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A Scoping Review of Quality of Life Questionnaires in Glaucoma Patients

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Precis: Multiple questionnaires exist to measure glaucoma's impact on quality of life (QoL). Selecting the right questionnaire for the research question is essential, as is patients' acceptability of the questionnaire to enable collection of relevant patient-reported outcomes.

Purpose: QoL relating to a disease and its treatment is an important dimension to capture. This scoping review sought to identify the questionnaires most appropriate for capturing the impact of glaucoma on QoL.

Methods: A literature search of QoL questionnaires used in glaucoma, including patient-reported outcomes measures, was conducted and the identified questionnaires were analyzed using a developed quality criteria assessment.

Results: Forty-one QoL questionnaires were found which were analyzed with the detailed quality criteria assessment leading to a summary score. This identified the top 10 scoring QoL questionnaires rated by a synthesis of the quality criteria grid, considering aspects such as reliability and reproducibility, and the authors' expert clinical opinion. The results were ratified in consultation with an international panel of ophthalmologists (N = 49) from the Educational Club of Ocular Surface and Glaucoma representing 23 countries.

Conclusions: Wide variability among questionnaires used to determine vision related QoL in glaucoma and in the responses elicited was identified. In conclusion, no single existing QoL questionnaire design is suitable for all purposes in glaucoma research, rather we have identified the top 10 from which the questionnaire most appropriate to the study objective may be selected. Development of a new questionnaire that could better distinguish between treatments in terms of vision and treatment-related QoL would be useful that includes the patient perspective of treatment effects as well as meeting requirements of regulatory and health authorities. Future work could involve development of a formal weighting system with which to comprehensively assess the quality of QoL questionnaires used in glaucoma.

Key Words: glaucoma, patient-reported outcomes measure, quality of life, questionnaire, treatment

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Glaucoma is a group of chronic diseases that cause progressive damage to the optic nerve and result in loss of visual field. Primary open-angle glaucoma, which accounts for three-quarters of all glaucoma cases, may be initially asymptomatic and difficult to assess, but ultimately can result in significant vision loss.[1] The global prevalence of glaucoma among people aged 40 to 80 years is 3.5%, with glaucoma estimated to affect 76 million in 2020 and projected to reach 112 million by 2040.[2] When lost, sight cannot be regained; however, although blindness is a real risk, most people with chronic glaucoma will not experience serious visual impairment and will retain a good quality of life (QoL).[3] Once loss of visual field is at an advanced stage a tipping point is reached at which loss of sight has significant impact on a patient's vision related QoL and psychological condition.[4–6] Glaucoma negatively impacts on patients' self-reporting of visual functioning, mobility, independence, and emotional wellbeing, particularly in those with late stage disease.

In ophthalmology, it has been acknowledged that traditional clinical measures such as high contrast visual acuity do not reflect the patient's experience or the impact of disease on patients' lives.[7] QoL measures may be the most important overall assessments of treatment effect for patients as they capture how their life experience is affected by interventions. Outcomes including impact on daily

functioning, mobility, emotional wellbeing, and social activities are of paramount concern for people being treated for glaucoma. Measurement of QoL can be achieved using patient-reported outcome measures (PROMs), which are defined as: "any report of the status of patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else."[8] PROMs are standardised, validated questionnaires, that are completed by patients to ascertain perceptions of health status, perceived level of impairment, disability, and QoL. PROMs allow for the systematic collection of data relating to QoL and can be helpful for monitoring health condition by assessing changes over time. Ocular disease and its treatment can have adverse effects on many aspects of a patient's health including systemic side effects, psychological, social, and emotional impact. Thus, PROMs provide an instrument to understand the progression of ophthalmic disease and its overall impact on a patient's functional vision and QoL.

PROMs also offer a tool for audit or service evaluation of glaucoma services, and for designing glaucoma trials. PROMs are essential for clinical research and several decision makers, for example the Food and Drug Administration (FDA), mandate the assessment of PROMs in all clinical trials and endorse the use of PROMs as primary endpoints in glaucoma trials for new drug development.[9] Consequently, PROMs are now often used as both primary and secondary endpoints in ophthalmic clinical trials.[10–12] PROMs provide a means for measuring treatment benefits by capturing concepts related to how a patient feels or functions with respect to his or her health or condition.[8,9] The use of PROMs can allow a greater understanding of, and sometimes improve, clinical outcomes. Nonetheless, in clinical glaucoma research there is a need for well-validated and easy to implement PROMs, as while numerous PROMs have been used there is no gold standard in clinical use for glaucoma.

