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West Indies Glaucoma Laser Study (WIGLS): 2. Predictors of Selective Laser Trabeculoplasty Efficacy in Afro-Caribbeans with Glaucoma

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Abstract

Purpose: To identify factors associated with intraocular pressure (IOP) reduction following selective laser trabeculoplasty (SLT) in Afro-Caribbean people with primary open-angle glaucoma (POAG).

Design: Prospective stepped-wedge study

Methods: Data were drawn from 72 Afro-Caribbean subjects with primary open-angle glaucoma participating in the ongoing West Indies Glaucoma Laser Study (WIGLS). Multivariable mixed-model analysis was utilized to develop a predictive model for percent IOP reduction 12 months following SLT. Putative factors (age, gender, site, baseline IOP, prior use of prostaglandin therapy, number of pre-washout IOP-lowering medications, central corneal thickness, severity of glaucoma, duration of follow-up, and signs of acute postoperative inflammation) were evaluated in bivariate analysis. Factors significant at $p \leq 0.2$ were included in the final model. Right and left eye data were modeled separately.

Results: At Month 12 following SLT, mean IOP reductions in the WIGLS study were 6.2–6.5 mmHg (29.7–31.0%) in right and left eyes. The only factor significant in both eyes ($p=0.0005$ in right eyes and $p<0.0001$ in left eyes) was time, with IOP reductions being greatest at Month 3 and declining slightly over time through Month 12. Vertical cup-disc ratio ($p=0.006$) and prior prostaglandin therapy ($p=0.004$) were significant only in right eyes, and central corneal thickness ($p=0.014$) was significant only in left eyes. Factors significant only unilaterally did not approach significance in fellow eyes, suggesting the possibility that these represent Type 1 errors. Site (St. Lucia versus Dominica) was not a significant factor, establishing generalizability of these treatment outcomes to a broader population of African-derived people.

Conclusions: This analysis did not identify any subject-specific factors consistently predictive of therapeutic response to SLT. Of note, no factors predicted a suboptimal response. These findings favorably position SLT for broad application as primary therapy in African-derived people with primary open-angle glaucoma.

Introduction

Selective laser trabeculoplasty (SLT) is an effective and safe means of lowering intraocular pressure (IOP) in eyes with primary open-angle glaucoma (POAG). Its efficacy is comparable to that of a prostaglandin analogue^{1,2} while obviating the need for daily adherence—a well-documented limitation of daily medical therapy in glaucoma.³ The IOP-lowering efficacy of SLT diminishes over time, but the procedure can be effectively and safely repeated,^{4–10} offering the potential for long-term IOP control.

Some eyes fail to manifest a meaningful IOP reduction following SLT, and others may respond initially with rapid waning of effect. Several factors have been identified that predict SLT outcomes, including baseline IOP (better^{11–14} or worse¹⁵ outcome if higher), laser energy used (better if higher),^{15,16} age (worse if older),¹⁵ and prostaglandin analogue therapy (worse if taking^{14,17} or no effect^{18,19}).

POAG and glaucoma blindness disproportionately affect people of African descent, and glaucoma is a common cause of blindness in low- and middle-income countries (LMICs).^{20–24} Race was not included as a putative factor predicting SLT outcomes in any of the studies cited above.^{11–19} Only 1 study reported the racial make-up of the sample¹³ (12% black) and did not report outcomes of this subgroup separately. Thus, little is known about the factors that predict SLT efficacy in people of African descent.

The West Indies Glaucoma Laser Study (WIGLS) is an ongoing prospective evaluation of the efficacy and safety of monotherapy SLT in an Afro-Caribbean sample of subjects on the islands of St. Lucia and Dominica. WIGLS was designed to evaluate the role SLT might play as sole therapy in reducing global blindness from glaucoma. Primary outcomes at 12 months have been previously reported.²⁵ Efforts are now underway to globalize availability to SLT for people of African descent living in low-resource settings. In this report, we present the results of a planned analysis to identify factors associated with IOP reduction during the first 12 months following initial SLT treatment in people of African descent with POAG. The goal of this analysis is to identify potential patient characteristics that would render SLT more or less effective as a means of identifying optimal candidates for treatment in the future.

