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Comparison of Short-term Outcomes of Aurolab Aqueous Drainage Implant with Ahmed Glaucoma Valve in Post–Penetrating Keratoplasty Glaucoma

A Retrospective Follow-up Study at a Tertiary Care Center

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Purpose: Comparison of short-term outcomes of the Aurolab aqueous drainage implant (AADI) with the Ahmed glaucoma valve (AGV) in post–penetrating keratoplasty glaucoma (PPKG).

Design: Retrospective study design.

Participants: We analyzed the data of patients who underwent glaucoma drainage device (GDD) implantation for PPKG between the time period of 2008 to 2017. A total of 57 eyes of 55 patients were included.

Methods: Parameters including age, sex, corneal graft clarity, duration between the keratoplasty and glaucoma surgery, visual acuity (VA), intraocular pressure (IOP), the number of antiglaucoma drugs (topical and oral) before surgery, and type of GDD were studied. The patients were divided into 2 groups: group I, patients undergoing AADI implantation; and group II, patients undergoing AGV implantation. Patients with at least 6 months follow-up were included. The postoperative VA and IOP were analyzed on day 1 and at 1 week, 4 weeks, 6 weeks, 3 months, and 6 months. The success of GDD was defined as complete success (IOP $>$ 5 mmHg or $<$21 mmHg without topical antiglaucoma drug) or qualified success (IOP $>$ 5 mmHg or $<$21 mmHg with up to 2 topical antiglaucoma drugs). Failure was defined as IOP $<$ 5 mmHg or $>$21 mmHg with or without antiglaucoma medication; IOP $<$ 21 mmHg with 3 or more topical medications or use of systemic medications irrespective of the IOP; loss of perception of light; and/or need for further glaucoma surgery.

Results: Nineteen eyes in group I (mean age = 40.16±16.36 years) and 38 eyes in group II (mean age = 56.61±19.35 years) were studied. The mean baseline IOP in group I and group II was not significantly different (28.63±11.21 vs. 30±14.61 mmHg, $P = 0.72$). Mean postoperative IOP at 6 months was not significantly different in the 2 groups (12.11±4.86 mmHg vs. 14.95±6.35 mmHg, $P = 0.2$). There was statistically significant fall in IOP at each visit compared to preoperative IOP in both the groups ($P = 0.001$), but there was no significant difference between the 2 groups at any time point ($P > 0.05$). At 6 months overall success rate was 84.21% in both groups ($P = 1.00$), though the complete success was slightly higher in group II, which was nonsignificant (31.58% vs. 39.47%, $P = 0.56$). There was no significant difference between baseline and final VA in either group.

Conclusions: Both AADI and AGV are equally effective in controlling IOP in post–penetrating glaucoma. The AADI, being a cost-effective implant, may be more suitable for developing countries. *Ophthalmology Glaucoma 2019;2:172-177 © 2019 by the American Academy of Ophthalmology*

Post–penetrating keratoplasty glaucoma (PPKG) terminology signifies an elevated intraocular pressure (IOP) greater than 21 mmHg, after penetrating keratoplasty with or without associated visual field loss or optic nerve head changes.[1] The incidence of PPKG varies from 12.1% to 22.5%.[2] Pathophysiology of glaucoma in PPKG is multifactorial and may be related to distortion of the angle with collapse of the trabecular meshwork, suture technique, postoperative inflammation, use of corticosteroids, peripheral anterior synechiae formation, and preexisting glaucoma.[3] Additional risk factors include aphakia and pseudophakic bullous keratopathy, anterior mesenchymal dysgenesis, iridocorneal endothelial syndrome, adherent leukoma, previous penetrating keratoplasty, posttraumatic cases, combined keratoplasty and intracapsular cataract extraction, anterior chamber intraocular lenses, presence of vitreous fluid, and performance of an anterior vitrectomy during penetrating keratoplasty.[4–11]

Most of the patients who have PPKG are initially managed with medications, but they invariably require

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glaucoma surgery during their follow-up to control IOP. Post-penetrating keratoplasty glaucoma is one of many conditions that are refractory to medical treatment. Owing to conjunctival manipulation during keratoplasty, there is high chance of failure of trabeculectomy; hence a glaucoma drainage device (GDD) is needed in such patients.[12]

