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Title: The impact of primary open-angle glaucoma: Comparison of vision-specific (National Eye Institute Visual Function Questionnaire-25) and disease-specific (Glaucoma Quality of Life-15 and Viswanathan 10) patient-reported outcome (PRO) instruments.

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Abstract: Purpose: To compare a general vision-specific patient-reported outcomes (PRO) instrument, National Eye Institute Visual Function Questionnaire-25 (NEIVFQ-25) with two disease-specific PRO instruments, Glaucoma Quality of Life-15 (GQL-15), and Viswanathan 10 in patients with varying severity of primary open angle glaucoma (POAG). Methods: This hospital-based, prospective study enrolled 140 glaucoma patients. The patients were classified into mild, moderate, and severe glaucoma based on visual field defects. All these patients were administered the three PRO instruments and the results were statistically analyzed. Results: All the 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) There was a statistically significant difference between patients with mild, moderate, and severe POAG with all instruments ($P \leq 0.001$). The instruments correlated well across several parameters especially the peripheral vision and glare/dark adaptation. The disease-specific scales however are simpler and faster to administer. Conclusion: All three instruments were reliable in assessment of mild, moderate, and severe glaucoma. They correlated strongly with each other in most of the related subscales, domains, and questions. NEIVFQ-25 additionally

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The impact of primary open-angle glaucoma: Comparison of vision-specific (National Eye Institute Visual Function Questionnaire-25) and disease-specific (Glaucoma Quality of Life-15 and Viswanathan 10) patient-reported outcome (PRO) instruments

Purpose: To compare a general vision-specific patient-reported outcomes (PRO) instrument, National Eye Institute Visual Function Questionnaire-25 (NEIVFQ-25) with two disease-specific PRO instruments, Glaucoma Quality of Life-15 (GQL-15), and Viswanathan 10 in patients with varying severity of primary open angle glaucoma (POAG). **Methods:** This hospital-based, prospective study enrolled 140 glaucoma patients. The patients were classified into mild, moderate, and severe glaucoma based on visual field defects. All these patients were administered the three PRO instruments and the results were statistically analyzed. **Results:** All the 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) There was a statistically significant difference between patients with mild, moderate, and severe POAG with all instruments ($P \leq 0.001$). The instruments correlated well across several parameters especially the peripheral vision and glare/dark adaptation. The disease-specific scales however are simpler and faster to administer. **Conclusion:** All three instruments were reliable in assessment of mild, moderate, and severe glaucoma. They correlated strongly with each other in most of the related subscales, domains, and questions. NEIVFQ-25 additionally gave information regarding the general, psychological, and social effects of the disease.

Keywords: Impact; glaucoma; quality of life; National Eye Institute Visual Function Questionnaire-25; Glaucoma Quality of Life-15

From the patient's perspective, activities like reading, walking down the stairs, and recognizing people are more important than clinical endpoints like intraocular pressure (IOP) and visual fields (VFs).[1],[2] Therefore, currently there is a conscious shift on the part of clinician towards incorporation of patient centric outcomes rather than clinical outcomes to measure efficacy of treatment in glaucoma patients. Assessment of patient's perception-based QoL has become an integral part of overall evaluation and management of glaucoma patients.

Quality of life in glaucoma patients can be evaluated using various QoL instruments. A number of instruments have been developed and employed in the past decade. Currently, patient-reported outcomes (PROs) are being used to estimate functional status, disease status, or health-related QoL.[3] These PRO instruments are classified into three major categories that include instruments addressing functional status related to vision loss [Glaucoma Quality of Life 15 (GQL-15), Viswanathan 10 questionnaire, and Visual Activity Questionnaire], instruments addressing QoL [National Eye Institute Visual Function Questionnaire-51, NEIVFQ-51), the shorter

version NEIVFQ-25, Vision Core Module 1, Quality of Life, and Visual Function Questionnaire], and instruments assessing other factors related to disease and treatment like symptoms, side effects, adherence, satisfaction, and self-efficacy (Treatment Satisfaction Survey for Intraocular Pressure, the Comparison of Ophthalmic Medication for Tolerability, and Eye Drop Satisfaction Questionnaire).[4],[5],[6],[7],[8]

