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Duration of the hypotensive effect of modified transscleral cyclophotocoagulation in patients with diabetic neovascular glaucoma

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Purpose: *To determine the duration of the hypotensive effect of the modified transscleral cyclophotocoagulation (TSCPC) with an 810-nm laser (1.5 J/ pulse) versus a 1064-nm laser (1.0 J/ pulse) followed by a 12-month follow-up in patients with diabetic neovascular glaucoma (NVG), and to assess the need for repeat TSCPC.*

Material and Methods: *This prospective open-label study included patients with diabetic NVG with a follow-up of 12 months. Proliferative diabetic retinopathy (DR) was found in 31/46 patients (67%) and the fundus could not be visualized in 15/46 patients (33%). Nine patients (20%) had a history or retinal laser photocoagulation and no pattern vision. All patients received TSCPC with a diode laser (810 nm, 1.5 J/ pulse) or neodymium:yttrium-aluminum-garnet (Nd:YAG) laser (1064 nm, 1.0 J/ pulse). TSCPC success was defined as an IOP between 10 and 21 mmHg (or a reduction in IOP of ≥ 30% from baseline IOP), no ocular pain, and an improvement or no change in best-corrected visual acuity.*

Results: *There was no statistically significant difference (p = 0.87) in the duration of hypotensive effect in NVG patients between diode-laser TSCPC and Nd:YAG-laser TSCPC. At 12 months, IOP was ≤ 21.0 mmHg in eyes of 18/24 patients (75%) in group 1 (1064 nm) versus 17/22 patients (75%) in group 2 (810 nm). The regression model for predicting the need of repeat TSCPC in diabetic patients with NVG based on baseline IOP, presence of ocular complications of NVG, and ocular pain score and diabetes duration explained 94% of the variation in outcome (Nagelkerke's R2 = 0.94), and the model accuracy, sensitivity and specificity were 96.2% (p < 0.001), 0.958 and 0.882, respectively.*

Conclusion: *At 12 months, stable ocular hypotensive effect of the modified TSCPC with an 810-nm laser (1.5 J/ pulse) and a 1064-nm laser (1.0 J/ pulse) was observed in 77% and 75%, respectively, of diabetic patients with NVG. The independent variables with the largest impact on the need for repeat TSCPC in diabetic patients with NVG were the baseline pain numeric rating scale score ≥ 8 (odds ratio (OR), 4.0; 95% confidence interval (CI), 1.84-8.91), presence of ocular complications (OR, 3.02; 95% CI, 1.84-8.91), diabetes duration ≥7 years (OR, 2.03; 95% CI, 1.46-2.28) and IOP ≥35 mmHg (OR, 1.16; 95% CI, 1.4-3.3).*

Keywords:

diabetes mellitus, proliferative diabetic retinopathy, neovascular glaucoma, retina, ciliary body, cyclophotocoagulation

Introduction

Elevated intraocular pressure (IOP) is the most important risk factor for glaucoma progression and loss of vision. Current treatment strategies (medications, laser and incisional surgical techniques and their combinations) focus on achieving a reduction in IOP through either inhibition of aqueous production or increasing aqueous drainage [1]. Cyclophotocoagulation (CPC) aims to control the IOP by decreasing aqueous production in the ciliary body and had prolonged efficacy in patients with secondary glaucoma [2-4]. In conventional transscleral CPC (TSCPC) with a continuous-wave (CW) diode laser, the power is increased in increments until an audible pop is heard [5]. Although CPC provides effective IOP control, high-energy CPC increases the risk of complications, including phthisis, chronic hypotony, prolonged inflammation and vision loss/blindness [2-4]. In an attempt to reduce the rate of complications in conventional CPC, we have previously conducted pathohistological studies to lay the ground for optimization of diode laser energy settings [6, 7]. The modified TSCPC with optimized laser energy settings provided effective IOP control with a lower rate of complications than the conventional procedure in diabetes patients with secondary neovascular glaucoma (NVG) [8].

