

Surgical Outcomes of Ahmed Glaucoma Valve and Aurolab Aqueous Drainage Implant in Nepalese Eyes: Comparison in the First Year

Anil Parajuli¹, Indira Paudyal², Pratibha Lama Joshi², Suman Shamsher Thapa³

¹Himalaya Eye Hospital, Gharipatan, Pokhara, Kaski, Nepal ²Tilganga Institute of Ophthalmology, Gaushala, Kathmandu, Nepal ³Sudristi Eye Clinic, Kathmandu, Nepal

ABSTRACT

Introduction: Glaucoma is the leading cause of irreversible blindness worldwide. Though trabeculectomy still remains the surgical modality of choice for the management of glaucoma, the outcome of glaucoma drainage devices (GDDs) too has been encouraging in recent years.

Objectives: To compare the surgical outcomes of Ahmed glaucoma valve (AGV) and Aurolab aqueous drainage implant (AADI) in cases of refractory glaucoma in Nepalese eyes.

Materials and methods: We retrospectively studied the charts of the patients with refractory glaucoma who had undergone GDD implantation at Tilganga Institute of Ophthalmology (TIO), Kathmandu, Nepal. Depending on which GDD was implanted, the eyes of the patients were divided into: AGV group and AADI group. The outcome measures of the study were intraocular pressure (IOP), requirement of anti-glaucoma medications (AGMs), surgical success and complications.

Results: There were 24 eyes of 23 patients in AGV group and 31 eyes of 30 patients in AADI group with a median (quartiles) follow-up of 12 (12,12) months. In the final visit, IOP and AGMs were both significantly lower than the baseline in both the groups (P < 0.001). The median IOP in mmHg and AGMs were both significantly lower in the AADI group compared to AGV group in the final visit, p <0.001 and p=0.002, respectively. The overall success was similar in both the groups: AGV (n=22, 91.67%) and AADI (n=29, 93.55%), p=1.0. However, complete success was significantly more in AADI group (n=16, 51.61%) compared to AGV group (n=6, 25%), p=0.046. Complications and their rates were comparable between the two groups (p=0.4).

Conclusion: Both AGV and AADI safely and effectively reduced the IOP and the number of AGMs in cases of refractory glaucoma in Nepalese eyes.

Key words: Ahmed glaucoma valve, Aurolab aqueous drainage implant, Glaucoma drainage device, Refractory glaucoma.

Financial Interest : Nil Conflict of Interest : Nil

Corresponding Author Dr. Anil Parajuli Himalaya Eye Hospital, Gharipatan, Pokhara-17, Nepal. E-mail: anil.parajuli861@gmail.com





Access this article online

Website: www.nepjol.info/index.php/NEPJOPH DOI: https://doi.org/10.3126/nepjoph.v15i1.52436 Copyright © 2022 Nepal Ophthalmic Society ISSN: 2072-6805, E-ISSN: 2091-0320

This work is licensed under a Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License (CC BY-NC-ND).

Note: This article was presented as a poster at the 10th World Glaucoma Congress in Rome, Italy, June 28-July 1, 2023.

INTRODUCTION

Glaucoma is one of the leading causes of irreversible blindness worldwide (Pascolini and Mariotti, 2012; Quigley and Broman, 2006; Leske et al, 2003; Kass et al, 2002) including Nepal (Brilliant et al, 1985). Glaucoma drainage devices are being increasingly used in the management of high risk and complicated cases of glaucoma, both as primary and secondary surgical modality (Wilson et al, 2003; Ayyala et al, 2002; Lai et al, 2000; Wilson et al, 2000; Kook et al, 2000; Topouzis et al, 1999; Leuenberger et al, 1999; Huang et al, 1999; Ayyala et al, 1998; Coleman et al, 1995). This change in practice can be attributed mainly to the outcomes of the Tube Versus Trabeculectomy (TVT) study (Gedde et al, 2012a; Gedde et al, 2012b; Gedde et al, 2009).

Various manufacturers have developed different GDDs that differ in biochemical properties and the presence or absence of valve (Tsai et al, 2003). They all, however, share a common design in having a tube connecting the anterior chamber (AC) to a plate located in the equatorial region of the globe (Budenz et al, 2011). The valved GDDs were designed to reduce the incidence of postoperative hypotony, however, the long-term success in terms of reduction in IOP and number of AGMs has been better with the non-valved devices (Christakis et al, 2016; Budenz et al, 2015; Ayyala et al, 2002). The Ahmed glaucoma valve (AGV; New World Medical, Rancho Cucamonga, CA, USA) and the Baerveldt glaucoma implant (BGI; Advanced Medical Optics, Santa Ana, CA) are the two most commonly used valved and non-valved GDDs, respectively. The Aurolab aqueous drainage implant (AADI; Aurolab, Madurai, India) is a

non-valved GDD designed as a prototype of the BGI to remove the cost barrier to easy access to non-valved GDD in developing countries (Pathak et al, 2018b). AADI has already gained a European conformity (CE) mark and is yet to receive approval from the Food and Drug Administration (FDA). However, studies from India have shown that the outcomes of AADI are comparable to AGV implant (Pandav et al, 2020; Pathak et al, 2018a; Rathi et al, 2018). A recent retrospective study from Saudi Arabia reported that AADI was comparable to BGI in terms of safety and efficacy (Hafeezullah et al, 2021).

