


Utility Index and Patient-Reported Outcome Measures in Glaucomatous Patients Comparing with Normal Participants

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Purpose: Utility index is a significant outcome in terms of health economics assessment while patient-reported outcome measure (PROMs) evaluates quality of life (QOL) from patient's perspective. Our objective was to evaluate both utility indices and PROMs using generic and eye specific QOL in glaucomatous patients compared with normal population.

Methods: This is a case-control study. We interviewed normal and glaucomatous participants with the European Quality of Life questionnaire (EQ-5D-5L), the European visual analogue scale (EQ-VAS) and the visual function questionnaire 28 (Thai version) (VFQ-28). The visual function questionnaire utility index (VFQ-UI) and generic utility index from EQ-5D-5L were calculated.

Results: There were 47 normal and 127 glaucomatous participants in this study. Amongst glaucoma group, 35 participants were in the early stage of the disease, 43 were in the moderate stage, 30 normal vision participants were in the severe stage, 14 participants had blindness one eye, and 5 had blindness both eyes. The mean age of the participants in both groups was statistically similar (63.78 ± 6.84 vs 66.30 ± 8.93 years old, respectively, $p=0.062$). Underlying diseases between groups were also comparable. The EQ-5D-5L utility index score and the EQ-VAS score were not statistically different between normal and glaucomatous groups, respectively (EQ-5D-5L: 0.874 ± 0.122 vs 0.837 ± 0.191 , $p=0.215$; EQ VAS: 76.06 ± 15.07 vs 74.02 ± 15.10 , $p=0.43$). By contrast, VFQ-UI of the glaucomatous group was significantly lower than that of the normal group, (VFQ-UI: 0.833 ± 0.147 vs 0.895 ± 0.070 , accordingly, $p<0.05$).

Conclusions: Utility index from the VFQ-UI was a relevant PROMs for evaluating the QOL of glaucomatous patients in terms of visual function specificity and acceptable validity.

Keywords: quality of life in glaucomatous patients, utility index of glaucoma, patient-reported outcome measures, PROMs, the visual function questionnaire utility index in glaucoma, VFQ-UI, the European Quality of Life questionnaire in glaucoma, EQ-5D-5L, the visual function questionnaire 28 Thai-version, VFQ-28

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Introduction

Glaucoma is a disease that causes visual impairment, thereby hindering one's quality of life (QOL).¹ Several studies have found a link between having glaucoma and an increased risk of experiencing certain negative effects, such as a higher incident of automobile accidents, social withdrawal and even depressive disorders all of which negatively impact QOL.²⁻⁴ Due to the lack of visual symptoms in the early stages of glaucoma, the subsequent visual impairment—affecting both visual

acuity and visual field—becomes apparent only in the later stages of the disease. Without treatment, the disease will usually progress to the end-stage, in which complete blindness can occur.^{5,6} Fortunately, there are modern glaucoma treatment methods that can effectively halt the progression of the disease.^{7–10} However, there are also possible negative aspects to these treatment options, including side effects of certain medications,¹¹ cost of treatment options,¹² complications, or continuing effects from surgical procedures, which may require long-term care, and other considerations.¹³ Consequently, glaucoma can impact visual functioning in all areas of life, including work, recreation, and other normal day-to-day activities, activities, thereby significantly decreasing a person's QOL. At present, the objective of glaucoma management is not only to control the progression of the disease but also to preserve the patient's QOL as much as possible while utilizing rational treatment options.

