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Efficacy and Safety of a Low Cost Glaucoma Drainage Device Implantationin Refractory Glaucoma - A Prospective Longitudinal Study.

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ABSTRACT:

Purpose:

To determine theefficacy and safety of a low cost glaucoma drainage device implantation in refractory glaucoma .

Materials and Methods:

In this prospective, longitudinal study 30 Patients of refractory glaucoma where we implanted low cost glaucoma drainage device- Aurolab Aqueous Drainage Implant (AADI) werestudied between November 2021 to April 2022. All surgeries was performed by a single surgeon using the same technique eachtime . The patients were followed up for 3 months postoperatively. Outcome measures were postoperative intraocular pressure(IOP), Best corrected visual acuity (BCVA), number of anti-glaucoma medications and complication after surgery .Complete success was defined as an IOP ≥5 and ≤21 mm Hg, with no additional glaucoma medications.

Results:

The majority of the patients were male (56.7%), where female were 43.3%. The mean age was 24.97 (±16.5). There was significant decrease in mean preoperative IOP from 31.67 (±9.8) mmHg to 12.7 (±4.0) mmHg at 3 months follow up with mean percentage of reduction of 59.9% (P value <0.001). Mean number of preoperative topical antiglaucoma medications (AGM) decreased from 3.17 (±0.59) to 0.17 (±0.53) at 3 months follow up. Visual acuity remains 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 %), where hyphaema 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%).

Conclusions:

Non valved low cost glaucoma drainage device (AADI) is effective and safe for patients with refractory glaucoma with good intraocular pressure control. Still further follow-up is recommended to see sustainability over time.

Keywords: Non valved Glaucoma Drainage Device,GDD,refractory glaucoma, Aurolab Aqueous Drainage implant,AADI.

I. INTRODUCTION:

Refractory glaucomas are challenging to treat as medical therapy is usually ineffective; additionally, these either do not respond well to conventional filtering surgery or have high failure rates[1]

Aqueous drainage implants have become the mainstay in the management of eyes with refractory glaucoma, which typically involve eyes with prior failed trabeculectomy or secondary glaucomas that are known to be high risk for failure of trabeculectomy,[2]such as neovascular or uveitic glaucoma. Greater severity of glaucoma usually leads to more medications and escalating costs of treatment[3.]

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Typically, GDDs create alternate pathways by channeling aqueous from the anterior chamber to an equatorial plate through a long tube and promote bleb formation posteriorly.[4]

The most commonly used drainage devices are the Baerveldt glaucoma implant which is without a valve mechanism and the Ahmed glaucoma implant, which has an intrinsic valve mechanism to prevent overfiltration and thus prevent hypotony[5]. Two randomized control trials evaluated the safety and efficacy of the Baerveldt versus Ahmed valve for treating eyes with refractory glaucoma and found the Baerveldt to have lower failure rates at 5 years, but it carried a slightly higher risk of hypotony[5-7].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.

Most devices are imported from the West, expensive, and unaffordable to a large majority of patients with refractory glaucoma. Thus, there is a need for newer and more affordable drainage implants to address the situation and meet the increasing demand of drainage implants.

The Aurolab Aqueous Drainage Implant (AADI; Aurolab, Madurai, India) is a new, low-cost drainage implant based on similar principles as the Baerveldt implant, is without a valve, and has been shown to be effective in lowering IOP in some recent studies [8-11] .

Professor George Baerveldtauthorised the use of his very successful design, and the device was manufactured in collaboration with the Bascom Palmer Eye Institute, Miami, Florida. The AADI was made commercially available in India in June 2013. [12]

The 32-mm long end plate extends beyond 2 clock hours of circumference on the equatorial sclera. Though the implant is available for use in India, there are only a couple of published data about the safety or efficacy of this implant; [13,14]

There is evidence that non-valved implants fare better, with lower target IOP achievable with lesser number of anti-glaucoma medications and a lower failure rate. [15]

