Original Article

Long-term Efficacy and Safety of Micropulse Transscleral Cyclophotocoagulation in the Treatment of Refractory Glaucoma

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Objective: To evaluate the long-term efficacy and safety of micropulse transscleral cyclophotocoagulation (MP-TSCPC) in refractory glaucoma.

Materials and Methods: The present study was a prospective non-comparative interventional study. Patients diagnosed with refractory glaucoma were included for MP-TSCPC. The success rate was defined as an intraocular pressure (IOP) of 6 to 21 mmHg or a reduction of IOP by 20%. The percentage of IOP reduction, number of glaucoma medications, visual acuity (VA), additional procedures, and complications were evaluated.

Results: Twenty eyes of 14 patients were included. The mean follow-up time was 28.1±19.5 months and up to 48 months. The mean preoperative IOP was 22±10.4 mmHg. The success rate of MP-TSCPC was 43.8% at 36 and 48-months follow-ups. The cumulative proportional success was 47.6% at 48 months with a median survival time of 36 months. IOPs showed significant reduction at 1-week follow-up (P <.05) and were reduced 48.7% at 48 months. The overall number of glaucoma medications (p=0.25) and VA (p=0.23) showed no difference compared to baseline. Fifty percent of eyes required an additional procedure to control IOP. Complications included one case of corneal decompensation and three cases (15%) of cataract progression.

Conclusion: MP-TSCPC demonstrated a high success rate in short-term follow-up, then showed a moderate success rate at intermediate and long-term follow-ups in refractory glaucoma. The treatment should be used with caution in cases with a history of multiple ocular surgery to avoid long-term adverse effects.

Keywords: Glaucoma; Intraocular pressure; Laser coagulation; Laser therapy

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Glaucoma is the leading cause of irreversible blindness worldwide. Its global prevalence was estimated to be 76 million in 2020[1]. Management of glaucoma focuses on intraocular pressure (IOP) lowering. This can prevent visual field loss and optic nerve damage[2]. Currently, there has been an increase in the use of topical medications and laser therapy, and a decrease in invasive incisional glaucoma surgery[3].

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The continuous-wave transscleral cyclophotocoagulation (CW-TSCPC) has been used as an alternative treatment when surgeries failed to control IOP or to relieve symptoms of ocular pain in refractory glaucoma. Because of the risk of serious complications from high-intensity energy laser delivery, including marked inflammation, hypotony, cystoid macular edema, and phthisis bulbi[4], CW-TSCPC is reserved for patients with advanced glaucoma. The micropulse transscleral cyclophotocoagulation (MP-TSCPC) has been developed to diminish the above-mentioned complications. This diode laser emits in the infrared spectrum at a wavelength of 810 nm, and alternates between treatment or ON cycles and rest or OFF cycle. This results in energy accumulation in the pigmented ciliary epithelium without reaching the coagulation threshold to limit collateral thermal damage to adjacent tissues[5,6]. This allowed MP-TSCPC to have a better safety profile compared to CW-TSCPC[7], thus, it may play a role in early and moderate glaucoma.

Current studies reported similar effectiveness of MP-TSCPC and CW-TSCPC only at early[8,9] and intermediate-term[10-16] or at 6 months to 2 years follow-ups. The data of long-term outcomes are still limited[17]. Therefore, this study was aimed to report the long-term effectiveness and complications of MP-TSCPC treatment in patients with refractory glaucoma.

Materials and Methods

A prospective non-comparative interventional case series was performed. The present study was conducted in accordance with the tenets of the Declaration of Helsinki and was approved by the Khon Kaen University Ethics Committee for Human Research (HE601170). Patients with refractory glaucoma from Khon Kaen University Eye Center at Srinagarind Hospital scheduled for MP-TSCPC in November 2016 were included in the present study. Patients were enrolled only in November 2016 because they were the first group of patients that underwent this procedure. Informed consents were obtained from all participants. Refractory glaucoma was defined as IOP of more than 21 mmHg and unresponsive to maximal tolerated medical therapy with or without previous surgical intervention. Exclusion criteria were patients with active ocular inflammation, ocular infection, patients that underwent CW-TSCPC or any intraocular surgeries within two months prior to the enrolment, or patients that had scleral thinning of at least one clock hour.

