Evaluation of the Efficacy of Pars Plana Ahmed Glaucoma Valve Implantation with Vitrectomy in Uncontrolled Neovascular Glaucoma Secondary to Proliferative Diabetic Retinopathy: A Retrospective Analysis

Proliferatif Diyabetik Retinopatiye Sekonder Kontrolsüz Neovasküler Glokomda Vitrektomi ile Birlikte Pars Plana Ahmed Glokom Valfi İmplantasyonunun Etkinliğinin Değerlendirilmesi: Retrospektif Bir Analiz

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Background: Today, debate continues regarding the effective management of neovascular glaucoma (NVG) associated with proliferative diabetic retinopathy (PDR) and the success of the combination approach of pars plana (PP) Ahmed glaucoma valve (AGV) implantation and PP vitrectomy (PPV) in this patient. To evaluate the effect and tolerability of PP AGV implantation and PPV combined approach on intraocular pressure (IOP), visual acuity, and tolerability in patients with PDR and secondary uncontrolled NVG.

Materials and Methods: Thirty-seven patients with severe NVG secondary to PDR who were resistant to conventional medical therapies underwent surgery between May 2020 and January 2023. The surgical procedure involved 23-gauge PPV along with PP AGV implantation. Demographic information, surgical details, and complications were recorded. Statistical analyses were performed using the IBM SPSS statistics software.

Results: The mean age of the patients was 52.8 years. Preoperatively, the mean IOP was 36.9±12.3 mmHg, decreasing significantly to 19.1±4.0 mmHg at the 12 month follow-up. The mean number of glaucoma medications reduced from 3.9±0.2 to 1.9±1.5 postoperatively. Best-corrected visual acuity improved in 17 patients, remained unchanged in 11, and deteriorated in 9. The complications included fibrinoid reaction, hyphema, transient hypotony, choroidal effusion, and one case requiring fibrotic band excision. No retinal complications or corneal insufficiency were reported.

Conclusion: The study concludes that the combined surgical approach of PP AGV implantation and 23-gauge PPV is a promising and effective strategy for managing uncontrolled NVG secondary to PDR. The method demonstrated positive outcomes in terms of IOP control, medication reduction, and visual improvement, with manageable complication rates.

Keywords: Ahmed glaucoma valve, neovascular glaucoma, pars plana vitrectomy, proliferative diabetic retinopathy

Gereç ve Yöntemler: Medikal tedavilere dirençli, PDR'ye ikincil şiddetli NVG'si olan 37 hastaya Mayıs 2020 ile Ocak 2023 tarihleri arasında ameliyat yapıldı. Cerrahi prosedür, PP AGV implantasyonu ile birlikte 23-gauge PPV'yi içeriyordu. Demografik bilgiler, cerrahi ayrıntılar ve komplikasyonlar kaydedildi.



ÖZ

ABSTRACT

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Amaç: Günümüzde proliferatif diyabetik retinopatiye (PDR) ile ilişkili neovasküler glokomun (NVG) etkili bir şekilde yönetilmesi ve bu hastalarda uygulanan pars plana (PP) Ahmed glokom valfi (AGV) implantasyonu ve PP vitrektomi (PPV) kombinasyonu yaklaşımının başarısı konusunda tartışmalar devam etmektedir. Sekonder kontrol edilemeyen NVG'si olan PDR'li hastalarda, PP AGV implantasyonu ve PPV kombine yaklaşımın göz içi basıncı (GİB), görme keskinliği üzerine etkisini ve tolere edilebilirliğini değerlendirmek amaçlanmıştır.



