Clinical Ophthalmology Dovepress

Open Access Full Text Article ORIGINAL RESEARCH

Ahmed Glaucoma Valve Implantation in Jordan: Indications and Complications

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Aim: The main indications for Ahmed glaucoma valve (AGV) include neovascular glaucoma, congenital glaucoma, primary open angle glaucoma and patients with failed previous trabeculectomy. This article aims to investigate the complications of AGV in Jordanian glaucoma patients and to justify the main risk factors.

Methods: Retrospectively, we report 87 eyes of 83 patients who underwent AGV implantation for different indications. The database included demographic data, past ocular and medical history, the indication for surgery, the perioperative outcome parameters at different follow-up visits, and the developed complications at each post-operative visit.

Results: More than half of the patients (54%) were males. The mean age of the patients was 47.4 years. Neovascular glaucoma was the most common indication for AGV implantation. Valve encapsulation was the most encountered complication. About one quarter of the eyes at one time underwent valve revision. Younger patients, neovascular glaucoma and congenital glaucoma were associated significantly with AGV failure and for the need for revision surgery.

Conclusion: AGV is the predominant glaucoma surgery performed in Jordan. Valve encapsulation is the most common complication for AGV implant in Jordanian patients which may be related to racial and genetic factors. Neovascular glaucoma has a high burden in Jordan and secondary causes should be controlled adequately.

Keywords: glaucoma, neovascular glaucoma, pseudoexfoliation syndrome, encapsulation

Introduction

Glaucoma is defined as a group of diseases characterized by progressive damage (cupping of the optic disc) with corresponding visual field defects, that happens due to retinal ganglion cell loss. It is a progressive condition and is the second leading cause of blindness and the most common cause of irreversible blindness worldwide.[1,2] Elevated intraocular pressure (IOP) is a major risk factor in the pathogenesis of glaucoma and is currently the only modifiable risk factor.[3,4]

Managing glaucoma primarily depends on lowering IOP to a target level at which no further progression in the disease is expected,[5] this target level is called target pressure and depends partially on the stage of glaucomatous damage in the optic nerve.[6] Another determination factors for the target IOP include the pretreatment level of IOP, visual field loss, rate of glaucoma progression, age of the patient, and other risk factors for the development of glaucoma such as PEX.[5] Lowering IOP is generally achieved by three main modalities which are medications, laser therapy and surgical intervention.

Although many new glaucoma surgical procedures are evolving, classical filtration surgery of trabeculectomy is still the most commonly performed surgical procedure worldwide.[7] Glaucoma Drainage Devices (GDDs) are traditionally reserved for high-risk secondary glaucoma or after trabeculectomy failure. However, they are increasingly used as a primary glaucoma procedure.[8]

GDDs are divided into two categories, valved or non-valved. The main advantage of the valved devices is the low risk of hypotony (IOP< 5mmhg) postoperatively.[9] Ahmed Glaucoma Valve (AGV) (New World Medical, Inc., California,

Received: 29 October 2024
Accepted: 26 November 2024
Published: 4 December 2024

USA) is the conventional valved GDD used worldwide. In Jordan, AGV is the only available GDD used to control IOP. The only available AGV models are the adults FP7 silicone implant and the pediatrics FP8 silicone implants.

Complications of AGV implants have been studied and documented, these include hypotony,[10] IOP increase and excessive capsule fibrosis,[11,12] tube exposure due to conjunctival erosions,[13] corneal decompensation and edema,[14] infection and endophthalmitis,[15] diplopia and strabismus[16] lens damage and cataract formation[17] tube extrusion,[18] tube migration[19] tube blockage by blood, vitreous or iris tissues.[20]

In Jordan, complications of AGV have not been studied before. In this study, we report the complications of AGV in patients who underwent AGV implantation surgery in a tertiary hospital in Jordan. We also compare the rate of these complications with complications reported in different studies conducted in the USA and in Europe.

Materials and Methods

Patients and Data

The Institutional Review Board (IRB) approval was obtained from Jordan University of Science and Technology. The study was conducted retrospectively at King Abdullah University Hospital (KAUH), a tertiary ophthalmology center. We investigated patients who underwent GDD implantation during the period of January 2018 to December 2022. Using the hospital electronic medical records, demographics data (age, sex), past ocular history, and past medical history were allocated. Also, the diagnostic indications were studied. Furthermore, the perioperative details, visual outcome and postoperative complications were assessed.