Surgical procedure

The MP-TSCPC procedure was performed in the outpatient setting by three glaucoma specialists who were trained using the same protocol for laser treatment. Adequate topical 0.5% tetracaine (Alcon Laboratories, Thailand) and 3 mL of 2% lidocaine hydrochloride peribulbar anesthesia (Recipharm Monts, France) were given prior to the procedure. The Iridex Cyclo G6 Glaucoma Laser System (Iridex IQ810 Laser Systems, Mountain View, CA) was used to perform the treatments. The laser settings used were 2,000 mW of 810 nm infrared diode laser radiation set on the micropulse mode, was delivered over 80s treatment time. This consisted of micropulses during which the laser was ON for 0.5 milliseconds (ms) and OFF for 1.1 ms (duty cycle 31.3%) delivering energy of 63.6 Joules in total. The contact probe was then applied perpendicular to the limbus with firm pressure and moved in a continuous sliding motion over the superior and inferior quadrants by avoiding 3 and 9 o'clock meridians in all participants. Anti-inflammatory and cycloplegic eyedrops were given with continued use of anti-glaucoma drugs. Anti-glaucoma medications were adjusted to control IOP or reduced in a stepwise fashion if targeted IOP was attained.

Outcome measures

The primary outcome of the present study was the success outcome, defined as an IOP of 6 to 21 mmHg or a reduction of IOP by 20% with or without medications. Inability to meet aforementioned criteria for two consecutive follow-up visits for three months or need for incisional glaucoma surgery were defined as failure. Patients that underwent retreatment of CW-TSCPC were not considered a failure. Secondary outcomes were the mean IOP, percentage of IOP reduction from baseline, number of glaucoma medications used, best-corrected visual acuity (BCVA), and complications at each follow-up period. Post-operative data at 1 week, 1, 3, 6, 9, 12, 18, 24, 36, and 48 months after the procedure were recorded. IOP was measured using the Goldmann Applanation Tonometer in every visit by an outcome evaluator (PS) who did not perform the MP-TSCPC procedure. BCVA was converted from Snellen visual acuity to LogMAR equivalents[18].

Statistical analysis

Descriptive statistics were calculated using mean and standard deviation or median, minimum value and maximum value for continuous variables according to the data distribution, and the percentage for categorical variables. For analytical statistics, the Kruskal-Wallis test for multiple comparison and the Dunn's test with a Bonferroni adjustment for pairwise comparisons were used. A Kaplan-Meier survival plot was used to determine cumulative probability of success during the first 48 months of follow-up. Patients who loss to follow-up at each visit was considered as missing data at that time point. All statistical analyses were performed in Stata, version 10.1 (StataCorp LP, College Station, TX, USA) and p-value of less than 0.05 was considered to be statistically significant.

Results

Twenty eyes of 14 patients were included in the present study. Baseline demographics and ocular characteristics are summarized in Table 1. Among all participants, the mean age was 53±17.2 years old and 78.6% of them were male. The most common

Table 1. Baseline demographics and ocular characteristics

Characteristics	n=20
Age at surgery; mean±SD	53±17.2
Sex; n (%)	
Male	11 (78.6)
Female	3 (21.4)
Laterality (OD); n (%)	12 (60.0)
Glaucoma subtype; n (%)	
Primary open-angle glaucoma	6 (30.0)
Primary angle-closure glaucoma	5 (25.0)
Secondary open-angle glaucoma	6 (30.0)
Secondary angle-closure glaucoma	2 (10.0)
Neovascular glaucoma	1 (5.0)
Previous glaucoma surgery; n (%)	
Trabeculectomy	11 (55.0)
Trabeculectomy with endolaser cyclophotocoagulation	2 (10.0)
ExPRESS shunt	1 (5.0)
Pre-operative visual acuity (LogMAR); mean±SD	1.39±1.2
Pre-operative intraocular pressure (mmHg); mean±SD	22±10.4
Pre-operative number of glaucoma medications; mean±SD	3.7±0.9

BCVA=best-corrected visual acuity; LogMAR=logarithm of the minimum angle of resolution; OD=oculus dexter; SD=standard deviation

Table 2. Success rate, failure rate and cumulative proportion of success of MP-TSCPC over 48 months