With more Nepalese glaucoma specialists being trained to perform implant surgery, the number of GDD surgeries too is rising here. However, there is a lack of a study looking into the outcomes of implant surgeries in Nepalese eyes. This study aims to investigate and compare the safety and efficacy of AGV and AADI in Nepalese eyes.

MATERIALS AND METHODS

This retrospective chart review was conducted in accordance with the Declaration of Helsinki and good clinical practice guidelines. The authors retrospectively analyzed the data of patients who had undergone GDD surgery from April 2017 to May 2020 at a tertiary eye hospital in Nepal. The Institutional Review Committee of Tilganga Institute of Ophthalmology (TIO), Kathmandu, Nepal, approved the study and waived the requirement of informed consent because of the nature of the study (Reference number: 05/2022).

Electronic medical records of the hospital were reviewed to collect the detail demographic,



medical and ocular history of the patients. Besides recording which GDD the patients received, we also recorded pre-operative data like: IOP, number of AGMs, lens status, diagnosis and history of previous ocular surgery including filtration surgery.

IOP was measured with slit-lamp-mounted Haag-Streit Goldmann applanation tonometer (Haag-Streit, Bern, Switzerland). Eyes of the patients were divided into two groups depending on which GDD was implanted: AGV group {eyes that received AGV (AGV-FP7) implant} and AADI group {eyes that received AADI (AADI Model 350) implant}. We included only those patients who had a minimum follow-up of six months. We however, did not exclude the eyes that had undergone failure within the first six months of surgery, but their data of IOP and AGM were censored from further analysis. We excluded cases with no perception of light (NPL), those with a history of previous GDD surgery, cyclodestructive procedures and cases in which IOP was not monitored in two or more consecutive follow-up visits.

Patients were reviewed post-operatively on day one, week one, week two, month one, month two, month third, month six, month nine, and month 12. We recorded IOP and AGM on every post-operative visit and noted any complication.

All surgeries were performed by one of two fellowship-trained glaucoma specialists (SST and IP). Following localized conjunctival peritomy, the sub-tenon space was dissected, most commonly in the supero-temporal quadrant. The implant (AGV/AADI) was inserted into the subtenon space. In case of AADI the lateral expansions of the plate were

fashioned beneath the adjacent recti according to the surgeon's usual practice (under superior rectus and lateral rectus for supero-temporal GDDs). The plate was fixed to the sclera around 10 mm from limbus using 6-0 silk suture (Aurosilk; Aurolab, Madurai, India). The tube of AADI was ligated near tube plate junction with Polyglactin 910, 6-0 suture (Vicryl, Ethicon, Johnson & Johnson Ltd., India) and tested for occlusion. Two to three pairs of venting incisions were made anterior to the ligated tube and tested for patency. The tube of AGV was primed with balanced salt solution (BSS) to check for patency. A 23-gauge needle was used to create a scleral track starting 1.5-2 mm behind the limbus to enter the anterior chamber. The tube was shortened to the required length with a beveled tip opening towards the cornea. The tube was inserted through the needle track and secured to the sclera with monofilament polyamide black nylon, 10-0 suture (Ethilon; Ethicon, Johnson & Johnson Ltd., India). A corneal patch graft was used to cover the tube in the perilimbal area. The conjunctival peritomy was closed with Polyglactin 910, 8-0 suture (Vicryl, Ethicon, Johnson & Johnson Ltd., India).

Post-operatively, topical steroid (Pred Forte, Prednisolone Acetate 1%; Allergan India, Bengaluru, India) was prescribed in tapering doses for eight weeks. Topical antibiotic (Exocin, Ofloxacin 0.3%; Allergan India, Bengaluru, India) was used four times per day for one month and topical cycloplegic mydriatic (N-Pin, Atropine sulfate 1%; National Healthcare, Kathmandu, Nepal) was used three times per day for two weeks. The patients were also prescribed an antibiotic steroid combination

ointment containing Chloramphenicol 1%, Polymyxin B 10,000 units/gram, and Dexamethasone 0.1% (Ocupol-D[®], Centaur Pharmaceuticals, Mumbai, India) once daily for two weeks. Anti-glaucoma medications were prescribed post-operatively to control the IOP, at the operating surgeon's discretion.

Primary outcome measures of the study were IOP and AGMs. The secondary outcome measures were surgical success and complications. We defined success as IOP greater than 5 mmHg and less than or equal to 21 mmHg on final visit. Success was further classified as qualified or complete when the above-mentioned IOP was attained with or without the use of AGM, respectively. Failure to maintain IOP within 6-21 mmHg either with or without maximally tolerated AGMs, any additional glaucoma surgery to decrease IOP, removal of implant for any reason, or devastating complications like loss of perception of light and malignant glaucoma were defined as surgical failure. Surgical revisions performed in the operating room like: tube readjustment, re-suturing of conjunctiva, needling or removal of iris plugs were not considered glaucoma reoperations.

We defined any episode of IOP \leq 5mmHg on a single visit as transient hypotony, similar to Pandav et al (2020). Lai et al (2000) defined transient hypotony as IOP \leq 5 mmHg on any single visit post-operatively. We defined persistent hypotony as IOP \leq 5mmHg on two consecutive visits after three months postoperatively, similar to the TVT study (Gedde et al, 2009). We defined hypertensive phase (HTP) as a rise in IOP to >21 mmHg during the first three months of surgery after an initial reduction of IOP to <22 mm Hg during the first postoperative week and not associated with any evident cause; as defined by Nouri-Mahdavi and Caprioli (2003).

