Selective Laser Trabeculoplasty as a Substitute for Medications in Patients with Mild-to-moderate Glaucoma in the Brazilian Public Health System

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Précis: Selective laser trabeculoplasty can be used as a substitute for medications in patients with mild-to-moderate glaucoma, reducing the cost of eye drop distribution in the Brazilian public health system.

Purpose: To observe the effectiveness of selective laser trabeculoplasty (SLT) as a substitute for eye drops in patients with open angle glaucoma in the Brazilian Public Health System.

Materials and Methods: SLT was performed bilaterally after medication washout. This is a prospective interventional study comparing intraocular pressure (IOP) when using eye drops at baseline (post-washout), and at 12-month follow-up after SLT. Medication was added if the target IOP was not achieved, following the Brazilian Public Health System eye drops protocol, based on medication costs. Absolute (without eye drops) and qualified (with eye drops) success were measured with IOP $\leq$ 21, IOP $\leq$ 18, IOP $\leq$ 15 and IOP $\leq$ 12 mm Hg. Besides IOP evolution, the ability to reduce IOP (in %), and eye drops reduction were evaluated.

Results: Ninety-two eyes of 46 patients were included, 70 eyes with mild glaucoma and 22 with moderate glaucoma; the mean number of eye drops was 2.26 ± 1.06 (82.6% were using a prostaglandin analogue), and post-washout IOP of 21.10 ± 5.24 mm Hg. There was relative success at IOP $\leq$18 mm Hg, where the mild group had greater success than the moderate group (88.1% vs. 71.4%, $P = 0.824$). The average IOP reductions were 23.04% and 25.74% at 6 and 12 months, respectively. The average number of eye drops was 1.02, with 1.1% using a prostaglandin analogue. Furthermore, 68.19% of the patients had a decrease in the quantity of eye drops used.

Conclusion: SLT is effective in reducing IOP and replacing eye drops in patients in the Brazilian Public Health System. Moreover, there was a significant reduction in the use of prostaglandin analogues.

Key Words: open angle glaucoma, intraocular pressure, laser treatment, Brazilian public health

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Glaucoma is a leading cause of irreversible blindness worldwide. The global prevalence of glaucoma in people aged 40–80 years is estimated to be 3.5%.[1] With the growing number and proportion of elderly people in the population, it is projected that 111.8 million people will have glaucoma by 2040.[1] Increased intraocular pressure (IOP) is a main risk factor for glaucoma progression.[2,3] Currently, only its reduction has been proven to delay disease onset and progression.[4]

Three methods are available for achieving this goal: medication, laser treatment, and surgery.[5] Medication is typically the primary treatment option.[6] However, studies on persistence and adherence in glaucoma have listed multiple barriers to achieve an adequate treatment regimen with topical medication. Forgetfulness, the cost of medications, difficulty in instilling drops, and lack of clarification about the disease have been frequently reported.[7] As a result, self-reported treatment adherence rates are low (ranging from 30 to 80%),[8,9] and many patients discontinue their medication in the first year of treatment.[10] Low fidelity to treatment leads to uncontrolled IOP, and consequently, worsening of glaucomatous visual field defects.[11,12]

Selective laser trabeculoplasty (SLT) is an option for reducing IOP in eyes with open angle glaucoma and ocular hypertension.[13] This involves applying a laser to the trabecular meshwork, with the energy from each pulse being selectively absorbed by the pigmented cells of this tissue,[14] resulting in improved aqueous humor outflow and a consequent reduction in IOP. SLT has proven to be a valid alternative to medication as a first-line therapy,[15,16] and as replacement therapy for patients with controlled IOP.[17] The use of lasers to replace hypotensive medications tends to decrease the protagonism of the patient in the treatment, as it does not depend on patient adherence,[18,19] and, therefore may reduce the costs involved in topical treatment[20,21] and its side effects.[22]

This prospective clinical study aimed to evaluate the effectiveness of SLT as a substitute for topical medications for the treatment of open angle glaucoma. In addition, there was a reduction in the number of hypotensive eye drops over 1 year of follow-up in a public health service in Brazil, which distributes medications at no cost to patients included in the government program.