Follow-up	Success; n (%)	Failure; n (%)	Cumulative probability of success (95% CI)
3 months (n=20)	16 (80.0)	4 (20.0)	89.7 (64.9 to 97.3)
6 months (n=19)	12 (63.2)	7 (36.8)	72.9 (46.6 to 87.8)
9 months (n=17)	11 (64.7)	6 (35.3)	72.9 (40.4 to 83.6)
12 months (n=17)	9 (52.9)	8 (47.1)	66.8 (40.4 to 83.6)
18 months (n=17)	8 (47.1)	9 (52.9)	60.8 (34.6 to 79.2)
24 months (n=17)	8 (47.1)	9 (52.9)	54.4 (28.8 to 74.2)
36 months (n=16)	7 (43.8)	9 (56.3)	47.6 (22.9 to 68.7)
48 months (n=16)	7 (43.8)	9 (56.3)	47.6 (22.9 to 68.7)

CI=confidence interval

Table 3. Postoperative outcome measures

Follow-up	IOP (mmHg); mean±SD	Number of medications; mean±SD	BCVA (LogMAR); mean±SD
Baseline (n=20)	19.5 (5, 12)*	3.7±0.9	1.39±1.17
1 week (n=18)	8.5 (0, 3)*†	3.8±0.8	1.45±1.19
1 month (n=20)	17.1±7.7	3.0 (0, 4)*	1.56±1.23
3 months (n=20)	14.0 (5, 40)*	3.2±1.1	1.53±1.18
6 months (n=19)	18.1±10.0	3.1±1.0	1.64±1.15
9 months (n=17)	18.0 (7, 52)*	3.2±0.8	1.83±1.26
12 months (n=17)	16.8±9.2	3.5±1.2	2.42±1.79
18 months (n=17)	20.5±9.9	3.5 (0, 4)*	2.25±1.48
24 months (n=17)	17.9±9.4	3±1.7	2.73±1.72
36 months (n=16)	14.0 (0, 55)*	2.4±1.3	2.51±1.33
48 months (n=16)	10.0 (5, 55)*	2.6±1.8	3.00 (0.3, 3)*
p-value (overall)	0.0019‡	0.2539	0.2273

BCVA=best-corrected visual acuity; IOP=intraocular pressure; LogMAR=logarithm of the minimum angle of resolution; SD=standard deviation

* Median (min, max); † p-value <0.05, compare with baseline by Dunn's test (Bonferroni adjustment); ‡ Overall, by Kruskal-Wallis test

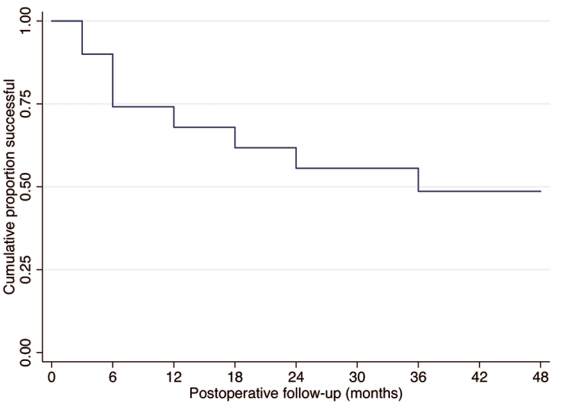

Figure 1. Kaplan-Meier survival plot of cumulative probability of success rate in patients underwent MP-TSCPC over 48 months.

glaucoma subtype and the previous glaucoma surgery were primary open-angle glaucoma (POAG; 30%) and trabeculectomy (55%). The mean preoperative IOP was 22±10.4 mmHg with 3.7±0.9 number of glaucoma medications. The mean length of follow-up was 28.1±19.5 months.

Table 2 demonstrates the success rates, failure rates, and cumulative success proportion of MP-TSCPC over 48 months. Some patients were loss to follow-up and was addressed at each follow-up. The rate of success was 80% and 63.2% at three and six months, then decreased overtime to 43.8% at 36 and 48 months after the treatment. The cumulative probabilities of success were 66.8%, 54.4%, 47.6%, and 47.6% at 12, 24, 36, and 48 months, as shown in Kaplan-Meier survival graph (Figure 1). The analysis demonstrated that the median effective time was 36 months. Out of nine eyes that met failure criteria, all eyes experienced IOP of greater than 21 mmHg with medications during follow-up.

