Intermediate and Long-Term Outcomes of Glaucoma Drainage Device Implantation by Glaucoma Fellows at a Tertiary Eye Center

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ABSTRACT

Objective: To describe surgical outcomes of glaucoma drainage device (GDD) implantation performed by glaucoma fellows, and to identify factors influencing success.

Methods: This is a retrospective case series of eyes with GDDs implanted by glaucoma fellows at a tertiary eye center in the Philippines from February 2015 to March 2017. Records with at least 6 months post-operative follow-up were included. The primary outcome variables were intraocular pressure (IOP), number of anti-glaucoma medications, and visual acuity (VA). Surgical outcomes were classified as a complete success, a qualified success, or a failure. A complete success was defined as IOP ≥6 mmHg and ≤21 mmHg at last follow-up, without any glaucoma medication or additional glaucoma surgery. A qualified success was defined as IOP ≥6 mmHg and ≤21 mmHg at last follow-up, and on at least one topical anti-glaucoma medication. Failure was defined as IOP >21 mmHg or <6 mmHg at last follow-up, or the need for additional glaucoma surgery or a cyclodestructive procedure.

Results: Seventeen eyes (16 subjects) were included in the study. Twelve (12) eyes were implanted with Ahmed® GDDs while 5 eyes received Baerveldt® GDDs. Mean follow-up time was 11.18 ± 6.74 months. There were significant decreases in the mean IOP (P<0.0001) and mean number of anti-glaucoma medications (P<0.0001) at final visit (16.29 ± 3.50 mmHg and 0.88 ± 0.39, respectively, from 28.16 mmHg ± 10.69 mmHg and 3.39 ± 1.05 prior to GDD implantation). VA was stable (P=0.22). GDD surgeries were classified as successful in 6/17 (35%) eyes, a qualified success in 8/17 (47%) eyes and as failures in 3/17 (18%) eyes. The complication rate was 10/17 (59%).

Conclusion: GDD implantations by glaucoma fellows in a single institution in the Philippines resulted to significant IOP decrease, reduction in number of anti-glaucoma medications, with good preservation of vision, however, complication rate was high.

Keywords: glaucoma drainage device, GDD, glaucoma, valve surgery

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Glaucoma drainage device (GDD) implantation is the surgical procedure of choice for complicated or recalcitrant glaucoma or for eyes with high-risk factors for trabeculectomy failure. Due to their prohibitive costs, it was only recently that GDD implantation was being done more frequently at the Department of Health (DOH) Eye Center, East Avenue Medical Center, Philippines. Glaucoma fellows at DOH Eye Center have only started performing GDD implantation in the last three years. To date, there has been no study analyzing the surgical outcomes of GDD implantation performed by fellows.

The objective of this study is to describe surgical outcomes of patients who underwent GDD implantation at the DOH Eye Center. While many studies provide evidence for efficacy and safety of GDD implants, these studies report outcomes of surgeries performed by experienced glaucoma surgeons. This study focuses on the outcomes of GDD surgery performed by glaucoma fellows, who are surgeons-in-training.

METHODS

This was a retrospective chart review of all consecutive GDDs implanted by glaucoma fellows from February 1, 2015 to March 31, 2017 at the DOH Eye Center of East Avenue Medical Center, Philippines. Only charts of patients with a minimum of 6 months post-operative follow-up were included in the study. The following information were collected from the charts: age, gender, race, glaucoma diagnosis, lens status (phakic, aphakic, or pseudophakic), previous intraocular surgery including trabeculectomy, type of GDD used (Ahmed® or Baerveldt®), and quadrant position of the drainage device (superotemporal, superonasal, inferotemporal, inferonasal). In addition, pre-operative and post-operative visual acuity (VA), intraocular pressure (IOP), and number of anti-glaucoma medications were recorded. Complications arising from GDD implantation in the post-operative period were also listed down.

