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Trabeculectomy with mitomycin C for glaucoma secondary to emulsified silicone oil after *pars plana* vitrectomy: a three-year follow-up

Trabekulektomija sa mitomicinom C kod sekundarnog glaukoma nakon *pars plana* vitrektomije sa emulzifikovanim silikonskim uljem: tri godine praćenja

Ivan Marjanović*†, Ranko Gvozdenović*†, Marija Božić*†, Vesna Marić*†, Milenko Stojković*†, Marija Marjanović†‡, Elena Jordanova§, Antonio Martinez‖

University Clinical Center of Serbia, *Eye Clinic, ‡Cardiology Clinic, Belgrade, Serbia; †University of Belgrade, Faculty of Medicine, Belgrade, Serbia; ‡Clinical Hospital Center Zemun, Clinic for Internal Medicine, Department of Nephrology, Belgrade, Serbia; ‖Clinical Research Department, Science Research and Sports, Ames, La Coruna, Spain

Abstract

Background/Aim. Different surgical interventions have been proposed, including trabeculectomy associated with antiproliferative agents because silicone oil (SO) removal cannot necessarily provide intraocular pressure (IOP) control. The aim of the study was to determine the efficacy of trabeculectomy with mitomycin C (MMC) for lowering IOP in patients with open-angle glaucoma (OAG) secondary to emulsified SO after *pars plana* vitrectomy. **Methods.** A single-center, prospective study was conducted, from December 2014 to December 2019, on 56 consecutive patients with an uncontrolled elevation of IOP after SO removal who were subjected to trabeculectomy with mitomycin MMC in that period. The primary end-point was the IOP at the three-year follow-up visit. Complete surgical success was defined as an IOP ranging from 7 mmHg to 18 mmHg without glaucoma medication. Qualified success was defined as IOP ≤ 21 mmHg with one or two topical medications. **Results.** Fifty-six patients with a mean age of 53.6 [standard deviation (SD)15.5] years had a mean baseline IOP of 42.3 (39.3 to 45.3) mmHg, which reduced to 18.6 (17.9 to 19.3) mmHg three years after surgery ($p < 0.0001$). Seventeen (30.4%) eyes were classified as a complete success, 21 (37,5%) as a qualified success, and 18 (32.1%) as a failure. In all successfully treated patients, the number of antiglaucoma medications was significantly reduced from 2.85 (SD 0.77) to 1.63 (SD 0.62), $p < 0.0001$. **Conclusion.** Trabeculectomy with MMC may be an option for lowering IOP in patients with OAG secondary to emulsified SO after *pars plana* vitrectomy, which was not controlled with maximum antiglaucomatous medical treatment.

Key words:
glaucoma, open-angle; mitomycin; ophthalmologic surgical procedures; silicone oils; trabeculectomy.

Apstrakt

Uvod/Cilj. Uklanjanje silikonskog ulja (SU) može biti povezano sa nepotpunom kontrolom intraokularnog pritiska (IOP), zbog čega su predložene različite hirurške intervencije, uključujući i trabekulektomiju primenom antiproliferativnih agenasa. Cilj rada bio je da se proceni efikasnost trabekulektomije sa mitomicinom C (MMC) u snižavanju IOP kod bolesnika sa sekundarnim glaukomom otvorenog ugla (OAG) nakon *pars plana* vitrektomije sa SU. **Metode**. Istraživanje je sprovedeno kao jednocentrična, prospektivna studija, od decembra 2014. do decembra 2019. godine, na 56 bolesnika sa nekontrolisanim povišenim IOP, nakon uklanjanja SU, koji su u tom periodu bili podvrgniti trabekulektomiji sa MMC. Krajnji ishod bio je IOP na kontrolnom pregledu nakon tri godine. Kompletan hirurški uspeh definisan je kao IOP u rasponu od 7 mmHg do 18 mmHg, bez lekova koji se primenjuju u lečenju glaukoma. Kvalifikovani uspeh definisan je kao IOP ≤ 21 mmHg, postignut uz primenu jednog ili dva topikalna leka. **Rezultati.** Ukupno 56 bolesnika prosečnog životnog doba od 53,6 [standardna devijacija (SD)15,5] godina imalo je srednji početni IOP od 42,3 (39,3 do 45,3) mmHg, koji se smanjio na 18,6 (od

