Comparison of Mitomycin C-Augmented Trabeculectomy and Mitomycin C-Augmented Ex-Press Miniature Device in the Management of Neovascular Glaucoma

Neovasküler Glokom Tedavisinde, Mitomisin C'li Trabekülektomi ve Ex-Press Mini İmplant Cerrahisinin Karşılaştırılması

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ABSTRACT

Purpose: Our aim was to compare the outcomes of initial trabeculectomy and Ex-Press miniature implant with mitomycin C (mit C) and preoperative intravitreal bevacizumab injection in the management of neovascular glaucoma (NVG).

Material and Methods: This retrospective study consisted of 11 eyes with NVG those underwent initial trabeculectomy with mit C and 9 eyes with NVG those underwent Ex-Press miniature implant with mit C. Preoperatively panretinal photocoagulation had been performed and intravitreal bevacizumab (1.25 mg/0.05 mL) had been injected 10 days before the surgery for all eyes. The intraocular pressure (IOP) and the number of anti-glaucomatous medications were compared at the first week, first month, third month, sixth month and first year after the surgery. Independent t, Kolmogorov-Smirnov and chi square tests were used for statistical analysis.

Results: In trabeculectomy group preoperative IOP was 39.4±3.6 mmHg and postoperative values were 10.4±2.3 mmHg (1st week), 11.4±1.9 mmHg (1st month), 15.2±2.04 mmHg (3rd month), 16.7±2.6 mmHg (6th month) and 18.9±3.6 mmHg (1st year). In Ex-Press group preoperative IOP was 38.4±5.8 mmHg and postoperative values were 10.3±2.1 mmHg (1st week), 11.5±2.3 mmHg (1st month), 15.4±1.8 mmHg (3rd month), 18.3±2.9 mmHg (6th month) and 18.2±3.9 mmHg (1st year). In both groups IOP and the number of medications reduced significantly postoperatively. There were no significant differences between the preoperative and the postoperative IOP values of the two groups.

Conclusion: Both mit C-augmented trabeculectomy and mit C-augmented Ex-Press implant provided similar reduction of IOP in cases with NVG in 1 year follow-up period.

Key Words: Neovascular glaucoma, trabeculectomy, mitomycin C, Ex-Press miniature implant.

ÖZ

Amaç: Neovasküler glokom (NVG) tedavisinde, preoperatif intravitreal bevacizumab enjeksiyonu sonrasında primer cerrahi olarak yapılan, mitomisin C'li (mit C) trabekülektomi ve Ex-Press mini implant cerrahisinin karşılaştırılması amaçlandı.

Gereç ve Yöntem: Retrospektif karşılaştırmalı çalışmamızda, primer cerrahi olarak mit C'li trabekülektomi yapılan 11 göz ve Ex-Press mini implant cerrahisi uygulanan 9 göz karşılaştırıldı. Tüm gözlere panretinal fotokuagulasyon ve cerrahiden 10 gün önce intravitreal bevacizumab (1.25 mg/0.05 mL) enjeksiyonu yapıldı. Cerrahi öncesi ve cerrahi sonrası 1. hafta, 1. ay, 3. ay, 6. ay ve 1. yıl göz içi basıncı (GİB) ve kullanılan antiglokomatöz ilaç sayısı kıyaslandı. İstatistiksel analizlerde bağımsız t, Kolmogorov-Smirnov ve ki-kare testleri kullanıldı.

Bulgular: Trabekülektomi gurubunda cerrahi öncesi GİB 39.4±3.6 mmHg iken, cerrahi sonrası 10.4±2.3 mmHg (1. hafta), 11.4±1.9 mmHg (1. ay), 15.2±2.04 mmHg (3. ay), 16.7±2.6 mmHg (6. ay) ve 18.9±3.6 mmHg (1. yıl) düzeyindeydi. Ex-Press gurubunda cerrahi öncesi GİB 38.4±5.8 mmHg iken, cerrahi sonrası 10.3±2.1 mmHg (1. hafta), 11.5±2.3 mmHg (1. ay), 15.4±1.8 mmHg (3. ay), 18.3±2.9 mmHg (6. ay) ve 18.2±3.9 mmHg (1. yıl) düzeyindeydi. Her iki grupta da cerrahi sonrası GİB ve kullanılan anti-glokomatöz ilaç sayısı anlamlı ölçüde azaldı. Cerrahi öncesi ve sonrası değerler açısından gruplar arasında farklılık izlenmedi.