The study population included all patients who underwent primary GDD for all possible indications. Excluded criteria comprised patients who have a history of previous glaucoma filtration surgery, who have more than one GDD in the same eye, other types of GDD other than AGV, cases of closure angle glaucoma, and patients who missed follow-up. These excluded criteria may interfere with the statistical results and confer a confounding effect.

Patients were categorized by the indications for 5 groups. The first group included patients who have primary open angle glaucoma (POAG), which was defined as an optic neuropathy with a high IOP, open, normal appearing anterior chamber angle and with no other secondary disease. The second group comprised patients with neovascular glaucoma; either as a result of advanced proliferative diabetic retinopathy (PDR) or ischemic central retinal venous occlusion (CRVO). The third group included patients with pseudoexfoliation (PEX) glaucoma which was diagnosed as optic nerve damage, high IOP and the deposition of a protein-like material within the anterior segment of the eye. The fourth group included congenital and infantile glaucoma, which were diagnosed before the age of 3 years. The last group comprised other secondary causes of glaucoma.

The studied medical illnesses included diabetes mellitus (DM) with its important control parameters (DM duration, HbA1c level) and systemic hypertension.

For all patients preoperatively and postoperatively at 1 month, 6 months and at the last follow-up visit, the visual outcome was compared and studied and the IOP was measured. The mean number of antiglaucoma (AG) medications was also assessed at all follow-up visits.

Furthermore, postoperative complications were compared and included hypotony, encapsulation, exposure of the valve, and the need for revision.

Perioperative Setting

All patients underwent comprehensive ophthalmic examinations by a glaucoma consultant or well-trained residents during the follow-up visits, including best-corrected visual acuity (BCVA), using a Snellen visual acuity chart by decimal unit. Then, the BCVA was converted to LogMAR visual acuity. For low visual acuities of counting fingers, hand motion, light perception or “no light perception”, they were converted as LogMAR units of more than 2.0 LogMAR units. Goldmann applanation tonometer was utilized to measure the intraocular pressure. Slit lamp and indirect biomicroscopes were used to assess the lens status, anterior segment, and fundus conditions. The appropriate gonio-lens were utilized to assess the angle structures. Humphrey automated perimetry was applied for most patients to investigate and follow the visual fields of the patients.

One consultant glaucoma ophthalmologist performed all operations using one standard technique. AGV device (New World Medical, Rancho Cucamonga, California, USA) was utilized for all patients. FP7 model for adult patients and FP8 for pediatric patients. General anesthesia was conducted for all patients. The eye was prepped and draped in the usual sterile ophthalmic fashion. A lid speculum was placed, and the operating microscope was brought into position with the surgeon seated at the superior position. A 6/0 vicryl clear cornea traction suture was applied superiorly. A fornix-based conjunctival and tenon capsule flap was created superior-temporally using Westcott scissors followed by blunt dissection of about 90 degrees. The AGV was then tested for patency and primed through injecting a balanced salt solution until a jet of fluid existed from the valve outlet. Posterior to the limbus, the plate after that was fixed to the sclera in approximately 10 mm in adults and 8 mm in children using two interrupted 10/0 nylon sutures. The anterior chamber was maintained by viscoelastic material. The tube was trimmed to exist 2 mm anterior to the surgical limbus and was cut in a bevel-up manner to protect from entrapment with iris tissue. After that, a fistula was created into the anterior chamber through a 23-gauge needle was used to make a tunnel starting 1 mm posterior to the limbus to the anterior chamber, and the tube was inserted. The tube was then secured by multiple 10/0 nylon sutures and covered by a human pericardium or donor scleral patch was and sutured to the sclera using 10/0 nylon sutures. The conjunctiva was sutured using interrupted 8/0 vicryl sutures. The anterior chamber was reformed with BSS through a paracentesis tract. Figure 1 demonstrates the details of AGV implantation.

Statistical Analysis

The IBM SPSS statistical package = v.26 (Armonk, New York, USA) was utilized for the statistical analysis. Nominal categorical variables (as gender or laterality) were presented as frequency (percentage). The normality of the continuous variables (as age) was tested through Kolmogorov–Smirnov test and expressed as mean ± standard error of the mean (SEM). Chi-square test was utilized to determine the statistical significance for categorical variables and the ANOVA test for continuous variables. A simple linear regression test was performed to investigate the association between two continuous variables. A statistically significant result was considered if $P \leq 0.05$.