A 2020 study [9] investigated the relationships of diabetes, hemoglobin A1c (HbA1c), and serum glucose with IOP and ocular hypertension (IOP> 21 mmHg) in 6786 non-glaucomatous Japanese adults. Hanyuda and colleagues [9] concluded that diabetes, elevated HbA1c, and

increased serum glucose are significant contributing factors for elevated IOP. The factors contributing to the development of diabetic complications include a long diabetes duration (> 6 years), moderate or severe diabetes with a transition to insulin therapy, obesity, arterial hypertension, etc. [10, 11]. Repeated procedures of TSCPC at high IOP in diabetic patients with NVG are associated with high initial values of expression of ICAM-1 in peripheral blood and high HbA1c. The strategy of management of patients with diabetic NVG should be aimed at intensive glucose control and local anti-inflammatory treatment [12]. Therefore, it should be reasonable to consider the prediction of the need of repeat TSCPC in patients with diabetic NVG with the use of clinical factors (age, diabetes duration, IOP, eye pain severity, and ocular complications found at baseline evaluation) as potential prognostic variables.

The purpose of this study was to determine the duration of the hypotensive effect of the modified TSCPC with a diode laser (810 nm, 1.5 J/ pulse) versus Nd:YAG laser (1064 nm, 1.0 J/ pulse) followed by a 12-month follow-up in patients with diabetic NVG, and to assess the need for repeat TSCPC.

Material and Methods

Study design and subjects

A prospective interventional crossover comparison open-label single-center study was conducted at State Institution "The Filatov Institute of Eye Diseases and Tissue Therapy". The study was conducted in accordance with the standards expressed in the Helsinki Declaration and was approved by the Filatov Institute ethics committee (Minutes no. 4, 2024). Written informed consent was obtained from all study patients.

This study included type 2 diabetic inpatients and outpatients with painful secondary NVG who were examined and treated at the Department of Laser Microsurgery of Eye Diseases, State Institution "The Filatov Institute of Eye Diseases and Tissue Therapy", during 2021 through 2023. Inclusion criteria included neovascularization of the iris or angle documented, ocular pain, an IOP ≥ 30 mmHg despite maximal hypotensive medication, and compensated diabetes (HbA1c < 8%). Exclusion criteria were NVG secondary to other disorder; systemic disease preventing TSCPC; or no eye pain.

Totally, 58 patients were included in the study and divided into two groups based on the type of laser used for treatment. Group 1 included patients who were treated with TSCPC with a 1064-nm Nd:YAG laser, and group 2 included patients who were treated with the modified TSCPC with an 810-nm diode laser.

Data collection

IOP, best-corrected visual acuity (BCVA), and the number of IOP-lowering medications used were documented at presentation and at 1 month and 3, 6 and 12 months after CPC. IOP was assessed by Goldmann applanation tonometry. Repeat CPC was employed in the case of lack of response to IOP lowering or loss of the obtained hypotensive effect. After treatment, eyes were dichotomized into three groups based on whether their BCVA improved, did not change or worsened postoperatively.

Numeric rating Scale for pain (NRS)

Ocular pain was self-assessed by patients using a conventional 11-point Numeric Rating Scale (NRS) for Pain [13]. It is scored from 0–10 (0 meaning no pain and 10 meaning the worst pain imaginable). We categorized pain NRS scores as mild (1-4), moderate (4-6), or severe (7-1) [14].

TSCPC procedure

Before TSCPC, the pars plicata was visualized by transpalpebral near-infrared transillumination [15]. A TSCPC procedure was performed as described previously [8]. Postoperative treatment included ophthalmic dexamethasone 1 drop (1 mg/1 ml, three times daily) over two weeks [16] to prevent inflammation and bromfenac ophthalmic solution over a month to reduce cyclooxygenase activity and inhibit prostaglandin synthesis [8].

Defining TSCPC efficacy

TSCPC success was defined as an IOP between 10 and 21 mmHg (or a reduction in IOP of ≥ 30% from baseline IOP,) no ocular pain, and an improvement or no change in BCVA.

TSCPC failure and the need for repeat CPC treatment was defined as an IOP of ≥ 22 mmHg despite ocular hypotensive treatment, the development of any complications (exudative fibrosis or phthisis), and a BCVA reduction from baseline [8].

