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ARTICLE

Efficacy of selective laser trabeculoplasty in primary angle closure disease

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Abstract

Background To study the role of selective laser trabeculoplasty (SLT) in intraocular pressure (IOP) reduction in post-laser iridotomy primary angle-closure disease patients with inadequately controlled IOP.

Methods In this prospective cross-sectional study, 34 patients with primary angle-closure disease with post-laser iridotomy open angles up to at least 180° were recruited. Following SLT, patients were examined at 1 day, 1 week, 1 and 3 months, 6 months and 1 year post SLT.

Results Data of 34 patients (34 eyes; 8 males and 26 females), with a mean age of 57.80 ± 6.44 years, were analysed. The reduction in IOP at each follow-up visit was significant ($p < 0.001$). The maximum reduction in IOP was noticed on post-laser day 1 and the least reduction was noticed 1 week post laser. Post-SLT range of IOP reduction varied from 9 to 46% at 1 year, which indicates the variability of a response to SLT. Mean IOP in both primary angle closure (PAC) and primary angle closure glaucoma (PACG) groups was comparable at all visits except at post-SLT week 1 when IOP in the PACG group was significantly higher than that in the PAC group ($p = 0.035$). None of the patients complained of pain and/or discomfort or had any clinically significant anterior segment inflammation on any of the follow-up visits. None of the patients underwent repeat SLT or surgery. The mean pre-SLT and post-SLT visual field index at 1-year follow-up was 95.47 ± 3.58 and 95.90 ± 4.13, respectively, which was not significant ($p = 0.84$).

Conclusions High baseline IOP significantly correlated with reduction in IOP. Our results suggest that SLT is a safe, cost-effective modality for reducing IOP in primary angle-closure disease with patent laser iridotomy with a visible trabecular meshwork.

Introduction

Glaucoma refers to a group of conditions characterised by typical changes to the retinal nerve fibre layer and optic nerve head, resulting in the corresponding reduced visual field sensitivity. Data from population-based surveys indicate that 1 in 40 adults older than 40 years have glaucoma with loss of visual function [1]. Primary angle closure glaucoma (PACG) has been shown to result in blindness more frequently than primary open- angle glaucoma (POAG); therefore, it is an important public health issue. Recent reports suggest that the total number of people with PACG worldwide is over 15 million, and that this figure is expected to increase to over 21 million by 2020 [2]. The highest prevalence rates of PACG have been reported in Japan (1.19%) and China (1.10%), followed by Middle East (0.97%), South East Asia (0.66%), and India (0.46%) [3].

Angle-closure glaucoma is commonly asymptomatic, and can lead to irreversible blindness; therefore, proper screening and early management of this disease can be critical. Laser and surgical modalities are used to address the different mechanisms involved in the manifestation of the disease and prevent its progression [4].

Laser peripheral iridotomy (LPI) and/or laser iridoplasty are the primary treatment for angle-closure disease. The EAGLE study has shown that clear lens extraction has

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greater efficacy and was more cost-effective than LPI, and therefore should be considered as an option for first-line treatment [5].

Studies have also shown that medical therapy is often required after LPI for intraocular pressure (IOP) control, but long-term medical therapy is confounded by poor persistence and adherence [6]. Quek et al. [7] documented a persistence of 22.5% at 1 year and 11.5% at 3 years with monotherapy and these parameters are worse in other Asian countries, including India where additional factors like poor availability, affordability, education level and awareness are the major barriers for long-term medication.

Selective laser trabeculoplasty (SLT) has been shown to result in IOP reduction in POAG, pigment dispersion syndrome and pseudo-exfoliation syndrome [8]. SLT has fewer complications compared to surgery, addresses the issue of compliance associated with medications and therefore maybe considered as a cost-effective treatment option in a developing country like India [8, 9]. SLT offers the advantage due to its mechanism where it uses a selective wavelength which specifically targets only the pigmented epithelium of trabecular meshwork. It does not distort the anatomy, so it is repeatable if required. SLT may potentially be a better prospect for the treatment of angle-closure disease, as it induces less inflammatory reaction and thus may be less likely to lead to or exacerbate peripheral anterior synechiae (PAS) formation. Further, post-LPI angle potentially behaves as an open angle in the absence of PAS.