II. METHODS

This prospective longitudinal study included 30 patients of refractory glaucoma who underwent AADI surgery from November 2021 to April 2022 with 3 months postoperative follow up.Informedconsent was obtained from all eligible participants before undertaking surgery. The institutional review board of IspahaniIslamia Eye Institute and Hospital provided ethical approval for this study. Inclusion criteria was eyes with uncontrolled IOP refractory to medical treatment and conventional filtering surgery and eyes considered at high risk of failure following conventional filtrering surgery .Exclusion criteria was eyes where Goldmannapplanation tonometry is hazardous likekeratoprosthesis, uncontrolled systemic disease ,active ocular disease and poor compliance or unable to give follow up.Patient demographics such as age ,gender, residence, were noted followed by comprehensive ophthalmological examination including recording of baseline best corrected visual acuity(BCVA),IOP, preoperative glaucoma parameters ,etiology of glaucoma,previous history of failed filtering surgery and visual field assessment, number of antiglaucoma medications(AGM) and complication after surgery. Main outcome variable was post operative intra ocular pressure.The secondary outcome measures were number of AGMs, BCVA, and complications. Complete success was defined as IOP $\geq$5 and $\leq$21 mm Hg without use of AGM. Qualified success was defined as fulfilling the above IOP criteria with the use of AGM. Total success included complete and qualified success. Failure was defined as the inability to fulfill IOP criteria, loss of perception of light, explantation of device, or any additional glaucoma surgery (second glaucoma drainage device, transscleral diode laser, endoscopic diode laser) to reduce IOP.

Surgical procedure

All surgeries was performed by a single surgeon. .The quadrant of choice for the implant was the superotemporal quadrant, followed by the inferior temporal, inferior nasal quadrants or superonasal quadrant, depending on the condition of the conjunctiva in that region. A 3-hour to 5-hour conjunctival peritomy was performed. Blunt dissection was used to lyse adhesions of conjunctiva and Tenon's capsule from the sclera in the selected quadrant. The superior and lateral recti muscles (for superotemporal implantation) or inferior and medial recti muscles (for inferonasal implantation) were sequentially isolated, and 1 wing of the AADI was placed beneath adjacent muscle bellies. Patency of tube is checked and tube is ligated with 6-0 vicryl .The explant was then secured to the sclera 9 to 10 mm posterior to the limbus using 2 interrupted sutures of 9-0 nylon (Aurolab) through the fixation holes. The suture knots were rotated into the fixation holes to prevent

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erosion through the conjunctiva. A non compressing 9-0 nylon suture in the form of a box mattress was used to stabilize the tube to the sclera.. The suture knots are rotated into the fixation eyelets to prevent erosion through the conjunctiva. The tube length is shortened to approximately 13 mm (measuring 3 mm when placed across the limbus), with a beveled tip opening toward the cornea. A 23-gauge needle is used to create a track 1.5-2 mm behind the limbus through which the tube is inserted either into the anterior chamber just anterior and parallel to the iris for anterior chamber placement or behind the iris for a sulcus placement. It is 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) is given.

Postoperative antibiotics was prescribed six times daily for 4 week, and topical corticosteroids are prescribed six to eight times daily for 6–8 weeks and tapered.Topicalcycloplegic eye drops were used as per requirement for 1-2 weeks.Antiglaucoma medications were continued as required for the postoperative IOP status.Follow-up visits scheduled at 1 day, 7 days, 1 month, 3 months postoperatively.Data was collected for the different outcome measures listed above which was analyzed using SPSS version 22 togenerate summary statistics (mean, median, range); percentages and proportions for the outcome measures listed above.

III. RESULTS

A total of 30 patients of refractory glaucoma were included in the study.The demographic and clinical data are summerized in tables below. The mean age was 24.97(±16.5)years, with male were 13(43.3%) and female were 17(56.7%).

Table 1: Distribution of Age group of the respondents

Age group of the Respondents	Frequency (n)	Percent (%)	Statistics
1 -16 Years	11	36.7	Mean= 24.97 (±16.5), Minimum= 5, Maximum= 63, Range= 58
17 - 40 Years	14	46.7	
41 - 60 Years	4	13.3	
Above 60 Years	1	3.3	
Total	30	100.0	

