ORIGINAL RESEARCH

Medium-term Outcomes of Micropulse Transscleral Cyclophotocoagulation in Refractory Glaucoma

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Abstract

Aim: To describe our first experience with the efficacy of micropulse transscleral cyclophotocoagulation (MP-TSCPC) procedure in the treatment of different glaucoma subtypes refractory to topical medication using a standard protocol.

Materials and methods: Retrospective, interventional study in a series of 35 eyes of 34 patients with refractory glaucoma who underwent MP-TSCPC. Treatment success was defined as an intraocular pressure (IOP) reduction of at least 20% compared to baseline with or without IOP-lowering medication or eventual retreatment.

Results: Mean age was 78.0 years. The glaucoma subtypes included pseudoexfoliative (PSXG) (16), neovascular (NVG) (9), primary open-angle (POAG) (7), congenital (1), aphakic (1), and secondary glaucoma (1). The mean preoperative IOP was 31.8 ± 10.5 mm Hg and at month 12 was 21.9 ± 10.6 mm Hg ($p < 0.05$). The average baseline number of glaucoma medications pretreatment was 3.0 ± 1.0 and at month 12 was 2.3 ± 1.2 ($p = 0.114$). At month 12, success was achieved in 15 eyes (42.9%) with an IOP-lowering effect of 31.1%. PSXG was correlated with IOP reduction ($p = 0.037$) and had a higher likelihood of success ($p = 0.031$). As complications, there was one case of prolonged hypotony and another case of developed postoperative neurotrophic keratopathy.

Conclusion: Using our standardized protocol, MP-TSCPC seems a safe and relatively effective treatment in the medium-term for refractory glaucoma, achieving good results in PSXG.

Clinical significance: There are few studies published about MP-TSCPC. The results of our study contribute to expanding on the short evidence reported at present, emphasizing our considerable percentage of PSGX.

Keywords: Diode laser, Intraocular pressure, Micropulse transscleral cyclophotocoagulation, Pseudoexfoliation, Refractory glaucoma.

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Introduction

Glaucoma is one of the leading causes of blindness worldwide.[1,2] The goal of glaucoma therapies is to decrease IOP and preserve residual optic nerve function. Transscleral cyclophotocoagulation (TSCPC) with diode laser is a type of glaucoma treatment that targets the melanin in the pigmented ciliary body epithelium and therefore destructs the ciliary body; this decreases the aqueous humor production, and in consequence IOP.[3,4]

There are two different types of TSCPC depending on their delivery mode: continuous wave transscleral cyclophotocoagulation (CW-TSCPC) and MP-TSCPC.[5,6] Despite being IOP-lowering effective, CW-TSCPC has traditionally been used for refractory glaucoma cases with low visual potential due to the risk of adverse effects, including phthisis, inflammation, and hypotony. These occur apparently because of injury of collateral structures.[3] MP-TSCPC is a novel technique that applies laser energy in brief repetitive pulses (on cycles), separated by rest periods (off cycles). This produces less heat generation and allows the surrounding nonpigmented structures to cool off during the off cycles, minimizing thermal injury to adjacent tissues. Therefore, MP-TSPCP is thought to be safer and at least equally effective as CW-TSCPC.[5,6]

Few studies have been published about MP-TSCPC, most of them reporting good results in terms of efficacy and side effects.[5–15] However, there is no consensus on the ideal laser parameters.[16] The aim of this study is to describe our first experience regarding the efficacy of MP-TSCPC in the treatment of different glaucoma subtypes refractory to topical medication using a standard protocol and to expand on the brief evidence currently available, highlighting a large percentage of refractory PSXG.

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Materials and Methods

Study Design

This retrospective interventional study was conducted at the Arquitecto Marcide Hospital (Ferrol, Spain) in accordance with the Declaration of Helsinki. We included all consecutive patients who underwent MP-TSCPC with a P3 probe by two single surgeons for the treatment of any type of glaucoma between May 2017 and July 2019. All patients were of Caucasian origin. Patients offered with the MP-TSCPC suffered from advanced glaucoma with uncontrolled ocular hypertension.

