Low Vision Rehabilitation

The 6-Item Vision-Related Quality of Life and Limitations **Questionnaire: Evaluation of Psychometric Properties**

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Purpose: We developed the Vision-related Quality of life and Limitations Questionnaire (VQL-6), a screening instrument to signal a need for additional care resulting from reduced vision-related quality of life in patients with chronic ophthalmic diseases. The aim of the present study was to evaluate psychometric properties.

Methods: A Dutch population-based sample of 2032 participants (mean age, 55 \pm 19 years) completed the VQL-6 and other questionnaires on vision-related quality of life, executive functioning, attention, mental health, and symptom validity. In addition, we recruited a sample of 208 ophthalmic patients (mean age, 72 ± 12 years) and 98 age and gender similar controls (mean age, 69 \pm 11 years) who completed the VQL-6 and the National Eye Institute Visual Function Questionnaire-25. We studied the factor structure, internal consistency, convergent and divergent validity, and known-groups validity.

Results: For the factor analyses, the population-based sample was split randomly in two subsamples. Exploratory factor analysis on the first subsample suggested a two-factor model (visual limitations and general health and quality of life), which was supported by confirmatory factor analyses on the second subsample, and on the patients. The VQL-6 demonstrated good internal consistency within each factor (0.78-0.89), sufficient convergent ($r^2 = 55\%$) and divergent validity ($r^2 = 11\% - 24\%$), and good known-groups validity (Cohen's r = 0.57; P < 0.001).

Conclusions: The VQL-6 has a robust two-factor structure and seems to be a valid tool to assess vision-related quality of life. Additional validation is needed in patients with chronic ophthalmic diseases.

Translational Relevance: Future research is needed to determine if the VQL-6 can be used to identify patients with chronic ophthalmic diseases who are in need of additional care.

Introduction

Globally, the number of visually impaired persons in 2015 was estimated at 217 million. Thirty-six million people were estimated to be blind. The quality of life of an individual with a visual impairment or blindness can be affected severely. A visual impairment has a profound impact on performing daily tasks,² and may decrease a person's independence and mobility.³ Moreover, vision loss has been linked to an increased risk of falls and injuries⁴ and is associated with numerous psychological problems, including poorer cognitive performance and an elevated risk for depression.^{5,6} Many affected individuals could benefit from additional care, such as medical social work, low vision services, or visual rehabilitation, to compensate for their visual impairment. A timely referral to these services could optimize their residual visual abilities and, ultimately, improve their quality of life.^{7,8}

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However, it has been a reported concern that patients in need of additional care resulting from reduced quality of life may often remain unnoticed in ophthalmic outpatient clinics. As a result, a timely referral may be delayed, prohibiting patients to reach their full potential.

One reason why a need for additional care is overlooked could be that measures of visual function, such as visual acuity and visual field, are used as the primary criterion for defining visual impairment and blindness.⁹ Although these measures are helpful in quantifying the extent of vision loss, they may not reflect the degree of visual disability accurately and poorly predict quality of life. 10-14 Hence, to guide further care and referral, it is important to consider the patient's perspective, not merely the extent of vision loss. 15 Another reason why a need for additional care could be overlooked is that patient-clinician communication about the patient's quality of life is still insufficient. 16 Due to demographic aging, the organization of ophthalmic care is challenged, resulting in a heavy workload and long waiting lists. 17,18 Finding time and resources in ophthalmic practice for a conversation to discuss how the patient copes with vision loss, and whether the individual experiences reduced quality of life, can be difficult. Therefore, a simple and efficient clinical instrument aiming at the assessment of patients' (vision-related) quality of life is of critical relevance. Routine use of such an instrument could improve patient-clinician communication about quality of life and improve timely deployment of additional care.