There have been studies comparing the clinical outcomes of the Ahmed glaucoma valve (AGV)[1] (New World Medical Inc, Rancho Cucamonga, CA) and trabeculectomy vs. AGV implantation in patients with penetrating keratoplasty.[12] Early AGV implantation after penetrating keratoplasty has been reported to have better outcomes in Asian populations with preexisting glaucoma.[13]

The Aurolab aqueous drainage implant (AADI, Aurolab, Madurai, India) is a low-cost novel device introduced by Aurolab, a manufacturing division of Aravind Eye Institute (Madurai, Tamil Naidu, India), that is based on the Baerveldt prototype. The AADI, a nonvalved glaucoma shunt, is indicated for glaucoma patients not responding to maximal medical therapy, for failed trabeculectomy, and for neovascular, congenital, and uveitic glaucoma. It is made of permanent implantable-grade silicone, a material used in manufacturing drainage devices. The 2 fixation holes in the silicone plate are used to suture the plate to the sclera using 5-0 Dacron (Polyester, Green Braided, Alcon Laboratories, Inc, Fort Worth, TX). There has been no study to compare the outcome of AGV with AADI in PPKG.

The aim of our study was to compare the short-term outcomes of AADI and AGV in PPKG.

Methods

This was a retrospective study done at a tertiary care center. We analyzed the data of patients who underwent GDD implantation for PPKG during the time period 2008 to 2017. The study complied with the principles of the Declaration of Helsinki and Institutional Ethics Clearance was obtained. The Institutional Review Board approved the study and waived the requirement for informed consent because of the retrospective nature of the study. The records of patients were reviewed for various parameters including age, sex, corneal graft clarity, duration between the keratoplasty and glaucoma surgery, visual acuity (VA), IOP, the number of antiglaucoma drugs (topical and oral) before surgery, and type of GDD. The postoperative VA and IOP were analyzed on day 1 and at 1 week, 4 weeks, 6 weeks, 3 months, and 6 months. The patients were divided into 2 groups: group I, patients undergoing AADI implantation; and group II, patients undergoing AGV implantation. Patients with a follow-up period less than 6 months were excluded.

Surgical Technique

Both the implants have similar surgical techniques with small differences. To expose sub-Tenon space, conjunctival peritomy was done in the superotemporal quadrant, followed by blunt dissection for adequate exposure of the surgical field. Muscle hooks were used to retract the superior rectus and lateral rectus. The AGV was primed by passing balanced salt solution through the tube, while patency of the AADI was similarly confirmed. In AADI, the tube was completely ligated near the plate end with 6-0 Vicryl (Braided coated polyglactin 910 violet, Ethicon, Johnson & Johnson Ltd, Barotiwala, Himachal Pradesh, India), whereas AGV has an in-built valve. The AADI plate was tucked underneath the lateral and superior rectus muscle, whereas in the AGV the plate is small so it does not need to be tucked under the muscle. The plate was sutured to the sclera with 5-0 Dacron suture (Polyester, Green Braided, Alcon Laboratories Inc, Fort Worth, TX). A scleral tunnel was created with a 23G needle and the tube was pushed through the scleral tunnel into the anterior chamber. We used a scleral patch graft to cover the tube in the perilimbal area.

Outcome Measures

The success of the GDD was defined as complete success (IOP $>$ 5 mmHg or $<$21 mmHg without topical antiglaucoma drug), qualified success (IOP $>$ 5 mmHg or $<$21 mmHg with up to 2 topical antiglaucoma drugs). Failure was defined as IOP $<$ 5 mmHg or $>$21 mmHg with or without antiglaucoma medication; IOP $<$ 21 mmHg with 3 or more topical medications or use of systemic medications irrespective of the IOP; loss of perception of light; and/or need for further glaucoma surgery. Complications, if any, were noted.