The QOL in glaucoma patients can be assessed by using various types of vision-specific, disease-specific, and generic QOL questionnaires. Generic QOL evaluated the general wellbeing of respondents and generated the utility index, for example, the Short-Form Six-Dimension health index (SF-6D), the Medical Outcomes Study 36-item short-form health survey (SF-36) and the EuroQOL's EQ-5D-5L.^{14–16} The National eye institute visual functioning questionnaire (NEI-VFQ) is widely used vision-specific QOL questionnaires in ophthalmology.^{17–19} The glaucoma symptom scale (GSS) and the Glaucoma quality of life-15 (GQL-15) questionnaire are glaucoma disease-specific QOL questionnaires.^{20,21}

QOL is primarily measured by using utility index applied to quality-adjusted life year (QALY) in cost-effectiveness analysis and health economics to assess the burden of diseases in social perspective.^{22–25} In this work, we compare utility indices and patient-reported outcome measures (PROMs) between glaucomatous patients in various stages of the disease to the general population within a similar age-range by using both generic utility index—the EuroQOL's EQ-5D-5L and the European visual analogue scale score (EQ-VAS)^{26–28} and the vision-specific QOL and vision-specific utility index—the visual function questionnaire 28-Thai version (VFQ-28)²⁹ and the visual function questionnaire-utility index (VFQ-UI).^{30,31} Both generic and eye-specific utility indices and PROMs of glaucomatous patients from these data would be beneficial for policymaking and resource allocation, as well as be an incentive for a more patient-based consideration.³²

Methods

This was a case–control study which adhered to the tenets of the Declaration of Helsinki and has been approved by the Mettapracharak (Wat Raikhing) research ethics committee in accordance with the international conference on harmonisation good clinical practice (ICH-GCP). Written informed consent was obtained from all participants. Data were collected between June 2015 and June 2016.

Non-glaucomatous participants were invited from both hospital-based eye screening programs for the elderly at the institute hospital and community-based screening mobile unit at Klong Mai subdistrict administrative organization, while glaucomatous participants were recruited from the glaucoma clinic at the institute hospital. The severity classification of glaucomatous participants was determined by referring to Hodapp, Parish and Anderson (H-P-A) glaucoma classification system³³ into early, moderate and severe stages with the different levels of mean deviation (MD) determined from the visual field testing. Sample size estimation in each group was calculated from the infinite population mean formula.

Sample Size = $Z^2_{1-\alpha/2} \sigma^2 / d^2$, where Z is standard normal variate, which was 1.96 ($p < 0.05$), α is 0.05, SD (σ) is the utility index scores' standard deviation evaluated by the EuroQol's EQ-5D-5L questionnaire from a pilot study of normal and glaucomatous participants and d is the absolute error, estimated to be 0.05. Estimated participants sample sizes were 29 normal (non-glaucomatous) participants (SD=0.136), 32 early stage glaucoma participants (SD=0.143), 44 moderate stage participants (SD=0.171) and 18 in the severe stages (SD=0.108).

Six-hundreds participants underwent a comprehensive eye examination including visual acuity testing, intraocular pressure measuring, optic nerve evaluating by fundus photograph and standard automated visual field testing to clarify the situation in suspect participants. Non-glaucoma participants were invited to interview with the quality of life questionnaires sequentially followed by a random table number, whereas glaucomatous participants were recruited voluntarily according to the sample size calculation.

Generic QOL was evaluated using the EuroQol's EQ-5D-5L questionnaire (Thai version) with the outcomes being the utility index and the European visual analogue scale score (EQ-VAS).^{28,34} The EQ-5D-5L evaluates the health status of respondents with a descriptive system of 5 dimensions (mobility, self-care, usual activities, pain/discomfort and

anxiety/depression) with each dimension having 5 levels (no problems, slight problems, moderate problems, severe problems, and extreme problems). The EQ-VAS represents the respondent's self-rated health and can be used as a quantitative measure of health as the visual analogue scale (value between 0 and 100). The unique health state of the respondent is defined by scoring in each dimension. Each EQ-5D-5L health state is converted into a single utility index value (value between 0 and 1: value 0 means dead while, 1 means perfectly health) with a country specific dataset that is easily applied in QALY calculation.

