Validation of Indonesian Graves' Ophthalmopathy Quality of Life Questionnaire and Its Association with Clinical Activity and Severity of Graves' Ophthalmopathy

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ABSTRACT

Background: *Graves' ophthalmopathy (GO) ocular abnormalities can persist even after treatment, negatively impacting patients' psychological and social health. The Indonesian Graves' Ophthalmopathy Quality of Life (GO-QoL) Questionnaire has not been validated, hence it cannot measure patient quality of life, which is crucial to GO treatment. We aimed to provide a reliable Indonesian GO-QoL Questionnaire and identify an association between patient quality of life and clinical activity and the severity of GO.* ***Methods****: The process of questionnaire validation involves transcultural adaptation and a cross-sectional design. The content validity index (CVI) and Cronbach's alpha assessed validity and reliability, respectively.* ***Results:*** *The CVI was 1.00 for the Indonesian GO-QoL questionnaire. The Cronbach's alpha for the visual function subscale value was 0.971, the appearance subscale value was 0.993, and the total score was 0.986. The appearance subscale and total score of GO patients' quality of life had a significant association with clinical activity score ($p<0.05$) and disease severity ($p<0.001$).* ***Conclusion:*** *The Indonesian version of the GO-QoL has good validity and reliability. Both the active clinical activity of GO and the severity of the disease decreased patients' appearance and general quality of life.*

Keywords**:** *Graves Ophthalmopathy, Quality of Life, Questionnaire, Indonesian GO-QoL.*

INTRODUCTION

Graves' ophthalmopathy (GO) is an autoimmune orbital disease with symptoms like diplopia, photophobia, pain, and eye discomfort.[1,2] About 45% of patients face anxiety, depression, or both, with 72% encountering work, financial, or family issues.[3] Ocular changes in GO rarely achieve full remission, necessitating a holistic approach that includes mental and social aspects.[4]

The European Group on Graves' Orbitopathy (EUGOGO) endorses the use of the GO-QoL Questionnaire to evaluate quality of life due to its strong validity, reliability, and correlation with clinical activity and GO severity across diverse ethnicities and languages.[5-6] However, the GO-QOL Questionnaire in Indonesian, adapted from EUGOGO, lacks validation, resulting in the absence of routine assessments of GO patients'

quality of life by Indonesian ophthalmologists. This study introduces a validated Indonesian GO-QoL Questionnaire, revealing an association between patients' quality of life, clinical activity, and the severity of GO.

METHODS

The research design was a cross-sectional study conducted at the Neuro-Ophthalmology Polyclinic of RSCM Kirana between May and October 2022. The inclusion criteria were patients with GO and thyroid disease treated routinely. The exclusion criteria were respondents who could not be contacted via video call or come again after two weeks for test-retest data collection. The sampling technique in this study was consecutive sampling, with a sample size of 52 respondents. This study was approved by the Ethical Committee of Faculty of Medicine Universitas Indonesia (Reference no. 297/UN2.F1/ETIK/PPM.00.02/2022).

The GO-QoL Questionnaire, originally developed in English, underwent a meticulous translation process into Indonesian. Two sworn translators performed forward translation, and the first synthesis incorporated input from three experts from the Department of Ophthalmology, the Department of Internal Medicine, the Endocrine Metabolic Division, and the Department of Ophthalmology. Back translation into English ensured fidelity to the original. The content validity index (CVI) was assessed by six experts during pre-focus group discussions, including specialists from ophthalmology, internal medicine, and community health medicine. The Indonesian version of the GO-QoL pre-final questionnaire emerged from focus group deliberations and was further validated through cognitive debriefing with five external respondents. After harmonization and finalization, test-retest reliability was assessed using SPSS Statistics version 25.0 two weeks later.

RESULTS

In the pre-focus group discussion, the item-level content validity index (I-CVI) in questions 1 and 11 was 0.67; questions 2, 6, 10, and 14 were 0.83; and the remaining questions were 1.00. The result of the scale-level content validity index (S-CVI) was 0.92. During the focus group discussions, changes were made to the questionnaire items in order for the I-CVI and S-CVI to reach 1.00 in this study.

There were 61 GO patients in the Neuro-Ophthalmology division of Cipto Mangunkusumo Hospital from May to October 2022. Fifty-five patients met the inclusion criteria, but three respondents were excluded because they could not be contacted for questionnaire retest data collection. The sociodemographic characteristics of the study subjects showed that the subjects were predominantly female (78.8%) with an average age of 39.81 ± 13.29 years.