ÖZ

Bulgular: Hastaların ortalama yaşı 52,8 idi. Ameliyat öncesi ortalama GİB 36,9±12,3 mmHg iken, 12 aylık takipte 19,1±4,0 mmHg'ye düşmüştür. Ortalama glokom ilacı sayısı ameliyat sonrasında 3,9±0,2'den 1,9±1,5'e düşmüştür. En iyi düzeltilmiş görme keskinliği 17 hastada iyileşti, 11'inde değişmedi ve 9'unda kötüleşti. Komplikasyonlar arasında fibrinoid reaksiyon, hifema, geçici hipotoni, koroidal efüzyon ve fibrotik bant eksizyonu gerektiren bir olgu yer aldı. Retinal komplikasyon veya kornea yetmezliği bildirilmedi.

Sonuç: Bu çalışma, PP AGV implantasyonu ve 23-gauge PPV kombine cerrahi yaklaşımının PDR'ye ikincil kontrolsüz NVG'yi yönetmek için umut verici ve etkili bir strateji olduğu sonucuna varmaktadır. Yöntem, yönetilebilir komplikasyon oranları ile GİB kontrolü, ilaçların azaltılması ve görsel iyileşme açısından olumlu sonuçlar ortaya koymaktadır.

Anahtar Kelimeler: Ahmed glokom valfi, neovasküler glokom, pars plana vitrektomi, proliferatif diyabetik retinopati

Introduction

Neovascular glaucoma (NVG), a challenging and potentially devastating consequence of proliferative diabetic retinopathy (PDR), is characterized by the growth of new, abnormal blood vessels on the iris and the anterior chamber angle, resulting in increased intraocular pressure (IOP) and optic nerve damage (1). Conventional medical therapies frequently fail to effectively manage NVG associated with PDR, necessitating more invasive interventions. Among these, the use of glaucoma drainage implants has emerged as a viable option for refractory glaucoma in the context of PDR. These devices typically involve the placement of a tube in the anterior chamber, which functions to divert aqueous humor to an extracorporeal reservoir, thereby alleviating elevated IOP (2). However, the clinical management of NVG in PDR is complicated by secondary complications such as vitreous hemorrhage or vitreous opacity. In such scenarios, vitrectomy might be necessary to clear the visual axis and allow for adequate laser treatment. Furthermore, anatomical and pathological considerations in advanced stages of the disease often render the anterior chamber an unsuitable site for tube placement (3,4).

In specific cases involving patients with uncontrolled glaucoma and concurrent posterior segment disease, the application of combined pars plana vitrectomy (PPV) alongside the placement of a glaucoma valve in the PP region may yield optimal outcomes. The anterior chamber may not be the optimal site for tube implantation in certain clinical scenarios, such as advanced glaucoma accompanied by secondary angle closure or angle neovascularization, as well as in cases involving corneal diseases and other anterior chamber abnormalities. In such instances, a more suitable alternative is the placement of the implant through the PP, concomitant with vitrectomy. This approach proves particularly beneficial when anterior segment disease poses a safety concern, making the conventional placement of the glaucoma tube in the anterior chamber impractical. This procedure not only addresses the challenges posed by anterior segment abnormalities but also provides a comprehensive solution for conditions necessitating both

glaucoma management and posterior segment intervention. The combined implementation of a drainage device, such as Ahmed glaucoma valve (AGV), and PPV presents a viable and judicious option for patients experiencing ocular hypertension despite undergoing maximum IOP-lowering treatments, along with complications such as vitreous hemorrhage (5,6). Furthermore, when challenges such as compromised retinal fundus visualization arise due to factors like dense cataract, corneal edema, hyphema, or vitreous hemorrhage, the inclusion of PPV becomes imperative for the comprehensive performance of panretinal photocoagulation. This integrated surgical strategy offers the advantage of addressing both pathologies in a single procedure, potentially streamlining the overall management and enhancing patient outcomes, as opposed to undertaking these surgeries at different time points.

Effective management of NVG associated with PDR has sparked controversy in current discussions. This study aimed to assess the outcomes of a combined approach involving PP AGV implantation and PPV in patients with PDR experiencing secondary uncontrolled NVG. The evaluation focuses on key parameters such as IOP, visual acuity, and tolerability. By investigating the impact of this combined intervention, we contribute valuable insights to the ongoing discourse surrounding the optimal treatment strategy for NVG associated with PDR.