The present study was carried out to study the role of SLT in IOP reduction in post-LPI primary angle-closure disease patients with inadequately controlled IOP. To the best of our knowledge, no previous study has been conducted in a North Indian population with primary angle closure (PAC)/PACG. Limited studies have been done regarding SLT as an adjunctive treatment modality for angle-closure disease patients worldwide [10–12].

Methods

In this prospective, cross-sectional study, patients were recruited in a non-controlled manner at a tertiary eye care centre in North India (Glaucoma Services, Advanced Eye Centre, Post Graduate Institute of Medical Education and Research, Chandigarh, India) spanning a period of 27 months from July 2013 to October 2015. The study was conducted in accordance with the tenets of the Declaration of Helsinki and was approved by the Institutional ethical board. Written informed consent was obtained from all the participants prior to enrolment.

Inclusion criteria

The study population included Asian Indian patients of either sex, aged 40 years or older with pre-LPI diagnosis of PAC or PACG in whom the angle opened up to at least 180° following LPI (defined as a visible pigmented trabecular meshwork for ≥180° on gonioscopy in primary gaze).

As per the International Society Geographical and Epidemiological Ophthalmology classification [13], primary angle-closure disease can be classified as

- *Primary angle closure suspects (PACS)* if an appositional contact was present between the peripheral iris and posterior trabecular meshwork and more than 270° of posterior trabecular meshwork could not be visualised.
- *Primary angle closure (PAC)* patients had an eye with occludable drainage angle, that is, the posterior (usually pigmented) trabecular meshwork is seen for <90° of angle circumference and features, indicating that trabecular obstruction by the peripheral iris has occurred, such as PAS, elevated IOP, iris whorling, 'glaucomfleken' lens opacities or excessive pigment deposition on the trabecular surface, with no optic nerve head changes.
- *Primary angle closure glaucoma (PACG)* was labelled if disc and field changes were present with PAC (appositional or synechial) as defined above, that is, a vertical cup-to-disc ratio (VCDR) of 0.7 or greater or asymmetry between the right and left VCDRs of 0.2 or more, and a visual field defect consistent with glaucoma. If the media opacities obscured optic disc assessment, then an IOP >26 mm Hg and visual acuity worse than 20/400, or evidence of previous glaucoma-filtering surgery was considered. The VCDR and IOP criteria described above were based on the 97.5th and 99.5th percentiles for 'hypernormals' in surveys described by Foster et al. [13].

All enroled subjects had patent peripheral laser iridotomy, IOP >21 mm Hg and <30 mm Hg at baseline evaluation, gonioscopically visible pigmented TM for at least 180° and were willing for follow-up to at least 6 months. In all eyes except two eyes, an indentation angle could be opened up to 360°.

For patients on antiglaucoma treatment, a washout period of at least 2 weeks for β-blockers and 4 weeks for prostaglandin analogues was given prior to SLT. All patients were given the option of medical treatment, SLT or surgical intervention (clear lens extraction), and the expected outcome of all was explained, and the decision to undergo SLT was left to patient preference.

Exclusion criteria

Patients with media opacities, retinal and macular diseases, secondary angle-closure glaucoma, advanced glaucomatous optic neuropathy (cup: disc ratio >0.9 or advanced visual field defects threatening fixation), previous Argon Laser Trabeculoplasty (ALT), surgical or non-surgical trauma were excluded. None of the patients had a history of an acute attack of angle closure or had undergone phacoemulsification.