Procedure

Glaucoma fellows performed all the surgeries and all first-time GDD implantations by them were under the direct supervision of a glaucoma consultant. Surgical techniques and post-operative management were generally similar for all cases. Conjunctival peritomy was done with blunt dissection of Tenon's fascia, exposing the scleral bed. GDDs were primed with balanced salt solution. The Ahmed® GDDs (New World Medical, Inc, Rancho Cucamonga, CA, USA) were inserted at least 10 mm posterior to the corneal limbus while the Baerveldt® GDDs (Pharmacia, Iovision, Irvine, CA, USA) were placed at least 12 mm posterior to the corneal limbus. The GDD plate was sutured to the sclera using nylon 10-0 suture. A scleral incision for the GDD tube to enter the anterior chamber was made around 4-5 mm posterior to the corneal limbus, where partial thickness dissection was done using a crescent knife. Unlike the conventional procedure, no scleral patch grafts to cover the GDD tubes were used in any of the cases. The anterior chamber was entered through the scleral incision with a 23-gauge needle parallel to the iris plane. The distal end of the GDD tube was cut bevel-up and inserted into the anterior chamber, taking care not to touch the corneal endothelium or the iris. Anterior chamber paracentesis was done, then the tube was anchored with a nylon 10-0 suture. For the Baerveldt® GDD, a polyglactin 7-0 ligature was tied tightly with fenestrations cut on the tube to control IOP immediately post-operatively. The conjunctival peritomy was closed with nylon 10-0 sutures. Post-operative prednisolone acetate and moxifloxacin eye drops were prescribed at least four times a day and adjusted with the clinical response. Anti-glaucoma medications were stopped immediately post-operatively for the Ahmed® GDD but partly maintained for the Baerveldt® GDD through the first post-operative month and adjusted as needed until there were signs that the ligature had already absorbed.

Outcome Criteria

The primary study outcome measures were IOP, number of anti-glaucoma medications, and visual acuity. Secondary outcome measures included post-operative complications rates as well as success and failure rates.

The baseline measurements for IOP and number of anti-glaucoma medications were recorded as the average of the last 3 measurements in the chart prior to GDD implantation. The most recent VA measurement prior to GDD surgery, usually one day pre-operatively, was recorded as the baseline VA. IOP and number of anti-glaucoma medications were collected on post-operative day 1, week 1, month 1, month 3, month 6, year 1, and year 2. Post-operative VA was taken starting at 1 month after GDD surgery

and then at months 3, 6, and years 1 and 2. VA was measured using an ETDRS chart and converted to logMAR. The baseline IOP, number of anti-glaucoma medications, and visual acuity were compared with the respective recorded measurement on final visit.

Post-operative complications were recorded. Eyes were classified as a complete success, a qualified success, or a failure. A complete success was defined as IOP ≥6 mmHg and ≤21 mmHg at last follow-up, without glaucoma medications or additional glaucoma surgery. A qualified success was defined as IOP ≥6 mmHg and ≤21 mmHg at last follow-up, and on at least one anti-glaucoma topical medication. Failure was defined as IOP >21 mmHg or <6 mmHg at last follow-up or the need for additional glaucoma surgery or a cyclodestructive surgery.

Statistical Methods

Summary statistics were reported as mean with standard deviation for continuous variables (e.g. age, IOP, and number of anti-glaucoma medications) and in percentages for categorical variables (e.g. gender, success rate, complications). Paired t-test was used to compare mean differences in IOP, number of anti-glaucoma medications and visual acuity during the pre-operative and post-operative periods. Yate's chi-square test was used to compare proportions. Analysis of variance was used to compare differences between type of implant from pre-operative to post-operative IOP, medications, and VA. Line graphs were generated to show trends in IOP and medications. Independent t-test was used to compare between complete success and qualified success or failure. Chi-square test of association was used to determine association between lens status, operations prior to and after GDD with complete success of GDD implantation. Statistical significance was based on P-value ≤0.05. Data processing and statistical analyses were performed using STATA v13.

RESULTS

A total of 17 eyes (16 subjects) were included in the study. All patients were Filipinos. Twelve eyes received the Ahmed® GDD, while five eyes received the Baerveldt® GDD. Patient demographics as well as GDD types are presented in **Table 1**. The mean follow-up time was 11.18 ± 6.74 months.

