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ORIGINAL ARTICLE

Patient Reported Outcomes to Assess Quality of Life in Glaucoma: An Overview

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Abstract

Glaucoma is the second leading cause of visual impairment worldwide. Glaucoma is a progressive optic neuropathy that may result in permanent loss of visual function with a significant decline in quality of life(QoL). Visual impairment due to glaucoma can have a negative impact on an individual's physical and mental health thus exposing them to a higher risk of systemic morbidity, motor vehicle accidents, social withdrawal, and various psychiatric disorders. Hence, patient's perspective is important to completely understand how glaucoma and its treatment affect QoL. A commonly used tool to measure QoL is patient reported outcomes (PRO's). This review article highlights the available PRO's and their limits.

Introduction

Glaucoma is the second leading cause of visual impairment worldwide.[1] In 2013, the estimated number of people with glaucoma was 64.3 million worldwide and was expected to multiply by two folds in 2040.[1] Literature shows that 50% of cases remain undiagnosed in developed countries and 90% in developing nations.[2,3] Glaucoma is a progressive optic neuropathy that may result in permanent loss of visual function with a significant decline in quality of life (QoL).[4]

The term QoL is defined by the World Health Organization as the subjective perception of well-being and wholeness.[5] QoL is a wide-ranging complex encompassing an individual's physical, social, and mental well-being. It is sum of objectively measurable parameters such as wealth together with subjective feeling of personal satisfaction in one's life.[6] Visual impairment due to glaucoma can have a negative impact on an individual's physical and mental health thus exposing them to a higher risk of systemic morbidity, motor vehicle accidents, social withdrawal, and various psychiatric disorders.[7-10] Hence, patient's perspective is important to completely understand how glaucoma and its treatment affect QoL. A commonly used tool to measure QoL is "patient reported outcomes (PRO's)".

The United States Food and Drug Administration recently recommended the term "PRO's" as an umbrella term covering a wide range of health data reported by the patient. PRO's are self-report questionnaires by the patient explaining the impact of disease and its treatment on their daily activities such as driving and reading. According to a systematic review, PROs in glaucoma can be divided into three major categories: PROs addressing functional status related to vision, PROs assessing other factors related to disease and treatment (symptoms, side effects, adherence, and self-efficacy), and PROs addressing overall QoL.[11,12]

The purpose of this article is to (a) identify available PRO instruments that have been used in research studies involving patients with glaucoma; (b) evaluate their content validity; and (c) describe the lacunae in existing PRO's.

Methods

The PubMed database was used for the literature search. The keywords searched included glaucoma, QoL, vision related QoL, questionnaire for QoL, subjective assessment of QoL, and PRO's. Combination of these terms was also used for the research.

Inclusion and exclusion criteria

Articles published in English reporting the use of PRO instruments in adult glaucoma patients were included in the

study. The articles published using PRO in regional language were excluded from the study. Letters and editorials were excluded from the study.

Results

As described above, the categories of PRO comprise numerous questionnaires which have been used widely in different languages. At present, Rasch analysis,[11] a popular method for validation is being used for validation of PRO's. It converts ordinal scales into interval scales to strengthen a PRO. Recently, Rasch analysis is being increasingly employed for ophthalmic researches. We hereby discuss some of the popularly used PRO's category wise and their validation.

The first category of PROs addressing functional status related to vision includes a set of questionnaires that identifies a patient's ability to undertake routine activities, fulfill life role, and perform actions for maintaining health and well-being.[13] All questionnaires includes activities that require visual function and the patient is asked to rate them according to the level of difficulty. In this category, fall many questionnaires as described in Table 1 but only two of them have been validated. One such PRO is the independent mobility questionnaire (IMQ) which is composed of 35 items covering activities related to orientation and motility such as moving around, walking in challenging lighting conditions, using steps and stairs and avoiding objects. In the original IMQ, each item was rated on a 5-point Likert-type scale ranging from 1 no difficulty to five extreme difficulty.[14] The IMQ was validated using Rasch analysis and had good response category functioning, scale precision (content validity), and item fit and person fit (construct validity).[14] IMQ was also subsequently validated using Rasch analysis in glaucoma patients.[15] Independent mobility perceived by glaucoma patients was associated with better mean deviation (MD) and visual acuity in the sound eye.[14]