Methods

The WIGLS protocol has been described in detail elsewhere²⁵ and was registered at clinicaltrials.gov prior to the enrollment of any subjects (NCT02375009). Briefly, a convenience sample of subjects with primary open-angle glaucoma (based on ISGEO criteria²⁶) was drawn from eyecare practices in St. Lucia and Dominica. Subjects with early or moderate POAG were enrolled. Key exclusion criteria included advanced glaucoma (defined as cup-disc ratio greater than 0.9 or automated visual field loss within the central 10

degrees in either eye), previous laser or incisional glaucoma surgery, intraocular inflammation within the past 3 months or ocular trauma or surgery within the past 6 months, or IOP outside the range of 18–32 mmHg, inclusive, after washout of all IOP-lowering medications. Qualifying subjects were randomized to immediate versus 3-month or 6-month delay before 6-week washout of topical IOP-lowering therapy followed by SLT treatment, in a stepped-wedge study design. This design, an extension of the cluster randomized design, features a sequential roll-out of an intervention to all participants in randomized groups (clusters) such that all participants will have received the intervention by study end; it is preferred to a parallel group design when the intervention is expected to be better than the comparator and/or when delivery of the intervention to all participants simultaneously is logistically difficult.²⁷ Randomization was stratified by use of prostaglandin analogue at the time of enrollment to ensure equal distribution of this putative predictive factor among the three groups. After washout, baseline IOP was determined in two sessions 1–3 days apart; immediately following the second session, SLT was performed using the Lumenis Selecta II portable slit-lamp mounted laser system. Approximately 100 treatment spots were delivered to the full 360 degrees of trabecular meshwork in each eye. Post-treatment assessments occurred at 1 hour, 1 week, 1 month, 3 months, and every 3 months thereafter. Repeat SLT could be performed based on prespecified criteria for failure of initial SLT.

The primary statistical objective of this report was to identify baseline factors predictive of IOP reduction following initial SLT in African-derived subjects with POAG. A random mixed-effects model was utilized to characterize longitudinal percent IOP reduction after SLT and to identify factors associated with IOP reduction. The model allowed the subjects to have different intercepts of percent IOP change on time. We assumed that the random effects in the model had shift in intercept for each subject. We have also assumed that the random effects had a normal distribution with mean zero and variance σ^2 . The maximum likelihood method was used to estimate the parameters from the multivariable mixed model and using the variance components as a covariance structure. Putative factors include age, gender, site (St. Lucia or Dominica), baseline IOP, prior use of prostaglandin therapy, number of pre-washout IOP-lowering medications, central corneal thickness, severity of glaucoma (based on cup-disc ratio and visual field parameters), total laser energy delivered, and duration of post-SLT follow-up. Factors significant at the $p < 0.2$ level in bivariate mixed-model analysis were included in the multivariable model.

Results

Overall, 78 subjects were enrolled in this study and 72 underwent SLT treatment (5 subjects withdrew consent prior to treatment and 1 had non-qualifying washout IOP). Twelve-month efficacy and safety data have been reported previously.²⁵ Mean baseline IOP values after washout in right and left eyes of subjects were 21.0 ± 3.3 mmHg and 20.9 ± 3.0 mmHg, respectively, and at Month 12, mean IOP values were 14.5 ± 4.0 mmHg and 14.2 ± 3.3 mmHg, respectively. These represent mean IOP reductions of 6.2 mmHg and 6.5 mmHg, respectively, and mean percent IOP reductions of 29.7% and 31.0%, respectively.

Factors evaluated as potential predictors of percent IOP reduction at 12 months are given in Table 1. These include subject demographic information as well as data on the severity of glaucoma and glaucoma therapies at the time of medication washout.

Table 2 gives the results of each potential predictor's effect size and significance in bivariate analysis. Factors that were statistically significant at $p < 0.05$ in one or both eyes included gender, follow-up time, central corneal thickness, vertical cup-disc ratio, and prior use of topical prostaglandin analogues (PGAs).

Table 3 gives the effect size and significance of predictors significantly associated with the percent IOP change at 12 months in the multivariable model. Of these, only follow-up time was significant in both right and left eyes, with maximal IOP reductions occurring at Month 3 and declining slightly over time. Vertical cup-disc ratio and prior prostaglandin use were significant in right eyes only, and central corneal thickness was significant in left eyes only.

The site term (representing enrollment in St. Lucia versus Dominica) was included specifically to evaluate generalizability of outcomes across Afro-Caribbean populations. This term was insignificant in univariate analysis and not included in multivariable models. Mean IOP reductions at Month 12 were 6.2 ± 4.0 mmHg and 6.5 ± 3.4 mmHg in right and left eyes of subjects from St. Lucia and 5.8 ± 3.7 mmHg and 6.5 ± 3.3 mmHg, respectively, in subjects from Dominica ($p = 0.567$ for St. Lucia versus Dominica in each eye).