Table 2: Distribution of Sex of the respondents

Sex	Frequency (n)	Percent (%)
Female	13	43.3
Male	17	56.7
Total	30	100.0

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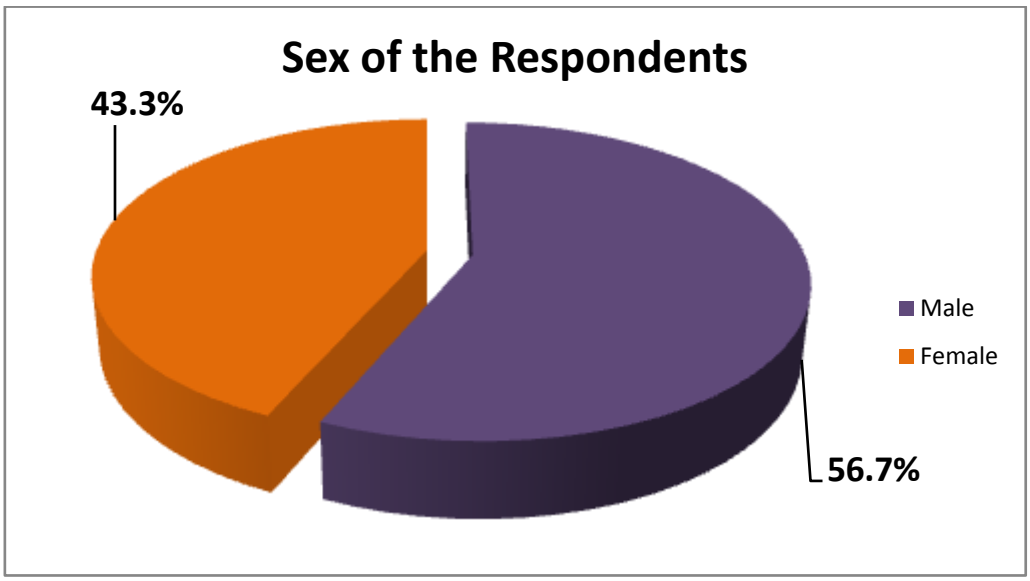

About 23.3% patients are illiterate, most of the patients(33.3%) complete their primary level,3.3% patients complete their graduation and 10% patients complete their post graduation.

Table 3: Level of Education of the respondents

Level of Education	Frequency (n)	Percent (%)
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
Total	30	100.0

Most of the patients around 36.7% werestudent,only 6.7% patients service holder,26.7% housewife,16.7% day labour and 13.3% patients were businessman.

Table 4: Occupational status of the respondents

Occupation	Frequency (n)	Percent (%)
Business	4	13.3
Day labor	5	16.7
Housewife	8	26.7
Service	2	6.7
Student	11	36.7
Total	30	100.0

Most of the patients(76.7%) came from rural area and only 23.3% patients came from urban.

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Table 5: Location of the respondents

Location of Address	Frequency (n)	Percent (%)
Rural	23	76.7
Urban	7	23.3
Total	30	100.0

Table6 : Etiology of glaucoma

	Frequency (n)	Percentage (%)
Absolute glaucoma + post DLCP	1	3.3
Posttrab + IOID	2	6.7
Congenital glaucoma + post trab	1	3.3
Post trauma + RD surgery	1	3.3
ICE syndrome +post trab	1	3.3
ICE syndrome	4	13.3
PACG + NVG	1	3.3
Lasered PDR + NVG	2	6.7
POAG +post trab+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 trab with pseudophakia	1	3.3
POAG+ Post Trab with ologen	1	3.3
Post PPV with trab	1	3.3

DLCP, Diode Laser Cyclophotocoagulation;IOID,Idiopathic orbital inflammatory disease;ICE ,Iridocorneal endothelial syndrome;PDR,Proliferativediabetec retinopathy , PACG-Primary angle closure glaucoma.POAG,Primary open angle glaucoma;NVG,Neovascularglaucoma;RD,Retinal detachment;PPV,Parsplanavitrectomy;SFIOL,Scleral fixation intraocular lens;IOID,Idiopathic orbital inflammatory disease;VKH,VogtKoyanagi Harada syndrome;Trab,trabeculectomy.

Visual acuity remained stable in 33.3% eyes, improved in 30% eyes and deteriorated in 36.7% eyes.

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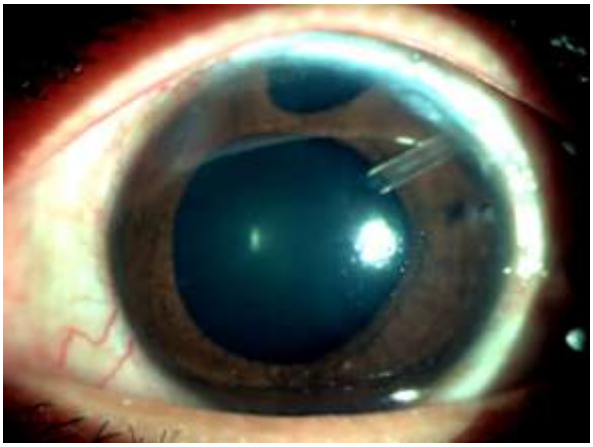
Table 7: Status of Visual Acuity following after Surgeries

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

The preoperative mean IOP was 31.67 (±9.8)mmHg which was decreased to 12.7 (±4.0)mmHg at 3 months follow up.The preoperative LogMAR visual acuity was 1.42 (±0.72) and at 3 months follow up it became 1.37 (±0.75). Number of preoperative antiglaucoma medication was decreased from 3.17 (±0.59) to 0.17 (±0.53) at 3 months postoperatively.

