Evaluation of Micropulse Transscleral Cyclophotocoagulation in Management of Primary Open Angle Glaucoma

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KEYWORDS
MP-TSCPC; Glaucoma; Angle.

ABSTRACT

Background: Glaucoma describes a group of eye illnesses in which there is progressive damage to the optic nerve, leading to impaired vision.

Aim: To evaluate the safety and efficiency of Micropulse Transscleral Cyclophotocoagulation (MP-TSCPC), in lowering IOP in cases that have 1ry open-angle glaucoma.

Patients and methods: This was a prospective, non-comparative interventional case series that was conducted on cases aged forty and older with 1ry open-angle glaucoma, whether controlled or uncontrolled, at the Memorial Institute of Ophthalmic Research in Cairo.

Results: The mean age was 63.86±13.26; there were seventeen cases (56.7%) that were men, and thirteen cases (43.3%) were women. The included right laterality eyes were 18 (56.7%). According to glaucoma severity, 2 patients (6.7%) were mild, 24 patients (80%) were moderate, 3 patients (10%) were advanced, and 1 patient (3.3%) was mild. There were 8 patients (26.7%) who had transient mydriasis, 3 patients (10%) who had inflammatory reaction in the anterior chamber, 2 patients (6.7%) who had subconjunctival hemorrhage, 2 patients (6.7%) who had IOP spikes, 2 patients (6.7%) who had cataract progression, 1 patient (3.3%) who had vision loss ≥ 2 lines, 1 patient (3.3%) who had mild hypotony, 3 patients (10%) who had pain during the procedure, and 2 patients (6.7%) who had pain during the early postoperative period.

Conclusion: The Micropulse Transscleral Cyclophotocoagulation (MP-TSCPC) effectively reduces IOP and medication burden in cases with mild-to-end-stage POAG, with minimal vision-threatening complications.

1. Introduction

Glaucoma is the 2nd most frequent cause of blindness global, characterized by the progressive damage to the optic nerve that results in impaired vision and, in some cases, blindness if left untreated (1).

Primary open-angle glaucoma (POAG) is a progressive, chronic, and irreversible multifactorial optic neuropathy with a characteristic acquired optic nerve fiber loss. In the lack of other known etiologies, this loss progresses in the presence of open anterior chamber angles, characteristic visual field abnormalities, and intraocular pressure that is high enough to maintain the eye's health (2). Traditionally, cyclophotocoagulation was a technique that has traditionally been used to permanently reduce intraocular pressure in non-seeing eyes or to relieve pain in refractory glaucoma cases. Weekers et al. in 1961 used xenon arc photocoagulation over the ciliary body to reduce IOP, with good results in terms of IOP but a lot of side effects (3).

In replacement of the traditional continuous high-intensity energy application that has been previously utilized, a micropulse mode is used to deliver a series of repetitive short pulses of energy with a rest duration in between, known as "Thermal Relaxation Time." In their initial research, Tan, Chew et al. (4) discovered that it was both safe and effective in reducing intraocular pressure by more than thirty percent, resulting in a reduction in the requirement for topical therapy (5).

The goal of this work was to evaluate the safety and efficiency of Micropulse Transscleral Cyclophotocoagulation (MP-TSCPC) in lowering IOP in cases with POAG.

Patients and methods

This was a prospective, non-comparative interventional case series that was conducted on cases aged forty and

older with primary open-angle glaucoma, whether controlled or uncontrolled, at the Memorial Institute of Ophthalmic Research in Cairo.

Sample size calculation

Assuming $\alpha = 0.05$ (two-tailed) and $\beta = 0.05$, a minimum sample size of 28 patients, followed up over a minimum of six different visits, is essential to identify an effect size (d) of 0.25 with a power of 95.39%.

Evaluation of sample size has been conducted for the repeated measures ANOVA utilizing computer program G * Power 3.1.9 (Franz Faul, Universität Kiel, Germany).

Inclusion criteria: Age over 40 years old, cases diagnosed with 1ry open-angle glaucoma, and a minimum follow-up of 9 months.

Exclusion criteria: Congenital glaucoma, cases having any intraocular operation within two months of enrollment, cases unable to give informed consent, and cases that underwent failed surgeries for primary open-angle glaucoma.

2. Method

All patients underwent a comprehensive evaluation prior to surgery, including a complete history, visual acuity assessment (both uncorrected and best corrected), intraocular pressure (IOP) measurement utilizing air puff and Goldmann applanation tonometer, anterior segment investigation, gonioscopy, fundus examination with optic disc photography, pachymetry, perimetry, and optical coherence tomography (OCT) of the optic nerve head. Additionally, the number and frequency of antiglaucoma medications used and corneal sensitivity were assessed.

