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An Educational Intervention to Increase Adoption of Selective Laser Trabeculoplasty as First-Line Treatment for Glaucoma

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Study Protocol

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Under the leadership of L. Jay Katz, MD, Director of the Wills Eye Glaucoma Service, and Lisa Hark, PhD, Director of the Wills Eye Glaucoma Research Center, we will conduct a study entitled: ***An Educational Intervention to Increase Adoption of Selective Laser Trabeculoplasty (SLT) as First-Line Treatment for Glaucoma.***

A. Background and Significance: Glaucoma is a chronic optic neuropathy with typical optic nerve changes, visual field defects, and progressive loss of vision (1-3). Glaucoma is a major global health issue, and is a leading cause of irreversible blindness worldwide (4). The prevalence of glaucoma is increasing, causing a significant economic burden (4,5). Due to the rapidly aging population, it is estimated to affect 3.36 million Americans by 2020, an approximate 50% increase from the current 2.2 million (6).

Despite the availability of advanced technology and diagnostic testing, 50% of those with glaucoma still remain undiagnosed because of its painless, asymptomatic, and initially monocular progression, resulting in diagnosis only in the advanced stages of the disease (4,6). When glaucoma is diagnosed in its early stages, however, appropriate treatment and management can almost always prevent blindness (7-10). In evaluating the initial treatment for open angle glaucoma there are 4 important considerations: 1) efficacy, 2) safety, 3) adherence, and 4) cost.

A.1. Efficacy*:* Laser treatment, as the primary or first-line treatment for glaucoma or ocular hypertension, has been indicated by the most recent issue of the *American Academy of Ophthalmology Primary Practice Guidelines for Glaucoma* (11). Data from the Glaucoma Laser Trial showed that after 2 years of follow-up, 44% of eyes that were lasered first were controlled by argon laser trabeculoplasty (ALT) alone (12). After 2 years, 30% of the eyes that received medication first remained controlled by timolol alone. This multicenter, randomized clinical trial enrolled 271 patients and was designed to assess the efficacy and safety of an alternative to treatment with topical medication for controlling intraocular pressure (IOP) in patients with newly diagnosed, previously untreated primary open-angle glaucoma (POAG) (12). Of note, disease stability, as measured by perimetry and disc photography, favored ALT.

For more than two decades, selective laser trabeculoplasty (SLT) has been used safely and effectively for the treatment of elevated IOP in patients with open-angle glaucoma (13). Comparative studies in the UK, Canada, Israel, and the US have demonstrated efficacy of SLT is comparable to latanoprost the most commonly used first- line medical agent for the treatment of open-angle glaucoma. It is an in-office procedure that may effectively reduce IOP in most glaucoma patients. During SLT, a laser is used to target certain cells in the trabecular meshwork (TM), bringing about biological changes in the microstructure of the TM, resulting in an improved outflow of aqueous humor, thereby reducing IOP.

At Wills Eye Hospital Glaucoma Research Center, we compared outcomes of selective laser trabeculoplasty (SLT) with drug therapy for glaucoma patients in a multi-centered prospective randomized clinical trial (14). We enrolled sixty-nine patients (127 eyes) with open-angle

glaucoma or ocular hypertension who were randomized to SLT or medical therapy. Target intraocular pressure (IOP) was determined using the Collaborative Initial Glaucoma Treatment Study formula. Patients were treated with SLT (100 applications 360 degrees) or medical therapy (prostaglandin analog). Six visits over 1 year followed initial treatment. If target IOP range was not attained with SLT, additional SLT was the next step, or in the medical arm additional medications were added.

Sixty-nine patients were treated. Data collection terminated with 54 patients reaching 9 to 12-months follow-up. Twenty-nine patients were in the SLT group, 25 patients in the medical group. Baseline mean IOP for all eyes was 24.5 mm Hg in the SLT group, 24.7 mm Hg in the medical group. Mean IOP (both eyes) at last follow-up was 18.2 mm Hg (6.3 mm Hg reduction) in the SLT arm, 17.7 mm Hg (7.0 mm Hg reduction) in the medical arm. By last follow-up, 11% of eyes received additional SLT, 27% required additional medication. There was not a statistically significant difference between the SLT and medication groups. Therefore, IOP reduction was similar in both arms after 9 to 12-months follow-up. More treatment steps were necessary to maintain target IOP in the medication group, although there was not a statistically significant difference between groups. These results support the option of SLT as a safe and effective initial therapy in open-angle glaucoma or high risk ocular hypertension (14).