A variety of vision-specific instruments have been developed, 19,20 including the Vision-related quality of life Core Measure, 21 the Impact of Vision Impairment profile,²² and the National Eye Institute Visual Function Questionnaire (NEI-VFQ-25).²³ The NEI-VFO-25 is widely used in ophthalmology and has been well-validated.²⁴ However, all these instruments are limited in their suitability for routine screening. They are designed primarily to capture information on visual disability from the patient's perspective or demonstrate changes in quality of life related to interventions. The items have not been selected or validated for the purpose of screening for a need for additional care. Furthermore, it is imperative that a screening instrument is as short as feasible and practical in use, because consultation time in outpatient clinics is limited.

Therefore, the aim of this study was to validate a short, practical, and easy-to-administer screening instrument for identifying patients with reduced visionrelated quality of life and in need of additional care. For this purpose, we designed the Visionrelated Quality of life and Limitations Questionnaire (VQL-6), which is a six-item screening tool. The VQL-6 is partly based on the NEI-VFQ-25 and was developed by a multidisciplinary team of experts in the field of ophthalmic care and rehabilitation. The VQL-6 was tested in a large, population-based sample and in a clinical sample consisting of patients with chronic ophthalmic diseases and controls. Psychometric properties were evaluated, including the factor structure, internal consistency, convergent and divergent validity, and known-groups validity.

Methods

Study Population

The study population consisted of three groups: (1) a Dutch population-based sample, (2) a sample of ophthalmic patients, and (3) a control group that was age and gender similar with respect to the patients. All participants were 18 years or older and spoke Dutch as their primary language. For the population-based sample, we used cross-sectional data of 2032 Dutch participants who completed the VQL-6 and other questionnaires online.²⁵ Age was approximately uniformly distributed from 18 to 95 years. Within each age bin of 10 years, gender and education level were equally represented (Table 1).

For the patient sample, we recruited patients (n = 208) diagnosed with either age-related macular degeneration (MD) or glaucoma (GL). This sample consisted of consecutive, regular visitors of the outpatient department of Ophthalmology of the University Medical Center Groningen. The age and gender similar controls were mainly the spouses or acquaintances of the patients. The controls (n = 98) had to be, by means of self-report, without any known eye disease (except for glasses or contact lenses) and without any known hereditary ophthalmic disorder running in the family.

The ethics board of the University Medical Center Groningen approved the study protocol (#201800249). All participants provided written informed consent. The study followed the tenets of the Declaration of Helsinki.

Data Collection

For the population-based sample, we acquired the complete dataset of 2032 Dutch participants originally collected by Huizinga et al. Huizinga et al distributed questionnaires online, including the VQL-6 and other questionnaires on vision-related quality of life (NEI-VFQ-25), executive functioning (Behavior Rating Inventory of Executive Function—Adult

Table 1. Participant Characteristics of the Population-Based Sample, the Patients, and the Controls

	Populat	Population-Based Part	Participants		Patients		Controls
	Subsample 1	Subsample 1 Subsample 2	Total			Total	Total
	(n=671) $(n=671)$	(n = 671)	(n = 1342)	MD ($n = 108$)	GL(n = 95)	(n = 203)	(n = 98)
Gender, female	346 (52)	333 (20)	679 (51)	56 (52)	48 (51)	104 (51)	53 (54)
Age (years) Mean	56.0 ± 18.5	56.0 ± 18.5 55.9 ± 18.6 55.9 ± 18.5	55.9 ± 18.5	75.0 ± 10.9	67.6 ± 11.6	71.6 ± 11.8	69.1 ± 10.6
Range	18–87	18–95	18–95	39–99	35–94	35–95	33-97
Education*							
Low	126 (19)	124 (18)	250 (18)	I	I	ı	I
Medium	299 (44)	297 (44)	596 (45)	ı	ı	I	I
High	245 (37)	248 (37)	493 (37)	I	ı	I	I
Visual acuity (logMAR)							
Worse eye	I	I	I	0.46 [0.17 to 1.30]	0.22 [0.08 to 0.52]	0.30 [0.15 to 0.80]	I
Better eye	I	I	ı	0.10 [0.00 to 0.22]	0.00 [0.00 to 0.15]	0.05 [0.00 to 0.18]	I
HFA MD (db)†							
Worse eye	I	1	I	ı	-10.8 [-20.5 to -5.5] -10.8 [-20.5 to -5.5]	-10.8 [-20.5 to -5.5]	1
Better eye	I	1	I	1	-3.8[-7.1 to -1.1]	-3.8[-7.1 to -1.1]	1

HFA MD, Humphrey Field Analyzer mean deviation.