Vision-specific QOL was assessed by the visual function questionnaire 28-Thai version (VFQ-28) which was constructed from the National Eye Institute 25-Item Visual Function Questionnaire (NEI VFQ-25) using forward and backward translation. Because its items were created from patients' perception, this Thai version has been tailored to capture issues relevant to Thai patients.^{17-19,29} The vision-specific utility index was evaluated by the visual function questionnaire utility index (VFQ-UI).^{30,31} The VFQ-28 consists of 28 vision targeted questions that can generate vision-targeted sub-scales including, global vision, difficulties with near/distance vision activities, limitations following these axes due to vision: limitations in social functioning, role limitations, dependency on others and mental health, driving difficulties, limitations with peripheral vision and color vision, and ocular pain. The results of these PROMs consist of composite scores (averaging of the vision-targeted sub-scales) and the generated VFQ-28 sub-scales averaging from each items, presented as range between 0 and 100 scores (0 being the worst possible score, 100 being the best).³⁵

The VFQ-UI is a vision-specific utility index that was developed by including 6 items from 6 NEI VFQ-25 sub-scales (near vision activities, distance vision activities, vision-specific social functioning, role difficulties, dependency, and mental health) and 8 health states preference values rather than 15,625 states were estimated. There are 3-steps to generate a VFQ-UI. Firstly, recording the values of each 6 items from respondents by using the scoring system. Secondly, estimating the severity (theta) score from the provided regression equation.

Estimated theta score = $2.6387 + [(-0.8296 * I6R1) + (-0.3246 * I6R2) + (-0.1918 * I6R3) + (-0.1226 * I6R4)] + [(-0.5809 * I11R1) + (-0.3172 * I11R2) + (-0.2629 * I11R3) + (-0.1275 * I11R4)] + [(-0.6473 * I14R1) + (-0.3067 * I14R2) + (-0.2671 * I14R3) + (-0.1742 * I14R4)] + [(-0.5067 * I18R1) + (-0.1751 * I18R2) +$

$(-0.1382 * I18R3) + (-0.0996 * I18R4)] + [(-0.4555 * I20R1) + (-0.2172 * I20R2) + (-0.1932 * I20R3) + (-0.1447 * I20R4)] + [(-0.3692 * I25R1) + (-0.1485 * I25R2) + (-0.1561 * I25R3) + (-0.0924 * I25R4)]$

where I = item; R = response category (after step 1 recoding), and its value is determined by $I[n]R[k] = 1$, when response to item n is k (after step 1 recoding), $I[n]R[k] = 0$, otherwise. Finally, the theta score is used to estimate the utility index from the equation.

Utility score = $0.87397 + (0.0009 * \text{age}) + (-0.10619 * \text{predicted theta}) + (-0.11218 * \text{predicted theta squared}) + (0.02779 * \text{predicted theta cubed})$.^{30,31}

Statistical Analysis

The data were analyzed by JASP Version 0.9.0.1. Descriptive statistics were applied to describe demographic data and results. The differences of demographic data, such as sex and other underlying diseases, between the normal and glaucoma groups, and within the glaucoma severity group, were tested by using Chi-squared test and the Fisher's exact test. The unpaired t -test and one-way analysis of variance (ANOVA) were used to assess differences of mean age, utility index score, EQ-VAS score, VFQ-28 score and VFQ-UI score between the normal and glaucomatous group and within the glaucoma groups. A $p < 0.05$ was considered statistically significant.

Results

A total of 174 participants were included. There were 47 participants without glaucoma and 127 glaucoma participants. The glaucoma group included 35 participants in the early stage, 43 moderate stage, 30 in the severe stage with normal vision, 14 with blindness in one eye, and 5 with blindness in both eyes. The mean age of the normal group was 63.78 ± 6.84 years old, similarly with the mean age in the glaucomatous group, 66.30 ± 8.93 years old ($p = 0.062$). Both males and females participated in equal proportions. Participants' underlying diseases were comparable (Table 1).

Results of the VFQ-UI and VFQ-28 were statistically significantly lower in the glaucomatous group as compared with the normal group, whereas the generic utility index and EQ-VAS results were indifferent (Table 2).