Sonuç: NVG' da 1 yıllık takiplerde, gerek mit C'li trabekülektominin, gerekse mit C'li Ex-Press implantın, GİB'nı düşürmede benzer şekilde etkili olduğu sonucuna gidildi.

Anahtar Kelimeler: Neovasküler glokom, trabekülektomi, mitomisin C, Ex-Press mini implant.

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INTRODUCTION

Neovascular glaucoma (NVG) is the one of the refractory glaucoma type which is strongly associated with a poor visual prognosis and intractable ocular pain. [1-3] The main cause of the disease is the posterior segment ischemia mainly caused by retinal vascular diseases like proliferative diabetic retinopathy (PDR) and central retinal vein occlusion (CRVO). [1-3] Pathologic new blood vessels cause synechial angle-closure glaucoma by the obstruction of humor aqueous (HA) drainage related with the development of fibrovascular membrane on iris and iridocorneal angle.[1-3] The angiogenic factors such as vascular endothelial growth factor (VEGF) are known to be key point for the pathogenesis of the disease.[4-6]

Medical antiglaucoma therapy is generally insufficient to control high intraocular pressure (IOP) and surgical procedures with mitomycin C (MMC) or fluorouracil (5-FU) are frequently performed. [7-15] Also, preoperative panretinal laser photocoagulation (PRP) and anti-VEGF agents increase surgical success by inhibiting neovascularization.[7-15]

Ex-Press miniature glaucoma device (Alcon Laboratories, Fort Worth, Texas, USA) is a kind of minimally invasive glaucoma surgery (MIGS) in which aqueous humor (AH) is drained from anterior chamber into the bleb area without sclerostomy and iridectomy and is alternative to trabeculectomy. [16] The aim of this study was to compare the outcomes of initial trabeculectomy with mit C and preoperative intravitreal bevacizumab injection and Ex-Press miniature glaucoma device with mit C and preoperative intravitreal bevacizumab injection, in the surgical management of NVG.

MATERIAL AND METHODS

Eleven eyes of 11 cases with NVG who underwent initial trabeculectomy with mit C and 9 eyes of 9 cases with NVG who underwent Ex-Press miniature glaucoma device with mit C between January 2015 and May 2016 at at Ulucanlar Eye Research Hospital were retrospectively enrolled in this study. Our study was approved by ethics committee of Ankara Numune Training Hospital.

The demographic and clinical characteristics were taken from the medical records of the patients. All the patients had undergone detailed ophthalmologic examinations, including best-corrected visual acuities (BCVA) with Snellen charts, anterior and posterior segment examinations, gonioscopy with Goldmann three-mirror lens and IOP measurements with Goldmann applanation tonometer. Visual field examinations with Humphrey automated perimeter had been done in the cases with visual acuities better than 20/200. Preoperative PRP of the entire peripheral retina of the eyes had been completed by retina specialists by using argon laser in multiple sessions.

The eyes with NVG were included to this study. The presence of rubeozis on iris and/or iridocorneal angle, ectropion uvea, IOP ≥ 22 mmHg with or without antiglaucoma treatment, optic nerve head changes like cup to disc ratio (c/d) ≥0.3, localized neuro-retinal rim defects, peripapillary choroidal atrophy, total optic atrophy or splitter hemorrhage revealed NVG. The eyes with cataract formation and had undergone combined cataract and glaucoma surgeries were not included. Exclusion criteria had also included history of malignancy, stroke or coronary artery disease, aphakia, history of ocular trauma or surgery other than cataract surgery.

