Efficacy of Selective Laser Trabeculoplasty in Primary Angle-Closure Glaucoma: A Randomized Clinical Trial

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IMPORTANCE Selective laser trabeculoplasty (SLT) should be explored as a therapeutic option in eyes with angle closure.

OBJECTIVE To assess the intraocular pressure (IOP)-lowering efficacy of SLT in eyes with primary angle closure (PAC) and PAC glaucoma (PACG).

DESIGN, SETTING, AND PARTICIPANTS Randomized clinical trial at tertiary eye care institutions of 100 patients diagnosed as having PAC or PAC glaucoma in which the angles had opened at least 180° (visible posterior trabecular meshwork on gonioscopy) after laser iridotomy. Recruitment and baseline were completed from June 2009 to April 2012 and 6-month follow-up was completed from December 2009 to November 2012.

INTERVENTIONS Eligible patients with a baseline IOP greater than 21 mm Hg were randomized to either SLT or prostaglandin analog (PGA; travoprost, 0.004%). The SLT was repeated if the IOP reduction was less than 20.0% from baseline at the 1- or 3-month follow-up visit.

MAIN OUTCOMES AND MEASURES The primary outcome measure was the change in IOP from baseline to the final follow-up visit (at 6 months). The frequency of additional postoperative treatments and complications were secondary outcomes.

RESULTS Fifty patients (96 eyes) were randomized to SLT and 50 patients (99 eyes) to PGA medical therapy. At 6 months, 49 patients in the SLT group and 47 in the PGA group completed follow-up. Analysis was based on intent to treat. At 6 months, IOP decreased by 4.0 mm Hg (95% CI, 3.2-4.8) in the SLT group (P < .001) and by 4.2 mm Hg (95% CI, 3.5-4.9) in the PGA group (P < .001). There were no differences between the SLT and PGA groups in the absolute mean reduction of IOP (4.0 vs 4.2 mm Hg, respectively; P = .78) or in the percentage of reduction in IOP (16.9% vs 18.5%, respectively; P = .52). Complete success (IOP ≤21 mm Hg without medications) was achieved in 60.0% eyes of the SLT group, compared with 84.0% of eyes in the PGA group (P = .008). No patients required glaucoma surgery. Additional medications were required in 22.0% of patients in the SLT group compared with 8.0% in the PGA group (P = .05). One patient in the SLT group (2.0%) had a transient posttreatment IOP spike greater than 5 mm Hg. The mean endothelial cell count showed a significant decrease from baseline in the SLT arm (4.8% decrease; P = .001). No other events such as persistent uveitis or increase in peripheral anterior synechiae were noted in eyes that underwent SLT. Two patients in the PGA group exited owing to drug-related complications (1 patient with uveitis and 1 with allergic conjunctivitis).

CONCLUSIONS AND RELEVANCE Eyes with PAC or PACG respond to SLT in the short term, but the overall long-term therapeutic effectiveness needs further evaluation.

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Laser peripheral iridotomy (LPI) is the current first-line treatment for primary angle-closure glaucoma (PACG).1–6 However, data from Singapore found that LPI alone did not prevent most eyes (94%) with PACG from developing a clinically significant increase in intraocular pressure (IOP) on follow-up.7 This was further substantiated by a study in New York, using the same methods as the Singapore study, that found most eyes with established PACG required further treatment to control IOP.8 The current preferred practice pattern to manage increased IOP after LPI is medical therapy first, but long-term medical therapy is fraught with major issues of poor persistence and adherence. A recent report by Quek et al9 documented a dismal persistence rate of 22.5% at 1 year and 11.5% at 3 years for glaucoma monotherapy among a Singaporean cohort of patients with glaucoma. These parameters are likely to be worse in other Asian countries where drug availability, cost, patient education, and awareness are potentially major barriers for effective long-term medical management.

Selective laser trabeculoplasty (SLT) has been used to lower IOP in the management of primary open-angle glaucoma (POAG).10–13 It could offer a new therapeutic option in a select group of patients with PACG whose angles have widened after LPI but who have persistently increased IOP. A prior non-controlled study reported the positive efficacy of SLT in eyes with angle closure.14 The authors reported an IOP reduction efficacy of 3 mm Hg or greater in 67.0% of eyes with PACG at 6 months. Apart from this study, there are no data that establish the therapeutic role and efficacy of SLT in patients with PACG. If SLT is found to be effective in IOP reduction in angle closure, it could potentially lead to reduced rates of medical therapy and help delay surgical intervention.

