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Original Article

Ophthalmology Section

Change in Intraocular Pressure after Selective Laser Trabeculoplasty in North Indian Primary Open Angle Glaucoma Patients: A Prospective Analytical Study

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ABSTRACT

Introduction: Glaucoma is the second leading cause of blindness in the world. The only known modifiable risk factor for the onset and progression of glaucoma is Intraocular Pressure (IOP). There are a limited number of studies documenting the IOP-lowering effect of Selective Laser Trabeculoplasty (SLT) in Primary Open Angle Glaucoma (POAG) patients, especially within the North Indian population. Understanding the effect of SLT on IOP reduction in this population is crucial for the proper management of glaucoma patients.

Aim: To study the IOP-lowering effect of SLT in North Indian POAG patients (who had not achieved target IOP on two or more antiglaucoma drugs) after a period of six months.

Materials and Methods: A hospital-based, single-arm, pre-post type of prospective analytical study was conducted at Lady Hardinge Medical College and associated hospitals in New Delhi, India, from January 2021 to June 2022. POAG patients aged 18 years or older, who had not achieved the target IOP while on two or more Antiglaucoma Medications (AGM), were given the option of treatment with SLT. A total of 33 eyes were considered for the study as per sample size calculations. Pre-SLT, IOP was recorded along with other baseline parameters. The SLT procedure was carried out according to the standard protocol. IOP was recorded during follow-ups at one week, one month, three months, and six months. The Friedman test was used to compare IOP values, with a significance level set at 0.05. Spearman correlation was employed to explore the correlation between baseline IOP and the change in IOP at six months.

Results: A total of 33 eyes were included in the study. Of these, 28 (84.8%) eyes had advanced glaucoma, while 5 (15.2%) eyes had moderate glaucoma according to International Classification of Diseases, Tenth Revision (ICD-10) staging. Patients were on two or more commonly used AGMs, including prostaglandin analogues, beta blockers, alpha agonists, topical carbonic anhydrase inhibitors, and rho kinase inhibitors. The mean number of topical AGMs that patients were using was 3.03. The number and type of AGMs for each patient remained consistent pre and post-SLT throughout the study period. The mean IOP (baseline) was 16.39±2.73 mmHg, and after six months, the mean IOP was 13.86±1.99 mmHg. The mean IOP reduced by 2.53 mm Hg (15.44%). There was a strong negative correlation between baseline IOP and the change in IOP at six months, which was statistically significant (rho=-0.78, p-value <0.001).

Conclusion: The present study indicates that SLT can be considered an adjunctive treatment for lowering IOP in North Indian POAG patients. A strong negative correlation was found between baseline IOP and IOP at six months post-SLT, suggesting that a higher reduction can be expected in patients with elevated baseline IOP.

Keywords: Applanation tonometry, Staging of glaucoma, Target, Trabecular meshwork, Visual field

INTRODUCTION

Glaucoma is a chronic progressive optic neuropathy caused by a group of ocular conditions that leads to the depletion of retinal ganglion cells, resulting in the loss of corresponding visual fields [1]. It is the second leading cause of blindness in the world. Prevalence of glaucoma expected to increase to 111.8 million by 2040 [2]. In India, glaucoma is estimated to affect 12 million people and is responsible for 12.8% of total blindness in the country [3].

POAG is the most common type of glaucoma [4]. POAG is characterised by an open anterior chamber angle, and the disease is generally bilateral. In POAG, there is a depletion of retinal ganglion cells along with characteristic morphological changes in the optic nerve head and Retinal Nerve Fibre Layer (RNFL), as well as associated visual field changes, occurring in the absence of underlying ocular diseases or congenital anomalies [5].