Health-related or generic vision-related instruments are lengthy, difficult to use, and have complex scoring system and parochial bias. Instruments addressing health-related/generic QoL are also less accurate in picking up glaucoma patients, especially in early/mild stage of disease.[3] However disease-specific instruments act as great discriminator between glaucoma patients and controls as they have stronger correlation with clinical parameters like VF indices as compared to vision-specific instruments.[9] The ideal glaucoma PRO instrument should be easy to use, reproducible, have simple questions and easily understandable scoring system. Till date, no single questionnaire satisfies this definition of an ideal glaucoma PRO instrument.

The NEIVFQ-25 is most commonly employed vision-specific instrument for assessing QoL in glaucoma patients.[10] It is considered gold standard to assess QoL in glaucoma patients and all newer and disease-specific tools are compared to it. GQL-15, a disease-specific instrument, can evaluate the effect of binocular VF loss on visual function.[4] As compared to NEIVFQ-25, GQL-15 is shorter, easier to use, and faster to administer.[4],[9],[2] Viswanathan and associates have designed a disease-specific 10-item PRO that directly target functions and activities influenced by glaucoma.[11]

A number of studies have found vision-specific instrument like NEIVFQ-25 to be useful in assessing QoL of glaucoma patients.[2],[9],[12] One study has compared vision-specific instrument, NEIVFQ-25 with disease-specific instrument GQL-15, and found GQL-15 to be better in terms of being quick and more user-friendly.[9] There is however still lack of literature regarding comparison of different instruments for assessing QoL in glaucoma patients. There is also lack of clarity as to which instrument is best for elucidating QoL amongst glaucoma patients. To the best of our knowledge, no study has simultaneously evaluated more than two instruments for assessing glaucoma patients. This study was designed to compare two disease-specific instruments (GQL-15 and Viswanathan 10) with one vision-specific instrument (NEIVFQ-25) for QoL assessment in Indian primary open angle glaucoma (POAG) patients.

Methods

Study design

The study was conducted as per the tenets of the Declaration of Helsinki after taking approval from the institutional ethics committee. It was a hospital-based, cross-sectional analytical study. All the subjects enrolled in the study gave a written informed consent before being included in the study. This was a pilot study, so a prior sample size calculation was not done. A total of 140 consecutive subjects visiting the outpatient services were enrolled in the study.

Comprehensive ocular examination

This included documentation of detailed ocular history, visual acuity testing with refraction, IOP testing, gonioscopy with four mirror lens, dilated fundus examination with stereoscopic biomicroscopy of the optic nerve head using slit-lamp, indirect ophthalmoscopy where indicated, and VF testing using 24-2 SITA FAST on Humphrey Field Analyser II. The Hodapp-Parrish-Anderson criteria were used to classify the cases into mild, moderate, and severe glaucoma, respectively, considering VF defects on HFA in the less severely affected eye.[13]

Patient selection

Inclusion criteria: Patients diagnosed with POAG with age 40 years or older and on medical therapy. POAG was diagnosed if the patient had evidence of optic nerve damage from either one or both of the following: glaucomatous optic disk or retinal nerve fiber layer abnormalities, reliable and reproducible glaucomatous VF abnormality, and open angles on gonioscopy.[14]

Exclusion criteria: In order to avoid factors that could preclude the patient from providing reliable and valid data, patients having preexisting visually significant cataract and history of cataract surgery in past 3 months were excluded from the study. Patients with neurological disease, diabetic retinopathy, hypertensive retinopathy, and age-related macular degeneration were also excluded from the study.

QoL assessment

The QoL instruments were orally administered by a single interviewer (Supplemental Material). The patient was conveyed the questions in their vernacular language by the interviewer. Over a course of two clinic visits (a week apart), the patient was administered GQL-15 and Viswanathan 10 in the index visit and NEIVFQ-25 in the follow-up visit. In order to ensure compliance, the patients were contacted and reminded in case they missed a visit. The patients requiring any change in treatment between the two clinic visits were excluded from the study.