The purpose of this study was to compare the efficacy of SLT with that of prostaglandin analog (PGA) over 6 months in patients with PACG after LPI in whom the angles had opened at least 180°.

### Methods

The study was a 3-center randomized clinical trial (Singapore National Eye Centre, Singapore; Department of Ophthalmology and Visual Sciences, Chinese University of Hong Kong, Hong Kong; and Jakarta Eye Center, Jakarta, Indonesia). It was conducted in accordance with the principles of the Declaration of Helsinki and had the approval of the ethics committees of the participating hospitals. Written informed consent was obtained from all participants. The lead investigators and examiners at all 3 centers in the trial were glaucoma-trained specialists.

The study population consisted of patients aged 40 years or older with a pre-LPI diagnosis of primary angle closure (PAC) or PACG in whom the angles had opened at least 180° (defined as visible pigmented trabecular meshwork [TM] for ≥180° on gonioscopy in the primary gaze) after LPI. We defined PACG as the presence of glaucomatous optic neuropathy (vertical cup-disc ratio >0.7 and/or neuroretinal rim narrowing) with associated visual field defect on automated perimetry (Swedish interactive thresholding algorithm standard 24-2 program; Humphrey field analyzer II 750i; Carl Zeiss Meditec) if the following were found: (1) glaucoma hemifield test results outside normal limits; (2) a cluster of 3 or more nonedge, contiguous points on the pattern deviation plot, not crossing the horizontal meridian with less than a 5% probability of being present in age-matched healthy individuals (one of which was <1%); and (3) pattern standard deviation less than 0.05. These were repeatable on 2 separate occasions in association with a closed angle before LPI (≥180° of angle in which the posterior TM was not visible on gonioscopy).15 Eyes with PAC had the same gonioscopic features along with peripheral anterior synechiae (PAS) and/or IOP greater than 21 mm Hg, but without glaucomatous optic neuropathy.15

Exclusion criteria were eyes with history of a previous acute angle closure, secondary causes of angle closure such as subluxed lens, uveitis, trauma, and neovascular glaucoma, a vertical cup-disc ratio of 0.9 or greater or visual field constriction involving less than 10° of the central visual field, visual acuity less than 20/40 due to cataract, previous intraocular surgery, laser trabeculoplasty, refractive surgery, or iridoplasty.

At baseline, detailed demographic characteristics and medical history were collected using a standardized questionnaire and all patients underwent a standardized examination that included assessment of best-corrected visual acuity, slit-lamp examination, gonioscopy using a Sussman 4-mirror lens (Ocular Instruments Inc), and dilated evaluation of the fundus with a 78-dioptr lens. Assessments of IOP were performed at 9 AM, 12 PM, and 5 PM (3 consecutive IOP measurements by Goldmann applanation tonometry at each time were documented) and averaged to obtain the mean IOP. Automated perimetry (Swedish interactive thresholding algorithm standard 24-2 program; Humphrey field analyzer II 750i; Carl Zeiss Meditec), central corneal thickness, and corneal endothelial cell counts (ECCs) were also obtained.

Recruitment and baseline were completed from June 2009 to April 2012 and 6-month follow-up was completed from December 2009 to November 2012.

### Randomization, Retreatment, Treatment Modification, and Follow-up

Randomization codes were allocated beforehand in blocks of 4 and placed in sealed envelopes that were opened on the visit day. Based on the code, each patient was randomized to receive either SLT or PGA therapy (travoprost, 0.004%) (Figure 1). All patients requiring bilateral therapy had the same intervention in both eyes.