Intravitreal bevacizumab (1.25 mg/0.05 mL) had been injected 10 days before the surgery for all eyes. All the eyes had been operated by the same surgeon. In trabeculectomy group, after placement of a merocell sponge that had been previously soaked in mit MMC C (0.2 mg/ml) underneath the fornix-based conjunctival flap for 3 minutes, a 4x4 mm scleral flap and 1.5 mm x 1.5 mm scleral block removal were performed under subtenon anesthesia. In Ex-Press group, after placement of a merocell sponge that had been previously soaked in mit MMC C (0.2 mg/ml) underneath the limbus-based conjunctival flap for 3 minutes, Ex-Press had been implanted under 4x4 mm partial-thickness scleral flap under subtenon anesthesia. The eyes had received topical prednisolone acetate 1% (5x1/day for 8 weeks), topical moxifloxacin (4x1/day for 4 weeks) and cyclopentolate HCL 1% twice daily for 1 month postoperatively.

The IOP and the number of anti-glaucomatous medications were compared at baseline, at the first week, first month, third month, sixth month and first year after the surgery. Independent t, paired-t, Kolmogorov-Smirnov and chi square tests were used for statistical analysis.

RESULTS

The mean age of 6 male (54.5%) and 5 female (45.5%) cases in trabeculectomy group was 66.9±5.5 (range, 57 to 74 years) and the mean age of 5 male (55.5%) and 4 female (44.5%) cases in Ex-Press group was 66.9±5.5 (range, 57 to 74 years). There were no significant differences in age and sex of the groups (p=0.32, p=0.66 respectively). Neovascular glaucoma was secondary to PDR in 15 cases (75%) and CRVO in 5 cases (25%) (table 1).

The preoperative BCVA values had been 20/80 to 20/100 in 4 eyes (36.3%), 20/200 to 20/400 in 4 eyes (36.3%), counting fingers in 2 eyes (18.2%), hand motion in 1 eyes (9.2%) in trabeculectomy group and 20/80 to 20/100 in 3 eyes (33.3%), 20/200 to 20/400 in 2 eyes (22.2%) and counting fingers in 4 eyes (44.5%) in Ex-Press group.

Table 1. *The demographic characteristics of the cases.*

	Trabeculectomy group	Ex-Press group	P value
Sex: (n/%)	6 male (54.5%) 5 female (45.5%)	5 male (55.5%) 4 female (44.5%)	p=0.66
Mean age (range)	66.9±5.5 (57-74 years)	66.9±5.5 (57-76 years)	p=0.32
Etiology of NVG	PDR: 9 eyes CRVO: 2 eyes	PDR: 6 eyes CRVO: 3 eyes	

NVG: Neovascular glaucoma, **PDR:** Proliferative diabetic retinopathy, **CRVO:** Central retinal venous occlusion

Before surgery, IOP was not adequately controlled despite maximum medical therapy. The mean preoperative IOP was 39.4±3.6 mmHg (range, 34 to 46 mmHg) under a mean number of 3.8±0.4 (range, 3 to 4) anti-glaucomatous agents in trabeculectomy group and 38.4±5.8 mmHg (range, 32 to 49 mmHg) under a mean number of 3.8 ± 0.4 (range, 3 to 4) anti-glaucomatous agents in Ex-Press group (table 2, figure 1). There were no significant differences between preoperative IOP and number of medications of the 2 groups (p=0.66, p=0.92 respectively). The IOP values and the number of medications are summarized in table 2. In both groups the IOP and the number of medications decreased significantly within the first year after the surgery. But no significant differences were observed in postoperative IOP values and the number of the medications between the two groups (table 2).

In both groups there were no significant differences between the IOP at the postoperative 1st week and month. In trabeculectomy group IOP raised significantly after 1st month until 1st year. In Ex-Press group IOP raised significantly after 1st month until 6th month, but there was no significant difference in IOP at the 6th month and 1st year (table 3).

Hyphema had occurred in 2 eyes in trabeculectomy and in 1 eye in Ex-Press group within the few days after the surgery but had resolved spontaneously without any surgical procedures. Needling with 5-FU injection had been performed for 3 eyes in trabeculectomy and 3 eyes in Ex-Press groups within the first postoperative month.

