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Safety and Efficacy of an Affordable Glaucoma Drainage Device Implantation (AADI) in Refractory Glaucoma

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Authors' contributions

This work was carried out in collaboration among all authors. Author HS did the conceptualization of the study. Author HS did data collection for the study. Author MSH did formal data analysis and prepared the first draft of the manuscript. Author HS wrote the original draft. Authors BKDS, KI and MSH reviewed and edited the manuscript. All authors proofread and approved the final version of the manuscript.

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ABSTRACT

Aims: This study aimed to assess the safety and efficacy of implanting an affordable 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)

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at Ispahani Islamia Eye Institute and Hospital, Dhaka, Bangladesh 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 safety and efficacy in patients with refractory glaucoma, exhibiting good intraocular pressure control. Further follow-up is recommended to assess sustainability over time.

Keywords: Glaucoma Drainage Device (GDD); refractory glaucoma; Aurolab Aqueous Drainage Implant (AADI).

1. INTRODUCTION

"Refractory glaucoma occurs when intraocular pressure remains uncontrolled despite maximum tolerated anti-glaucoma medications, unsuccessful non-seton surgical treatments, or a high risk of trabeculectomy failure" [1]. "It poses 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" [2]. "Initially, glaucoma drainage devices (GDD) were specifically utilized when trabeculectomy did not achieve the desired outcomes. However, Glaucoma drainage devices are now increasingly preferred as the primary surgical intervention for managing refractory glaucoma" [3]. "GDDs are surgically implanted to create a new passage for the aqueous humor to flow. The tube or implant within the eye allows the aqueous humor to bypass the natural drainage route and redirect it to a space beneath the conjunctiva" [4]. "The Ahmed glaucoma valve (AGV; New World Medical, Rancho Cucamonga, California, USA) and the Baerveldt glaucoma implant (BGI; Advanced Medical Optics, Santa Ana, California, USA) represent two frequently utilized glaucoma drainage devices implanted in the eye. These implants follow a similar structure, featuring a tube situated within the anterior chamber of the eye and linked to a plate positioned around the equatorial region of the eyeball" [5].8

"Several studies have compared the Ahmed and Baerveldt glaucoma drainage devices (GDDs) regarding their efficacy, safety, and outcomes in managing intraocular pressure (IOP) in patients with glaucoma. These studies highlighted that while both devices effectively reduced IOP, Baerveldt implants demonstrated a slightly greater success rate in achieving lower IOP levels over a more extended follow-up period compared to Ahmed implants" [6-8]. "However, Baerveldt implants were associated with a higher rate of complications such as hypotony in some cases" [7,8]. "Despite the proven efficacy of these devices in managing complicated eyes with intractable glaucoma the cost burden prohibits their widespread application, especially in the developing world where patients socio-economic status is an important determinant for choosing treatment options" [9,10]. "The majority of these devices are sourced from Western countries, carrying high costs that render them inaccessible to a significant portion of patients dealing with refractory glaucoma due to their unaffordability" [11].

"The Aurolab aqueous drainage implant (AADI) which is a non-valved silicone implant with a 350-mm2 surface area, developed by Aurolab, a division of the Aravind Eye Institute in Madurai, India" [12]. "It has obtained European conformity (CE) certification and has demonstrated its safety and effectiveness in both pediatric and adult populations" [13]. "The AADI is notably more

economical, being approximately one-fifth of the cost of the AGV" [14].

"Most studies comparing AADI to AGV have demonstrated AADI's superior success rates with notably reduced postoperative intraocular pressure (IOP) and decreased reliance on antiglaucoma medications (AGM), predominantly conducted on Indian eyes, considering AADI's origin in India" [2,3,15,16]. "One study, involving a diverse adult and pediatric group in the Middle East, revealed positive results, whereas another study focused on younger children reported a high incidence of adverse events in their outcomes" [17, 18].

The aim of the current study was to assess the safety and efficacy of an affordable glaucoma drainage device (AADI) in Bangladeshi patients with refractory glaucoma.

2. MATERIALS AND METHODS

This prospective longitudinal study involved 30 patients diagnosed with refractory glaucoma who underwent AADI surgery at Ispahani Islamia Eye Institute and Hospital, Dhaka, Bangladesh 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