In the 2017 clinical guidance for glaucoma, the National Institute for Health and Care Excellence (NICE) identified a research need for a new questionnaire to measure QoL in patients with glaucoma, recognizing that uncertainty exists as to which PROM should be used to measure outcomes of glaucoma interventions [treatments that aim to lower intraocular pressure (IOP), ie, a medication or surgical procedure].[3] A suitable questionnaire would be helpful to inform health care professionals and policy makers about the effectiveness of glaucoma interventions on QoL benefit. To potentially achieve access to new medicines, a previous evaluation by health authorities (regulators and health technology assessment bodies) who need to be convinced of the clinical and QoL benefit of such new medicines, is required. The identification of a valid and responsive PROM in glaucoma would allow this questionnaire to be adopted in future clinical trials and glaucoma audits and would ensure meaningful comparisons between different interventions.[3] This scoping review sought to identify the questionnaires most appropriate for capturing the impact of glaucoma on QoL. A secondary objective was to identify whether a difference between glaucoma treatments in terms of impact on QoL could be quantified using an available questionnaire. To meet these objectives, a literature review and assessment of all available questionnaires, including PROMs, used to assess vision related QoL in glaucoma research was conducted.

METHODS

The analysis was conducted in three parts. First, a literature search was performed to identify all relevant questionnaires, including PROMs, used to measure vision related QoL in glaucoma and a quality analysis grid was devised with which the instruments were analyzed. The top 10 questionnaires most applicable to glaucoma were determined by assimilating the results of the grid analyses and the authors' expert clinical opinion. These 10 questionnaires were then further assessed by the wider group of experts of the Educational Club of Ocular Surface and Glaucoma (ECOS-G).

Part 1: Identification of Questionnaires

A bibliographic search in electronic databases including PubMed and Embase (with an additional search on Google Scholar) was performed to identify relevant publications from database inception up until April 2019. The search terms used included, but were not limited to, glaucoma, QoL, questionnaire, patient-reported outcomes measure, treatment (see also the document, Supplemental Digital Content 1, which contains full details of the search methodology, http://links.lww.com/IJG/A560).

Eligible studies for inclusion involved people diagnosed with glaucoma and ocular hypertension and were written in English (other languages were excluded). However, the questionnaire included could be written in another language if at least one other publication about the questionnaire was available in English (eg, Glau-QOL, Glausat). In addition, studies had to consider the impact of glaucoma/ocular hypertension/visual field loss on QoL using a QoL questionnaire or PROM. As most aspects of patient QoL were considered, studies included did not necessarily have to consider a glaucoma treatment effect (topical medication, surgery, or laser treatment). Scales such as the Ocular Surface Disease Index (OSDI), Oxford, Efron, and McMonnies were excluded as their primary purpose is not to assess QoL, rather they are standard instruments used to establish a diagnosis of ocular surface disease. Other reasons for exclusion included: only abstract published, studies not including glaucoma or ocular hypertension patients, studies carried out in very local regions or in a specific population (ethnicity). We chose to focus on measuring QoL for the population with primary open-angle glaucoma with the exclusion of all secondary glaucomas, which often exhibit more rapid change and greater vision loss.

Part 2: Qualitative and Quantitative Analysis Round 1

To assess the questionnaires used to measure QoL in glaucoma patients, an evaluation grid of quality criteria with a rating scale was developed (see the document, Supplemental Digital Content 2, which contains the quality criteria grid template, http://links.lww.com/IJG/A561). The grid design was based on the literature and the authors' expertise when interviewing their patients (Table 1).[13–25]

Some studies have already thoroughly assessed measurement properties of QoL questionnaires and have proposed lists of key quality criteria to address. All these studies and works were used as a guide to create the quality grid analysis. For example, The Scientific Advisory Committee of the Medical Outcomes Trust made review criteria which addressed 8 attributes or characteristics of an instrument:[21,26]

TABLE 1. Summary of the Process Adopted to Create the Quality Criteria Analysis Grid

Step 1	Identifying existing scoring of QoL questionnaires (including PROMs) in primary publications and review articles found during the literature review and thus related to glaucoma,[13–20] and other publications appraising the quality of the QoL questionnaire against set criteria[21–25]
Step 2	Indexing all the parameters used to assess a QoL questionnaires
Step 3	Comparing with parameters used to assess each of the QoL questionnaires in the publications included: add missing ones and remove duplicates
Step 4	Identifying common 'themes' among all parameters
Step 5	Synthesizing findings in a table with a 4-point scoring scale: ++ high; + medium; – low; 0 not reported
Step 6	Validating results with a panel of experts

PROM indicates patient-reported outcomes measure; QoL, quality of life.

- Conceptual and measurement model
- Reliability
- Validity
- Responsiveness
- Interpretability
- Alternative forms
- Respondent and administrative burden
- Cultural and language adaptations

The COSMIN (COnsensus-based Standards for the selection of health status Measurement INstruments) study reached international consensus on definitions of measurement properties for health-related PROMs.[22] This checklist was also used to implement our grid analysis. The COSMIN checklist normally consists of 9 boxes divided over 3 domains (reliability, validity, and responsiveness), with methodological standards for how each measurement property should be assessed:[24,27]

(I) Reliability
  (1) Internal consistency
  (2) Measurement error
  (3) Test-retest reliability

(II) Validity
  (4) Content validity
  (5) Structural validity
  (6) Hypotheses testing
  (7) Translation
  (8) Cross-cultural validity

