GDD), Refractory glaucoma, Aurolab Aqueous Drainage implant (AADI)

1. INTRODUCTION

Refractory glaucomas pose a treatment challenge as medical therapies often prove ineffective. Moreover, these conditions either exhibit poor responsiveness to conventional filtering surgeries or exhibit high failure rates. Aqueous drainage implants have become

pivotal in managing refractory glaucoma, particularly in eyes with previously failed trabeculectomy or high-risk secondary glaucomas, such as neovascular or uveitic glaucoma [1, 2]. The increased severity of glaucoma usually translates to elevated medication use and escalating treatment costs [3].

Generally, Glaucoma Drainage Devices (GDDs) establish alternative pathways by directing aqueous humor from the anterior chamber through a lengthy tube to an equatorial plate, promoting posterior bleb formation [4]. The commonly utilized drainage devices include the Baerveldt glaucoma implant lacking a valve mechanism and the Ahmed glaucoma implant, which incorporates an intrinsic valve mechanism to prevent overfiltration and subsequent hypotony [5]. Randomized control trials comparing Baerveldt versus Ahmed valve implants in refractory glaucoma treatment demonstrated lower failure rates with Baerveldt at 5 years, albeit with a slightly increased risk of hypotony [5–7].

Despite their proven efficacy in managing complicated glaucomatous eyes, the cost implications limit widespread application, especially in developing nations where patients' socioeconomic status heavily influences treatment choices. Most devices, predominantly imported from the West, remain expensive and unaffordable for a majority of refractory glaucoma patients.

There exists a pressing need for newer, more cost-effective drainage implants to address this situation and meet the increasing demand. The Aurolab Aqueous Drainage Implant (AADI; Aurolab, Madurai, India) is a novel, affordable drainage implant based on principles akin to the Baerveldt implant, lacking a valve mechanism. Recent studies have demonstrated its efficacy in reducing intraocular pressure (IOP) [8–10].

Professor George Baerveldt authorized the use of his highly successful design, leading to collaboration with the Bascom Palmer Eye Institute, Miami, Florida, for manufacturing the AADI. This implant became commercially available in India in June 2013 [11]. The 32-mm long end plate extends beyond 2 clock hours of circumference on the equatorial sclera. Despite its availability in India, there are only limited published data regarding the safety or efficacy of this implant [12, 13].

Evidence suggests that non-valved implants perform better, achieving lower target IOP with fewer anti-glaucoma medications and a reduced failure rate [14].

2. MATERIAL AND METHODS

This prospective longitudinal study involved 30 patients diagnosed with refractory glaucoma who underwent AADI surgery between November 2021 and April 2022, followed by a 3-month postoperative observation period. Informed consent was obtained from all eligible participants before surgery, and ethical approval was granted by the institutional review board of Ispahani Islamia Eye Institute and Hospital, Dhaka, Bangladesh. Inclusion criteria encompassed eyes with uncontrolled intraocular pressure (IOP) refractory to medical treatment and conventional filtering surgery, as well as eyes considered at high risk of failure following conventional filtering surgery. Exclusion criteria comprised eyes where Goldmann applanation tonometry was hazardous, such as those with keratoprosthesis, uncontrolled systemic disease, active ocular disease, poor compliance, or those unable to follow up.

Patient demographics including age, gender, and residence were recorded, followed by a comprehensive ophthalmological examination. This examination involved baseline assessment of best-corrected visual acuity (BCVA), IOP, preoperative glaucoma

parameters, etiology of glaucoma, previous history of failed filtering surgery, visual field assessment, number of antiglaucoma medications (AGM), and post-surgery complications. The main outcome variable assessed was postoperative intraocular pressure (IOP), while secondary outcome measures included the number of AGMs, BCVA, and complications. Complete success was defined as achieving an IOP between ≥5 and ≤21 mm Hg without the use of AGM. Qualified success was defined as meeting the aforementioned IOP criteria while using AGM. Total success included both complete and qualified success. Failure was characterized by an inability to fulfill IOP criteria, loss of light perception, device explantation, or the need for additional glaucoma surgery (such as a second glaucoma drainage device, transscleral diode laser, or endoscopic diode laser) to reduce IOP.