Minimal criteria for labelling a glaucomatous visual field defect were as follows: glaucoma hemifield test outside normal limits, PSD with p values <5% or a cluster of three or more points in the pattern deviation plot in a single hemifield with p values <5%, one of which must have a p value <1%. Any one of the preceding criteria, if found again on repeat testing on two tests within 1 month, was considered sufficient evidence of a glaucomatous visual field defect. Visual fields were done for patients with best-corrected visual acuity (BCVA) of 20/200 or better. Advanced field defects were defined as mean deviation > −12 dB, and on a pattern deviation plot, points below 5% between 37 and 55 with points below 1% were ranging from 19 to 36 [14].

All patients were subjected to a detailed ophthalmological examination, including BCVA with refraction, detailed slit-lamp examination, IOP measurement by Goldman applanation tonometry (GAT; in mm Hg), gonioscopy (using Zeiss four-mirror and the modified Schaffer classification) [15] in primary gaze, detailed stereoscopic examination of fundus with +90 D lens (Volk lens), central corneal thickness, disc picture, spectral domain ocular coherence tomography (Cirrus-OCT) and visual field testing using the Swedish interactive thresholding algorithm (SITA) standard programme 24-2 on Humphrey Field analyser (Humphrey® Field Analyser/ HFA™ II-*i* Series).

Only one eye was included for analysis. All eyes were treated with Pilocarpine (2%) eye drops two times at an interval of 15 min instilled 2 h prior to the procedure, followed by a drop of Brimonidine (2 mg/mL) 30 min before SLT and a drop of topical anaesthesia (Proparacaine 0.05%) immediately before the procedure. Latina lens (Ocular Instruments Inc., Bellevue, WA, USA) with a coupling agent (carboxymethyl cellulose 1%) was placed on the cornea. The aiming beam was focused on the trabecular meshwork. During SLT, a standardised spot size of 400 µm and a duration of 3 ns was used. Energy was variable from 0.6 to 1.2 mJ. Starting at a minimum of 0.6 mJ, energy was increased in increments of 0.1 mJ until champagne-like bubbles were visible, which demonstrated the threshold energy. Following this, energy was decreased by 0.1 mJ, and at least 100 spots were applied to cover 360° of the trabecular meshwork. Spots were placed contiguous, confluent and non-overlapping.

All patients were treated with 360° of a trabecular meshwork in a single sitting except two eyes where only 180° were treated.

Following SLT, patients were managed with need-based oral analgesics. Ocular examination was done at 1 day, 1 week, 1 and 3 months, 6 months and 1 year post SLT, which included BCVA, IOP (GAT in mmHg), slit- lamp examination and a visual field (baseline and at 1 year).

Statistical analysis

Considering the power to be 90%, and an α-value of 0.05 and a dropout rate of 10%, SD of 5 mm Hg, 34 patients was recruited. Quantitative data were described as mean ± SD for most of the parameters. The statistical analysis was carried out using Statistical Package for Social Sciences (SPSS 20.0 for Windows). The effect of the intervention SLT was analysed using Student's t test (paired) for normally distributed data. Repeated-measure analysis of variance was also being performed to find the trend in the measurable data like VA and IOP. Qualitative or categorical data were described as frequencies and proportions and analysed for its changes pre-SLT to post SLT (from visit to visit) using McNemar test for significance of changes. The data were also graphically presented by bar diagrams and line diagrams to show the IOP trends at each visit post SLT. A p value <0.05 was considered significant in all the tests.

Results

Thirty-six patients were assessed for eligibility, but two refused to be a part of the study; therefore, data of 34 patients (34 eyes), only the right eye per person were analysed. There were 8 male and 26 female patients, with a mean age of 57.80 ± 6.44 years. The age varied from 44 to 70 years and maximum subjects were in the age group between 50 and 60 years. The baseline IOP in males was 23.50 ± 1.77 mm Hg, while in females, it was 23.84 ± 1.95 mm Hg and the difference was not statistically significant. Out of 34 patients, 23 (67.6%) were PAC and 11 were PACG. All the subjects had brown irides.