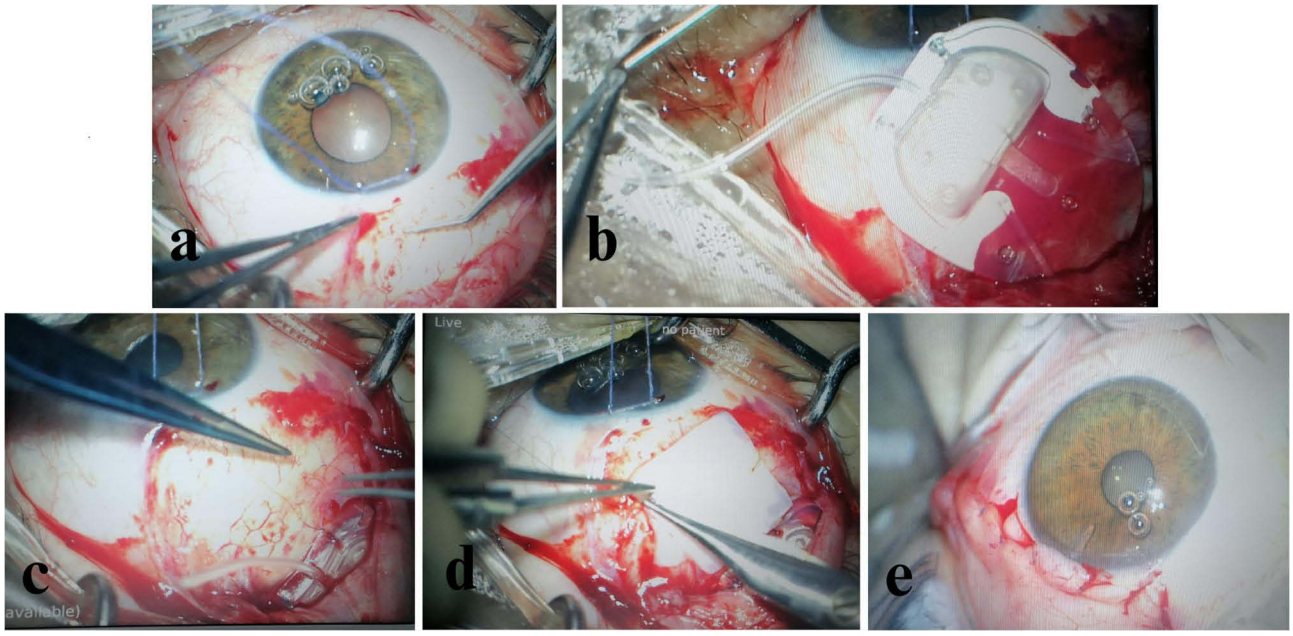

Figure 1 The figure shows steps in AGV surgery. (**a**) Tractional suture with conjunctival dissection. (**b**) Priming of the AGV. (**c**) Implantation and suturing of the plate. (**d**) Pericardial patch covering. (**e**) The tube in the anterior chamber.

Results

General Characteristics

Eighty-seven eyes of 83 patients were included in the study. More than half of the patients (54%) were males. Th mean age of the patients was 47.4 years. The GDD was implanted in the right eye in 49 (56.3%) of the eyes. Half of the patients have DM and 42.5% of patients have systemic hypertension.

Neovascular glaucoma was the most common indication for GDD implantation (39 of the eyes; 44.8%). POAG was the second most indication and the GDD was implanted in 21 of the eyes (24.1%). Congenital glaucoma was the indicative diagnosis in 12 of the eyes (13.8%) and 3 patients had PEX glaucoma. Table 1 summarizes the general characteristics of the study population.

Table 1 General Demographical and Medical Characteristics

Variables	Number*	Percentage (%)
		Mean ± SEM
Sex		
Male	47	54
Female	40	46
Age (years)	47.4 ± 2.4	
Side of procedure (laterality)		
Right	49	56.3
Left	38	43.7
Comorbidities		
DM	44	50.6
HTN	37	42.5
HbA1c (%)	8.5 ± 0.3	
Indication of surgery (type of glaucoma)		
POAG	21	24.1
Neovascular	39	44.8
Congenital	12	13.8
PEX	3	3.4
Other secondary causes	12	13.8
Mean BCVA (LogMAR):		
At presentation		1.282 ± 0.08
At 6 months postoperative		1.235 ± 0.09
At last FU visit		1.387 ± 0.1
IOP measurement (mmHg)		
At presentation		31.1 ± 1.1
At 6 months postoperative		16.4 ± 0.8
At last FU visit		16.6 ± 0.8
Mean number of AG use:		
At presentation		3.59 ± 0.09
At 6 months postoperative		1.97 ± 0.1
At last FU visit		2.67 ± 0.2

(*Continued*)

Table 1 (Continued).