Correspondence to: Ivan Marjanović, University of Belgrade, Faculty of Medicine, University Clinical Center of Serbia, Eye Clinic, Pasterova 2, 11 000 Belgrade, Serbia. E-mail: Ivanmarjanovic007@gmail.com

17,9 do 19,3) mmHg, 3 godine nakon operacije (p < 0,0001). Kao potpuni uspeh klasifikovano je 17 (30,4%) očiju, kao kvalifikovani uspeh 21 (37,5%) očiju, a 18 (32,1%) očiju klasifikovano je kao neuspeh. Kod svih uspešno operisanih bolesnika broj lekova protiv glaukoma bio je značajno smanjen, sa 2,85 (SD 0,77) na 1,63 (SD 0,62), p < 0,0001. **Zaključak.** Trabekulektomija sa MMC može biti opcija za snižavanje IOP kod bolesnika sa sekundarnim OAG nakon *pars plana* vitrektomije sa emulzifikovanim SU, koji nije bio kontrolisan maksimalnom medikamentnom terapijom protiv glaukoma.

Ključne reči:
glaukom, otvorenog ugla; mitomicini; hirurgija, oftalmološka, procedure; ulja, slikonska; trabekulektomija.

Introduction

Pars plana vitrectomy, combined with artificial vitreous substitutes, is an important treatment for severe retinal detachment (RD) caused by various retinopathies [1, 2]. Among the different vitreous substitutes, silicone oil (SO), introduced by Cibis et al. [3] in 1962, has been widely used in the treatment of complex vitreoretinal diseases over the past several decades [1, 2, 4–6]. However, its ocular tolerance has been repeatedly questioned.

Many different intraocular complications associated with the SO have been previously reported [7, 8]. Among them, the elevation of the intraocular pressure (IOP) is one of the most common complications of SO [7, 9]. Different etiopathogenic mechanisms have been associated with secondary glaucoma to SO, including pupillary block, inflammation, synechial angle closure, rubeosis iridis, and migration of emulsified or non-emulsified SO into the anterior chamber [10, 11].

Although the first therapeutic approach is medical and can include topical or systemic aqueous humor suppressants, surgical management is required if the medical therapy fails to control IOP. However, the optimal surgical intervention for controlling the elevated IOP has not been established.

Since SO removal cannot necessarily provide IOP control, other surgical interventions have been proposed, including trabeculectomy associated with antiproliferative agents, transscleral cyclophotocoagulation, or glaucoma drainage devices which could represent valuable treatment options [12–14]. However, trabeculectomy with mitomycin C (MMC) seems to be associated with lower success rates, as compared with other techniques, mainly due to alterations of the conjunctiva from prior vitreoretinal procedures [11, 14, 15]. In a prospective and randomized study by Errico et al. [12] conducted on patients with ocular hypertension after *pars plana* vitrectomy and SO, who underwent trabeculectomy, a complete and qualified success rate of 40% and 60% of eyes, respectively, was observed.

Similarly, El-Saied and Abdelhakim [14], in a prospective comparative study, reported a success rate with trabeculectomy of 50%, while the success rate with the Ahmed valve was 80%. However, Singh et al. [15], in a prospective study that included 19 patients who underwent trabeculectomy with MMC for glaucoma after vitreoretinal surgery, found that the total success rate was 36.9% at the end of one year, whereas the absolute success rate was only 15.8%. The differences in success rates may be due to the characteristics of the study population or the surgical technique.

The aim of this study was to assess the efficacy of trabeculectomy with MMC for lowering IOP in a cohort of Caucasian patients with OAG secondary to emulsified SO after *pars plana* vitrectomy.

Methods

A single-center prospective interventional case series study was conducted from December 2014 to December 2019 on 56 consecutive patients with uncontrolled elevation of IOP after SO removal, recruited or referred to the University Eye Clinic, Clinical Center of Serbia in Belgrade, previously operated on the territory of the whole Serbia, counting our and three other university clinics and private clinics.

The study protocol was approved by the institutional review board of the University Eye Clinic, Clinical Center of Serbia. All patients were fully informed about the details of the study, and patients provided written informed consent at the beginning of the study. The ethical principles outlined in the Declaration of Helsinki and Good Clinical Practice were followed.

