

Simultaneous pars plana vitrectomy, panretinal photocoagulation, cryotherapy, and Ahmed valve implantation for neovascular glaucoma

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Abstract

• **AIM:** To describe and evaluate the efficacy of Ahmed glaucoma valve implantation (AGV) combined with pars plana vitrectomy (PPV) in a single surgical act for the treatment of advanced neovascular glaucoma (NVG).

• **METHODS:** Retrospective observational case series included 51 eyes from 50 patients with severe NVG treated with PPV, AGV, and panretinal photocoagulation and/or cryotherapy in a single surgical act during a 13-year period (2005-2018). Preoperative, intraoperative and postoperative data at day 1 and months 1, 3, 6, 21, and 24 were systematically collected. Definition of surgical success was established at IOP between 6 and 21 mm Hg with or without topical treatment.

• **RESULTS:** Main indications for surgery were NVG secondary to proliferative diabetic retinopathy (39.2%) and central retinal vein occlusion (37.3%). Mean (\pm SD) preoperative IOP was 42.0 ± 11.2 mm Hg decreasing to 15.5 ± 7.1 mm Hg at 12mo and 15.8 ± 9.1 mm Hg at 24mo of follow up. Cumulative incidence of success of IOP control was 76.0% at first postoperative month, reaching 88.3% at 6mo. Prevalence of successful IOP control at long term was 74.4% at 12mo and 71.4% at 24mo. Eye enucleation for unsuccessful NVG management was required in 1 case (2.0%).

• **CONCLUSION:** Combination of AGV implantation and PPV in a single act may be a suitable option for severe forms of NVG in a case-by-case basis for effective IOP control and a complete panretinal photocoagulation.

• **KEYWORDS:** neovascular glaucoma; Ahmed valve; pars plana vitrectomy; panretinal photocoagulation; cryotherapy
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INTRODUCTION

Neovascular glaucoma (NVG) is a sight threatening entity found in some retinal diseases with severe retinal ischemia. Persistent hypoxic condition of the retina stimulates the production of vascular endothelial growth factor (VEGF) and several cytokines, favorizing the development of a fibrovascular membrane in the trabecular meshwork which limits aqueous humor outflow and, consequently, intraocular pressure (IOP) rises^[1-3]. NVG management may be difficult due to its underlying causing disease, which must be confronted as well as aiming at the IOP control. Therefore, efficiently dealing with severe cases of NVG is still nowadays a challenging eye condition.

NGV has been most frequently described in proliferative diabetic retinopathy (PDR), central retinal vein occlusion (CRVO), ocular ischemic syndrome and central retinal artery occlusion (CRAO), branch retinal vein occlusion (BRVO), Eales' disease and sickle cell retinopathy^[2]. Regarding the treatment of retinal ischemia, panretinal photocoagulation (PRP) and anti-VEGF intravitreal injections, have both demonstrated to reduce new vessel growth, acting directly against the underlying cause of NVG^[3-4]. Injected anti-VEGF agents induce neovascularization involution earlier than PRP, although long-standing large destruction of ischemic tissue produced by PRP remains the standard treatment for NVG^[2,5]. However, treating the cause does not always assure regression of NVG. In cases with persistent ocular hypertension, Ahmed glaucoma valve (AGV) implantation has demonstrated to

significantly decrease IOP^[3,6-8]. The combination of a draining device (AGV) and PPV seems to be a rightful option for patients with ocular hypertension despite of maximum IOP-lowering treatment and vitreous hemorrhage^[9]. In addition, whenever retinal fundus visualization is compromised in cases of poor mydriasis, corneal edema, hyphema, dense cataract or vitreous hemorrhage, PPV may be necessary to perform a complete PRP. Overall, simultaneous surgery of PPV and AGV implantation may be more efficient than performing both surgeries at different time points.

We hereby present an observational case series study of NVG patients treated with PPV and AGV implantation in one surgical act. The aim of this study is to describe the outcomes of this treatment in complex NVG cases when performed in association with intraoperative PRP, cryotherapy and/or anti-VEGF injection. Moreover, since most of the reports published describing this simultaneous technique are small observational studies, we aim to bring together more evidence of the effectiveness of PPV and AGV implantation to the debate of which is the best treatment for advanced cases of NVG.