Statistical Analysis

The data were analyzed using IBM SPSS (IBM SPSS version 21.0 for Windows, IBM Corp, Armonk, NY) software. Efficacy of device in a study is measured in terms of reduction of IOP and antiglaucoma medication required postoperatively to control IOP. To calculate the power of the study, we have to consider both factors. Even though IOP reduction in the AADI group in the published study[14] was statistically significant, the effect size was small (1 mmHg) at 1 year. This would mean that to have power of 80%, one would require a large sample size (i.e., 188 in each group). However, going by the reduction in medications, the AADI group needed 50% less medication in the postoperative period as compared with AGV. Going by this, for 80% power, sample size required would be 15 eyes in each group. Therefore we believe that our study has adequate power and the results are meaningful. The data were tested for normal distribution using the Shapiro-Wilk test. Discrete categorical data were expressed in the form of a number or a percentage. The normally distributed data were described as mean and standard deviation whereas the skewed data were represented as median and interquartile range, as per the requirement. The Wilcoxon signed rank test was used to compare the final follow-up VA and IOP with baseline parameters in both of the groups. The Mann Whitney U test was used to compute significance between baseline and final follow-up parameters between the 2 groups. The Multiple group comparisons 1-way analysis of variance test was used to compare variables at different time points. All the statistical tests were 2-sided and were performed at a significance level of $\alpha = 0.05$. A P value of $<$0.05 was considered significant.

Results

We recruited 57 eyes of 55 patients, with mean age of 51.12±19.86 years, comprising 44 male and 11 female patients. Nineteen eyes underwent AADI implantation (group 1) and 38 eyes underwent AGV implantation (group 2). Table 1 summarizes the preoperative parameters. The patients in the AADI groups were younger, with a mean age of 40.16±16.36 years, as compared with the AGV group, with mean age 56.61±19.35 years (P $<$ 0.002). The mean baseline VA (Snellen best-corrected VA was converted into logarithm of minimum angle of resolution for analysis by using a VA conversion table, available at http://publicfiles.jaeb.org/drcrnet/Misc/VAScoreConversionChart.pdf) in the AADI group was 0.68±0.24 and in the AGV group was 0.79±0.11, with no statistical difference (P = 0.06). The mean baseline IOP in the

Table 1. Preoperative Parameters of Both Groups

Parameter	AADI	AGV	P Value
Age (years)	40.16±16.36	56.61±19.34	<0.01
Duration between OPK and GDD (months)	15.32±15.63	32.29±52.38	0.72
Visual acuity	0.68±0.24	0.79±0.11	0.06
Intraocular pressure	28.63±11.21	30±14.61	0.72
No. of topical drugs before surgery	3.37±0.76	2.95±1.11	0.29
No of oral drugs preoperatively	1.26±0.45	0.95±0.34	0.02

AADI = Aurolab aqueous drainage implant; AGV = Ahmed glaucoma valve; GDD = glaucoma drainage device; OPK = optical penetrating keratoplasty.

AADI group was 28.63±11.21 mmHg and in the AGV group was 30±14.61 mmHg, with no statistical difference ($P = 0.72$). Similarly, there was no significant difference in baseline topical medications between the 2 groups, but the patients in the AADI group were on a higher number of oral antiglaucoma medications (1.26±0.45) as compared with the AGV group (0.95±0.54) ($P = 0.015$). Regarding corneal graft at time of surgery, 21 eyes (36.8%) had a clear corneal graft. Six eyes in group I (AADI) and 8 eyes in group II (AGV) had corneal edema. The patients were followed for a minimum period of 6 months after the surgery. The mean follow-up time period in the AADI group was 23.47±29.78 months (range, 6−132 months) and in the AGV group mean follow-up time was 23.79±23.67 months (range, 6−96 months).

Intragroup Variations in Visual Acuity and Intraocular Pressure

There was no statistical difference in preoperative and final VA in both groups (AADI: $P = 0.94$ and AGV: $P = 0.30$). There was a statistically significant drop in IOP at each visit compared with preoperative IOP in both groups (AADI group: $P = 0.008$, $P = 0.01$, $P = 0.009$, $P = 0.001$, $P = 0.00$, $P = 0.001$ and in AGV $P = 0.00$ at postoperative day 1 and at 1 week, 4 weeks, 6 weeks, 3 months, and 6 months respectively; Fig 1).

Intergroup Variations in Visual Acuity and Intraocular Pressure

There was no significant difference in the mean best-corrected VA in both groups at baseline and at 1 week, 4 weeks, 6 weeks, 3 months, and 6 months ($P > 0.05$). There was no significant difference in IOP between the 2 groups at any of the visits ($P > 0.05$). We compared the drop in IOP at the final follow-up with the preoperative IOP in both groups and there was no statistically significant difference in the drop in IOP in between the 2 groups ($P = 0.72$). The trend of IOP in the postoperative period in both groups is shown in Figure 1.

