Special Article

Health Related Quality of Life Instruments for Glaucoma: A Comprehensive Review

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Health related quality of life (HRQOL) outcome is becoming important and of interest for clinicians and patients alike. HRQOL can be affected immediately after the initial diagnosis of the disease through anxiety of blindness. Further impairment in various aspects of HRQOL is expected over time as the disease progresses, reducing daily activities. Without a gold standard for HRQOL construct in this population, a number of instruments have become available with different characteristics and foci. This article reviews published HRQOL instruments and their psychometric properties in glaucoma patients. Of the 10 instruments reviewed, 2 were generic, 4 were vision-specific and 4 were glaucoma-specific instruments. Overall, vision- and glaucoma-specific instruments appear to be more sensitive than generic instruments in detecting potential changes of HRQOL in the patients. The shortcoming of existing instruments, however, arises from being predominantly focused on physical functions while omitting other aspects relevant to patients HRQOL such as psychological and social well-being. In addition, many vision-specific instruments have inadequate coverage of important issues, such as peripheral and color vision, which are affected by glaucoma disease. Validation of the instruments using various magnitudes of visual field is warranted and further investigation of their responsiveness is required for them to be more useful for outcome evaluation in the clinical setting. Refinement of an instrument to enhance the incorporation of HRQOL in routine management of patients with glaucoma is briefly described.

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Glaucoma is a chronic, progressive, ocular disorder involving optic neuropathy accompanied with visual field loss and blindness. In the year 2000, it was estimated that the number of glaucoma patients was approximately 67 million globally and 6.7 million of these people were blind[1]. In Thailand, glaucoma is the second leading cause of blindness after cataract. The prevalence in Thailand has been reported from 2.5% to 3.8%[2,3]. One of the reports expected that, over the next 50 years, the rate of glaucoma incidence would rise threefold for males and fourfold for females[2].

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With its incurable nature, glaucoma patients require a regular visit to ophthalmologists throughout their life to preserve their vision. The cost of treatment and support for patients with glaucoma was approximately 1 billion dollars per year in the US with higher cost of treatment is usually expected for patients with more disease severity[4,5]. Glaucoma does not only affect visual function and increase cost for treatment, but also influences patients' health related quality of life (HRQOL)[6,7]. The perception of a patient's HRQOL may worsen after the diagnosis of the disease because of the anxiety of blindness[8]. More impairment in HRQOL is usually expected as the disease progresses due to further damage in visual function leading to a reduction in activities of daily living[6,9] and loss of confidence when performing outdoor activities[10].

HRQOL outcome has become increasingly important in the assessment of comprehensive care of glaucoma patients. Various instruments have been developed and used to measure HRQOL of these patients. Although Lee and Wilson[11] has reviewed several HRQOL instruments for glaucoma and cataract patients, there was no comprehensive review of HRQOL instruments specifically for glaucoma. This article comprehensively reviews HRQOL instruments published from 1970 to 2005 in the Medline database using the keywords 'quality of life' and 'glaucoma'. Of the ten instruments found, two were generic instruments developed for the general population, four were vision specific instruments with different aspects of HRQOL being assessed for various eye diseases, and four were specifically developed for glaucoma.

The characteristics of the instruments and their psychometric properties when used with glaucoma patients are evaluated in Table 1. An appropriate instrument should have good coverage to capture what patients value in their HRQOL. It should be easy to complete and preferably have an interview version available as the eye condition may preclude some patients from completing the questionnaire themselves. Finally, it should have collective evidence of its reliability and validity to assure a meaningful and accurate measure. In addition, an instrument showing good responsiveness is of value when evaluating the effect of the treatment or providing care over time.