The visually impaired groups showed worse scores as compared to the normal vision group, accordingly: early, moderate, severe, blindness in one eye and blindness in both eyes, respectively (Table 3 and Figure 1). Due to the central visual field sparing nature of glaucoma diseases,

Table 1 Demographic Data of Normal and Glaucomatous Group

	Normal (47)	Glaucoma (127)	p-value
Age, mean (SD), Age range, year	63.78 (6.84), 56–90	66.30 (8.93), 45–88	0.062 ^a
Sex			0.14 ^b
Male	16 (34%)	59 (46%)	
Female	31 (66%)	68 (54%)	
Underlying disease	13 (27.7%)	24 (18.9%)	0.209 ^b
-Essential hypertension	3 (6.4%)	8 (6.3%)	
-Diabetics	5 (10.6%)	10 (7.9%)	
-Heart disease	2 (4.2%)	4 (3.1%)	
-Dyslipidemia	6 (12.7%)	8 (6.3%)	

Notes: ^aStudent's t-test, ^bChi-squared test.

quality of life of visually intact groups was unaffected unless they are in the more advanced stages of the disease.

VFQ-28 scale scores were compared between the normal and glaucomatous groups. Almost all visual-related item scores were lower in the glaucomatous group than in the normal group. The glaucomatous group scored worse than the normal group in both dependency and social function items (Table 4 and Figure 2).

When comparing within the glaucoma group, the visually impaired groups (blindness in one eye and

blindness in both eyes) showed significantly worse scores than the visually intact groups (Table 5 and Figure 3).

Discussion

A utility index is a significant outcome measurement applied in cost-utility and cost-effectiveness evaluation models. In some countries, these methods are mandatory in the health technology assessment and healthcare decision-making process. However, patient-reported outcome measures (PROMs) that represent a disease's impact from a patient's perspective are also equally important. The QOL of glaucoma patients evaluated by EQ-5D-5L and SF-6D, representing the utility index score, showed insignificant differences between early stage glaucoma and healthy participants. However, this ability was increased in visually impaired, constricted visual field, and severe stage respondents.^{15,36–39} Our results are in good agreement with the above. EQ-5D-5L and EQ VAS results in the glaucoma group were not statistically different from that of the non-glaucoma group. However, when comparing within the glaucoma group, the EQ-5D-5L results were worse for respondents in the severe stages of the disease and the visually impaired. The precision of this test was degraded because central vision sparing was frequently observed even in very late stages of glaucoma.^{36,40,41} According to its structure, 5 dimensions of the EQ-5D-5L evaluate

Table 2 EQ-5D-5L, EQ VAS, VFQ-UI and VFQ-28 Between Normal and Glaucomatous Groups

	Normal (47) Mean (SD)	Glaucoma (127) Mean (SD)	Mean Difference	p-value	95% CI for Mean Difference	
					Lower	Upper
EQ-5D-5L	0.874(0.122)	0.837(0.191)	0.037	0.215	−0.022	0.097
EQ VAS	76.06(15.07)	74.02(15.10)	2.048	0.428	−3.043	7.139
VFQ-UI	0.895(0.070)	0.833(0.147)	0.060	0.008	0.016	0.103
VFQ-28	87.21(8.80)	79.65(18.42)	7.552	0.008	2.023	13.080
Student's t-test						

Table 3 EQ-5D-5L, EQ-VAS, VFQ-UI and VFQ-28 Within Glaucomatous Groups

	Early (35) Mean (SD)	Moderate (43) Mean (SD)	Severe (30) Mean (SD)	Blindness One Eye (14) Mean (SD)	Blindness Both Eyes (5) Mean (SD)	p-value
EQ-5D-5L	0.888 (0.096)	0.824 (0.227)	0.868 (0.165)	0.762 (0.249)	0.612 (0.156)	0.012
EQ VAS	75.29 (13.982)	74.42 (15.322)	76.83 (16.054)	68.57 (14.991)	60.00 (7.071)	0.113
VFQ-UI	0.887 (0.095)	0.850 (0.122)	0.857 (0.123)	0.723 (0.196)	0.519 (0.039)	< 0.001
VFQ-28	87.20 (9.523)	82.83 (13.519)	82.26 (16.245)	62.09 (21.840)	33.07 (8.865)	< 0.001
ANOVA						

