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Efficacy of surgery plus anti-VEGF for the treatment of neovascular glaucoma

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Background: *Secondary neovascular glaucoma (NVG) is a refractory type of glaucoma, with its surgical treatment being a challenge.*

Purpose: *To compare the efficacy of trabeculectomy (TE) with the formation of a filtering channel versus Ex-PRESS mini shunt surgery in surgical plus anti-VEGF treatment for NVG.*

Material and Methods: ***This study included 32 neovascular glaucoma patients (32 eyes) that received surge****ry due to elevated intraocular pressure (IOP > 26 mmHg) not controlled by glaucoma medication. Mean patient age was 65.2 ± 10.1 years. NVG was caused by diabetic mellitus in 22 eyes and central retinal or branch vein occlusion in 10 eyes. The TE group (23 patients) underwent our modified TE procedure (with the formation of a filtering channel), and the Ex-PRESS group (9 patients), an Ex-PRESS mini-shunt surgery. A 0.5-mg intravitreal ranibizumab injection was administered 3-5 days before surgery.*

Results: *Study eyes had regression or resolution of iris neovascularization 3-5 days after intravitreal ranibizumab injection. In the total sample of patients, mean IOP changed from 30.9 ± 7.1 mm Hg before surgery to 17.0 ± 3.6 mm Hg at day 7 and 22.1 ± 2.9 mm Hg at 12 months. In the TE group, mean IOP changed from 31.3 ± 8.4 mm Hg before surgery to 16.7 ± 3.7 mm Hg at day 7 and 21.6 ± 2.5 mm Hg at 12 months. In the Ex-PRESS group, mean IOP changed from 30.0 ± 1.7 mm Hg before surgery to 18.0 ± 3.2 mm Hg at day 7 and 23.3 ± 2.3 mm Hg at 12 months. Mean number of anti-glaucoma medications used reduced from 2.4 ± 0.7 before surgery to 1.3 ± 0.6 at 1 month in the total sample of patients, from 2.4 ± 0.8 before surgery to 1.0 ± 0.6 at 1 month in the TE group, and from 2.6 ± 0.5 before surgery to 1.5 ± 0.7 at 1 month in the Ex-PRESS group.*

Conclusion: *Our modification of TE (with the formation of a filtering channel) combined with preoperative 0.5-mg intravitreal ranibizumab injection is an effective treatment for NVG, and is not less effective than Ex-PRESS mini-shunt surgery with preoperative 0.5-mg intravitreal ranibizumab injection for this purpose.*

Keywords:

secondary neovascular glaucoma, trabeculectomy with the formation of a filtering channel, Ex-PRESS mini-shunt surgery, intravitreal anti-VEGF injection, intraocular pressure

Introduction

Neovascular glaucoma (NVG) is a severe eye disease that develops due to the formation of neovascular membranes in the anterior chamber angle and is accompanied by elevated intraocular pressure (IOP), leading to atrophy of the optic nerve. NVG is slightly more prevalent in men than in women, more commonly affects elderly persons, and may lead to blindness, with visual acuity decreased to light perception or hand motion in as much as 70% of patients. It was observed that 46.16 % of the patients were between 60 and 79 years of age at onset and 30.68 % were over the age of 80 [1].

The most common causes of NVG are diabetic retinopathy, thrombosis of the central retinal vein or its branches and central retinal vein occlusion [1].

NVG is a refractory type of glaucoma, with its surgical treatment being a challenge. The aim of surgical treatment is to create an additional aqueous outflow system. Surgery failure is usually caused by obliteration of the filtering zone due to increased fibroblast activity and neovascular membrane growth in the anterior chamber of the eye [1, 2].

The above reasons warrant the development of new techniques involving surgery plus anti-VEGF treatment.

The purpose of this study was to compare the efficacy of trabeculectomy (TE) with the formation of a filtering channel versus Ex-PRESS mini shunt surgery in surgical plus anti-VEGF treatment for NVG.