Table 1. Existing health related quality of life instruments that have been used with glaucoma patients

Instrument	No. of items (domain)	Rating scale	Scoring	Administration time*	Psychometric property evaluation		
					Reliability	Validity	Responsiveness
Generic instrument							
SF-36[12]	36 (8)	2, 3, 5, 6-Likert	Scales, Summary (0-100)	5-10 mins (IW, SA)	Cronbach's α (0.63-0.77)	Content validity Known group CV / DV † Factor analysis	Tested
SIP[15]	136 (12)	Numeric scale	Categories, Dimensions, Total (0-100)	20-30 mins (IW, SA)	Cronbach's α (0.94) Test-retest (0.92)	CV / DV † Clinical validity ‡	Tested
Vision-specific instrument							
VF-14[23]	14 (-)	5-point Likert	Total (0-100)	NA (IW)	Cronbach's α (0.85) Test-retest (0.79)	Content validity Known group CV / DV Factor analysis ** Clinical validity ‡	Tested[23]

Generic Instruments

The Medical Outcomes Study Short Form-36 (SF-36)[12]

The SF-36 was developed for the medical outcome study. It consists of 36 items which assess eight health concepts (physical functioning, social functioning, general health, mental health, bodily pain, physical role limitation, emotional role limitation, and vitality). Scale scores range from 0 to 100, with higher scores reflecting a better health status. The instrument is reliable, exhibiting reliability coefficients above 0.7 in most domains. The validation, however, presents conflicting results. While some studies suggested that the questionnaire could distinguish between patients with and without glaucoma[6,13] when lower HRQOL scores were indicated, one study did not show any score difference[14]. In addition, all domains of the SF-36 have shown only weak correlation with visual acuity or visual field impairment[9].

The Sickness Impact Profile (SIP)[15]

The SIP consists of 136 items which are cate-

Instrument	No. of items (domain)	Rating scale	Scoring	Administration time*	Psychometric property evaluation		
					Reliability	Validity	Responsiveness
Vision-specific instrument (cont.)							
NEI-VFQ[16]	51 (12)	5-point, 6-point Likert	Subscale (0-100)	15 mins (IW)	Cronbach's α (0.66-0.94) Test-retest (0.68-0.91)	Content validity Known group CV / DV Clinical validity ‡	Not tested
NEI-VFQ-25[17]	25 (12)	5-point, 6-point Likert	Subscale, Total (0-100)	5 mins (IW)	Cronbach's α (0.71-0.85)	Content validation Known group CV / DV Clinical validity ‡	Not tested
ADVS[25]	20 (5)	5-point Likert	Subscale, Total (0-100)	NA (IW)	Cronbach's α (0.91-0.94) Inter-rater (0.82-0.97) Test-retest (0.87)	Factor analysis Clinical validity ‡	Tested
Glaucoma-specific instrument							
GSS[256]	10 (2)	5-point Likert	Subscale (0-100)	NA (SA)	Cronbach's α (0.74-0.83) Factor analysis Clinical validity ‡	CV / DV Known group	Not tested
COMTOL[27]	37 (13), 4 global	6-point, 7-point Likert	Domain (0-5, 0-6)	NA (IW)	Cronbach's α (0.73-0.98) ICC (0.75-0.94) CCC (0.74-0.93)	Known group Factor analysis ** Construct validity ‖	Tested
GQL-15[28]	15 (4)	5-point Likert	Total (0-100)	NA (SA)	Cronbach's α(0.95) Test-retest (0.87)	Known group Factor analysis **	Not tested
SIG[29]	43 (4)	5-point Likert	Subscale § Total (0-215)	NA (IW)	Cronbach's α (0.63-0.88) Test-retest (0.79)	Known group Clinical validity ‡	Not tested

NA = not available, No. = number, IW = interview, SA = self-administration, ICC = intraclass correlation coefficient, CCC = concordance correlation coefficient, CV / DV = Convergent / divergent validity

* time of questionnaire administration † multitrait-multimethod ‡ correlated with clinical measure

§ visual function (0-55), local eye (0-35), systemic (0-100), psychological (0-25) ‖ correlate with global question

** The results of factor analysis did not confirm the researchers' expectations

gorized into 12 domains (sleep and rest, eating, work, home management, recreation and pastimes, ambulation, mobility, body care and movement, social interaction, alertness behavior, emotional behavior, and communication). The scores range from 0 to 100, with higher scores indicating worse health status. The validity and reliability of this instrument have been demonstrated. However, the length of the questionnaire limits its routine use. The Collaborative Initial Glaucoma Treatment Study (CIGTS) included the SIP as one of several questionnaires to assess HRQOL in patients with newly diagnosed glaucoma who were randomized to receive medical or surgical treatment[8]. No treatment difference was found using this generic instrument.

