

Short-Term Results of Ahmed Glaucoma Valve Implantation in Refractory Glaucoma

 Raziye Dönmez Gün,  Şaban Şimşek

Department of Ophthalmology,
University of Health Sciences, Kartal
Dr. Lütfi Kırdar Training and
Research Hospital, İstanbul, Turkey

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Correspondence: Raziye Dönmez Gün,
SBÜ Kartal Dr. Lütfi Kırdar Eğitim
ve Araştırma Hastanesi, Göz
Hastalıkları Kliniği, İstanbul, Turkey
E-mail: rdmstf84@gmail.com



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ABSTRACT

Objective: The aim of this study was to evaluate short-term outcomes of Ahmed glaucoma valve (AGV) (New World Medical Inc., Rancho Cucamonga, CA, USA) implantation in cases of refractory glaucoma.

Methods: The records of 31 patients who underwent AGV implantation between January 2018 and March 2019 for refractory glaucoma were retrospectively evaluated. Patients with a visual acuity of at least light perception and postoperative follow-up records of at least 6 months were included in the study. Preoperative and postoperative best corrected visual acuity (BCVA), intraocular pressure (IOP), number of topical antiglaucoma medications used, and central corneal thickness (CCT) measurements were recorded, as well as any postoperative complications.

Results: The surgical outcome was graded as complete success for an IOP of 5 to 22 mmHg without antiglaucomatous medication, qualified success for an IOP of 5 to 2 mmHg with antiglaucomatous medication, or failure for an IOP >22 mmHg despite medication. The sum of the complete success and qualified success groups was considered the total success rate. The mean length of follow-up was 12.94 ± 4.98 months. The preoperative mean IOP level and number of topical antiglaucoma medications had decreased from 40.84 ± 8.27 mmHg to 13.84 ± 2.95 mmHg and 3.68 ± 0.54 to 1.10 ± 1.35 , respectively, at the final postoperative examination. There were no significant differences between the preoperative and postoperative CCT and BCVA values ($p > 0.05$). The most common ($n=3$) complication was encapsulated cyst formation in the AGV plate region. The complete, qualified, and total success rates were 45.2% ($n=14$), 54.8% ($n=17$) and 100% ($n=31$), respectively.

Conclusion: Although the mean preoperative IOP level is typically quite high in refractory glaucoma cases, AGV implantation is an effective surgery for reducing IOP in the short term. Longer follow up will show the sustainable impact of AGV implantation on IOP.

INTRODUCTION

Glaucoma is one of the leading causes of irreversible blindness worldwide.^[1] Refractory glaucoma, as seen in patients with neovascular glaucoma, uveitic glaucoma, angle-recession glaucoma, previous unsuccessful glaucoma surgery, and other types of secondary glaucoma are considered to have a low chance of successful treatment with conventional medical and surgical glaucoma treatment methods.^[2-4] Glaucoma drainage devices (GDD) are an important alternative in such cases.^[5] The Ahmed glaucoma valve (AGV) (New World Medical, Inc., Rancho Cucamonga, CA, USA), which has a venturi-based flow-restriction valve, is a GDD designed to decrease postoperative hypotonia and the related complications. The AGV is an effective tool for reducing IOP in cases with refractory glaucoma.^[6,7] This study was an examination of the short-term results of AGV implantation in

patients with refractive glaucoma and the postoperative complications.

MATERIALS AND METHODS

This was a single center study and the data were obtained retrospectively from patients who had undergone AGV implantation between January 2018 and March 2019. Written, informed consent was obtained from all of the patients and the study was conducted according to the principles of the Helsinki Declaration. The Kartal Dr. Lütfi Kırdar Training and Research Hospital Research Ethics Committee granted approval of the study on December 6, 2019 (no: 2019/514/167/11).

The preoperative visual acuity of the study subjects was at least light perception and all of the participants had complete records for at least 6 months of postoperative follow-up. Patients with primary refractory glaucoma, neo-

vascular glaucoma, uveitic glaucoma, glaucoma secondary to penetrating keratoplasty, congenital glaucoma, traumatic glaucoma, or glaucoma secondary to silicone oil use who were resistant to medical and/or surgical treatment were accepted as cases of refractory glaucoma.