Material and Methods

This study included 32 neovascular glaucoma patients (32 eyes) that received surgery due to elevated IOP (> 26 mmHg) not controlled by glaucoma medication. Only one eye from each patient was included in the study, in order to improve the significance of results. Half of the patients were females, and mean age plus or minus standard deviation (SD) was 65.2 ± 10.1 years. NVG was caused by diabetes mellitus in 22 eyes and central retinal or branch vein occlusion in 10 eyes. Patients were divided into two groups. Group 1 (23 patients) underwent our modified trabeculectomy (TE) procedure (with the formation of a filtering channel), and group 2 (9 patients), an Ex-PRESS mini-shunt surgery. Of the 23 eyes of group 1, 18 received a TE alone, and five, a TE combined with phacoemulsification (phaco). Of the nine eyes of group 2, seven received an Ex-PRESS mini-shunt surgery alone, and two, an Ex-PRESS mini-shunt surgery combined with phaco.

Patients with a history of glaucoma surgery or laser cyclocoagulation were excluded.

Preoperatively, patients underwent visual acuity assessment, Maklakoff tonometry, anterior segment and fundus examination with a Volk Digital Wide Field® Slit Lamp Lens, and gonioscopy with a three-mirror Goldmann lens (Volk Optical Inc, Mentor, OH). Anterior segment biomicroscopy found neovascularization of the pupillary margin of the iris in all patients. There was gonioscopy evidence of a neovascular membrane in the anterior chamber angle in 24 eyes, and goniosynechia in 8 eyes. The number of glaucoma medications used before and after surgery was noted.

Patients were followed up at days 1 and 7 and months 1, 3, 6, 9 and 12, and more frequently, if required. The minimal follow-up period was 12 months.

Efficacy measures were the number and type of complications and Maklakov IOP < 26 mm Hg. Complete surgical success was defined as Maklakov IOP < 26 mm Hg with no additional anti-glaucoma medication and partial surgical success was defined as Maklakov IOP < 26 mm Hg with additional anti-glaucoma medications. A postoperative reduction in the number of anti-glaucoma medications and a requirement for resurgery (if any) were also taken into account.

All patients involved in clinical studies were examined and followed at the affiliated clinical sites of the Department of Ophthalmology, School of Post-Graduate Education (Eye Microsurgery Department, Municipal Clinical Hospital No. 8 and Oculus medical center at the city of Lviv). Informed consent for examination, surgical treatment and participation in the study was obtained from all patients. The study complied with the Declaration of Helsinki and was approved by the Ethics Committee of the Danylo Halytsky Lviv National Medical University (the protocol was issued on October 26, 2020).

The study was part of the research activities (register No. 0118U000103) of the Department of Ophthalmology, School of Post-Graduate Education, Danylo Halytsky Lviv National Medical University.

A 0.5-mg intravitreal ranibizumab injection was administered 3-5 days before surgery. An intravitreal injection was combined with paracentesis of the anterior chamber if the eye developed an IOP exceeding 26 mmHg.

Twelve patients with diabetes mellitus underwent panretinal photocoagulation of the retina two weeks to three months after surgery.

We have developed a modified trabeculectomy procedure (with the formation of a filtering channel) that involves classic trabeculectomy combined with deep sclerectomy, with the top of the deep sclerectomy site located outside the episcleral flap (Fig. 1) to improve the filtering effect of glaucoma surgery.

Operation technique for trabeculectomy with the formation of a filtering channel

After epibulbar anesthesia with a solution of Alcaine 0.5% and parabalbar anesthesia with 2 ml of a solution of Lidocain 2%, an 8-0 traction suture is placed on the cornea, and some 6 mm of conjunctiva is excised from the limbus. Thermocoagulation of the episcleral vessels is performed. A superficial scleral flap, trapezoid in shape, and approximately one-third scleral thickness, 5 mm at the limbus and 4 mm at the apex is outlined and dissected. Mytomycin C at a concentration of 2.5 mg/ml is applied for 4 minutes. The conjunctival sac is washed with Ringer's solution. An anterior chamber paracentesis is made with

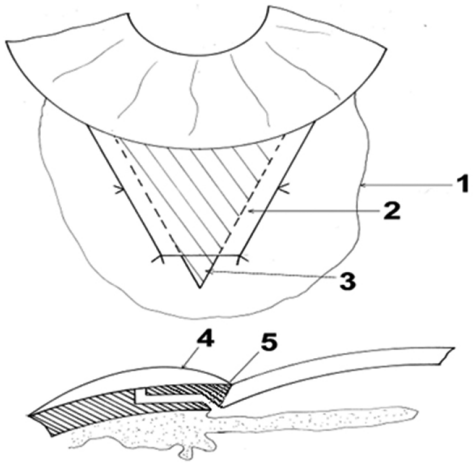

Fig. 1. Scheme of trabeculectomy with the formation of a filtering channel. Notes. 1, margin of conjunctival excision; 2, episcleral flap; 3, site of deep sclerectomy and outlet of filtering channel; 4, filtering bleb; 5, filtering channel