Vision-Specific Instruments

The National Eye Institute Visual Function Questionnaire (NEI-VFQ)[16]

The NEI-VFQ is a targeted multidimensional survey that assesses the influence of vision problems on HRQOL. It consists of 51 items and employs 12 domains (general vision, ocular pain, near vision, distance vision, color vision, peripheral vision, driving, vision-specific role difficulties, vision-specific dependency, vision specific social function, vision specific mental health, vision specific expectation) plus one item on general health. Scale scores range from 0 to 100, with 100 representing the best health status. NEI-VFQ is a multidimensional measure and has a good coverage in various eye diseases. It was reported to be more sensitive than SF-36 in differentiating between patients with and without glaucoma[9,13] and 3 out of 13 domains correlated moderately with visual field impairment[9]. However, the instrument correlated only weakly to moderately with visual field loss and visual acuity, and known group validation shows discrimination only between patients with low vision and the reference group instead of with magnitude of vision loss. The length of the instrument also limits its use in clinical settings.

The 25-item National Eye Institute Visual Function Questionnaire (NEI-VFQ-25)[17]

The NEI-VFQ-25 was developed by item-reduction of the 51-item NEI-VFQ. The NEI-VFQ-25 yields 12 domains similar to that of the 51-item NEI-VFQ. The reliability and validity of the NEI-VFQ-25 are comparable to those of the 51-item NEI-VFQ, but preferable due to its brevity and higher internal consistency. The questionnaire has been used with a number of studies in eye diseases. Current studies show that difficulty with topical medication use and topical drug side effects were strongly associated with decreased HRQOL[18-19]. The questionnaire has also been translated into several languages[20-22]. Despite its good coverage, the instrument was not developed specifically for glaucoma patients. Known group validation has only been tested by visual acuity, regardless of visual field. Therefore, the psychometric properties of the instrument as influenced by the severity of visual field defect need further investigation. Factor analysis to confirm its 12-domain construct should also be evaluated.

The VF-14[23]

The VF-14 was developed to assess vision related HRQOL affected by cataract. The VF-14 consists of 14 items of vision-targeted activities. The scores range from 0 to 100, with 100 representing the best health status. It is short, simple and has been shown to have good reproducibility and responsiveness[23-24]. It was reported to have reliable and valid measure of functional impairment influenced by cataract, and was more sensitive than generic instruments in discriminating patients with and without glaucoma[9,13]. The VF-14 also showed moderate correlation with visual field impairment in glaucoma patients. However, it emphasizes only physical functions that are mostly relevant to visual acuity, which are dramatically affected by cataract. Issues affected by visual field, such as peripheral and color vision, that are most relevant to glaucoma patients are not evaluated. In addition, other aspects of HRQOL such as mental and social well-being are not included.

The Activities of Daily Vision Scale (ADVS)[25]

The ADVS was developed for evaluating visual function of patients with cataract. It consists of 20 visual activities, which are categorized into 5 domains (day vision, night vision, far vision, near vision, and glare impact). Using a 5-item response scale, the score is then transformed to a 0 to 100 score, with 100 representing no difficulty with visual activities. The instrument is properly constructed with factor analysis. It is short and has a good test-retest and inter-rater reliability as well as responsiveness. Among patients with glaucoma, visual acuity and visual field correlated significantly with all ADVS subscales[6]. However, it has limited coverage and emphasizes only physical functions without the focus on peripheral vision, which is a dominant defect in glaucoma.

Glaucoma-specific instruments

The Glaucoma Symptom Scale (GSS)[26]

The GSS consists of 10 ocular complaints and two domains; the first six items are non-visual ophthalmic symptoms (SYMP-6) and the rest are visual ophthalmic symptoms (FUNC-4). The scores range from 0 to 4 for each eye. The original score is then transformed to 0 to 100, with higher scores representing fewer problems. The instrument has a good reliability with Cronbach's α above 0.7 in both domains. The construct validity is established by convergent/divergent and factor analysis. It is simple and short. However, emphasizing only physical functions, it does not cover other aspects of HRQOL that are relevant to the patients. In addition, the questionnaire cannot specifically identify whether those symptoms are of the disease or treatment.