Antiglaucoma Medications

Regarding the number of topical medications in each group, the mean number of topical medications in AADI was 3.37±0.76 and in AGV was 2.95±1.11 at baseline, with no statistical difference between the 2 groups ($P = 0.14$). There was significant reduction

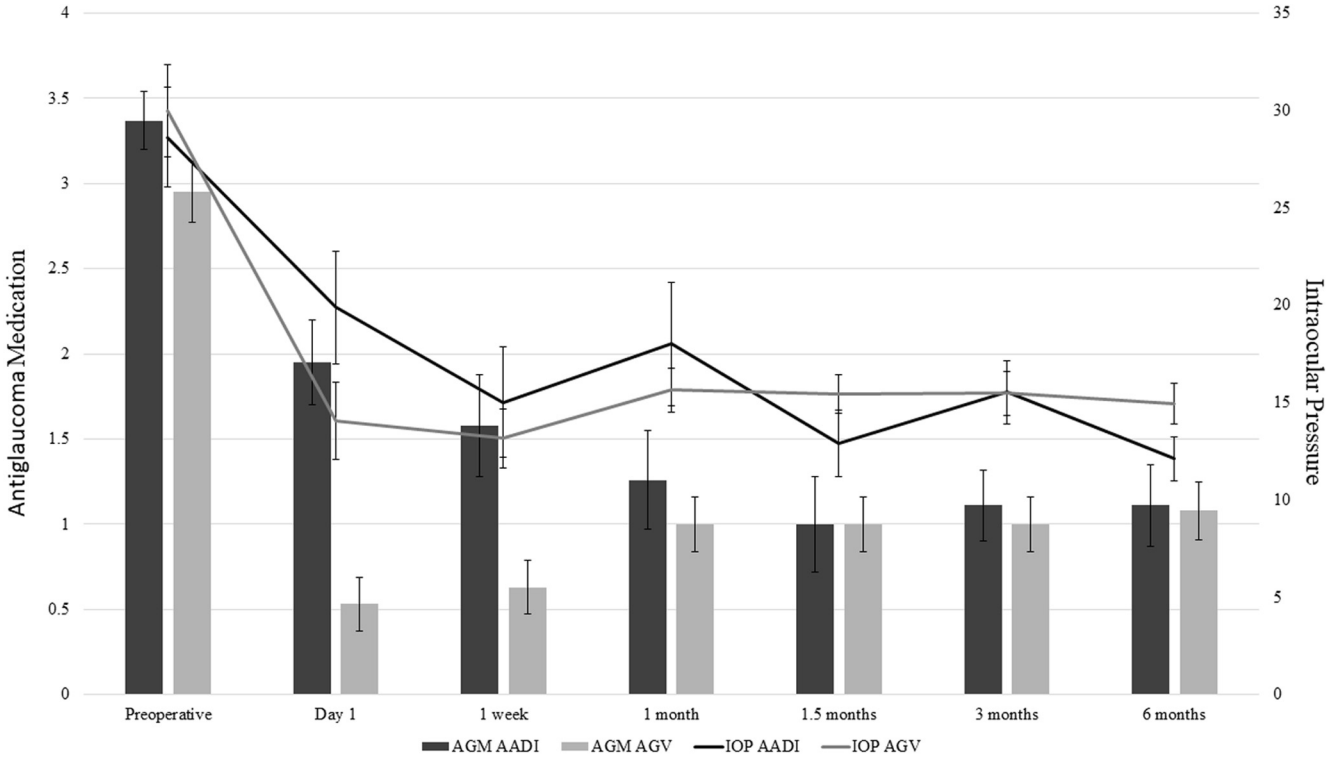

Figure 1. The intraocular pressure (IOP) trend and topical antiglaucoma medications (AGM) trend in postoperative period (error bars: standard error of mean). AADI = Aurolab aqueous drainage implant; AGV = Ahmed glaucoma valve.

in the mean number of topical medications in each group at 6 months follow-up ($P = 0.00$). The mean number of topical medications in the AADI group was 1.17±1.04 and in the AGV group was 1.05±1.07 at 6 months follow-up. The AADI implants take approximately 4 to 6 weeks to begin acting, so medications were not stopped in this group but rather were tapered according to the IOP at 4 to 6 weeks follow-up. The trend of topical medication requirements in each group is depicted in Figure 1.