A.2. Adherence: Studies have shown that less than 50% of patients with glaucoma treated with prescription eye drops are indeed adherent to their medications (15-20). There are many obstacles to adherence with medical therapy for glaucoma: difficulty in placing eye drops, remembering to place eye drops, side effects, chronicity with no immediate tangible benefit, and cost. On the other hand, laser trabeculoplasty provides 100% adherence.

A.3. Side Effects: Medical therapy is frequently limited by ocular and systemic side effects. Local effects such as red eyes, allergic blepharoconjunctivitis, irreversible iris hyperchromia, periorbital fat atrophy, keratitis, and blurred vision may occur and not only affect quality of life, but impact ocular medication adherence. Even the preservatives in glaucoma bottles (most commonly benzalkonium chloride) are associated with problems such as exacerbation of dry eye symptoms. Of even deeper concern are systemic side effects of glaucoma medications, such as precipitating asthma, altering heart rate, lethargy, an increased risk of falling and subsequent injury, depression, rash which may lead to increased office visits, hospitalization, and rarely, death. In contrast, SLT may result in mild and transient IOP elevation, which is typically a minimal risk and rarely of any significance. Other side effects of laser are extremely rare including iritis, blurred vision, hyphema and keratitis.

A.4. Cost: Long-term use of eye drops can be costly, which may deter patients from adhering to their treatment regimens. Numerous cost analyses have been conducted to determine the most cost-effective treatment option for patients with newly diagnosed mild open-angle glaucoma (21-26). One observational study, conducted by Stein and coworkers, evaluated treatment of glaucoma with generic topical prostaglandin analogs (PGAs) versus treatment with laser trabeculoplasty (LTP). Using a Markov model with a 25-year horizon, the investigators compared the incremental cost-effectiveness of treating newly diagnosed mild open-angle glaucoma with PGAs, LTP, or observation only. Incremental cost-effectiveness of LTP over no treatment was $16,824 per quality-adjusted life year. By comparison, incremental cost-effectiveness of PGAs versus no treatment is $14,179 per quality-adjusted life year, and

PGAs provide greater health-related quality of life relative to LTP. The results supported that LTP can confer greater value since PGAs are 25% less effective due to poor patient adherence (21). A cost analysis by Cantor has shown that SLT is less expensive when compared with the cost of a topical generic glaucoma medication over a 5-year period. Patients treated with SLT initially, then followed by topical medication, had a cost saving of $2.50 for every $1.00 spent (25). Another observational study conducted by Seider found that SLT would be less costly then generic medication after 13.1 months (24). A 6-year cost comparison of SLT to primary medical therapy in Canada found that over a 3-year scenario, patients using SLT primary over "mono, bi and tri-drug therapy produced a 6-year cumulative cost savings of $580.52, $2042.82 and 2266.65 per patient" (26).

A.5. Significance: Cost-comparative studies in Canada, Australia, and the USA have tended to favor SLT as a first-line option. For these reasons, SLT would be an excellent alternative in the treatment of glaucoma, as it is reimbursed by Medicare and other insurance companies, has fewer side effects, and unlike the use of eye drops, requires no additional effort or adherence measures on the patient's part. Although glaucoma specialists consider the effect of SLT in lowering IOP to be similar to glaucoma medications, SLT is significantly underutilized as first-line treatment in glaucoma patients (24-26). Patient-related barriers may include lack of knowledge about SLT, confusion with other types of lasers, or fear of severe post-procedure complications. Ophthalmologists' attitudes may also be based on outdated information and inaccurate beliefs about SLT. Third party payers may not understand that SLT as first-line therapy may prove more convenient for patients, and may ultimately be more cost-effective (24-26).

B. Study Aims: The aims of this study are to:

AIM 1: Develop an Educational Intervention to directly inform patients with glaucoma of the benefit/risk of SLT versus ocular medications while also indirectly educating staff and physicians.

AIM 2: Conduct a randomized controlled trial to measure the effectiveness of an Educational Intervention with a group of patients by comparing conversions to SLT in the follow-up visits between the Usual Care group and the Educational Intervention group.

AIM 3: Assess the beliefs and attitudes of a group of ophthalmologists about SLT as first line therapy before and after viewing the Educational Intervention.