Statistical analysis

All analyses were carried out using JASP (JASP Team software, Version 0.19.2, University of Amsterdam, Amsterdam, The Netherlands). Descriptive statistics for categorical variables are reported as frequencies and percentages. Quantitative data were evaluated for normality using the Shapiro-Wilk test and presented as median and interquartile range (IQR) where not normally distributed. Wilcoxon test was used for comparison of continuous variables over time. A 2-proportion calculator was used to calculate the comparison of frequencies expressed as percentages. Spearman correlation (rs) was used to assess relationships between study variables. Multiple regression analysis was used to determine the parameters influencing the clinical outcome. Receiver operator characteristic (ROC) analysis was used to calculate the area under curve (AUC) for the regression model and determine the need of repeat TSCPC. The level of significance $p \leq 0.05$ was assumed.

Results

Baseline demographic data

Totally, 58 patients with diabetic NVG were included in the study. Of these, 46 patients completed the study at 12 months, and 12 patients dropped out for the reasons unrelated to treatment. At 12 months, there were 46 patients (46 eyes) with a mean age of 66 years (range, 62-68 years). Of these, 20 (43%) were men and 16 (35%) had a history of surgery for glaucoma. At the last visit (V12), there were 24 patients (24 eyes) in group 1 and 22 patients (22 eyes)

in group 2. Proliferative diabetic retinopathy (DR) was found in 31/46 patients (67%) and the fundus could not be visualized in 15/46 patients (33%). Nine patients (20%) had a history or retinal laser photocoagulation. Cataract was found in 31/46 patients (67%), and pseudophakia, in 15/46 patients (33%).

Changes in BCVA over 12 months

Baseline BCVA in the worse-seeing eye was 0.02 (0.01 – 0.02) and 0.02 (0.02 – 0.06) in group 1 and group 2, respectively (p = 0.05). At baseline, 20/58 worse-seeing eyes (34%) had no pattern vision. Baseline BCVA in the fellow eye was 0.55 (0.4 – 0.84) and 0.24 (0.06 – 0.5) in group 1 and group 2, respectively, but the difference was not significant (p > 0.05).

At 12 months, BCVA in the worse-seeing eye stabilized to 0.05 (0.02-0.06) in 16/24 eyes (67%) in group 1 and to 0.06 (0.05 – 0.06) in 15/22 eyes (68%) in group 2 (p = 0.47) (Table1, Fig.1). In addition, 15/46 worse-seeing eyes (33%) had no pattern vision.

Duration of ocular hypotensive effect at 12 months

Baseline IOP was 48.0 (33.0 – 40.0) mmHg and 36.0 (33.0 – 40.5) mmHg in group 1 and group 2, respectively (p = 0.53). At month 12, the number of treatment sessions performed was 3.2 times larger for group 1 than for group 2 (median (IQR) value, 5.47 (3; 8.75) and 1.71 (1; 2.25), respectively) (Fig. 2).

In addition, IOP was 20.0 (18.0 – 22.5) mmHg and 21.0 (20.0 – 21.5) mmHg in group 1 and group 2, respectively (p = 0.87) (Fig. 3).

There was no significant difference in the duration of ocular hypotensive effect between eyes with diabetic NVG treated with diode laser CPC (810 nm, 1.5 J/ pulse) and those treated with Nd:YAG laser CPC (1064 nm, 1.0 J/ pulse) (p = 0.87) and, at 12 months, IOP was ≤ 21.0 mmHg in eyes of 18/24 patients (75%) in group 1 versus 17/22 patients (75%) in group 2.

Ocular complications of NVG

At baseline, ocular complications associated with NVG (bullous keratopathy, corneal edema and either hyphema or vitreous hemorrhage) were found in 5/58 (9%), 7/58 (13%), and 5/58 (9%) eyes with diabetic NVG, respectively.