The only known modifiable risk factor for the onset and progression of glaucoma is IOP [6]. There are several methods to control IOP; laser trabeculoplasty is usually indicated when the target IOP is not achieved with maximal medical therapy (using one medication from each available class of AGMs), in cases where patients are non compliant with their medications, or when intolerable side-effects occur due to the medications. Additionally, laser trabeculoplasty can help reduce financial burdens by decreasing the number of AGMs needed, which in turn reduces the number of hospital visits in the long run [7]. Furthermore, laser trabeculoplasty minimises systemic and local side-effects as well as chronic inflammation associated with AGMs [8-11]. Therefore, laser trabeculoplasty is also beneficial in increasing the success rate of any future filtration surgeries compared to medications [12].

SLT selectively targets pigmented cells of the trabecular meshwork without causing thermal or collateral damage to non pigmented cells, generally without producing any gonioscopically observable permanent changes in the angle structures post-SLT [13,14]. In SLT, a 532 nm Q-switched, frequency-doubled neodymium: Yttrium-Aluminum-Garnet (Nd:YAG) laser is used. The phagocytic action of activated macrophages and the release of cytokines lead to changes in the trabecular meshwork and Schlemm's canal, ultimately increasing the outflow of aqueous humour and resulting in decreased IOP [14].

There are a limited number of studies documenting the IOP-lowering effect of SLT. A thorough search of the literature reveals only a few studies from India on this topic, with even fewer published from northern India [15-18]. As SLT has become one of the main modalities in the management of glaucoma, understanding its IOP-lowering effect in our population is crucial for planning various interventions to achieve target IOP levels in glaucoma patients. Keeping this in mind, this study was planned and aimed to study the IOP-lowering effect of SLT in North Indian patients with POAG who have not achieved the target IOP on two or more AGMs after a period of six months.

Null hypothesis: SLT has no significant effect on lowering IOP at the end of a six month follow-up in patients with POAG.

Alternate hypothesis: SLT causes a reduction in IOP at the end of a six month follow-up period in patients with POAG.

MATERIALS AND METHODS

A hospital-based, single-arm, pre-post type prospective analytical study was conducted at Lady Hardinge Medical College and associated hospitals in New Delhi, India, from January 2021 to June 2022. The study was carried out after obtaining clearance from the Institutional Ethics Committee (Institutional Ethics Committee approval letter no. LHMC/IEC/2020/PG Thesis/88 dated 29-12-2020). The research adhered to the Declaration of Helsinki and involved obtaining proper informed consent from all participants.

Glaucoma severity was classified according to the staging of glaucoma as per the International Classification of Diseases, Tenth Revision (ICD-10) [19]. The target IOP for each glaucoma patient visiting the glaucoma clinic was calculated based on the recommendations of the Glaucoma Research Facility and Clinical Services at Dr. Rajendra Prasad Centre (RPC) for Ophthalmic Sciences, All India Institute of Medical Sciences (AIIMS), New Delhi [20].

Inclusion criteria: POAG patients aged 18 years or older, who had not achieved the target IOP on two or more AGMs for at least one month of treatment, were given the option of treatment with SLT. Patients who provided their informed consent for SLT and for participation in the study were included in the study.

Exclusion criteria: Patients with traumatic glaucoma, neovascular glaucoma, uveitic glaucoma, those who had failed to complete at least one week of follow-up, eyes with a history of filtration surgeries including trabeculectomy or glaucoma drainage device implantation, and eyes that had previously undergone SLT were excluded from the study.

Sample size: The sample size was calculated as follows: the mean IOP in North Indian open-angle glaucoma patients, as reported in a previous study, was 24.62 mm Hg, with a standard deviation of 6.38 [15]. The effect size (E) was taken as 20% of the mean, which amounts to 4.92. The standardised effect was calculated as (E/S)=4.92/6.38=0.77. A two-sided alpha was set at 0.05, and beta was set at 0.20. Using tables for sample size calculation for comparing means of continuous variables, a sample size of 26 was determined. Considering an attrition rate of 20%, the sample size was increased by a factor of 1/(1-0.20)=1.25. Therefore, the final sample size was calculated to be (26×1.25=32.5), which was rounded up to 33 eyes for the study.

Study Procedure

A complete history was taken after explaining the study plan to each patient. Every participant underwent a routine general physical examination and a comprehensive ophthalmic evaluation.