The Comparison of Ophthalmic Medication for Tolerability (COMTOL)[27]

The COMTOL was designed to assess the frequency and bothersomeness of topical glaucoma drugs' side effects. The COMTOL consists of 13 domains and four global questions. The compliance and satisfaction with the medication are assessed by the global questions. The response scale of each domain is different, with higher scores indicating more discomfort. The instrument shows a good internal consistency, reproducibility, and responsiveness. However, the measure was developed for use in clinical trial to compare the tolerability of topical glaucoma medication and emphasizes only physical functions. Therefore, its benefit as a HRQOL instrument in routine clinical use is still limited.

The Glaucoma Quality of Life-15 (GQL-15)[28]

The GQL-15 has a wide range of questions covering most aspects of daily activities that are highly associated with visual field loss. It consists of 15 questions, which are categorized into four domains (central and near vision, peripheral vision, glare and dark adaptation, and outdoor mobility). The scores range from 0 to 100, with 100 representing no difficulties. The GQL-15 is short and has good internal consistency and test-retest reliability. It discriminates well between mild and severe visual field loss, but neither mild and moderate nor moderate and severe. The questionnaire construct is established by factor analysis, but the sample size was too small for its interpretation. Again, it emphasizes only physical functions and ignores other HRQOL aspects.

The Symptom Impact Glaucoma Score (SIG)[29]

The SIG is a new measure developed specifically for use in the CIGTS study. It is developed from a symptom checklist by adding a bothersome score for each problem symptom. It consists of 43 items, which are categorized into four domains (visual function, local eye, systemic, psychological). The score for each item ranges from 1 (not at all) to 5 (a lot). The subscale score is calculated by the total score of all items, with higher scores indicating more bothersome symptoms. The instrument has good internal consistency and test-retest reliability. Validity is established by known group validation using visual field. Although it adequately assesses physical and psychological domains, the social domain is still omitted[8].

Discussion

HRQOL is currently becoming an important issue in glaucoma management. Although various instruments have been developed and used in these patients, no particular instrument has been universally accepted. Nevertheless, vision-specific and glaucoma-specific instruments are of value and of interest by clinicians and patients themselves, as these instruments are more sensitive to glaucoma patients than generic instruments. The major shortcoming of the existing instruments is their limited coverage. The majority focuses predominately on physical symptoms and functions while psychological and social well-being are often omitted. This has weakened their value for assessing various aspects of HRQOL relevant to the patients. In addition, many vision-specific instruments have inadequate coverage of important issues, such as peripheral and color vision, which are affected by glaucoma.

Most common validations of these instruments are known group and clinical validity that correlated with visual acuity and visual field. The validation using various magnitudes of visual field is warranted and confirmation of the questionnaire construct using factor analysis is still limited. Likewise, the investigation of the questionnaires on their responsiveness is inadequately tested. This may lower their sensitivity in detecting the association between the change of measure scores and true values during a period of time, which is of important for measuring the impact of care.

The number of items and the time used for administering the questionnaire should also be considered to ensure patients' compliance. Some of the instruments, however, seem to be quite lengthy and require a lot of time and effort to complete. This may

limit their use in both clinical research and routine practice. In addition, as an interview version is important in this population, those that provide such a version still have inadequate testing of their inter-rater reliability. This is important to ensure the reproducibility of the scores when used by different interviewers.

Where should we go from here?

In Thailand, there is currently no published instrument available for measuring HRQOL in glaucoma patients despite an increasing need for HRQOL evaluation. Taking into account the shortcomings of the existing instruments, the Thai Visual Function Questionnaire 28 (VFQ-28 Thai)[30] was recently developed by a multi-disciplinary research group. It is a multidimensional instrument with glaucoma specific and administered via an interview. The items were generated from the list that patients valued as important to their HRQOL. It is the authors hope that the "VFQ-28 Thai" will capture issues relevant to Thai patients that may otherwise be omitted by other aforementioned Western-based HRQOL instruments. The construct of the questionnaire was based on the NEI-VFQ-25 and relevant items were taken using forward and backward translation.

