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Vision-Targeted Health-Related Quality-of-life Survey for Evaluating Minimally Invasive Glaucoma Surgery

Qi N. Cui[1,*], **Ron D. Hays**[2,6], **Michelle E. Tarver**[3], **George L. Spaeth**[4], **Sylvia H. Paz**[5], **Beverly Weidmer**[6], **Ronald L. Fellman**[7], **Steven D. Vold**[8], **Malvina Eydelman**[9], **Kuldev Singh**[10]

[1]Scheie Eye Institute, University of Pennsylvania, Philadelphia, PA, USA

[2]Department of Medicine, University of California, Los Angeles, CA, USA

[3]Office of Strategic Partnerships and Technology Innovation, Center for Devices and Radiological Health, United States Food and Drug Administration, White Oak, MD, USA

[4]Wills Eye Hospital, Sidney Kimmel School of Medicine, Thomas Jefferson University, Philadelphia, PA, USA

[5]Department of Medicine, University of California, Los Angeles, CA, USA

[6]RAND Corporation, Santa Monica, CA, USA

[7]Glaucoma Associates of Texas, Dallas, TX, USA

[8]Vold Vision, Fayetteville, AR, USA

[9]Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, Center for Devices and Radiological Health United States Food and Drug Administration, White Oak, MD, USA

[10]Stanford University School of Medicine, Stanford, CA, USA

Abstract

Purpose: To develop a vision-targeted health-related quality-of-life (HRQoL) instrument for patients with glaucoma who are candidates for minimally invasive glaucoma surgery (MIGS).

Design: Development of a health-related quality-of-life instrument.

Participants: Twelve practicing ophthalmologists and 41 glaucoma patients.

Methods: A questionnaire was constructed to assess functional limitations, vision-related symptoms, aesthetics, psychosocial issues, and surgical satisfaction for MIGS candidates. Questions were drafted following a review of the literature, and subsequently refined based upon input from one physician and four patient focus groups. Nineteen cognitive interviews were used to ensure questions were understandable to respondents.

[*]Corresponding author: Scheie Eye Institute, 51 N. 39th Street, Philadelphia, PA 19104; Phone: 215-316-5151; qi.cui@pennmedicine.upenn.edu.

Results: The focus group identified the following key issues and concerns as being important to glaucoma patients: functional limitations (e.g. driving), bodily discomfort (e.g. stinging from drops), changes in appearance (e.g. drooping eyelid), and psychosocial concerns (e.g. burden associated with a diagnosis of glaucoma, financial burden of treatment). Cognitive interviews resulted in the following improvements to the questionnaire: changes in wording to clarify lighting conditions, additional questions addressing psychosocial issues such as job loss, severity of disease, and perception of MIGS.

Conclusions: A patient-reported outcome (PRO) instrument, the Glaucoma Outcomes Survey (GOS), was developed to evaluate MIGS for patients with mild to moderate glaucoma. Next steps include electronic administration to patients selected from the American Academy of Ophthalmology IRIS registry. An electronic patient-reported outcome (ePRO) platform will be used to administer the questionnaire before and after MIGS. The questionnaire will improve understanding of how surgical interventions such as MIGS impact vision-targeted HRQoL in patients with mild to moderate glaucoma.

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A vision-targeted health-related quality of life instrument was developed to assess functional limitations, vision-related symptoms, aesthetics, psychosocial issues, and satisfaction with surgery for glaucoma patients who are candidates for minimally invasive glaucoma surgery. The resulting patient-reported outcome instrument, the Glaucoma Outcomes Survey, following psychometric field testing, will be electronically administered to patients before and after minimally invasive glaucoma surgery to improve understanding of surgical impact in patients with mild to moderate glaucoma.