The difference in pre-laser and post-laser IOP between males and females was not significant except at 3 months; however, the groups were not sex-matched. So, the results indicated that age and sex were independent parameters.

The mean baseline IOP and post-SLT IOP at each study visit for the enroled subjects are elucidated in Table 1. The reduction in IOP at each follow-up visit was significant ($p <$ 0.001). The maximum reduction in IOP was noticed on post-laser day 1 and the least reduction was noticed on post-

Table 1 Mean baseline IOP, IOP reduction and percentage of IOP reduction compared to baseline at each follow-up visit

Follow-up time	Number of patients	Mean ± SD (mm Hg)	IOP range (mm Hg)	IOP reduction (mean ± SD)	IOP reduction (%)	*p* Value
Baseline	34	23.76 ± 1.92	22–28			
Day 1	34	16.00 ± 2.74	10–20	7.76 ± 3.9	32.65	<0.001
1 week	33	19.76 ± 4.68	10–34	4.00 ± 4.79	16.83	<0.001
1 month	33	18.67 ± 2.27	12–24	5.09 ± 2.78	21.42	<0.001
3 months	33	19.09 ± 2.29	14–26	4.66 ± 2.94	19.61	<0.001
6 months	33	18.42 ± 2.16	14–22	5.33 ± 2.67	22.43	<0.001
1 year	28	16.964 ± 2.828	14–22	6.821 ± 3.495	28.70	<0.001

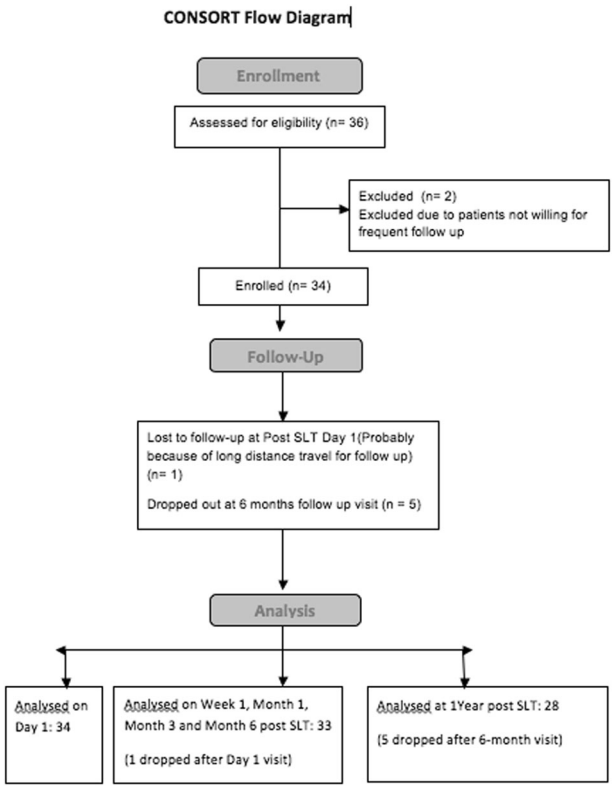

Fig. 1 CONSORT flow diagram detailing the phases of the study

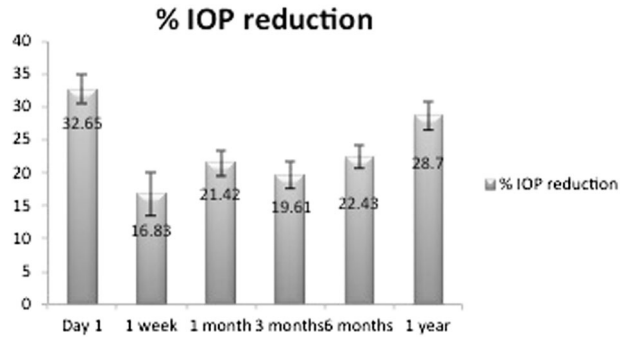

Fig. 2 Bar diagram showing the percentage of IOP reduction at each follow-up visit

laser 1 week. Figure 1 is the CONSORT flow diagram detailing the phases of the study. Figure 2 shows the percentage reduction of IOP in each follow-up from the baseline.