Surgical technique

Laser Intervention

All eyes were exposed to the same conditions of surgery, which used one device (OcuLight SLx 810 nanometer diode laser photocoagulator and the Iridex G6-probe). Treatment was done under local anesthesia. The treatment plan is the same for all eyes, which involves treating 360 degrees of the ciliary body, sparing the three and nine o'clock meridians for a period of 90-120 seconds per 180 degrees.

Procedure

The treatment protocol described involved the use of an OcuLight SLx 810 nanometer diode laser photocoagulator in micropulse mode for transscleral cyclophotocoagulation. The laser settings include a power of 2000 milliwatts with a duty cycle of 31.33%, applied for a total of 160 seconds, divided evenly between the superior and inferior hemispheres of the eye. The probe is positioned three millimeters behind the limbal margin and is applied with stable pressure in a back-and-forth motion, avoiding the three o'clock and nine o'clock positions to protect ciliary arteries and nerves. An ocular patch is applied post-procedure.

Postoperative

Topical prednisolone acetate 1% was administered to all eyes four times per day for a minimum of one week. The dosage was subsequently tapered in accordance with the severity of the inflammation. Initially, all preoperative antiglaucoma drugs have been maintained, and they have been adjusted at each monitoring visit in accordance with the intraocular pressure level. In the event that a laser-induced intraocular pressure-lowering effect showed up, antiglaucoma drugs were gradually decreased starting with oral acetazolamide. Re-management or additional incisional operation decisions have been made at the surgeon's clinical discretion and in accordance with the details of each case.

Follow-up: cases were checked one day following operation, then at one week, and then monthly for a period of 9 months. At each visit, an ophthalmological assessment was done, including visual acuity assessment (uncorrected and best corrected), IOP (air puff & Goldmann applanation tonometer), and anterior segment examination for flare and cells, gonioscopic examination, fundus examination with recording of optic disc structure and antiglaucoma medications (number and frequency), postoperative complications, corneal sensitivity, and any complaints from the patient.

After 3 months and 9 months of each surgery, the following were repeated: perimetry and OCT optic nerve head.

Possible Risk: Failure of the procedure to decrease intraocular pressure and decrease the need for IOP-lowering

drugs or other surgical procedures and Loss of more than five letters in BCVA.

Outcome Measurements

Primary outcome: Success in reduction of intraocular pressure from baseline and success in reduction of number and frequency of IOP-lowering medications.

Secondary outcome parameters: Any complications observed after the procedure and Need for repeated treatment.

Ethical Consideration

The information that has been collected from participants is considered confidential. The research participants haven't been recognized by name in any publication or report that addressed this research. The purpose and nature of the research, as well as the risk-benefit assessment, have been explained to the participants prior to their admission to it. Informed consent has been obtained.

Statistical Analysis

The Statistical Package for Social Sciences (SPSS) has been utilized to manage and analyze the information. Median and range for ordinal (scores) data and non-parametric measures. The numerical data has been shown as means ± standard deviations (SD). Numbers and percentages have been used to represent categorical data. In case of parametric data, repeated measures The ANOVA test has been utilized to compare the effect change within factors among the various visits, while the Friedman test has been utilized to compare the groups with respect to non-parametric data. The p-values were two-sided. Significant P-values have been defined as those that were less than 0.05.

3. Results

Table (1): Distribution of demographic data in the studied group.

	Studied group (N=30)	
	mean	±SD
Age (years)	63.86	13.26
	N	%
Sex		
Male	17	56.7%
Female	13	43.3%
Laterality		
Left	12	40%
Right	18	60%
Glaucoma severity		
Mild	2	6.7%
Moderate	24	80%
Advanced	3	10%
End-stage	1	3.3%

SD: standard deviation.

Table 1 showed that the mean age was 63.86±13.26, there were seventeen cases (56.7 percent) that were men, and thirteen cases (43.3 percent) were women. The included right laterality eyes were 18 (56.7 percent). According to glaucoma severity, 2 patients (6.7 percent) were mild, 24 patients (80 percent) were moderate, 3 patients (10 percent) were advanced, and 1 patient (3.3 percent) was mild.

Table (2): Distribution of IOP in the studied group.

	Studied group (N=30)	
	Mean	±SD
Baseline (before surgical intervention)	28.9	7.81
After surgical intervention		
1 day	21.4	6.48

1 week	19.3	6.06
1 month	19.6	5.49
3 months	20	4.59
6 months	20.2	4.04
9 months	20.3	2.23
P value	<0.001	

Anova test

Table 2 showed that, IOP significantly decreased throughout the follow-up.

Table (3): Distribution of Number of intraocular Pressure-Lowering drugs in the studied group.