(III) Responsiveness
  (9) Responsiveness

Reliability is defined as the extent to which scores for patients who have not change are the same for repeated measurement under several conditions. Responsiveness is defined as the ability of an instrument to detect change over time in the construct to be measured.[22] Validity is the extent to which scores on instruments are an adequate reflection of a gold standard and are consistent with hypothesis. Multiple types of test validity were incorporated into the grid analysis (Supplemental Digital Content 2, http://links.lww.com/IJG/A561) to determine the accuracy of the components of a measure, including:[25]

- Content validity—the extent to which the content meets the prestudy hypothesis specifications
- Criterion validity—the extent to which scores on instruments are an adequate reflection of a gold standard
- Construct validity—the extent to which scores of an instrument are consistent with hypothesis, based on existing knowledge about the construct
- Structural validity—the degree to which the scores of an instrument are an adequate reflection of the (uni) dimensionality of the construct to be measured using factor analysis to confirm the number of subscales present in a questionnaire
- Cross-cultural validity—the degree to which the performance of the items on a translated or culturally adapted instrument is an adequate reflection of the performance of the items of the original version of the instrument

The final grid analysis resulted in 3 main domains (instrument description, instrument development, and psychometric evaluation) of quality criteria including assessments in the areas detailed in Table 2.[22] Note that a description of each item and methodological standards for how each item should be assessed were detailed in the grid for the appraiser who evaluated the questionnaire (see the document, Supplemental Digital Content 2, for this information which is contained in the quality criteria grid template, http://links.lww.com/IJG/A561).

From the completed quality criteria grid for the 41 QoL questionnaires, a further quantitative assessment was

TABLE 2. Quality Criteria Analysis Grid Domains and Parameters Assessed for Each Quality of Life Questionnaire

Domains	Parameters Assessed
Instrument description	Concept, general, vision or glaucoma-specific, number of items, rating scale, interpretation score, mode of administration, effort to respond
Instrument development	Prestudy hypothesis, content validity, item selection, unidimensionality, item fit statistics (Rasch model), response scale, scoring
Psychometric evaluation	Criterion validity: the extent to which scores on instruments are an adequate reflection of a gold standard[22] Construct validity: the extent to which scores of an instrument are consistent with hypothesis, based on existing knowledge about the construct Reliability: the extent to which scores for patients who have not change are the same for repeated measurement under several conditions

For each appropriate quality parameter, a score was assigned as follows:
++ high; + medium; – low; 0 not reported

TABLE 3. Simplified Quality Criteria Analysis Grid for Assessing Quality of Life Questionnaires Used in Glaucoma

Quality Parameters	Guidance	Circle Your Response and Justify if Needed*			
1. Prestudy hypothesis	Is the rational of the questionnaire explained (here or in former publications)?	++	+	–	0
2. Intended population	Are glaucoma patients involved? If no, what is the other population?_____ Is this studied/intended population relevant vs. glaucoma patients?	++	+	–	0
3. Item identification and selection	Were items collected from: Literature review? Patient interviews/patient groups? Expert opinion? Was the pilot questionnaire tested (rash or factor analysis, statistical justification of final items)? Are the items clinically relevant to the target population?	++	+	–	0
4. Scoring	Is there a description of the different parameters and of how the questionnaire should be scored?	++	+	–	0
5. Validity	Was the questionnaire previously compared with another (or other measurements)? If yes, did the questionnaire correlate with scores of the other questionnaire/measurements?	++	+	–	0
6. Sensitivity	Is the questionnaire able to discriminate? A glaucoma patient from a nonglaucoma patient? Different stages and severity of the disease?	++	+	–	0
7. Responsiveness	Is the questionnaire able to detect clinical changes and trends over time?	++	+	–	0
8. Ease of use	Is the questionnaire easy to administer/fill-in for the patient? (training needed, time to fill-in, clear items, etc.)	++	+	–	0

*Assessment using a 4-point scoring scale: ++ high; + medium; – low; 0 not reported.

made by applying a score to the 28 qualities assessed in parts II and III (part II: instrument development and part III: psychometric properties). Note that part I contains qualitative descriptive parameters only that cannot be scored. The 4-point rating scale: ++ high; + medium; – low; 0 not reported was converted to a numerical scoring value as follows: ++ = 2, + = 1, – = –1 and 0 = 0, allowing for a maximum total score of 52 (as not every parameter had an available score of 2, eg, measurement error was rated from –1 to 1; see Supplemental Digital Content 2 for rating guidance, http://links.lww.com/IJG/A561).

Part 3: Qualitative Analysis Round 2

For the second-round analysis by the ECOS-G experts of the top 10 scoring identified QoL questionnaires, a panel of international ophthalmologists from 23 countries, a simplified evaluation grid was developed (see Table 3) including 8 quality parameters and using the same 4-point scoring scale: ++ high; + medium; – low; 0 not reported.