Discussion

The West Indies Glaucoma Laser Study (WIGLS) was undertaken specifically to characterize the IOP-lowering efficacy of SLT in an Afro-Caribbean population and to identify baseline factors associated with the therapeutic response to SLT. In this analysis, no subject-specific characteristics were consistently associated with 12-month SLT efficacy. The only factor found to be significantly associated with 12-month IOP response to SLT in both eyes was time: at every visit from Months 3–12, IOP trended higher. This is consistent with the well-documented natural history of IOP responses to SLT, in which an initial IOP reduction is achieved that slowly wears off over time. In simplest terms, it seems that whatever detrimental effect glaucoma produces in the trabecular meshwork to impede aqueous outflow is ameliorated by SLT until such time as progressive glaucoma reverses SLT's beneficial effect. This hypothesis is supported by the now well-established utility of repeat SLT to re-establish IOP control upon the waning of initial SLT's effect.^{4–10}

Several other factors were significantly associated with IOP reduction in only one eye. These included vertical cup-disc ratio and prior prostaglandin use in right eyes and central corneal thickness in left eyes. It is tempting to speculate that larger vertical cup-disc ratio is a marker for more advanced disease, which may be less amenable to SLT therapy by virtue of more advanced meshwork damage. Likewise, SLT's effect was also incrementally reduced in left (but not right) eyes with thinner corneas; while statistically significant, the effect size—approximately a 4% difference in IOP reduction for every 50 microns of change in corneal thickness—is of marginal clinical significance. However, the more likely explanation for both these findings—given that they were significant in only one eye—is that they represent

Type 1 errors (false positive finding of significance); evidence for this can be found in the fellow-eye p-values (0.153 for central corneal thickness in right eyes and 0.111 for vertical cup-disc ratio in left eyes), which did not trend toward significance—there was in fact an order of magnitude between-eye difference in significance for both.

The issue of prostaglandin use as a predictive factor for SLT outcomes is more complex. Song and colleagues reported a retrospective analysis of SLT (180 degrees) in which prostaglandin use was not significantly associated with IOP outcomes.¹⁸ Likewise, Martow and colleagues found no effect of prostaglandin use on SLT outcomes.¹⁹ Hirn and colleagues retrospectively compared IOP reductions following SLT in prostaglandin-treated and prostaglandin-naïve eyes and found mean IOP reductions to be significantly greater in naïve eyes through the first 1 year of follow-up but not thereafter.¹⁷ Bruen and colleagues reported that prostaglandin use was significantly associated with lesser IOP reduction after SLT in a fellow-eye analysis but not a change-from-baseline analysis.¹⁴ It has been proposed that prostaglandins and SLT have similar mechanism of action and therefore may not be fully additive.¹⁸ In our study, all IOP-lowering medications were stopped prior to SLT treatment. Prostaglandin use prior to washout was a significant predictive factor in our multivariable model only in right eyes and was not even marginally significant ($p=0.205$, a more than 50-fold between-eye difference in significance) in left eyes. As with the other unilateral findings discussed above, we are inclined to consider this a Type 1 error in our analysis as well but acknowledge that inconsistent findings in our data and in the literature do not preclude a possible relationship between prostaglandin use and SLT efficacy. However, we feel the issue is moot in the application of an SLT-based treatment program in developing countries where up to 90% of people with glaucoma are undiagnosed, untreated, and thus naïve not only to prostaglandins but to all glaucoma therapies.

We found no significant differences in SLT responses among subjects from St. Lucia and Dominica. Mean IOP reductions were similar in both subgroups and the site term was insignificant in bivariate analysis. This provides evidence for generalizability of our results of other populations of African-derived people and is consistent with other studies in similar populations. In a previous publication, we reported 12-month IOP reductions averaging 30% in this cohort of patients with POAG.²⁵ This therapeutic effect compares favorably with a prior prospective study conducted by Realini in an independent cohort in St. Lucia that demonstrated mean IOP reductions on the order of 40% at 12 months,²⁸ and a more recent retrospective analysis of SLT in black Africans in Durban, South Africa by Goosen and colleagues yielding IOP reductions of approximately 42% at 12 months post-SLT.²⁹ An additional retrospective study was reported in black Africans in which SLT was employed chiefly to reduce medication burden, with substantial reductions in both medication use and IOP.³⁰ Twelve-month response rates averaged 80–90% in each of these studies.^{25,28–30}

Our study's sample size was determined based on power analysis to analyze the primary outcome of IOP reduction. While the sample size was adequate for the current predictive model analysis,³¹ a larger sample size may have permitted broader exploration of more potential factors that might be associated with IOP response to SLT.