The hypertensive phase (IOP > 21 mmHg, with or without topical medications, during the first 3 months postoperatively) was seen in 13 eyes (34.21%) in the AGV group. Twenty-five eyes (65.79%) did not manifest any hypertensive phase. In the AGV group, the patients were started on prophylactic single topical medications if the IOP rose >12 mmHg at postoperative 1 week. Twenty-seven eyes (71.05%) were started on prophylactic medications at 7 to 10 days, when the IOP was >12 mmHg.

There was no statistically significant difference in outcomes among the 2 groups at 6 months follow-up (Table 2). Both groups had equal overall success (84.21%) at 6 months follow-up. The AGV group had a higher complete success rate of 39.47% as compared with 31.58% in the AADI group, but AADI had a higher qualified success rate of 52.63% as compared with 44.74% in AGV. On performing logistic regression analysis, we did not find any preoperative patient characteristics that were associated with intervention failure in each group.

We further looked into the status of the corneal grafts in both groups at 6 months follow-up. Six eyes (31.59%) belonging to the AADI group had corneal graft edema before surgery, of which 3 grafts cleared, whereas 8 eyes (21.05%) belonging to the AGV group had graft edema before surgery but none of them cleared in follow-up. One eye from each group developed graft failure in the follow-up period.

There was no statistical difference in complication rates among the 2 groups. The postoperative complications encountered in each group during follow-up are shown in Table 3. Of the 4 eyes with hypotony in both the groups, 1 eye in the AADI group was found to have choroidals and 3 eyes in the AGV group had choroidals. The hypotony and choroidals were transient and resolved with conservative management. One eye in each group had GDD tube blockage and received anterior vitrectomy, and 1 eye from each group had conjunctival retraction. One eye from the AGV group had endophthalmitis, which was managed with intravitreal antibiotics.

According to Kaplan–Meier plots, the survival probability of the AADI and AGV group at 6 months was 84.2%±8.4% and 84.2%±5.9%, respectively ($P = 0.95$), as highlighted in Figure 2.

Table 2. Success Rate of Aurolab Aqueous Drainage Implant and Ahmed Glaucoma Valve at 6 Months

	AADI (N = 19)	AGV (N = 38)	P Value
Complete success	6 (31.58%)	15 (39.47%)	0.56
Qualified success	10 (52.63%)	17 (44.74%)	0.57
Failure	3 (15.79)	6 (15.79%)	1.00
Percentage success (complete and qualified)	16 (84.21%)	32 (84.21%)	1.00

AADI = Aurolab aqueous drainage implant; AGV = Ahmed glaucoma valve.

Table 3. Complications in Both Groups during Follow-up Period

	Group		
	AADI	AGV	P Value
Total number of eyes	19	38	
Total eyes with complications	9 (47.38%)	11 (28.95%)	0.17
Complications			
Hypotony	4 (21.05%)	4 (10.53%)	0.28
Choroidals in hypotony	1 (5.26%)	3 (7.89%)	0.71
Tube blockage	1 (5.26%)	1 (2.63%)	0.61
Anterior vitrectomy	1 (5.26%)	1 (2.63%)	0.61
Conjunctiva retraction	1 (5.26%)	1 (2.63%)	0.61
Recurrent endophthalmitis	0	1 (2.63%)	0.47
Hyphema	1 (5.26%)	0	0.15

AADI = Aurolab aqueous drainage implant; AGV = Ahmed glaucoma valve.

Discussion

Surgical treatment has been reported in PPKG cases that are refractory to medications. Trabeculectomy and GDDs are the most commonly performed surgical procedures for treatment of PPKG, whereas cyclo-destructive procedures are used when other surgical interventions have failed.[15,16]

The main aim of our study was to compare the efficacy of 2 GDDs, AADI and AGV, in PPKG patients. In this study, we have used the AADI because it is a low-cost alternative for patients with refractory glaucoma in resource-poor communities in the developing world. All modern glaucoma drainage implants are costly, which restricts their use in poor populations. The AADI is a nonvalved aqueous shunt made of Nusil permanent implant silicone elastomer, which has passed tissue culture cytotoxicity testing. Its design has been heavily influenced by the original Baerveldt glaucoma implant 350. The use of various implants including AGV, Molteno, and Baerveldt for controlling refractory glaucoma is well known,[2,17] but there has been no study on the efficacy of AADI in PPKG.