IBM SPSS Statistics for Macintosh, Version 20.0. Armonk, NY: IBM Corp. was used for statistical analysis. The test of normality of the data was done using the Shapiro-Wilk test. Pearson's Chi-square (χ^2) test and Fisher's exact test were used wherever applicable to see the difference between the two groups by various qualitative variables. Wilcoxon signed rank test was used to compare the baseline and final follow-up parameters within the group. We used Mann-Whitney U test to compare the various baseline and final follow-up parameters between the two groups. Kaplan-Meier survival analysis was performed to compare times to failure. p values less than 0.05 were considered statistically significant.

RESULTS

A total of 55 eyes of 53 patients were included in the study. There were 24 eyes of 23 patients in AGV group and 31 eyes of 30 patients in AADI group. The median (quartiles) follow-up in both groups was 12 (12,12) months. There was no significant difference between the two groups (AGV vs. AADI) in terms of median age, gender, preoperative IOP, number of AGMs, lens status, history of previous filtration surgery and etiology of glaucoma (**Table 1 and 2**).

	Shunt g		
Characteristics	AGV (N=23, n=24)	AADI (N=30, n=31)	P value
Age (years)	19.0 (9.0, 30.0)	19.5 (12.75, 30.0)	0.587*
Gender (M: F)	15:8	24:6	0.226#
Pre-op IOP (mmHg)	32.0 (26.5,38.0)	34.0(28.0,40.0)	0.549*
Pre-op AGM	4.0 (3.25,4.0)	4 (3.0,4.0)	0.911*
Lens status			
Phakic	12	17	0.721#
Pseudophakic	9	8	0.352#
Apakic	3	6	0.716@
Previous filtration surgery	10	8	0.214#

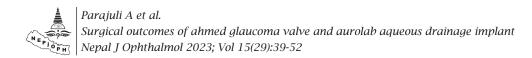
Table 1: Demographic and baseline characteristics of participants

Note: Age and pre-op IOP values are presented as median (quartiles). N = number of patients, n = number of eyes, $_*$ = Mann-Whitney U test, # = Chi-square test, @ = Fisher's Exact Test

Diagnosis	AGV	AADI	P value*
POAG	0	2	0.499
JOAG	3	5	1.0
PCG	1	2	1.0
Aniridia	0	3	0.248
Aphakic glaucoma	2	3	1.0
Bechet's disease	1	0	0.436
ICE syndrome	4	1	0.156
NVG	0	2	0.499
PACG	1	0	0.436
Post PK	2	5	0.451
Post PPV	3	3	1.0
Pseudophakic glaucoma	2	0	0.186
Traumatic glaucoma	2	4	0.686
Uveitic glaucoma	3	1	0.307
Total (n)	24	31	

Table 2: Etiology of glaucoma

Note: POAG= Primary open angle glaucoma, JOAG= Juvenile open angle glaucoma, PCG = Primary congenital glaucoma, ICE syndrome= Iridocorneal endothelial syndrome, NVG= Neovascular glaucoma, PACG= Primary angle closure glaucoma, Post PK= Post penetrating keratoplasty, Post PPV= Post Pars Plana Vitrectomy; *= Fisher's Exact Test



The median (quartiles) IOP in mmHg in AGV and AADI group decreased from 32 (26.5,38) and 34 (28,40), respectively, at baseline, to 16.5 (16,18) and 16 (14,16), respectively, at final visit (both, P <0.001). Similarly, the

median (quartiles) AGMs in AGV and AADI groups decreased from 4 (3.25,4) and 4 (3,4), respectively, at baseline, to 2 (0,2) and 0 (0,1), respectively, at final visit (both, P <0.001) (Table 3 and Figure 1).

Table 3: Comparison of IOP and AGMs between the two groups at baseline and various
follow-ups

Timeline	AGV AADI		P value*	AGV		AADI		P value*		
Timenine	IOP (mmHg)	n	IOP (mmHg)	n	1 value	AGM	n	AGM	n	1 value
Pre-op	32 (26.5,38.0)	24	34 (28,40)	31	0.549	4.0 (3.25,4.0)	24	4 (3.0,4.0)	31	0.911
POD1	10 (9.25,14.0)	24	20 (18.0,22.0)	31	< 0.001	-	-	-	-	-
POW1	12 (10.0,16.0)	24	20 (18.0,24.0)	31	< 0.001	0 (0,0)	24	0 (0,1)	31	0.008
POW2	14 (14.0,16.0)	24	20 (18.0,21.0)	31	< 0.001	0 (0,0)	24	1 (0,1)	31	< 0.001
POM1	17.5 (14.0,20.0)	24	18 (16.0,20.0)	31	0.322	0 (0,0)	24	1 (0,1)	31	< 0.001
POM2	22 (17.5,26.0)	22	16 (14.0,16.0)	31	< 0.001	0 (0,0.25)	22	1 (0,1)	31	0.009
POM3	18 (16.0,18.5)	22	16 (14.0,16)	31	< 0.001	2 (0.0,2.0)	22	1 (0,1)	31	0.028
POM6	17 (16.0,18.0)	22	16 (14.0,16.0)	31	< 0.001	2 (0.0,2.0)	22	1 (0,1)	31	0.002
POM9	17 (16.0,18.0)	20	16 (14.0,16.0)	26	0.001	2 (0.0,2.0)	20	1 (0,1)	26	0.011
POM12	17 (16.0,18.0)	19	15 (14.0,16.0)	25	< 0.001	2 (0.0,2.0)	19	0 (0,1)	25	0.003
Final visit	16.5 (16.0,18.0)	22	16 (14.0,16.0)	29	< 0.001	2 (0,2)	22	0 (0,1)	29	0.002