All eyes requiring SLT were pretreated with brimonidine tartrate, 0.15%, and pilocarpine hydrochloride, 2.0%, prior to the procedure. The SLT procedure was performed under topical anesthesia using the Latina lens (Ocular Instruments Inc); power was initially set at 0.6 mJ and increased in 0.1-mJ steps until small bubbles appeared from the treated area of the TM. Contiguous nonoverlapping shots were placed onto at least 180° of the visible TM, avoiding areas of PAS. More nonoverlapping shots were placed when a greater extent of the trabeculum was visible. The IOP was checked 30 to 60 minutes after the procedure and all IOP spikes of 5 mm Hg or greater were treated with 250 mg of oral acetazolamide if not contraindi-
A standardized regimen of prednisolone acetate, 1.0%, eyedrops 4 times daily was prescribed for 1 week. At 1 week following SLT, the IOP was checked; if it was 28 mm Hg or higher, acetazolamide was administered for 3 more days at a dosage of 250 mg 4 times daily.

If there was less than a 20% reduction of IOP from baseline at either the 1-month or 3-month follow-up visit in the SLT group, SLT was repeated using the same laser parameters as described earlier. Treatment modification was permitted when IOP was uncontrolled (defined as IOP >21 mm Hg) 4 weeks after retreatment with SLT or at any follow-up visit in the group receiving PGA therapy. Provided there were no contraindications, the additional treatments for both groups were administered in the following order: topical timolol maleate, 0.5%, twice daily; dorzolamide hydrochloride, 2%, twice daily; and brimonidine tartrate, 0.15%, twice daily. The schedules of visits and evaluations are documented in eTable 1 in the Supplement.

Outcome Measures
The primary outcome measure was the change in IOP at 6 months compared with baseline. Secondary outcome measures were proportion of eyes with IOP of 21 mm Hg or lower and eyes with more than a 20% reduction in IOP at 6 months. Success was classified as follows: patients with an IOP lower than 21 mm Hg and without any additional IOP-lowering medications at 6 months were categorized as complete success; those with an IOP lower than 21 mm Hg who required IOP-lowering medication were categorized as qualified success. Failure was defined as IOP higher than 21 mm Hg after medications (and repeated SLT in the SLT group) or requiring glaucoma surgery.

Statistical Analysis
Prior evidence indicated an IOP reduction of 7.5 mm Hg with PGA therapy and an IOP reduction of 5.5 mm Hg with SLT in eyes with PACG. To detect a difference of 2.0 mm Hg between the groups (power, 85.0%; SD, ±3.00 mm Hg; α = .05) using a 2-sided 2-sample t test, the estimated sample size was 40 patients per group. Accounting for the loss of follow-up to be about 20%, we estimated a final sample of 50 patients in each arm of the study.

Statistical analysis was performed using the statistical package IBM SPSS Statistics for Windows version 19.0 (IBM Corp). Data from 1 eye per patient were included in the final analysis; for patients in whom both eyes were treated, data from the right eye were used. The analysis was based on intent to treat, and the last-observation-carried-forward method was adopted for patients with missing data. The within-group differences between average baseline IOP and IOP at 6 months after SLT or PGA treatment were compared using the paired t test for continuous variables. Independent t test was used to compare between the groups. For comparison of mean IOP change between the groups, analysis of covariance adjusting for baseline IOP was used. Categorical variables were compared using χ² or Fisher exact test as appropriate. P < .05 was considered statistically significant.

Results
A total of 342 patients were invited to be counseled for the study. Among them, 114 declined participation after the counseling process. Of the remaining 228 patients, 128 failed to meet the inclusion criteria. The final tally resulted in an enrollment of 100 patients in the study (center 1, n = 76; center 2, n = 11; center 3, n = 13); 50 patients (96 eyes) were randomized to SLT and 50 patients (99 eyes) to PGA medical therapy. At 6 months, 49 patients in the SLT group and 47 in the PGA group completed follow-up. The screening, recruitment, and flow of randomization of patients are detailed in Figure 1.
At baseline (Table 1), a higher mean (SD) IOP was found in the SLT group than in the PGA group (23.5 [2.5] vs 22.4 [2.5] mmHg, respectively; \( P = .04 \)). The mean (SD) extent of angle treated by SLT was 322° (58.7°). The mean (SD) energy and number of shots delivered were 90.2 (33.2) mJ and 117.6 (25.6), respectively. Fourteen of 49 eyes (28.6%) received SLT twice.