Laser Intervention

A transscleral diode laser, the Cyclo G6 Laser System (MP-TSCPC; IRIDEX IQ810 Laser Systems, Mountain View, California, USA) with a P3 probe, was used for this intervention. The protocol was standardized for all patients, even for retreatment if necessary: power 2000 mW and duty cycle at 31.33% (0.5 ms of "ON time" and 1.1 ms of "OFF time").

All procedures were carried out in the operating room under retrobulbar anesthesia (1:1 mixture of 2% lidocaine and 0.5% bupivacaine). The P3 probe was placed over the conjunctival surface at the limbus, so the fiber optic tip seats are at 3 mm posterior to the limbus perpendicular to the globe. It was held with firm pressure and moved in a slow and continuous manner, clockwise for 10 seconds and counter clockwise for another 10 seconds, beginning at the superior or inferior arc. To avoid ciliary neurovascular structures, the 3 and 9 o'clock meridians were bypassed. The laser time for each arc depended on previous IOP: if 30 mm Hg or under, 80 seconds; if over 30 mm Hg, 90 seconds; the total energy delivered was 100 or 112 J, respectively. The eye was patched for 6 hours until the anesthesia effect disappeared.

Postoperative treatment included four drops of tobramycin-dexamethasone four times a day for 5 days, three times a day for 5 days, two times a day for 5 days, and one time a day for 5 days. Preoperative glaucoma medications were maintained and readjusted at each follow-up according to IOP.

Data

Pre and postoperative parameters were recorded, including age, sex, glaucoma type, previous glaucoma surgery, visual acuity, IOP, and number of glaucoma medications (one per drug class of drops and one per acetazolamide tablet). IOP was measured using Perkins applanation tonometry. Postoperative data were collected from day 1, month 1, month 3, month 6, and month 12. In each follow-up visit, pain, inflammation, hypotony, or any other complications were evaluated.

Surgical Success

Treatment was considered successful, with or without IOP-lowering medication or eventual retreatment, according to three criteria, in accordance with the standard of the World Glaucoma Association.[17]

- Criterion A: An IOP reduction of >20% compared to baseline.
- Criterion B: Criteria A and IOP ≤18 mm Hg
- Criterion C: Criteria A and IOP ≤15 mm Hg

Failure was defined as the inability to meet any criteria for success, hypotony (IOP <6 mm Hg), or the need of another glaucoma surgery. In the last case, follow-up was ended at that point.

Statistical Analysis

The statistical analysis was performed using SPPS software version 21.0 (SPSS Inc., Chicago, Illinois, USA). A *p*-value <0.05 was considered significant. Descriptive statistics were reported as mean ± standard deviation (SD) for continuous variables and as a percentage for categorical variables. To verify the correlation between paired variables, paired sample *t*-test (normal distribution) and Wilcoxon signed-rank test (non-normal distribution) were used. To verify the association between categorical variables Chi-square test was used. Binary logistic regression was applied to identify significant independent predictors of success. Multiple linear regression was made to assess which variables were associated with IOP reduction.

Results

A total of 35 eyes of 34 patients underwent the MP-TSCPC treatment during the study period. The mean age was 78.0 ± 9.8 years (range: 47–91), and there were more men (60%). When categorized by glaucoma subtype, 16 had PSXG, nine had NVG, seven had POAG, one had congenital glaucoma, one had aphakic glaucoma, and one had secondary glaucoma (retropupilar lens). Nine eyes (25.7%) had previous glaucoma surgery (Table 1).

Mean preoperative IOP was 31.8 ± 10.5 mm Hg. Mean postoperative IOP was 23.8 ± 9.3, 23.3 ± 10.0, 21.1 ± 9.5, 22.4 ± 9.7, and 21.9 ± 10.6 mm Hg at day 1, months 1, 3, 6, and 12, respectively, all significative ($p < 0.05$). IOP was 31.1% lower at month 12. The average baseline number of glaucoma medications was 3.0 ± 1.0. Post-treatment, it was 2.7 ± 1.1 ($p = 0.054$), 2.5 ± 1.1 ($p = 0.084$), 2.2 ± 1.2 ($p = 0.019$), and 2.3 ± 1.2 ($p = 0.114$) at months 1, 3, 6, and 12 (Table 2 and Fig. 1).