MATERIALS AND METHODS

Study Design and Subjects

This prospective, nonrandomized, single-arm interventional study was conducted in accordance with the principles of the Declaration of Helsinki. The study protocol was reviewed and approved by the Research Ethics Committee of Hospital das Clínicas, Faculty of Medicine, University of São

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Paulo. All study participants provided written informed consent before participation. The study was registered at ensaiosclinicos.org.br with the Universal Trial Number U1111-1255-1601.

The inclusion criteria were as follows: patients aged over 40 years, with mild to moderate open angle glaucoma (defined perimetrically with mean deviation better than −12 dB, the defect did not threaten fixation, and no point with a sensitivity of 0 db in the central 5°), who were already undergoing treatment with hypotensive eye drops. The exclusion criteria were as follows: advanced glaucoma (defined as mean deviation worse than −12 dB or threatening fixation), previous incisional or laser glaucoma surgery, intraocular inflammation in the last three months, ocular trauma or surgery in the last 6 months, and corneal changes that could prevent IOP measurement.

Initial Exam

All participants who met the selection criteria underwent a comprehensive ophthalmologic examination, including visual acuity (ETDRS logMAR), tonometry with a Goldmann tonometer calibrated for all measurements and checked regularly for correlation (Haag-Streit, Koeniz, Switzerland), gonioscopy, central corneal thickness measurement, fundoscopy, and Humphrey's visual field (HFA II 750; Carl Zeiss Meditec Inc., Dublin, CA).

After selection, participants underwent a washout of antiglaucoma medications being used for a period that varied according to the class of hypotensive medications: 4 weeks for beta-blockers and prostaglandin analogues, 2 weeks for adrenergic agonists, and 5 days for cholinergic agonists and carbonic anhydrase inhibitors.

After the medication washout period, the participants underwent an IOP measurement, which was called the baseline IOP. Patients who presented baseline IOP after the washout period $\geq$35 mm Hg were excluded from the study. The measurements were performed by the same certified examiner using the same calibrated tonometer. This examiner was not involved in the SLT application and was masked in relation to the number of postoperative days.

Procedure Technique

Bilateral treatment with SLT 360° was performed in a single session by an experienced physician (L.E.O.B) (20–25 shots per quadrant). Previously, a single drop of 0.2% brimonidine was administered to prevent the occurrence of pressure peaks.[23] The LIGHTL as SLT DeuxTM device (Lightmed, San Clemente, CA) and Volk model SLT lens (Volk, Mentor–OH) were used. The laser energy was initially set to 0.7 mJ, and a single laser pulse was delivered at the 12 o'clock position. If a cavitation bubble appeared, the laser energy was reduced in 0.1 mJ increments until minimal bubble formation was observed. Treatment was continued at this energy level. If no cavitation bubbles were observed, the pulse energy was increased in 0.1 mJ steps until the bubble formed.[24] Anti-inflammatory drugs were not routinely used postoperatively[25]; ketorolac tromethamine 5 mg/mL was prescribed every 8 h for 5 days only if necessary, at the physician's discretion.

Post-procedure Follow-up

Patients were evaluated 7 ($\pm$ 1 d), 30 ($\pm$ 3 d), 90 ($\pm$ 10 d), 180 ($\pm$ 15 d), 270 ($\pm$ 15 d), and 360 ($\pm$ 30 d) days after treatment. All IOP assessments were obtained with the Goldman applanation tonometer at the same time of day ($\pm$2 h). The target IOP was calculated as a 25% reduction from the baseline IOP and rounded to the nearest mm Hg or to 21 mm Hg, whichever was less. From the month 3 visit, the target IOP was assessed. If the mean IOP exceeded the target IOP at any visit starting at month 3, hypotensive medication was added, following the clinical protocol and therapeutic guidelines for glaucoma from the National Commission for Incorporation of Technologies of the Brazilian Public Health System (CONITEC).[26] The hypotensive was introduced in the following sequence (observing contraindications): 1st line (timolol maleate), 2nd line (Dorzolamide, Brimonidine, or Brinzolamide), and 3rd line (prostaglandin analogues). In the face of an IOP peak of >10 mm Hg, rescue medication was allowed, following the same guidelines.