SUBJECTS AND METHODS

Ethical Approval The study protocol was approved by the Institutional Review Board at Hospital Clinic of Barcelona (CEIC, HCB/2020/0640) and follows the Declaration of Helsinki. Informed consent was waived due to the retrospective nature of the study.

Study Design Retrospective observational case series study of NVG cases treated in a single surgical act with PPV, AGV implantation and endolaser and/or cryotherapy in a 13-year period (2005-2018) in the Retinal Department of a tertiary hospital (Hospital Clinic of Barcelona). Systematic revision of electronic medical records was performed for data collection.

A total of 51 eyes of 50 patients with NVG that underwent PPV and Ahmed valve implantation in a single surgical act were included. IOP inclusion criteria was IOP \geq 21 mm Hg with maximum IOP-lowering treatment, IOP \geq 21 mm Hg at facultative discretion when IOP control with IOP-lowering treatment was not considered optimal, or IOP \geq 21 mm Hg with associated vitreous hemorrhage. Exclusion criteria included previous glaucoma surgery or previous PPV. Patients with lower than six-months follow-up were also excluded from final analysis.

Preoperative, intraoperative, and postoperative data were systematically collected from electronic medical records. Preoperative data included demographics, underlying ocular cause for NVG, history of previous PRP, best-measured visual acuity (BMVA) measured in decimal scale and transformed to logMAR notation, IOP measured with Goldmann applanation tonometer, slit lamp examination for lens status, funduscopy (using 90 D lens or 20 D if indirect fundus examination was

performed), gonioscopy for the assessment of anterior segment neovascularization, funduscopy and IOP-lowering treatment register (oral and drops). Intraoperative surgical details included PPV gauge (20/23G), association of lens removal (phacoemulsification or lensectomy), intraoperative PRP or cryotherapy, and anti-VEGF intravitreal treatment (IVT). Postoperative data were collected during routine follow-up visits and included slit lamp examination to assess anterior chamber inflammation gradation (no fibrin, fibrin <75%, fibrin \geq 75%, hyphema), funduscopy, BMVA, IOP, IOP-lowering treatment and other surgical reinterventions performed. When IOP was not properly controlled with IOP-lowering treatment after surgery, diode laser cyclophotocoagulation (DCPC) was indicated. Evaluation of surgical success was considered within IOP control, given that BMVA outcome in these patients is usually poor. Main outcome was set on surgical success and was considered when IOP ranged 6-21 mm Hg with or without IOP-lowering treatment at each of the different follow-up time points^[9-10].

Surgical Technique All patients underwent simultaneous PPV and AGV implantation by two experienced vitreoretinal consultants (Navarro-Angulo MJ and Pelegrín L). The surgical technique was undertaken under peribulbar anesthesia by a mixture of 4 mL of 0.5% bupivacaine and 4 mL of 1% mepivacaine. Bulbar conjunctiva was cut along corneal limbus and hemostasis was achieved by diathermy cauterization. Three sclerotomies were performed in the superotemporal, superonasal, and inferotemporal quadrants, at 3.5 or 4 mm from the mid-limbus depending on whether the eye was pseudophakic or phakic, respectively. Superior and lateral rectus muscles were exposed. A pocket between episcleral and Tenon's capsule was performed by blunt dissection. Valve's tube was irrigated with balanced saline solution to open valve's mechanism and the AGV body was placed between lateral rectus and superior rectus at 10 mm behind the corneal limbus and a 6-0 non-absorbable suture was fastened to the sclera (Figure 1A). Cataract surgery with either lensectomy, using the vitreous cutter through the pars plana for the removal of the crystalline lens, or phacoemulsification, performing cataract surgery with an anterior approach through small incisions and using an ultrasonic probe to emulsify and aspirate the crystalline lens from the eye, was performed in phakic eyes. Lens removal was completed in all phakic eyes with the aim of having a better fundus visualization during the surgery and posterior follow-up. Intraocular lens (IOL) implantation was performed if there was enough capsular support. Otherwise, patients were left in aphakia for secondary IOL implantation. Central and peripheral PPV were completed with posterior segment maneuvers when indicated: endo ocular PRP in eyes with no previous or incomplete PRP, cryotherapy in all cases