Note: IOP and AGM are presented as median (quartiles), *= Mann-Whitney U test, POD= Postoperative day, POW= Post-operative week, POM= Post-operative month, n= number of eyes

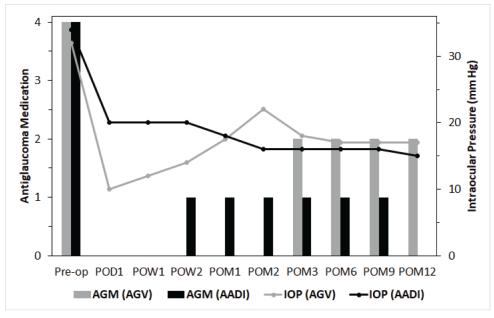


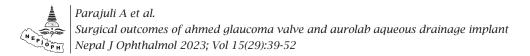
Figure 1: Trend of IOP and AGMs in both the groups at various post-operative periods

The median IOP was significantly lower in AGV group than AADI group at post-operative day one, week one, and week two (all P < 0.001). There was no significant difference in median IOP between the two groups at one month post-operatively. The median IOP in AADI group was significantly lower than AGV group at every post-operative visit after one month. The AGV group required significantly fewer AGMs than the AADI group until two months post-operatively. The AADI group required significantly fewer AGMs than the AGV group at every post-operative visit after the second post-operative month.

Two eyes with Ahmed implant had undergone failure within three months post-operatively and were excluded from analysis for hypertensive phase. Fifteen eyes (68.18%) out of 22 in AGV group and six eyes (19.35%) out of 31 eyes in AADI group developed hypertensive phase (p < 0.001).

Complications	AGV, n	AADI, n	p value	Intervention	
Early (<3 months)					
Transient Hypotony	4	6	1.0*	All managed conservatively	
CD	1	3	0.624*	All managed conservatively except one with	
				persistent CD underwent explantation at 6 month [@]	
Exposed plate, flat AC	1	0	0.436*	Implant removed	
Hyphema	1	2	1.0*	All encountered at POD 1 and managed con- servatively	
Persistent Hypotony	0	1	1.0	Implant removed at 6 months due to persister CD [@]	
Tube cornea touch	1	1	1.0*	Tube trimming	
Malignant Glaucoma	1	0	0.436*	Core vitrectomy and implant removal	
Tube exposure	0	3	0.248*	Conjunctival resuturing	
Late (>3 months)					
Clogged Iris	1	0	0.436*	Surgical release of blockage	
Long tube touching lens	0	1	1.0*	Phacoemulsification with PCIOL and tube trimming	
Exposed plate, flat AC	0	1	1.0*	Implant removed	
Total complications (early+late)	10	18	0.228#		

Note: One eye could have had more than 1 complication, n= number of eyes, *= Fisher's Exact test, # Chi-square test, CD= choroidal detachment, AC= anterior chamber, @ = this case developed hypotony with CD at 2nd post-operative month (POM) and the implant was removed at 6th POM because of no improvement.



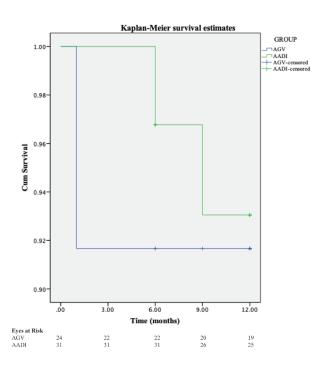


Figure 2: Kaplan-Meier survival plots for overall success in AGV group and AADI group

None of the eyes developed any significant intraoperative complication. Both groups had comparable early (<3 months) and late (\geq 3 months) complications. (**Table 4**). As one eye could have had more than one complication, total number of eyes with complications in AGV group was 6 (24%) and 11 (35.48%) in AADI group (p=0.4, Chi-square test).

At final follow-up, two eyes (8.33% vs. 6.45%)in each group (AGV vs. AADI) had surgical failure; complete success was seen in 6 eyes (25.00%) and qualified success in 16 eyes (66.67%) eyes in AGV group (overall success n=22,91.67%) while complete success was seen in 16 eyes (51.61%) and qualified success in 13 eyes (41.94%) of eyes (overall success n=29, 93.55%) in AADI group. Though there was no significant difference between the two groups in terms of overall success (p=1.0, Fisher's Exact Test), AADI group had significantly higher complete success compared to AGV group (p=0.046, Chi-square test). None of the eyes in either group failed on the IOP criterion.

The cumulative probability of survival at one year using Kaplan-Meier analysis was 91.7% in AGV group and 93.1% in AADI group (p=0.7, Log Rank test) (**Figure 2**).