DISCUSSION

Especially after the development of secondary synechial angle-closure glaucoma, the treatment of NVG is difficult and the prognosis is disappointing. [1-3] The VEGF family is known to play the most important role in the angiogenesis process of the pathogenesis of the disease. [4-17] Chen et al [4] detected high concentrations of VEGF family, with the exception of VEGF-B in AH of NVG cases and mentioned a positive correlation between VEGF-A and placenta growth factor (PlGF). So treatment with anti-VEGF agents should be one of the key points for the therapy of NVG like PRP. Here in this study, we performed intravitreal bevacizumab injection for all of our cases before surgical treatment of NVG. We also completed PRP in order to improve surgical success. Olmos et al. [18] investigated 163 eyes of 151 cases

Table 2. *The preoperative and postoperative intraocular pressure values and the number of anti-glaucoma medications.*

	Trabeculectomy	Ex-Press	p value
IOP baseline: Number of medication:	39.4±3.6 mmHg (3.8±0.4)	38.4±5.8 mmHg (3.8±0.4)	p=0.066 p=0.625
IOP postop. 1st week: Number of medication:	10.4±2.3 mmHg (no medication)	10.3±2.1 mmHg (no medication)	p=0.067
IOP postop. 1st month: Number of medication:	11.4±1.9 mmHg (no medication)	11.5±2.2 mmHg (no medication)	p=0.91
IOP postop. 3rd month Number of medication:	15.1±2.0 mmHg (0.4±0.5)	15.4±1.8 mmHg (0.5±0.5)	p=0.77 p=0.342
IOP postop. 6th month Number of medication:	16.7±2.6 mmHg (0.8±0.7)	18.3±2.9 mmHg (1.2±0.8)	p=0.21 p=0.648
IOP postop. 1st year: Number of medication:	18.90 ± 3.61 (2.2±0.9)	18.2 ± 3.9 (1.6±1.0)	p=0.68 p=0.155

IOP: Intraocular pressure **postop:** Postoperative

Table 3. *The differences in intraocular pressure within the first postoperative year between the groups.*

Ex-Press: IOP baseline- IOP 3rd month	p<0.001*
IOP baseline- IOP 6th month	p<0.001*
IOP 1st month- IOP 3rd month	p=0.003*
IOP 3rd month- IOP 6th month	p=0.013*
IOP 6th month- IOP 1st year	p=0.91
Trabeculectomy: IOP baseline- IOP 3rd month	p<0.001*
IOP baseline- IOP 6th month	p<0.001*
IOP 1st month- IOP 3rd month	p=0.001*
IOP 3rd month- IOP 6th month	p=0.012*
IOP 6th month- IOP 1st year	p=0.021*

IOP: Intraocular pressure *:Statistically significant

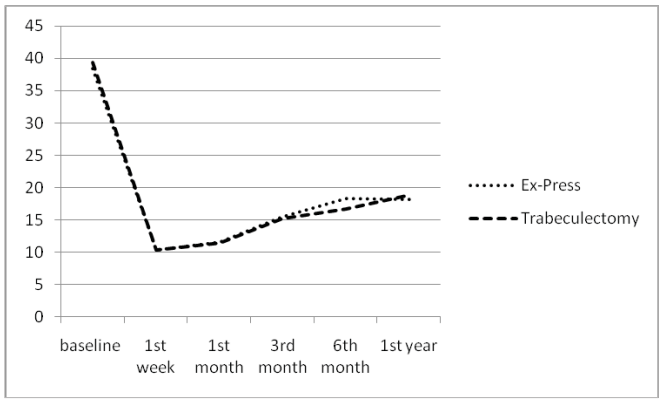

Figure 1. *The postoperative IOP values of both groups.*

IOP: Intraocular pressure

with NVG those had or had not received intravitreal bevacizumab injection in their study. They observed bevacizumab had delayed the need for glaucoma surgery but mentioned that PRP had been the most important factor for the success of the treatment and control IOP eliminating the stimulus for neovascularization. Treatment of the primary disease by PRP causes improvement of retinal ischemia.

Generally the success rate of trabeculectomy in the treatment of NVG in spite of complete preoperative PRP and the use of antifibrotic agents is not good enough. Takihara et al. [19] found a 51.7% of success rate of trabeculectomy with mit C at 5 years and mentioned younger age, previous vitrectomy, having a fellow eye with NVG and persistent proliferative membrane and/or retinal detachment after vitrectomy as risk factors for poor prognosis. Anti-VEGF agents are well-known to improve surgical success of trabeculectomy.[7-9] Kobayashi et al. [7] evaluated the long-term outcomes of trabeculectomy with mit C and preoperative intravitreal bevacizumab injection and determined the cumulative surgical success rate as 83.3% at 1 year and 83.3% at 3 years. They stated that anti-VEGF agents might have been effective in improving long-term surgical success. Elmekawey et al. [8] used different agent and different way of injection in their study. They used intracameral ranibizumab in trabeculectomy with mit C in NVG and achieved 93.3% of complete or qualified success rate in 6 months after the surgery. In our study we performed intravitreal bevacizumab injection 10 days before the surgery in both trabeculectomy and Ex-Press groups.