Table8: 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



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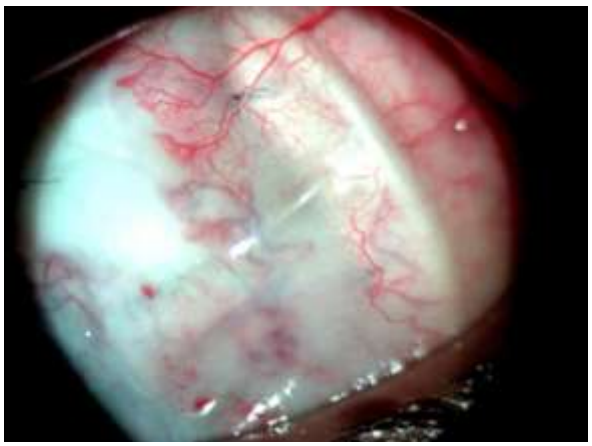
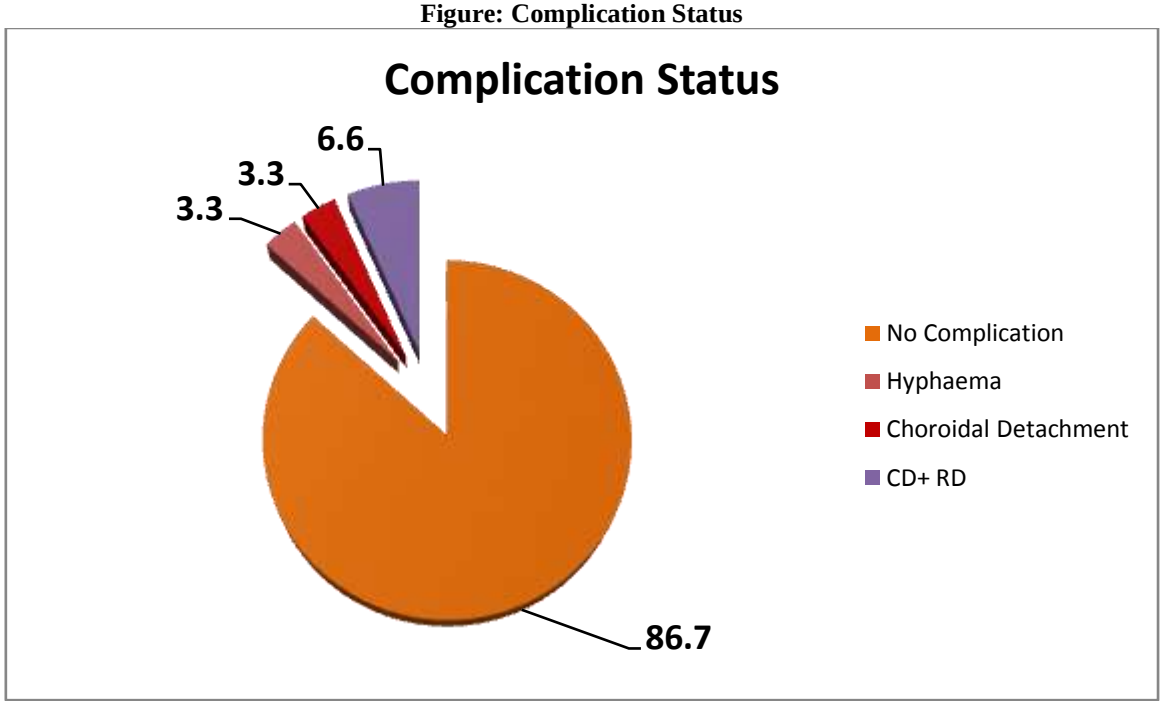


Figure: AADI tube in anterior chamber and plate in supero temporal region.

Complications included hyphaema(3.3%), choroidal detachment (3.3%)and choroidal and retinal detachment(6.6%).

Figure: Complication Status



IV. DISCUSSION:

Glaucoma drainage devices have been used widely in the treatment of refractive glaucoma and even as a primary glaucoma procedure.[19]

The Aurolab Aqueous Drainage Implant is a new low-cost GDD which has been recently introduced; its design is inspired by the non-valvedBaerveldt Glaucoma Implant (BGI) 350 mm 2 .