Treatment success following criterion A was achieved at month 1 in 23 of 35 eyes (65.7%); if not, retreatment or another glaucoma surgery was proposed based on surgeon's discretion. Consecutively, treatment success was reached in 18 (51.4%), 17 (48.6%), and 15 eyes (42.9%) at months 3, 6, and 12. Criteria B and C were achieved, respectively, in 14 (40%) and 8 (23.9%) eyes at month 1, 14 (40%) and 7 (20%) at month 3, 12 (34.3%) and 7 (20%) at month 6, and 11 (31.4%) and 6 (17.1%) at month 12 (Table 3).

Eight patients (22.9%) (three POAG, three PSXG, one NVG, and one secondary glaucoma) underwent another glaucoma surgery (five trabeculectomy, two CW-TSCPC, and one Ahmed valve implant).

There were no statistically significant changes in terms of visual acuity in 1 year after treatment ($p = 0.652$).

In the subgroup analysis, only PSXG was correlated with IOP reduction [F (4,97) = 4.973; R^2= 0.199; $p = 0.037$] and had a higher likelihood for success following criterion A (OR: 0.214; 95% CI: 0.051–0.902; $p = 0.031$) and criterion B (OR: 0.146; 95% CI: 0.030–0.708; $p = 0.017$) but not criterion C. Age, sex, visual acuity, number of previous glaucoma medications, previous glaucoma surgery, baseline IOP, laser time depending on baseline IOP, and other glaucoma types were not significantly associated with IOP reduction or success (Table 4).

Regarding adverse effects, few complications occurred. One eye developed postoperative neurotrophic keratopathy after 1 week and required autologous serum and amniotic membrane transplantation to heal. An NVG patient presented prolonged

Table 1: Patient demographics

Characteristics	*Statistics*
Number of patients	34
Number of eyes	35
Age	78.0 ± 9.8 (47–91)
Women/Men	14/21
Number of eyes with previous glaucoma surgery	9 (25.7%)
Type of glaucoma	
- PSXG	16 (45.7%)
- NVG	9 (25.7%)
- POAG	7 (20.0%)
- Congenital	1 (2.9%)
- Aphakic	1 (2.9%)
- Secondary	1 (2.9%)

hypotony during the study period between months 1 and 6 but resolved at month 12. Despite corticoid drops, IOP remained low. There was no development of phthisis bulbi, mydriasis, or persistent inflammation.

Discussion

In our study, MP-TSCPC was effective at lowering IOP in patients with glaucoma refractory to topical medications, with relatively few complications. IOP was significantly reduced from the first day until the end of the follow-up period in month 12. The number of topical medications was also reduced.

Table 2: Evolution of IOP and mean number of glaucoma medications

	Mean IOP ± SD (mm Hg) (%IOP reduction from baseline)	*Glaucoma medications ± SD*
Preoperative (*n* = 35)	31.8 ± 10.5*	3.0 ± 1.0
1 day (*n* = 35)	23.8 ± 9.3* (25.2%)	**
1 month (*n* = 35)	23.3 ± 10.0* (26.7%)	2.7 ± 1.1
3 months (*n* = 28)	21.1 ± 9.5* (33.6%)	2.5 ± 1.1
6 months (*n* = 19)	22.4 ± 9.7* (29.6%)	2.2 ± 1.2*
12 months (*n* = 22)	21.9 ± 10.6* (31.1%)	2.3 ± 1.2

*$p < 0.05$; **Glaucoma medication was not changed at day 1

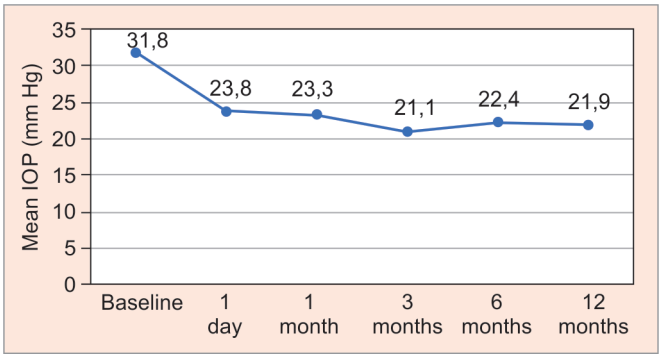

Fig. 1: Mean IOP of patients at each follow-up point. Postoperative mean IOP was significantly lower than baseline mean IOP at every point

