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Selective laser trabeculoplasty versus drops for newly diagnosed ocular hypertension and glaucoma: the LiGHT RCT

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Abstract

Background: Newly diagnosed open-angle glaucoma (OAG) and ocular hypertension (OHT) are habitually treated with intraocular pressure (IOP)-lowering eyedrops. Selective laser trabeculoplasty (SLT) is a safe alternative to drops and is rarely used as first-line treatment.

Objectives: To compare health-related quality of life (HRQoL) in newly diagnosed, treatment-naive patients with OAG or OHT, treated with two treatment pathways: topical IOP-lowering medication from the outset (Medicine-1st) or primary SLT followed by topical medications as required (Laser-1st). We also compared the clinical effectiveness and cost-effectiveness of the two pathways.

Design: A 36-month pragmatic, unmasked, multicentre randomised controlled trial.

Settings: Six collaborating specialist glaucoma clinics across the UK.

Participants: Newly diagnosed patients with OAG or OHT in one or both eyes who were aged ≥ 18 years and able to provide informed consent and read and understand English. Patients needed to qualify for treatment, be able to perform a reliable visual field (VF) test and have visual acuity of at least 6 out of 36 in the study eye. Patients with VF loss mean deviation worse than -12 dB in the better eye or -15 dB in the worse eye were excluded. Patients were also excluded if they had congenital, early childhood or secondary glaucoma or ocular comorbidities; if they had any previous ocular surgery except phacoemulsification, at least 1 year prior to recruitment or any active treatment for ophthalmic conditions; if they were pregnant; or if they were unable to use topical medical therapy or had contraindications to SLT.

Interventions: SLT according to a predefined protocol compared with IOP-lowering eyedrops, as per national guidelines.

Main outcome measures: The primary outcome was HRQoL at 3 years [as measured using the EuroQol-5 Dimensions, five-level version (EQ-5D-5L) questionnaire]. Secondary outcomes were cost and cost-effectiveness, disease-specific HRQoL, clinical effectiveness and safety.

Results: Of the 718 patients enrolled, 356 were randomised to Laser-1st (initial SLT followed by routine medical treatment) and 362 to Medicine-1st (routine medical treatment only). A total of 652 (91%) patients returned the primary outcome questionnaire at 36 months. The EQ-5D-5L score was not significantly different between the two arms [adjusted mean difference (Laser-1st - Medicine-1st) 0.01, 95% confidence interval (CI) -0.01 to 0.03; $p = 0.23$] at 36 months. Over 36 months, the proportion of visits at which IOP was within the target range was higher in the Laser-1st arm (93.0%, 95% CI 91.9% to 94.0%) than in the Medicine-1st arm (91.3%, 95% CI 89.9% to 92.5%), with IOP-lowering glaucoma surgery required in 0 and 11 patients, respectively. There was a 97% probability of Laser-1st being more cost-effective than Medicine-1st for the NHS, at a willingness to pay for a quality-adjusted life-year of £20,000, with a reduction in ophthalmology costs of £458 per patient (95% of bootstrap iterations between -£585 and -£345).

Limitation: An unmasked design, although a limitation, was essential to capture any treatment effects on patients' perception. The EQ-5D-5L questionnaire is a generic tool used in multiple settings and may not have been the most sensitive tool to investigate HRQoL.

Conclusions: Compared with medication, SLT provided a stable, drop-free IOP control to 74.2% of patients for at least 3 years, with a reduced need for surgery, lower cost and comparable HRQoL. Based on the evidence, SLT seems to be the most cost-effective first-line treatment option for OAG and OHT, also providing better clinical outcomes.

Future work: Longitudinal research into the clinical efficacy of SLT as a first-line treatment will specify the long-term differences of disease progression, treatment intensity and ocular surgery rates between the two pathways.

Trial registration: Current Controlled Trials ISRCTN32038223.

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Keywords: COST-EFFECTIVENESS; GLAUCOMA; INTRAOCULAR PRESSURE; OCULAR HYPERTENSION; PRIMARY OPEN-ANGLE GLAUCOMA; PROSTAGLANDIN ANALOGUES; QUALITY OF LIFE; SELECTIVE LASER TRABECULOPLASTY.

Plain language summary

Glaucoma is an eye condition in which the optic nerve becomes damaged and, if left untreated, will lead to loss of vision. Ocular hypertension (OHT) is the medical name for high pressure in the eye that increases the risk of getting glaucoma. Lowering the eye pressure is the only known way to prevent glaucoma from getting worse. Before this trial, the standard initial treatment of these conditions was the prescription of eyedrops to lower the pressure in the eye. An alternative is a laser therapy that is known to reduce the eye pressure. This study investigated if starting treatment of glaucoma or OHT with laser therapy (using eyedrops later, if needed) affected the patients' quality of life (QoL) more or less than starting treatment with eyedrops alone. The study also investigated if initial treatment with laser and initial treatment with eyedrops are equally good at controlling eye pressure and are equally safe and how much they cost the NHS. Patients were randomly assigned to starting treatment with either laser or eyedrops and the two groups were then compared. The study found that for the first 3 years QoL was similar regardless of treatment. However, three-quarters of patients initially treated with laser did not need any eyedrops to control their eye pressure for 3 years. Patients initially treated with laser were less likely to require cataract surgery, and none needed any glaucoma surgery in the first 3 years. In contrast, among those patients treated with eyedrops, glaucoma surgery was required in 11 eyes (out of 622 eyes). Initial treatment with laser was cheaper than initial treatment with eyedrops. The results of this study suggest that laser is an efficient, safe and cheaper alternative to eyedrops, and that three-quarters of the patients initially treated with laser do not need any eyedrops for the first 3 years of treatment.

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