In our study, we found significant reduction in IOP in both groups at 6 months as compared with baseline, but there was no statistical difference in mean IOP between the 2 groups at 6 months. In the AADI group alone, there was a 57% reduction in IOP at 6 months as compared with the baseline. Knape et al[18] studied the outcome in 3 different GDDs—Schocket-style, Baerveldt (350 mm^2), and double-plate Molteno devices—in penetrating keratoplasty glaucoma. There was similar significant reduction in IOP in each group at 5 years follow-up as compared with the preoperative baseline. Panda et al[1] reported a significant reduction in IOP from preoperative IOP of 42.95±10.24 mmHg to 19.62±5.82 mmHg at 6 months in patients undergoing AGV implantation, which was analogous to our AGV group. A drop of 42.95% in IOP has been found in our AGV group as compared with the baseline at 6 months. Most of the patients in our study were on the maximum number of topical medications. At 6 months follow-up, there was significant reduction in the number of topical medications, with most of the patients in both groups

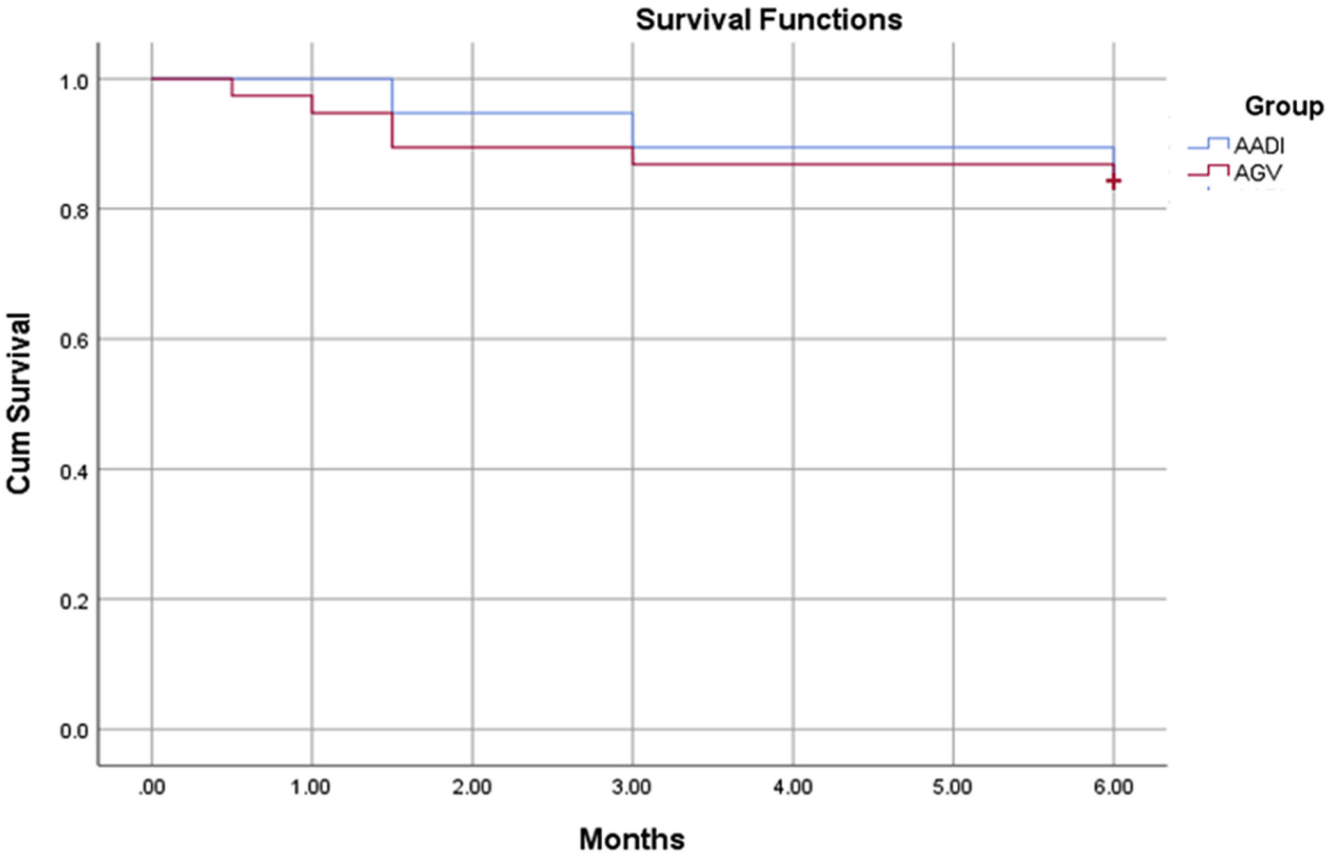

Figure 2. The Kaplan–Meier survival plot for the 2 groups at 6 months follow-up. AADI = Aurolab aqueous drainage implant; AGV = Ahmed glaucoma valve.

reduced to single topical medications. Knape et al[18] reported comparable reduction in topical medications at 5 years follow-up as compared with baseline in his study of 3 different GDDs—Schocket-style, Baerveldt (350 mm^2), and double-plate Molteno devices. A similar outcome has been reported in PPKG patients undergoing AGV implantation in another study.

We observed the usual hypertensive phase in only 34.21% of patients in the AGV group. The hypertensive phase was blunted using prophylactic topical medications if the IOP rose >12 mmHg at postoperative 1 week. Aqueous suppression initiated in the early postoperative period while IOPs were still in the low teens was able to reduce the incidence of IOP spike associated with the hypertensive phase without an increased complication rate.[19]

There was no significant change in VA within the groups at 6 months follow-up compared with baseline. Most of the patients had poor vision on preoperative evaluation. Panda et al[1] studied the outcome of AGV in keratoplasty patients and found no significant change in VA at 6 months.

