

Glaucoma Screenings and Treatment Under Siege

When will the evidence be enough?

BY EVE J. HIGGINBOTHAM, SM, MD

At the beginning of my academic career, we physicians who care for patients with glaucoma were besieged by economists who asserted that there was insufficient evidence to support the treatment of the disease.¹ In the early stages of this tsunami, clinical researchers supported by resources primarily from the National Eye Institute were galvanized to create the necessary proof that treatment works. We are all familiar with the array of clinical trials conducted in the 1980s and 1990s: the Fluorouracil Filtering Surgery Study (FFSS), Glaucoma Laser Trial (GLT), Advanced Glaucoma Intervention Study (AGIS), Collaborative Initial Glaucoma Treatment Study (CIGTS), Ocular Hypertension Treatment Study (OHTS), Early Manifest Glaucoma Trial (EMGT),² and Collaborative Normal Tension Glaucoma Study (CNTGS; not supported by the National Eye Institute).³ All were performed in earnest to prove the naysayers wrong and advance the treatment of this silent thief of sight.

Although we thought we had developed the best evidence, two reports released last year by the Agency for Healthcare Research and Quality (AHRQ) as part of its Effective Healthcare Program have provided guidance on improving the quality of our evidence. In 2003, the AHRQ was directed by Congress to carry out research on the comparative effectiveness of interventions to improve the quality of health care. A network of Evidence-based Practice Centers performs analyses related to the screening of specific diseases and the effectiveness of available treatments. The audiences for these analyses range from key decision makers to the lay public with the understanding that these documents will shape policy as well as choices by patients for their own care. This objective is laudable at a time

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when performance will be continually assessed using metrics. Transparency is another part of the mantra in this new era of value-based purchasing for health care.

There was a public response period last fall during which comments were invited to enrich the reports. The final reports were released on April 12, 2012, and they appeared to reflect comments expressed during the public period. Although the original conclusions of the reports noted in the previous drafts had not changed, the authors continued to encourage the researchers in our discipline to seek the necessary evidence in future trials.

THE AHRQ'S REPORTS

The Comparative Effectiveness of Screening for Glaucoma report examined the diagnostic accuracy of various screening methods.⁴ It also evaluated the impact of screening on the patient-reported outcomes and elements of indicators that suggest progressive disease such as uncontrolled IOP, loss of visual field, and deterioration of the optic nerve. Most of the report focused on the technical aspects of screening rather than on who should be screened. The adverse effects of screening were also assessed. Based on their analyses, the authors of this report did not identify any benefits of screening that can be linked to a reduction in the

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indicators of glaucomatous progression. They acknowledged that screening techniques have improved, but they noted that the activity of screening cannot be supported by available evidence. Moreover, given the side effects of screening such as corneal abrasion, the benefits of screening must be further examined.

What could have received greater emphasis in the report? First of all, the economic burden of not treating early disease has been assessed in the literature and could have been highlighted. Another point worthy of emphasis is that screening high-risk groups could uncover a greater number of individuals who would most benefit from early treatment. In conducting such systematic reviews, the role of such clinical points is not as easily considered as the specific objectives of the review. The authors did, however, acknowledge certain challenges in conducting the necessary studies that may demonstrate the benefits of screening such as variations in defining the diagnostic criteria for glaucoma and the long, progressive nature of the disease process.

The second report, Comparative Effectiveness for Treatment of Glaucoma, examined the safety and effectiveness of various treatments (ie, medical, laser, and incisional surgical) for the disease.⁵ The authors of this report found no benefit from these treatments as far as visual impairment or patient-reported outcomes. The authors did find, however, that medical and surgical treatment lowers IOP and can thus prevent further visual impairment and deterioration of the optic nerve.

In my estimation, the second report presents more challenges to the field, given the inherent variations in the different interventions we have available. Chief among the challenges is the ultimate difficulty of proving the true benefits of treatment, because such evidence would require that known glaucoma patients go untreated for a period of time. In fact, the EMGT² randomized individuals with known glaucoma to groups that were treated versus not treated and clearly demonstrated the benefits of intervention. Future studies will need to focus on self-assessment of outcomes for patients in addition to greater emphasis on the impact on quality of life.

During the public comment period last fall, members of the American Academy of Ophthalmology and the American Glaucoma Society issued a formal response to the AHRQ's reports. Among other points, these organizations emphasized the reports' lack of discussion of how early visual field loss compromises patients' quality of life and the omission of additional evidence on glaucoma treatment's impact on quality of life.^{6,7}

CONCLUSION

As a glaucoma specialist who has practiced medicine for more than 30 years, I fully appreciate the value of the care we provide, but we must continue to demonstrate that value in a more objective and patient-centered way. In the meantime, we continue to see patients with advanced disease, while the need to establish the burden of proof of the value of our treatment increases.

Over decades, millions of patients have benefited from our careful monitoring and nurturing. In their statistics, analysts never see our patients who presented with bilateral 5° central islands but have maintained their central vision for 10 years with treatment or the glaucoma suspects with a family history of blindness for whom we initiate medical therapy. For how long will we be allowed to treat these individuals and receive reimbursement for their care? It appears that history indeed repeats itself and that we are in the midst of another call to action to find the necessary evidence. Time is of the essence. ■

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