The age of the patient, gender, type of glaucoma, number and duration of AGMs, Best Corrected Visual Acuity (BCVA), IOP in Both Eyes (BE) using the gold standard method of Goldmann Applanation Tonometry (GAT), gonioscopy findings, and lens status prior to SLT were documented. The minimum fall in IOP post-SLT required to define success was specified as a decrease of ≥ 20% from pre-SLT values without any further addition of IOP-lowering medications or surgery [16,21].

Brimonidine (0.2%) eye drops were instilled 15 minutes prior to the procedure, followed by Proparacaine eye drops five minutes before the SLT. A frequency-doubled (532-nm) Q-switched Nd:YAG laser machine from Appasamy Associates (Model: 507) was used. All procedures were performed by a single glaucoma specialist. The starting laser energy was set at 0.8 mJ, with adjustments made based on the reaction observed. Fixed laser settings included a spot size of 400 µm and a pulse duration of three nanoseconds, with treatment applied to a 360° angle. SLT parameters, such as energy used and the number of shots administered, were documented. IOP was measured one hour after the procedure to document any immediate IOP spike. After the procedure, Loteprednol (0.5%) eye drops were added four times daily for one week, along with the continued AGMs. IOP (using GAT) and compliance with AGM use were recorded at follow-up visits at one week, one month, three months, and six months. The number and type of AGMs for each patient remained unchanged pre- and post-SLT throughout the entire study period. SLT was performed alongside continued AGMs with the aim of achieving the target IOP.

STATISTICAL ANALYSIS

The assessment of changes in IOP over time was conducted using the Friedman test. Post-hoc pairwise tests for the Friedman test were performed using the Nemenyi test method for p-value correction. The level of significance was set at 0.05. Spearman correlation was used to explore the relationship between baseline IOP and the change in IOP after six months.

RESULTS

A total of 19 POAG patients (33 eyes) were included in the study, of which 14 (73.7%) were male and 5 (26.3%) were female. The mean age of all participants was 59.89±7.94 years. Out of the 19 patients, BE of 14 (73.7%) patients, only the Right Eye (RE) of 2 (10.5%) patients, and only the Left Eye (LE) of 3 (15.8%) patients met the inclusion criteria and were included in the study. Baseline details about the ocular examination are summarised in [Table/Fig-1]. Patients were on an average of 3.03 (0.85) topical AGM, both pre and post-SLT, during the entire study period. The patients were on two or more commonly used AGMs, which included prostaglandin analogues, beta blockers, alpha agonists, topical carbonic anhydrase inhibitors, and rho kinase inhibitors. The number and type of antiglaucoma medications for each patient remained the same both pre and post-SLT throughout the study period. According to the ICD-10, 28 eyes were classified

Ocular examination	Frequency %
Best corrected visual acuity	
<6/60	16 (48.5)
6/60-6/24	1 (3.0)
6/18-6/12	16 (48.5)
6/9-6/6	0
Lens status	
Normal	11 (33.3)
IMSC (Immature Senile Cataract)	12 (36.4)
Pseudo-phakia (Posterior Chamber IOL)	10 (30.3)
Mean central corneal thickness (µm)	521.30±30.29 (441.00-570.00)
International classification of diseases 10 staging	
Advanced	28 (84.8%)
Moderate	5 (15.2%)

[Table/Fig-1]: Base line ocular examination.

as being in the advanced stage, and five eyes were in the moderate stage. The cup-to-disc ratio of the eyes ranged from 0.7 to 0.9. The Mean Deviation (MD) of the visual fields was -9.13±2.89. As per the recommendations of the glaucoma research facility and clinical services at the Dr. Rajendra Prasad Centre for Ophthalmic Sciences, All India Institute of Medical Sciences (AIIMS), New Delhi, the target IOP for the advanced group was set at 10 to 12 mm Hg, while the target IOP for the moderate group was set at 12 to 15 mm Hg. A total of 16 patients (28 eyes) completed the final six months of the follow-up period.