Introduction

Glaucoma is the leading cause of irreversible blindness worldwide, and is characterized by progressive optic nerve abnormality with corresponding visual field defects secondary to retinal ganglion cell loss and ensuing optic neuropathy.[1] Traditional glaucoma surgical procedures, including trabeculectomy and glaucoma drainage implants, are associated with potentially vision-threatening short- and long-term complications. In the short term, complications may include bleb leak, hyphema, flat anterior chamber, hypotony, diplopia, and choroidal detachment. In the long-term, blebitis or drainage device erosion/exposure can evolve into vision-threatening endophthalmitis, and cataract progression is often more rapid after incisional glaucoma surgery. These surgically related adverse events can impact visual function in the short-term and sometimes result in permanent vision reduction.

By comparison, minimally invasive glaucoma surgery (MIGS), which often involves device implantation, is a rapidly evolving subset of innovative ophthalmic procedures designed to increase aqueous outflow using a variety of techniques with limited conjunctival and scleral disruption.[2] In 2012, the U.S. Food and Drug Administration (FDA) approved the first MIGS implantable device, the iStent Trabecular Micro-Bypass Stent (Glaukos; San Clemente, CA), for the treatment of mild to moderate open-angle glaucoma.[3] Other commercially available MIGS implantable devices approved by the FDA to date include the Xen gel stent (Allergan; Madison, NJ), the Hydrus microstent (Ivantis; Irvine, CA),

and the iStent inject.[4–6] Still other implantable devices, including the PreserFlo MicroShunt (formally InnFocus; Santen; Osaka, Japan) are presently being evaluated for FDA approval. While the efficacy of many MIGS implantable devices have been modest compared to traditional glaucoma drainage procedures, positive trade-offs consisting of shorter recovery time, improved safety profile, and fewer vision threatening complications have been postulated.[2] The long-term efficacy and safety of MIGS implantable devices remain to be determined. For example, the Cypass microshunt (Alcon; Fort Worth, TX) received FDA approval in 2016, but was voluntarily withdrawn in 2018 due to evidence of increased endothelial cell loss five years after implantation when compared to cataract surgery alone.[7,8]

Given the myriad of MIGS devices in development and/or seeking FDA approval, the objective of determining the appropriate glaucoma procedure(s) to suit the needs of individual glaucoma sufferers is critically important. As with any surgical procedure with the potential to impact a patient's daily functioning and well-being, an evaluation of that impact is paramount. Patient-reported outcome (PRO) measures function to help assure ophthalmic surgeons that their understanding of risks and benefits associated with a procedure reflects what matters to their patients.[9,10] While ophthalmologists routinely use measures such as intraocular pressure (IOP), central corneal thickness, optic nerve assessment, and visual field testing to make treatment decisions for glaucoma, associations between changes in these factors with PRO measures are less certain.[11,12]

Existing vision-targeted health-related quality of life (HRQoL) measures are numerous, and include the National Eye Institute (NEI) 25-Item Visual Function Questionnaire that assesses physical, mental, and social well-being in those afflicted by chronic eye conditions including glaucoma.[10,13,14] Other vision-targeted HRQoL instruments assess impacts of specific ocular pathologies and include the NEI Refractive Error QoL Instrument, the Visual Function Index (VF-14) assessment of functional impairment related to Cataracts, the Impact of Dry Eye on Everyday Life PRO instrument, the Quality of Vision (QoV) questionnaire, the QoL Questionnaire for Graves' Ophthalmopathy, and the Glaucoma Symptoms Scale.[15–19] None of these assessments, however, directly evaluate the impact of MIGS.[20]

In response to the need for a vision-targeted HRQoL instrument sensitive to the impact of glaucoma and glaucoma treatment on patients eligible for MIGS, the FDA, FDA's Center of Excellence in Regulatory Science and Innovation (CERSI) at the University of California, San Francisco (UCSF)/Stanford, and the American Glaucoma Society (AGS) collaborated on a study to develop a questionnaire targeted at persons with glaucoma who are candidates for MIGS. This paper describes the methods used to develop this instrument.