The surgical procedure, performed by a single surgeon, involved selecting the quadrant for implantation based on conjunctival condition (superotemporal, inferior temporal, inferior nasal, or superonasal quadrant)(Fig 1). A 3 to 5-hour conjunctival peritomy was conducted, followed by blunt dissection to free adhesions of conjunctiva and Tenon's capsule from the sclera in the chosen quadrant. The AADI wing was positioned beneath adjacent muscle bellies, and tube patency was verified before ligating the tube with 6-0 vicryl. The explant was secured to the sclera posterior to the limbus using two interrupted sutures of 9-0 nylon through fixation holes, with suture knots rotated into these holes to prevent conjunctival erosion. Additionally, a non-compressing 9-0 nylon suture was utilized to stabilize the tube to the sclera. The tube length was adjusted, and a beveled tip was created opening toward the cornea. A 23-gauge needle was then used to create a track behind the limbus for tube insertion either into the anterior chamber or behind the iris, covered with a partial-thickness scleral patch graft. Conjunctiva and Tenon's capsule were reapproximated to the limbus and closed with 8-0 vicryl. At the conclusion of the procedure, a subconjunctival injection of steroid (Dexamethasone 2mg) was administered.

Postoperative antibiotics were prescribed six times daily for four weeks, while topical corticosteroids were prescribed six to eight times daily for 6–8 weeks and tapered gradually. Topical cycloplegic eye drops were administered as required for 1-2 weeks. Antiglaucoma medications were continued based on postoperative IOP status. Follow-up visits were scheduled at 1 day, 7 days, 1 month, and 3 months postoperatively. Data collected for the various outcome measures were analyzed using SPSS version 22 to generate summary statistics (mean, median, range), percentages, and proportions for the listed outcome measures.

3. RESULTS

The study involved 30 patients with refractory glaucoma. The mean age was 24.97 (±16.5) years, comprising 13 males (43.3%) and 17 females (56.7%). Approximately 23.3% of patients were illiterate, while the majority (33.3%) completed primary education. A smaller percentage completed graduation (3.3%) or post-graduation (10%). Regarding occupation, 36.7% were students, 26.7% housewives, 16.7% day laborers, 13.3% businessmen, and only 6.7% were in service. Most patients (76.7%) came from rural areas, while 23.3% came from urban areas. The demographic areshown in the table 1.

Table 1: Demographic Data of the respondents

Demographic Variables	Frequency (n)	Percent (%)
Age group of the Respondents Mean Age= 24.97±16.5		
1 -16 Years	11	36.7
17 - 40 Years	14	46.7
41 - 60 Years	4	13.3
Above 60 Years	1	3.3
Sex		
Female	13	43.3
Male	17	56.7
Level of Education		
Illiterate	7	23.3
Primary	10	33.3
Secondary	6	20.0
Higher Secondary	3	10.0
Post-graduation	3	10.0
Graduation	1	3.3
Occupation		
Business	4	13.3
Day labor	5	16.7
Housewife	8	26.7
Service	2	6.7
Student	11	36.7
Location of Address		
Rural	23	76.7
Urban	7	23.3

Etiologies of glaucoma varied, including different types and post-operative statuses (Table 2). Visual acuity remained stable in 33.3% of eyes, improved in 30% of eyes, and deteriorated in 36.7% of eyes following surgeries (Table 3).

Table2: Etiology of glaucoma

Etiology of glaucoma	Frequency (n)	Percentage (%)
Absolute Glaucoma + Post DLCP	1	3.3
Post Trabeculectomy+ IOID	2	6.7
Congenital Glaucoma + Post Trabeculectomy	1	3.3
Post Trauma + RD Surgery	1	3.3
ICE Syndrome +Post Trabeculectomy	1	3.3
ICE Syndrome	4	13.3
PACG + NVG	1	3.3
Lasered PDR + NVG	2	6.7
POAG + Post Trabeculectomy+ Pseudophakia	1	3.3
Pseudophakia + Secondary Glaucoma	3	10
Pseudophakia + Post RD Surgery	1	3.3
ROP + Post PPV	1	3.3
Post PPV+ Ciliary Staphyloma	1	3.3
Post Repair Corneal Injury + RD+ Aphakia	1	3.3
Post SFIOL	2	6.7
Sturge-Weber syndrome	3	10
Viral Uveitis	1	3.3
VKH +Post Trabeculectomy with Pseudophakia	1	3.3
POAG+ Post Trabeculectomywith Ologen	1	3.3
Post PPV with Trabeculectomy	1	3.3