In our study both groups showed comparable high overall success rates of 84.21% at the end of 6 months. Parallel high success rates have been reported by other studies. Romaniuk[20] stated 73.5% success rate of AGV in controlling PPKG at 1 year, and Knape et al[18] studied the outcome of different GDDs (Schocket-style, Baerveldt [350 mm^2], and double-plate Molteno devices) in keratoplasty, reporting a success rate of 96% at 1 year.

The incidence of graft rejection following AGV is a serious issue and previous studies have reported incidences between 15% and 41%.[17,18,20–22] We encountered graft rejection in 1 eye from each group. Graft rejection in 1 eye was attributed to tube touch and accentuated by the second surgical repair for its adjustment. Because the follow-up time period of our study was only 6 months, it is not possible to comment on the status of corneal grafts of these patients in the long run.

There have been few studies in literature comparing the outcomes of AADI vs. AGV that have demonstrated lower IOP, lesser requirement of topical medications and higher rate of complete success in the AADI group at a mean follow up of 6 months and 1-year.[14,23]

In conclusion, we found that both AADI and AGV are equally effective in terms of success and IOP control. The strength of our study is its large sample size. To the best of our knowledge, it is also one of the few studies that has compared the outcome of AADI with the well-established AGV implant in postkeratoplasty eyes. The limitations in our study are its shorter duration of follow-up and retrospective analysis. Long-term studies are still needed. The AADI, being a cost-effective implant, may be more suitable for developing countries.

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Footnotes and Financial Disclosures

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HUMAN SUBJECTS: Human subjects were included in this study. This was a retrospective study done at a tertiary care center involving analysis of the data of patients who underwent glaucoma drainage device implantation during the time period 2008 to 2017. The study complied with the principles of the Declaration of Helsinki and Institutional Ethics Clearance was obtained. The Institutional Review Board waived the requirement for informed consent because of the retrospective nature of the study.

No animal subjects were used in this study.

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Abbreviations and Acronyms:
AADI = Aurolab aqueous drainage implant; **AGV** = Ahmed glaucoma valve; **GDD** = glaucoma drainage device; **IOP** = intraocular pressure; **PPKG** = post−penetrating keratoplasty glaucoma; **VA** = visual acuity.

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