DISCUSSION

Glaucoma is a public health problem (Thapa et al, 2021;Lawlor and Thomas, 2014; Kyari et al, 2013). The number of people with glaucoma worldwide is expected to increase to 111 million by 2040, disproportionately affecting Africans and Asians (Tham et al, 2014). Though

trabeculectomy still remains the most commonly performed glaucoma surgery worldwide (Leite et al, 2011; Racette et al, 2003; Thomas et al, 2003), the use of glaucoma drainage devices in the management of glaucoma too is rising (Wilson et al, 2003; Ayyala et al, 2002; Kook et al, 2000; Lai et al, 2000; Wilson et al, 2000; Leuenberger et al, 1999; Huang et al, 1999; Topouzis et al, 1999; Avyala et al, 1998; Coleman et al, 1995). However, the high price of the GDDs is a huge barrier to its easy availability to the general public of developing countries like Nepal where the gross domestic product (GDP) per capita is just over US\$ 1000 (Finance and Nepal, 2019). With the price of approximately US \$50, the AADI implant has the potential to break this barrier.

To our knowledge, this is the first study on outcomes of GDDs in Nepalese eyes. We observed that both AGV and AADI lowered IOP and AGMs significantly at each post-operative visit compared to the baseline. Compared to the AADI group, the AGV group had significantly lower IOP until the second post-operative week and required fewer AGMs until two months post-operatively. The AADI group had significantly lower IOP starting from second post-operative month and required significantly fewer AGMs starting from third post-operative month. Similar findings have been reported by studies comparing AGV and AADI in the Indian population (Pandav et al, 2020; Pathak et al, 2018a; Rathi et al, 2018). The Ahmed Baerveldt Comparison study (Budenz et al, 2015) and the Ahmed Versus Baerveldt study (Christakis et al, 2016) compared Baerveldt implant with the AGV implant. These studies also reported significantly lower IOP and fewer AGM use in the AGV group during the first few months post-operatively that was followed by significantly lower IOP and fewer AGMs in the Baerveldt group in the long run (Christakis et al., 2016Budenz et al., 2015;Barton et al., 2014; Budenz et al., 2011).

We observed similar overall success in both groups, AGV (n=22, 91.67%) and AADI (n=29, 93.55%), p=1.93.55 However, AADI group had a significantly higher rate of complete success compared to AGV group (n=16, 51.61% vs. n=6, 25%, p=0.046). Studies comparing the outcome of AADI and AGV implant in the Indian population too have reported similar outcomes at six months (Rathi et al, 2018) and one-year (Pandav et al, 2020; Pathak et al, 2018a) follow-up. Studies from India (Pandav et al, 2020; Pathak et al, 2018a) and Egypt (Elhefney et al, 2018) have reported the overall and complete success at one year in cases of AGV implant to range from 66.24% to 88.7% and 11.46% to 58.1%, respectively. Likewise, the overall and complete success at one year in cases of AADI have been reported to range from 83.33% to 92.6% and 38.0% to 66.6%, respectively, in studies from India (Pandav et al, 2020; Pathak et al, 2018a; Pathak et al., 2018b). The findings of these studies match with our results.

The cumulative survival probability at 1 year in case of AGV in our study was 91.7%, which is higher than that reported in studies from India {80.5% and 68.9% by Pathak et al(2018a) and Pandav et al (2020) respectively}. The cumulative survival probability at one year in case of AADI in our study was 93.1%, which is similar to studies from India [92.3%, 88.0%, and 90.5% reported by Pathak et al (2018a); Pandav et al (2020); Puthuran et al (2019) respectively].

Posterior encapsulation is an established complication after implant surgery with a higher prevalence in cases with AGV implant (Schwartz et al, 2006; Tsai et al, 2003; Lai et al, 2000). None of our patients developed this complication. Das et al (2005) in their study on AGV implant, also reported that none of their cases developed posterior encapsulation.

We observed hypertensive phase (HTP) in 15 eyes (68.18%) out of 22 eyes in AGV group and 6 eyes (19.35%) out of 31 eyes in AADI group (p <0.001). Our results for AGV group match with the studies, which based on different criteria, have reported HTP to range from 21.3% to 84.6% in cases of AGV (Pandav et al, 2020; Osman et al, 2020; Nouri-Mahdavi and Caprioli, 2003; Pathak et al, 2018a; Jung et al., 2015; Ayyala et al, 1998). However, there are conflicting reports on incidence of hypertensive phase (HTP) in cases of non-valved implants. Some studies have asserted HTP to be unusual after the non-valved implants (Nouri-Mahdavi and Caprioli, 2003, Siegner et al, 1995). Few studies reporting the outcomes of AADI implant have not commented on HTP (Pandav et al, 2020; Puthuran et al, 2019; Kaushik et al, 2017). Additionally, there are studies that have reported HTP to range from 21.1% to 31.2% in cases of AADI (Ray and Rao, 2020; Pathak et al, 2018b; Pathak et al, 2018a). Our results for AADI group match with the ones reporting HTP and seem to suggest that HTP is not an unusual occurrence after non-valved GDD surgery as well.