[DLCP= Diode Laser Cyclophotocoagulation; IOID= Idiopathic Orbital Inflammatory Disease; ICE= Iridocorneal Endothelial Syndrome; PDR= Proliferative Diabetic Retinopathy; PACG= Primary Angle Closure Glaucoma; POAG= Primary Open Angle Glaucoma; NVG= Neovascular glaucoma; RD= Retinal Detachment; PPV= Pars plana vitrectomy; SFIOL= Scleral Fixation Intraocular Lens; VKH= Vogt-Koyanagi-Harada disease]

Table 3: Status of Visual Acuity following after Surgeries

Visual Acuity Status	Frequency	Percent
Deteriorated	11	36.7
Improved	9	30.0
Stable	10	33.3
Total	30	100.0

Preoperative mean IOP was 31.67 (±9.8) mmHg, decreased to 12.7 (±4.0) mmHg at 3 months follow-up. Preoperative LogMAR visual acuity was 1.42 (±0.72), and at 3 months follow-up, it was 1.37 (±0.75). The number of preoperative antiglaucoma medications reduced from 3.17 (±0.59) to 0.17 (±0.53) at 3 months postoperatively (Table 4).Complications included hyphaema(3.3%), choroidal detachment (3.3%)and choroidal and retinal detachment(6.6%) (Fig 2).

Table 4: Preoperative and 3 Months follow up

Parameters	Preoperative (n=30)	3 Months follow up(n=30)	*P value*
IOP	31.67 (±9.8)	12.7 (±4.0)	<0.001
LogMAR Visual Acuity	1.42 (±0.72)	1.37 (±0.75)	0.627
AGM	3.17 (±0.59)	0.17 (±0.53)	<0.001

Figure 1: AADI tube in anterior chamber and plate in supero temporal region

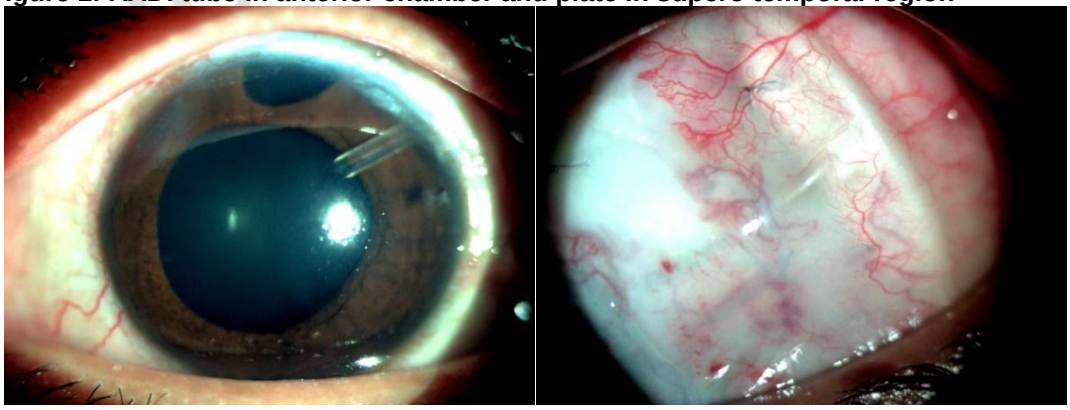
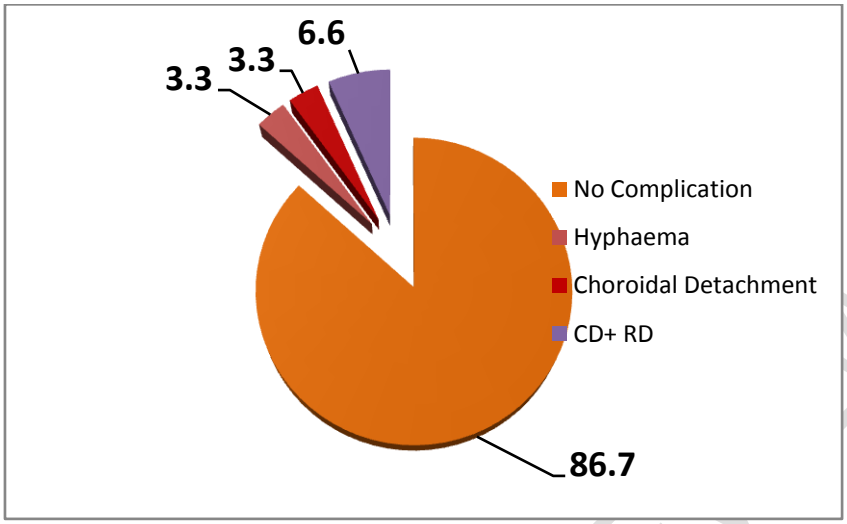