Methods

Physician Focus Group

The University of California, Los Angeles (UCLA) Office of the Human Research Protection Program Institutional Review Board (IRB# 16–001107) approved this cross-sectional survey, which includes prospective administration of focus groups and cognitive

interviews. A group of 12 ophthalmologists convened in Fort Lauderdale, FL during the AGS Annual meeting on March 2, 2016. Most participants were AGS members who regularly cared for patients with glaucoma. None received compensation for participation. Physicians were asked about their perceptions of disease symptoms experienced by glaucoma patients, how glaucoma and treatment modalities affected patients' functioning and well-being, limitations of medical and surgical glaucoma treatments, and desired treatment outcomes. The physicians also reviewed and commented on items from the NIH Toolbox Vision-Related Quality of Life instrument.[21,22]

Patient Focus Groups

In 2017, four patient focus groups were conducted at two academic centers, the Stein Eye Institute at UCLA and the Scheie Eye Institute at the University of Pennsylvania, and two private practices, Glaucoma Associates of Texas in Dallas, and Vold Vision in Arkansas. The recruitment sites were selected to encompass different socioeconomic groups and racial/ethnic backgrounds, as well as to pick up regional differences in patient perspectives. The Arkansas group, for example, consisted entirely of Hispanic, Spanish-speaking patients and were conducted in Spanish. Eligibility criteria for the patient focus groups were as follows: 1) age 22 years and older, 2) glaucomatous optic neuropathy as determined by a glaucoma specialist, and 3) open drainage angles confirmed on gonioscopy.

A list of eligible patients was generated by staff at each of the four practices based on above criteria. Project staff confirmed eligibility prior to contacting the patients via phone to explain the study and elicit participation. Some practices chose to discuss the project with their patients prior to contact by research project staff. Written informed consent was obtained from all participants prior to each focus group. A bilingual moderator (BW) conducted all focus groups. Each session was 90 minutes in length and each patient received $75 in cash for participation. During each session, moderators asked participants open-ended questions regarding the impact of glaucoma on their lives, their understanding of available treatment options, treatment limitations, and concerns. In addition, focus group participants were asked to review each of the 53 questions in the NIH Toolbox Vision-Related Quality of Life Survey and indicate whether they agreed with each item. This NIH Toolbox questionnaire assesses 6 domains of vision-associated functioning and well-being: 1) color vision, 2) distance vision, 3) near vision, 4) ocular symptoms, 5) psychosocial well-being, and 6) role performance.[21]

The focus group sessions were audio recorded and written transcripts were transcribed verbatim, removing all identifying information in compliance with the Health Insurance Portability and Accountability Act of 1996. A summary of each focus group was also written by the moderator. Contents of participants' responses were categorized in logical groupings by an independent coder, compared to the core and sub-domains identified in the NIH Toolbox Vision-Related Quality of Life and coded for emerging themes. A major feature of content validity is when saturation is reached, defined as the point when no new relevant information emerges with additional patient interviews, and collecting additional data will not improve understanding of how patients perceive the concept(s) of interest and the items in the questionnaire. The COnsensus-based Standards for the selection of health

Measurement INstruments (COSMIN) conducted a Delphi study on what constitutes good content validity of PRO measures, and determined that at least 7 patients and 7 professionals are needed to earn a “very good” rating in a qualitative study to evaluate item relevance and comprehensibility.[23] The number of focus groups and participants in this study were selected to surpassed a “very good” rating based on this criteria.[24]

Cognitive Interviews and Questionnaire Refinement

Cognitive interviews were used to assess respondents’ understanding and ability to answer draft questions generated based on focus group input. We conducted 19 cognitive interviews in 3 academic locations, UCLA Doheny Eye Institute in Pasadena and Orange County, Scheie Eye Institute in Philadelphia, and one private practice location, Glaucoma Associates of Texas in Dallas. Interviews were completed with approximately 5 patients from each site. Patients were identified by practice staff based on eligibility criteria listed above. Interviews were conducted in person (n=5), online (n=8), or over the telephone (n=6), by an experienced survey researcher using a scripted interview protocol. All participants received a UCLA IRB approved informational sheet prior to participation in the cognitive interview. Participants were asked to read and answer the survey and then briefly explain their chosen answers. At the end of the interview, each respondent received a $50 Amazon gift card for participation.