Variables	Number*	Percentage (%)
		Mean ± SEM
Postoperative complications:		
Encysted valve	25	28.7
Hypotony	12	13.8
Valve/tube exposure	3	3.4
Need for revision	21	24.1
Time from operation to revision (weeks)	15.2 ± 5.0	
Number of FU visits	13.9 ± 0.9	

Note: *N = 87.
Abbreviations: SEM, standard error; POAG, primary open angle glaucoma; PEX, pseudoexfoliation; BCVA, best corrected visual acuity; IOP, intraocular pressure; FU, follow up; AG, anti-glaucoma agent; DM, diabetes mellitus; HTN, systemic hypertension.

The mean BCVA was 1.282 LogMAR, 1.235 LogMAR, and 1.387 LogMAR at presentation, 6 months postoperatively and at the last follow-up, respectively. In addition, the mean IOP was 31.1 mmHg, 16.4 mmHg, and 16.6 mmHg at presentation, 6 months postoperatively and at the last follow-up, respectively.

Regarding the postoperative complication, valve encapsulation was the most commonly encountered complication, which developed in 25 of the eyes (28.7%). Hypotony with its subsequent ocular complications occurred in 12 of the eyes (13.8%). Moreover, 3 of the eyes had valve exposure. About one-quarter of the eyes at one time underwent valve revision.

Factors Affecting the Development of Complication

Regarding valve encapsulation, it was found that patients factors, the indications, and the visual outcomes were not associated with the rate of valve encapsulation. However, valve encapsulation was associated significantly with the need for revision in about half of the cases. Although it was not significant, the rate of encapsulation was higher in younger. Table 2 summarizes the factors affecting the occurrence of valve encapsulation.

The need for revision was affected significantly with the age of the patients, the younger the patients, the more the chance of valve revision. In addition, congenital glaucoma and neovascular glaucoma were the most common type of glaucoma associated with valve revision. Moreover, the higher the readings of IOP were correlated with the higher chance of the need for revision. Table 3 summarizes the factors affecting the need for valve revision.

Table 2 Factors Affecting the Development of Certain Complications (Encysted Valve)

Variables	Number (Percentage)* or Mean ± SEM**		
	Encysted Valve N=25	**No Encysted Valve N= 62**	***P*-value**
Sex			
Male	13 (52.0)	34 (54.8)	NS
Female	12 (48.0)	28 (45.2)	
Age (years)	47.3 ± 3.4	47.4 ± 3.0	NS
Side of procedure (laterality)			
Right (OD)	15 (60.0)	34 (54.8)	NS
Left (OS)	10 (40.0)	28 (45.2)	

(*Continued*)

Table 2 (Continued).

Variables	Number (Percentage)* or Mean ± SEM**		
	Encysted Valve N=25	**No Encysted Valve N= 62**	***P*-value**
Comorbidities			
DM	11 (44.0)	33 (53.2)	NS
HTN	12 (48.0)	25 (40.3)	NS
HbA1c (%)	8.0 ± 1.5	8.7 ± 0.3	NS
Indication of surgery (type of glaucoma)			
POAG	8 (32.0)	13 (21.0)	NS
Neovascular	11 (44.0)	28 (45.2)	
Congenital	2 (8.0)	7 (11.3)	
PEX	0 (0.0)	3 (4.8)	
Other secondary causes	4 (16.0)	11 (17.7)	
Mean BCVA (LogMAR):			
At presentation	1.196 ± 0.14	1.213 ± 0.2	NS
At 6 months postoperative	1.018 ± 0.18	1.091 ± 0.1	NS
At last FU visit	1.095 ± 0.16	1.101 ± 0.1	NS
IOP measurement (mmHg)			
At presentation	32.6 ± 1.2	30.5 ± 1.1	NS
At 6 months postoperative	17.4 ± 0.9	16.0 ± 0.9	NS
At last FU visit	18.7 ± 1.5	15.6 ± 1.0	NS
Mean number of AG use:			
At presentation	3.7 ± 0.7	3.5 ± 0.1	NS
At 6 months postoperative	2.5 ± 0.4	1.7 ± 0.2	0.04
At last FU visit	3.1 ± 0.6	2.4 ± 0.2	0.008
Need for revision	13 (52.0)	8 (12.9)	0.001
Time from operation to revision (weeks)	9.1 ± 1.2	22.3 ± 2.8	NS
Number of FU visits	14.8 ± 6.1	13.5 ± 1.2	NS

Notes: *Chi-square test. **ANOVA test.
Abbreviations: SEM, standard error; POAG, primary open angle glaucoma; PEX, pseudoexfoliation; BCVA, best corrected visual acuity; IOP, intraocular pressure; FU, follow up; AG, anti-glaucoma agent; DM, diabetes mellitus; HTN, systemic hypertension.