At 6 months (Table 2), IOP decreased by 4.0 mm Hg (95% CI, 3.2-4.8) in the SLT group (\( P < .001 \)) and by 4.2 mm Hg (95% CI, 3.5-4.9) in the PGA group (\( P < .001 \)). A difference was not identified between the SLT and PGA groups in either the absolute mean reduction of IOP (4.0 vs 4.2 mm Hg, respectively; \( P = .78 \)) or in the percentage of reduction in IOP (16.9% vs 18.5%, respectively; \( P = .52 \)). After adjusting for baseline differences in IOP, the effectiveness of IOP reduction between the 2 groups was not significant (\( P = .17 \)). The mean IOP and change from baseline at all follow-up visits after treatment are shown in Figure 2.

The overall trend reveals similar intraocular pressure lowering between prostaglandin analog and selective laser trabeculoplasty at month 3 and month 6.

The rates of complete success and qualified success are presented in Table 3. Complete success (IOP ≤21 mm Hg with no additional IOP-lowering medication at 6 months) was achieved in 60.0% eyes of the SLT group, compared with 84.0% eyes in the PGA group (\( P = .008 \)). Qualified success (IOP ≤21 mm Hg but requiring additional IOP-lowering medication at 6 months) was achieved in 18.5%, respectively (\( P = .52 \)). After adjusting for baseline differences in IOP, the effectiveness of IOP reduction between the 2 groups was not significant (\( P = .17 \)). The mean IOP and change from baseline at all follow-up visits after treatment are shown in Figure 2.

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Selective Laser Trabeculoplasty in Primary Angle-Closure Glaucoma

Table 3. Success Rate at Final Follow-up at 6 Months

<table>
<thead>
<tr>
<th>IOP</th>
<th>Completea SLT, No. (%)</th>
<th>PGA, No. (%)</th>
<th>P Value</th>
<th>Success SLT, No. (%)</th>
<th>PGA, No. (%)</th>
<th>P Value</th>
<th>Qualifiedb SLT, No. (%)</th>
<th>PGA, No. (%)</th>
<th>P Value</th>
<th>Overall Failurec SLT, No. (%)</th>
<th>PGA, No. (%)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤18 mm Hg</td>
<td>16 (32.0)</td>
<td>24 (48.0)</td>
<td>.10</td>
<td>2 (4.0)</td>
<td>0</td>
<td>.49</td>
<td>32 (64.0)</td>
<td>26 (52.0)</td>
<td>.22</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤21 mm Hg</td>
<td>30 (60.0)</td>
<td>42 (84.0)</td>
<td>.008</td>
<td>9 (18.0)</td>
<td>3 (6.0)</td>
<td>.06</td>
<td>11 (22.0)</td>
<td>5 (10.0)</td>
<td>.10</td>
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Abbreviations: IOP, intraocular pressure; PGA, prostaglandin analog; SLT, selective laser trabeculoplasty.

In a subgroup analysis, the effectiveness outcome was specifically evaluated in eyes with complete success (eTable 2 in the Supplement). No difference was found between the 2 groups in terms of mean reduction, percentage reduction, or proportion of reduction in IOP achieved. Additional medications were required in 22.0% of patients in the SLT group compared with 8.0% in the PGA group (P = .05) (eTable 3 in the Supplement).

As for complications, 1 eye (2.0%) undergoing SLT had a postlaser IOP spike greater than 5 mm Hg, which was controlled with short-term medical therapy (eTable 3 in the Supplement). The mean ECC showed a significant decrease from baseline in the SLT arm (4.8% decrease; P = .001). No other events such as persistent uveitis or increase in PAS were noted in eyes that underwent SLT. Two patients in the PGA group exited owing to drug-related complications (1 patient with acute uveitis and 1 with allergic conjunctivitis from travoprost).

Discussion

To our knowledge, this is the first report of a randomized clinical trial to evaluate the therapeutic potential of SLT in PACG. The results from this study reveal the efficacy of SLT in terms of IOP reduction in eyes with PAC and PACG to be similar to that of PGA for 6 months. We noted that a statistically significant reduction of IOP (approximately 4.0 mm Hg; 17.0%) could be achieved with SLT therapy in eyes with angle closure that have widened angles after LPI. This proportion was comparable to that achieved with PGA therapy (IOP reduction of 4.2 mm Hg; 18.5%). In a study involving patients with angle closure, Ho et al14 also reported a similar IOP reduction of 3.0 mm Hg or greater following SLT. These findings substantiate the potential role of SLT in a subset of angle-closure disease and also open an alternative strategy to manage increased IOP amidst growing concerns of poor adherence, increasing cost, and unsatisfactory quality of life associated with long-term medical therapy.17-23