The age, gender, preoperative and postoperative best corrected visual acuity, and the preoperative and postoperative first week, first month, third month, sixth month, first year, and most recent examination IOP levels were recorded. Preoperative and postoperative topical anti-glaucoma drug count and central corneal thickness (CCT) values were also noted. All postoperative complications and any medical or surgical interventions performed were documented in detail.

Local anesthesia was administered preoperatively in all cases. A silicone AGV implant model FP7 was used for all of the study patients. In 1 patient, the AGV was implanted in the superior nasal quadrant rather than the superior temporal quadrant as the latter was the site of a prior scleral perforation. A fornix-based conjunctival incision was made at the quadrant where the valve was to be placed. A limbus-based, half-thickness, 4x5-mm scleral flap was then prepared. Balanced salt solution was administered at the tube opening to activate the valve mechanism under the microscope. The reservoir of the Ahmed valve was advanced to the globe equator under the conjunctiva and the reservoir was sutured to the sclera with 6/0 Vicryl sutures (Ethicon, Inc., Somerville, NJ, USA) at a distance of 9 mm from the limbus. A black-tipped 22-G needle was used to enter the anterior chamber under the scleral flap (in a vitrectomized case with widespread peripheral anterior synechiae, we entered through the posterior chamber). The tube tip was cut with a slant to leave 2 to 3 mm inside the anterior chamber and placed into the anterior chamber. The scleral flap was sutured with separate 10/0 nylon sutures. A nylon U suture fixed the tube at the scleral flap entry site. The tenon and conjunctiva were separately sutured with continuous 8/0 Vicryl sutures. Topical antibiotics were prescribed for 2 weeks and topical steroids for 4 weeks postoperative use.

On the condition that no further glaucoma surgery was needed, a postoperative IOP of 5 to 22 mmHg with medication was accepted as a qualified success and 5 to 22 mmHg without medication as a complete success. The combination of qualified and complete successes was considered the total surgical success. An IOP \leq 5 mmHg was considered hypotonia. Hypotonia that developed within the first 3 postoperative months was regarded as early hypotonia. Early complications were defined as those occurring within the first 3 postoperative months and those seen later were described as late complications. Early hypotonia, a need for repositioning due to tube tip contact with the cornea (as long as corneal edema had not developed), cyst development in the AGV plate region, and revision surgery (as long as the tube was not displaced and the IOP was controlled with and/or without medication) were not considered surgical failures. Loss of light sensa-

tion, withdrawal of the valve due to complications related to AGV implantation and the need for additional glaucoma surgical procedures to decrease IOP were considered a surgical failure.

NCSS 2007 software (NCSS LLC, Kaysville, UT, USA) was used to perform the statistical analyses. Descriptive methods (mean, SD, median, frequency, percentage, minimum, maximum) were used to evaluate the study data. The compliance of the quantitative data with a normal distribution was tested with the Shapiro-Wilk test and graphical evaluations. The Wilcoxon signed-rank test was used for binary comparisons without a normal distribution. The Friedman test was used to compare 3 or 5 follow-ups without a normal distribution and the Bonferroni-Dunn test for pairwise comparisons. The accepted level of statistical significance was $p < 0.05$.

RESULTS

In all, 31 patients who underwent AGV implantation for refractory glaucoma between January 2018 and March 2019 were included in the study. Of these cases, 74.2% ($n=23$) were male and 25.8% ($n=8$) were female; the age range was 30 to 82 years, with a mean of 55.55 ± 12.81 years. Surgery was performed on the right eye of 51.6% ($n=16$) and the left eye of 48.4% ($n=15$) of the patients. The distribution of glaucoma type was 35.5% ($n=11$) primary refractory, 29% ($n=9$) neovascular, 16.2% ($n=5$) secondary to penetrating keratoplasty, 3.2% ($n=1$) congenital, 3.2% ($n=1$) secondary to trauma, 9.7% ($n=3$) secondary to silicone oil use, and 3.2% ($n=1$) uveitic glaucoma. The postoperative follow-up duration varied between 6 and 20 months, with a mean length of 12.94 ± 4.98 months (Table 1).

The change in IOP between the preoperative period and the most recent postoperative follow-up was statistically significant ($p=0.001$; $p < 0.01$). The values recorded at the postoperative first week ($p=0.001$), first month ($p=0.001$), third month ($p=0.001$), sixth month ($p=0.001$) and final examination in the study period ($p=0.001$) were significantly lower than the preoperative IOP values ($p < 0.01$) (Table 2) (Fig. 1).

