Baseline IOP predicts selective laser trabeculoplasty success at 1 year post-treatment: results from a randomised clinical trial

W G Hodge, K F Damji, W Rock, R Buhrmann, A M Bovell, Y Pan

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Methods: As part of a randomised clinical trial comparing the efficacy and safety of SLT to ALT, data on 72 SLT patients were collected, and successful SLT defined as having an SLT induced intraocular pressure (IOP) reduction of ≥20% at 1 year post-treatment follow up.

Results: 43 out of the 72 patients who had completed their 1 year follow up visit had an IOP reduction of ≥20% from baseline. No glaucoma risk factors studied predicted successful SLT. The amount of trabecular meshwork pigmentation was not a significant predictor. However, it was discovered that baseline IOP strongly predicted SLT success (odds ratio = 1.16; p = 0.0001).

Conclusion: SLT success was significantly predicted by baseline IOP but not by age, sex, other glaucoma risk factors, type of open angle glaucoma, or by degree of trabecular meshwork pigmentation.

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better SLT outcome. Significantly higher IOP reduction was found in patients with ≥22 mm Hg baseline IOP in a prospective non-randomised trial, but no prognostic importance of this finding has been suggested. Kano, et al discovered that lower baseline IOP is a significant success predictor, whereas factors such as, age, sex, previously failed ALT, and goniopigmentation were found to be non-significant. Similarly, Odberg and Sandvik indicated significantly higher risk for failure when a patient’s baseline IOP was ≥32 mm Hg. Results of age and degree of angle pigmentation in relation to SLT success were mixed.

The objective of the present study is to determine the factors that predict successful SLT at 1 year post-treatment.

MATERIALS AND METHODS

Details of patient recruitment, materials, and methods are given in a previous publication of this study. Briefly, the study took place at the University of Ottawa Eye Institute and was approved by the Ottawa Hospital research ethics board. Potential study subjects were drawn from the patient pool of the institute’s glaucoma clinic, from March 1997 to March 2003. Our inclusion criteria required the study patients to: (i) present with any type of open angle glaucoma including pseudoexfoliation and pigmentary glaucoma; (ii) have uncontrolled IOP of ≥16 mm Hg with maximal medical therapy (three or more antiglaucoma drugs tolerated by the patient) or had failed previous 180/360 degree ALT treatment; (iii) be over 18 years of age; and (iv) have two sighted eyes. Subjects were excluded if s/he (i) had a type of glaucoma other than open angle; (ii) had advanced visual field defect; (iii) had any previous ocular surgery other than ALT or peripheral laser iridotomy (PI) done in the study eye, or required any ocular surgery within 6 months of this study enrolment; (iv) had cornea disease precluding accurate applanation tonometry; or (v) was or would be on systemic steroids during the study period. All patients were required to sign the informed consent at enrolment. Follow ups were scheduled to take place at 1 week, 1, 3, 6, and 12 months after treatment. Intraocular pressure, best corrected visual acuity and IOP change between the success and non-success groups. For normal continuous variables, appropriate Student’s t tests were used to detect statistical significance; for categorical variables χ² tests and the non-parametric Fisher’s exact test; and for nominal categorical variables the Kruskal-Wallis test. Any covariates that achieved p<0.10 for the bivariate analyses were included in the final multivariate logistic regression model. Multicollinearity was checked before determining the final model. All statistical analyses were performed using the Stata 7.0 software.

RESULTS

Out of the 89 patients who received SLT (table 1), 72 completed their 1 year follow up visit; 43 of which had achieved an IOP reduction of ≥20% from their baseline IOP. Seventeen patients were lost to follow up because of moving, unwillingness to return for further examinations, sickness, or death.