	Studied group (N=30)	
	Mean	SD
intraocular Pressure-Lowering drugs		
Baseline (before surgical intervention)	3.30	1.02
After surgical intervention		
1 day	3.07	0.91
1 week	2.93	0.69
1 month	1.60	0.50
3 months	1.80	0.41
6 months	1.83	0.38
9 months	1.90	0.48
P value	≤0.001	

SD: standard deviation. Anova test

Table 3 showed, Number of intraocular Pressure-Lowering drugs significantly decreased throughout the monitoring.

Table (4): Distribution of Log-MAR BCVA at various postoperative time points in the studied group.

	Studied group (N=30)	
	Mean	SD
Baseline (before surgical intervention)	0.35	0.19
After surgical intervention		
1 day	0.34	0.15
1 week	0.33	0.21
1 month	0.29	0.19
3 months	0.25	0.15
6 months	0.21	0.13
9 months	0.15	0.1
P value	<0.001	

Anova test

Table 4 showed, there was significant improvement throughout the follow-up regarding Log-MAR BCVA.

Table (5): Distribution of complications in the studied group.

	Studied group (N=30)	
	N	%
Transient mydriasis	8	26.7%
Inflammatory reaction in the anterior chamber	3	10%
Subconjunctival hemorrhage	2	6.7%
intraocular Pressure spikes	2	6.7%
Cataract progression	2	6.7%
Vision loss not less than two lines	1	3.3%
Mild hypotony	1	3.3%

Pain throughout the procedure	3	10%
Pain throughout the early postoperative period	2	6.7%

According to table 5, there were 8 patients (26.7%) who had transient mydriasis, 3 patients (10%) who had inflammatory reaction in the anterior chamber, 2 patients (6.7%) who had subconjunctival hemorrhage, 2 patients (6.7%) who had intraocular pressure spikes, 2 patients (6.7%) who had cataract progression, 1 patient (3.3%) who had vision loss not less than two lines, 1 patient (3.3%) who had mild hypotony, 3 patients (10%) who had pain throughout the procedure, and 2 patients (6.7%) who had pain throughout the early postoperative period.

4. Discussion

Transscleral cyclophotocoagulation (TSCPC) is a laser-assisted form of cycloablation that is efficacious in the treatment of every form of glaucoma (5).

Transscleral cyclophotocoagulation causes coagulative tissue alterations in both the non-pigmented and pigmented epithelium by targeting melanin in the ciliary body, thereby reducing the aqueous humor production rate. In cases that are not suitable for surgery and have low visual potential, the traditional transscleral cyclophotocoagulation method, utilizing a continuous-wave diode, is often used (6).

In our study, we showed that regarding demographic data, we found that the mean age was 63.86±13.26, there were seventeen cases (56.7 percent) that were men, and thirteen cases (43.3 percent) were women. The included right laterality eyes were 18 (60 percent), and left laterality eyes were 40 percent. According to glaucoma severity, 2 patients (6.7 percent) were mild, 24 patients (80 percent) were moderate, 3 patients (10 percent) were advanced, and 1 patient (3.3 percent) was in the ending stage.

In accordance with our findings, Chang et al. (7), who intended to assess the (MP-TSCPC) safety and effectiveness as a primary procedure in primary open-angle glaucoma throughout the pandemic of COVID-19, found that the mean age was 65.0 ± 15.8, there were 53.8% males, and 46.2% were females. The included right laterality eyes were 48.1%, left laterality eyes were 36.5%, and bilateral were 15.4%. Regarding glaucoma severity, there were 8.3% mild, 80.0% moderate, 10.0% advanced, and 1.7% end-stage.

In our study, the distribution of IOP in the studied group revealed a significant decrease in IOP throughout the follow-up period.

As well, agreed with de Crom et al. (8), they found that the mean before operation intraocular pressure was 23.5 ± 9.4 millimeters of mercury, and the mean following operation intraocular pressure dropped to 16.8 ± 8.4, 17.0 ± 7.8, and 16.8 ± 9.2 millimeters of mercury, following 12, 18, and 24 months, respectively.

Also, Nguyen et al. (9), who aimed to define their clinical experience with the safety and effectiveness of MP-TSCPC as a management for glaucoma, revealed that the mean before-operation IOP was 25.1 ± 5.3 millimeters of mercury, and the mean following-operation intraocular pressure at twelve months significantly decreased to 17.5 ± 5.1 millimeters of mercury with p value = 0.004.

In our study, we demonstrated that the distribution of intraocular pressure-lowering drugs in the studied group was consistent with a significant decrease in these drugs throughout the monitoring period.

As well, Kuchar et al. (10), who aimed to define their experience with the novel micropulse transscleral cyclophotocoagulation in cases with advanced glaucoma, revealed that the mean number of glaucoma drugs diminished from 2.6 before the operation to 1.9 following the operation.