Results

Physician Focus Group

A total of 12 ophthalmologists (9 males and 3 females) participated in the focus group and self-identified as Non-Hispanic White (n=9), Asian (n=2), and African American (n=1; Table 1). Physician participants were mostly middle-aged or older and comprised of individuals working in both academic and private settings from multiple U.S. regions. Most specialized in glaucoma, with self-reported number of weekly patient visits for glaucoma ranging from 0 to 225. Key issues identified for glaucoma patients by the physician panel can be divided into 4 categories: 1) functional limitations including driving, reading, color/depth perception, sexual function, and mobility (e.g. difficulty with climbing stairs, walking, falls, and navigating unfamiliar places), 2) changes in appearance (e.g. sunken eyes, periocular skin changes), 3) bodily discomfort (e.g. dry and irritated eyes, foreign body sensation, taste disturbance, shortness of breath), and 4) psychosocial concerns (e.g. fears about functional limitations, job loss, safety, and blindness as well as annoyance and anger about glaucoma and glaucoma treatment).

Patient Focus Groups

A total of 41 patients (22 male and 19 female) participated in the focus groups and consisted of 16 self-identified Non-Hispanic Whites, 7 Hispanics, 3 Asians, and 15 African Americans (Table 1). Compared to the key issues identified by the physician focus group, patient focus groups placed greater emphasis on activity restrictions (in particular, night driving) and the mental and economic burden of living with a chronic disease like glaucoma, with relatively fewer mentions of systemic side-effects of glaucoma treatment such as taste disturbance and shortness of breath. In the Dallas focus group, for example, the constant awareness of

glaucoma was described as “overwhelming” and “depressing” and treatments were noted to be “a huge inconvenience”. Many in the same group also expressed frustration with the unpredictability and the perceived “randomness” of the disease. The financial burden of treatment was a standout for the Arkansas focus group, with participants, all of whom are on Medicare and/or Medicaid, reporting difficulty paying for medications and related medical expenses on a monthly basis.

A majority of participants in all four focus groups reported a lack of knowledge regarding alternative treatment options. Two groups reported a desire for a detailed discussion of individualized therapeutic options, while the other two groups stated that they trusted their physicians to choose the best therapeutic options for them. In addition to functional limitations (e.g. driving limitations due to loss of vision), changes in appearance (e.g. drooping eye lids), and bodily discomfort (e.g. stinging from drops) were also identified by patients as significant concerns. As might be expected, functional limitations and symptoms reported by patients were individualized secondary to differences in daily job and activity demands, ranging from difficulty identifying subtle color variations while painting to difficulty threading a needle while sewing. Participants in all four groups endorsed difficulty with increased light sensitivity and glare.

The focus group transcripts and group responses to the NIH Toolbox questionnaire were used to draft a 32-question survey. These items were designed to represent the following: 1) functional limitations (20 items), 2) vision-related symptoms (6 items), and 3) psychosocial issues related to either eyesight or vision (6 items; Supplemental Table 1).

Cognitive Interviews and Questionnaire Refinement

Following multiple rounds of recommendations from glaucoma specialists to improve item wording, a refined questionnaire consisting of 49 questions was generated from the initial 32 items and administered in cognitive interviews. Of the 17 new additions, 5 questions addressed functional limitations related to peripheral vision, computer, and cellphone use. Two questions functioned to clarify vision-related symptoms during low indoor-lighting versus sunlit conditions and to specifically address ocular irritation. Four questions separately queried psychosocial issues such as “annoyance” versus “anger” about eyesight, fear of job loss, and fear about the future. Seven questions addressed demographic information, self-perception of glaucoma severity, and attitude towards MIGS. One question regarding “smeared” vision was deemed redundant and removed.