a 1.2-mm blade. One-third thickness deep sclerectomy is performed subsclerally within a 4 x 5 mm triangle in combination with trabeculectomy. Basal iridectomy is performed, and the sclera is closed with four 10-0 nylon interrupted sutures to keep the scleral flap stretched. The anterior chamber is one-third filled with viscoelastic. Finally, the conjunctiva is secured to the limbus with four interrupted sutures.

Ex-PRESS® mini shunt surgery was performed classically.

Phacoemulsification was followed by glaucoma surgery during a combination procedure.

Postoperative topical medications included a combination of a wide-spectrum antibiotic and dexamethasone five times daily for 10 days followed by dexamethasone only three times daily for 20 days. Glaucoma medications were withdrawn, changed or reduced not earlier than day 7 after surgery. More or less intensive massage of the globe through the lids was used over 1-3 months to facilitate effective bleb formation.

MS Excel software was used for statistical analysis. The Student t test was used for paired samples. Data are presented as mean plus or minus standard deviation (SD). The level of significance $p \leq 0.05$ was assumed. The Kaplan-Meier curve was used to estimate the IOP-lowering effect of surgery.

Results

Study eyes had regression or resolution of iris neovascularization 3-5 days after intravitreal ranibizumab injection.

The only perioperative complication was mild anterior chamber hemorrhage in 3 of the 23 eyes that received TE.

Postoperative hypotony and shallow anterior chamber due to excessive filtration were noted in 3 of the 23 eyes that received TE. Hyphema of 3 mm or less was observed in 5 of 32 eyes (15.6%), particularly, 4 of the 23 eyes that received TE, and 1 of the 9 eyes that received Ex-PRESS® mini shunt surgery. Signs of postoperative iridocyclitis were noted in 6 eyes in the TE group and 2 eyes in the Ex-PRESS group. Anterior chamber depth normalized and iridocyclitis relieved within a week after surgery.

Table 1 shows mean visual acuity values in groups before surgery and at various time points after surgery. Although visual acuity somewhat improved postoperatively, no significant difference between preoperative and postoperative visual acuity was observed for either group.

Changes in IOP after surgery are presented in Table 2 and Fig. 2. There was a statistically significant reduction in IOP both after trabeculectomy with the formation of a filtering channel and after Ex-PRESS® mini shunt surgery ($p = 0.0000$). That is, there was a similarity in the pattern of changes in visual acuity after surgery for the latter group and for the former group.

No significant difference ($p > 0.05$) in IOP was observed between the two groups at various postoperative time points. There was a statistically significant difference between the IOP at day 7 and the IOP at month 12 ($p = 0.0000$), with an increase from 16.7 ± 3.7 mm Hg to 21.6 ± 2.5 mm Hg for the TE group and from 18.8 ± 3.2 mm Hg to 23.3 ± 2.3 mm Hg for the Ex-PRESS group. However, after month 6, the IOP in the former group increased only slightly, whereas the IOP in the latter group increased somewhat more substantially.

We found no significant difference in the hypotensive effect between the patients that received only glaucoma surgery and those that received combined glaucoma and phacoemulsification surgery. Thus, before surgery and at months 1, 3, 6, 9 and 12, IOP was 29.9 ± 7.7 mm Hg 18.3 ± 5.2 mm Hg; 20.1± 5.2 mm Hg; 21.7 ± 4.8 mm Hg; 20.4 ± 2.7 mm Hg and 19.8 ± 2.8 mm Hg, respectively, for the eyes that received TE only, versus 36 ± 9.7 mm Hg, 17.2 ± 4.0 mm Hg; 19.8 ± 1.1 mm Hg; 21.4 ± 0.0 mm Hg; 21 ± 1.6 mm Hg and 19.6 ± 1.1 mm Hg, for the eyes that received TE plus phaco, with no significant difference ($p > 0.05$) between groups for all time points. In a similar way, before surgery and at months 1, 3, 6, 9 and 12, IOP was 30 ± 1.9 mm Hg; 20.9 ± 3.8 mm Hg; 18.7± 1.7 mm Hg; 20.3 ± 2.3 mm Hg; 20.4 ± 1.9 mm Hg and 21.9 ± 2.0 mm Hg, respectively, for the eyes that received Ex-PRESS mini shunt surgery only, versus 30 ± 1.4 mm Hg; 21 ± 1.4 mm Hg; 19 ± 1.4 mm Hg; 20 ± 1.4 mm Hg; 22 ± 1.4