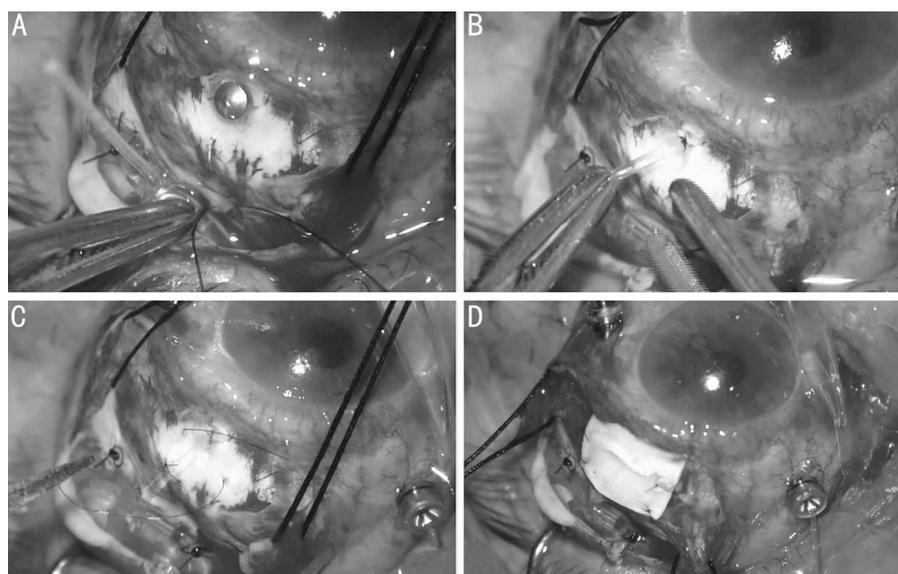


Figure 1 Surgical technique Non-absorbable suture fixed the Ahmed valve body between the lateral rectus and superior rectus muscles (A). Drainage tube valve was inserted through a sclerotomy (B) and fixed with non-absorbable nylon suture (C). Scleral graft is sutured over the tube valve (D).

where PRP was completed and/or anti-VEGF when considered necessary as an adjuvant treatment at surgeon discretion and according to the characteristics of each specific case. AGV drainage tube was then inserted through the upper temporal sclerotomy (Figure 1B), at 3.5 mm from the corneal limbus, into the vitreous cavity. Drainage tube was fixed with non-absorbable 8-0 nylon suture (Figure 1C). A human scleral graft was also sutured with 8-0 nylon over the tube to avoid its future exposure (Figure 1D). Finally, conjunctival flap was sutured with 7 or 8-0 vicryl. Postoperative treatment for all patients consisted of topic dexamethasone (1 mg/mL) and wide spectrum antibiotic drops for a 4-week period. IOP-lowering treatment was added when necessary.

Statistical Analysis Description of quantitative variables was performed using mean, standard deviation (SD) and confidence interval (CI). Absolute frequencies and percentages were used to describe categorical variables. Normality of distribution was assessed by the Shapiro-Wilk test. Changes in IOP throughout follow-up was analyzed by paired *t*-test. Comparison of IOP outcomes between different groups of diagnosis was performed by independent *t*-test for quantitative variables and Chi-square analysis for categorical ones. The cumulative incidence of the IOP control success event at 24mo is presented as a survival curve using the Kaplan-Meier method^[11]. A bilateral type I error of 5% was established. Cox regression analysis was performed to assess baseline characteristics influence on the investigated IOP control success rate. Variables with a significance <0.1 in the univariate analysis were included as independent factors. The statistical package STATA v.15.1 (StataCorp, College Station, Texas, USA) was used for the analysis.

RESULTS

A total of 51 eyes from 50 patients were included. Baseline characteristics are summarized in Table 1. The mean patient age was 69.6y (range 38-91y) and the mean follow-up time was 40.6mo (range 8.7-125 mo). One patient underwent bilateral surgery at different time points. Main indication for surgery was NVG secondary to PDR (39.2%, 20/51), CRVO (37.3%, 19/51), CRAO (11.8%, 6/51), ocular ischemic syndrome (3.9%, 2/51) or others (not specified, 7.8%, 4/51). Approximately half of the eyes (49%) were pseudophakic at baseline, 43.2% were phakic and 7.8% aphakic.