On comparing PACG and PAC subgroup's baseline with post-SLT year 1 IOP, it was noted that high baseline IOP was the primary factor which correlated with maximum reduction in IOP (Fig. 3a, b). The success rate of SLT is shown in Table 2. At 6 months follow-up, an absolute reduction of ≥4 mm Hg with additional antiglaucoma medications (single topical antiglaucoma drug was added in four patients) was achieved in 84.84% of eyes, and in 82.15% (1–2 drugs in seven eyes) at 1-year follow-up. The same amount of IOP reduction was achieved in 72.72% eyes without any antiglaucoma medication at 6 months, whereas this figure reduced to 57.14% at the end of 1-year follow-up. At 1 year, 46.42% eyes achieved ≥6 mm Hg IOP reduction without any IOP-lowering drugs, whereas 67.85% eyes required additional topical drugs (average 1.5). Twenty percent or more reduction in IOP without any antiglaucoma medication was achieved in 51.51% of eyes at 6 months and 46.42% at 1 year. During 1-year follow-up, 7 (25%) out of 28 eyes required additional drugs (average 1.5 drugs) to achieve their preset lower mid-teen target IOP, even though they achieved significant reduction with SLT alone. With additional drugs, these patients achieved 25–50% IOP reduction. Some patients achieved even better IOP reduction than their 6-month IOP value. The effectiveness of SLT (the range of IOP reduction) varied from 9 to 46% at 1 year, which indicates the variability of a response to SLT.

The mean IOP in both PAC and PACG groups was comparable at all visits except at post-SLT week 1 when IOP in the PACG group was significantly higher than the PAC group ($p = 0.035$).

None of the patients complained of pain and/or discomfort on the first day post SLT. No patient had any clinically significant anterior segment inflammation on any of the follow-up visits (cells 1+ or more according to Standardisation of Uveitis Nomenclature, SUN classification) [16]. No eyes developed hypotony during any of the follow-up visits. Out of 34 patients, four patients (11.7%)

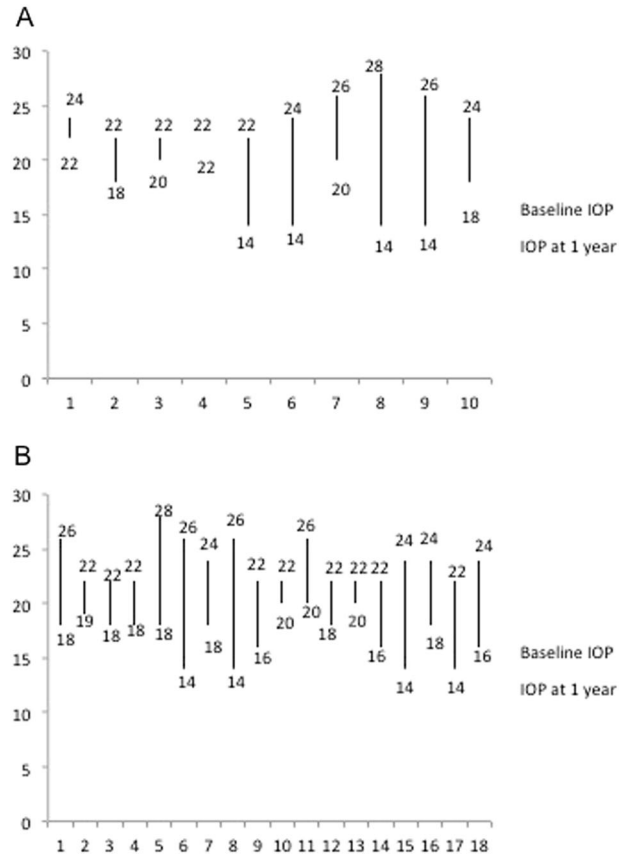

Fig. 3 **a** Line diagram showing the baseline IOP and final IOP of the PACG subgroup. **b** Line diagram showing the baseline IOP and final IOP of the PAC subgroup