Objective

Following the guidelines on design reporting glaucoma surgical trials of the World Glaucoma Association,[27] absolute success (without eye drops) and qualified success (with eye drops) were measured as the primary efficacy end point with IOP $\leq$ 21 mm Hg, IOP $\leq$ 18 mm Hg, IOP $\leq$ 15 mm Hg, and IOP $\leq$ 12 mm Hg at 6- and 12-month follow-up visits. Secondary outcomes were the evolution of IOP over the entire follow-up period, the ability to reduce IOP (in %) at each visit, and the reduction in eye drops over one year of follow-up.

Statistical Analysis

Qualitative variables were summarized as absolute and relative frequencies (%), and quantitative variables were expressed as means, SDs, quartiles, and minimum and maximum values. For comparisons related to IOP and percentage differences, mixed-effects models that considered the dependence between the 2 eyes were used. Two factors were considered in these models: the time of assessment, the severity of glaucoma (mild or moderate), and the interaction between them. For statistical analysis, patients were grouped into mild and moderate cases, according to the MD (mean deviation) values (better than -6 and -6 to -12, respectively). Graphs of individual profiles and averages were depicted to illustrate the evolution of patients over time. The eyes with mild and moderate glaucoma were compared for procedural success (absolute or relative) using generalized estimating equation models with a binomial distribution. On an exploratory basis, Kaplan-Meier curves were constructed to analyze the time to reach absolute success (IOP$\leq$18 without eyedrops). In this analysis, it was considered an event to have achieved success and maintained it until the end of the follow-up. The statistical program used was SPSS V25 (IBM, Armonk, New York, EUA)

RESULTS

Demographic and Clinical Data

A total of 46 participants (92 eyes) were included in this study. Demographic and clinical data before the procedure are shown in Table 1. The mean age was 66 $\pm$ 8.5 y (47–79). All patients received at least 1 eye drop before the protocol.

Table 2 presents the distribution of patients according to the perimetric staging of mild-to-moderate glaucoma. Although the average IOP in the moderate group was slightly higher than that in the mild group, there was no statistical difference in the baseline IOPs ($P=0.062$) or in the number of eye drops previously used ($P=0.078$).

TABLE 1. Characterization of Patients in Terms of Demographic and Clinical Aspects

	Frequency (%)
Sex	
Male	15 (32.6)
Female	31 (67.4)
Race	
White	19 (41.3)
Black	14 (30.4)
Brown	13 (28.3)
Amount of eye drops before the washout	
One	16 (34.8)
Two	7 (15.2)
Three	18 (39.1)
Four	5 (10.9)
Type of eye drops used before the washout*	
Prostaglandin analogue	38 (82.6)
Timolol Maleate	33 (71.7)
Dorzolamide hydrochloride	21 (45.6)
Brimonidine tartrate	12 (26.1)

*For this variable, the sum of the percentages was greater than 100% because a patient could use more than one eye drop.

Intraocular Pressure

Primary Outcome

Tables 3 and 4 show the absolute (without eye drops) and relative (with eye drops) success rates at the end of 6 and 12 months of follow-up, respectively. By analyzing the table, we noticed that there was no statistically significant difference between the mild and moderate glaucoma groups, both for absolute and relative success for different IOP values. Among the 29 eyes without eye drops (indicating absolute success), 14 (48.26%) were utilizing a single prior medication, while the remainder were on multiple medications. In eyes achieving relative success, 31.81% continued with their initially prescribed quantity of eye drops. Among these, 53.57% transitioned from prostaglandin analog to timolol maleate. Another 42.86% reverted to using timolol maleate, which they had been using before undergoing SLT. In addition, 3.57% reintroduced the prostaglandin analogue.