Another validated questionnaire in the same category of PRO is glaucoma symptom identifier (GSI).The GSI is a tool increases awareness about how much glaucoma symptoms impact daily QoL, and helps improves communication between clinicians and glaucoma patients. GSI consisted of 32 glaucoma symptom impact items.[16] Overall, GSI items covered ten areas of likely impairment: Indoors and outdoors mobility, house chores and daily living activities, frontal and lateral vision, adapting to bright or low light, driving, and socializing. Each question asks the patient if their vision causes difficulty with the task described in the question with one of the following answers (1) None or I do not do this for non-visual reasons, (2) A little or some difficulty, and (3) Yes or I no longer do this for visual reasons. The GSI showed good reliability and validity. The impact of various severity of glaucoma on QoL is adequately covered in the GSI. Hence, GSI was identified as a psychometrically valid tool, appropriate for glaucoma patients' self-administration within a clinician's routine practice to help both the patient and physician assess the patient's present and potential future symptoms of glaucoma.[17]

Table 1: Patient-reported outcomes addressing functional status related to vision

Questionnaire	No. of items	Validation
Visual activity questionnaire (VAQ)[18]	33	No
Questionnaire of Ross *et al.*[19]	16	No
Questionnaire of Mills and Drance[20]	15	No
Viswanathan *et al.*[21,22]	10	No
Glaucoma QoL questionnaire (GQL-15)[23]	15	No
IMQ[14,15]	35	Yes
GSI[16,17]	32	Yes

IMQ: Independent mobility questionnaire, GSI: Glaucoma symptom identifier, QOL: Quality of life

The second category of PRO assesses the overall QoL. There is a numerous questionnaire fitting in this category. However, the validation of these PRO's is not universally accepted as the technique used to validate these instruments differ. Some of them were validated using the Rasch analysis while other using the classical validation technique. The most widely used questionnaire in this category of PRO includes The National Eye Institute Vision Function Questionnaires (NEI-VFQ-25 and -51 items). It measures vision-targeted functioning and influence of vision problems on health-related QoL across several eye conditions.[24,25] The NEI-VFQ, both in the 51-item and the shorter 25-item version, have been widely used and produce consistent, reproducible[26] results in glaucoma patients.[27] Various randomized clinical trials, such as the Early Manifest Glaucoma Trial,[28] and The Tube versus Trabeculectomy Study[29] have used NEI-VFQ in their trails.

Table 2 shows the list of available PRO's assessing overall QoL.

The third category of PRO includes questionnaires which assess the effect of topical treatment or disease related factors which have an impact on QoL. The most commonly used PRO in this category is the treatment satisfaction survey-intraocular pressure (TSS-IOP) which was designed for evaluating patient satisfaction with different aspects of topical anti-glaucoma medications.[49] It consists of 42 questions developed in 2003 by the Pfizer Inc (USA). Although it has been used widely to compare different class of topical medications, it has not been validated yet.[50] Another instrument in this category of PRO is The Comparison of Ophthalmic Medications for Tolerability (COMTOL) questionnaire, which utilizes common side effects reported by patients in trials.[51] However, it was only validated for patients using timolol and pilocarpine, so it cannot highlight the side effects of other drugs or surgical interventions. COMTOL questionnaire was validated using Rasch analysis.

Table 3 enlists different PRO's assessing factors related to disease and treatment.

Table 2: Patient-reported outcomes addressing QoL

Questionnaire	No.of items	Validation
Glaucoma QoL questionnaire (Glau-QoL)[30]	36	No
Vision QoL index[31,32]	6	No
Glaucoma health perception index[33,34]	6	No
National eye institute visual function index-51 items[24,25]	51	Yes
Nursing home vision QoL questionnaire[35,36]	57	No
Glaucoma utility index[37]	32	No
Low vision QoL questionnaire[38-41]	18	No
QoL and visual function questionnaire[42]	17	No
Vision core module[43-45]	10	No
Impact of vision impairment[46-48]	28	No