At 12 months, bullous keratopathy of corneal edema was found in 8/46 (17%), vitreous hemorrhage was found

Table 1. Distribution of patients with diabetic neovascular glaucoma over best-corrected visual acuity categories before and 12 months after TSCPC for group 1 (1064 nm) versus group 2 (810 nm)

BCVA	Group 1	Group 2	p
Baseline (V0)	n=30	n=28	p = 0.05
BCVA (V0)	0.02 (0.01–0.02)	0.02 (0.02-0.06)	
0 (zero)	11 (37%)	9 (32%)	
0.01–0.1	19 (63%)	19 (68%)	
12 months (V12)	n=24	n=22	p = 0.47
BCVA (V12)	0.04 (0.02–0.06)	0.06 (0.04-0.06)	
0 (zero)	8 (33%)	7 (32%)	
0.01–0.4	16 (63%)	15 (68%)	

Note: Data are presented as median (interquartile range). BCVA, best-corrected visual acuity; P, P-value as assessed by the Mann-Whitney test

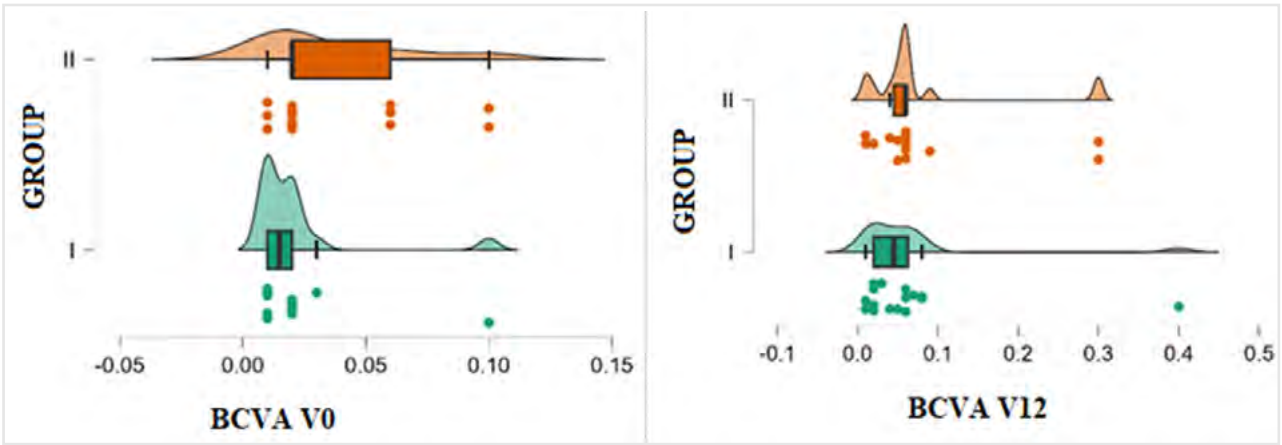

Fig. 1. Best-corrected visual acuity (BCVA) in diabetic patients with neovascular glaucoma at baseline (V0) and 12 months after (V12) TSCPC with a 1064-nm laser (group 1) versus an 810-nm laser (group 2).

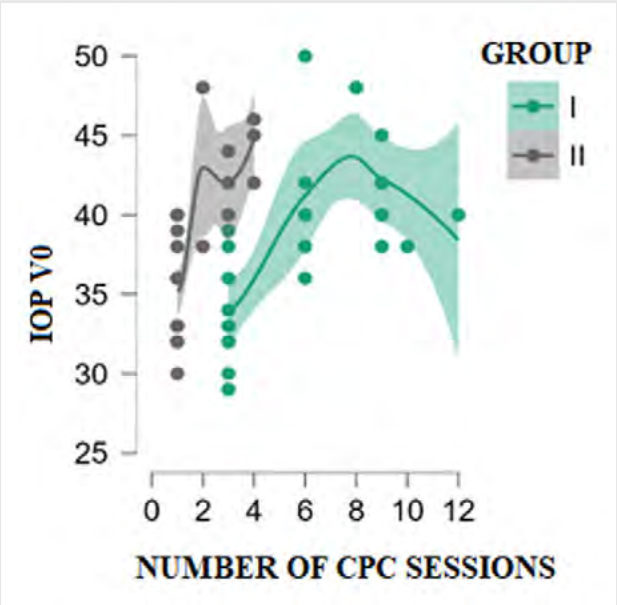

Fig. 2. Number of CPC sessions performed over 12 months versus baseline intraocular pressure (IOP) V0 for the two groups of diabetic patients with neovascular glaucoma

in 1/46 (2%), and signs of inflammation were still seen in 14/46 (30%) eyes with diabetic NVG.