Table 1 shows the disease characteristics of the study subjects, with 88.5% of subjects having inactive clinical activity scores (CASs) and 51.9% of subjects having mild degrees of disease severity. Most respondents had mildly inactive GO (51.9%).

Table 1. Disease Characteristics of Research Subjects.

Variable	N (52)	Variable	N (52)
Duration of Graves' ophthalmopathy	3.51 (0.17–21) years	Chief complaint of Graves' disease	
Duration of Graves' disease	4.48 (0.25–20.00) years	Preferred cold weather	1 (1.9%)
Status of thyroid hormone		Nausea/vomiting/diarrhea	2 (3.8%)
Euthyroid	25 (48.1%)	Ocular problem	19 (36.5%)
Hyperthyroid	8 (15.4%)	Dyspnea	2 (3.8%)
Subclinical hyperthyroid	13 (25%)	Excessive sweating	1 (1.9%)
Hypothyroid	2 (3.8%)	Excessive decrease in body weight	1 (1.9%)
Subclinical hypothyroid	3 (7.7%)	Tremor	4 (7.7%)
Exophthalmos	35 (67.3%)	Fatigue	5 (9.6%)
Eyelid retraction	52 (100%)	Anxiety	2 (3.8%)
Ocular tissue involvement	9 (17.3%)	Insomnia	4 (7.7%)

Table 1. Disease Characteristics of Research Subjects.

Variable	N (52)	Variable	N (52)
Diplopia	14 (25%)	Palpitation	7 (13.5%)
Visual acuity impairment		No complaint	4 (7.7%)
No impairment	44 (84.6%)	Treatment of GO	
Mild	4 (7.7%)	No treatment	18 (34.6%)
Moderate	3 (5.8%)	Selenium	23 (44.2%)
Severe	1 (1.9%)	History of IV methylprednisolone	16 (30.8%)
Clinical activity score (CAS)		History of orbital radiation	1 (1.9%)
Active	6 (11.5%)	Immunosuppressant	5 (9.6%)
Inactive	46 (88.5%)	Treatment of Graves	
Disease severity		No treatment	7 (13.5%)
Mild	27 (51.9%)	PTU	12 (23.1%)
Moderate-severe	20 (38.5%)	Thiamazole	33 (63.5%)
Sight threatening	5 (9.6%)	Levothyroxine	4 (7.7%)
Chief complaint of GO		Radioactive iodine thyroid ablation	2 (3.8%)
Orbital pain	6 (11.5%)	Thyroidectomy	3 (5.8%)
Pain during ocular movement	3 (5.8%)		
Blurred vision	5 (9.6%)		
Red eye/edema of eyelid	5 (9.6%)		
Diplopia	4 (7.7%)		
Proptosis	12 (23.1%)		
Strabismus	2 (3.8%)		
Gritty/watery eye, photophobia	6 (11.5%)		
No complaints	9 (17.3%)		

Table 2 shows response frequencies for the Indonesian GO-QoL Questionnaire. Questions 1 and 2 in the visual function subscale had a 38.5% missing response rate as many respondents reported that they could not drive or own vehicles. Most respondents did not have activity limitations from GO-related visual impairment. The predominant psychosocial impact of GO was changes in appearance (46.2%).

Table 2. Frequency of Responses to the Indonesian Version of the GO-QoL Questionnaire.

Visual Function	Seriously limited [n (%)]	A little limited [n (%)]	Not at all limited [n (%)]	Missing response [n (%)]
1. Riding a bicycle (you have never learned how to ride a bicycle □)	5 (9.6%)	6 (11.5%)	21 (40.4%)	20 (38.5%) [a]
2. Driving (you do not have a driver's license □)	5 (9.6%)	7 (13.5%)	20 (38.5%)	20 (38.5%) [b]
3. Doing any indoor activity which requires movement	1(1.9%)	9 (17.3%)	42 (80.8%)	0 (0%)
4. Doing any outdoor activity which requires movement	3 (5.8%)	14 (26.9%)	35 (67.3%)	0 (0%)
5. Reading	3 (5.8%)	11 (21.2%)	38 (73.1%)	0 (0%)
6. Watching TV	4 (7.7%)	6 (11.5%)	42 (80.8%)	0 (0%)
7. Doing your hobby or spending your spare time doing ……..	3 (5.8%)	7 (13.5%)	42 (80.8%)	0 (0%)
8. In the last week, have you felt obstructed from doing the things that you want to do due to your thyroid eye disease?	4 (7.7%)	10 (19.2%)	38 (73.1%)	0 (0%)
Appearance	Seriously limited [n (%)]	A little limited [n (%)]	Not at all limited [n (%)]	Missing response [n (%)]
9. Do you feel that your appearance has changed due to your thyroid eye disease?	24 (46.2%)	15 (28.8%)	13 (25.0%)	0 (0%)