Inclusion criteria were the following: eligible patients were aged 18 or older with an IOP ≥ 21mmHg on maximum antiglaucomatous medical treatment, defined as 3 drugs in two bottles plus oral carbonic anhydrase inhibitors (if not topically administered); SO droplets in the anterior chamber (slit lamp) or anterior chamber angle (gonioscopy) at the time of removal; an attached retina after removal; an open anterior chamber angle.

Exclusion criteria were as follows: any type of angle closure glaucoma; an elevated IOP level attributed to previous vitreoretinal surgery except emulsified SO, such as a scleral buckling procedure; previous laser or surgical glaucoma interventions.

The following data were recorded: demographic, visual acuity (VA), number of glaucoma medications, underlying retinal pathologic findings that required vitreoretinal surgery with SO injection, and status of the lens and anterior chamber angle.

A preoperative evaluation was performed, including measurement of best corrected VA (BCVA) *via* Snellen chart, measurement of IOP *via* Goldmann applanation tonometry, gonioscopy, slit lamp biomicroscopy, and stereoscopic optic disc evaluation with a 90-diopter lens. Dilated fundus examination with binocular indirect ophthalmoscopy was performed between the third and seventh day prior to trabeculectomy.

Surgical technique

Trabeculectomy was performed at least two months after SO removal.

All surgeries were performed under topical anesthesia by a single surgeon who used the same technique. Fornix-based conjunctival dissection was performed at the superior quadrant, supported by 8-0 nylon corneal traction suture. A 15-degree knife was used to delineate, and a crescent knife to create a half-thickness, 4 × 5 mm, rectangular-shaped scleral flap. In all eyes, for a duration of 3 min, MMC 0.04% (0.4 mg/mL) soaked Weck-Cel sponges were applied in Tenon's capsule pocket and also under the sclera flap. After the removal of the sponges, the surgical area was rinsed with 30 mL buffered saline solution. A corneal paracentesis was performed with a 15-degree knife without injecting a viscoelastic solution into the anterior chamber. Sclerectomy was done with a new 15-degree knife, and a peripheral iridectomy was performed in all cases [16]. The scleral flap was sutured with three interrupted 10-0 nylon sutures, and the conjunctiva was sutured with two interrupted 10-0 nylon wing sutures. After the operation, a topical fixed combination of dexamethasone and tobramycin was instilled 4 times daily for 4 weeks, and cyclopentolate 1% one drop twice daily for 2 weeks.

Follow-up evaluation and outcome measures

Postoperative data were collected on days 1 and 7 and months 1, 3, 6, and every 6 months afterward until month 36 of follow-up.

The primary outcome measure was the IOP. According to the Errico et al. [12] criteria, complete surgical success was defined as IOP ranging from 7 mmHg to 18 mmHg without glaucoma medication. Qualified success was defined as IOP ≤ 21 mmHg with one or two topical medications. Those eyes with an IOP > 22 mmHg or an IOP ≤ 21 with more than two glaucoma medications or with the need for additional glaucoma surgery or sight-threatening complications were considered surgical failure.

Postoperative VA was not statistically monitored due to large variations over time, taking into account changes from diabetic retinopathy, the frequency of secondary cataracts, changes in visual field reports, etc.

Statistical analysis

Before the study, it was determined that a sample of at least 53 patients was required to detect a difference of 4 mm Hg in mean IOP at a significance level of 0.05, with a power of 0.90, assuming a standard deviation (SD) of 8 mm Hg. A follow-up loss rate of 20% has been estimated.

A standard statistical analysis was performed using MedCalc Statistical Software version 18.11 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2018). Data are expressed as number (percentage), mean (SD), mean [95% confidence interval (95% CI)], or median (95% CI) as appropriate.

Comparisons between preintervention and postintervention values were performed for IOP, a number of antiglaucoma medications, and BCVA.

We analyzed distribution using a D'Agostino-Pearson test. If data were normally distributed, repeated measures ANOVA and the Greenhouse-Geisser correction were used for determining the changes in IOP, the number of antiglaucoma medications, and BCVA. A linear mixed model in order to consider the correlations between the repeated measures and the existence of missing data was used. If data were not normally distributed, the comparisons of the changes in IOP and the number of antiglaucoma medications were performed using the Friedman's two-way analysis test.

Intent-to-treat (ITT) efficacy analyses included all patients who underwent surgery and had at least a valid month one visit.

Per protocol (PP) analyses, which excluded patients who did not complete the study (month 36 visit) or who had major protocol violations, were also conducted to confirm the ITT results.