Figure 2: Complication Status of the respondents



DISCUSSION

Glaucoma drainage devices are widely used in treating refractive glaucoma, often serving as primary glaucoma procedures [15]. The Aurolab Aqueous Drainage Implant (AADI) is a recently introduced, affordable GDD inspired by the non-valved Baerveldt Glaucoma Implant (BGI) [16].AADI, a valveless drainage device without a flow restrictor [17, 18], requires intraoperative tube ligation to prevent postoperative hypotony. This results in persistent high IOP postoperatively until the ligation suture dissolves or is removed. Once patent, non-valved implants achieve substantial IOP reduction owing to their large filtration surface area [19]. However, hypotony and its complications are more common without flow restriction using a suture ligature [6, 20-21]. This suture typically dissolves 5–6 weeks postoperatively.

This prospective longitudinal study, conducted at a tertiary eye hospital in Bangladesh, evaluated 30 patients with refractory glaucoma treated with the AurolabAquous Drainage Implant. Surgeries were performed by a single surgeon using consistent techniques in the glaucoma department.In our study, the mean age was 24.97 (±16.5) years, with the majority being female at 56.7%, and male patients were 13 (43.3%). The preoperative mean IOP was 31.67 (±9.8) mmHg, which decreased to 12.7 (±4.0) mmHg at the 3-month follow-up. The number of preoperative antiglaucoma medications decreased from 3.17 (±0.59) to 0.17 (±0.53) at the final follow-up. Our study's results differ from others. For instance, George V. Puthuran, Paul Palmberg found different mean preoperative IOP and medication usage [21]. Another study by Sushmita Kaushik, Pankaj Kataria reported different IOP reductions at various postoperative intervals [11].

At the last follow-up, none of the patients required oral acetazolamide for IOP control. The preoperative LogMAR visual acuity was 1.42 (±0.72), and at 3 months follow-up, it became 1.37 (±0.75). Visual acuity remained stable in 10 (33.3%) eyes, improved in 9 (30%) eyes, and deteriorated in 11 (36.7%) eyes. The most common causes for vision loss were glaucoma, followed by corneal edema or cataract. Our study differs from another study by Vanita Pathak Ray, Divya P Rao, where median LogMAR BCVA did not change pre- and

postoperatively [23]. Approximately 70% of eyes in their study showed stable or improved VA. In a study by Sirisha Senthil, VA outcomes varied [24].

Complete success was 90%, and qualified success was 96.6%. Our study's results differ from other studies, such as Vanita Pathak Ray and Divya P Rao, who found overall success to be 87.5% [23]. Another study by Sushmita Kaushik, Pankaj Kataria reported different probabilities of success at various intervals [11].

Complications occurred in 4 patients after AADI implantation. Choroidal detachment (3.3%) due to hypotony occurred in the early postoperative period. Hyphema occurred in 1 (3.3%) patient, and choroidal detachment with retinal detachment occurred in 2 (6.6%). In our study, no eyes developed other serious sight-threatening complications like endophthalmitis or aqueous misdirection. A study by Paul Palmberg, George V. Puthuran reported various complications during their study period [22].

However, this study has limitations, including its small sample size and relatively shorter follow-up period. Prospective, randomized trials with longer follow-up periods are necessary to validate this technique. Despite these limitations, the surgical outcomes of this study show that the valveless Aurolab Aqueous Drainage Implant is effective in lowering IOP from baseline.

CONCLUSION

Our findings suggest that the utilization of a non-valved, affordable glaucoma drainage device demonstrates effectiveness in managing intraocular pressure among patients with refractory glaucoma. This cost-efficient solution presents promising potential for addressing the needs of individuals afflicted with this condition.The observed control of intraocular pressure signifies the device's efficacy in providing a viable alternative for patients seeking treatment for refractory glaucoma. However, to comprehensively assess its long-term viability and durability, further extensive follow-up studies are recommended. These subsequent evaluations would serve to elucidate the device's failure rate over extended periods, providing essential insights into its sustained efficacy and reliability as a treatment option for refractory glaucoma.

ETHICAL APPROVAL

The study was approved by the institutional review board of Ispahani Islamia Eye Institute and Hospital, Dhaka,Bangladeshand has therefore been performed in accordance with the ethical standards laid down in the 1964 declaration of helsinki.

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