Hypothesis: *Better informed patients and ophthalmologists tend to select SLT in place of ocular medications as either first line or in place of medications after initially using medications.*

C. Research Design and Methods:

C.1. Human Subjects and Informed Consent: The study involves human subjects, all of whom will give informed consent prior to enrollment. The study will seek approval from Wills Eye Hospital's Institutional Review Board, and will be conducted in accordance with the Health Insurance Portability and Accountability Act. Study procedures will adhere to the Declaration of Helsinki for research involving human subjects.

C.2. Development of the SLT Educational Intervention (AIM 1): The Educational Intervention about SLT as first line therapy to treat glaucoma will be developed by the principal investigator, co-investigators, the research coordinator, and research assistants using the American Academy of Ophthalmology Practice Pattern Guidelines, and the Glaucoma Research Foundation resources. The intervention will be developed with the aim of improving patients' understanding of what laser treatment is, what are the benefits, and why it should be strongly considered as a first-line treatment for glaucoma before any medications. We will adapt the content from the Glaucoma Research Foundation web page as well as the material in the *Understanding and Living with Glaucoma* booklet (www.glaucoma.org/treatment/laser-surgery.php).

Once the laser procedure is described alongside images and text written at the 4th grade reading level, a MS Powerpoint presentation will be developed, in consultation with a small group of patients (n=5) who have elected to have a laser procedure in at least one eye to treat glaucoma. We will share the Educational Intervention with these patients before and after they have the SLT procedure, and ask them to assist us in providing culturally and linguistically appropriate terms and language to describe the procedure.

We will also ask them to help us develop the "frequently asked questions" section including the answers that they feel would be most helpful to advocate for SLT as first line therapy for glaucoma. We will base these responses on the Glaucoma Research Foundation's web site intervention (www.glaucoma.org/treatment/selective-laser-trabeculoplasty-10-commonly-asked-questions.php).

Once the SLT Educational Intervention is developed, we will produce a 10 minute video recording of glaucoma specialists, (Dr. Katz or Dr. Fudemberg) explaining why patients would benefit from SLT as first line therapy to treat glaucoma. The video may include step-by-step footage of a patient being treated with laser at the Wills Eye Glaucoma Service and an interview with a patient after the procedure. This will provide patients with information about laser from a trusted source and a peer. The video will be embedded into the Powerpoint slide presentation.

C.3. Recruitment and Inclusion Criteria:

Patients: A total of 40 patients will be recruited from the Wills Eye Hospital Glaucoma Care Specialists' private practice and the resident-run Glaucoma Clinic over an 6-month period for this pilot study. Eligible patients will be between 40 and 90 years of age, and have either high-risk ocular hypertension, primary open-angle glaucoma, or pseudo-exfoliation glaucoma with no previous laser trabeculoplasty. Eligible patients will be naive to medication and laser **or** currently being treated with glaucoma eye drop(s). Only patients within three years of a glaucoma-related diagnosis and stable intraocular pressure will be invited to participate.

After IRB approval, the patients' electronic medical records will be reviewed in advance of their next scheduled eye exam. Eligible patients will be invited to participate in the study by letter and/or telephone call, in advance of their scheduled appointment. Eligible patients may also be approached by our study team when checking in on the same day of their eye exam appointment.

All patients will be asked to provide written informed consent, prior to meeting with their ophthalmologist. Once patients are consented, a yellow-colored page with large font **(Patient Enrolled: SLT vs. Meds Study)** will be inserted into the patient's medical chart folder to alert the doctor that the patient is enrolled in the study and that both treatment options should be discussed in detail.

Those enrolled will be randomized to either the SLT Educational Intervention group (n=20) or the Usual Care group (n=20). The knowledge, beliefs, barriers, and attitudes about SLT vs. medication as first line treatment of glaucoma will be assessed in both groups.

C.4. Study Procedures:

Educational Intervention group: The 20 patients randomized to the SLT Educational Intervention group will meet with their ophthalmologist who will discuss both SLT and medication options for treatment of glaucoma, which is currently standard of care. After their eye exam, the patient will meet with the research coordinator. The research coordinator will then ask the patient questions to assess their knowledge, beliefs, barriers, and attitudes about SLT vs. medication as first line treatment of glaucoma (See section D.2.a). The patient will then review the SLT Educational Intervention and be shown the PowerPoint presentation about SLT. After the presentation, the patient will be asked more questions (See section D.2 b). After viewing all information, the Intervention patient will have the opportunity to ask questions to the research coordinator about SLT. If the patient elects to schedule an SLT after the Educational Intervention, they will be assisted with making this appointment.