As required, categorical variables were compared using the $\chi 2$ and Fisher's exact tests.

A p-value < 0.05 was considered statistically significant.

Results

A total of 56 eyes of 56 patients were included in this study, 33 (58.9%) male and 23 (41.1%) female. The mean age was 53.6 (SD 15.5) years, ranging from 18 to 92. Among the study patients, 14 were aphakic and 42 were pseudophakic. At baseline, the mean BCVA was 0.39 (SD 0.26). The main demographic and clinical characteristics of the intent-to-treat (ITT) population are shown in Table 1.

In the ITT population, the mean [95% confidence interval (CI)] baseline IOP was significantly decreased from 42.3 (39.3 to 45.3) mmHg to 18.6 (17.9 to 19.3) mmHg at month 36, $p < 0.0001$ (repeated measures ANOVA and the Greenhouse-Geisser correction) (Figure 1).

Fourteen patients underwent new trabeculectomies with MMC between months 3 and 9 after the first surgery and were considered a failure.

In the per-protocol (PP) study population population, mean (95% CI) baseline IOP was significantly decreased from 41.4 (38.0 to 44.7) mmHg to 19.0 (18.3 to 19.7) mmHg at month 36, $p < 0.0001$ (repeated measures ANOVA and the Greenhouse-Geisser correction) (Figure 2).

After three years of follow-up, 17 (30.4%) eyes were classified as a complete success, 21 (37.5%) as a qualified success, and 18 (32.1%) as a failure.

In the ITT population, the number of antiglaucoma medications was significantly reduced from 2.85 (0.77) to 1.63 (0.62), $p < 0.0001$.

In the ITT population, the values of IOP, VA, and the number of antiglaucoma medications for all three groups are shown in Table 2.

Table 1

Baseline demographic and clinical characteristics of the intent to treat (ITT) study population

Variable	Values
Age (years), mean (SD), 95% CI	53.6 (15.5), 49.4 to 57.7
Sex (man/woman), n (%)	33 (58.9)/23 (41.1)
IOP (mm Hg), mean (SD), 95% CI	42.3 (10.6), 39.3 to 45.3
BCVA, mean (SD), 95% CI	0.39 (0.26), 0.32 to 0.46
Mean defect (dB), mean (SD), 95% CI	-8.0 (2.3), -9.3 to -6.8
Cup-to-disk ratio, mean (SD), 95% CI	0.47 (0.22), 0.41 to 0.52
Antiglaucoma medication, n mean (SD), 95% CI	2.85 (0.77), 2.31 to 3.19

SD – standard deviation; CI – confidence interval; n – number; IOP – intraocular pressure; BCVA – best corrected visual acuity; dB – decibels.

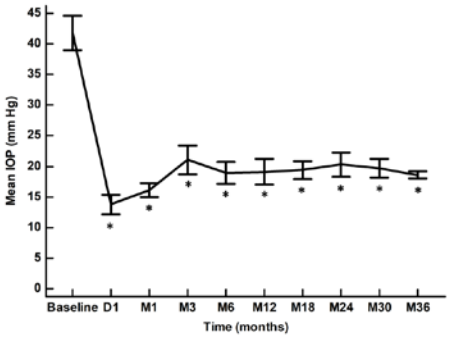


Fig. 1 – Mean intraocular pressure (IOP) over the course of follow-up in the intent to treat (ITT) study population. The vertical bars represent the 95% confidence interval.
***p < 0.001 as compared to baseline (repeated measures ANOVA and the Greenhouse-Geisser correction).**

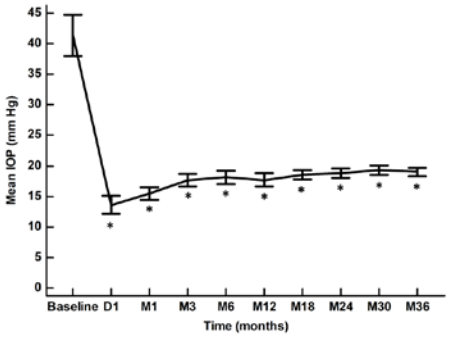


Fig. 2 – Mean intraocular pressure (IOP) over the course of follow-up in the per-protocol study population. The vertical bars represent the 95% confidence interval.
***p < 0.001 as compared to baseline (repeated measures ANOVA and the Greenhouse-Geisser correction).**