Complications were comparable between the two groups in our study. Majority of the complications were transient and managed conservatively. We observed transient hypotony in four (16.67%) eyes in AGV group and six (19.35%) eyes in AADI group, among which one (4.16%) eye from AGV group and two (6.45%) eyes from AADI group developed transient choroidal detachment (CD) as well. We observed persistent hypotony in one (3.22%) eye in the AADI group that also developed persistent CD. Transient hypotony in cases of AGV has been reported to range from 3.27% to 12.17% in different studies (Pandav et al, 2020; Lai et al, 2000; Huang et al, 1999; Das et al, 2005), which is similar to our study. Puthuran et al (2019) reported 8% of cases with transient CD due to hypotony in their study on outcomes of AADI implant which also matches the result of our study. In their study on AGV implant, Das et al (2005) reported four (3.27%) cases of transient hypotony, among which one (0.82%) developed shallow AC with transient CD. Pandav et al (2020) reported persistent hypotony in 3.40% of eyes in AADI group and 0.53 % of eyes in AGV group. Tube exposure was seen only in AADI group (9.67%) in our study (P=0.24). Pandav et al (2020) too reported the incidence of tube exposure only in cases of AADI group (3.4%). The incidence of tube exposure was equal (5.26%) in cases of AADI and AGV in a study by Rathi et al (2018).

As a retrospective study, there was no randomization between the two groups, which is a major limitation of our study. Most of our surgeries were performed as a charity, using implants donated to the glaucoma department of the institute. As such, in most cases, the type of implant used depended upon the availability of the implant (free of cost). No standardized protocol was followed while adding IOPlowering drugs post-operatively and this was left to the discretion of the operating surgeon. This may have affected the ratio of complete to qualified success.

In conclusion, both AGV and AADI appear to be safe and effective in decreasing IOP and AGMs significantly in cases of refractory glaucoma in Nepalese eyes.

ACKNOWLEDGMENTS

The authors would like to thank Santosh Koirala, PhD, for his assistance in data analysis.



REFERENCES

Ayyala RS, Zurakowski D, Monshizadeh R, Hong CH, Richards D, Layden WE, Hutchinson BT, Bellows AR (2002). Comparison of double-plate Molteno and Ahmed glaucoma valve in patients with advanced uncontrolled glaucoma. Ophthalmic Surgery, Lasers and Imaging Retina;33(2):94-9. https://doi.org/10.3928/1542-8877-20020301-04

Ayyala RS, Zurakowski D, Smith JA, Monshizadeh R, Netland PA, Richards DW, Layden WE (1998). A clinical study of the Ahmed glaucoma valve implant in advanced glaucoma. Ophthalmology;105(10):1968-76.https://doi. org/10.1016/S0161-6420(98)91049-1

Barton K, Feuer WJ, Budenz DL, Schiffman J, Costa VP, Godfrey DG, Buys YM, Ahmed Baerveldt Comparison Study Group (2014). Three-year treatment outcomes in the Ahmed Baerveldt comparison study. Ophthalmology;121(8):1547-57. https://doi.org/10.1016/j.ophtha.2014.01.036

Brilliant LB, Pokhrel RP, Grasset NC, Lepkowski JM, Kolstad A, Hawks W, Pararajasegaram R, Brilliant GE, Gilbert S, Shrestha SR, Kuo J (1985). Epidemiology of blindness in Nepal. Bulletin of the World Health Organization;63(2):375. PMID: 3874717

Budenz DL, Barton K, Feuer WJ, Schiffman J, Costa VP, Godfrey DG, Buys YM, Ahmed Baerveldt Comparison Study Group (2011). Treatment outcomes in the Ahmed Baerveldt Comparison Study after 1 year of follow-up. Ophthalmology;118(3):443-52 https://doi.org/10.1016/j.ophtha.2010.07.016.

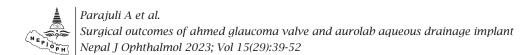
Budenz DL, Barton K, Gedde SJ, Feuer WJ, Schiffman J, Costa VP, Godfrey DG, Buys YM, Ahmed Baerveldt Comparison Study Group (2015). Five-year treatment outcomes in the Ahmed Baerveldt comparison study. Ophthalmology;122(2):308-16.https://doi.org/10.1016/j.ophtha.2014.08.043

Christakis PG, Kalenak JW, Tsai JC, Zurakowski D, Kammer JA, Harasymowycz PJ, Mura JJ, Cantor LB, Ahmed II (2016). The Ahmed versus Baerveldt study: five-year treatment outcomes. Ophthalmology;123(10):2093-102. https://doi.org/10.1016/j.ophtha.2016.06.035

Coleman AL, Hill R, Wilson MR, Choplin N, Kotas-Neumann R, Tam MA, Bacharach J, Panek WC (1995). Initial clinical experience with the Ahmed glaucoma valve implant. American journal of ophthalmology;120(1):23-31. https://doi.org/10.1016/S0002-9394(14)73755-9

Das JC, Chaudhuri Z, Sharma P, Bhomaj S (2005). The Ahmed glaucoma valve in refractory glaucoma: experiences in Indian eyes. Eye;19(2):183-90. https://doi.org/10.1038/sj.eye.6701447

Elhefney E, Mokbel T, Abou Samra W, Kishk H, Mohsen T, El-Kannishy A (2018). Long-term results of Ahmed glaucoma valve implantation in Egyptian population. International journal of ophthalmology;11(3):416. <u>https://doi.org/10.18240%2Fijo.2018.03.11</u>



Finance, M. O. & Nepal, G. O. (2019) Economic Survey 2019/20 [Online]. Available at: https://mof.gov.np/uploads/ document/file/Economic%20Survey%202019_20201125024153.pdf [Accessed 5-11-21].