NRS pain scores

At 12 months, in both groups, NRS pain scores substantially decreased compared to baseline ($p < 0.05$). In addition, NRS pain scores decreased from 7.9 to 1.4 in patients in group 1, and from 7 to 1.36 in patients in group 2, with no significant difference in between groups at month 12 ($p > 0.05$).

The need for repeat TSCPC in eyes with secondary painful diabetic NVG was directly and significantly correlated with the IOP ($rs = 0.77$, $p < 0.001$), diabetes duration ($rs = 0.71$, $p < 0.001$), pain NRS score ($rs = 0.56$, $p < 0.001$), and presence of ocular complications ($rs = 0.38$, $p = 0.01$), and mildly inversely correlated with BCVA ($rs = -0.22$, $p = 0.05$).

Univariate logistic regression analysis was performed to identify predictors of the need of repeat TSCPC in diabetics with secondary NVG. The analysis conducted indicated that the need of repeat TSCPC was strongly associated with the baseline IOP (Nagelkerke's coefficient of determination $R2 = 0.76$) and diabetes duration (Nagelkerke's $R2 = 0.74$), moderately associated with the baseline pain NRS score (Nagelkerke's $R2 = 0.59$), and weakly associated with the presence of ocular complications at baseline (Nagelkerke's $R2 = 0.09$).

Figure 4 shows the impact of the baseline IOP, diabetes duration, baseline pain NRS score, and the presence of ocular complications at baseline on the need for repeat TSCPC in diabetics with secondary NVG.

We used multivariate logistic regressions to assess associations of independent variables (IOP, presence of ocular complications of NVG, ocular pain score and diabetes duration) with the need of repeat TSCPC. A multivariate logistic regression model for predicting the need of repeat TSCPC in diabetic patients with NVG was built based on the statistically significant independent variables (Table 2).

ROC curve was built to assess the predictive performance of the model for discrimination, and AUC was calculated (Fig. 5).

The regression model for predicting the need of repeat TSCPC in diabetic patients with NVG based on baseline IOP, presence of ocular complications of NVG, and ocular pain score and diabetes duration explained 94% of the variation in outcome (Nagelkerke's $R2 = 0.94$), and the model accuracy, sensitivity and specificity were 96.2% ($p < 0.001$), 0.958 and 0.882, respectively.

Discussion

In our previous experimental and clinical studies with the use of an 810-nm laser (1.5 J/ pulse), we have not observed severe histological changes in the eye (collagen coagulation, destruction of the ciliary stroma, and full-thickness destruction of ciliary epithelium) noted in a study by Moussa and colleagues [18] in cadaveric eyes treated with CW-TSCPC. This also confirms our hypothesis that, in or-

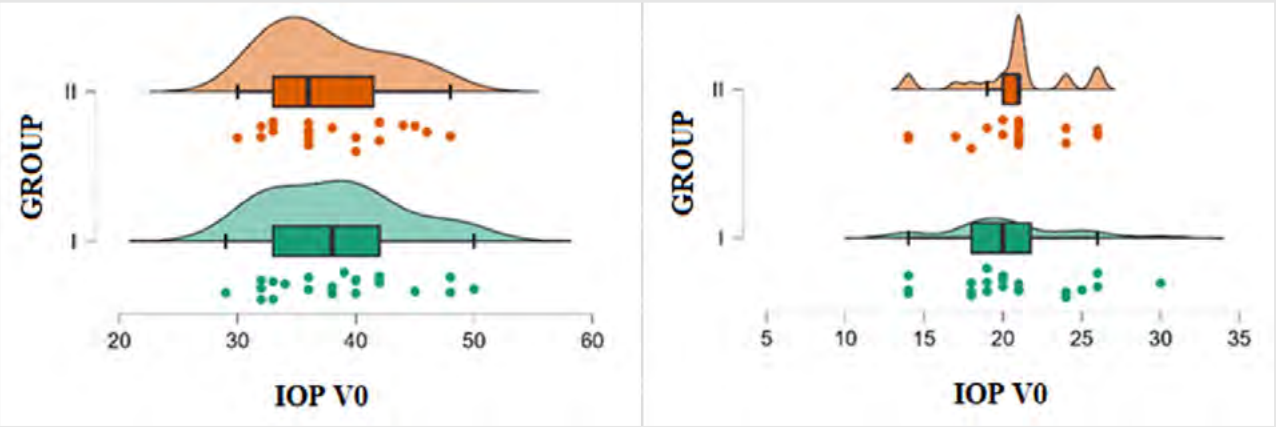

Fig. 3. Intraocular pressure (IOP) in diabetic patients with neovascular glaucoma at baseline (V0) and 12 months after (V12) TSCPC with a 1064-nm laser (group 1) versus an 810-nm laser (group 2).