IOP and Success

Intraocular pressure-lowering effect was achieved quickly, at postoperative day 1 was significantly lower than baseline (25.2%), and at month 12, IOP was 31.1% lower. This correlates with published studies, showing lowering percentages among 23.7% and 51%.[5,6,8,9,12–15,18,19]

Our success rate was 42.9% at 12 months according to criterion A and dropped to 31.3 and 17.1% with the more restrictive criteria B and C. Other published works show high success rates from 52 to 100%, with a mean follow-up from 1 to 24 months.[5,6,8,9,11,12,14,15,19–21] Only three studies report a success rate below 50% like ours: Souissi et al.,[13] 35% at 12 months including retreatment (success defined as IOP between 8 and 18 mm Hg and at least 20% IOP reduction); Sanchez et al.,[10] 41% without MP-TSCPC retreatment with a 6-month follow-up (success defined as IOP between 5 and 21 mm Hg and at least 20% IOP reduction); and Radhakrishnan et al.,[22] 36.5% at month 12 without retreatment (success defined as 20% IOP reduction). We show one of the lowest success rates of the studies published; it can be explained by some factors.

A few glaucoma subtypes may be more difficult to treat with MP-TSCPC. Tan et al.[6] found half of their failures in eyes with NVG. In our study, NVG represents 30% of the failures (6 out of 20).

When success was not achieved at any visit, retreatment was then offered. Some patients declined and continued with medication or underwent another glaucoma surgery, thus were considered failures. Retreatment was performed in six patients, reaching success in two of them. Any patient was treated more than twice. This differs from other studies where several patients underwent multiple retreatments.[5,6,8,12] Nguyen et al.[12] reported a 76.8% success rate after one treatment and a 100% with multiple retreatments. In the same line, Kaba et al.[18] showed further IOP reduction by 16% with each repeat MP-TSCPC treatment. Conversely, Radhakrishnan et al.,[22] considering retreatment as a failure, showed the lowest success of the works reviewed. Only 17.1% (6/35) of our patients underwent additional treatment, suggesting it is one of the main factors contributing to our low success rate.

Laser settings were similar to those of other studies. Sanchez et al.,[16] in their review, hypothesized that the ideal laser parameters would be located between an amount of total energy of approximately 112–150 J. Balancing between effectiveness

Table 3: Success at follow-up points

Success	*Month 1*	*Month 3*	*Month 6*	*Month 12*
Criterion A (IOP reduction ≥20%)	23 (65.7%)	18 (51.4%)	17 (48.6%)	15 (42.9%)
Criterion B (criterion A and IOP ≤18 mm Hg)	14 (40%)	14 (40%)	12 (34.3%)	11 (31.4%)
Criterion C (criterion A and IOP ≤15 mm Hg)	8 (23.9%)	7 (20%)	7 (20%)	6 (17.1%)

Table 4: Results per glaucoma type

	PSXG n = 16	*Other types n = 19*	*Significance (p)*
Mean IOP ± SD (mm Hg) (%IOP reduction from baseline)			
- Preoperative	29.1 ± 8.2	34.1 ± 11.8	0.160
- 12 months	16.2 ± 2.8 (44.3%)	27.6 ± 12.6 (19.1%)	0.037
Success (at month 12)	10 (62.5%)	5 (26.3%)	0.031

Other types include NVG, POAG, aphakic, congenital, and secondary glaucoma. Grouped as one due to low numbers