Usual Care group procedures: The 20 patients randomized to the Usual Care group will meet with their ophthalmologist who will recommend both SLT and medication options for treatment of glaucoma, which is currently standard of care. After their eye exam, the patient will meet with the research coordinator who will answer any questions they have about treatment options. The research coordinator will then ask the patient questions to assess their knowledge, beliefs, barriers, and attitudes about SLT vs. medication as first line treatment of glaucoma (See section D.2.a). The Usual Care group will not be exposed to SLT Educational Intervention and will not be asked to watch a video about SLT. If the patient elects to have SLT at any point during the study, we will provide the phone number for them to schedule the procedure. Patients in the Usual Care group will not be assisted with making any SLT appointments.

If patients in either group would like to consult with their ophthalmologist again, we will provide a message to the physician and he/she will call the patient to discuss treatment options again. Doctors will be masked to the group assignment to reduce biasing the outcome. We will track how many patients wanted to speak to their ophthalmologist over the phone or in person in both groups and the outcome of these calls.

C.5. Tracking Outcomes: The goal of Aim 1 is to determine if the SLT Educational Intervention used by the research coordinator and physicians with patients could lead to greater utilization of SLT by patients. Rates of SLT will be tracked in each group after patients are asked the first set of questions and after the Intervention group is shown the video. Follow-up eye exam appointments for patients in both groups will be tracked for a 6-month period to

assess the number of patients who elect to have SLT. The rate of SLT will be compared between the SLT Educational Intervention group and the Usual Care group at these time periods.

Patients will provide their name and date of birth on the consent form, both of which will be used to extract and de-identify data from their electronic medical record, including demographics, disease severity, and prior and current glaucoma treatments. Demographic data will include race/ethnicity, gender, and age.

C.6. Assess Ophthalmologists' Beliefs and Attitudes about Laser (AIM 3): A total of 15 glaucoma specialists and 20 general ophthalmologists will be interviewed by the research coordinator via telephone or in person. These ophthalmologists will be recruited from the Wills Eye Hospital Glaucoma Service, Wills Eye Hospital Primary Eye Care Service, Wills Eye Medical Staff, community ophthalmologists affiliated with Wills Eye Hospital, and other ophthalmologists as needed. We will recruit these ophthalmologists by asking for their input in helping patients make informed decisions about glaucoma treatment and management and assess how they approach patients with glaucoma.

These ophthalmologists, who will be asked to fill out a survey, will be considered study subjects and will be requested to sign an informed consent form prior to participation. After obtaining informed consent, we will request their input to answer several questions over the phone. Once they agree to participate and complete the phone screening questions, the research coordinator will send them a link to the Powerpoint slides including the video, and request they complete a survey (survey monkey) after viewing the intervention (See Section D.2.c).

D.1 Data Management and Analysis

D.1.a. Assessment Measures: The primary outcome measure is the number of patients who complete an SLT over the study period. Rates of SLT procedures will be compared between patients enrolled in the SLT Educational Intervention group versus the Usual Care group. Rates of SLT will be tracked in each group after patients are asked the first set of questions and after the Intervention group is shown the video. Follow-up eye exam appointments for patients in both groups will be tracked for a 6-month period to assess the number of patients who elect to have SLT.

The secondary outcome is to assess the beliefs and attitudes of patients and a group of ophthalmologists about SLT as first line therapy before and after viewing Educational Intervention. The research coordinator will ask all patients questions about their knowledge, beliefs, barriers, and attitudes about SLT vs. medication as first line treatment of glaucoma. These questions will be developed with Dr. Robin Casten, a psychologist and vision researcher at Sidney Kimmel Medical College with extensive experience in survey development and sampling techniques. She will be consulted during the development phase to revise and implement the following questions. If a more understandable explanation of the risks/benefits of SLT versus medications results in a significant increase in SLT treatments, that suggests that the real barrier is patient understanding and perhaps to a lesser extent physician education.