Materials and Methods

The present study, which was conducted with the approval of the Ethics Committee of Başakşehir Çam and Sakura City Hospital (KAEK/17.01.2024.01, date: 18.01.2024) and in adherence to the principles of the Declaration of Helsinki, aimed to retrospectively analyze the clinical outcomes of a combined surgical approach in patients with PDR complicated by uncontrolled NVG. This study focused on cases where NVG was resistant to conventional medical therapies and necessitated the implementation of a 23-gauge vitrectomy in conjunction with AGV implantation. Patients who underwent surgery between May 1, 2020 and January 31, 2023 were included in the study.

The patient inclusion criteria for this study were defined to encompass individuals experiencing severe NVG, as evidenced by an IOP of 30 mmHg. In addition, vitreous hemorrhage or dense vitreous opacity with underlying pathology of PDR was observed in eligible patients. In total, 37 patients were identified who met these criteria and were thus included in the study. Phakic patients were not included in the study. Demographic information of the patients was recorded, and complications arising from surgery were tracked.

Surgical Procedure

The surgical procedure, conducted under general anesthesia, began with a fornix-based periotomy complemented by superotemporal and superonasal relaxing incisions. The extraocular rectus muscles were carefully isolated using a muscle hook. The functionality and patency of the AGV were verified using balanced saline solution. Subsequently, the AGV was anchored to the sclera using an ethibond suture approximately 9-10 mm from the limbus in the superotemporal quadrant. Vitrectomy was performed using a 23-gauge vitreous cutter driven by a vitrectomy unit. A sclerotomy was placed 3.5 mm posterior to the limbus in all eyes. Panretinal endolaser photocoagulation was executed. To place the AGV tubes in the PP, a 23-gauge sclerotomy was performed at a distance of 3.5 mm from the limbus. Notably, this was performed without creating a scleral flap. The tubes were then sutured to the sclera. Postoperative care included a regimen of topical antibiotics (moxifloxacin administered four times daily), corticosteroids (dexamethasone four times daily), and cycloplegic agents (cyclopentolate three times daily) for 1 month.

Statistical Analysis

Statistical analyses for this study were conducted using IBM SPSS Statistics software, version 28. Descriptive statistics were employed to summarize continuous variables, with mean values presented along with standard deviations and medians accompanied by minimum and maximum range values. Categorical variables are reported using numbers and percentages. For the analysis of more than two repeated measurements, Friedman test (Non-parametric repeated measures ANOVA) with post-test (Dunn's multiple comparisons test) and repeated measures ANOVA with post-test (Tukey-Kramer multiple comparisons test) were applied. Pairwise comparisons before and after surgery were conducted using the Wilcoxon matched-pairs signed-ranks test. The chosen significance level for all analyses was set at 95%, deeming results as statistically significant when the p-value was 0.05.

Results

The study comprised 37 patients who developed NVG as a complication of PDR and subsequently underwent AGV implantation. Table 1 presents the demographic and clinical characteristics of the patients. The mean age at the time of surgery was 52.8±15.8 years, with 51.3% of the patients being male and 48.7% female. The mean axial length was 21.9±1.4 mm. When the preoperative and postoperative data of the patients were compared (Table 2), it was determined that the preoperative IOP values of the patients were significantly higher than the postoperative 1st, 3rd, and 12th IOP values (36.9±12.3, 19.4±6.5, 18.9±3.6 and 19.1±4.0; p<0.001, respectively) (Figure 1). However, there was no statistically significant difference between the postoperative 1st, 3rd, and 12th IOP values (p>0.05). Table 2 elucidates the alterations in the mean anti-glaucoma medication number (AGM-N) used by the patients in the pre- and postoperative periods. When the patients' preoperative and postoperative AGM-Ns were compared (Table 2), preoperative AGM-N values were higher than the numbers of postoperative 1st, 3rd, and 12th month AGM-N (3.9±0.2, 1.4±1.4, 1.8±1.5 and 1.9±1.5; p<0.001, respectively). However, there was no statistical difference between the AGM-Ns at postoperative 1st, 3rd, and 12th month (p>0.05).