RESULTS

Part 1: Identification of Questionnaires

The study selection process is outlined in Figure 1 (Flowchart). Ultimately, 64 publications and 7 reviews (71 publications) were identified from the literature relating to 41 different QoL questionnaires (general health, vision-specific and glaucoma-specific questionnaires) which were included in the qualitative analysis (see Table, Supplemental Digital Content 3, which lists the 41 QoL questionnaires included in the analysis, http://links.lww.com/IJG/A562).[15,28–81]

Part 2: Qualitative and Quantitative Analysis Round 1

Quality appraisal was conducted on 41 questionnaires using the quality criteria grid (see the document, Supplemental Digital Content 2, which contains the quality criteria grid template, http://links.lww.com/IJG/A561). From the detailed qualitative analysis of the 41 QoL questionnaires provided by completion of the quality criteria grid, a further quantitative assessment was made by calculating a total score for each of the 41 QoL questionnaires as presented in the Supplementary Digital Content 4 (http://links.lww.com/IJG/A563). The score reflected a trade-off between the psychometric properties, the number and frequency of citations in the literature, the simplicity of the language used, length of the items, time taken to complete the questionnaire, whether the questionnaire is widely translated, etc., which was all captured within the quality criteria grid.

From assessment of the 41 questionnaires, the top scoring 12 questionnaires were reviewed by the authors and the top 10 performing questionnaires agreed upon by consensus after discussion. Both the Glausat and SHPC questionnaires scored highly (within the top 10) but were not taken forward as either were not provided in English or only supported by a low level of evidence and so were considered not widely applicable (Supplementary Digital Content 4, http://links.lww.com/IJG/A563). A further qualitative assessment of the top 10 questionnaires is provided in Table 4 as a summary of advantages and disadvantages for each questionnaire identified from a synthesis of reports in the literature and from views provided by the 4 authors. The results of the literature survey and top 10 questionnaire selection were submitted to a panel of international experts (ECOS-G) for a second round of review and validation.

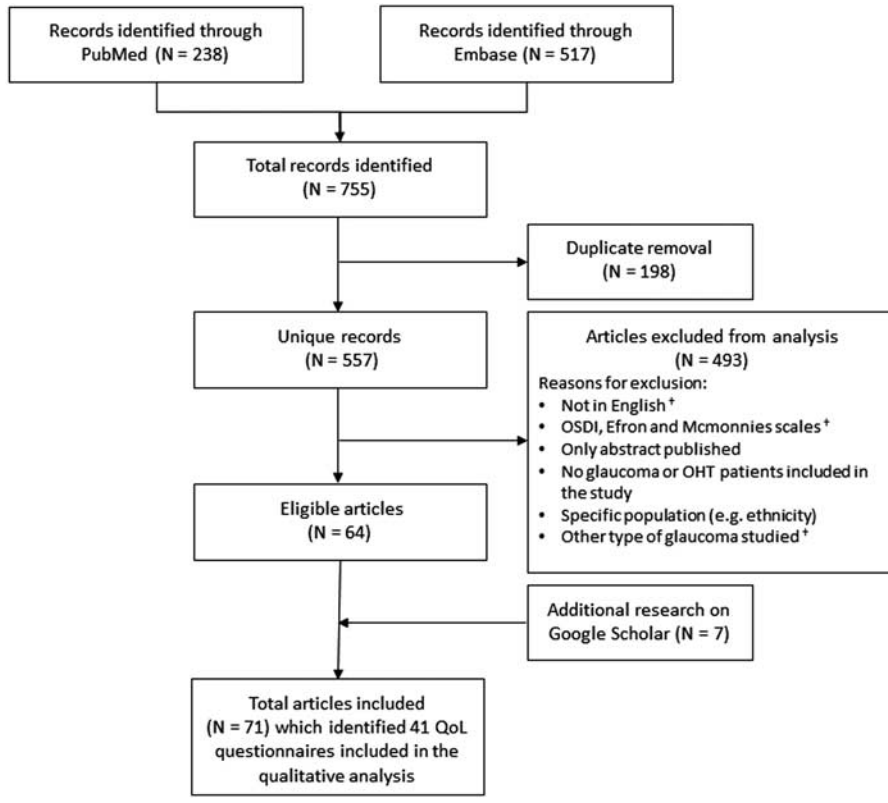

FIGURE 1. Study selection process. †Explanation provided in methods section part 1. OHT indicates ocular hypertension; OSDI, Ocular Surface Disease Index; QoL, quality of life.

Part 3: Qualitative Analysis Round 2

The top 10 questionnaires assessing vision related QoL for glaucoma patients were further assessed by the ECOS-G experts. The results of the second-round assessment using a simplified quality grid analysis validated the first-round results and are presented in Table 5.

DISCUSSION

From a review of the literature and evaluation of the array of questionnaires and PROMs used in glaucoma to assess QoL, the top 10 questionnaires most appropriate for use in QoL-related research in glaucoma were identified by the synthesis of a literature search and the authors' expert opinion (Table 4). The findings on the advantages and disadvantages of these questionnaires were a synthesis of literature reports and personal experience of the authors and are largely in agreement with earlier reviews.[14,16,18,20,28,44] Each of the questionnaires selected is unique and presents interesting and useful parameters. Questionnaires and PROMs used to assess QoL in glaucoma are diverse and not all are disease specific; the 10 that we identified include the best glaucoma specific, vision specific, treatment specific, and general health questionnaires currently available. While this assessment identified glaucoma-specific scales to be most appropriate in the main for identifying disease-related impact on health, some vision-specific (NEIVFQ-25) and general health (MOS SF-36) questionnaires were also identified that are appropriate for gathering holistic information, such as social and psychological dimensions. For the secondary study objective, the TSS-IOP and COMTol scales may be the most appropriate for determining differences between 2 treatments in terms of factors affecting QoL.