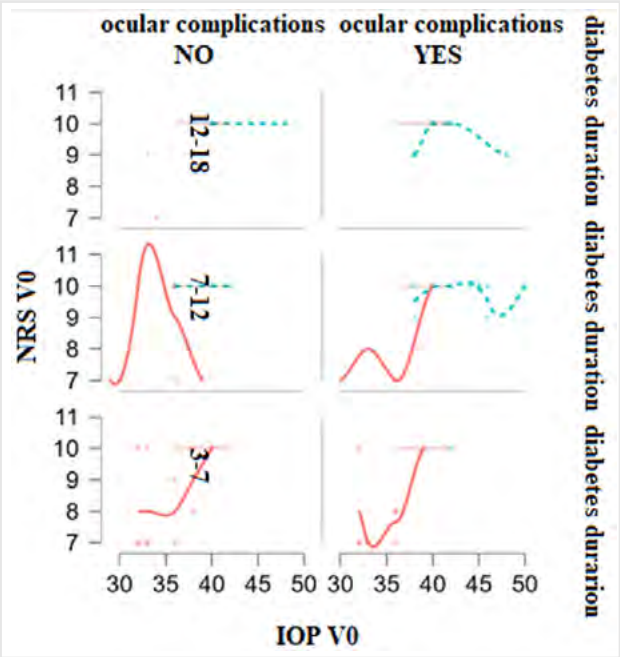

Fig. 4. Distribution of patients with diabetic neovascular glaucoma which required repeat TSCPC courses depending on diabetes duration, baseline IOP, presence of ocular complications and pain NRS score

der to reduce the rate of complications of transscleral laser cyclodestruction, it is reasonable to review the current conventional approaches to the selection of diode laser energy settings and favor relatively low laser energy settings that enable selective effects on the ciliary epithelium [6]. The prolonged IOP reduction effect, stabilization of BCVA, and the need for repeat CPC are, however, also important in TSCPC management of glaucoma.

In the current study, at 12 months, BCVA in the worse-seeing eye stabilized in 16/24 eyes (67%) in group 1 and 15/22 eyes (68%) in group 2 ($p = 0.47$).

Ocular pain is a condition that is difficult to treat, and is often debilitating for patients, and affects their daily lives. At 12 months, in both groups, NRS pain scores substantially decreased compared to baseline ($p < 0.05$). In addition, NRS pain scores decreased from 7.9 to 1.4 in patients in group 1, and from 7 to 1.36 in patients in group 2, with no significant difference in between groups at month 12 ($p > 0.05$).

We found that diabetic patients with painful NVG required repeat TSCPC when the baseline IOP was higher than 35 mmHg or diabetes duration was longer than 7 years (Fig. 4). In addition, the univariate logistic regression analysis conducted indicated that the need of repeat TSCPC was strongly associated with the baseline IOP