10. Do you feel that people are looking at you when you walk down the street due to your thyroid eye disease?	16 (30.8%)	11 (21.2%)	25 (48.1%)	0 (0%)
11. Do you feel that other people are reacting unpleasantly due to your thyroid eye disease?	7 (13.5%)	14 (26.9%)	31 (59.6%)	0 (0%)
12. Do you feel that your thyroid eye disease is affecting your self-confidence?	15 (28.8%)	17 (32.7%)	20 (38.5%)	0 (0%)
13. Do you feel socially isolated due to your thyroid eye disease?	1 (1.9%)	8 (15.4%)	43 (82.7%)	0 (0%)
14. Do you feel that your thyroid eye disease is affecting you in gaining friends?	3 (5.8%)	4 (7.7%)	45 (86.5%)	0 (0%)
15. Do you feel that presently you do not appear in photographs as often as before you suffered from the thyroid eye disease?	13 (25.0%)	12 (23.1%)	27 (51.9%)	0 (0%)
16. Do you try to conceal the change of appearance in your eyes due to your thyroid eye disease?	9 (17.3%)	6 (11.5%)	37 (71.2%)	0 (0%)

a) missing response if the respondent had never learned to ride a bicycle and does not own one; b) missing response if the respondent does not have a driver's license, cannot drive, and does not own a motorized vehicle

In **Table 3**, the validity test of the instrument through the calculation of the corrected item-total correlation (r) shows a value of more than 0.273 for the visual function and appearance subscales. The value of the Cronbach's alpha visual function subscale was 0.879, the appearance subscale was 0.861, and the total was 0.903. The three calculations of this value reached more than 0.7.

Table 3. Instrument Validity and Reliability Test.

Question items	Corrected Item-total correlation	Cronbach's alpha	Cronbach's alpha if item deleted
Visual function		0,879	
Question 1	0.792		0.846
Question 2	0.813		0.843
Question 3	0.810		0.859
Question 4	0.668		0.861
Question 5	0.358		0.889
Question 6	0.669		0.862
Question 7	0.568		0.871
Question 8	0.609		0.868
Appearance		0.861	
Question 9	0.662		0.837
Question 10	0.771		0.822
Question 11	0.687		0.835
Question 12	0.756		0.825
Question 13	0.453		0.860
Question 14	0.375		0.865
Question 15	0.547		0.852
Question 16	0.614		0.843
Total		0,903	

Corrected item-total correlation r>0.273 valid ; <0.273 invalid; Cronbach's alpha <0.7 unreliable ; >0.7 = reliable

The interclass correlation coefficient (ICC) values for test-retest reliability (**Table 4**) were 0.941 for the visual function subscale, 0.986 for the appearance subscale, and 0.971 overall. The Cronbach's alpha values were 0.971 for the visual function subscale, 0.993 for the appearance subscale, and 0.986 for the total. These results indicate the questionnaire's good reliability. A p-value >0.05 confirms consistent results between the two data collections. The GO-QoL value of the visual function subscale was higher than the GO-QoL value of the visual function subscale. The research data on the visual function subscale were not normally distributed. In the first sampling, there were extreme values ranging from the lowest value of 18.75 to the highest value of 100. One respondent with a moderate degree of inactivity scored 18.75, while two respondents with an inactive sight-threatening degree scored the highest possible value of 100.

In **Table 5**, the relationship between GO patients' quality of life and clinical activity is shown to be statistically significant ($p<0.05$) for the appearance and overall subscales. Clinical activity in GO is inversely related to its GO-QoL value. Respondents in the active CAS group had lower QoL scores on the appearance and total subscales.

Table 6 shows that the patients' quality of life had a statistically significant relationship with the severity of GO ($p<0.05$) on the performance subscale and overall. GO severity was inversely related to GO-QoL, with decreasing quality of life as the disease worsens.

Post-hoc analysis compared GO-QoL values across different severity groups on the appearance subscale and total GO-QoL. For the appearance subscale, statistically significant differences were found between mild and moderate ($p<0.001$) and sight threatening ($p<0.05$) degrees of disease severity. No significant difference was observed

Table 4. Test-Retest Reliability.

