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Patient-Reported Outcomes for Minimally Invasive Glaucoma Surgery

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EDITORIAL

Patient-Reported Outcomes for Minimally Invasive Glaucoma Surgery

KULDEV SINGH, GEORGE L. SPAETH, RON D. HAYS, DAVID W. PARKE II, MICHELLE E. TARVER, AND MALVINA EYDELMAN, ON BEHALF OF THE GLAUCOMA OUTCOME SURVEY COLLABORATIVE STUDY GROUP

Glaucomatous disease is among the most common causes of worldwide blindness, but the impact on patients varies and is associated with a plethora of factors. Most importantly, the proportion of those individuals with the disease who experience symptomatic vision loss is relatively small compared to those with conditions such as age-related macular degeneration and diabetic retinopathy.[1] Primary open angle glaucoma is uncommonly visually disabling in the mild-to-moderate stages, and thus treatment of patients at the milder end of the spectrum has been focused on non-surgical lowering of intraocular pressure (IOP). Surgical therapy has traditionally been reserved for patients with advanced and/or rapidly progressive disease, or those with documented disease progression refractory to IOP-lowering medications and laser trabeculoplasty.

The emergence over the past 2 decades of microincisional and minimally invasive surgical techniques to reduce IOP has led to a paradigm shift in which surgical options are considered earlier in the continuum of glaucomatous disease.[2] This trend has been aided by data showing that, on average, there is clinically significant IOP lowering with the combination of cataract removal and minimally invasive glaucoma surgery (MIGS) that can reduce the postoperative dependence on IOP-lowering medications among patients with mild-to-moderate disease. Given the innovation in MIGS procedures, tools are needed to assess them and to ensure that patients are well served by such novel approaches.[3]

Although numerous microincisional techniques with a variety of instruments have been used to enhance the outflow of aqueous humor and reduce IOP, only a few have been studied in adequately controlled, prospective, multicenter randomized trials. Some implantable devices have shown reasonable assurance of safety and effectiveness and have received approval from the US Food and Drug Administration (FDA).[4,5] The FDA places patients at the center of all phases of the medical device innovation pathway. Patient-centered data are routinely collected in various study phases, and patient-reported outcomes are playing an increasingly important role in regulatory decisions. The importance of patient input about treatment alternatives for glaucoma is critical because symptoms and signs of disease progression may not coincide, and all therapeutic options can have an impact on health-related quality of life.

The emergence of a robust ecosystem of innovation in MIGS and the subsequent increase in novel product submissions led the Center for Devices and Radiologic Health (CDRH) to issue a guidance document to clarify regulatory recommendations.[3] This guidance followed a joint meeting hosted by CDRH and the American Glaucoma Society (AGS), the proceedings of which further elucidated views on what evidence may be needed to support new implantable MIGS devices.[6] The Glaucoma Outcomes Survey (GOS) was developed for patients with mild-to- moderate disease who are candidates for MIGS procedures. Beginning with physician and patient focus groups, a Web-based survey was created. This survey was refined by cognitive testing of glaucoma patients and then field-tested at 22 clinical sites across the United States. Efforts are underway to make the GOS publicly available.

The GOS was administered to 196 individuals who were scheduled to undergo implantation of any FDA-approved implantable MIGS device in combination with cataract surgery. The most implanted device in the field test study participants was the Hydrus (70%), followed by iStent Inject (26%) and iStent Model GTS 100 (4%). The 41-item GOS was administered at baseline and 3 months after surgery. To assess test–retest reliability, a subset of the sample also completed the survey 1 month post-baseline before surgery. In addition to the GOS, the Patient-Reported

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Outcomes Measurement Information System (PROMIS) global health items were administered to assess physical and mental health.[7] Assessment of the reliability and validity of the GOS in the field test are reported by Hays et al.[8] Field testing showed that the greatest impact of combined cataract and MIGS surgery was on functional limitations, with 48% and 4% of participants reporting significant improvement and worsening, respectively. The GOS Psychosocial Concerns and Vision-Related Symptoms scales showed significant improvement more often than worsening, but greater than three-fourths of participants reported no change in these measures. PROMIS Global Physical Health and Global Mental Health did not change from baseline to 3 months after surgery for 93% and 92% of participants, respectively. Older age was associated with greater functional limitations, vision-related symptoms, and psychosocial concerns, but also with better PROMIS global mental health.[8] Having diabetes was associated with worse PROMIS and GOS scores at baseline.

Although IOP and mean deviation were not associated with PROMIS or GOS scale scores, improvement of visual acuity of the study eye from baseline correlated strongly with improvement in functioning. In all, 49% of the study participants reported being "completely satisfied" with the combined cataract and MIGS surgery, with 35% and 9% being "very satisfied" and "somewhat satisfied," respectively, 3 months postoperatively. Although it is not possible in this study to assess the relative roles of the cataract and glaucoma procedures in determining improvements in functional limitations and patient satisfaction, it is noteworthy that the variable that correlated best with improvement in functional limitations was visual acuity, a measure that is known to improve in most patients undergoing cataract surgery and that is not likely to be positively affected by glaucoma surgery unless it is via the reduction of postoperative glaucoma medications.

The data highlight the importance of understanding patients' experiences living with mild-to-moderate glaucoma and with minimally invasive glaucoma surgical devices. The GOS can be incorporated in future studies of mild-to-moderate glaucoma patients receiving minimally invasive devices. As with any patient-reported outcome measure, refinements of this instrument based on future data collection will aid in further use of the measure in clinical studies. Given that the GOS was developed for patients with mild-to-moderate glaucoma, it is likely that the tool could be used, modified, or adapted to assess the impact on patients using other glaucoma treatments, including nonsurgical therapies.

CONFLICT OF INTEREST

All authors have completed and submitted the ICMJE disclosure form. (all the disclosures are listed there)

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

Kuldev Singh: Conceptualization, Investigation, Writing – original draft, Writing – review & editing. **George L. Spaeth:** Conceptualization, Investigation, Writing – review & editing. **Ron D. Hays:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – review & editing. **David W. Parke II:** Investigation, Writing – review & editing. **Michelle E. Tarver:** Conceptualization, Data curation, Formal analysis, Investigation, Supervision, Writing – review & editing. **Malvina Eydelman:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Validation, Writing – review & editing.

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