Table 1: Patient Demographics and Distribution of Types of Glaucoma Drainage Device

Gender, n (%)	
Male	12 (71%)
Female	5 (29%)
Mean age ± standard deviation, in years	49 ± 18.10
Mean follow-up duration ± standard deviation, in months	11 ± 6.74
Glaucoma diagnosis, n (%)	
Secondary angle closure glaucoma	12 (71%)
Primary angle closure glaucoma	3 (18%)
Primary open angle glaucoma	1 (6%)
Angle recession	1 (6%)
Lens status, n (%)	
Phakic	6 (35%)
Aphakic	1 (6%)
Pseudophakic	10 (59%)
Prior trabeculectomy, n (%)	
With	7 (41%)
Without	10 (59%)
Prior intraocular surgery other than trabeculectomy, n (%)	
With	12 (71%)
Without	5 (29%)
Type of glaucoma drainage device implant, n (%)	
Ahmed®	12 (71%)
Baerveldt®	5 (29%)
Glaucoma drainage device tube position, n (%)	
Superotemporal	14 (82%)
Superonasal	1 (6%)
Temporal	1 (6%)
Inferotemporal	1 (6%)

Table 2 summarizes the primary outcome variables (IOP, number of anti-glaucoma medications, and VA) at baseline and final visit for all eyes that underwent GDD implantation. Preoperative mean IOP decreased from 28.16 ± 10.69 mmHg to 16.29 ± 3.50 mmHg at final visit. This difference was statistically significant (P<0.0001). There was also statistically significant reduction in the number of anti-glaucoma medication (P<0.0001) at final visit after GDD implantation compared to baseline (from 3.39 ± 1.06 eye drops at baseline to 0.88 ± 0.93 at final visit). Lastly, there was no significant change in the mean VA at baseline and final visit.

Table 2: Primary Outcome Measures in Eyes Implanted with GDD at Baseline and Final visit

Outcome Measure	Baseline	Final Visit	*P*-value
Mean IOP, in mmHg	28.16 ± 10.69	16.29 ± 3.50	<0.0001
Mean number of anti-glaucoma medications	3.39 ± 1.06	0.88 ± 0.93	<0.0001
Mean visual acuity, in LogMAR	0.84 ± 0.53	0.92 ± 0.58	0.223

Table 3 summarizes the primary outcome variables (IOP, number of anti-glaucoma medications, and VA), complication rates and pre-defined surgical outcomes (complete success, qualified success, failure) according to GDD type. In the Ahmed® GDD group, there was significant reduction in the mean IOP (P=0.003) and mean number of anti-glaucoma medications (P<0.0001) at the final visit. Mean VA was unchanged (P=0.713). Five eyes (41.67%) had at least one complication. Four eyes (33%) were classified as complete success. Six (50%) and two (17%) eyes were classified as qualified success and failure, respectively. In the Baerveldt® GDD group, significant reduction in the mean IOP was likewise observed (from 34.40 ± 14.63 mmHg to 15.80 ± 5.50 mmHg at final visit, P=0.019). Although there was a decrease in the number of anti-glaucoma medications on the final visit (1.0 ± 1.0 from 2.83 ± 1.0), this change was not statistically significant (P=0.052). There was also no significant difference in the VA at final visit when compared to baseline (P=0.269). All 10 eyes implanted with Baerveldt® GDD developed at least one complication (100%). Two eyes were classified as a complete success (40%); two more eyes were classified as a qualified success (40%). One eye was classified as a failure (20%). Overall, surgical outcome was classified as a success in 6/17 (35%) of eyes, a qualified success in 8/17 (47%) of eyes, and a failure 3/17 (18%) of eyes. Fourteen (14) out of 17 eyes (82%) were able to maintain IOPs within target levels of 6 to 21 mmHg with or without additional medication on last follow-up.

Table 3: Outcome Measures Grouped by Type of GDD

	Ahmed® implant (n = 12)	**Baerveldt® implant** (n= 5)
Mean IOP, mmHg		
Baseline	25.56 ± 7.96	34.40 ± 14.63
Final Visit	16.50 ± 2.58	15.80 ± 5.50
P-value	0.003	0.019
Mean number of anti-glaucoma medications		
Baseline	3.62 ± 1.02	2.83 ± 1.0
Final Visit	0.83 ± 0.94	1.0 ± 1.0
P-value	<0.0001	0.052
Mean visual acuity, in LogMAR		
Baseline	0.72 ± 0.54	1.14 ± 0.42
Final Visit	0.73 ± 0.45	1.36 ± 0.65
P-value	0.713	0.269
Complication rate	5 (41.67%)	5 (100%)
Surgical outcome		
Complete success	4 (33%)	2 (40%)
Qualified success	6 (50%)	2 (40%)
Failure	2 (17%)	1 (20%)