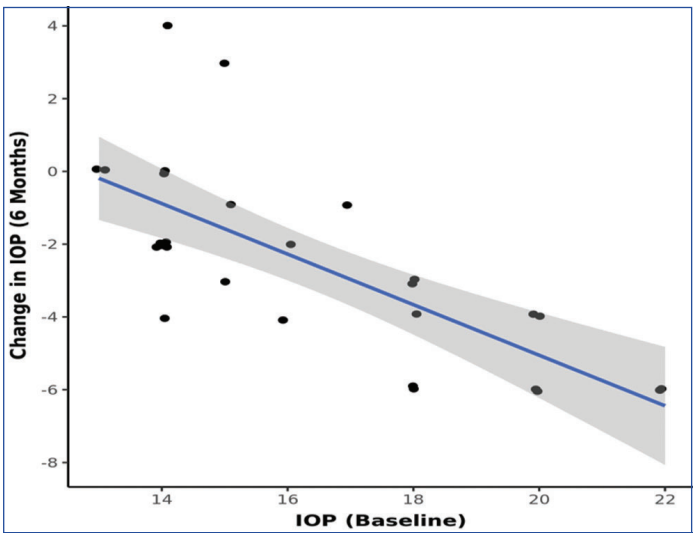
The mean IOP decreased from a maximum of 16.39 mm Hg at the baseline time point to a minimum of 13.86 mm Hg at the six-month time point. This change was statistically significant (Friedman Test: χ^2=26.3, p-value <0.001) [Table/Fig-2].

Timepoint	IOP			Friedman test	
	Mean±SD	Median (IQR)	Range	χ^2	p-value
Baseline	16.39±2.73	15.00 (4.00)	13.00-22.00	26.3	<0.001
One hour	15.15±3.94	14.00 (6.00)	10.00-24.00		
One week	14.76±2.56	14.00 (4.00)	12.00-20.00		
One month	13.94±2.81	14.00 (4.00)	8.00-18.00		
Three months	13.91±1.86	14.00 (4.00)	10.00-18.00		
Six months	13.86±1.99	14.00 (3.25)	10.00-18.00		

[Table/Fig-2]: Assessment of change in IOP over time (n=28).

The minimum reduction in IOP post-SLT required to define success was set at a ≥20% reduction of pre-SLT values, without any further addition of IOP-lowering medications or surgery. This criterion was achieved in 42.9% of eyes at the end of six months. The number and type of AGM for each patient remained the same before and after SLT throughout the entire study period.

There was a strong negative correlation between IOP at baseline and the change in IOP at six months [Table/Fig-3], and this correlation was statistically significant (rho=-0.78, p-value <0.001) [Table/Fig-4]. For every one-unit increase in IOP at baseline, the IOP at six months decreased by 0.69 units. Conversely, for every one-unit increase in IOP at six months, the IOP at baseline decreased by 0.77 units.

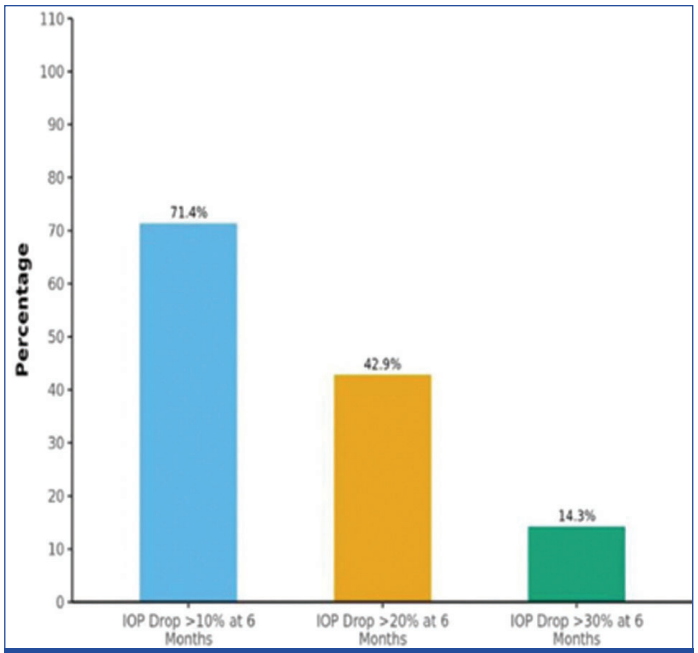


[Table/Fig-3]: Scatterplot depicting the correlation between IOP (Baseline) and change in IOP (six months).
*Individual points represent individual cases. The blue trend line represents the general trend of correlation between the two variables