While the mean number of antiglaucoma drugs used according to the number of active ingredients was 3.68 ± 0.54 in the preoperative period; it was 1.10 ± 1.35 at the most recent postoperative examination. The postoperative decrease in the number of drugs compared to the preoperative period was statistically significant ($p=0.001$; $p < 0.01$) (Table 3) (Fig. 2).

The preoperative CCT measurements were 440 μ m to 650 μ m and the mean value was 545.24 ± 48.49 μ m, while the postoperative values were 426 μ m to 620 μ m and the mean value was 549.71 ± 54.74 μ m. These changes in CCT measurements in the postoperative period compared with the preoperative values were not statistically significant ($p > 0.05$) (Table 3).

Table 1. Demographic information of the AGV implantation patients

	n (%)
Age (years)	
Min-Max (Median)	30–82 (55)
Mean±SD	55.55±12.81
Gender (%)	
Male	23 (74.2)
Female	8 (25.8)
AGV implantation site (%)	
Right eye	16 (51.6)
Left eye	15 (48.4)
Glaucoma type (%)	
Primary refractory glaucoma	11 (35.5)
Neovascular glaucoma	9 (29.0)
Glaucoma secondary to keratoplasty	5 (16.2)
Congenital glaucoma	1 (3.2)
Glaucoma secondary to trauma	1 (3.2)
Glaucoma secondary to silicone oil use	3 (9.7)
Uveitic glaucoma	1 (3.2)
Follow-up duration (months)	
Min-Max (Median)	6–20 (12)
Mean±SD	12.94±4.98

AGV: Ahmed glaucoma valve; SD: Standard deviation.

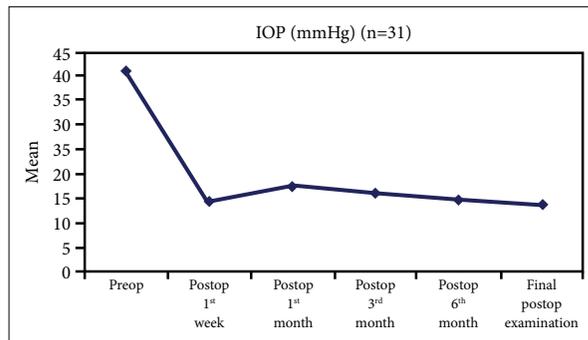


Figure 1. The preoperative and postoperative intraocular pressure (IOP) measurements.

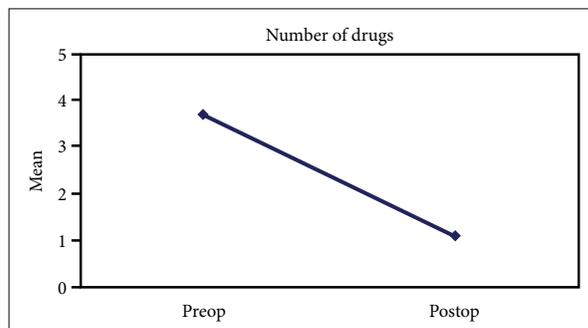


Figure 2. The number of drugs used in the preoperative and postoperative periods.

Table 2. IOP values before and after AGV implantation

	Min-Max (Median)	Mean±SD
IOP (mmHg) (n=31)		
¹ Preoperative	30–65 (38)	40.84±8.27
² Postoperative 1 st week	5–30 (16)	14.29±6.17
³ Postoperative 1 st month	7–32 (18)	17.77±6.13
⁴ Postoperative 3 rd month	7–37 (14)	16.23±6.42
⁵ Postoperative 6 th month	8–27 (14)	14.65±4.02
⁶ Final postoperative examination	8–20 (14)	13.84±2.95
^b p	0.001*	
^c p (2–1)	0.001*	
^c p (3–1)	0.001*	
^c p (4–1)	0.001*	
^c p (5–1)	0.001*	
^c p (6–1)	0.001*	
Difference (2–1)	-477–10 (-26)	-26.55±9.42
Difference (3–1)	-38/–10 (-19)	-23.06±9.55
Difference (4–1)	-47–5 (-25)	-24.61±11.32
Difference (5–1)	-56/–11 (-25)	-26.19±9.24
Difference (6–1)	-56/–15 (-25)	-27.00±8.85

^bFriedman test; ^cBonferroni-Dunn test; *p<0.01. IOP: Intraocular pressure; AGV: Ahmed glaucoma valve; SD: Standard deviation.