Figure 1 shows the change in the mean IOP during post-operative period. There was a drop in the overall mean IOP (blue line) in the immediate post-operative period (day 1 to week 1). However, when the eyes were stratified according to GDD received, IOP rise greater than the baseline was observed on post-operative day 1 in the Baerveldt® group. This was immediately followed by an IOP reduction on post-operative week 1. Compared to the Ahmed® group, the Baerveldt® group had higher mean IOPs at post-operative week 1 and month 1.

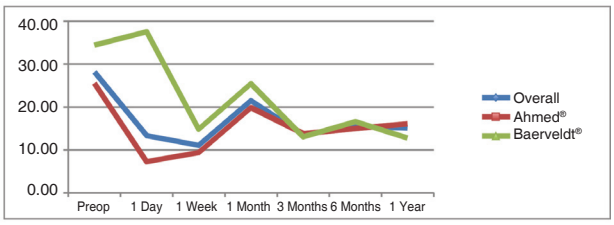

Figure 1: Change in Intraocular Pressure after Implantation with GDD over Time

Figure 2 shows the change in number of anti-glaucoma medications during follow-up period. There was an overall reduction in the number of anti-glaucoma medications. Of note, the Baerveldt® group had a higher mean number of anti-glaucoma medications at post-operative month 1.

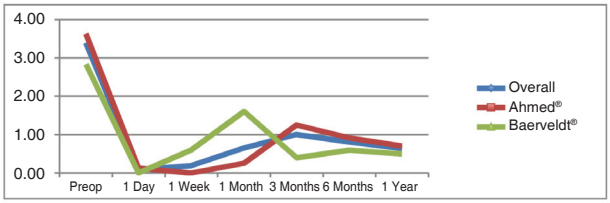

Figure 2: Number of Anti-Glaucoma Medications after Implantation of GDD over Time

Table 4 summarizes the overall complication rates and types after GDD implantation. Ten eyes developed at least one complication. The most common complication was post-operative hyphema seen in 5 cases. In all cases, hyphemas spontaneously resolved after a few days without the need for a secondary surgical interventions. There were 2 cases of vitreous hemorrhage that also resolved spontaneously with conservative management. Two eyes developed choroidal detachment that responded well to a short course of oral prednisone. There was one case of tube obstruction with IOP spike that required a second surgery to flush the GDD tube. Additionally, tube exposure was noted in 2/17 cases

(12%). Conjunctival resuturing was performed in one eye, while conservative management was decided in the other case. None of the eyes developed endophthalmitis at final visit. Two eyes had cataract progression following GDD implantation. Cataract surgery was performed in one eye.

Table 4: Complications after GDD Implantation

Type of Complication	Number of Eyes
Hyphema	5
Vitreous hemorrhage	2
Choroidal detachment	2
Corneal decompensation	2
Cataract progression	2
Tube obstruction	1
Tube exposure	2

Table 5 shows the list of ocular factors that may influence success and failure in eyes that underwent GDD implantation. There is a trend that a lower mean pre-operative IOP is a predictor for success. The eyes that had successful outcomes defined by good IOP control without need for anti-glaucoma medications had lower mean pre-operative IOPs compared to eyes that were classified as qualified success or failure (22.28 vs 31.26 mmHg, P=0.05). Lens status, previous intraocular surgery, and additional intraocular surgery after GDD implantation were not predictive of success.