Values are number (%), mean \pm standard deviation, or median [IQR], unless otherwise indicated.

*Based on the International 2011 Standard Classification of Education. 60 † 40 missing values (owing to other type of perimetry and/or patients with only one functioning eye).

[BRIEF-A]), attention (Questionnaire for Experiences of Attention Deficit [Fragebogen erlebter Defizite der Aufmerkzamkeit] [FEDA]), emotional distress (Depression Anxiety Stress Scale–21 [DASS-21]), and symptom validity (Structured Inventory for Malingered Symptomatology [SIMS]). Completion of all questionnaires was estimated to last around 40–50 minutes. See Huizinga et al²⁵ for a detailed description of the methods.

For the patient and control samples, we asked eligible patients during a regular visit to complete one set of questionnaires, including the VQL-6 and the NEI-VFQ-25, and to give a second set of questionnaires to their spouse or an acquaintance. The questionnaires were completed at home and returned by post. Time to complete both questionnaires was estimated to take approximately 10 minutes. Ophthalmic information of the patients was obtained from treating ophthalmologists.

Materials

The 6-Item Vision-Related Quality of Life and Limitations (VQL-6)

The VQL-6 questionnaire was developed to gain insight into the vision-related quality of life and signal a need for additional care in patients with chronic ophthalmic diseases. The VQL-6 includes items that were chosen based on their association with quality of life and a need for additional care.26 A need for additional care may be multifaceted and influenced by various factors, including mental health, comorbidities, coping, and social support, areas that are reflected in the VQL-6.14,15,27,28 The questionnaire items were carefully defined by a multidisciplinary team of experts in the field of visual rehabilitation and ophthalmology. We constructed novel items and reviewed existing questionnaires, including the NEI-VFO-25, for relevant items that were adapted to fit the aim of our questionnaire.

The VQL-6 comprises six items. On items 1, 2, and 3 respondents are asked to indicate, on a scale of 0 to 10, their (1) general health, (2) general quality of life, and (3) the extent of experienced limitations by their visual impairment. The subsequent items measured whether the respondent, because of their visual impairment, (4) worries about the future, (5) feels like he/she accomplishes less, and (6) feels dependent on others. Items 4, 5, and 6 were scored on a 5-point Likert scale with answer options never, rarely, sometimes, often, and always. Respondents are instructed to answer the questions based on their situation in the past month while considering their use of glasses or contact lenses, if applicable. For analysis, all VQL-6 items were

converted to a 0 to 10 scale (by transforming the 5-point Likert scale answer options to 0, 2.5, 5.0, 7.5, and 10.0) to ensure all items received equal weight. In addition, all items were transformed so that a higher score represents better functioning to enable a fair comparison between items.

NEI-VFQ-25

The NEI-VFQ-25 is a questionnaire consisting of 25 items and a supplement of 14 additional items measuring vision-related quality of life.²³ The NEI-VFQ-25 generates one subscale related to general health (general health), and the following visionspecific subscales: global vision, near activities, distance activities, social functioning, role limitations, dependency, mental health, driving, peripheral vision, color vision, and ocular pain. Most NEI-VFQ-25 items include 5-point Likert scale answer categories with scores ranging from 0 to 100. Total scores on the subscales were calculated by averaging the scores on the corresponding items. In addition, a total composite score on the NEI-VFQ-25 was calculated by averaging the scores of all subscales, with the exception of general health, giving equal weight to each subscale. A higher score on the NEI-VFQ-25 indicates a better vision-related quality of life.