and side effects, they open the possibility to dose the treatment. To increase or reduce the total energy delivered, laser power or treatment duration can be modified. Kaba et al.[18] found greater IOP reduction at month 12 with higher laser power (31.5% with more than 2500 mW compared to 17.8% with lower power). Sarrafpour et al.[23] also reported greater IOP reduction with higher power at 12 months (57.2% with 2400 mW, 51.3% with 2400 mW, 51.2% with 2250 mW, and 30.1% with 2000 mW). Preda et al.,[24] with power setting at 2000 mW increased the application time for groups with higher IOP, but showed variable success rates (IOP < 26 mm Hg, laser time 80 seconds, success rate 90.9%; IOP 26–30 mm Hg, 100 seconds, 70%; IOP 31–49 mm Hg, 120 seconds, 65.63%; IOP > 50 mm Hg, 130 seconds, 84.6%). As Sanchez et al.[25] mention in a recent review, there are several variables involved in energy delivery (power, treatment duration, probe positioning, motion and dwell time, etc.) which, combined with the limited data available from studies, make it difficult to establish linear associations between laser energy and outcomes. In our study, we delivered higher energy to patients with higher IOP (above 30 mm Hg), but our maximum energy amount was 112 J, situated in the lower part of the suggested range. Our success rates could have been improved by delivering higher energy or increasing treatment duration.

We found more success and IOP reduction in PSXG cases compared to the rest of the eyes. Sanchez et al.[10] also reported the highest success (two eyes of six) and IOP reduction in successful cases (48%) in PSGX eyes, compared to congenital (two of seven, 36%) and other glaucoma types (2 of 10, 33%). Tan et al.[6] observed the highest failure in NVG eyes (6 of 12). Both studies had small numbers and showed no statistical significance. Tekeli and Köse[15] recently reported parallel success rates (defined as IOP ≤18 mm Hg and ≥20% reduction in IOP) between POAG (68.8%), PSXG (66.6%), and other glaucoma subtypes (64.7%) at 12-month follow-up. In our study, PSXG success rate is comparable (62.5%). This shows that in PSXG, in which IOP is usually more difficult to control with topical medication than in POAG, MP-TSCPC appears to have similar efficacy.

Number of Glaucoma Treatments

After MP-TSCPC, we account for a reduction in the number of antiglaucoma medications (dropped from 3 to 2.3 at the end of the follow-up). Previous studies have reported a significative decrease, ranging from 2.1 to 4.7 at baseline to 1.3 to 3.6 medications on average at the final visit; the higher the number of medications at baseline, the higher at the last follow-up.[5,6,8,9,11–14,20,21]

Complications

In our series, MP-TSCPC shows a good safety profile, with only two cases which represent a 5.7% complication rate (one case of persistent hypotony and one case of corneal ulcer). This is consistent with the results published to date. Persistent hypotony corresponded to a 70-year-old man with NVG. Only four studies report persistent hypotony, ranging from 2.7 to 8.8%.[7,8,13,14] Most of them associate hypotony with prolonged laser time, which means more energy delivered. Conversely, in our case, treatment time was short, 160 seconds (100 J).

A neurotrophic corneal ulcer occurred in an elderly woman with a long time PSXG under multiple topical medications and previous cataract surgery. It developed 1 week after laser. Perez et al.[26] have reported two cases of neurotrophic keratitis after MP-TSCPC, at weeks 3 and 4, in patients with predisposing factors for decreased corneal sensation. Neurotrophic keratitis developed after CW-TSCPC has been related to the damage of the long ciliary nerves in patients with predisposing factors of corneal hypoesthesia prior to surgery like chronic use of topical beta blockers, surgery with corneal incisions, diabetes mellitus, or corneal dystrophies; with a mean time for diagnosing of 3 weeks.[27]

Study Limitations

This study is based on our daily clinical practice, and, therefore, it has a series of limitations derived from it: retrospective design, small sample size, retreatment refusal due to off-study reasons, and that our study population cannot be representative of other areas due to the high percentage of PSXG that we present in our environment.

Conclusion

Micropulse transscleral cyclophotocoagulation, with our standardized protocol, appears to be a safe and relatively effective treatment in the medium-term for advanced glaucoma refractory to topical medication, mostly in patients with PSXG. With one or two sessions, success decreases over time. IOP-lowering effect is achieved early within the first 24 hours. Further large and randomized studies are needed to evaluate the efficacy and safety of this procedure and to better determine factors for success or failure.

Clinical Significance

Micropulse transscleral cyclophotocoagulation is a new glaucoma treatment, and results of daily clinical practice have been published in recent years. The results of this study contribute to expanding on the short evidence reported at present, emphasizing our considerable percentage of PSGX.

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