Table 5: Ocular Factors That May be Predictive of Complete Success or Failure of GDD Implantation

	Complete success (n = 6)	Qualified success and failure (n = 11)	*P*-value
Pre-operative IOP in mmHg	22.28 ± 6.06	31.36 ± 11.51	0.050
Lens status			
Pseudophakic	2 (33.3%)	8 (72.7%)	0.219
Phakic	3 (50.0%)	3 (27.3%)	
Aphakic	1 (16.7%)	0 (0%)	
History of intraocular surgery			
With	3 (50.0%)	9 (81.8%)	0.280
Without	3 (50.0%)	2 (18.2%)	
Additional intraocular surgery after GDD			
With	1 (16.7%)	5 (45.5%)	0.333
Without	5 (83.3%)	6 (54.5%)	

DISCUSSION

This study describes the surgical outcomes of 17 glaucomatous eyes that underwent GDD implantation by glaucoma fellows at a single institution. IOP on the average was noted to be elevated at 1 month post-operatively, most likely due to the phenomenon of the hypertensive phase, which decreased at 3 months post-operatively. The hypertensive phase is a period of elevated IOP usually within 1-6 weeks post-operatively, which is probably due to the early exposure of aqueous humor to the GDD capsule.[1] With early exposure of the GDD capsule to aqueous humor, the capsule becomes theoretically less permeable and thick-walled, resulting in higher IOPs.[2] Baerveldt® GDDs had higher mean IOP in the early post-operative period but by month 3, the mean IOP of both implants were already similar. This could be probably explained by the effect of the polyglactin ligature tied on the Baerveldt® GDD tube to prevent post-operative hypotony, which typically dissolves in about 6 weeks.

Anti-glaucoma medications were still maintained in patients with Baerveldt® GDDs post-operatively despite the venting slits created on the tube. This was due to the standard practice of maintaining all glaucoma medications during immediate post-operative period since no or little flow is expected through the tube because of the tight polyglactin ligature. After month 1, the mean IOP decreased for Baerveldt® GDD, with a corresponding decrease in number of medications. At 3 months, the Baerveldt® GDD patients had slightly lesser number of glaucoma medications compared to Ahmed® GDD patients.

This study shows that VA remained stable in eyes that underwent GDD implantation. There was no significant change in the pre-operative and post-operative VA. This is consistent with a published study on GDD implantation in Asian eyes wherein VA remained stable over a mean follow-up period of 13.41 months.[3]

Results of our study show that GDD implantation performed by glaucoma fellows at a single institution, led to stable VA, and considerable reductions in IOP and number of anti-glaucoma medications. This is consistent with Asian retrospective studies that investigated the efficacy and safety of GDD implantation.[4] However, their data were based on outcomes of experienced glaucoma surgeons, not fellows-in-training.

Despite good outcomes, the complication rate following GDD implantation was high in our study. Our tube exposure rate was 12% which is higher than

those reported in other studies (2%-7%).[4-10] Non-utilization of a scleral patch graft to cover the tube in this patient cohort could explain the slightly higher rate of this complication. Tube exposure increases the chance of endophthalmitis. In the retrospective study of Wilson et al of 542 eyes with GDD implantation, endophthalmitis was noted in 9 eyes (1.7%).[12] In 6 of 9 eyes, tube exposure was present. Multiple regression analysis showed that factors associated with endophthalmitis were tube exposure ($P<0.01$) and younger age ($P<0.05$). In this study, both patients with tube exposure did not develop endophthalmitis at last follow-up.

Complication rate was also significantly higher in the Baerveldt® group (100%) than in the Ahmed® group (41.6%) ($P<0.0001$). This may have been due to the limited surgical experience in handling Baerveldt® GDDs by the fellows.

The ideal outcome for GDD implantation is to attain long-term IOP control, without the use of medications or additional procedures. The overall rate for complete success in this study cohort was 35%. One factor that may be predictive of GDD implantation success is a lower pre-operative IOP ($P=0.05$). Our study shows that eyes that had a successful outcome defined by good IOP control without need for anti-glaucoma medications had a lower mean pre-operative IOP compared to eyes that were classified as qualified success or failure. Lens status, previous intraocular surgery, and additional intraocular surgery after GDD implantation were not predictive of success. This is contrary to other studies that show better outcomes following GDD implantation in "virgin" eyes compared to eyes that had previous intraocular surgery. [11-13]

This study is limited by its retrospective nature and small sample size. Despite its limitation, results of the present study illustrate the differences in outcomes and complication rates between eyes implanted with Ahmed® and Baerveldt® GDDs by glaucoma fellows.

In conclusion, GDD implantations by glaucoma fellows showed significant decrease in IOP, number of medications, with good preservation of vision after GDD surgery. However, the complication rate was high. Despite limited experience, glaucoma fellows showed successful outcomes comparable to those of more experienced surgeons.

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