GO-QoL	First measurement	Second measurement	Cronbach's alpha	Interclass correlation coefficient (ICC)	p-value
Visual function	91.83 (18.75–100)	92.86 (28.57–100)	0.971	0.941	0.068
Appearance	68.14 ± 26.40 [a]	69.23 ± 25.57 [a]	0.993	0.986	0.072
Total	75.58 ± 19.52 [a]	76.80 ± 18.97 [a]	0.986	0.971	0.060

[a] Mean ± standard deviation

Cronbach's alpha <0.7 not reliable ; >0.7 = reliable

ICC<0.5 low reliability; 0,5<ICC< 0.75 moderate reliability; 0.75<ICC< 0.9 good reliability; >0.9 excellent reliability

Table 5. Association between Patient Quality of Life (Based on GO-QoL) and Graves' Ophthalmopathy Clinical Activity Score (CAS).

GO-QoL	Clinical activity score		p-value
	Inactive	Active	
Visual function	92.43 (18.75–100)	83.48 (33.33–100)	0.280
Appearance	75 (18.75–100)	31.25 (12.50–68.75)	<0.05*
Total	81.67 (31.25–100)	58.33 (21.43–75)	<0.01*

Table 6. Association between Patient Quality of Life (Based on GO-QoL) and Severity of GO.

GO-QoL	Disease severity			p-value
	Mild	Moderate to severe	Sight threatening	
Visual function	100 (28.75–100)	82.29 (18.75–100)	100 (33.33–100)	0.115
Appearance	93.75 (50–100)	46.87 (18.75–87.50)	31.25 (12.5–75)	<0.001*
Total	90 (63.33–100)	63.33 (31.25–93.33)	65.62 (21.43–85.71)	<0.001*

between moderate and sight-threatening degrees of disease severity (p=0.357). In the total GO-QoL score, significant differences were found between mild and moderate (p<0.001) and mild and sight-threatening (p<0.05) degrees of disease severity, while no significant differences were found between moderate and sight-threatening degrees of disease severity.

DISCUSSION

The Indonesian version of the GO-QoL Questionnaire can be used directly in the future without the need for additional explanation beyond the sentences of the questionnaire, which can be biased in data collection with a great CVI of 0.97.6.[7]

The visual function subscale in this study showed a 38% missing response rate for questions on limitations in riding a bicycle and driving. Similar studies in India, Argentina, and China have reported missing response rates ranging from 22.7% to 47% on comparable questions.[8-10] The likelihood of missing responses can be influenced by various factors, such as economic and psychosocial conditions related to vehicle ownership and driving ability. Terwee et al.[11] developed a formula to calculate GO-QoL values considering the possibility of missing responses, defining a response as missing if more than half of the questions are unanswered. Fortunately, this research had no missing values that could impact the results.

Regarding instrument validity, the corrected item-total correlation between subscales and total valid questions (r>0.273) was followed by reliability, which was expressed by the Cronbach's alpha value of the visual function subscale of 0.879, the appearance subscale of 0.861, and a total of 0.903. Studies in Korea and Brazil, including research by Choi et al., reported good internal consistency with Cronbach's alpha values of 0.90 for the visual function subscale and 0.88 for the appearance subscale in Korea, and values of 0.8425 and 0.9163, respectively, in Brazil. [12-14] For a questionnaire to effectively differentiate quality of life, all its items should correlate with subscale scores or overall questions. The adapted GO-QoL questionnaire from EUGOGO has demonstrated good validity in various studies, including those in Korea, Brazil, and Thailand. [6,12-13]

GO may present fluctuations, potentially affecting questionnaire reliability. However, high ICC scores and a Cronbach's alpha >0.9 indicate reliability. Non-significant test-retest p-values suggest that the questionnaire yields consistent data over time. Hoppe et al. [15] observed enhanced quality of life in new GO patients after six months of treatment. Similarly, the Thai version of the GO-QoL validation achieved a high ICC score of 0.92 and a Cronbach's alpha of 0.86. These findings confirm the questionnaire's strong internal consistency, establishing it as a reliable tool for assessing quality of life in GO patients in Indonesia.

The GO-QOL value on the vision subscale of this study was higher, with a median of 91.83, compared to research in India,[8] with a median of 81.3. The GO-QoL value of the appearance subscale in this study was an average of 68.14, almost the same as research in India,[8] with a median of 62.5, and research in Argentina, 24 with an average of 67.4, respectively. Racial disparities impact the clinical features of GO. Asians with GO generally exhibit milder characteristics compared to Caucasians, potentially influencing GO-QoL values. Despite these racial differences, however, GO-QoL scores are nearly identical between racial groups.[6,9] This similarity suggests shared Asian racial characteristics between Indonesia and India, while differences between Asian and Caucasian racial groups in Indonesia and Argentina minimally affect GO-QoL values.