Statistical analysis

The data were recorded in a spreadsheet and QoL scoring was done as per standard recommended scoring algorithm for that questionnaire.[4],[11],[10],[15] Higher values of NEIVFQ-25 and Vishwanathan 10 scale indicate better QoL, while in GQL-15, higher values indicate a lower QoL. The data were then analyzed using IBM Statistical Package for Social Sciences (SPSS Version 21 for Windows, Armonk, NY: IBM Corp.). ANOVA was used to compare the QoL scores across various severity of glaucoma and Pearson's correlation coefficient was used to assess the correlation of the scores with each other. Cronbach's alpha was calculated to assess the internal reliability of the instruments.

Results

The mean QoL scores in mild, moderate, and severe glaucoma using NEIVFQ-25, GQL-15, and Viswanathan instruments are shown in [Figure 1] and [Figure 2]. All the three instruments showed statistically significant difference between mild, moderate, and severe grades of glaucoma (P values in [Table 1]). There was no statistically significant difference between the three groups based on age and gender (P > 0.05).{Figure 1} {Figure 2}{Table 1}

All the instruments showed good internal reliability. Cronbach's alpha for GQL-15, NEIVFQ-25, and Viswanathan 10 was 0.918, 0.937, and 0.929, respectively. Average time taken to administer the instruments was 5, 7, and 14 min for Viswanathan, GQL-15, and NEIVFQ-25, respectively.

Correlations:

NEIVFQ-25 and GQL-15: Correlation between NEIVFQ-25 and GQL 15 is shown in [Table 2]. The subscales of NEIVFQ-25 and domains of GQL-15 showed statistically significant correlation as shown in [Table 3]. Near activities subscale of NEIVFQ-25 correlated strongly with central and near vision domain of GQL 15 ($r = -0.672$). Peripheral vision subscale of NEIVFQ-25 correlated with outdoor mobility domain of GQL-15 ($r =$

-0.663). Driving subscale of NEIVFQ-25 correlated with the peripheral and glare/dark adaptation domain of GQL-15 ($r = -0.635$ and -0.615 , respectively). NEIVFQ-25 and Viswanathan 10: The subscales of NEIVFQ-25 and questions of Viswanathan 10 instrument showed statistically significant correlation as shown in [Table 4]. General health subscale of NEIVFQ-25 correlated strongly with the question, Do you have particular difficulty seeing after moving from a light to a dark room?; near vision subscale correlated with the question, Do you ever have trouble following a line of print or finding the next line when reading?; distance vision subscale with questions like Do you ever notice that parts of your field of vision are missing?, Have you noticed any deterioration in your sight over the last few years?, and Have you had to give up activities because of your sight?; the driving subscale correlated with questions like Do you ever notice that parts of your field of vision are missing?, Are you troubled by glare or dazzled on sunny days or in bright lighting?, and Do you have particular difficulty seeing after moving from a light to a dark room? GQL-15 and Viswanathan 10: The domains of GQL-15 instruments showed statistically significant correlation with relevant questions of Viswanathan 10 instrument as shown in [Table 5]. Central/Near domain correlated strongly with the question, Do you ever have trouble following a line of print or finding the next line when reading?; Peripheral domain with questions like Have you noticed any deterioration in your sight over the last few years? and Do you have difficulty finding things that you have dropped?; glare/dark adaptation with questions like Have you had to give up activities because of your sight?, Are you troubled by glare or dazzled on sunny days or in bright lighting?, and Do you have particular difficulty seeing after moving from a light to a dark room?; and outdoor mobility with question like Have you had to give up activities because of your sight? {Table 2}{Table 3}{Table 4}{Table 5}

Discussion

PRO is a broad term comprising of health status of patients as perceived by them. Current day QoL instruments may provide important information regarding disease and its treatment aspects and form essential part of their management strategy. However, it is a challenge to the glaucoma specialist to select appropriate and most useful instrument for their patients. In this study, we have compared three instruments and tried to find the best-suited QoL instrument for our glaucoma patients.