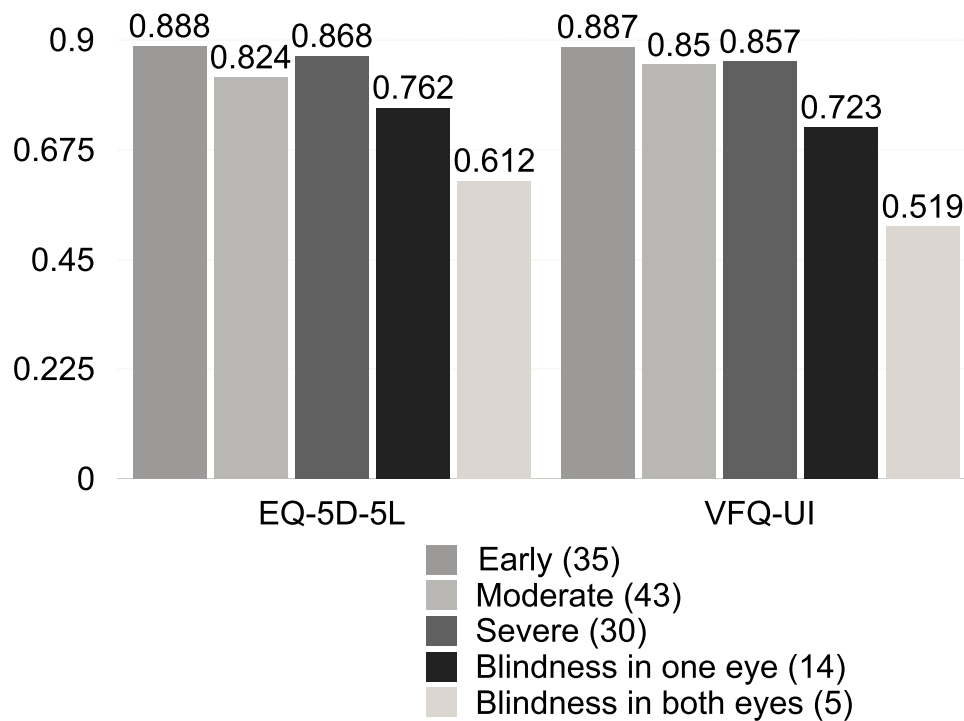


Figure 1 EQ-5D-5L and VFQ-UI bar chart comparing within glaucomatous groups.

mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Therefore, the total utility score is indirectly affected by visual impairment. This infers low sensitivity and determination capability of the EQ-5D-5L and EQ-VAS among different stages in visually intact glaucoma respondents, as well as the ability to distinguish between glaucoma and normal participants. McClure et al reported the minimally important difference (MID) range of 0.037 to 0.069 for the EuroQOL’s

EQ-5D-5L index scores, and group mean values of 0.069 (0.007) and 0.048 (0.004) for Chinese and Japanese, respectively.⁴² Although our EQ-5D-5L index score showed a mean difference of 0.037 between glaucoma and non-glaucoma groups, equal to the lowest MID value from the aforementioned studies, the results were not different statistically. This may suggest inadequate power when estimating sample size, in which 0.05 was applied as the absolute error.