A total of 19 participants (10 male and 9 female) completed cognitive interviews (Table 2). Each interviewee was presented with all 49 questions from the refined questionnaire. Twelve were self-identified Non-Hispanic Whites, one was Asian, and 6 were African American. All were older than 50 years of age and were from the states of California, Texas, or Pennsylvania. Any questionnaire item that was unclear to 5 or more participants was clarified with changes in wording and/or adapting response options. The revised questionnaire, the Glaucoma Outcomes Survey (GOS), consists of 43 items covering assessments of functional limitations, vision-related symptoms, aesthetics, and psychosocial issues, and 7 questions assessing demographic characteristics and self-perceived severity of glaucoma. Two additional questions were added after cognitive interviews to address global

perceptions of change in quality of life related to glaucoma and functioning (Supplemental Table 2; changes from the 49-item questionnaire are as indicated). These relatively minor revisions were not subjected to additional cognitive interviews.

Discussion

The goal of this project was to generate a PRO instrument targeting persons with glaucoma who are candidates for MIGS procedures. Our process involved: 1) a literature review of existing vision-targeted PRO and quality of life measures, 2) a physician and multiple patient focus groups to generate a draft questionnaire of 32 items based upon the NIH Toolbox Vision-Related Quality of Life Survey, 3) instrument refinement through specialist feedback to generate an expanded 49-item questionnaire, and 4) cognitive interviews to assess patients' ability to understand and answer the questions in the instrument. The physician focus group consisted of ophthalmologists experienced in the treatment of glaucoma, with most having received fellowship training in the field. Patient focus groups were chosen to encompass diverse geographical areas, socioeconomic groups, and racial/ethnic backgrounds.

The focus groups highlighted the following topics as being relevant to glaucoma patients: functional limitations, changes in appearance, bodily discomfort, and psychosocial concerns. Many bodily discomforts mentioned by both physicians and patients are related to medication administration, and may be alleviated following MIGS procedures that decrease the dependence on IOP lowering medications. It is also conceivable that MIGS and other glaucoma procedures may ameliorate the long-term costs associated with chronic medication use, which was an expressed concern of multiple focus group participants. Apart from gaining insight on the PRO measure, the focus groups also highlighted the need for individualized conversations with patients to not only explain available treatment options but to elicit concerns specific to the needs of each patient. Understanding a patient's goals and preferences is necessary for shared decision making, which has occupied an increasingly prominent position in clinical practice, and is associated with improved treatment outcomes.[25,26] Examples of draft questionnaire improvement as a result of cognitive interviews included: clarification of issues relating to correction of refractive errors, the distinction between "blurry" and "smeared" vision, and the splitting of questions to improve clarity. In addition to cognitive interviews with patients, multiple rounds of input from glaucoma specialists further functioned to enrich content and improve wording.

The 50-item GOS was developed based on existing literature, revised following extensive input from physicians and glaucoma patients, and underwent multiple revisions to clarify item wording. The focus groups were designed to represent a range of patients in terms of demographics (e.g., gender, race/ethnicity, age range), location, and self-perceived disease severity. The inclusion of patients self-identified as having severe glaucoma in addition to mild and moderate glaucoma diversified focus group input by including all glaucoma suffers who may become MIGS eligible. This will be particularly relevant should MIGS continue to expand in scope in the coming years.

The GOS will be administered to mild and moderate glaucoma patients who are candidates for MIGS. Administration will be conducted using an electronic patient-reported outcome (ePRO) platform. A sample of 500–700 mild or moderate glaucoma patients will be selected from clinical sites using the American Academy of Ophthalmology IRIS Registry, which consists of de-identified patient data from over 15,000 clinicians in ophthalmology practices across the U.S.[27,28] As of September 1, 2020, the registry has amassed more than 349 million patient visits from 60 million unique patients.

As we had done with focus group selection, an effort will be made to enroll a diverse sample of patients with an emphasis on those with mild and moderate glaucoma, as defined by the FDA guide for premarket studies of implantable MIGS devices, with respect to age, gender, race/ethnicity, geographical location within the U.S., smoking status, and glaucoma risk factors such as IOP.[29] Briefly, mild and moderate glaucoma were defined in the guide as: 1) Humphrey visual field (HVF) mean deviation < −12dB, and focal depression on pattern deviation in a location consistent with early glaucomatous loss and/or “outside normal limits” in the glaucoma hemi-field test, and 2) optic nerve and/or retinal nerve fiber layer abnormalities consistent with glaucomatous damage. Patients will be excluded if one of the following applied: 1) HVF mean deviation ≥ −12dB and focal depression on pattern deviation suggestive of advanced glaucomatous loss, 2) fixation-threatening HVF loss in either eye, and 3) best corrected visual acuity worse or equal to 20/200 due to glaucoma.