The questionnaires available are often complex with multidimensional scales that differ in the categories of assessments included. Consequently, it can be very difficult to comparatively assess the questionnaires as there are many parameters involved, and not all are assessing the same aspects of glaucoma care, for example, some are more focused on the impact on daily activities, others on disease progression, while others on patient satisfaction. None of the questionnaires scored well across all set criteria in this analysis (in the simplified grid, Table 5). The scales identified also vary in the level of validation and sensitivity to measure appropriate outcomes. None capture all relevant information, so selection of a scale is a trade-off based upon the most important factors under investigation.

Generally, currently available questionnaires are not sufficiently sensitive to monitor changes in QoL over time, especially in patients at early stages of glaucoma. Moreover, differences in scores for patients with stable or progressing glaucoma may only be evident on some questionnaires and not others. However, if QoL questionnaires are to be used to shape policy, secure funding, and manage patients, to be effective, they must be sensitive to disease progression. In this regard, the glaucoma-specific Glau-QoL 36, and the shorter versions GQL-15 and GAL-9 may be the best tools to detect deterioration in QoL correlating with disease progression, and for identifying differences between patients who have progressed and those who have not.[11] GQL-15 is reliable in assessment of mild, moderate, and severe glaucoma, and may be the most clinically relevant tool.[16,44] The

GAL-9 (GAL-10) may also offer advantages as a high-quality questionnaire for assessing activity limitation and mobility that can be completed in a relatively short time.[18] The Viswanathan questionnaire is also able to detect significant differences between patients with mild, moderate, and severe glaucoma in terms of visual disability and correlates well with visual field indices.[28,80] In comparison, the Symptom Impact Glaucoma Score (SIG) is a questionnaire containing 43 items that is responsive to treatment effects and disease severity, but may be most appropriately used in research because of its length.[16,20] The AGQ was designed to evaluate the effectiveness of glaucoma screening compared with no formal screening (opportunistic case detection) in a randomised clinical trial.[70] It was shown to discriminate between people without glaucoma and those with significant disease in a hospital-based sample population.[71] However, while a promising questionnaire, it is lengthy (31 items) and requires further validation, so may be best suited to research purposes at this time.

For a general-heath perspective, the MOS SF-36 although not found to correlate well with visual field indices does offer an assessment of the patient's general health and wellbeing by capturing both physical and mental health status and requires on average less than 10 minutes to complete.[28,81,82] The NEIVFQ-25 also provides additional information regarding the general, psychological, and social effects of glaucoma and has high content validity.[20,44,78] It is worth highlighting that our review did not directly consider performance-based measures where tasks are used to measure functional performance.[83–85] Such approaches have been shown to be psychometrically valid and could be useful along with hybrid methods that try to capture a measure of a person's so-called patient-reported outcome and experience (POEM).[86]

Other questionnaires such as the Glaucoma Satisfaction Questionnaire (Glausat) and the Symptom Health Problem Checklist (SHPC) were identified as interesting options and were thoroughly considered but were subsequently excluded from the top 10 questionnaires because of either a lack of evidence or no availability in English language. The SHCP, an 18-item version of the SIG [which consisted of 43 items, 4-domain tool, in the Collaborative Initial Glaucoma Treatment Study (CIGTS)] proposed by Musch et al,[68] was able to differentiate between disease severity on local eye and visual function ($P < 0.05$) and that patients who underwent trabeculectomy reported higher frequency of local eye symptoms than those with topical medications ($P < 0.01$). However, it should be tested in other clinical settings to demonstrate its general applicability. In a study using the Glausat,[72] a 22-item Spanish questionnaire containing 7 dimensions (expectations and beliefs about treatment, ease of use, efficacy, undesired effects, impact on health-related QoL, medical care, general satisfaction with treatment), the authors demonstrated that the questionnaire is reliable and structurally valid. No information is currently available on the stability of this questionnaire over time, sensitivity to change, ability to discriminate between pathologic groups, or concurrent validity with other alternative measures.