Table 3. Comparison of preoperative and recent postoperative AGV implantation findings

	Min-Max (Median)	Mean±SD
Number of drugs		
Preoperative	2–4 (4)	3.68±0.54
Postoperative	0–4 (0)	1.10±1.35
^a p	0.001*	
Difference	-4–1 (-3)	-2.58±1.54
CCT (µm)		
Preoperative	440–650 (550)	545.24±48.49
Postoperative	426–620 (570)	549.71±54.74
^a p	0.600	
Difference	-50–60 (7)	4.48±26.77
Vision (logMAR)		
Preoperative	0.1–2.8 (2)	1.70±0.78
Postoperative	0.1–3 (1.7)	1.69±0.82
^a p	0.779	
Difference	-1.2–1.5 (0)	-0.01±0.48

^aWilcoxon signed-rank test; *p<0.01. AGV: Ahmed glaucoma valve; CCT: Central corneal thickness; SD: Standard deviation.

The preoperative BCVA was between 0.1 and 2.8 logMAR, with a mean value of 1.70±0.78 logMAR, while the post-

operative values were between 0.1 and 3 logMAR and the mean value was 1.69±0.82 logMAR. The BCVA values in the postoperative period were not statistically significantly different from the preoperative values (p>0.05) (Table 3). A postoperative decrease in BCVA was observed in 3

patients (9.6%). Decreased vision was caused in 1 patient with secondary glaucoma following penetrating keratoplasty who developed corneal edema related to peripheral anterior synechia. In 2 patients who were diagnosed with neovascular glaucoma secondary to diabetic retinopathy, the main reason for decreased vision was progression of the diabetic retinopathy.

A postoperative complication was noted in 22.6% (n=7) of the cases. A postoperative early-stage anterior chamber reaction was present in 3.2% (n=1), choroidal detachment in 6.4% (n=2), encapsulated cyst development in the AGV plate region in 9.6% (n=3), and contact of the tube tip with the cornea (without corneal edema) in 3.2% (n=1) of the study patients. Early hypotonia was seen in only 1 case (3.2%). One patient diagnosed with neovascular glaucoma was found to have both early choroidal detachment and late encapsulated cyst development. The rate of early complications was 16.1% (n=5) and the rate of late complications was 6.4% (n=2) (Table 4). In the case with an anterior chamber reaction, topical dexamethasone and

cycloplegic treatment resulted in complete recovery. No intervention was performed in cases with choroidal detachment. These patients were followed up closely and the choroidal detachment regressed spontaneously. In cases with cyst development at the AGV plate region, the roof of the encapsulated cyst was excised under sub-Tenon anesthesia and sub-Tenon mitomycin C (MMC) (0.2 mg/mL) was administered to the edges of the excision site for 3 minutes. No recurring cyst formation was observed during follow-up. Revision surgery was performed in the primary refractory glaucoma case where the tube tip was seen to be in contact with the cornea. There was no recurrence of contact or any other complication during later follow-up. In the single case with hypotonia, the IOP was 12 mmHg at the 1-week follow-up examination and increasing the frequency of use of a topical steroid made treatment possible without additional surgery.

Complete success was found in 45.2% (n=14) of the cases and qualified success was assessed in 54.8% (n=17). The total surgical success for all cases was 100% (n=31). Complete success was attained in 4 and qualified success in 7 of the primary refractory glaucoma cases. Complete success was present 5 and qualified success in 4 of the cases diagnosed with neovascular glaucoma. Complete success was found in 2 and qualified success in 3 of the cases diagnosed with glaucoma secondary to keratoplasty. Qualified success was achieved in 1 case diagnosed with congenital glaucoma. Complete success was realized in 1 case diagnosed with glaucoma secondary to trauma. There was also complete success in 1 and qualified success in 2 of the 3 cases diagnosed with glaucoma secondary to the use of silicone oil. Complete success was attained in 1 case diagnosed with uveitic glaucoma (Table 5).