Correlation	Spearman correlation coefficient	p-value
IOP (Baseline) vs Change in IOP (six Months)	-0.78	<0.001

[Table/Fig-4]: Correlation between IOP (baseline) and change in IOP (six months).
*Spearman Correlation was used to explore the correlation between the two variables. There was a strong negative correlation between IOP (Baseline) and Change in IOP (6 Months), and this correlation was statistically significant (rho=-0.78, p=<0.001)

The IOP differed significantly from the baseline time point at the following time points: one month, three months, and six months. The maximum change from the baseline time point was observed at the six-month time point [Table/Fig-2,5]. Fifty percent (14) of the eyes achieved target IOP with SLT at the six-month follow-up, while the remaining 50% (14) did not achieve the target IOP. Vision remained stable in all eyes at all follow-ups.



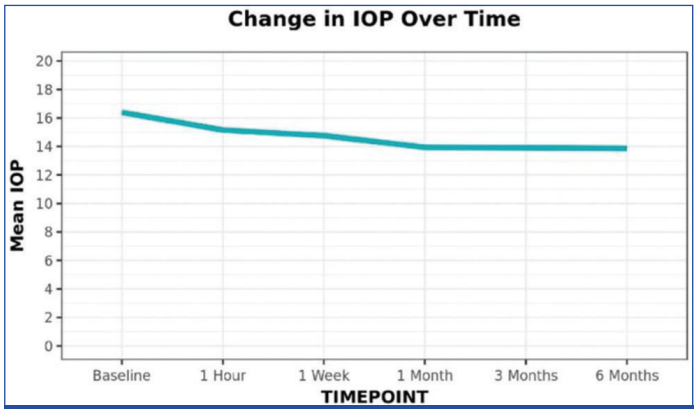
[Table/Fig-5]: Histogram showing IOP drop after six months.

Post-hoc pairwise tests for the Friedman test were performed using the Nemenyi test method for p-value correction [Table/Fig-6].

Present study results show a continuous trend of decrease in IOP with increased follow-up time [Table/Fig-7]. Study participants were kept under serial follow-up after the study period, and optimal management was considered if necessary. The 14 eyes that did not meet the target IOP after the completion of the six-month study

Comparison of IOP at various timepoints with baseline	Mean±SD of difference	Median (IQR†) of difference	Range of difference	p-value
One hour-baseline	-1.24±3.06	-1.00 (2.00)	-8.00-8.00	0.053
One week baseline	-1.64±2.38	-2.00 (3.00)	-8.00-2.00	0.251
One month baseline	-2.45±3.54	-2.00 (4.00)	-12.00-4.00	**0.004**
Three months baseline	-2.48±2.24	-2.00 (3.00)	-8.00-2.00	**<0.001**
Six months baseline	-2.53±2.64	-2.50 (3.00)	-6.00-4.00	**0.024**

[Table/Fig-6]: Comparison of IOP at various time points with baseline.
*SD: Standard deviation; †IQR: Interquartile range; ‡post-hoc pairwise tests for Friedman test performed using Nemenyi Test method for p-value correction. Shaded background denotes statistically significant difference at p<0.05



[Table/Fig-7]: Line diagram depicting the change in IOP over time.

period were treated with the addition of AGM, and trabeculectomy was needed in four eyes after the completion of the study period.