Table 4 VFQ-28 Scale Scores Between Normal and Glaucomatous Groups

	Normal (47)	Glaucoma (127)	Mean Difference	p-value	95% CI for Mean Difference	
					Lower	Upper
General health	50.00 (23.313)	44.69 (20.077)	5.315	0.140	-1.759	12.389
General vision	72.34(11.461)	66.14(16.235)	6.199	0.017	1.108	11.290
Near activities	84.22(18.572)	74.54(28.508)	9.679	0.032	0.842	18.516
Distant vision	83.19(15.860)	74.57(21.520)	8.625	0.013	1.830	15.419
Driving	82.14(16.730)	71.96(21.260)	10.190	0.054	-0.169	20.540
Peripheral vision	85.64(20.520)	77.46(27.097)	8.178	0.062	-0.417	16.773
Color vision	96.81(11.201)	91.34(21.217)	5.470	0.095	-0.954	11.894
Ocular pain	84.84(19.667)	85.73(17.588)	-0.888	0.775	-7.010	5.235
Role limitation	88.30(18.505)	81.59(29.582)	6.703	0.149	-2.418	15.825
Dependency	95.21(16.802)	83.56(30.322)	11.650	0.014	2.427	20.873
Social function	96.54(7.234)	82.48(24.963)	14.062	< 0.001	6.752	21.372
Mental health	85.64(17.895)	78.46(26.318)	7.174	0.086	-1.033	15.381
Student’s t-test						

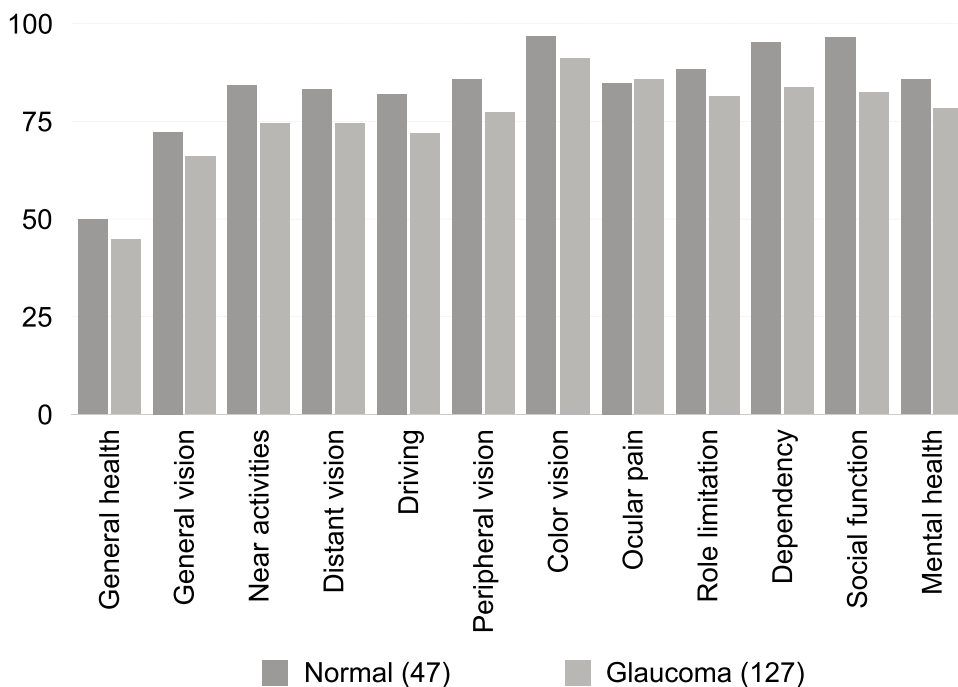


Figure 2 VFQ-28 scale scores bar chart comparing between normal and glaucomatous groups.

In contrast, the vision-specific NEI-VFQ 25 evaluated in chronic eye disease patients, such as those with dry eye syndrome,⁴³ cataracts,^{44,45} diabetic macular oedema,^{46,47} age-related macular degeneration,⁴⁸ as well as glaucoma,¹⁷ revealed a negative correlation between the QOL scores and severity of the disease or participants’ remaining vision. In the same way, our VFQ-28’ scores (adapted from the NEI-VFQ 25) were also inversely related to the severity of glaucomatous damage. Although the VFQ-28

can efficiently discriminate between normal and glaucomatous participants, we could not evaluate the utility index and utility value from this vision-specific QOL for applications in health economics assessment. Several studies have generated utility index scores by mapping the NEI-VFQ 25 to EuroQol. However, the predictive power of this approach has been proven to be low (squared Spearman correlation coefficient, $r_s=0.34$ and Ordinary Least Square, adjusted $R^2=0.3349$).^{49,50} Other methods of assessing the