Although there is now a requirement to collect QoL data in studies, the recommendations of which questionnaire should be used in clinical trials remain unclear and the ones currently recognized by health authorities may not be relevant depending on the aim of the study.[87] QoL questionnaires may offer value when 2 interventions have been established to be equally efficacious in terms of a traditional outcome measure (eg, IOP-lowering effect), but where differences are anticipated in terms of side effects, cost, or convenience. However, while questionnaires may have a very useful role in practice for reflecting patient perspectives, evidence suggests QoL questionnaires lack sensitivity at distinguishing between treatment groups or even versus placebo.[11] Nonetheless, QoL is a requirement of regulatory and health authorities when assessing the benefit of new treatments. QoL assessment is mandated by the FDA and the French health technology assessment body (Haute Autorité de Santé; HAS) for chronic diseases.[8,87] The US FDA endorses the use of QoL questionnaires (including PROMs) as primary endpoints in glaucoma trials, but also recognizes the challenges in developing appropriate questionnaires.[9,88] The HAS requires QoL data to be collected in double-blinded studies, including detailed methodology with validated questionnaires and scales and clinically relevant criteria in the study population of interest.[87] Our analysis has identified the 2 questionnaires TSS-IOP and COMTol that among the questionnaires currently available may be the most appropriate to reach health authorities' expectations of determining differences between 2 treatments in terms of factors affecting QoL. The TSS-IOP may be the highest quality tool for measuring topical treatment side effects.[14,17] It is designed to assess patient satisfaction with topical ocular medications used to control IOP and has high content validity across eye drop classes.[20] In comparison with COMTol, the TSS-IOP used a higher quality developmental process for identifying and selecting items and has better validity evidence. COMTol is designed to capture the frequency and "bothersomeness" of common side effects of topical therapy for lowering IOP and the extent to which these side effects impact on QoL.[20] COMTol has been tested and used in the framework of a crossover design and can be adapted for other study comparative designs. It is also designed for comparison of topical medicines only; did not detect a difference between eye drops and selective laser trabeculoplasty in one study.[52] Nonetheless, it is a questionnaire recognized by the HAS for capturing QoL data in clinical trials.

It is a limitation of our study that a formal weighting system is not available with which to comprehensively assess the quality of QoL questionnaires used in glaucoma. As the process undertaken for our assessment was very detailed, and thus time consuming, one limitation of the study is that because of resource constraints not all questionnaires were screened by all experts. The top scoring 12 questionnaires were reviewed by the authors and the top 10 performing questionnaires agreed upon by consensus after discussion. In our opinion, the 10 selected most broadly represent QoL questionnaires ideally suited to measure aspects of QoL associated with glaucoma treatment. As this was a Scoping review, future work could entail a more detailed assessment of QoL questionnaires including development of a formal weighting system with which to comprehensively assess the quality of QoL questionnaires used in glaucoma.

In summary, wide variability in the questionnaires used to determine QoL in glaucoma and in the responses elicited was identified. No single existing QoL questionnaire design is suitable for all purposes in glaucoma research, rather we have identified the top 10 from which the questionnaire most appropriate to the study objective may be selected. Development of a new questionnaire that could better distinguish between treatments in terms of vision and treatment-related QoL would be useful that includes the patient perspective of treatment effects as well as meeting requirements of regulatory and health authorities. The desirable attributes of a new glaucoma-specific QoL questionnaire would include ease of use (short, self-administered, simplicity of language), with an easily understandable scoring system and high reliability and reproducibility, sensitivity, and validity. The

TABLE 4. The Top 10 Questionnaires Identified as Appropriate for Use in Vision Related Quality of Life Research in Glaucoma: Advantages and Disadvantages

Instrument	Description	Advantages	Disadvantages
Medical Outcomes Study 36-item Short Form (MOS SF-36)[28,81]	Focus: General health Design: to measure patient health Domains: physical activities, social activities, usual role activities, bodily pain, general mental health, emotional, vitality, general health Number of items: 36 Effort to complete: Low Time to administer: Average 8 min[82]	Good correlation with age[28] Recognized by the HAS for adding QoL data in clinical trials	Weak correlation between SF-36 scores and visual field indices (MD and Corrected Pattern SD)[28]
National Eye Institute-Visual Function Questionnaire (NEIVFQ-25)[44–46,78]	Focus: Vision-specific Design: to measure QoL Domains: general health, general vision, mental health, ocular pain, near vision, distance vision, peripheral vision, social function, color vision, driving, role limitation, dependency Number of items: 25 Effort to respond: Low Time to administer: Average 14 min[44]	Gives information regarding the general, psychological, and social effects of glaucoma Recognized by the HAS for adding QoL data in clinical trials	Lack of visual field consideration is a limitation in comparison to specific glaucoma tools[16]
Glaucoma Quality of Life-36 (Glau-QoL 36)[65,79]	Focus: Glaucoma-specific Design: to assess problems encountered on a daily basis because of glaucoma vision and treatment, and impact on everyday life Domains: psychological wellbeing, self-image, daily life, burden of treatment, driving, anxiety, and confidence in health care Number of items: 36 Effort to respond: High Time to administer: NA	Excellent correlations with disease progression Tested on 800 patients Only tool to have both tested convergent and discriminant validity Detects QoL effects in patients who do not have problems in functioning (unlike other questionnaires) Overall QoL assessment French, English, Polish, and Indian languages Shorter 17-item version convenient for patients[79] Recognized by the HAS for adding QoL data in clinical trials	Cannot differentiate between 2 treatments regarding satisfaction, compliance, ease of use, etc. Focus is on psychological wellbeing regarding glaucoma Long Does it have any advantage over the GQL-15/GAL-9 which are shorter?
Glaucoma Quality of Life (GQL-15)[52,66,67]	Focus: Glaucoma-specific Design: to measure the effect of binocular visual field loss on functional vision Domains: outdoor mobility, peripheral vision, near vision, glare/dark adaptation Number of items: 15 Effort to respond: Low Time to administer: Average 7 min[44]	Detects association of decreased vision with glaucoma–good to assess disease progression Differentiates different stages of the disease even between mild and moderate in some cases[67] Good psychometric properties Very known and widely used in studies Tested with Rash-analysis Considered as the most useful and clinically relevant tool[16] User-friendly in clinical practice Recognized by the HAS for adding QoL data in clinical trials Good reliability	Does not capture scope or burden of symptoms and broad QoL factors Only functional status measurement Does not take side effects into account No difference between treatment and placebo[11] (same for GAL-9) Not recommended by Khadka et al 2013 because it violates the condition of unidimensionality[18] Shorter version GAL-9/10 is available which is a higher quality instrument for assessing activity limitation and mobility[18]