All patients underwent PPV and AGV implantation in a single surgical act, 92.2% with 20-gauge PPV and 7.8% with 23-gauge PPV. Associated interventions at the time of the combined surgery included cataract removal (43.2%), intraoperative PRP and/or cryotherapy (88.2%), and anti-VEGF IVT (33.3%).

Regarding visual outcomes, mean preoperative BMVA (logMAR) was 1.5 ± 0.4 (range 0.4-1.7). Baseline visual acuity in patients with NVG secondary to PDR was significantly better than patients with NVG secondary to CRVO ($P < 0.05$). Mean final postoperative BMVA was 1.4 ± 0.5 (0.05-1.7) with not significantly differences found regarding baseline and final follow-up mean BMVA as per paired analysis ($P = 0.18$).

Considering the main outcome measure, IOP control, preoperative IOP (mean \pm SD) was 42.0 ± 11.2 mm Hg (range 22-68), decreasing to 18.8 ± 9.0 mm Hg (6-46) at postoperative day 1. Mean final IOP change from baseline was 25.0 ± 16.0 mm Hg. Evolution of mean IOP and surgical success rate at each follow-up time is described in Table 2. Mean IOP was 15.5 ± 7.1 mm Hg (4-30) at 12mo and 15.8 ± 9.1 mm Hg (1-41) at 24mo. IOP control

Table 1 Baseline characteristics of the study group mean±SD

Baseline characteristics	Total (n=51)
Age (y)	69.6±13.9
Laterality, n (%)	
Right eye	24 (47.1)
Left eye	27 (52.9)
Etiology of neovascular glaucoma, n (%)	
Proliferative diabetic retinopathy	20 (39.2)
Central retinal vein occlusion	19 (37.3)
Central retinal artery occlusion	6 (11.8)
Ocular ischemic syndrome	2 (3.9)
Other	4 (7.8)
Best-measured visual acuity (logMAR)	1.5±0.4
IOP (mm Hg)	42.0±11.2
Number of IOP-lowering drops	1.5±1.3
Oral acetazolamide	13 (25.5)
Previous PRP	17 (33.3)
Lens status, n (%)	
Phakic	22 (43.2)
Pseudophakic	25 (49)
Aphakic	4 (7.8)
Vitreous hemorrhage, n (%)	18 (35.3)
Follow-up time (mo)	40.6±29.6

IOP: Intraocular pressure; PRP: Panretinal laser photocoagulation; SD: Standard deviation.

Table 2 Evolution of IOP at each follow-up time

Time	Cases	IOP mean±SD (mm Hg)	IOP range (mm Hg)	IOP success ^a (%)
Baseline	51	42.0±11.2	22-68	-
24h	41	18.8±9.0	6-46	68.3
1mo	49	14.9±7.6	2-38	75.5
3mo	46	20.0±9.7	4-46	63.0
6mo	42	17.3±10.6	2-48	59.5
12mo	39	15.5±7.1	4-30	74.4
24mo	28	15.8±9.1	1-41	71.4

IOP: Intraocular pressure; SD: Standard deviation. ^aIOP ranging 6-21 mm Hg with or without IOP-lowering treatment.

success rates are shown in Table 2, reaching at long term 74.4% and 71.4% of success at 12 and 24mo respectively. Cumulative incidence of postoperative IOP success as per Kaplan-Meier survival analysis was 76.0% (95%CI 63.6%-86.7%) at one month of follow-up, reaching 88.3% (95%CI 77.6%-95.4%) at 6mo (Figure 2). Cox regression analysis found no baseline characteristic to independently influence IOP success control rate ($P>0.1$ in all variables univariate analysis). Regarding IOP-lowering measures, baseline mean number of topical treatments was 1.5 and 25.5% of patients were under oral acetazolamide. Six months after surgery, 4.9% of patients were receiving treatment with oral acetazolamide, decreasing to 0 at 12 and 24mo of follow-up. Sub analysis