DASS-21

The DASS-21 is a questionnaire that measures emotional distress in the domains of depression, anxiety, and stress.²⁹ The 21 items are scored on a 4-point Likert scale with the answer options never (0), sometimes (1), often (2), or very often (3). A total composite score of the DASS-21 was calculated by summing the scores of all items. Higher scores indicate more severe symptoms of emotional distress.

FEDA

The FEDA aims to measure experienced deficits in attention in everyday situations.³⁰ The questionnaire comprises 27 items on a 5-point Likert scale with the answer options never (1), rarely (2), sometimes (3), often (4), or very often (5). A total score is formed by calculating the sum of all items. A higher score represents poorer attentional functions.

SIMS

The SIMS is a 75-item questionnaire designed to evaluate symptom validity by screening for noncredible symptom reporting.³¹ The questionnaire depicts items that refer to atypical and bizarre symptoms in five domains: low intelligence, affective disorders, neurological impairment, psychosis, and amnesia. In total the questionnaire consists of 75 yes/no items. The

sum score of all items was calculated to provide an overall indication of symptom validity. Respondents who scored 17 or higher, indicative of noncredible symptom reporting, were excluded from our sample.

BRIEF-A

The BRIEF-A measures respondents' own perception of executive functioning in their day-to-day life.³² The questionnaire is composed of 75 items on which respondents indicate how often a described problem has occurred over the past month, with response choices never (1), sometimes (2), or often (3). A total composite score is formed by summing the scores for all items. A higher score represents poorer executive functioning in everyday life. In addition, the BRIEF-A contains three scales to check the validity of answers: inconsistency, negativity, and infrequency. Respondents who scored above the cut-offs defined in the manual on any of the scales were excluded from the sample (negativity >3, inconsistency >7, and infrequency >2).

Data Analysis

Data management and analysis were performed using SPSS software (version 26.0.0.1)³³ and RStudio (2022.02.0).³⁴ Confirmatory factor analyses (CFA) were carried out using LISREL (8.8).³⁵ Data was checked for normality and linearity; if the assumptions were violated, nonparametric tests were performed. A *P* value of 0.05 or less was considered statistically significant.

Descriptive Statistics

Participant characteristics were described with mean and standard deviation. Age, gender, and education level between groups were compared using independent t tests and χ^2 tests. To evaluate effect size, Cramer's V and Phi (φ) were calculated and interpreted following Cohen's criteria. 36

Factor Structure

For the factor analyses, the population-based sample was randomly split into subsample 1 and subsample 2. Kaiser Meyer-Olkin measure of sampling adequacy and Barlett's test of sphericity were performed to test the appropriateness of the data for factor analysis.

Exploratory factor analysis (EFA) was performed on subsample 1 of the population-based sample using principal axis factoring with oblique rotation. Parallel analysis was performed to determine the number of factors to retain. In a parallel analysis, random data matrices of similar size as the actual dataset were generated and eigenvalues were computed for the correlation matrices of each of the random datasets. Subsequently, the eigenvalues of the random datasets were compared with the eigenvalues generated from the EFA. Factors were retained if the eigenvalues of the actual dataset exceeded the eigenvalues of the random dataset.³⁷ Additionally, an inspection of the scree plot was performed to support the factor extraction criterion of the parallel analysis.

CFA were performed using a diagonally weighted least squares estimation method because of the ordered categorical response format. The analyses were carried out on subsample 2 of the population-based sample and on the patient sample, both of which exceed the criterion of a minimum sample size of 200 respondents for CFA.³⁸ The goodness of fit of the factor structure was evaluated by the following statistics of CFA: χ^2 value with corresponding P value, normed χ^2 (χ^2/df), root mean squared error of approximation (RMSEA), standardized root mean square residual (SRMR), and the comparative fit index (CFI). In addition, we compared fit statistics of a single factor model with the fit statistics of the hypothesized models. The goodness of fit statistics of the respective models were evaluated according to the following criteria and recommendations: χ^2 *P* value of greater than 0.05,³⁹ normed χ^2 of less than 3.0,⁴⁰ RMSEA of 0.07 or less,⁴¹ SRMR of 0.08 or less,³⁹ and a CFI of 0.95 or greater.³⁹