While 11 patients experienced no change in visual acuity, 9 patients exhibited a decrease, and 17 patients demonstrated an improvement. The mean best-corrected visual acuity (BCVA-logMAR) values were 1.06±0.64 preoperatively and 0.91±0.45 postoperatively. The postoperative 12th month visual acuity levels of the patients were found to be lower than the preoperative month visual acuity levels (p=0.0039) (Figure 2). Fibrinoid reaction in three patients and hyphema in four patients occurred and

participants						
		Avg. ± SD	Median (minmax.)			
Surgical age (years)		52.8±15.8	53.0 (41-68)			
Sex	Male	19 (51.3%)				
	Female	18 (48.7%)	%)			
Axial length (mm)		21.9±1.4	21.8 (20.3-25.4)			
Preoperative BCVA (logMAR)		0.91±0.46	1.00 (0.7-1.3)			
IOP (preoperative)		37.6±8.1	39.0 (29.0-55.0)			
Number of anti-glaucoma medications (preoperative)		3.8±0.5	4.0 (3.0-4.0)			
Continuous variables are presented as the mean ± standard deviation/median (min-max.). Categorical variables are presented as numbers (%) Avg.: Average, BCVA: Best corrected visual acuity, IOP: Intraocular pressure, SD: Standard deviation.min-max.: Minimum. maximum						

Table 1. Demographics and clinical characteristics of the



Table 2. Comparison of the preoperative and postoperative results of the study groups							
	Preoperative (A)	Postoperative 1 st month (B)	Postoperative 3 rd month (C)	Postoperative 12 th month (D)	p-value		
n	37	37	37	37	-		
IOP, mmHg	36.9±12.3 36.0 (15.0-60.0)	19.4±6.5 19 (10-35)	18.9±3.6 19 (14-29)	19.1±4.0 19 (13-29)	^b <0.0001		
Comparison p	<0.001, <0.001, <0.01, >0.05, >0.05, >0.05						
AGM-N, n	3.9±0.2 4 (3-4)	1.4±1.4 1 (0-3)	1.8±1.5 2 (0-4)	1.9±1.5 2 (0-4)	^a <0.0001		
Comparison p	<0.001, <0.001, >0.05, >0.05, >0.05						
Visual acuity (logMAR)	1.06±0.64 1.00 (0.00-2.00)			0.91±0.45 1.00 (0.00-1.30)	٥.0039		

a: Friedman test (Non-parametric repeated measures ANOVA) with post-test (Dunn's multiple comparisons test)

^b: Repeated measures ANOVA with post-test (Tukey-Kramer multiple comparisons test)

^c: Wilcoxon matched-pairs signed-ranks test

Statistical significance level =p<0.05. When p values obtained by ANOVA tests are <0.05, comparison p values between groups are determined (group A-B, group A-C, group A-D, group B-D, group B-D, group C-D, respectively). Non-parametric data are given as mean ± SD and median (min.-max.)

SD: Standard deviation, IOP: Intraocular pressure, AGM-N: Number of anti-glaucoma medications, min-max.: Minimum, maximum

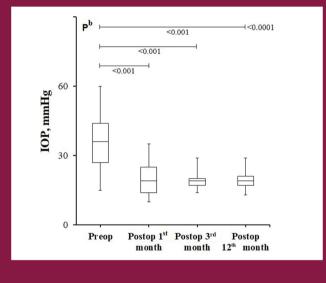


Figure 1. Comparison of preop and postop IOP values. It is seen that the IOP values of the postoperative 1st, 3rd, and 12th months are lower than the preoperative IOP values b: Repeated measures ANOVA with post-test *IOP: Intraocular pressure*