DISCUSSION

Present study was conducted on 33 eyes of 19 patients with POAG. Out of the 33 eyes, 28 eyes from 16 patients completed the six-month follow-up period. The minimum reduction in IOP post-SLT required to define success was a ≥20% decrease from pre-SLT values, without any further addition of IOP-lowering medications or surgery. This criterion was met in 42.9% of the eyes by the end of the six months. The mean pre-SLT IOP for the 33 eyes was 16.39±2.73 mm Hg, while the mean IOP at the end of the six-month follow-up for the 28 eyes was 13.86±1.99 mm Hg. The mean reduction in IOP, with standard deviation, in our study was 2.53±2.64 mm Hg, representing a reduction of 15.44%.

In discussing IOP reduction in other similar studies, a study conducted by Latina MA et al., reported a mean IOP reduction of 4.6 mm Hg at 26 weeks [22]. Ojha S et al., found a reduction of 4.04 mm Hg at one year, while Nangia P et al., observed a reduction of 3.83 mm Hg at six months [15,23]. Hodge WG et al., reported a reduction of 5.54 mm Hg at one year, and Johnson PB et al., found a reduction of 3.74 mm Hg at three months [24,25].

In a prospective, multicentre, randomised controlled trial known as the Laser in Glaucoma and Ocular Hypertension Trial (LIGHT trial), patients were randomly allocated to receive either initial SLT or eye drops. Overall, 94.2% of eyes initially treated with SLT were at target IOP at 72 months. The study concluded that SLT is a safe treatment for open-angle glaucoma and ocular hypertension, providing better long-term disease control compared to initial drop therapy [26].

There is a paucity of literature on the IOP-lowering effects of SLT in the Indian population. Ojha S et al., conducted a prospective interventional pilot study that included 29 eyes of North Indian patients with open-angle glaucoma [15]. The mean pre-SLT IOP in this study was 24.62±6.38 mm Hg. At six months, they reported a 31.23% reduction from baseline IOP. In this study, the baseline IOP was higher than that in the present study and they found a greater reduction in IOP.

Nangia P and Ronnie JG carried out a study in central India [23]. The baseline IOP in their study was 20.6±5.2 mm Hg, and they found a reduction of 3.83 mm Hg (18.59%) at six months post-SLT. Gupta V et al., reported a 31.62% reduction in IOP post-SLT in patients with juvenile open-angle glaucoma at 12 months [16]. Varshney T et al., included patients with Juvenile-onset Open-angle Glaucoma (JOAG) without angle dysgenesis on gonioscopy, and they found a 29.6% reduction in IOP after six months post-SLT [17]. Raj S et al., recruited 34 patients with primary angle-closure disease who had undergone post-laser iridotomy and had open angles of at least 180° [18]. In this group, the range of IOP reduction post-SLT varied from 9% to 46% at one year, indicating the variability of the response to SLT in this angle-closure disease population.

In present study, a ≥20% fall in IOP from pre-SLT values was found in 42.9% of eyes at the six-month follow-up period. This was comparable to a past study conducted in the central Indian population by Nangia P and Ronnie JG which reported an IOP reduction of ≥ 20% in 45.7% of eyes at six months follow-up [23]. A similar study in the north Indian population by Ojha S et al., found that 95.65% of eyes maintained at least a 20% reduction in IOP at the one-year follow-up period [15].

Present study overall success rate of 42.9% was lower than that reported in several other studies; however, this can be explained by the variable criteria for success used in different studies, as well as the differing durations for which success was evaluated. [27,28] Additionally, the baseline IOP in present study was lower compared to that in other similar studies [15,23-25,28-30]. A strong negative correlation was found between baseline IOP and the change in IOP at six months, a finding that was consistent with results from other studies [31]. Given the lower baseline IOP in present study, a lesser reduction in post-SLT IOP is expected. One study indicated a better success rate over a longer follow-up period. Study conducted by Patel V et al., the mean IOP was significantly reduced at one year of follow-up, with further reductions observed at three and five years [32].