AADI is a valve-less drainage device without any flow restrictor,[20,21]requiring intraoperative tube ligation to prevent postoperative hypotony. This results in persistence of high IOP in postoperative period until the ligation-suture dissolves or is removed. Once patent, the nonvalved implants achieve good IOP reduction owing to its large filtration surface area, [22]buthypotony and its resultant complications are much more common if flow is not restricted by

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using a suture ligature[23-25] This suture usually dissolves in 5–6 weeks postoperatively.

This prospective longitudinal study conducted at a tertiary eye hospital in Bangladesh evaluated 30 patients of refractory glaucoma treated with AurolabAquous Drainage Implant. The surgeries were done by single surgeonusing the same technique each time in the glaucoma department.

In our study The mean age was 24.97 (±16.5)years, the majority of patients were female at 56.7%,with male were 13(43.3%) .The preoperative mean IOP was 31.67 (±9.8)mmHg which was decreased to 12.7 (±4.0)mmHg at 3 months follow up.,Number of preoperative antiglaucoma medication was decreased from 3.17 (±0.59) to 0.17 (±0.53) at final follow up.Our study result is differing from other study, George V. Puthuran,PaulPalmberg found the mean preoperative IOP was 34.7±9.9 mmHg with 3.2±0.7 AGMs. At 1 year, the mean IOP decreased to 15.10±6.7 mmHg with 1.51±1.1 medications[26].Another study ofSushmita Kaushik, Pankaj Kataria, IOP reduced from preoperative mean 27.4±7.5mm Hg on maximum medication (including systemic acetazolamide) to 14.6±10.74mm Hg, 13.8±7.5mm Hg, 12.8±5.6mm Hg and 14.7±5.8mm Hg at 1 week, 6 months, 1 year and 2 years postoperatively, respectively [12].

None of the patients required oral acetazolamide for control of IOP at the last follow-up.The preoperative LogMAR visual acuity was 1.42 (±0.72) and at 3 months follow up it became 1.37 (±0.75).Visual acuity remains stable in 10 (33.3%) eyes, improved in 9 (30%) eyes and deteriorated in 11 (36.7%) eyes.The most common cause for vision loss was glaucoma followed by corneal oedema or cataract.Our study differ from another study Vanita PathakRay,Divya P RaomedianLogMAR BCVA did not change pre- and postoperatively at last follow-up; notably, none developed loss of perception of light. Approximately 70% of eyes had stable or improvement of VA.[28] A study of SirishaSenthilshowedIn the AADI group, VA was same in 19 eyes (52.8%), improved in 11 eyes (30.6%), and decreased in 6 eyes (16.7**%)**[27]**.**

Complete success was 90% and qualified success was 96.6%.Our study result is differing from other study,Vanita Pathak Ray and Divya P Rao they found overall success was 87.5%[28]**.**Another study of SushmitaKaushik ,PankajKataria reported the cumulative probability of success was 91.18% at 6 months and 81.7% at 18–24 months.[12]

Complications occurred in 4 patients after AADI implant. Choroidal detachment(3.3%) due to hypotony occurred in early postoperative period,Hyphaema occurred in 1(3.3%) patient and choroidal with retinal detachment occurred in 2 (6.6%).In our studyno eyes developed other serious sight threatening complications likeendophthalmitis or aqueous misdirection.A study of George V.Puthuran,PaulPalmbergreportedforty-seven complications were seen in 38 eyes (24%) during the study period .During the early postoperative period (1 year)choroidal detachment was the most common complication followed by fibrinous reaction in anterior chamber and hypotony,Tube occlusion was seen in 2 eyes ,1 eye had retinal detachment.Delayed complications occurred in the form of corneal decompensation, graft failure, and delayed hypotony.Significant vision loss occurred in 9 eyes (5.7%) as the result of corneal decompensation (n = 3), retinal detachment (n =1), aqueous misdirection (n =1), and hypotony maculopathy (n =4).[26]

The shortcomings of this study include its small sample size and shorter follow-up period. Prospective, randomized trials with longer follow-up periods is needed to validate this technique. Despite these limitations, the surgical outcomes of this study show that valvelessAurolab Aqueous Drainage Implant is effective in lowering IOP from base line IOP.

V. CONCLUSIONS:

We conclude that non valved low cost glaucoma drainage device is effective for controlling intraocular pressure and has the ability to be a viable low cost solutions for patients with refractory glaucoma.Still further follow-up is recommended to determine failure rate.

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