Glaucoma Activity Limitation (GAL-9)[69]	Focus: Glaucoma-specific Design: to measure vision related activity limitations (Rasch analyzed version of GQL-15) Domains: outdoor mobility, peripheral vision, near vision, glare/dark adaptation Number of items: 9 Effort to respond: Low Time to administer: NA	Short version GAL-9 (GAL-10 in India): higher quality than GQL-15 for assessing activity limitation and mobility[18] GAL-9 is quicker to administer than GQL-15 and has same properties as the 15 questions Highly cited[69] Has similar properties in determining differences between patients who have progressed and those who have not[11]	
Aberdeen Glaucoma Questionnaire (AGQ)[70,71]	Focus: Glaucoma-specific Design: to evaluate the effectiveness of glaucoma screening compared with no formal screening (opportunistic case detection) Domains: participation, moving around and communication, emotional function, walking around obstacles, light, domestic and social life, mobility Number of items: 68 (31 items in revised AGQ) Effort to respond: High Time to complete: NA	Able to discriminate between people without glaucoma and those with significant disease[71] Uses the ICF as a theoretical framework to code the AGQ item content by identifying meaningful concepts (ie, ideas or information) contained within each AGQ item and linking each meaningful concept to the most precise ICF category Provides a robust method for linking the empirical factors with a theoretical factor structure and for assigning theoretically informed labels during early testing of new PROM instruments using Classical Test Theory techniques Pre-validation development was conducted in a previous study[70] NEIVFQ-25 was included as a benchmark to assess the AGQ Items are clear Promising instrument and method	Scoring method to be further investigated: the use of scores for identifying individual-level severity would not be appropriate Further testing (eg, Rasch analysis) should be conducted to provide greater insight into the psychometric properties and dimensionality of the AGQ As far as we know, it has not been used in other studies No items related to medication Too many items
Viswanathan Questionnaire[15,28,80]	Focus: Glaucoma-specific Design: to measure visual disability Domains: quality of vision, ability to perform activities Number of items: 10 Effort to respond: Low Time to administer: Average 5 min[44]	High internal consistency (Cronbach's $\alpha = 0.929$)[44] Statistically significant difference between patients with mild, moderate, and severe glaucoma detected ($P \leq 0.001$)[44] Simple and fast to administer Good correlation with NEIVFQ-25 and GQL-15, especially for peripheral vision and glare/dark adaptation[44] Correlated with visual field indices (MD and Corrected Pattern SD)[28]	
Symptom Impact Glaucoma (SIG)[32]	Focus: Glaucoma-specific Design: to measure frequency of symptoms related to the disease and/or side effects of treatments, and bothersomeness Domains: visual function, local eye symptoms, systemic symptoms Number of items: 43 (4 domains) Effort to respond: High Time to complete: NA	Captures local eye and visual function symptoms of glaucoma and its treatment Responsive to treatment effects and disease severity Consistent, statistically significant correlation with NEIVFQ-25 Good responsiveness (longitudinal psychometric assessment) Long-term follow-up (54 mo) Large sample of patients (607 at baseline and 510 at 54 mo)	Does not take side effects into account All questions relate to eye/vision symptoms No questions to assess systemic side effects Items relating to eye symptoms do not necessarily cover all glaucoma treatment side effects, such as skin/eyelash pigmentation It appears long. May take a long time to administer

TABLE 4. (*continued*)