Table 4. Postoperative complications

	n (%)
Presence of complication*	
No complication was seen	24 (77.4)
Anterior chamber reaction	1 (3.2)
Choroidal detachment	2 (6.4)
Cyst development in the AGV plate region	3 (9.6)
Tube tip contact with the cornea	1 (3.2)
Hypotonia	1 (3.2)
Early complications (First 3 postoperative months)	
No	24 (77.5)
Yes	7 (22.5)
Late complications (After the first 3 postoperative months)	
No	30 (96.8)
Yes	1 (3.2)

*Since two complications were observed in one case, the rate within the total is shown. AGV: Ahmed glaucoma valve.

DISCUSSION

GDDs are usually used to control IOP in refractory glaucoma cases.^[8] One of the most commonly used GDDs is AGV. The AGV is a one-way valve to prevent postoperative hypotonia and a shallow anterior chamber.^[9,10] Surgical success rates at 1 year of follow-up varying between 63% and 100% have been reported in patients who underwent AGV implantation in studies of various types of

Table 5. Success by glaucoma type

	Complete success n (%)	Qualified success n (%)
Primary refractory glaucoma (n=11)	4 (36.4)	7 (63.6)
Neovascular glaucoma (n=9)	5 (55.6)	4 (44.4)
Glaucoma secondary to penetrating keratoplasty (n=5)	2 (40.0)	3 (60.0)
Congenital glaucoma (n=1)	0 (0)	1 (100)
Glaucoma secondary to trauma (n=1)	1 (100)	0 (0)
Glaucoma secondary to silicone oil use (n=3)	1 (33.3)	2 (66.7)
Uveitic glaucoma (n=1)	1 (100)	0 (0)
Success status (all cases)	14 (45.2)	17 (54.8)

glaucoma using different success criteria.^[11-13] Moschos et al.^[14] reported a mean IOP level of 28.3 ± 9.3 mmHg in the preoperative period that decreased to 13.4 ± 6.9 mmHg in the first postoperative year in a large group that had undergone AGV implantation for complicated glaucoma. A mean of 3.5 ± 1.1 drugs were used preoperatively, which was reduced to 1.5 ± 1.4 in the postoperative first year. Yazgan et al.^[7] reported that a preoperative mean IOP level of 39.2 ± 9.4 mmHg regressed to 17.02 ± 4.29 mmHg in the final postoperative examination following AGV implantation, and a decrease in the number of drugs from 3.47 ± 0.92 to 1.52 ± 1.09 . The mean follow-up duration was 32.3 ± 20.7 months in that study of 48 refractory glaucoma cases.^[7] The mean preoperative IOP level of our patients (40.84 ± 8.27 mmHg) was much higher than that reported by Moschos et al.^[14] The reason may be that our study group included more complicated cases. Our IOP results at the final postoperative examination (13.84 ± 2.95 mmHg) were similar to those of Moschos et al.,^[14] but lower than those reported by Yazgan et al.^[7] This may have been due to the longer postoperative follow-up duration in the Yazgan et al.^[7] study. Although the preoperative IOP values of our cases were much higher than those of Moschos et al.,^[14] a satisfactory postoperative success rate (complete success in 45.2% and qualified success in 54.8% for a total of 100% surgical success) was determined. However, the success rate may decrease with longer follow-up. The number of medications used for glaucoma in our study group according to the number of active ingredients was 3.68 ± 0.54 in the preoperative period and decreased to 1.10 ± 1.35 at the most recent postoperative examination, similar to the results of both Moschos et al.^[14] and Yazgan et al.^[7]

The most common complication observed in our study was cyst development in the AGV plate region ($n=3$, 9.6%). These cases were in the neovascular glaucoma ($n=1$), congenital glaucoma ($n=1$) and uveitic glaucoma ($n=1$) groups. Elhefney et al.^[15] reported encapsulated cyst development in 51 (41.1%) of 124 cases in their article describing long-term AGV implantation results. The main cause of failure was excessive fibrosis and encapsulated cyst development. They treated the cysts with needling and MMC injection in 18 (14.5%) cases and excision in 20 (16.1%) cases. A review of some studies from Turkey revealed that encapsulated cysts were not found in the study of refractive glaucoma cases conducted by Yazgan et al.^[7] or in the study reported by Bayraktar et al.^[16] of 25 refractive glaucoma cases. There is significant variation in the cyst development rate in the literature. All of the patients with cyst development in our study underwent cyst excision and sub-Tenon MMC was administered to the excision region edges. Cyst development did not recur in any of these cases. Among these cases of cyst excision, complete success was achieved in a uveitic glaucoma case, while qualified success was recorded in 2 cases in other groups.