D.2.a. Questions for Patients in Both Groups after Consenting and Eye Exam

Are you aware that glaucoma can be treated with laser therapy instead of eye drops?
Did you know that laser therapy is a possible first option for treating glaucoma before eye drops?
Did you discuss laser therapy with your glaucoma doctor today?
Would you consider having laser treatment? Why or why not?
Would you consider having this laser therapy instead of filling your prescription for eye drops?
If no, please describe reasons.

D.2.b. Questions for Intervention Patients After Viewing the Presentation and Video

Did you have any questions about the educational program we showed you?
Would you consider having laser therapy to treat your glaucoma?
Would you consider having this laser therapy instead of filling your prescription for eye drops?
If no or maybe, let's discuss why?
If yes, can I help you to schedule a laser appointment at your convenience?

In order to assess the beliefs and attitudes of a group of ophthalmologists about SLT as first line therapy before and after viewing Educational Intervention, we will ask the following questions to determine how they approach newly diagnosed patients with glaucoma.

D.2.c. Ophthalmologists' Questions Before Viewing the Presentation and Video:

1) What treatment options do you currently offer your newly diagnosed glaucoma patients?
2) What is your preferred treatment for newly diagnosed glaucoma patients? Why?
3) What percentage of your newly diagnosed glaucoma patients receive SLT? Why?
4) Where do you see SLT in the glaucoma treatment paradigm?
5) Would you use SLT as first line therapy for all/most of your newly diagnosed POAG patients?
If yes, why?
If no, what would persuade you to use SLT more frequently?

D.2.d. Ophthalmologists' Questions After Viewing the Presentation and Video:

1) Did this educational program convince you that SLT is appropriate as first line therapy instead of medication? Why or why not?
2) If you are reluctant to recommend SLT as first line therapy, please explain why.
3) What additional information would you like to know to help make an informed decision?

E. Study Timeline: The study will be conducted between July 1, 2017 and June 31, 2018. We will complete all IRB submission and staff training prior to July 1, 2017. We will develop the Educational Intervention and video during the initial 3 months of funding period. We will identify, recruit, consent and enroll 40 patients, who will be randomized, 20 to the Educational Intervention group and 20 to the Usual Care group between August 1, 2017 and January 30, 2018. Data cleaning, analysis, and dissemination of findings will be completed by June 30, 2018 and a dissemination plan will be implemented to include submitting publication and

abstracts for presentations at national research meetings such as American Glaucoma Society and American Academy of Ophthalmology.

F. Statistical Analysis: All data analyses will be conducted using R (R core team, Vienna, Austria). Fisher's exact test for count data will be used to compare the pre- and post-SLT Educational Intervention survey answers. Descriptive statistics will be used to present patient demographic and clinical data.

G. Program Management:

Principal Investigator: L. Jay Katz, MD has 30 years of experience as a glaucoma specialist, and will oversee all study personnel. Dr. Katz will devote 5% of his time.

Project Director: Lisa Hark, RD, PhD has 25 years of experience as a co-investigator and project director, and works closely with Dr. Katz. Dr. Hark will devote 5% of her time.

Project Coordinator/Interviewer: Sheryl Wizov, COA is an ocular technician with 30 years of experience coordinating glaucoma research studies, and will be involved in the recruitment of patients, as well as in the administration of the meetings with patients. Ms. Wizov will devote 20% of her time.

Project Administrator: Mary Jo Schwartz has 30 years of administration experience, and will assist in scheduling all interviews and submitting all documents for IRB approval. Ms. Schwartz will devote 10% of her time.

Project Assistant: Several Sidney Kimmel College of Medicine first and second year students will volunteer over the summer of 2017 and during the academic year 2017-2018 to assist the research team with developing the Educational Intervention. Medical students will also participate in data extraction from medical records, data entry, data verification, conducting the pilot study interviews, and writing and submitting the manuscript.

Program Consultant:

Robin Casten, PhD, is Professor of Psychiatry and Human Behavior, Thomas Jefferson University in Philadelphia and has been working closely with the Glaucoma Research Center and Midatlantic Retina for more than 15 years. We have budgeted $500 for 10 hours of support, at a rate of $50 per hour, to assist with the development of the survey questions and techniques to assess knowledge, beliefs, barriers, and attitudes about SLT vs. medication as first line treatment of glaucoma.

Video Production: Under the leadership of Jack Scully, Director of Wills Eye Audio Visual Services, we will assume the cost of filming, editing, producing, and completing a 10-minute video about SLT to be embedded into the Powerpoint presentation.

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