Mean QoL scores for all instruments correlated well with the VF indices [Table 1]. Pourjawan et al. have found stronger correlation of NEIVFQ-25 scores with mean deviation, pattern SD as compared to GQL-15.[12] However, Mbadunga et al. showed results similar to our study.[9] Viswanathan questionnaire has also been shown to have strong correlation with VF indices similar to our study.[16]

There was statistically significant difference between mild, moderate, and severe glaucoma with all three instruments ($P < 0.001$). Goldberg used GQL-15 to differentiate mild, moderate, and severe glaucoma and reported similar findings as ours.[4] However, Nelson was not able to differentiate mild glaucoma from moderate glaucoma by using GQL-15 instrument.[15] In another study, the authors were not able to differentiate mild glaucoma from moderate glaucoma with NEIVFQ-25 and GQL-15 instrument.[9] These facts deviate from our findings but varied ways to grade disease severity in different studies may account for this difference.

NEIVFQ-25 (nonvisual subscales)

Nonvisual subscales of NEIVFQ-25 like general health, mental health, social function, and role limitation showed significant decrease in scores corresponding to increased severity of glaucoma [Table 5]. All these subscales were able to differentiate between mild, moderate, and severe glaucoma ($P < 0.001$).

These results demonstrate the importance of nonvisual or general health-related subscales while assessing QoL in glaucoma patients. Jung et al. have previously reported the higher levels of depression, anxiety, altered sleep, psychological stress, and suicidal ideation in patients with glaucoma when compared to controls.[17] These findings highlight the fact that glaucoma despite being an ocular disease has huge impact on general and psychological health-related QoL. Thus, nonvisual parameters like general health, psychological health, and social health form an integral part of any QoL instrument.

Correlation of NEIVFQ-25 and GQL-15

The scores of different domain and subscales showed significant correlation in both the instruments [Table 2]. The near and peripheral vision subscales of NEIVFQ-25 correlated well with the near and peripheral vision domain of GQL 15. This is similar to the previously reported results.[9] We also found strongest correlation between the general health and peripheral vision subscale of NEIVFQ-25 and outdoor mobility domain of GQL-15. A significant correlation between the peripheral vision subscales of the NEIVFQ-25 with the outdoor mobility domains of the GQL-15 was demonstrated by Mbadugha et al. They however did not show correlation with general health subscale which is in contrast to our findings. This correlation can be explained by the fact that any deterioration in general health will be reflected in decreased outdoor activities.

The driving subscale of NEIVFQ-25 in our study correlated best with the peripheral vision and glare/dark adaptation domain of GQL-15. Mbadugha et al. have previously shown that driving subscale of NEIVFQ-25 strongly correlated with the glare and dark adaptation but not with the peripheral vision domain of GQL-15.[9] Our findings again highlight the importance of peripheral vision while driving in daylight. We agree that glaucoma patients may also have difficulty in driving at night due to glare and poor dark adaptation. Previous studies have also shown that glare and dark adaptation were most disturbing problems especially during early stage of disease but get less problematic as disease progresses, probably because patients adapt to these problems over a period of time.[15],[18],[19] The inability to drive leads to decreased outdoor mobility and hence adversely affects the quality of life of these patients. The assessment of glare and dark adaptation is thus of paramount importance in the clinical management of all stages of glaucoma patients.

Correlation of NEIVFQ-25 subscales and Viswanathan 10

The scores of different subscales of NEIVFQ-25 and different questions of Viswanathan 10 showed significant correlation [Table 3]. In our study, the question, Do you ever notice that parts of your field of vision are missing? in Viswanathan 10 instrument, has strong correlation with general vision subscales of NEIVFQ-25. Near vision subscale of NEIVFQ-25 showed strong correlation with question, Do you ever have trouble following a line of print or finding the next line while reading? in Viswanathan 10 instrument. Color vision subscale of NEIVFQ-25 showed significant correlation with question, Do you notice variations in color intensity? of Viswanathan 10 instrument. All these facts highlight high degree of agreement between different subscales and related questions of these two instruments.