The IOP, BCVA in LogMAR and number of glaucoma medications are shown in Table 3. The median preoperative IOP was 19.5 mmHg with 3.7 medications used. The IOP was 8.5 mmHg (mean) at one week, 16.8 mmHg (mean) at 12 months, 17.9 mmHg (mean) at 24 months, 14 mmHg (median) at

36 months, and 10 mmHg (median) at 48 months after the treatment. Postoperative IOP showed an overall significant difference (p=0.0019) and a pairwise significant difference at one week (p<0.05) compared to preoperative IOP. The IOP reduction from baseline was 58% at one week, 14% at 12 months, 8.2% at 24 months, 28.2% at 36 months, and 48.7% at 48 months. The number of glaucoma medications were reduced from 3.7±0.9 to 2.6±1.8 at 48 months. VA decreased from 1.39±1.17 to 3.00 at 48 months. The number of medications (p=0.25) and VA (p=0.23), however, did not demonstrate a difference compared to preoperative data.

Among all eyes, ten eyes (50%) needed an additional procedure to control IOP. Four eyes (20%) needed retreatment of CW-TSCPC with three eyes at 3-month follow-up and one eye at 12-month follow-up, one eye (5%) needed trabeculectomy at 36-month follow-up, and five eyes (25%) needed a glaucoma drainage device implantation with two eyes at 6-month follow-up, two eyes at 18-month follow-up, and one eye at 36-month follow-up.

There were no intraoperative complications in patients having undergone MP-TSCPC. Post-operatively, there was one eye (5%) that developed corneal decompensation. This participant with a history of multiple surgeries developed corneal decompensation and hypotony three years after the procedure. After discontinuation of the antiglaucoma eyedrops, the IOP increased to 5 mmHg. Cataract progression was found in three eyes (15%). One of them developed a mature cataract three months after MP-TSCPC. This patient had undergone secondary trabeculectomy before being included in the study. One POAG patient with uncontrolled IOP had a reduction in vision from hand motion to no light perception at one year.

Discussion

In the present study, the success rate defined as an IOP of 6 to 21 mmHg or a reduction of IOP by 20% with or without medications was 43.75% at 48 months. The cumulative proportional success was 47.6% at 48 months with a median effective time at 36 months. The IOP was reduced 48.7% from baseline and showed a significant reduction at 1-week follow-up.

From the previous studies considering the IOP reduction by 20% and IOP in the normal range as success criteria, a large-scale study[17] with a mean follow-up duration at 18.7 months demonstrated a decreased success rate from 44% at one year to 18.5% at three years. The percentage of IOP reduction was 32.7% at the 3-year follow-up and median effective time was nine months. Even the present study showed a higher success rate over three years with longer median survival time, a dissimilarity of baseline characteristics and sample size of the studies might result in a different rate of success throughout the follow-up.

Studies with 12-months follow-up reported a success rate of 56.7% to 85.42%[10-13], which is in the higher range compared to the current study (52.94%) at the same period of time. Aside from IOP value, the criteria for determining success in other studies included no use of oral carbonic anhydrase inhibitors and no loss of light perception vision, which might affect the percent of success rate. The IOP reductions from baseline were 27%, 35.4%, and 40.2%[11-13], which is also higher than the current study. It is assumed that the amount of IOP reduction from the laser treatment depends on the laser treatment time and baseline IOP, hence the result from a current study with shorter treatment time and low baseline IOP might demonstrate a lower IOP reduction compared to those[11-13] with higher baseline. Nevertheless, no study has reported the association between baseline IOP and IOP reduction. The study from Yelenskiy et al[11] showed a high success rate with a 27% IOP reduction, which had a low baseline IOP in participants. Thus, the low preoperative IOP in the present study might be one of the causes of low IOP reduction despite the effect of the laser treatment.

Short-term follow-up studies demonstrated a success rate of 73.7% at two months and 66.7% at six months[8,9], which was similar to the current study's results. The IOP reduction was 40% and 51% from baseline, which can be explained by the effectiveness of the laser and the high preoperative IOP in these studies when compared to a lower reduction in the present study.

There were studies that defined 30% or more of IOP reduction as one of the success criteria. The results showed a high rate of success at short-term follow-up[14] and the rate decreased overtime to 66% to 75% at 12 months[15,19], then varies from 52% to 90% at 18 months[15,16,20]. These studies with high baseline IOP also demonstrated high IOP reduction of 41.6% and 52% at 12-months follow-up[14,19].