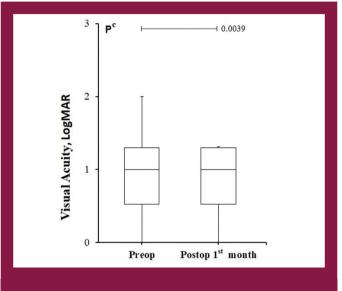


Figure 2. Comparison of preop and postop visual acuity values. It can be seen that the visual acuity values of the postoperative 12^{th} month are lower than the preoperative visual acuity values : Wilcoxon matched-pairs signed-ranks test

resolved with topical treatment. Transient hypotony and choroidal effusion were observed in seven patients, with one patient requiring fibrotic band excision from the tube tip 2 months postoperatively. Ten patients had elevated IOP above 21 at the 12-month examination. Notably, no retinal complications or corneal insufficiency were reported in any patient.

Discussion

This retrospective study focused on evaluating the efficacy of PP AGV implantation in patients with NVG. The primary findings of this study revealed a significant improvement in both IOP control and a reduction in the need for glaucoma medications postoperatively. At the end of the 12-month follow-up period, IOP <21 was observed in



26 (70.2%) patients. The mean AGM-Ns used decreased from 3.9±0.2 to 1.9±1.5. The study by Yalvac et al. (7) provided valuable insights into the 1-year surgical success rate of AGV implantation for NVG. In their investigation involving 38 eyes with NVG, the reported 1-year surgical success rate was 63.3%. In comparison, Netland (8) reported a slightly higher 1-year surgical success rate of 73.1% in a study involving 38 eyes with NVG.

In the management of complex glaucoma cases, particularly those involving concurrent PDR, the integration of PPV with PP placement of a glaucoma drainage device has emerged as a promising therapeutic strategy. The literature reflects a growing interest in this technique, with studies examining the efficacy and safety profiles of various glaucoma valves, including Baerveldt (5,6) Molteno (5,7) and AGV (8,9), each presenting unique characteristics and challenges. The Baerveldt and Molteno tubes are noted for their unregulated flow feature, which, while effective in reducing IOP, carries the risk of postoperative complications such as hypotony and choroidal detachment. On the other hand, the AGV, distinguished by its built-in flow regulation mechanism, offers a significant advantage in preventing hypotony (10). This feature is particularly advantageous in complex glaucoma cases where the regulation of IOP is crucial. Additionally, the AGV is often considered technically easier to insert, a factor that can influence surgical outcomes and postoperative recovery.

The success of PP placement of glaucoma drainage devices, such as Baerveldt or Molteno tubes, in lowering IOP in patients with NVG has been well documented in previous studies. A seminal study by Luttrull and Avery (9) in 1995 demonstrated compelling results, showcasing IOP control below 22 mmHg in all 2 patients with NVG following PP placement of Baerveldt or Molteno tubes. The mean IOP exhibited a remarkable decrease from 46 mmHq to 16 mmHq, accompanied by a reduction in AGM-Ns from 2.9 to 0.7. Subsequent investigations, such as the study by Faghihi et al. (5), focused on the PP placement of an AGV combined with vitrectomy in 18 eyes with NVG. The mean preoperative IOP was notably high at 53.3 mmHg, with 2.7 drugs, and IOP improved to 16.3 managed by 0.94 drugs postoperatively. Similarly, Jeong et al. (6) demonstrated favorable outcomes with PP AGV in 11 eyes, achieving IOP levels between 8 mmHq and 18 mmHq. In our current study involving the PP placement of the AGV for NVG, we observed outcomes consistent with those reported for Baerveldt and Molteno tubes. Specifically, 70.2% of the NVG eyes in our study achieved IOP levels below 21 mmHg at the final examination. Collective evidence from these studies suggests that PP placement of various glaucoma drainage devices, including AGV, yields favorable outcomes in terms of IOP control and reduction in AGM dependence for patients with NVG. These findings contribute to the growing body of knowledge supporting the efficacy of this surgical approach in managing the complex challenges posed by NVG.