Table 2

Overview of the values of intraocular pressure (IOP), visual acuity, and number of antiglaucoma medications and their changes to baseline in the intent to treat (ITT), complete success, qualified success, and failure populations

Variable	ITT (patients, n = 56)	*p**	Complete success (patients, n = 17)	*p* **	Qualified success (patients, n = 21)	*p* **	Failure‡ (patients, n = 18)	*p* **
IOP	-42.3 (-45.3 to 39.3)	< 0.0001	-13.8 (-17.9 to -7.0)	< 0.0001	-15.6 (-21.0 to -12.3)	< 0.0001	-25.1 (-29.9 to -19.2)	< 0.0001
BCVA	-0.03 (-0.08 to 0.02)	0.1851	-0.05 (-0.14 to 0.04)	0.2620	-0.01 (-0.11 to 0.13)	0.8481	-0.07 (-0.10 to -0.05)	< 0.0001
Antiglaucoma medications, n	-2.85 (-3.52 to 2.13)	< 0.0001	0	/	-1.5 (-2.0 to -1.0)	0.8123	-2.62 (-3.24 to 2.05)	0.0977

All values are expressed as mean (95% CI) difference from baseline.
n – number; CI – confidence interval; IOP – intraocular pressure; BCVA – best corrected visual acuity.
***repeated measures ANOVA and the Greenhouse-Geisser correction; ****Friedman test; ‡mean difference was calculated comparing the baseline IOP of the first surgery with the last IOP measurement of the second trabeculectomy.**

Besides the fourteen patients requiring additional filtration surgeries, two patients had a choroidal abscess and one had an vitreous hemorrhage (required medical treatment). None of the patients developed hypotony.

Discussion

The results of this study, partly previously presented at congress [17], found that trabeculectomy with MMC

effectively reduces the elevated IOP in patients with open-angle glaucoma secondary to emulsified SO after *pars plana* vitrectomy. Although the rate of complete success was relatively low and lower than reported for most refractory glaucoma, it was in line with the scientific evidence.

In line with our results, Errico et al. [12] found in their study that complete success was achieved in 40% of eyes that underwent trabeculectomy, using the same criteria for complete and qualified success. However, comparing our results to those of Errico et al. [12] is difficult because the follow-up period of our study was 36 months, while the one in the Errico et al. [12] study was 24 months.

The results of this study are much better than those reported by Singh et al. [15], who reported a complete success rate of 15.8% in a prospective study conducted on patients who underwent trabeculectomy with MMC for glaucoma after vitreoretinal surgery.

However, the success rate found in our study is slightly lower than that observed by El-Saied and Abdelhakim [14], who, in a prospective study, compared the outcome of four different surgical procedures, namely trabeculectomy, deep sclerectomy, Ahmed valve, and Ex-Press Minishunt. The success rate in the trabeculectomy group in their study was 50%, slightly greater than that observed in our study (30.4%).

When comparing the outcomes of glaucoma surgery, it is essential to bear in mind that the surgical technique may have variations among surgeons and may have different results depending on the study population (race, age, etc.).

Therefore, the different success rates may be partially explained by the existence of variable study designs, treatment periods, and ethnic populations.

The success rate in our study is much lower than that in other types of glaucoma [18, 19].

The high failure rate of trabeculectomy, either with or without antimetabolites, may be due to different factors, including conjunctival scarring from the vitreoretinal surgery, the presence of macrophages, and an inflammatory reaction in the internal ostium [6, 7].

Although the tubes have shown better results, it is noteworthy mentioning that the treatment of this type of glaucoma must be customized [13, 14, 20]. However, it should be mentioned that although drainage implants are an alternative surgical option, oil migration can occur through the tube into the subconjunctival space inciting an inflammatory reaction [21].

Regarding tolerability, our study suggested that trabeculectomy with MMC was, on average, well tolerated in these patients.

This study has inherent limitations concerning the interpretation of its results as it is an open-label, non-randomized, non-controlled study by design, and caution needs to be employed while deriving conclusions. Nevertheless, the sample size was calculated prior to the study.

Conclusion

The results of this study suggested that trabeculectomy with MMC may be an option for treating OAG glaucoma secondary to SO, although its success rate was relatively low.

However, the study design does not allow us to reach decisive conclusions on the comparative efficacy and safety of trabeculectomy with MMC in such patients.

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