Table 1. Mean plus or minus standard deviation values of visual acuity (LogMar) in study groups before and after surgery

Groups	Baseline and time points					
	Baseline	1 mnth	3 mnths	6 mnths	9 mnths	12 mnths
Total study sample, n = 32	0.98 ± 0.45	1.01 ± 0.43	0.91 ± 0.47	0.87 ± 0.47	0.87 ± 0.46	0.86 ± 0.45
P value		= 0.79	= 0.55	= 0.34	= 0.34	= 0.29
Group 1 (TE), n = 23	0.97 ± 0.46	1.06 ± 0.48	0.93 ± 0.52	0.86 ± 0.53	0.88 ± 0.49	0.88 ± 0.47
P value		= 0.52	= 0.78	= 0.46	= 0.52	= 0.52
Group 2 (Ex-PRESS), n = 9	1.02 ± 0.46	0.90 ± 0.27	0.88 ± 0.29	0.90 ± 0.30	0.83 ± 0.40	0.82 ± 0.41
P value		= 0.51	= 0.45	= 0.52	= 0.36	= 0.34

Note: p, significance of difference between baseline and postoperative time points; n, number of patients

Table 2. Mean plus or minus standard deviation values of intraocular pressure (IOP) in mm Hg in study groups before and after surgery

Groups	Baseline and time points						
	Baseline	Day 7	1 mnth	3 mnths	6 mnths	9 mnths	12 mnths
Total study sample, n = 32	30.9 ± 7.1	17.0 ± 3.6	18.8 ± 4.7	19.8 ± 4.0	20.7 ± 3.8	21.5 ± 2.8	22.1 ± 2.9
p		= 0.0000	= 0.0000	= 0.0000	= 0.0000	= 0.0000	= 0.0000
p*		p7-1 = 0.09	p1-3 = 0.36	p3-6 = 0.36	p6-9 = 0.34	p9-12 = 0.40	p7-12 = 0.0000
Group 1 (TE), n = 23	31.3 ± 8.4	16.7 ± 3.7	18.0 ± 4.9	20.0 ± 4.6	20.8 ± 4.2	21.3 ± 2.5	21.6 ± 2.5
p		= 0.0000	= 0.0000	= 0.0000	= 0.0000	= 0.0000	= 0.0000
p*		p7-1 = 0.32	p1-3 = 0.16	p3-6 = 0.54	p6-9 = 0.62	p9-12 = 0.69	p7-12 = 0.0000
Group 2 (Ex-PRESS), n = 9	30.0±1.7	18.0 ± 3.2	20.9 ± 3.3	19.1 ± 1.7	20.4 ± 2.0	21.9 ± 3.5	23.3 ± 2.3
p		= 0.0000	= 0.0000	= 0.0000	= 0.0000	= 0.0000	= 0.0000
p*		p7-1 = 0.07	p1-3 = 0.17	p3-6 = 0.16	p6-9 = 0.28	p9-12 = 0.33	p7-12 = 0.0000

Note: p, significance of difference between baseline and postoperative time points; p*, significance of difference between postoperative time points; n, number of patients