Bayraktar et al.^[16] reported a success rate of 84% in their study with 8.5 ± 8.9 months of follow-up on 25 refractory glaucoma cases of various types. However, they reported

that success could only be achieved by adding medication in 40% of the patients. Total success was present in 100% ($n=31$) of our cases, and qualified success was attained in 54.8% ($n=17$) in our study, which included various types of refractive glaucoma with a follow-up duration that varied between 6 and 20 months. Although our total success rate was high, adding medication was required in almost half of our patients during follow-up, similar to the results seen by Bayraktar et al.^[16]

In conclusion, although the mean preoperative IOP level is generally quite high in refractory glaucoma cases, in the short term, AGV implantation is effective at lowering IOP. Various complications may occur after surgery, but most can be managed medically or surgically. The main limitation of this study was a relatively short length of follow-up. Longer follow-up will demonstrate the sustained impact of AGV implantation on IOP.

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Ethics Committee Approval

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Peer-review

Internally peer-reviewed.

Authorship Contributions

Concept: R.D.G.; Design: R.D.G.; Supervision: Ş.Ş.; Materials: R.D.G., Ş.Ş.; Data: R.D.G., Ş.Ş.; Analysis: R.D.G., Ş.Ş.; Literature search: R.D.G.; Writing: R.D.G., Ş.Ş.; Critical revision: R.D.G., Ş.Ş.

Conflict of Interest

None declared.

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Dirençli Glokom Olgularında Ahmed Glokom Valv İmplantasyonu Kısa Dönem Sonuçları

Amaç: Amacımız tedaviye dirençli glokom olgularında Ahmed glokom valv (AGV) implantasyonu kısa dönem sonuçlarını değerlendirmektir.

Gereç ve Yöntem: Ocak 2018–Mart 2019 tarihlerinde dirençli glokom tanısıyla AGV implantasyonu uygulanan 31 olgu geriye dönük incelendi. Görme keskinliği en az ışık hissi düzeyinde olan ve en az 6 aylık ameliyat sonrası takibi bulunan hastalar çalışmaya alındı. Olguların ameliyat öncesi ve sonrası en iyi düzeltilmiş görme keskinlikleri (EİDGK), göz içi basıncı (GİB) düzeyleri, topikal antiglokomatöz ilaç sayıları, santral kornea kalınlığı (SKK) değerleri kaydedildi. Ameliyat sonrası tüm komplikasyonlar ayrıntılı olarak not edildi.

Bulgular: Ameliyat sonrası GİB'in ilaçsız 5–22 mmHg arasında olması tam başarı, ilaçla 5–22 mmHg arasında olması kısmi başarı, ilaca rağmen >22 mmHg olması ise başarısızlık olarak kabul edildi. Tam başarı ve kısmi başarının toplamı toplam cerrahi başarı olarak tanımlandı. Ortalama takip süresi 12.94±4.98 aydı. Ameliyat öncesi 40.84±8.27 mmHg olan ortalama GİB düzeyleri ameliyat sonrası son muayenede 13.84±2.95 mmHg'ya; ameliyat öncesi ortalama 3.68±0.54 olan antiglokomatöz ilaç sayısı ameliyat sonrası son muayenede 1.10±1.35'e düştü. Ameliyat öncesi ve sonrası SKK ve EİDGK'de anlamlı değişme saptanmadı (p>0.05). Olguların %22.6'sında (n=7) komplikasyon görüldü. En sık (n=3) rastlanılan komplikasyon AGV plate bölgesinde enkapsüle kist gelişimi oldu. Olguların %45.2'sinde (n=14) tam, %54.8'inde (n=17) kısmi olmak üzere toplam %100 (n=31) cerrahi başarı elde edildi.

Sonuç: Dirençli glokom olgularında ameliyat öncesi ortalama GİB düzeyleri oldukça yüksek olsa da, kısa dönemde, AGV implantasyonu GİB'yi düşürmede etkili bir cerrahidir. Uzun süreli takiplerle, AGV implantasyonunun GİB'yi düşürmedeki sürdürülebilir etkisini göstermek mümkün olacaktır.

Anahtar Sözcükler: Ahmed glokom valvi; dirençli glokom; göz içi basıncı.