In summary, our analysis did not identify any subject-specific factors consistently predictive of therapeutic response to SLT. Consistent with the known natural history of SLT's effect on IOP, the magnitude of IOP reduction was time-dependent, diminishing with the passage of time. No subject-specific factors predicted a suboptimal response—thus, no patient profiles were identified for whom SLT is unlikely to be effective. In the setting of a pan-African public health initiative to prevent glaucoma vision loss in resource-limited regions, these findings favorably position SLT for broad application as primary therapy in African-derived people with primary open-angle glaucoma.

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Table 1

Putative predictors of percent intraocular pressure reduction following selective laser trabeculoplasty in the West Indies Glaucoma Laser Study.

Factor	Value
Gender, n (%) female	43 (59.7)
Age (yr), mean (SD)	61 (11.4)
Site, n (%) St. Lucia	47 (65.3)
Baseline IOP (mmHg), mean (SD)	
Right eyes	21.3 (3.3)
Left eyes	20.9 (3.0)
Central corneal thickness (microns), mean (SD)	
Right eyes	537 (36)
Left eyes	543 (38)
Visual field mean deviation (dB), mean (SD)	
Right eyes	-4.6 (5.2)
Left eyes	-3.9 (3.8)
Vertical cup-disc ratio, mean (SD)	
Right eyes	0.7 (0.1)
Left eyes	0.7 (0.1)
Number of IOP-lowering medications, mean (SD)	
Right eyes	1.3 (0.7)
Left eyes	1.3 (0.7)
Prior use of prostaglandin analogue, n (%)	
Right eyes	35 (48.6)
Left eyes	35 (48.6)
Total laser energy, mJ (SD)	
Right eyes	86.0 (21.1)
Left eyes	87.7 (20.6)

Table 2

Bivariate analysis of putative predictive factors for 12-month response (percent intraocular pressure reduction) to selective laser trabeculoplasty in the West Indies Glaucoma Laser Study.

Variables	Right eye		Left eye	
	Estimate (SE)	p value	Estimate (SE)	p value
Baseline IOP (per mmHg)	0.62 (0.49)	0.211	0.58 (0.45)	0.193
Age (per year)	-0.202 (0.14)	0.137	-0.22 (0.12)	0.059
Gender (ref: female)	-6.16 (3.05)	0.045	-7.24 (2.52)	0.004
Site (ref: Dominica)	-3.61 (3.20)	0.262	-3.19 (2.74)	0.246
Time (ref: Month 12)				
Month 3	9.38 (2.32)		10.84 (2.20)	
Month 6	8.46 (2.35)	0.0004	6.79 (2.22)	<.0001
Month 9	6.72 (2.37)		5.82 (2.24)	
Number of IOP lowering Medications (ref: 0)				
1	-0.79 (5.78)		-0.25 (5.47)	
2	-2.96 (6.32)	0.764	-4.01 (5.90)	0.419
3	4.53 (8.42)		5.55 (7.59)	
Central Corneal Thickness (per micron)	-0.08 (0.04)	0.083	-0.08 (0.04)	0.027
Vertical cup-disc ratio (per 1.0 unit)	22.12 (10.93)	0.044	24.45 (11.83)	0.040
Visual field mean deviation (per dB)	0.13 (0.31)	0.682	-0.29 (0.34)	0.400
Visual field pattern standard deviation (per dB)	-0.18 (0.55)	0.743	0.55 (0.54)	0.308
Prior use of Prostaglandin therapy (ref: no)	-7.39 (2.97)	0.014	-3.60 (2.62)	0.170
Total laser energy (per mJ)	0.085(0.076)	0.259	0.096(0.064)	0.137

Table 3

Factors significantly associated with percent intraocular pressure reduction 12 months following selective laser trabeculoplasty in the West Indies Glaucoma Laser Study in multivariable analysis.

Significant Factors	Right eye		Left eye	
	Estimate(SE)	p value	Estimate(SE)	p value
Time (ref: Month 12)				
Month 3	9.29(2.32)		10.5(2.22)	
Month 6	8.42(2.36)	0.0005	6.49(2.24)	<0.0001
Month 9	6.78(2.37)		5.75(2.26)	
Central Corneal Thickness (per micron)	-0.06(0.04)	0.153	-0.08(0.03)	0.014
Vertical cup-disc ratio (per 0.1 unit)	30.5(11.1)	0.006	18.3(11.4)	0.111
Prior use of Prostaglandin therapy (ref: no)	-8.37(2.86)	0.004	-3.10(2.44)	0.205