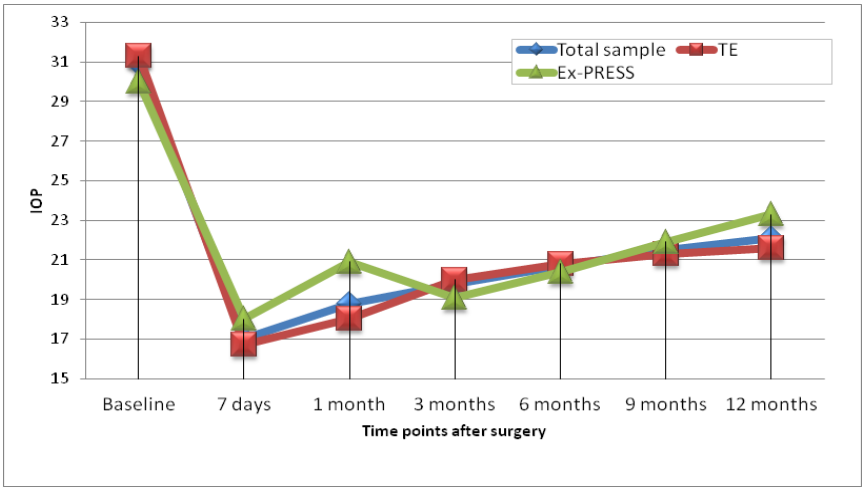

Fig. 2. Intraocular pressure (IOP) measured in mm Hg in study groups before and after surgery. Note. The ordinate displays the IOP level in mm Hg and the abscess, baseline and time points after surgery.

mm Hg and 21 ± 1.4 mm Hg, respectively, for the eyes that received Ex-PRESS mini shunt surgery plus phaco, with no significant difference between groups for all time points.

In the total sample, the TE group and the Ex-PRESS group, sum of complete and partial success rates gave a total success rate of 84%, 83.8%, and 84.6%, respectively, at month 6, and 76.4%, 78.2% and 71.7%, respectively, at month 12.

In all patients, there was a reduction in the number of anti-glaucoma medications after surgery, and this difference was statistically significant ($p < 0.01$).

Twenty-seven eyes had one to three repeat anti-VEGF injections spaced a month apart due to iris neovascularization or neovascular epiretinal membranes in the presence of diabetes.

Twelve patients with diabetes mellitus received panretinal photocoagulation of the retina two weeks to three months after surgery.

Three of the 23 eyes (13.0%) in the TE group and one of the nine eyes (11.1%) in the Ex-PRESS group underwent drain restoration one to three months after surgery. Two of the 23 eyes (8.7%) in the TE group and two of the nine eyes (22.2%) in the Ex-PRESS group underwent repeat glaucoma surgery at more than 6 months after their initial surgery.

Discussion

NVG is a refractory form of glaucoma; patients with NVG have a poor prognosis due to recurrent neovascularization. We found that intravitreal ranibizumab injection clearly reduced the number of newly formed

Table 3. Mean plus or minus standard deviation values of numbers of hypotensive medications in study groups before and after surgery

Groups	Baseline and time points					
	Baseline	1 mnth	3 mnths	6 mnths	9 mnths	12 mnths
Total study sample, n = 32	2.4 ± 0.7	1.3 ± 0.6	0.3 ± 0.5	1.2 ± 0.4	1.2 ± 0.4	1.3 ± 0.5
P value		= 0.0000	= 0.0000	= 0.0000	= 0.0000	= 0.0000
Group 1 (TE), n = 23	2.4 ± 0.8	1.0	0.3 ± 0.4	1.2 ± 0.4	1.2 ± 0.4	1.2 ± 0.4
P value		= 0.0000	= 0.0000	= 0.0000	= 0.0000	= 0.0000
Group 2 (Ex-PRESS), n = 9	2.6 ± 0.5	1.5 ± 0.7	1.3 ± 0.5	1.3 ± 0.6	1.3 ± 0.6	1.7 ± 0.6
P value		= 0.0015	= 0.0000	= 0.0001	= 0.0001	= 0.0032

Note: p, significance of difference between baseline and postoperative time points; n, number of patients

vessels in the iris of NVG eyes. Because neovascularization is a major cause of NVG, intraocular anti-VRGF injection increases the likelihood of success of subsequent glaucoma surgery.

Preoperative and postoperative anti-VEGF therapy has been reported to be a beneficial adjunct to surgery for neovascular glaucoma, with improvements primarily in rates of perioperative and postoperative hemorrhagic complications [3, 4]. In the current study, the rate of hemorrhagic complications (a hyphema of 3 mm or less) was as low as 15.6%; patients with these complications did not require additional surgical treatment, and this did not result in irreversible vision loss.

It is important to apply anti-VEGF medications postoperatively to prevent the formation of neovascular membranes at the site of surgical intervention, because glaucoma surgery per se does not reduce production of angiogenic factors [4-6]. Others [7, 8], however, believe that the hypotensive effect of glaucoma surgery does reduce production of angiogenic factors. The optimal timing and the optimal route of administration for anti-VEGF drugs are, however, still uncertain [4, 9].