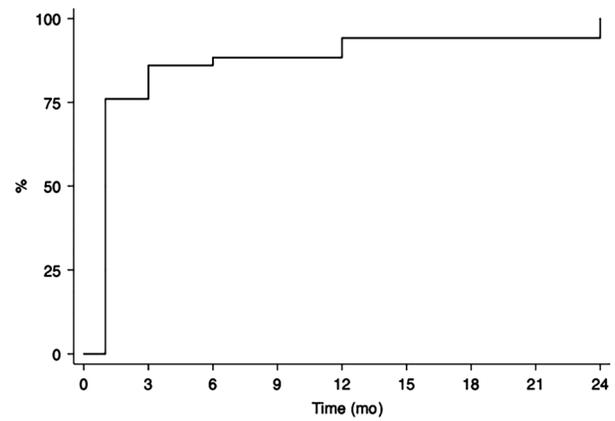


Figure 2 Cumulative incidence of successful IOP control Kaplan-Meier curve of the cumulative probability of successful IOP control.

of postoperative IOP according to NVG cause showed not statistically significantly differences ($P=0.814$) at 12-month follow-up between PDR eyes (mean 14.7±6.8) and CRVO ones (15.4±8.5). No differences in additional postoperative IOP-lowering treatments at the end of follow-up were found according to NVG cause between PDR and CRVO ($P=0.26$); none were needed in 63.2% of PDR and 87.5% CRVO cases, topical agents were used in 15.8% of PDR and 6.2% of CRVO, and DCPC was applied in 21.0% of PDR and 6.2% of CRVO cases. As a whole, DCPC after PPV and AGV implant was performed in 8 eyes (15.7%) for IOP control during follow-up. Final IOP in patients with DCPC was not significantly different compared to other eyes not receiving DCPC (18.3±8.9 vs 14.1±13.1, $P=0.289$). Despite wide range of ages included (38-91y), no statistically significant differences ($P=0.361$) were found in final IOP between the young-age group (<60y) and the older group (≥60y).

Addition of anti-VEGF IVT to PPV and AGV implantation did not report statistically significant differences in mean IOP at any studied time point. All the same, there were not significant differences ($P=0.571$) in final IOP-lowering additional treatment rates (none, drops or DCPC) according to the association of IVT. Regarding simultaneous cataract surgery, it was related with a better final postoperative IOP control ($P<0.05$) in terms of eyes with no additional treatment compared with cases that needed IOP-lowering drops or DCPC. However, no statistically significant differences were found as per cataract surgery association in terms of mean postoperative IOP at day 1 ($P=0.37$), 12mo ($P=0.61$) and 24mo after surgery ($P=0.5$). Anterior chamber inflammation at day 1 after surgery was higher in patients undergoing cataract surgery, even though such difference was not significant ($P>0.05$) at any of the studied time points.

Postoperative complications included vitreous hemorrhage with secondary PPV in 17.6% (9/51) of eyes. No statistically significant difference ($P=0.12$) was found on this rate regarding

the association of intraoperative IVT. PPV for postoperative retinal detachment was undertaken in 3.9% (2/51) of eyes. Three eyes (5.9%) needed an AGV tube revision surgery because of tube obstruction. Main indication for evisceration was painful blind eye and it was only performed in one eye (2.0%; Table 3).

DISCUSSION

Management of NVG still remains challenging even though many surgical options have been proposed^[1,3]. This disease commonly affects patients with extensive vascular comorbidities and elder age so a treatment approach using a single surgical act would be optimal. In this observational study, we present the largest case series to date with 51 cases of NVG treated with PPV and simultaneous AGV implantation, resulting in good and long-term standing postoperative IOP control.

Treatment of NVG requires a combined strategy regarding IOP control and treatment of the underlying cause of retinal ischemia^[12]. PRP still remains as the standard treatment for established NVG influencing its development and evolution and improving long term prognosis^[2,13]. Recently, the association of anti-VEGF agents has also demonstrated to control neovascular disease^[2]. In our series, perioperative treatment with intravitreal anti-VEGF did not correspond with a significant better prognosis in terms of IOP control during follow-up. However, Wang *et al*^[9] reported a significant decrease in IOP in patients with preoperative intravitreal anti-VEGF IVT. At this point, anti-VEGF IVT may be useful as a temporary treatment to reduce the surgical risk of anterior segment bleeding and to increase surgical success after AGV implantation^[13-17]. In cases of severe NVG, development of corneal edema, hyphema and/or vitreous hemorrhage may hamper performing a complete PRP. In these cases, PPV and/or anti-VEGF IVT may be necessary^[8,18-20].