In present study, the number and type of AGM for each patient remained unchanged pre- and post-SLT throughout the entire study period. As there was no change in each patient's AGM, authors were able to accurately assess the true IOP-lowering effect of SLT. Since glaucoma patients exhibit varying levels of compliance, along with different contraindications and side-effect profiles, a uniform regimen of AGM cannot be prescribed to all patients.

The mean age of patients in present study was 59.89±7.94 years. Previous data have not found a significant influence of age on the IOP lowering effect of SLT, which aligns with present study observations [23,27,33,34]. There was no effect of gender on the response to SLT at six months, a finding that has been reported by many other authors [23,28,34]. At the six-month follow-up period after SLT, present study found no correlation between IOP lowering and BCVA (χ^2=3.388, p-value=0.184). Changes in the depth of the anterior chamber due to lens status (i.e., phakic and pseudo-phakic lenses) may influence the response to SLT, as SLT acts on the trabecular meshwork at the anterior chamber angle. Present study also did not find a significant difference in response to SLT between phakic and pseudo-phakic eyes (χ^2=3.167, p-value=0.205), which was consistent with the findings of many other authors [23,28,34].

Some previous studies support the use of 360° SLT treatment of the anterior chamber angle over 180° treatment [35,36]. One study reported an IOP reduction of >20% in 34% of eyes treated with 90 degrees, 65% with 180 degrees, and 82% with 360-degree SLT treatment [35]. Therefore, in present study, authors chose to treat the 360° trabecular meshwork in a single session. However, other authors have reported that the degree of angle covered does not affect post-laser IOP reduction [23,37,38].

Present study enrolled participants who were using two or more AGMs and had not achieved the target IOP. No correlation was found between the IOP lowering efficacy of SLT and the number of topical AGMs used, which was consistent with other studies [15,23]. Present study administered Loteprednol 0.2% drops four times a day for one-week post-SLT to reduce any post-laser inflammation. According to many authors, there was no difference in final IOP outcomes with the use of steroids post-laser; however, patients' comfort was noted to be better with post-laser steroid use [38,39]. Conversely, another study indicated that short-term postoperative use of NSAIDs or steroid drops similarly improves IOP reduction after SLT [40].

In present study, five eyes 5 (15.2%) experienced a raised IOP one hour after the procedure. This finding was consistent with many similar studies, which have reported that approximately 25% of patients experience transient IOP elevation after the procedure [22,41,42].

This study aims to determine the IOP lowering effect of SLT in North Indian patients with POAG over a six-month period. As the majority of patients in this study were in an advanced stage (84.8%),

the findings specifically address IOP reduction in this group. The null hypothesis was rejected, and the alternative hypothesis was accepted, as SLT resulted in a lower IOP at the end of the six-month follow-up period in POAG patients. Additionally, there was a strong negative correlation between baseline IOP and the change in IOP after six months, which was statistically significant.

Limitation(s)

The limitations of this study include a shorter time period and the absence of a control group. Patients were on two or more AGMs, but the medications remained the same for each patient before and after SLT for the entire study period. The efficacy of repeat SLT was not evaluated in this study; repeat SLT may be effective in eyes that did not respond to the first treatment, potentially increasing the overall success rate. Given that glaucoma patients have varying compliance factors, contraindications, and side-effect profiles, a uniform medication regimen cannot be prescribed to all patients. The number and type of medications for each patient remained constant before and after SLT.

Because there was no change in each patient's AGM before and after SLT, the actual IOP lowering effect of SLT was determined. Vision remained stable at all follow-ups. The primary variable studied was IOP reduction. Due to the irreversible nature of vision loss in glaucoma, the stability of vision was a primary aim of SLT, achieved by reducing IOP, in accordance with all other glaucoma treatment interventions.

CONCLUSION(S)

The present study showed that SLT can be considered an adjunctive treatment for lowering IOP in North Indian patients with POAG. Although the IOP-lowering efficacy may vary among individuals, additional treatment may be necessary for effective control in certain cases. A strong negative correlation was found between baseline IOP and IOP at six months post-SLT, indicating that a greater reduction can be expected in patients with higher baseline IOP.

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