The biological basis of SLT has been proposed to be a selective photothermolysis targeting the melanin in TM.24,25 This sets off immune and cellular processes that modulate trabecular health and eventually result in an increased outflow through the TM.25 Further, the molecular effects of SLT and PGA on the Schlemm canal TM have been proposed to be similar.26 While all this evidence supports the efficacy of SLT in POAG, the concern is whether the response would be similar in eyes with angle closure. Sihota et al27 recently published their findings on scanning electron microscopy studies performed on TM samples from eyes with chronic angle closure and POAG. They found only subtle differences in the pathological composition of the TM between eyes with chronic PACG (nonsynechial areas) and POAG. The findings were predominantly widening and fusion of adjacent trabecular beams and homogeneous deposit emmeshing the TM tissue. This is an interesting finding and suggests that the status of the TM in eyes with PACG is similar to that in eyes with POAG and thus SLT may likewise be effective in eyes with PACG.

The effectiveness of SLT in POAG is well documented.10-13 Sustained IOP lowering of up to 5 mm Hg has been demonstrated in white and Asian patients with POAG.11,12 Studies have reported an IOP reduction of 30.0% from baseline, and this efficacy is comparable to PGA therapy.13,28 However, our study showed that the overall efficacy of SLT in achieving complete success is slightly suboptimal when compared with PGA therapy (60.0% vs 84.0%, respectively) (Table 3). Possible reasons for this could be inadequate treatment area or a true variation in the way eyes with angle closure respond. In a prospective trial, Nagar et al28 reported that the effectiveness of SLT was greatest with 360° treatment. We analyzed the proportion of eyes that received 360° treatment and found that about 65.0% of eyes in this study received it. However, it would be difficult to treat 360° in all eyes with angle closure; therefore, response and efficacy may never correspond to those achieved in eyes with POAG.

Achievement of controlled IOP from additional interventions in the form of adjunctive medications was marginally higher in the SLT group (but statistically insignificant). No eyes required surgical intervention during the study period. Most prior studies29 report a postlaser IOP spike (>5 mm Hg) that varied between 4.5% and 25.0%; more specifically, the study by Ho et al14 involving eyes with angle closure reported this proportion as 8.3%. Our study noted a rather lower rate of IOP spike (2.0%), which could be attributed to prophylactic use of α-agonist as well as the use of pretreatment pilocarpine. Interestingly, the mean ECC showed a significant decline from baseline in eyes undergoing SLT. Prior reports in eyes with POAG suggest a transient decline in ECC following SLT, with eventual recovery at 1 month.30,31 However, our study has demonstrated a decline of about 5.0% at 6 months. This is a matter of concern and needs long-term evaluation in a larger sample. Possible reasons for a decline in ECC could be the very nature...
of eyes with angle closure, wherein the anterior chamber remains shallow and the angle recess crowded in a significant proportion of eyes despite a patent iridotomy. It would therefore be prudent to document the baseline ECC and follow-up ECC status in this group of patients before embarking on SLT therapy. We did not note any persistent inflammatory sequence following SLT in our study. A major concern would be progression of PAS in this group of eyes with PACG. We specifically evaluated this aspect and noted no change in the extent of PAS 6 months following SLT. This reaffirms its low impact on angle morphology in eyes with angle closure.

Some of the limitations of our study were exclusion of patients with advanced glaucoma and the relatively short follow-up period of 6 months. Furthermore, it would have been ideal if follow-up was done by observers masked to the allocated treatment. However, the use of travoprost (with many patients having signs of ocular hyperemia and eyelash hypertrichosis) precluded us from including a masked protocol for the follow-up evaluation in our study. The strengths of our study, on the other hand, were the multicenter randomized format and the inclusion of Asian patients from 3 countries.

Conclusions

We found that eyes with angle closure that have widened angle recess and increased IOP respond to SLT in the short term, but our data failed to show a difference in the therapeutic effectiveness of SLT when compared with PGA therapy. The role of SLT as a potential therapeutic option in angle-closure disease needs to be explored in the long term.

REFERENCES