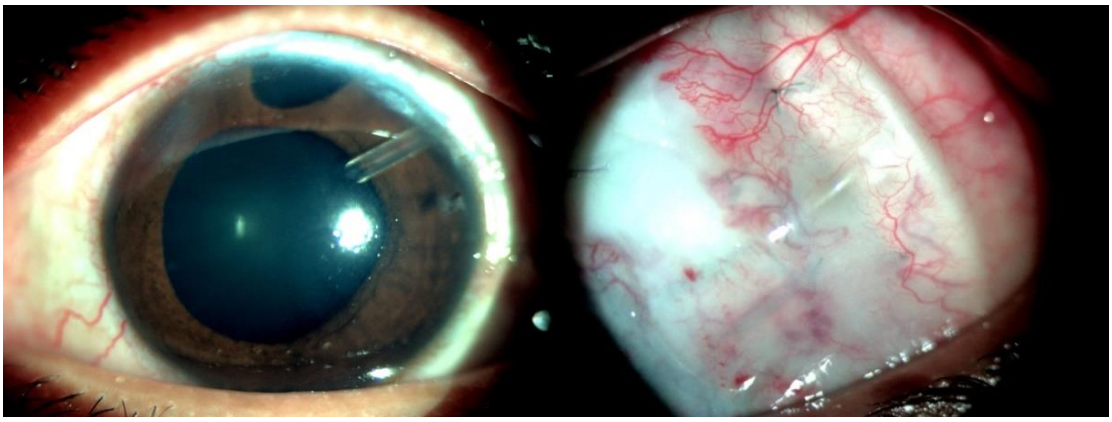

Fig. 1. AADI tube in anterior chamber and plate in supero temporal region

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. Chi square test was used as appropriate, to evaluate the statistical significance of the differences between the preoperative and post-operative findings of the participants. Inferential statistics were done at a 95% confidence interval and 5% level of significance.

3. RESULTS AND DISCUSSION

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 are shown in the Table 1.

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).

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

Table 2. 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 Trabeculectomy with 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). The complete success rate was 90% (27 cases), defined as post-operative IOP between ≥5 and ≤21 mm Hg without the use of AGM. The qualified success rate was 96.6% (29 cases), indicating meeting the aforementioned IOP criteria while using AGM (as shown in Table 5).

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

Table 5. Status of success rate

Success rate	Number (N)	Percentage (%)
IOP ≥5 and ≤21 mm Hg without use of AGM	27	90%
IOP ≥5 and ≤21 mm Hg with the use of AGM	29	96.6%

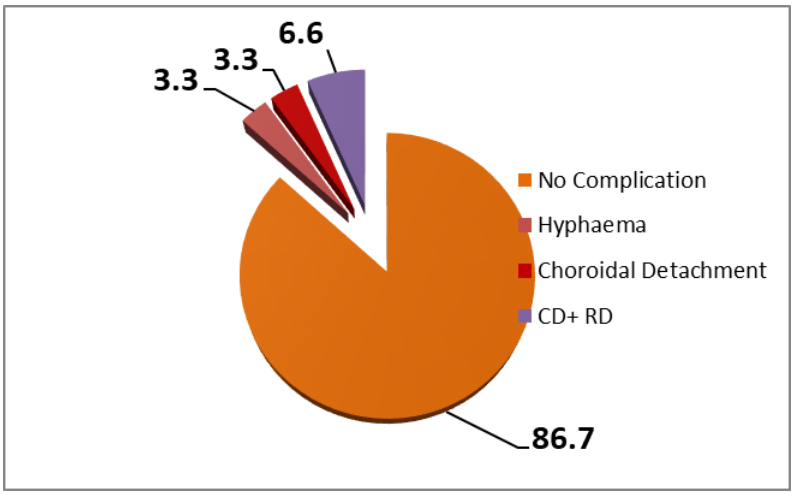

Fig. 2. Complication Status of the respondents

"Glaucoma drainage devices are widely used in treating refractive glaucoma, often serving as primary glaucoma procedures. The Aurolab Aqueous Drainage Implant (AADI) is a recently introduced, affordable GDD inspired by the non-valved Baerveldt Glaucoma Implant (BGI)" [5].

The AADI, a valveless drainage device without flow restriction, necessitates intraoperative tube ligation to prevent postoperative hypotony [19,20]. Consequently, high intraocular pressure (IOP) persists until the dissolving or removal of the ligature, yet once it's removed, these nonvalved implants effectively reduce IOP due to their extensive filtration surface area [21]. However, instances of hypotony and its related complications are more prevalent when flow is not regulated by employing a suture ligature [5,7], which typically dissolves around 5 to 6 weeks after surgery.

This prospective longitudinal study, conducted at a tertiary eye hospital in Bangladesh, evaluated 30 patients with refractory glaucoma treated with the Aurolab Aquous 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, Puthuran, et al. found different mean preoperative IOP and medication usage [11]. Another study by Kaushik et al. reported different IOP reductions at various postoperative intervals [19].

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 Pathak Ray, where median LogMAR BCVA did not change pre- and postoperatively [2]. Approximately 70% of eyes in their study showed stable or improved VA. In a study by Sirisha Senthil, VA outcomes varied [15].

In our study, complete success rate was 90%, and qualified success rate was 96.6%. Our study's results differ from other studies, such as Ray and Divya, who found overall success to be 87.5% [2]. Another study by Kaushik et al. reported different probabilities of success at various intervals [19].

"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 Puthuran et al. reported various complications during their study period" [11].

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.

4. 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.

CONSENT AND ETHICAL APPROVAL

The study was approved by the institutional review board of Ispahani Islamia Eye Institute and Hospital, Dhaka, Bangladesh (Reference No: IIEIH/ERC/21-03) and has therefore been performed in accordance with the ethical standards laid down in the 1964 declaration of helsinki. The aims and objective of the study along with its procedure, methods, risks and benefits of this study was explained to the patients in easily understandable local language and then informed consent was taken from the patient. It was assured that all information and records will be kept confidential and the procedure will be helpful for both the physicians and the patients in making rational approach of the case management.

COMPETING INTERESTS

Authors have declared that no competing interests exist

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