Table 3 Factors Affecting the Need for Revision

Variables	Number (Percentage)* or Mean ± SEM**		
	Need for Revision N=21	**No Need for Revision N=66**	***P*-value**
Sex			
Male	8 (38.1)	39 (59.1)	NS
Female	13 (61.9)	27 (40.9)	
Age (years)	36.7 ± 4.8	50.7 ± 2.6	0.011
Side of procedure (laterality)			
Right (OD)	12 (57.1)	37 (56.1)	NS
Left (OS)	9 (42.9)	29 (43.9)	

(*Continued*)

Table 3 (Continued).

Variables	Number (Percentage)* or Mean ± SEM**		
	Need for Revision N=21	**No Need for Revision N=66**	***P*-value**
Comorbidities			
DM	7 (33.3)	37 (56.1)	NS
HTN	7 (33.3)	30 (45.5)	NS
HbA1c	8.50 ± 0.8	8.4 ± 0.3	NS
Indication of surgery (type of glaucoma)			
POAG	5 (23.8)	16 (24.2)	0.049
Neovascular	8 (38.1)	31 (47.0)	
Congenital	6 (28.6)	7 (10.6)	
PEX	0 (0.0)	3 (4.5)	
Other secondary causes	2 (9.5)	9 (13.6)	
Mean BCVA (LogMAR):			
At presentation	1.213 ± 0.2	1.201 ± 0.1	NS
At 6 months postoperative	1.000 ± 0.1	1.091 ± 0.2	NS
At last FU visit	1.153 ± 0.2	1.178 ± 0.1	NS
IOP measurement (mmHg)			
At presentation	35.0 ± 1.1	29.8 ± 1.2	0.039
At 6 months postoperative	16.2 ± 1.2	16.5 ± 0.9	NS
At last FU visit	21.8 ± 1.7	14.6 ± 0.7	0.001
Mean number of AG use:			
At presentation	3.4 ± 0.2	3.6 ± 0.1	NS
At 6 months postoperative	2.6 ± 0.3	1.8 ± 0.3	NS
At last FU visit	3.3 ± 0.2	2.4 ± 0.2	0.019
Postoperative complications:			
Encysted valve	13 (61.9)	12 (18.2)	0.0001
Hypotony	2 (9.5)	10 (15.2)	NS
Number of FU visits	16.3 ± 1.8	13.1 ± 1.1	NS

Notes: *Chi-square test. **ANOVA test.
Abbreviations: SEM, standard error; POAG, primary open angle glaucoma; PEX, pseudoexfoliation; BCVA, best corrected visual acuity; IOP, intraocular pressure; FU, follow up; AG, anti-glaucoma agent; DM, diabetes mellitus; HTN, systemic hypertension.

Discussion

This is the first study in Jordan conducted to assess the clinical practice of AGV implantation and factors affecting the development of complications. There is an increasing trend towards using glaucoma drainage implants compared to trabeculectomy,[20] this is partly because of less postoperative follow-up visits needed and more predictable postoperative course.[21] AGV is available in Jordan, and it is increasingly used. Main indications for AGV in Jordan include neovascular glaucoma, congenital glaucoma, POAG and patients with failed previous trabeculectomy. However, many glaucoma surgeons in Jordan are increasingly using AGV instead of trabeculectomy in almost every type of glaucoma especially during the era of COVID-19 pandemic where access to the health system and the postoperative frequent follow-up visits required for trabeculectomy patients were very limited.

AVG influences the aqueous flow by placing a tube between the conjunctiva and sclera. Theoretically, due to the inclusion of a restrictive valve-like device, the AGV implant has the significant benefit of controlling early postoperative IOP and reducing the risk of hypotony compared to trabeculectomy.[22] AGV implantation is a procedure that has been

performed by glaucoma surgeons in Jordan for more than 15 years. However, complications of AGV in Jordan were not studied before, and our report represents the first manuscript to study the complications of AGV in Jordanian patients. Although we found similar complications to what has been reported in literature, the rate of some of these complications relatively differed.