Furthermore, agreed with Chen et al. (8), they found that the mean number of glaucoma drugs at baseline was 3.8 ± 0.2, and the mean numbers of glaucoma drugs at following operation months three, six, twelve, and twenty-four in successful cases were 2.6 ± 0.7, 2.8 ± 0.6, 2.5 ± 1.4, and 2.6 ± 1.4, correspondingly.

In our study, we showed that regarding the distribution of Log-MAR BCVA at various postoperative time points in the studied group, we revealed that there was no significant improvement throughout the follow-up.

In accordance with our results, Chang et al. (7) reported an insignificant reduction in the mean LogMAR BCDVA from the baseline (0.62 ± 0.40) to one month (0.59 ± 0.45 with p value = 0.703), three months (0.53 ± 0.43 with p value = 0.164), six months (0.56 ± 0.49 with p value = 0.369), nine months (0.59 ± 0.51 with p value = 0.476), or twelve months following operation (0.57 ± 0.51 with p value = 0.365).

Also, agreed with Zaarour et al. (11), they found that the mean CDVA at baseline was 0.86 ± 0.66 log-MAR,

which ranged from 0 to 2.1, and reported that significant reduction in CDVA has been noted only in the short following operation duration up to the 1-month monitoring, while, at the remaining monitoring durations, CDVA is still stable.

As well, agreed with Ariga et al. (12), who aimed to assess the safety and effectiveness of micro-pulse trans-scleral diode laser cyclophotocoagulation in Indian eyes with refractory glaucoma, they reported that visual acuity, in log-MAR, at baseline was 1.38 0.99 ±. At one week, one month, and three months, it was 1.43 ± 0.93 with p value = 0.06, 1.47 ± 0.94 with p value = 0.07, and 1.47 ± 0.96 with p value = 0.10, respectively.

In our investigation, we showed that according to the distribution of complications in the studied group, our results showed that there were 8 patients (26.7%) who had transient mydriasis, 3 patients (10%) who had inflammatory reaction in the anterior chamber, 2 patients (6.7%) who had subconjunctival hemorrhage, 2 patients (6.7%) who had IOP spikes, 2 patients (6.7%) who had cataract progression, 1 patient (3.3%) who had vision loss ≥ 2 lines, 1 patient (3.3%) who had mild hypotony, 3 patients (10%) who had pain during the procedure, and 2 patients (6.7%) who had pain during the early postoperative period.

In supporting our results, Chang et al. (8) found that the complication that is most frequent in their study was transient mydriasis (28.3 percent), followed by inflammatory reaction in the anterior chamber (11.7 percent), pain during the procedure (11.5 percent), subconjunctival bleeding (8.3 percent), intraocular pressure spikes (6.7 percent), cataract progression (6.1 percent), pain during the early postoperative period (5.8 percent), vision loss not less than two lines (1.7 percent), and mild hypotony (1.7 percent).

Also, supported by Preda et al. (13), who aimed to assess the clinical results of micropulse transscleral cyclophotocoagulation in cases of refractory glaucoma, they found that the complications were as follows: three cases of ocular hypotonia PIO less than six millimeters of mercury and five cases had a reduction in their visual acuity; inflammatory reaction of the anterior chamber in thirty cases, but resolved under local anti-inflammatory therapy, 1 line.

Additionally, Youssef et al. (14), who sought to assess the effectiveness and safety of micropulse transscleral diode laser cyclophotocoagulation in reducing intraocular pressure in a variety of glaucoma cases in the Egyptian population, stated that seventy percent of the eyes did not exhibit any following surgery complications. During the initial following surgery duration, 22.5 percent of the eyes exhibited dilated pupils with a loss of accommodation, which resolved spontaneously after one month. Additionally, 2.5 percent of the neovascular glaucoma cases experienced hypotony, 2.5 percent of the eyes experienced hyphema, and 2.5 percent of the eyes had neurotrophic keratitis (NK).

5. Conclusion

We concluded from our study that IOP-lowering medications significantly decreased throughout the follow-up with a modest effect in IOP lowering, and there were no significant complications with no significant improvement throughout the follow-up regarding LogMAR BCVA with a p-value less than 0.001. In cases with mild-to-end-stage 1ry open-angle glaucoma (POAG), MP-TSCPC has been demonstrated to be a primary surgical treatment that is efficacious in reducing the intracranial pressure and drug burden with minimal vision-threatening complications. Although some cases might require re-management to achieve a maintained intraocular pressure-lowering effect, a significant reduction in intraocular pressure may be predicted within one week.

6. Recommendations

More investigations with larger sample sizes are needed to confirm the current results. Further investigations with longer monitoring are needed to assess the safety and efficiency of MP-TSCPC in lowering IOP in cases with 1ry open-angle glaucoma. It is recommended that future investigations be conducted using well-designed randomized controlled trials or large, comparative observational studies.

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