Secondary Outcome

IOP Evolution and Reduction (in %)

The IOP was evaluated before performing SLT (previous and post-washout) and at the following time points: 7 days, 30 days, 3 months, 6 months, 9 months, and 12 months. The charts below summarize these data.

Although the mean IOP was slightly higher in the moderate glaucoma group than in the mild glaucoma group ($P = 0.062$), the change in IOP over time was similar in both groups ($P = 0.771$). On average, there was a significant increase post-washout, then a gradual decrease over time. After 12 months, the mean values were similar to those during the pre-washout period ($P > 0.999$) (Fig. 1).

Regarding the percentage reduction in relation to the post-washout baseline, after 7 days there was an average reduction of 10.58% after 7 days. After 30 days, the reduction reached 20.08% and remained relatively stable for 3 months, when an average reduction of 19.99% was observed. The IOP reduction gradually increased, averaging 23.04% at 6 months, 24.74% at 9 months, and 25.74% at 12 months (Fig. 2).

TABLE 2. Characterization of the Patients in Relation to The Staging of Mild and Moderate Glaucoma

	Mild glaucoma	Moderate glaucoma	Total
No. eyes	70 (76,1%)	22 (23.9%)	92
No. eye drops	2.37 ± 1.07	1.91 ± 0.97	2.26 ± 1.06
Previous washout IOP	15.09 ± 2.92	16.25 ± 2.94	15.37 ± 2.95
Postwashout IOP	20.56 ± 5.11	22.82 ± 5.41	21.10 ± 5.24

IOP indicates intraocular pressure.

TABLE 3. Absolute (Without Eyedrops) and Relative (with Eyedrops) Success Rates for Different IOP Levels at 6 Months

Success criteria	Mild glaucoma (n = 70), %	Moderate glaucoma (n = 22), %	*P*
IOP ≤ 21 mm Hg			
Absolute	62.3	71.4	*0.233*
Relative	100	95.2	—
IOP ≤ 18 mm Hg			
Absolute	58.0	66.7	*0.168*
Relative	88.4	81.0	*0.081*
IOP ≤ 15 mm Hg			
Absolute	36.2	19.0	*0.096*
Relative	52.2	23.8	*0.118*
IOP ≤ 12 mm Hg			
Absolute	10.1	9.5	*0.959*
Relative	15.9	9.5	*0.604*

Italic values statistically significance p 0.05, 95%.
IOP indicates intraocular pressure.

Number of Eye Drops

Table 5 shows the changes in eye drop use during the follow-up period. In summary, most patients returned to using eye drops; however, the number of eye drops decreased. There was no statistically significant difference between the groups regarding the number of eye drops used, with an average at the end of 12 months of 1.03 and 1.00 compared with the mild and moderate glaucoma groups, respectively ($P = 0.675$).

TABLE 4. Absolute (Without Eyedrops) and Relative (with Eyedrops) Success Rates for Different IOP Levels at 12 Months

Success criteria	Mild glaucoma (n = 70), %	Moderate glaucoma (n = 22), %	*P*
IOP ≤ 21 mm Hg			
Absolute	31.3	33.0	*0.436*
Relative	100	98.9	—
IOP ≤ 18 mm Hg			
Absolute	26.9	19.0	*0.307*
Relative	88.1	71.4	*0.824*
IOP ≤ 15 mm Hg			
Absolute	20.9	9.5	*0.193*
Relative	64.2	42.9	*0.470*
IOP ≤ 12 mm Hg			
Absolute	10.1	10.0	*0.959*
Relative	31.3	28.4	*0.213*

Italic values statistically significance p 0.05, 95%.
IOP indicates intraocular pressure.