The success group has considerably higher baseline and 1 hour post-treatment IOP than the non-success group. There are no significant differences in the distribution of glaucoma risk factors and other prognostic factors except for hypertension and family history of glaucoma, which were only marginally significant between groups (p<0.05) (table 2). Four out of the 72 patients (6%), two in each outcome group

Table 1  Baseline characteristics of the total study sample

<table>
<thead>
<tr>
<th>Covariates</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD) (range)</td>
<td>69.08 (10.52) (36.57-88.37)</td>
</tr>
<tr>
<td>Sex (male/female)</td>
<td>36/53</td>
</tr>
<tr>
<td>Glaucoma type, No (%)</td>
<td>OAG (POAG/OAG after PI/post CE) 54 (60.67%) PXG 23 (25.84%) PG 7 (8.77%) Combined mechanism 3 (3.5%) Others 2 (2.2%)</td>
</tr>
<tr>
<td>Pretreatment IOP, mean (SD) (range)</td>
<td>23.84 (4.88) (10, 40)</td>
</tr>
<tr>
<td>Previous ALT (Yes/No)</td>
<td>28/61</td>
</tr>
<tr>
<td>BCVA, median (range)</td>
<td>20/85 (20/20, 20/800)</td>
</tr>
<tr>
<td>Risk factors (Yes/No)</td>
<td>Hypertension 16/67 DM 2/81 Migraine 9/74 Family history 17/66 Multiple 9/74 Other 14/69 Nil 39/44</td>
</tr>
</tbody>
</table>

OAG, open angle glaucoma; POAG, primary open angle glaucoma; PI, peripheral iridotomy; CE, cataract extraction; PXG, pseudoexfoliation glaucoma; PG, pigmentary glaucoma; IOP, intraocular pressure; BCVA, best corrected visual acuity.
had an IOP spike defined as having ≥6 mm Hg rise in IOP from baseline at 1 hour post-treatment.

The baseline IOP for the success group ranged from 18–36 mm Hg and for the non-success group 16–28 mm Hg. A clear trend of steady post-treatment IOP reduction was observed in the success group, whereas in the non-success group there was no significant improvement in terms of IOP reduction throughout the 12 months (table 3). In both outcome groups, patients with lower baseline IOP had lower IOP at 1 year post-treatment (success: p = 0.0002; non-success: p = 0.0001). On the other hand, it was observed in the success group that patients with higher baseline IOP had significantly greater IOP reduction induced by SLT (p = 0.00001), but not in the non-success group (p = 0.2292). The best corrected visual acuity was similar in both groups at baseline and throughout the 1 year follow up. As for the effect of previous ALT treatment, there is no significant difference in IOP regardless of the patients’ outcome groups, patients with lower baseline IOP had lower IOP at 1 year post-treatment (success: p = 0.0002; non-success: p = 0.0001), but not in the non-success group (p = 0.2292). The best corrected visual acuity was similar in both groups at baseline and throughout the 1 year follow up.

The final multivariate logistic model provided an OR of 10 times.

Table 2: Comparison of the success and non-success groups (SD)

<table>
<thead>
<tr>
<th>Covariate</th>
<th>SLT success* at 1 year</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Continuous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>70.76 (10.68)</td>
<td>68.62 (10.48)</td>
</tr>
<tr>
<td>Baseline IOP (mm Hg)</td>
<td>26.05 (4.82)</td>
<td>20.97 (2.85)</td>
</tr>
<tr>
<td>IOP (mm Hg) at 1 hour post-treatment</td>
<td>25.23 (5.76)</td>
<td>21.14 (4.82)</td>
</tr>
<tr>
<td>Total energy (mJ)</td>
<td>44.95 (10.73)</td>
<td>43.87 (10.83)</td>
</tr>
<tr>
<td>Categorical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (F/M)</td>
<td>18/25</td>
<td>12/17</td>
</tr>
<tr>
<td>Glaucoma type (OAG/others)</td>
<td>29/14</td>
<td>17/12</td>
</tr>
<tr>
<td>Previous ALT (Y/N)</td>
<td>12/31</td>
<td>7/22</td>
</tr>
<tr>
<td>Other surgery during study (Y/N)</td>
<td>20/19</td>
<td>13/14</td>
</tr>
<tr>
<td>Hypertension (Y/N)</td>
<td>5/34</td>
<td>9/20</td>
</tr>
<tr>
<td>Diabetes mellitus (Y/N)</td>
<td>1/38</td>
<td>1/28</td>
</tr>
<tr>
<td>Myopia (Y/N)</td>
<td>3/36</td>
<td>3/26</td>
</tr>
<tr>
<td>Family history of glaucoma (Y/N)</td>
<td>9/30</td>
<td>2/27</td>
</tr>
<tr>
<td>TM pigmentation (grade 1–4)</td>
<td>1256</td>
<td>955</td>
</tr>
<tr>
<td>BCVA (median)†</td>
<td>20/30</td>
<td>20/30</td>
</tr>
</tbody>
</table>