Table 2 Success rate of SLT

	At 6 months ($n = 33$)		At 1 year ($n = 28$)	
	n (% eyes) (with medicines)	*n* (% eyes) (without medicines)	*n* (% eyes) (with medicines)	*n* (% eyes) (without medicines)
IOP reduction				
≥4 mm Hg	28 (84.84)	24 (72.72)	23 (82.15)	16 (57.14)
≥6 mm Hg	19 (57.57)	16 (48.48)	19 (67.85)	13 (46.42)
≥20%	20 (60.60)	17 (51.51)	19 (67.85)	13 (46.42)
≥25%	14 (42.42)	12 (36.36)	18 (64.28)	11 (39.28)
IOP				
<12 mm Hg	–	–	–	–
12–15 mm Hg	2 (6.00)	3 (9.00)	4 (14.28)	10 (35.70)
16–18 mm Hg	15 (45.45)	17 (51.52)	7 (25.00)	11 (39.28)
19–21 mm Hg	10 (30.30)	10 (30.30)	6 (21.43)	6 (21.42)
>21 mm Hg	2 (6.00)	3 (9.00)	1 (3.60)	1 (3.60)

IOP intraocular pressure

had high IOP at 1 week post SLT, which was controlled with topical drugs. One patient was lost to follow-up after day 1 post SLT visit and five patients dropped out after 6 months post SLT visit. None of the patients underwent repeat SLT or surgery. The mean pre-SLT and post-SLT visual field index at 1-year follow-up was 95.47 ± 3.58 and 95.90 ± 4.13, respectively, which was not significant ($p = 0.84$).

Discussion

Primary angle-closure disease is a major cause of irreversible bilateral blindness in Asian population. SLT is emerging as a treatment modality not only for open angle but also for primary angle-closure disease patients. SLT addresses the issues of non-compliance and economic burden as the procedure is repeatable, avoids systemic adverse effects of medications, surgical complications and psychological trauma. It can be safely used in patients who are allergic to medications, pregnant women, systemically unstable patients who are unfit for surgery and patients not willing for surgery.

It is hypothesised that SLT will work in post-LPI–PAC/PACG eyes as similarities exist between PACG and POAG on an electron microscopy level such as the presence of pigment granules in trabecular cells, deposits of amorphous material in the extracellular matrix with occasional fusion of trabecular beams and changes in the endothelium of the Schlemm canal [17]. Therefore, we planned this study to find the efficacy and safety of SLT for primary angle-closure disease in the Indian population.

We treated 360° of a trabecular meshwork in a single sitting in all eyes except two eyes where only 180° were treated. The average energy used 0.56 mJ with an average number of 128 spots. Various treatment protocols have been described in literature varying from 90° to 360° treatment [18–20].

Nagar et al. [21] have shown an IOP reduction of >20% in 34% of eyes treated with 90°, 65% with 180° and 82% with 360° in POAG patients. Ho et al. [9] reported IOP reduction by 3 mm Hg or more in 67% patients at 6 months, while Narayanaswamy et al. [11] reported a reduction of 4 mm Hg at 6 months. Ali Aljasim et al. [12] reported that a clinically significant IOP reduction of 20% or more from the baseline, or discontinuation of one or more of glaucoma medications was seen in 84.7% patients in the PAC/PACG group and 79.6% in the POAG group ($p = 0.47$). In their study, 59% in the PAC/PACG group and 85% in the POAG group had 360° treatment, with 74 and 78 shots at 0.53 and 0.62 mJ per laser application, respectively [12]. Our study and the study by Ali Aljasim et al. [12] had atleast 180° of visible treatment for SLT, while in the study by Ho et al. [10], some of the eyes had only 90° visible TM.