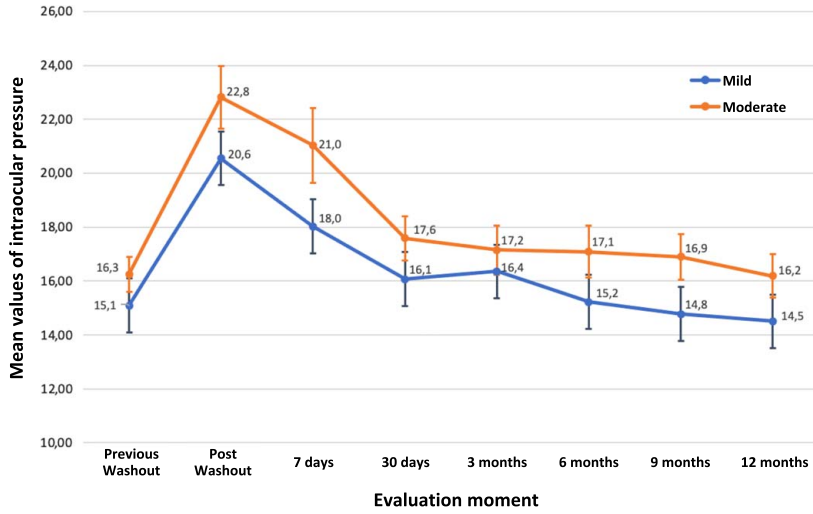

FIGURE 1. Graph of the mean IOP at the evaluation times according to mild glaucoma and moderate glaucoma groups. IOP indicates intraocular pressure. Figure 1 can be viewed in color online at www.glaucomajournal.com.

Survival Curve Without Eye Drops

The following analysis shows the evolution of patients regarding the success of the procedure (defined as not using eye drops). The mean "eyedrop-free" time was estimated at 10.4 months (95% CI:10.125;10.689). According to the Kaplan-Meier curve, the estimates of eyedrop-free probabilities were 97.9% at 30 days, 98.5% at 3 months, 85.8% at 6 months, 62.9% at 9 months, and 18.9% at 12 months. (Fig. 3).

DISCUSSION

To the best of our knowledge, there are no prospective studies on the effect of SLT in Brazilian patients with glaucoma who are already under treatment. In this prospective interventional study, we aimed to determine whether SLT could replace hypotensive eye drops in patients with open angle glaucoma at a Brazilian public service. The eye drops are part of a high-cost list distributed free of charge by the government, so by reducing the amount of medication, we can relieve resources for the health system. We demonstrated that after washout of medications and selective laser trabeculoplasty, most patients returned to the use of eye drops after 1 year of follow-up, but in smaller quantities when compared previously, with an average time without eye drops of 10.4 months.

Our results differ from those of some studies regarding the success of patients free of eye drops after 1 year, which showed a success rate ranging from 58% to 94%.[14] A possible explanation may be the fact that studies considered a reduction of 20% or IOP < 21 mm Hg to be successful. In our study, a more judicious IOP reduction of 25% was considered. All patients had to achieve this reduction, even if the administration of medications was necessary; as previous eye drops use averaged 2.26 ± 1.06, reducing this amount of medications is difficult. However, when we compared the success of eye drop reduction, the results were similar to those of published studies.[17,28] Another explanation is that in our study, the average IOP after washout was lower than in the LIGHT trial.[29] This may partially explain the slightly lower success rates than in that randomized controlled trial.