OAG, open angle glaucoma; Y/N, yes/no; TM, trabecular meshwork; BCVA, best corrected visual acuity.

*SLT induced IOP reduction greater than or equal to 20% of pretreatment IOP.
†Kruskal-Wallis rank sum test.
‡Fisher’s exact test for equality of median.

DISCUSSION

To the best of our knowledge, our study is the first highly successful SLT predictor study derived from high quality data of a randomised clinical trial. The results suggest that SLT success does not depend on age or sex. None of the glaucoma risk factors were found to be significant predictors. Family history of glaucoma was the closest to being significant, but since the analysis was not adequately powered to detect a difference, we cannot draw conclusions based on these data.

Interestingly, unlike ALT, TM pigmentation and type of glaucoma did not predict better outcome. Our results agree with previous findings that lower baseline IOP predicts lower post-treatment IOP; and patients with higher baseline IOP benefit more from the laser treatment in terms of total IOP reduction. Unlike previous studies where arbitrary cut offs of high baseline IOP were used in the analysis, we demonstrated a continuous relation between baseline IOP and post-treatment IOP reduction to be significant. Since our definition of success is based on the patients’ relative response to the SLT treatment, we expect to observe most patients in the success group to have higher baseline IOP. As reported in the results section, the non-success group had a narrower range of baseline IOP than the success group, and all non-success patients had a baseline IOP of <29 mm Hg; thus, the data might seem to indicate a regression towards the mean effect. However, the fact that even after all patients with IOP ≥30 mm Hg at baseline were excluded in a separate analysis, the results still suggested that higher baseline IOP
predicted better chance of SLT outcome in terms of post-treatment IOP reduction.

Our result regarding predictors of successful SLT are comparable to previous studies on successful ALT. Baseline IOP was found to correlate with IOP reduction post-ALT as well.$^{13,14}$ Lower baseline IOP predicts lower post-ALT IOP, and higher baseline IOP predicts greater IOP reduction post-ALT. Interestingly, in ALT studies it was also found that presence of pseudoexfoliation,$^{15}$ ALT performed as primary therapy,$^{16,17}$ grade of pigmentation,$^{18,19}$ and number of preoperative antiglaucoma medications correlated with success.$^{20}$ In our study previous ALT did not influence the success of SLT at 1 year.

ACKNOWLEDGEMENTS
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REFERENCES

Table 4 Multivariate logistic regression analysis result

<table>
<thead>
<tr>
<th>Models</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Multivariate</th>
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<tr>
<td>Covariates</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Odds ratio (%95% confidence interval)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline IOP</td>
<td>1.47 (1.2, 1.8)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IOP at 1 hour</td>
<td>1.16 (1.0, 1.3)</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.33 (0.1, 1.1)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Family history</td>
<td>1.58 (1.2, 2.1)</td>
<td>0.91 (0.8, 1.1)</td>
<td>0.59 (0.1, 2.8)</td>
<td>4.05 (0.8, 20.4)</td>
<td>2.56 (0.2, 24.8)</td>
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