QOL: Quality of life

Table 3: PRO's assessing factors related to disease and treatment

Questionnaire	No. of items	Validation
TSS-IOP[49,50]	42	No
Comparison of ophthalmic medication for tolerability[51]	13	Yes
Glausat[52]	22	No
Eye drop satisfaction questionnaire[53]	21	No
Adherence questionnaire[54]	62	No
Symptom impact of glaucoma scale[33,34]	43	No
Glaucoma symptom scale[16]	10	No
Glaucoma self-efficacy scale[55]	21	No
Outcome expectations scale[55]	4	No

PRO: Patient reported outcomes, TSS-IOP: Treatment satisfaction survey-intraocular pressure

Discussion

In the present scenario, the clinician mainly relies on the objective parameters such as visual fields, visual acuity, and IOP to document the disease progression and ultimate treatment success. However, patient's perspective of the impact of the disease and treatment is far more important for overall satisfaction. The side effects and tolerability of eye drops and their impact on patients QoL are important and needs to be documented. Hence, PRO instruments are becoming an important aspect of routine clinical practices and clinical trials. PRO can become relevant endpoint measures of disease impact, treatment efficacy, and future decision making.

To ease out the choice of which PRO is best for further clinical trials, this article provides an overview of the available PRO in each of the three categories as mentioned above. Of the available PRO in the functional status category, further research needs to be done to prove their validity and application to the general population. The visual function testing PRO NEI-VFQ25 which is being widely used to measure QoL has some major flaws, the major being that it has never been tested on its dimensionality.[24-26] A study was conducted evaluating QoL using vision specific PRO NEIVFQ-25 and glaucoma specific PRO GQL-15 and Viswanathan 10 instrument. It was concluded that there was a decrease in score in all the three PRO's among glaucoma cases as compared to the controls.[56] Similarly in another study, vision specific PRO NEIVFQ-25 was compared to the glaucoma specific PRO GQL-15 and Viswanathan 10 instrument in patients with varying severity of glaucoma. All three instruments showed high internal consistency (Cronbach's alpha for GQL-15, NEIVFQ-25, and Viswanathan 10 were 0.918, 0.937, and 0.929, respectively).[57] The difference was statistically significant between patients with mild, moderate, and severe POAG with all instruments ($P \leq 0.001$). The disease specific scales however are simpler and faster to administer.

The last category of PRO addressing disease and treatment related side effects is the least researched territory for QoL. Eye drops related discomfort, compliance, and cost factor are some of the parameters which are necessary to prevent the disease progression and thus improve QoL in glaucoma patients. The TSS-IOP is the highest quality instrument to assess side effects across different topical treatments,[49,50] but it needs to be validated using Rasch-analysis.

Pitfalls of existing PRO's

First of all, there is no conceptual framework explaining the interrelationship between different items in domains of the PRO. This results in difficulty in grouping and scoring these items, their analysis and the PRO's outcome. Second, most PRO's are generated using items listed in the literature. Thus, they are inappropriate without patients involvement and fail to apply to different population groups because of the difference in population characteristics (age and sex). Third, because of being subjective most of the oral PRO's are influenced by numerous factors such as culture, language, and education.[58] These background variables may be accountable for the variable results observed in patients' responses to these instruments.[59] Fourth, a lot of the PRO's have not statistically defined their rating scales and scoring systems. A more calibrated scale needs to be developed rather than the concept of "one size fits all" scoring approach. Fifth, most of the PRO's have not been validated. The ideal developmental process as described

in the framework of Pesudovs *et al*.[60] should be followed by researchers to develop a valid, reliable and responsive PRO instrument. Sixth, most papers have reported only a limited amount of information related to the practical use of the PRO instrument.

Hence, a lot needs to be done to improve the quality and applicability of the existing PRO's. Moreover, the newly developed PRO should follow the conceptual framework outlined by Pesudovs *et al*.[60] The new PRO's should use more of patients perspective for generating items in PRO domains. This can be accomplished by organizing target groups and in depth interviews. And to conclude all these PRP's should be validated using either Rasch analysis.

Conclusion

Glaucoma is a progressive sight threatening disorder which can have a significant morbidity. The burden of the disease process and its treatment can take a toll on patient's life thus affecting his QoL. PRO's are thus an invaluable tool to document a patient's QoL and at the same time can provide useful inputs to help the physician to improve their patient's well-being while continuing the treatment process. The need of the time is a valid, reliable, and responsive PRO which can be applied universally.

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