In this study, the relationship between the quality of life (GO-QoL values in appearance and total subscales) of GO patients and CAS was examined. Active clinical activity in GO resulted in lower GO-QoL values in the appearance and total subscales. Zeng et al.[10] found an inverse correlation between CAS and GO-QoL values (r=-0.266), a view supported by Villagelin et al.[13] across all subscales. CAS serves to assess inflammatory conditions that cause changes in appearance and potentially disrupt visual function. Despite a lower GO-QoL value on the visual subscale in the active CAS group in this study, the difference was not statistically significant. This might be attributed to the

majority (88.5%) of respondents being inactive, preventing significant visual impairment from inflammation.

The severity of GO is assessed by the EUGOGO classification, which evaluates soft tissue involvement, exophthalmos, diplopia, lid retraction, corneal defects, and optic nerve compression.[10] These clinical criteria significantly impact the visual function and appearance of GO patients. The results showed that the quality of life of GO patients on the appearance subscale had a relationship with the degree of disease severity. Zeng et al.[10] also found an inverse relationship between disease severity and GO-QoL values. With increasing disease severity, both appearance subscale and overall quality of life values declined. Post hoc analysis revealed significant differences between mild and moderate degrees of GO, as well as mild and sight-threatening degrees on the appearance subscale. While the moderate-severe and sight-threatening groups lacked statistically significant differences, there was a trend toward lower GO-QoL values in the sight-threatening group on the visual function subscale. We found no significant differences in GO-QoL values on the visual function subscale based on clinical activity and the degree of severity of GO. A substantial proportion of respondents (84.6%) did not experience visual disturbances based on visual examination, and subjectively, only 9.6% of patients complained of blurry vision. The proportion of patients who were mildly inactive (51.9%) might cause the results to not be too significantly different. Outliers in the visual function subscale of GO-QoL led to abnormal data distribution, rendering the results statistically insignificant. The lack of significance between the GO-QoL value on the visual function subscale, CAS, and the degree of disease severity suggests that a patient's clinical condition may not always impact his quality of life. Respondents with greater disease severity that is sight-threatening had a very good quality of life value (GO-QoL value of the vision subscale of 100) when compared to respondents with mild degrees of disease severity (GO-QoL value of the vision subscale of 18.75). This suggests that clinical condition alone cannot reliably indicate treatment success for each individual patient with GO in Indonesia.

There are domains that have not been studied due to the unavailability of appropriate instruments by ophthalmologists to determine the quality of life of GO patients. The objective difference between a clinical examination and a patient's subjective perception of recovery affects a patient's quality of life.[6] The Indonesian version of the GO-QoL Questionnaire should be used in accordance with clinical practice guidelines for the management of GO in the clinical practice of ophthalmologists to determine the treatment needed.[16] According to clinical practice guidelines for the management of GO, the indication for corticosteroid therapy and rehabilitation surgery for inactive GO patients is a disturbed quality of life.[16]

This study introduces the first valid and reliable quality-of-life instrument in Indonesia for GO patients in Jakarta, capturing individual characteristics and therapy success indicators. Concerns arise about respondent differences as those seeking treatment at research institutions may differ from the broader GO patient community, potentially impacting their ability to access therapy at national referral hospitals. Although the study acknowledges the unique nature of GO, it suggests that neuro-ophthalmology subspecialty doctors at hospitals or eye clinics could cater to more affordable populations. While the consecutive sampling technique was suitable for the low prevalence of GO, potential selection bias makes the study less representative of Indonesia's target population. The study recommends multicenter research, cluster sampling, and randomization at each health facility to reduce bias. The cross-sectional design limits the ability to establish causality, providing only causal hypotheses about factors affecting quality of life for GO patients without indicating specific causal factors.

The Indonesian version of the GO-QoL Questionnaire has high validity values, with I-CVI and S-CVI reaching 1.00, and it has a high reliability value based on the Cronbach's alpha of the visual function subscale (0.971) and the appearance subscale (0.993) for a total of 0.986. Active GO clinical activity worsens the

quality of life of patients on both the appearance and overall subscales. The higher the severity of GO, the worse a patient's quality of life is on the appearance and overall subscales.

CONCLUSION

The Indonesian version of the GO-QoL has good validity and reliability. Both the active clinical activity of GO and the severity of the disease decreased patients' appearance and general quality of life.

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