In our patients, we did not use any anti-inflammatory medications in the post-laser regimen. At present, there is

no consensus as regards the use of steroidal or non-steroidal anti-inflammatory agents. Topical steroids have been used to counter the post-SLT anterior segment inflammation. The most accepted mechanism of SLT includes 'Biological Theory' [20, 22] in which there is an increase in the recruitment of macrophages in the trabecular meshwork due to the release of cytokines, which causes remodelling of the extracellular matrix, allowing increased aqueous outflow from the eye and leads to reduction in IOP [22]. Therefore, it is believed that the use of anti-inflammatory therapy may compromise the decrease in IOP-lowering efficacy of SLT as proposed by Alvarado et al. [23]. Unlike our study, Narayanswamy et al. [11] prescribed topical prednisolone acetate 1.0% eyedrops four times daily for 1 week post SLT.

Various adverse effects following SLT are documented in the literature which includes a transient IOP spike, anterior chamber inflammation, ocular pain or discomfort, photophobia, conjunctival hyperaemia, increase in pre-existing peripheral anterior synechiae, severe iritis and choroidal effusion, hyphaema, transient corneal haze and cystoid macular oedema [24]. In the present study, SLT did not produce clinically significant inflammation, even when the eyes were treated for 360°. Our results agree with other authors who have reported no significant difference in anterior chamber inflammation before or after SLT measured clinically with a slit lamp as well as objectively with the laser flare metre [25].

None of our patients had ocular discomfort following SLT in the immediate post-laser days. Nagar and coworkers [21] reported a rate of 39% discomfort in eyes undergoing 360° SLT. Latina et al. [26] reported that 15% of eyes receiving SLT reported discomfort after the procedure.

In our study, out of 34 patients, only four patients (11.76%) had an IOP spike (4.74 mm Hg) at the end of 1 week which was successfully managed with topical antiglaucoma medications. No plausible reason can explain this 1-week post-SLT IOP spike, as the clinical examination was unremarkable. Previous studies reported a post-laser IOP spike (>5 mm Hg) that varied between 4.5 and 25%. In eyes with angle closure, Ho et al. [10] have reported an IOP spike in 8.3% subjects. Narayanaswamy et al. [11] showed a lower rate of an IOP spike (2.0%), which could be attributed to prophylactic use of the α-agonist as well as the use of pre-treatment pilocarpine. Ali Aljasim et al. [12] reported an IOP spike in 10% ($n = 6$) of patients in PACG/PAC and 5% ($n = 3$) in POAG, which was controlled with topical medications ($p = 0.49$).

In the present study, just under half of patients (46.4%) achieved more than 6 mm Hg of IOP lowering without any antiglaucoma drops even 12 months post laser. This illustrates the potential cost savings of the technique for patients who would otherwise need to pay for their medication.

The visual fields remained relatively stable during the course of follow-up. A few patients showed improvement in their visual field indices, which could be due to their initial learning curve. The follow-up of 12 months was, however, not sufficient to comment on the ability of SLT in halting visual field progression.

The limitations of the study include a small sample size and a limited follow-up period. Future studies with a larger sample size and having a longer follow-up are needed to demonstrate the efficacy, repeatability and to look for adverse effects/complications of SLT. To conclude, our results suggest that SLT is a safe and effective modality for reducing IOP in primary angle-closure disease with patent laser iridotomy with a visible trabecular meshwork.

Summary

What was known before

- SLT works for open-angle glaucoma.
- Limited literature existed regarding SLT as an adjunctive treatment modality for angle-closure disease patients worldwide, but no literature for SLT in Indian eyes with primary angle-closure disease.

What this study adds

- SLT is a safe and effective modality for reducing IOP in primary angle-closure disease with patent laser iridotomy with a visible trabecular meshwork, in Indian patients where additional factors like poor availability, affordability, education level and awareness are the major barriers for long-term medication.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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