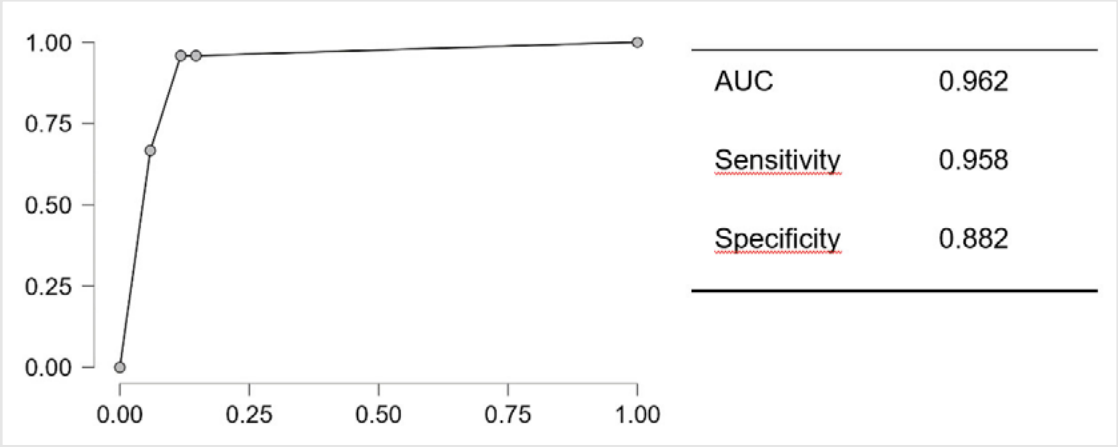

Fig. 5. Receiver operating characteristic (ROC) curve of the regression model for predicting the need for repeat TSCPC in patients with diabetic neovascular glaucoma. The area under ROC curve (AUC) was 0.962 (95% confidence interval, 0.73-0.89).

Table 2. Results of logistic regression analysis for associations between risk factors and the need for repeat TSCPC in patients with diabetic neovascular glaucoma (a four-factor regression model)

Independent variable	b ± m	OR (95% CI)	Nagelkerke's R^2	p
IOP V0	0.77±0.22	1.16 (1.4-3.3)	0.94	<0.001
Pain NRS score V0	1.39±0.4	4.0 (1.84-8.91)		
Duration of diabetes V0	0.71±0.17	2.03 (1.46-2.82)		
Ocular complications of NVG V0	1.37±0.57	3.92 (1.28-12.02)		

Note: b, standardized regression coefficient of the equation; m, standard error of b; Nagelkerke's R^2, Nagelkerke's coefficient of determination R^2; OR, odds ratio; CI, confidence interval

(Nagelkerke's R2 = 0.75) and diabetes duration (Nagelkerke's R2 = 0.67), moderately associated with the baseline pain NRS score (Nagelkerke's R2 = 0.47), and weakly associated with the presence of ocular complications at baseline (Nagelkerke's R2 = 0.14) (Table 1, Fig. 4).

Mohapatra and colleagues [19] described the clinical profile and complications of DR and uveitis in patients with coexisting conditions. They concluded that (1) treatment should aim at limiting the duration and intensity of inflammation and (2) strict glycemic control is essential for inflammation control and preventing the progression of DR to more advanced stages. Duerr and colleagues [20] compared the outcomes of standard pop-titrated TSCPC (a starting power of 1.75 W and 2.0-second duration) and slow-coagulation TSCPC (1.25 W and 4.0 to 4.5-second duration for dark or light brown irises, and 1.5 W and 3.5 to 4.0-second duration for other iris pigmentation). They concluded that the former technique had a higher incidence of prolonged inflammation postoperatively (73% versus 34%).

In our multivariate logistic regression model, the independent variables with the largest impact on the need for repeat TSCPC in diabetic patients with NVG were the baseline NRS ≥ 8 (OR = 4.0) and the presence of ocular complications (OR = 4.0), which underlies the impact of ocular inflammation [21] on the efficacy of treatment [12]. In a study by Hwang and colleagues [22], aqueous flare values increased 3.9 times compared to baseline values 3 months after slow-coagulation TSCPC in patients with medically uncontrolled glaucoma, and this increase was statistically significant. In a study by Parekh and colleagues [23], 85.7 % of glaucoma patients had prolonged anterior chamber inflammation beyond 1 month, which persisted in 10.7 % at last follow-up (11.6 ± 8.3 months) after slow-coagulation TSCPC. Others [17, 24] also reported on anterior chamber inflammation after slow-coagulation TSCPC in glaucoma patients, and noted the impact of this inflammation on the efficacy of treatment and the need for inflammation control.

In addition, in our multivariate logistic regression model, patients with NVG with a diabetes duration ≥ 7 years had 2.03 times higher odds of the need for repeat TSCPC compared to those with a shorter diabetes duration, and those with IOP ≥ 35 mmHg had 1.16 times higher odds of the need for repeat TSCPC compared to those with a lower IOP (Table 2).