Gedde SJ, Schiffman JC, Feuer WJ, Herndon LW, Brandt JD, Budenz DL, Tube Versus Trabeculectomy Study Group (2009). Three-year follow-up of the tube versus trabeculectomy study. American journal of ophthalmology;148(5):670-84. https://doi.org/10.1016/j.ajo.2009.06.018

Gedde SJ, Schiffman JC, Feuer WJ, Herndon LW, Brandt JD, Budenz DL, Tube versus Trabeculectomy Study Group (2012). Treatment outcomes in the Tube Versus Trabeculectomy (TVT) study after five years of follow-up. American journal of ophthalmology;153(5):789-803. https://doi.org/10.1016/j.ajo.2011.10.026

Gedde SJ, Singh K, Schiffman JC, Feuer WJ, Tube Versus Trabeculectomy Study Group (2012). The Tube Versus Trabeculectomy Study: interpretation of results and application to clinical practice. Current opinion in ophthalmology;23(2):118-26. DOI: 10.1097/ICU.0b013e32834ff2d1

Hafeezullah N, AlHilali S, Alghulaydhawi F, Edward DP, Ahmad S, Malik R (2021). A preliminary comparison of the Aravind aurolab drainage implant with the Baerveldt glaucoma implant: a matched case-control study. European Journal of Ophthalmology;31(2):445-52. https://doi.org/10.1177/1120672120912383

Huang MC, Netland PA, Coleman AL, Siegner SW, Moster MR, Hill RA (1999). Intermediate-term clinical experience with the Ahmed glaucoma valve implant. American journal of ophthalmology;127(1):27-33. https://doi.org/10.1016/S0002-9394(98)00394-8

Jung KI, Park H, Jung Y, Park CK (2015). Serial changes in the bleb wall after glaucoma drainage implant surgery: characteristics during the hypertensive phase. Acta ophthalmologica;93(4):e248-53.https://doi.org/10.1111/aos.12571

Kass MA, Heuer DK, Higginbotham EJ, Johnson CA, Keltner JL, Miller JP, Parrish RK, Wilson MR, Gordon MO, Ocular Hypertension Treatment Study Group (2002). The Ocular Hypertension Treatment Study: a randomized trial determines that topical ocular hypotensive medication delays or prevents the onset of primary open-angle glaucoma. Archives of ophthalmology;120(6):701-13. doi:10.1001/archopht.120.6.701

Kaushik S, Kataria P, Raj S, Pandav SS, Ram J (2017). Safety and efficacy of a low-cost glaucoma drainage device for refractory childhood glaucoma. British Journal of Ophthalmology;101(12):1623-7. http://dx.doi.org/10.1136/ bjophthalmol-2017-310276

Kook MS, Yoon J, Kim J, Lee MS (2000). Clinical results of Ahmed glaucoma valve implantation in refractory glaucoma with adjunctive mitomycin C. Ophthalmic Surgery, Lasers and Imaging Retina;31(2):100-6. <u>https://doi.org/10.3928/1542-8877-20000301-05</u>

Kyari F, Abdull MM, Bastawrous A, Gilbert CE, Faal H (2013). Epidemiology of glaucoma in sub-saharan Africa: prevalence, incidence and risk factors. Middle East African journal of ophthalmology;20(2):111-125.https://doi. org/10.4103%2F0974-9233.110605

Lai JS, Poon AS, Chua JK, Tham CC, Leung AT, Lam DS (2000). Efficacy and safety of the Ahmed glaucoma valve implant in Chinese eyes with complicated glaucoma. British journal of ophthalmology;84(7):718-21. http://dx.doi. org/10.1136/bjo.84.7.718

Lawlor M, Thomas R (2014). Addressing glaucoma in the developing countries of the Asia Pacific region: An opportunity to transition from disease-specific responses to integration of eye care. The Asia-Pacific Journal of Ophthalmology;3(1):4-8. DOI: 10.1097/APO.0000000000024

Leite MT, Sakata LM, Medeiros FA (2011). Managing glaucoma in developing countries. Arquivos brasileiros de oftalmologia;74:83-4.https://doi.org/10.1590/S0004-27492011000200001



Leske MC, Heijl A, Hussein M, Bengtsson B, Hyman L, Komaroff E, Early Manifest Glaucoma Trial Group (2003). Factors for glaucoma progression and the effect of treatment: the early manifest glaucoma trial. Archives of ophthalmology;121(1):48-56. doi:10.1001/archopht.121.1.48

Leuenberger EU, Grosskreutz CL, Walton DS, Pasquale LR (1999). Advances in aqueous shunting procedures. International ophthalmology clinics;39(1):139-53.