The results obtained by us demonstrate a high efficacy of the comprehensive approach to the surgical management of NVG, with the perioperative use of antimetabolites (mitomycin C) reducing the postoperative fibroblast activity in the tissue and increasing the duration of the hypotensive effect. In our total study sample, sum of complete and partial success rates gave a total success rate of 76.4% at month 12, whereas Rodrigues and colleagues [1] reported a total success rate of 54% at month 18.

The importance of our work lies in the fact that we have developed a modified trabeculectomy procedure (with the formation of a filtering channel); this substantially improved the efficacy of surgery due to more pronounced filtration of the anterior chamber aqueous humor which is likely to prevent drain occlusion, thus leading to improved hypotensive effect of surgery for NVG. Thus, in the TE group and the Ex-PRESS group, sum of complete and partial success rates gave a total success rate of 78.2% and 71.7%, respectively, at month 12. This is in some agreement with the results of Kawabata and colleagues (2019) [10], who found that, during a 1-year follow up, Ex-PRESS mini shunt surgery was a less effective treatment for NVG compared with trabeculectomy.

Including both patients receiving glaucoma surgery alone and those receiving glaucoma surgery combined with phaco in one group have certain disadvantages. Some studies pointed to an additional hypotensive effect of phaco on glaucoma surgery. This opinion, however, has not been finally confirmed. Particularly, there is no data on the long-term hypotensive effect of phacoemulsification in open angle glaucoma. Arimura and colleagues (2021) [11] compared 5-year outcomes between trabeculectomy combined with phacoemulsification and trabeculectomy followed by phacoemulsification. The main outcome was the cumulative probability of success based on IOP within 5 years. No significant difference was found in the cumulative probability of success as the main outcome.

To the best of our knowledge, there is no data on the hypotensive effect of phacoemulsification in NVG. Several studies compared the hypotensive effect of Ex-PRESS mini shunt surgery with and without phaco. AlSemari and colleagues (2021) [12] assessed the efficacy of ExPress mini shunt in a heterogenous group of glaucoma patients, with a total of 35 eyes of 31 patients involved, including 6 patients (37.1%) with NVG. They also compared a group of combined ExPress mini-shunt implant with cataract surgery (14 eyes; 40%) versus ExPress mini-shunt implant alone, but found no additional hypotensive effect of phaco.

In studies performing surgical procedures for glaucoma both involving and non-involving phaco, different surgical procedures were compared in terms of efficacy without taking into account whether they involved phaco. Moisseiev and colleagues (2015) [13] compared the efficacy and safety between standard trabeculectomy and the ex-PRESS shunt implantation in a retrospective review of 100 eyes of 100 patients with primary open-angle glaucoma (POAG), pseudoexfoliative glaucoma, uveitic glaucoma, chronic angle-closure glaucoma, or NVG. Surgery was combined with phaco in 24 (39.3%) of the eyes that underwent trabeculectomy and 15 (39.3%) of

those that underwent Ex-PRESS shunt implantation. Those authors, however, did not assess the efficacy of standalone glaucoma surgery versus glaucoma surgery combined with phaco. Mariotti and colleagues (2014) [14, 15] reported on the long-term outcomes with the EX-PRESS shunt implanted under a scleral flap in 248 eyes of 211 consecutive patients with various types of glaucoma. Of these eyes, 112 (45%) underwent a combined operation of cataract extraction with EX-PRESS implantation. Mariotti and colleagues, however, also did not assess the efficacy of standalone glaucoma surgery versus glaucoma surgery combined with phaco.

Therefore, in the opinion of numerous researchers, TE or Ex-PRESS mini shunt surgery combined with phaco has no additional hypotensive effect on NVG compared to TE or Ex-PRESS mini shunt surgery alone. These findings are in agreement with ours.

Conclusion

First, our modification of TE (with the formation of a filtering channel) combined with preoperative 0.5-mg intravitreal ranibizumab injection is an effective treatment for NVG, and is not less effective than Ex-PRESS mini-shunt surgery with preoperative 0.5-mg intravitreal ranibizumab injection for this purpose.

Second, glaucoma filtration surgery (TE or Ex-PRESS mini-shunt surgery) combined with phaco for NVG provides no statistically significant additional hypotensive effect compared to glaucoma filtration surgery alone.

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Disclosures

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The study was conducted with human participants. This study was approved by the local bioethics committee. All patients gave informed consent to participate in the study. The study was conducted in accordance with the Declaration of Helsinki. This study did not include animal experiments.