Instrument	Description	Advantages	Disadvantages
		Considered as an excellent research tool[16,20] Part of the exam set-up by the CIGTS reference study evaluating the relation between QoL and visual field[32]	
Comparison of Ophthalmic Medications for Tolerability (COMTol)[46,52–54]	Focus: Treatment specific Design: to capture the frequency and bother of common side effects of topical therapy for lowering IOP. Also measures the extent to which these side effects and any associated limitations in routine living activities interfere with QoL, medication compliance, and patient satisfaction Domains: Symptom frequency, bothersomeness, activity limitations, global QoL, satisfaction, adherence Number of items: 37 items (13 domains) Effort to respond: Low–Moderate Time to complete: NA	Influence of glaucoma therapy on QoL considering frequency and severity of common side effects Good assessment by Che Hamzah et al[20] Good psychometric properties Strong correlation between frequency, bother and patient-perceived measures Responsiveness to change Tested and used in the framework of a crossover design Demonstrated sharp improvement after a switch from bimatoprost-timolol to tafluprost-timolol for almost all symptoms and limitations (no statistical analyses were performed)[77] Recognized by the HAS for adding QoL data in clinical trials	Designed for topical medication only (not surgery/laser) (no difference eye drops vs. SLT in Lee et al)[52] Only differentiation between timolol and pilocarpine so far Should be adapted if no crossover design No patient knowledge and perception of treatment Very lengthy and likely to be burdensome to complete. This would also incur greater costs because of time commitments
Treatment Satisfaction Survey for Intraocular Pressure (TSS-IOP)[37,62]	Focus: Treatment specific Design: to assess patient satisfaction with topical ocular medications to control IOP Domains: effectiveness, side effects, eye appearance, convenience of use, ease of administration Number of items: 15 (+27 supplemental items) Effort to respond: Low Time to administer: NA	Investigates side effects because of topical medication: Patient knowledge and perception of treatment Validation on a large sample of patients Derived from a generic questionnaire (IQVIA's Treatment Satisfaction Questionnaire for Medication [TSQM]) Shows acceptable reliability and good validity across all eye drop classes Compared with COMTol: higher quality developmental process in view of identifying and selecting items and better validity evidence Covers relevant side effects and issues with eye appearance, which might relate to patients Considered by: Vandenbroeck et al[14] 2001 as the highest quality tool for measuring topical treatment side effects Hamzah et al[20] as having the highest content validity Quaranta et al[17] as the instrument of choice for comparing different classes of topical medication	Only performed on available patients that were already scheduled for clinic Focus is on satisfaction regarding treatment, no data on efficacy of the treatment or progression of the disease Does not assess visual problems per se

CIGTS indicates Collaborative Initial Glaucoma Treatment Study; HAS, Haute Autorité de Santé (French health technology assessment body); ICF, International Classification of Functioning and Disability; IOP, intraocular pressure; NA, not available; PROM, patient-reported outcomes measure; QoL, quality of life; SLT, selective laser trabeculoplasty.

TABLE 5. Results of the Simplified Quality Criteria Grid (8 Parameters) Assessment of the Top 10 Questionnaires Used in Glaucoma to Determine Vision Related Quality of Life*

Instrument	Prestudy Hypothesis	Intended Population	Item Identification and Selection	Scoring	Validity	Sensitivity	Responsiveness	Ease of Use
Medical Outcomes Study 36-Item Short Form (MOS SF-36)[28]	+/–	+/–	++/+	++/+	+/–	–	–	–
National Eye Institute-Visual Function Questionnaire (NEIVFQ-25)[44–46]	+	++	+	+/–	++	+/–	+	+/–
Glaucoma Quality of Life-36 (Glau-QoL® 36)[52,65]	–	++	++	+	+	+	++	+/–
Glaucoma Quality of Life (GQL-15)[52,66,67]	++	++	++	++/+	++/+	+/–	+/–	++/+
Glaucoma Activity Limitation (GAL-9)[69]	++	++	++	++	0	+	+	+/–
Aberdeen Glaucoma Questionnaire (AGQ)[70,71]	0	++	0	+	0	+	+	+
Viswanathan Questionnaire[15,28,80]	++	++	+	+	–	–	+	++
Symptom Impact Glaucoma (SIG)[32]	++	++	+	++	0	+	–	–
Comparison of Ophthalmic Medications for Tolerability (COMTol)[46,52–54]	++/+	++	0	++	–	–	+	+
Treatment Satisfaction Survey for Intraocular Pressure (TSS-IOP)[37,62]	+	+	+	0	0	0	+	–

*Assessment using a 4-point scoring scale: ++ high; + medium; – low; 0 not reported; please refer to Table 3 for an explanation of the 8 quality criteria parameters assessed here.

mode of administration may influence patient responses and is worth considering. Self-administered questionnaires (PROMs) are to be preferred, while a lengthy questionnaire, complex language, or distorted adaptations because of translation issues can be burdensome for the patient. The effort required to provide a full response to the questionnaire and the time taken to complete are important to consider when making the questionnaire patient friendly. To be effective, the questionnaire needs to be understandable to its respondents. A recent study determined that over half of questionnaires commonly used in ophthalmology require a reading comprehension level better than that recommended by the American Medical Association (AMA) and National Institutes of Health (NIH) as appropriate for patient materials.[89] In future, item banking and computerized adaptive testing methods may address the multiple limitations of paper-pencil questionnaires, customize their administration, and have the potential to improve health care outcomes for patients with glaucoma.[90] The collection of patient-reported QoL data will enable better understanding of vision related QoL that can improve patient–physician interaction and enhance treatment adherence by providing patient-centric care that can ultimately optimize the long-term prognosis for glaucoma patients.

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