Driving subscales of NEIVFQ-25 showed strong correlation with questions, Do you ever notice that parts of your field of vision are missing? and Do you have particular difficulty seeing after moving from a light to a dark room?, and Are you troubled by glare or dazzled on sunny days or in bright lighting? of Viswanathan 10 instrument. So driving subscales of NEIVFQ-25 is strongly correlating with questions related to dark adaptation, glare as well as peripheral vision. The findings of these two instruments correlate well with the findings discussed previously, highlighting the importance of glare/dark adaptation and peripheral vision in activities like driving.

In our study, vision-related subscales of NEIVFQ-25 are strongly correlating with questions of Viswanathan 10 related to activities dependent on vision. Our findings are quite similar to those reported previously, which highlight the importance of questions relating to near and peripheral vision in assessment of progressive glaucomatous decrease in QoL.[11]

Correlation of GQL-15 and Viswanathan 10

The scores of different domains of GQL-15 and related questions of Viswanathan 10 instrument also showed significant correlation [Table 4]. In our study, the question, Do you ever have trouble following a line of print or finding the next line when reading of Viswanathan 10 correlated best with the central-near vision domain of GQL-15. Questions, Do you have difficulty finding things that you have dropped? and Have you noticed any deterioration in your sight over the last few years?, of Viswanathan 10 correlated best with the peripheral vision domain of GQL-15. The question, Have you had to give up activities because of your sight?, correlated best with the glare/dark adaptation and outdoor mobility domains. The questions, Are you troubled by glare or dazzled on sunny days or in bright lighting? and Do you have particular difficulty seeing after moving from a light to a dark room?, also correlated best with the glare/dark adaptation and outdoor mobility domains of GQL-15.

In a previous study, the following questions of Viswanathan 10 instrument, Do you notice variations in color intensity?, Do you bump into things sometimes?, Do you trip on things or have difficulty with stairs?, and Do you have difficulty finding things that you have dropped?, were the most useful questions to evaluate patients' limitations due to glaucomatous damage.[16] In our study, the most useful question which strongly correlated with other instruments, Have you had to give up activities because of your sight?, correlated best with the glare/dark adaptation, and outdoor mobility domains, Are you troubled by glare or dazzled on sunny days or in bright lighting? and Do you have particular difficulty seeing after moving from a light to a dark room? also correlated best with the glare/dark adaptation and outdoor mobility domains. These findings highlight that both instruments have strong agreement between similar domains.

Our study however has its limitations. These limitations stem from the fact that this study is a clinic-based one. The study population is more male dominated and this may not be applicable to other centers having a different gender distribution. The analysis of the three instruments indicates that essentially all three are in good agreement while evaluating the functional impact of glaucoma on similar visual domains. Disease-specific instruments like GQL-15 and Viswanathan 10 have advantage of being shorter, less time-consuming, and are easy to administer as compared to NEIVFQ-25. NEIVFQ-25 provides additional information like general health, mental health, role limitation, and outdoor mobility that better indicate overall QoL. The inclusion of such parameters is vital for any PRO instrument design.

Conclusion

In our study, one vision-specific and both disease-specific instruments were able to differentiate between mild, moderate, and severe glaucoma. In pairwise comparison most subscales of NEIVFQ-25, domains of GQL-15 and questions of Viswanathan 10 strongly correlate. Most disease-specific instruments assess symptoms and their effects on various activities of patients but lack general health-related assessment. Vision-related instruments like NEIVFQ-25 assess overall QoL but are difficult to administer. We believe that with the current available tools, use of multiple instruments to assess QoL offers a more comprehensive assessment than using a single tool. More studies are required to develop a precise and user-friendly future instrument for QoL assessment in glaucoma patients after incorporating factors such as emotional concerns, financial impacts of medications, or other treatment-related issues.

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Conflicts of interest

There are no conflicts of interest.

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