Combination of PPV and AGV implant in a single surgical act in patients with NVG and ocular hypertension despite of maximum medical glaucoma treatment has been reported to be successful in aiming for IOP control^[8,20]. AGV has an intrinsic flow regulation which prevents from excessive aqueous drainage and hypotension, and thus it is commonly used as a primary option for the treatment of NVG with satisfactory results in terms of IOP control and visual acuity^[2,6-7,9,20]. Moreover, when compared with other glaucoma surgeries, Wang *et al*^[9] demonstrated a significantly lower IOP level in the AGV group when combined with PPV than in the trabeculectomy group. In our series, PPV, PRP, cryotherapy (when necessary) and AGV implantation were performed with favorable IOP control results at long term follow-up (Table 2), success rates which are consistent with other publications^[9]. Mean IOP decreased promptly after surgery and was notably

Table 3 Postoperative complications

Postoperative complications	Total (%)
Vitreous hemorrhage	17.6
Retinal detachment	3.9
Tube obstruction	5.9
Evisceration	2.0

maintained at long term (Figure 2). Interestingly, almost three quarters of cases reached a successful IOP control within the first three months after surgery, which has to be considered as a great advantage of this technique. By contrast, we reported a low failure rate with only one patient eviscerated and 15.7% of patients requiring an additional ablative treatment with DCPC which was effective. This procedure, although been an IOP-lowering treatment, did not significantly modify the final IOP result compared to those not having a DCPC, which is consistent with the IOP success results obtained. Moreover, the number of eyes treated with IOP-lowering drops also decreased after surgery. No significant differences were found in IOP outcomes between different diagnosis groups (PDR and CRVO) in our series, suggesting that subjacent NVG cause does not influence the final IOP prognosis. Performing a combined surgery supposes a series of benefits for the patient as well, reducing the number of times in the operating room and consequently reducing possible stress derived from surgery, as well as shortening the treatment waiting time and the results obtention. Taking into account that most of these patients will probably finish with both surgeries (glaucoma and vitreoretinal), seems more efficient to perform both in one time.

Even though visual acuity improvement was not considered as a success criterion for NVG treatment in this study, other reports have found improvement after PPV and AGV implant in patients with NVG and PDR^[20]. Poor visual acuity outcomes in our series might be explained by extended retinal ischemia of such severe NVG cases and optic nerve atrophy secondary to long standing high IOP levels.

In this study, the main cause for secondary PPV was vitreous hemorrhage. Other transient complications such as AGV tube obstruction were solved with surgical valve revision. We reported 2 cases of retinal detachment. Only one eye developed phthisis bulbi requiring evisceration during the study period. Given a severe and bad prognostic disease such as NVG, in general, the reported surgical technique was safe and did not produce additional complications in this scenario.

This study has several limitations to disclose. Due to its retrospective nature, loss of follow-up has to be considered, as well as the lack of standardized exploration times since decisions were taken based on clinical practice. Therefore, selection biases could exist on losing cases with poor

outcomes or by contrast, good ones exiting long term follow up. However, such observational analysis is to be considered as a rightful clinical mirror of real life, even more important when managing a disease with extensive social and economic implications. Another possible limitation of the study is the multiple procedures performed to the study eyes which may, at some point, generate some confusion. However, complicated NVG cases need a personalized treatment and, consequently, is difficult to treat them identically in common clinical practice. Therefore, this observational research provides strong external validity results that would need further prospective and comparative clinical trials to increase evidence on the proposed treatment and to define a standardized protocol for the management of severe cases of NVG.

As a whole, our series have reported the effectivity and safeness of IOP control after simultaneous PPV and AGV implantation in patients with severe NVG. This surgical management directly treats the underlying cause of NVG by performing a complete PRP as well as lowering the IOP by an AGV implant. Such approach is to be positively considered, especially in order to decrease treatment burden. Nevertheless, further studies are needed in this topic with the aim of determining which is the most adequate treatment for NVG in a case-by-case basis.

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