The regression model for predicting the need of repeat TSCPC in diabetic patients with NVG based on baseline IOP, presence of ocular complications of NVG, and ocular pain score and diabetes duration explained 94% of the variation in outcome (Nagelkerke's R2 = 0.94), and the model accuracy, sensitivity and specificity were 96.2% ($p < 0.001$), 0.958 and 0.882, respectively (Fig. 5).

Of note, in our previous study [8], the modified TSCPC with an Nd:YAG laser resulted in a reduction in IOP to ≤ 21 mmHg at month 12 in 75%, and diode laser, in 77% of patients with diabetic NVG. Therefore, irrespective of how effective laser treatment is provided, and whether an 810-nm or 1064-nm laser is used for TSCPC in a diabetic with NVG, it is difficult to avoid repeat TSCPC (i.e., avoid ineffective initial TSCPC) if the patient present with prolonged and uncompensated diabetes, elevated IOP with ocular pain and diagnosed ocular complications of NVG (bullous keratopathy, corneal edema and either hyphema or vitreous hemorrhage) [8, 12]. Consequently, a diabetic with NVG should have regular examinations by the endocrinologist, therapist and ophthalmologist, should have his/her diabetes stabilized, and should receive his/her therapeutic treatment before the development of ocular ischemia. To address these conditions, the patient should receive additional ocular hypotensive, analgesic and anti-inflammatory therapy.

Several limitations should be taken in account when considering the results of the current study. First, the study has a small sample size, and further studies with a larger sample size are warranted. Second, a large proportion of the eyes included in this study had no pattern vision, which impedes the interpretation of the results with regards to the stabilization of functional vision. Finally, we did not compare the modified diode TSCPC with the standard diode TSCPC in diabetics with secondary NVG with regard to the duration of the hypotensive effect, which could affect the results as has been supposed by others [24]. Further research without these limitations would be reasonable.

Recommendations on the prolonged ocular hypotensive effect (success) in patients with diabetic neovascular glaucoma

We found that four factors have an impact on the prolonged ocular hypotensive effect of the modified TSCPC in diabetics with NVG. The most significant factors are the presence of marked ocular pain and ocular complications of NVG (bullous keratopathy, corneal edema and either hyphema or vitreous hemorrhage), which stresses the importance of prolonged control of intraocular inflammation. Patients with uncompensated diabetes must have a consultation with an endocrinologist. We typically determine the number of laser interventions required and the numbers of topical and oral hypotensive medications based on the degree of IOP elevation. Aggressive control of inflammation is critical for decreasing sight affecting fibrin, excessive cell and flare, cystoid macular edema, and other complications of TSCPC laser [24]. Recommended therapy entails subconjunctival dexamethasone, followed by preservative-free single dose unit dexamethasone eye drops and keterolac for 4 weeks. The taper of steroids is also very slow at a minimum of one drop less every 2–3 weeks in conjunction with ketorolac.

Conclusion

At 12 months, stable ocular hypotensive effect of the modified TSCPC with an 810-nm laser (1.5 J/ pulse) and a 1064-nm laser (1.0 J/ pulse) was observed in 77% and 75%, respectively, of diabetic patients with NVG. The independent variables with the largest impact on the need

for repeat TSCPC in diabetic patients with NVG were the baseline pain NRS score ≥ 8 (OR, 4.0; 95% CI, 1.84-8.91) and the presence of ocular complications of NVG (bullous keratopathy, corneal edema and either hyphema or vitreous hemorrhage) (OR, 3.02; 95% CI, 1.84-8.91), which underlies the presence and severity of ocular inflammation. In addition, patients with NVG with a diabetes duration ≥ 7 years had 2.03 times higher odds of the need for repeat TSCPC compared to those with a shorter diabetes duration, and those with IOP ≥ 35 mmHg had 1.16 times higher odds of the need for repeat TSCPC compared to those with a lower IOP.

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Abbreviations: *BCVA, best-corrected visual acuity; CPC, cyclophotocoagulation; DM, diabetes mellitus; DR, diabetic retinopathy; IOP, intraocular pressure; Nd:YAG, Neodymium:yttrium-aluminum-garnet; NVG, neovascular glaucoma; PDR, proliferative diabetic retinopathy; TSCPC, transscleral cyclophotocoagulation*