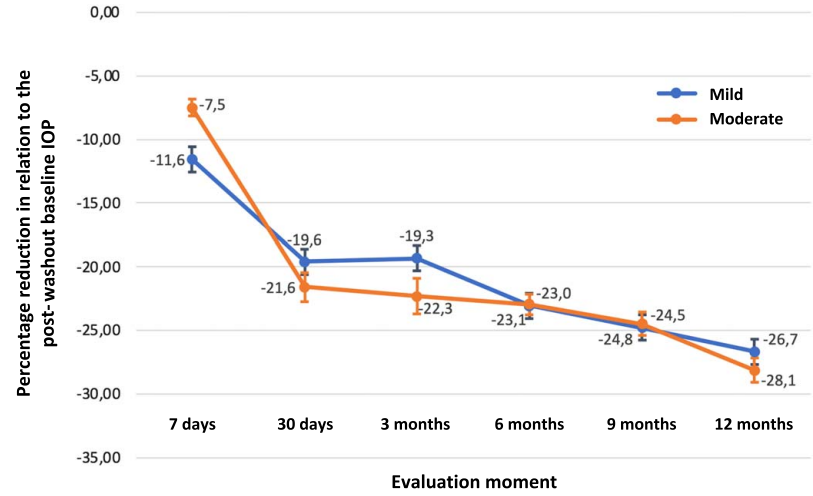

FIGURE 2. Percentage IOP reduction in different groups, comparing with postwashout IOP. IOP indicates intraocular pressure. Figure 2 can be viewed in color online at www.glaucomajournal.com.

TABLE 5. Number of Eye Drops According to Observation Time. N (%)

	Evaluation moment					
No. eyedrops	**Previous SLT (%)**	**30 d, %**	**3 mo, %**	**6 mo, %**	**9 mo, %**	**12 mo, %**
0	0	90 (97.8)	86 (95.6)	58 (64.4)	42 (47.7)	29 (33.0)
1	32 (34.8)	—	2 (2.2)	26 (28.9)	32 (36.4)	32 (36.4)
2	14 (15.2)	2 (2.2)	2 (2.2)	6 (6.7)	14 (15.9)	24 (27.3)
3	36 (39.1)	—	—	—	—	2 (2.3)
4	10 (10.9)	—	—	—	—	1 (1.1)
N	92 (100)	92 (100)	90 (100)	90 (100)	88 (100)	88 (100)
Average	*2.26*	*0.04*	*0.07*	*0.42*	*0.68*	*1.02*

Italic values statistically significance p 0.05, 95%.
SLT indicates selective laser trabeculoplasty.

Dividing the groups into mild and moderate glaucoma, one might presume that early-stage glaucoma cases exhibit a lower degree of trabecular damage (due to a shorter disease duration), potentially resulting in a higher likelihood of achieving lower IOP levels and, consequently, a more pronounced treatment success.[30,31] In addition, it could be anticipated that eyes with higher baseline IOP would experience a more substantial reduction in their initial IOP levels.[32] However, despite the moderate glaucoma group having slightly elevated mean IOP values compared with the mild glaucoma group, our analyses, encompassing parameters such as absolute or relative success, the impact of IOP reduction, and the quantity of eye drops used, did not reveal statistically significant differences. These findings underscore that, irrespective of the stage, SLT remains a viable alternative to traditional eye drop therapy. When we set IOP $\leq$ 18 mm Hg with relative success (with eye drops), we observed that, despite not being statistically significant, the mild glaucoma group had greater success (88.1% versus 71.4%) than the moderate group ($P = 0.824$). According to the results of the Advanced Glaucoma Intervention Study, this mean cutoff IOP is important for controlling progression in the visual field.[33]

It was observed that 82.6% of the eyes used prostaglandin analogues, which are the most effective agents in reducing IOP,[34] but at a higher cost in the medication distribution program. At the end of the follow-up period, only 1.1% of the eyes used this class of medication. Initially, the majority of patients (39.1%) used 3 classes of hypotensives; at the end, most used only one class, being timolol maleate (36.4%). Thus, we could withdraw the most expensive medication from the public system and replace it with the least expensive.

In our analysis of the relationship between the use of eye drops and the outcomes of absolute and relative success, it initially appeared that the number of eye drops might serve as a significant predictor of absolute success. However, when we examined the subset of 29 eyes that achieved absolute success without requiring additional medications, we found that 14 of them (48.26%) were using only a single medication before the procedure, while the remainder were on multiple medications. This observation suggests that the number of eye drops did not play a significant role in predicting absolute success. Concerning cases of relative success, we observed that 31.81% of the patients maintained the same quantity of eye drops they had been using before. Among these patients, a noteworthy 53.57% switched from the most expensive medication, a prostaglandin analog, to the more economical option of timolol maleate. These findings reinforce the notion that there is a potential for cost reduction associated with the treatment after 1 year of follow-up.