"VFQ-28 Thai" is simple and consists of 28 items (11 domains) covering aspects relevant to general eye disease, plus 10 symptoms that are specific to glaucoma. Content validity has been tested by experts (n = 4) and patients (n = 20). The preliminary results of 266 patients showed good internal consistency reliability in all domains. The questionnaire could also differentiate between patients with various visual field magnitudes. Further investigation of its psychometric properties is on going. If confirmed, this could enhance the incorporation of HRQOL in the routine management of glaucoma and enable an evaluation of the comprehensive care provision for glaucoma patients in Thailand.

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การประเมินเครื่องมือวัดคุณภาพชีวิตด้านสุขภาพสำหรับผู้ป่วยโรคต้อหิน

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การประเมินผลลัพธ์คุณภาพชีวิตด้านสุขภาพ มีความสำคัญและได้รับความสนใจจากบุคลากรทางการแพทย์และผู้ป่วยมากขึ้น โรคต้อหินส่งผลกระทบต่อคุณภาพชีวิตของผู้ป่วย ตั้งแต่เริ่มได้รับการวินิจฉัยโรค ซึ่งเป็นผลจากความวิตกกังวลเกี่ยวกับโอกาสที่จะสูญเสียการมองเห็นที่อาจเกิดขึ้นจากโรค และเมื่อความรุนแรงของโรคมากขึ้น ผู้ป่วยจะมีความสามารถในการทำกิจกรรมประจำวันลดลง ซึ่งส่งผลทางด้านลบให้กับคุณภาพชีวิตของผู้ป่วย เนื่องจากยังไม่มีข้อกำหนดมาตรฐานของโครงสร้างเครื่องมือวัดคุณภาพชีวิตสำหรับผู้ป่วยกลุ่มนี้ จึงทำให้เครื่องมือวัดคุณภาพชีวิตที่มีอยู่ในปัจจุบันมีลักษณะแตกต่างกันไป บทความนี้ได้ทบทวนเครื่องมือวัดคุณภาพชีวิตที่มีใช้อยู่ในปัจจุบันทั้งหมด 10 ชนิด โดยแบ่งเป็นเครื่องมือแบบทั่วไป 2 ชนิด เครื่องมือเฉพาะสำหรับสายตา 4 ชนิด และเครื่องมือเฉพาะสำหรับโรคต้อหิน 4 ชนิด โดยภาพรวมพบว่าเครื่องมือเฉพาะสำหรับสายตาและเฉพาะสำหรับโรคต้อหินมีความไวในการวัดความเปลี่ยนแปลงคุณภาพชีวิตของผู้ป่วยได้ดีกว่าเครื่องมือแบบทั่วไป เครื่องมือวัดคุณภาพชีวิตที่มีในปัจจุบันมีข้อจำกัดที่เน้นการประเมินมิติทางร่างกายเป็นส่วนใหญ่ แต่ไม่ได้ครอบคลุมมิติทางด้านจิตใจและสังคม ซึ่งมีความสำคัญกับผู้ป่วยต้อหิน นอกจากนี้ เครื่องมือเฉพาะสำหรับสายตาหลายชนิดไม่ได้ครอบคลุมเนื้อหาในเรื่องการมองเห็นส่วนริมของลานสายตา (peripheral vision) และการมองเห็นสี (color vision) ซึ่งเป็นผลกระทบโดยตรงของโรคต้อหิน และเพื่อให้เครื่องมือวัดคุณภาพชีวิตมีประโยชน์มากยิ่งขึ้นในการประเมินผลลัพธ์ในการดูแลผู้ป่วย การทดสอบความถูกต้องของเครื่องมือควรใช้การเปรียบเทียบกับระดับการสูญเสียของลานสายตาที่แตกต่างกันของผู้ป่วย และควรมีการทดสอบความไวของเครื่องมือต่อการเปลี่ยนแปลงร่วมด้วย ซึ่งในที่นี้ได้สรุปเกี่ยวกับการสร้างและปรับปรุงเครื่องมือวัดคุณภาพชีวิตที่เหมาะสมสำหรับผู้ป่วยโรคต้อหินไว้ด้วย