Study participants will be evaluated before, and 6–12 months after, receipt of MIGS. The following anchors will be used to evaluate the instrument’s responsiveness to change: 1) patients’ retrospective reports of change in vision-targeted HRQoL, 2) physicians’ rating of visual field results (i.e. no visual field loss in either eye, probable but not definitive visual field loss in at least one eye, definitive visual field loss in at least one eye, advanced visual field loss in only one eye, or severe field loss in both eyes), 3) physicians’ retrospective report of change on patients’ glaucoma status, and 4) changes in glaucoma risk factors (e.g. IOP). Resulting data will be used to evaluate psychometric properties (reliability and construct validity) of the GOS, and to determine whether higher-order and more specific subdomains are supported by the instrument. Following revision, the GOS will be made available for researchers working to improve glaucoma surgical interventions including MIGS devices. The revised instrument may also be incorporated as a part of clinical care for elucidating patient concerns and to facilitate shared decision making in glaucoma treatment.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Biography

Kuldev Singh is Professor at the Stanford University School of Medicine. He received MD and MPH degrees from the Johns Hopkins University and was a Dana Fellow at the Wilmer Eye Institute. His residency and clinical fellowship training was at the Casey and Bascom Palmer Eye Institutes, respectively, Dr. Singh has published over 200 peer-reviewed articles and delivered over 70 named or keynote lectures/visiting professorships, edited three textbooks and served on 11 publication editorial boards.

Qi Cui, MD PhD is an assistant professor at the University of Pennsylvania. She received MD/PhD training at the University of Rochester, followed by residency at UCSF, and glaucoma fellowship at Wills Eye Hospital. Her research is supported by a NIH/NEI K08 award and focuses on the effects of genetic factors and neuroinflammation on glaucoma pathogenesis. She is a past recipient of the AGS Young Clinician Scientist Award and a current recipient of the Shaffer Grant from the Glaucoma Research Foundation.

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Highlights

- A questionnaire was constructed to assess patient-reported outcomes in MIGS.
- The questionnaire was constructed based upon inputs from physicians and patients.
- The Glaucoma Outcomes Survey will be administered to patients before and after MIGS.
- The survey aims to incorporate patient preference into MIGS evaluations.

Table 1:

Focus group demographics.

Focus Group	Physician		Patient	
Characteristics	**N**	**%**	**N**	**%**
Gender				
Female	3	25	22	54
Male	9	75	19	46
Ethnicity				
Non-Hispanic White	9	75	16	39
Asian	2	17	3	7
African American	1	8	15	37
Hispanic	0	0	7	17
Age				
31–50	7	58	5	12
51–70	3	25	23	56
≥ 71	2	17	13	32
Practice Setting				
Academic	4	33	20	49
Private	8	67	21	51
Primary Specialty			N/A	N/A
Glaucoma	11	92		
General Ophthalmology	1	8		
Glaucoma Patients Treated Weekly			N/A	N/A
≤ 50	4	33		
90–120	5	42		
≥ 140	3	25		
Self-reported Glaucoma Severity	N/A	N/A		
Mild			15	37
Moderate			7	17
Severe			12	29
Unknown			7	17

Table 2:

Cognitive interview participant demographics.

Characteristics	N	%
Gender		
Female	9	47
Male	10	53
Race/Ethnicity		
Non-Hispanic White	12	63
Asian	1	5
African American	6	32
Hispanic	0	0
Age (years)		
51–60	5	26
61–70	6	32
71–80	3	16
≥ 81	5	26
Location		
California	9	47
Texas	5	26.5
Pennsylvania	5	26.5
Time since glaucoma diagnosis (years)		
< 5	4	21
6–10	4	21
11–20	5	26.5
21–40	5	26.5
≥ 40	1	5