Although most studies reported a high safety profile of MP-TSCPC over CW-TSCPC[10,15,17,21], the present study observed one patient (5%) with controlled IOP who developed corneal decompensation and three (15%) had cataract progression, in which one developed mature cataract after a long follow-

up. Cataract progression, which was seen in 40% of phakic eyes, was reported as one of the common complications after MP-TSCPC[12]. There was also a report of corneal edema in a non-phthisis eye during 12 months of follow-up[12]. A history of multiple intraocular surgery in these patients might also play role in developing corneal decompensation and cataract progression. The endothelial cell count was not recorded after previous surgeries, so the documents about a decrease overtime of endothelial cells were not available. Previous surgical procedures were also reported as a potential risk for failure in terms of IOP control[17]. In the present study, there was a reduction of vision in the POAG patient with uncontrolled IOP after the laser treatment. Although visual deterioration was associated with hypotony[15], patients in the present study herein tended to have decreased vision due to cataract progression and an over-target IOP. The neovascular glaucoma (NVG) patient retained vision of hand motion throughout the study with uncontrolled IOP at the intermediate-term and the targeted IOP at the long-term follow-up. Since the ciliary muscle is responsible for accommodation of the eye, the shrinkage of the muscle after laser treatment might result in loss of accommodation. A previous study reported this condition in one patient after MP-TSCPC, but no more specific information was provided[22]. In the current study, no patients complained about loss of accommodation. This may be because most of the patients had poor vision at baseline and they already lost the accommodation due to their age.

There are factors that were assumed to be associated with the IOP reduction after laser treatment. The laser treatment time was varied among studies. Studies that used a non-standard treatment protocol wherein the average treatment time range from 120 to 360 seconds[9] demonstrated a higher decrease of IOP compared to others that used the shorter treatment time including the current study. To get the optimal laser energy, the probe should be pressed firmly to the globe while sliding to transfer the maximal energy to the ciliary body. This might cause pain during the procedure, so adequate anesthesia is another crucial factor for success outcome. Intraocular inflammation, in which Asian population tended to have more pigment and higher incidence of prolonged intraocular inflammation[9] than white race, also played a role in IOP reduction in the early postoperative period. Pediatric participants in the present study only had IOP reduction in the short-term follow-up, then IOP increased in every participant. Finally, they required the reoperation during 15 months of follow-up. The effect of MP-TSCPC seemed to be short-lived in pediatric patients[10] but stayed longer in adult. Last but not least, glaucoma subtype might be another factor associated with successful outcome of MP-TSCPC. However, the sample size is too small to perform regression analysis to conclude which is the significant associated factors.

The strength of the present study includes the long-term follow-up period after the MP-TSCPC and a single outcome evaluator. There are limitations. First is the small sample size. The limited number of patients was due to limited use of the Micropulse laser machine in the present study hospital, Srinagarind Hospital. However, the authors had tried to include all eligible patients into the study. Second, the retreatment of the laser in the present study was the traditional CW-TSCPC due to the previous limitation. The outcome data about this combined procedure had not been provided. Lastly, the observations in the present tertiary care hospital, in which patients with a socioeconomic issue may have difficulty in gaining access. In some situations, they prefer to be referred back to their primary or secondary care hospitals, which results in more lost data overtime.

Conclusion

The success rate of MP-TSCPC was high in short-term follow-up and reduced overtime during intermediate and long-term follow-ups until 48 months in eyes with refractory glaucoma. Although MP-TSCPC demonstrated a high safety profile, it should be used with caution in patients with good visual potential who had undergone multiple intraocular procedures to avoid adverse visual effects. These results may improve glaucoma treatment planning and help ophthalmologists provide better care for glaucoma patients after MP-TSCPC treatment. A further longitudinal study with a high number of patients is suggested to explore possible long-term adverse effects from the treatment.

What is already known on this topic?

MP-TSCPC is used to lower IOP in refractory glaucoma. The rate of treatment success was high at short-term follow-up and reduced overtime in intermediate follow-up. However, MP-TSCPC was reported with high safety profile.

What this study adds?

At long-term follow-up, the success rate of MP-TSCPC was stable compared to those at intermediate

period. Visual deterioration after the treatment was associated with cataract progression and high IOP. The laser should be used with caution in patients with good visual potential who had undergone multiple intraocular surgeries to avoid long-term adverse visual effects.

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Conflicts of interest

The authors declare no conflict of interest.

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