Table 5 VFQ-28 Scale Scores Within Glaucomatous Groups

	Early (35)	Moderate (43)	Severe (30)	Blindness in One Eye (14)	Blindness in Both Eyes (5)	p-value
General health	42.86(19.714)	44.77(17.727)	50.00(26.261)	35.71(12.839)	50.00(0.00)	0.237
General vision	70.86(16.34)	66.51(16.17)	66.67(12.13)	62.86(10.69)	36.00(21.91)	< 0.001
Near activities	87.38(16.83)	74.81(29.52)	74.72(25.38)	60.12(32.88)	21.67(13.94)	< 0.001
Distant vision	80.57(17.23)	77.56(17.50)	78.67(21.13)	56.42(22.57)	33.00(10.37)	< 0.001
Driving	75.83(20.20)	72.81(20.38)	75.00(22.63)	54.17(17.28)	–	< 0.001
Peripheral vision	88.57(18.780)	77.91(24.676)	83.33(24.419)	52.68(30.689)	30.00(6.847)	< 0.001
Color vision	98.57(5.899)	95.35(13.645)	91.67(23.057)	78.57(32.310)	40.00(13.693)	< 0.001
Ocular pain	87.86(15.60)	90.70(12.53)	87.50(17.68)	74.11(17.31)	50.00(19.76)	< 0.001
Role limitation	85.36(29.00)	87.50(23.62)	87.91(20.10)	58.03(41.49)	32.50(16.77)	< 0.001
Dependency	95.00(16.10)	88.08(24.39)	89.58(26.48)	50.89(38.44)	20.00(14.25)	< 0.001
Social function	89.29(19.45)	85.76(24.79)	81.25(24.29)	74.11(26.16)	37.5(12.5)	< 0.001
Mental health	86.28(14.18)	83.72(20.29)	80.66(26.22)	48.57(29.83)	27.00(9.08)	< 0.001
ANOVA						