Nouri-Mahdavi K, Caprioli J (2003). Evaluation of the hypertensive phase after insertion of the Ahmed Glaucoma Valve. American journal of ophthalmology;136(6):1001-8. https://doi.org/10.1016/S0002-9394(03)00630-5

Osman EA, Alkheraiji NF, Abouammoh MA, Mousa A, Al-Obeidan S (2020). Safety and efficacy of ahmed valve on intractable glaucoma in Saudi population. Middle East African Journal of Ophthalmology;27(1):40 -46. https://doi. org/10.4103%2Fmeajo.MEAJO 249 19

Pandav SS, Seth NG, Thattaruthody F, Kaur M, Akella M, Vats A, Kaushik S, Raj S (2020). Long-term outcome of low-cost glaucoma drainage device (Aurolab aqueous drainage implant) compared with Ahmed glaucoma valve. British Journal of Ophthalmology;104(4):557-62. http://dx.doi.org/10.1136/bjophthalmol-2019-313942

Pascolini D, Mariotti SP (2012). Global estimates of visual impairment: 2010. British Journal of Ophthalmology;96(5):614-8.http://dx.doi.org/10.1136/bjophthalmol-2011-300539

Ray VP, Rao DP (2019). Surgical outcomes of a new affordable non-valved glaucoma drainage device and Ahmed glaucoma valve: comparison in the first year. British Journal of Ophthalmology;103(5):659-65. http://dx.doi. org/10.1136/bjophthalmol-2017-311716

Ray VP, Rao DP (2018). Surgical outcomes of a new low-cost Nonvalved glaucoma drainage device in refractory glaucoma: results at 1 year. Journal of glaucoma;27(5):433-9. DOI: 10.1097/IJG.000000000000930

Puthuran GV, Palmberg P, Wijesinghe HK, Krishnadas SR, Robin A (2019). Intermediate-Term outcomes of an affordable aqueous drainage implant in adults with refractory glaucoma. Ophthalmology Glaucoma;2(4):258-66. https://doi.org/10.1016/j.ogla.2019.03.009

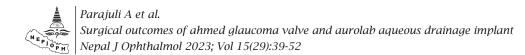
Ouigley HA, Broman AT (2006). The number of people with glaucoma worldwide in 2010 and 2020. British journal of ophthalmology;90(3):262-7. http://dx.doi.org/10.1136/bjo.2005.081224

Racette L, Wilson MR, Zangwill LM, Weinreb RN, Sample PA (2003). Primary open-angle glaucoma in blacks: a review. Survey of ophthalmology;48(3):295-313. https://doi.org/10.1016/S0039-6257(03)00028-6.

Rathi SG, Seth NG, Kaur S, Thattaruthody F, Kaushik S, Raj S, Pandav SS, Ram J (2018). A prospective randomized controlled study of Aurolab aqueous drainage implant versus Ahmed glaucoma valve in refractory glaucoma: a pilot study. Indian Journal of Ophthalmology;66(11):1580. https://doi.org/10.4103%2Fijo.IJO 427 18

Ray VP, Rao DP (2020). Two-year outcomes of the new low-cost nonvalved Aurolab aqueous drainage implant in refractory glaucoma. Journal of Glaucoma;29(9):767-72. DOI: 10.1097/IJG.000000000001532

Schwartz KS, Lee RK, Gedde SJ (2006). Glaucoma drainage implants: a critical comparison of types. Current opinion in ophthalmology;17(2):181-9. DOI: 10.1097/01.icu.0000193080.55240.7e



Siegner SW, Netland PA, Urban Jr RC, Williams AS, Richards DW, Latina MA, Brandt JD (1995). Clinical experience with the Baerveldt glaucoma drainage implant. Ophthalmology;102(9):1298-307.https://doi.org/10.1016/S0161-6420(95)30871-8

Tham YC, Li X, Wong TY, Quigley HA, Aung T, Cheng CY (2014). Global prevalence of glaucoma and projections of glaucoma burden through 2040: a systematic review and meta-analysis. Ophthalmology;121(11):2081-90.https:// doi.org/10.1016/j.ophtha.2014.05.013

Thapa SS, Paudyal I, Joshi PL, Singh K, Parajuli A (2021). Glaucoma in developing countries. Nepalese Journal of Ophthalmology;13(1):112-21.https://doi.org/10.3126/nepjoph.v13i1.35606

Thomas R, Paul P, Muliyil J (2003). Glaucoma in India. Journal of Glaucoma;12(1):81-7. .

Topouzis F, Coleman AL, Choplin N, Bethlem MM, Hill R, Yu F, Panek WC, Wilson MR (1999). Follow-up of the original cohort with the Ahmed glaucoma valve implant. American journal of ophthalmology;128(2):198-204. https://doi.org/10.1016/S0002-9394(99)00080-X

Tsai JC, Johnson CC, Dietrich MS (2003). The Ahmed shunt versus the Baerveldt shunt for refractory glaucoma: a single-surgeon comparison of outcome. Ophthalmology;110(9):1814-21. https://doi.org/10.1016/S0161-6420(03)00574-8

Wilson MR, Mendis U, Paliwal A, Haynatzka V (2003). Long-term follow-up of primary glaucoma surgery with Ahmed glaucoma valve implant versus trabeculectomy. American journal of ophthalmology;136(3):464-70. https://doi.org/10.1016/S0002-9394(03)00239-3

Wilson MR, Mendis U, Smith SD, Paliwal A (2000). Ahmed glaucoma valve implant vs trabeculectomy in the surgical treatment of glaucoma: a randomized clinical trial. American journal of ophthalmology;130(3):267-73. https://doi. org/10.1016/S0002-9394(00)00473-6