Our results showed comparable rates of hypotony, and tube-related defects to reports found in literature for these complications in patients in the USA and Europe.[23] However, we found a relatively higher rate of bleb encapsulation and a significantly lower rate of tube erosion in Jordanian patients. We believe these differences are related to genetic and racial differences in conjunctival thickness. Valve encapsulation by Tenon's cyst develops when Tenon's capsule adheres to the episclera forming a high, domed, smooth, two-layered bleb.[24] The encapsulated cyst is resistant to aqueous humor outflow, which results in elevation of IOP.

Conjunctival and tenons capsule thickness was previously studied using optical coherence tomography.[25,26] It was found that older patients showed significantly lower conjunctival and tenons thickness than younger patients, which could influence the final bleb morphology and may predict the risk of bleb encapsulation and failure or thin avascular blebs in trabeculectomy. The age-related thinning in conjunctiva was attributed to many factors including the decline in metabolic function of the epithelia, conjunctival inflammation and the reduction in the diameter of subepithelial fibers of the conjunctiva.[27] Young patients in our report have relatively higher risk of bleb encapsulation, and based on the previous findings that young patients have thicker conjunctiva and tenons capsule, we believe that our findings of significantly higher rate of bleb encapsulation and significantly lower rate of tube erosions after AGV implant in Jordanian patients compared to previous reports in patients of Caucasian ancestry is related to genetic and racial differences in conjunctiva and tenons thickness.[24] However, this needs to be further studied and investigated.

The rate of post-AGV implantation hypotony was reported from 1% to 37%. Even AGV is a valved shunt device, many mechanisms explain the hypotony and include decrease in aqueous production due to ciliary body shutdown, choroidal effusion, over-priming of the tube with valve failure, and secondary routes of outflow of aqueous humor around the silicone tube. Hypotony may be complicated by choroidal effusion, hypotony maculopathy, and shallow or flat anterior chamber. Accordingly, partial ligation of the tube with sutures can be addressed intraoperatively to prevent early ocular hypotony.[28] Fortunately, we have 12 cases of postoperative hypotony without significant sequelae and improved with conservative management.

A study by Netland indicates that neovascular glaucoma patients have greater risk of surgical failure after Ahmed glaucoma valve surgery compared with controls. Despite improved mean IOP with drainage implants, visual outcomes may be poor, possibly due to progression of underlying disease.[29] A study by WuDunn et al in a group of 108 eyes treated with the Baerveldt implant found neovascular glaucoma patients significantly more likely to fail due to elevated IOP.[30] These results are consistent with our results in the higher failure rate in neovascular glaucoma.

Another form of GDDs is the non-valved device. In non-valved GDD, a temporary limitation for outflow of aqueous by tube ligation (either internal or external) is carried out until encapsulation or adhesions around plate develops. This technique permits resistance to aqueous outflow and thus decreases the risk of hypotony. The non-valved implants are Molteno, Baerveldt types of GDD.[31,32] A comparative study between these types of GDD was conducted by Rojananuangnit et al.[33] They compared the surgical outcomes of AGV, Baerveldt glaucoma implants, and Aurolab implants, and they found that the rate of complications was not different between valved and non-valved GDD. Neovascular glaucoma and lens-induced glaucoma were an independent factor for surgical failure.[33] The Ahmed Baerveldt Comparison study reported that failure and complications as hypotony, explantation, and loss of light perception was found more in the Baerveldt glaucoma implants than in the AGV, while they reported no significant difference in surgical success rates between both types at five years.[34]

Conclusions

GDDs are typically indicated in eyes with a high risk of failure after standard filtering surgery, previous failure of glaucoma surgery or in situations where the follow-up visits may be affected. AGV implant is one of the most widely used GDDs worldwide. This is the first study to investigate the clinical practice of AGV implant in Jordanian population.

It indicates that neovascular glaucoma is the most common indication in Jordan. This type of glaucoma is highly associated with failure and needs revision surgery. Valve encapsulation is the most encountered complication.

Data Sharing Statement

The datasets generated and analyzed during the current study are available from the corresponding author.

Ethical Approval

This research was approved by the IRB at Jordan University of Science and Technology and King Abdullah University Hospital, Irbid, Jordan (420/2018). This study has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendment. The authors confirm that the patients' privacy was saved, and the data was anonymized and kept confidential. The IRB waived the need for consent due to the study's retrospective nature.

Consent for Publication

Written informed consent was obtained from the patient with demonstrated figure.

Funding

The authors have not declared any grant for this work from any funding authority.

Disclosure

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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