The combined approach of AGV with vitrectomy offers several advantages in patients with PDR suffering from uncontrolled IOP. This methodology not only addresses elevated IOP but also directly combats the underlying issues associated with PDR and NVG. The combined surgery facilitates the removal of vitreous hemorrhages and opacities. This clearance is crucial because it allows for an improved evaluation of the fundus during the early postoperative period, which is essential for monitoring the patient's progress and detecting any potential complications. By combining these procedures, both NVG and PDR can be addressed in a single operation. This approach is not only efficient but also reduces the patient's exposure to multiple surgical risks and recovery periods. In addition, intraoperative endolaser photocoagulation, often performed during vitrectomy, can induce regression of iris neovascularization, a significant factor in NVG. Placing the drainage implant in the PP region minimizes the risk of endothelial touch and hyphema (10). This placement is especially beneficial in patients with compromised anterior segments. However, this combined surgical approach is not without potential complications. Posterior segment issues such as incorrect placement of the tube and retinal detachment are risks that need to be considered (5,11). Furthermore, when the tube is placed in the anterior chamber, it allows for easier visualization and diagnosis of tube obstruction. Preference is based on the belief that the final visual outcome in these patients is influenced not only by the management of IOP but also by the progression and control of the underlying diabetic retinopathy.

The comparison of complications associated with the use of PP drainage implants in various studies highlights the general safety and manageability of this approach, although it is not without risks. In a previous study involving PP Baerveldt or Molteno tubes, the reported complications included one instance each of vitreous hemorrhage, hyphema, and choroidal hemorrhage along with eight cases of choroidal effusion (12). These complications, while serious, appear to be relatively rare. Faghihi et al. (5) reported a slightly broader range of complications, with one patient each developing vitreous hemorrhage, hypotony, and choroidal effusion, and two patients experiencing phthisis bulbi. This indicates a risk of more severe outcomes, albeit in a minority of cases. This suggests that while complications can occur, they can often be managed effectively without long-term detriment to the patient. In your study, the most common complication was hyphema formation, occurring in



4 eyes (10.8%). There were no cases requiring the removal of the AGV because of persistent hypotony, and issues like transient hypotony and choroidal effusion were resolved with topical treatment. These findings suggest that while there is a risk of complications with PP drainage implants in patients with NVG, these complications are generally limited and manageable. This supports the use of these implants as a viable option for treating NVG, particularly in complex cases where other treatments have failed.

Study Limitations

This study has several limitations that must be acknowledged. As a retrospective study, it inherently lacks the control and randomization of a prospective trial. There was a potential loss of follow-up data. The follow-up schedule was not standardized but was based on clinical necessity. The non-randomized nature of the study and the variable follow-up periods could lead to selection biases. Our findings, while promising, underscore the need for more rigorous prospective and comparative clinical trials.

Conclusion

In conclusion, while this study contributes valuable data to the existing body of knowledge on NVG treatment, these limitations highlight the need for continued research. Future studies, particularly those that are prospective and comparative, are essential to further validate and refine the treatment strategies for NVG.

Ethics

Ethics Committee Approval: The present study, which was conducted with the approval of the Ethics Committee of Başakşehir Çam and Sakura City Hospital (KAEK/17.01.2024.01, date: 18.01.2024) and in adherence to the principles of the Declaration of Helsinki.

Informed Consent: Retrospective study.

Authorship Contributions

Surgical and Medical Practices: M.K., D.Ö., Concept: M.K., D.Ö., D.Ç.Y., Design: M.K., D.Ç.Y., Data Collection or Processing:

M.K., C.G., Analysis or Interpretation: M.K., D.Ö., Literature Search: C.G., D.Ç.Y., Writing: M.K., C.G., D.Ö.

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