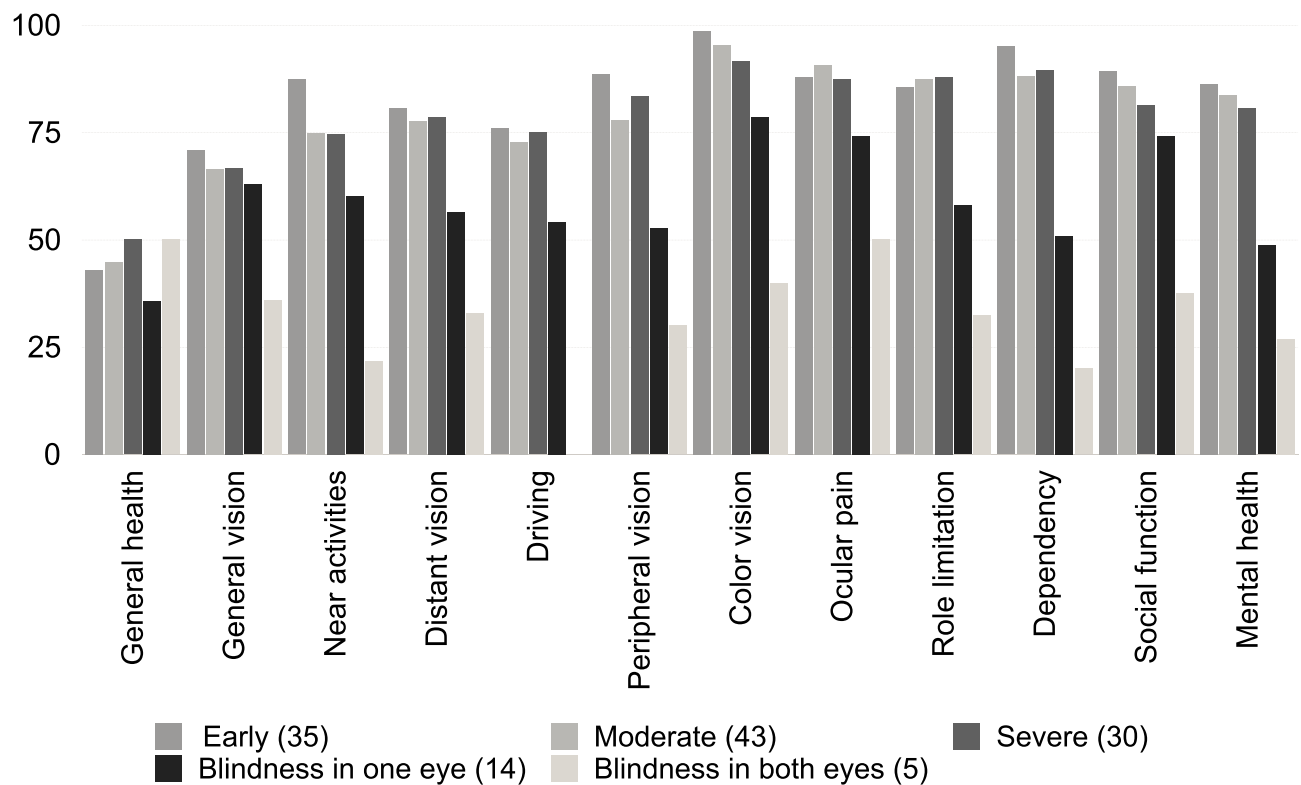


Figure 3 VFQ-28 scale scores bar chart comparing within glaucomatous groups.

utility scores in glaucoma were time trade-off (TTO) and standard gamble (gamble for blindness) methods.⁵¹ Lower scores were observed in the more severe stages of the disease.^{52–54} However, these methods may not be compatible within the Thai cultural context in which death and disability are not openly discussed.^{55,56}

The VFQ-UI would be a potentially useful PROMs in eye diseases, because it can evaluate both the QOL from the patient's perspective and utility indices for health economics assessment. In this study the VFQ-UI could determine the difference between normal and glaucoma groups. Although the difference of VFQ-UI between severity stages within glaucoma groups was not distinct, the difference was found between the visually intact and visually impaired groups. Goh et al had studied the validity of the VFQ-UI as a measurement of vision-related function and preference-based status in glaucomatous patients.⁵⁷ Even though they observed good convergent and divergent validity but the limitation of this PROMs was limited by poor targeting, similarly to our results. The discriminating power would increase in the more severe and visually impaired groups.

Over-rating was one of our limitations. According to Thailand's normative database, the EQ-5D utility index

was 0.694 (in stratified age-range of 55–64 years old) and 0.670 (in stratified age-range of 65–74 years old)⁵⁸ which was lower than our utility index results from both the normal and glaucoma groups. The average age of glaucoma groups was older than that of the non-glaucoma group by 3 years but was not statistically significant (63.78 ± 6.84 vs 66.30 ± 8.93 year-old, $p=0.062$). In Thailand, the elderly are classified as those over 60 years old as the retirement age. Therefore, the 3 years of difference may not affect the results.

Assessing QOL is significant both from perspectives of patients and the society. The ideal glaucoma-specific QOL is still being developed, as it has been throughout the natural history of the disease. The VFQ-UI is a promising candidate as both utility index and PROMs of glaucoma patients due to the ease of use and acceptable validity.

Conclusions

The impact of glaucomatous disease can evaluate from various perspectives. Eye specific utility index results were significantly lower and more specific in the glaucomatous group than in the normal group. Therefore, the

VFQ-UI could potentially be a useful tool for assessing the QOL of glaucomatous patients.

Abbreviations

EQ-5D-5L, European Quality of Life questionnaire; EQ-VAS, European visual analogue scale score; NEI VFQ-25, National Eye Institute 25-Item Visual Function Questionnaire; VFQ-28, visual function questionnaire 28-Thai version; VFQ-UI, visual specific utility index from the visual function questionnaire-utility index; PROMs, patients-reported outcome measures.

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Disclosure

The authors report no conflicts of interest in this work.

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