Implantations of some drainage devices such as Ahmed valve, Krupin valve, Molteno and Baerveldt implants are alternative surgical procedures ±anti-VEGF agents for controlling IOP in eyes with NVG. [10-13] Zhang et al. [10] determined cumulative probabilities of valve survival by Kaplan-Meier analysis as 82.9%, 74.1% and 71.0% at 12, 24 and 36 months after Ahmed glaucoma valve with preoperative bevacizumab injection and stated that it was a safe and effective surgery in NVG. Some previous studies compared glaucoma drainage implant surgeries with or without anti-VEGF agents. [11-13]. Zhou et al. [11] evaluated the efficacy and tolerability of Ahmed glaucoma valve implantation with or without intravitreal bevacizumab injection in NVG. They observed lower rates of hyphema in bevacizumab group but similar qualified success rates in both groups. Like Zhou et al. [11], Arcieri et al. [12] and Sahyoun et al. [13] also observed similar survival success rates in Ahmed glaucoma valve with or without bevacizumab injection groups of NVG.

The Ex-Press, an FDA-approved mini glaucoma device, simplifies and makes trabeculectomy faster, safer and easier. [16, 20-21] XVT study compared trabeculectomy and Ex-Press implant results in the postoperative 2 years in open-angle glaucoma cases who had had undergone initial glaucoma surgery and mit C was used in both procedures. [16] In spite of similar surgical success rates in controlling IOP, less postoperative complications like hyphema were observed in Ex-Press group. It was also stated to be effective in lowering IOP in vitrectomized eyes. [22] As complications like hyphema is known to be less in Ex-Press than trabeculectomy, it is logical to perform Ex-Press in also NVG cases. We compared the outcomes of mit C-augmented trabeculectomy and mit C-augmented Ex-Press implant in NVG cases. We performed intravitreal bevacizumab injection in both groups. Guven et al. [23] evaluated the efficacy and safety of Ex-Press mini glaucoma implant in NVG with preoperative intracameral bevacizumab injection and observed significant decreases in IOP and the number of the medications in a mean 20 months follow-up period. Like in our study they performed bevacizumab injection 10 days before the surgery but different from ours they used intracameral injection. Hanna et al. [24] recently presented their case series with NVG associated with PDR who underwent EX-Press filtration surgery and stated that the implant had a good IOP-lowering effect and a low rate of complications.

In our study we observed significant decreases In IOP and the number of anti-glaucoma medications in both groups but no significant differences of IOP were detected between the groups. As marked ocular inflammation caused by hyphema is one of the main factors which cause high incidence of fibrotic reactions and reduce the success of trabeculectomy in NVG, we expected more success in Ex-Press group, which was minimally invasive than trabeculectomy. We observed hyphema in only 3 eyes within the few postoperative days and all had spontaneous resorption. It is strongly probable that preoperative bevacizumab injection and the completed PRP should have prevented higher rates of hyphema and this should have been the main reason for similar success rates within the first postoperative year of the two groups in our study.

Depending on these results we proposed that preoperative intravitreal bevacizumab injection and completed PRP before both surgeries reduced the rate of postoperative hyphema in cases with NVG and caused similar reductions in IOP and the number of the medications in our study. The major limitations of our study were its retrospective design before of ethical rules and the small number of our cases because of exclusion criteria. In conclusion both mit C-augmented trabeculectomy and mit C-augmented Ex-Press implant with preoperative intravitreal bevacizumab injection are safe and effective surgeries in NVG cases with completed PRP. Both of the procedures effectively controlled IOP and reduced the need for medications; however studies with longer follow-up period are required in order to demonstrate the long-term results of this surgical technique.

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