It is not clear whether previous use of medications can reduce the effectiveness of SLT, and our results demonstrate that even in patients who were already undergoing

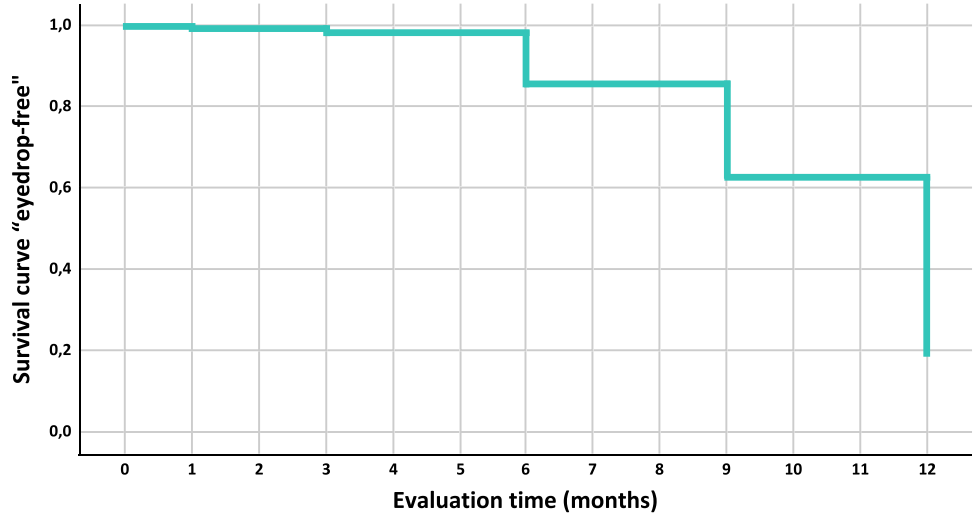

FIGURE 3. Survival curve—"eyedrop-free" time. Figure 3 can be viewed in color online at www.glaucomajournal.com.

treatment, the effect could be beneficial. Data from the literature indicate that concomitant use is not associated with an increased risk of primary failure.[35–37]

Previous studies have demonstrated the cost-effectiveness of SLT compared with eye drops as a first-line treatment.[20,29,38–41] The chronic use of hypotensive eye drops is one of the main factors responsible for the high cost of treating glaucoma.[42–44] In a developing country with scarce resources, a treatment that extends the introduction of eye drops for glaucoma can reduce the direct medical costs of the public health system.[45] Unlike the Light trial, which recruited only newly diagnosed patients, we decided to cover our study for patients who had already used the medications, thus observing an effect, in real life, of the reduction of eye drops and, consequently, direct costs to the Brazilian public system.

Our study had some limitations. Despite being a prospective study, the number of patients was restricted, and we compared the patients with themselves during the IOP follow-up, thus offering a lower level of comparison with randomized controlled trials. Second, is the lack of information regarding the duration of diagnosis as well as previous IOP profile (eg, IOP without medication at the time of diagnosis) and response to eye drops during the follow-up period. On the contrary, our study sample accurately represents the real-world population, where such information is often unavailable and, consequently, may not be reliable parameters for estimating SLT response. Another is that we chose not to administer anti-inflammatory treatment after SLT; however, to date, there is no consensus on the ideal anti-inflammatory treatment regimen.[46,47] Finally, the nonrepetition of SLT with the immediate introduction of eye drops may have influenced the number of eye drops at the end of the follow-up period, considering that current studies show good results with the repetition of SLT.[48,49]

In conclusion, our study shows that SLT can be an effective treatment to replace eye drops in the Brazilian Public Health System, leading to a cost reduction. Managing to maintain, at the end of 1 year, IOPs similar to those previously controlled with medications and therefore reduce the use of the most costly eye drops. When treatment costs tend to increase, and public resources become increasingly scarce, a cost-effectiveness analysis based on clinical studies in the Brazilian population can guide us towards a better allocation of these resources.

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