Item and Scale Evaluation

Item quality was assessed in the population-based sample and the patient sample by evaluating the descriptive statistics of the recoded item scores and examining evidence of floor or ceiling effects (<15% of the respondents endorsing the highest or lowest response category was considered acceptable). The suitability of scoring items together on a common scale was assessed with item-rest correlations (acceptable if >0.30), as well as inter-item correlations to identify possible item redundancy (acceptable if <0.80). Internal consistency of the established factors and the entire VQL-6 was evaluated with McDonald's ω . Spearman–Brown's coefficient was calculated when the factor comprised a two-item scale. 42 Values of 0.70 and higher were considered as good internal consistency. 26

Convergent, Divergent, and Known-Groups Validity

To establish convergent validity, the relationship between the VQL-6 scores and the NEI-VFQ-25 scores was determined in the population-based sample and the patient sample. Divergent validity was evaluated in the population-based sample by correlating the VQL-6 and self-reported measures on attention (DASS-21), emotional distress (FEDA),

executive functioning (BRIEF-A), and symptom validity (SIMS). All associations were established by Spearman's correlation coefficients and were interpreted following Cohen's guidelines.³⁶ To adjust for multiple hypotheses testing, we used false discovery rate (FDR)–adjusted *P* values.⁴³

Known-groups validity was established by studying the relation between having an ophthalmic disease and self-reported vision-related quality of life on the VQL-6, adjusting for age and gender. It was hypothesized that patients with MD and patients with GL report lower vision-related quality of life, indicated by lower VQL-6 scores, than the controls. We normalized the VQL-6 scores to get proportion data and performed a beta regression analysis on the transformed VQL-6 scores. Furthermore, Kruskal–Wallis H tests and Mann-Whitney U tests were performed to analyze for significant differences between the patients and the controls on the VQL-6 using FDR adjusted P values. To indicate the magnitude of group differences Mann-Whitney U-based r was calculated and interpreted following Cohen's criteria of r.³⁶

Results

Descriptive Statistics

Table 1 presents the participant characteristics. Of the 2032 participants in the population-based sample that were considered for inclusion, 1342 participants were used for data analysis. In total, 204 participants were excluded owing to incomplete responses on the VQL-6. In addition, participants were excluded when the BRIEF-A revealed an infrequency (n = 301), negative tendency (n = 19), or inconsistency (n = 18) of answers, or when the SIMS indicated signs of noncredible symptom reporting (n = 118). Furthermore, double responses of the same participants were excluded from the sample (n = 123). For factor analyses, there were no significant differences between subsample 1 (n = 671) and subsample 2 (n = 671) with respect to age, t(1338)= 0.13, P = 0.90, d = 0.05; gender, $\chi^{2}(1) = 0.50, P = 0.05$ 0.48, $\phi = 0.02$; and education level, $\chi^{2}(2) = 0.07$, P =0.96, V = 0.01.

Of the patient sample, 208 patients were considered for inclusion. Five patients were excluded owing to incomplete answers on the VQL-6. Thus, 203 patients were used for data analysis, including 108 patients with MD and 95 patients with GL. Furthermore, 98 controls were included in this study. The patients and the controls did not significantly differ in gender, $\chi^2(2) = 0.68$, P = 0.71, V = 0.03. However, a significant difference was found for age, F(2, 298) = 13.04, P < 0.001,

Table 2. EFA of the Items of the VQL-6 in Subsample 1 of the Population-Based Sample (n = 671)

	Rotated Factor Loading			
Item	Visual Limitations	HQOL		
1 - General health	-0.01	0.90		
2 - General quality of life	0.02	0.89		
3 - Limitations in daily life	0.66	-0.07		
4 - Worry about the future	0.62	0.05		
5 - Accomplishments	0.85	0.04		
6 - Dependent of others	0.77	0.02		
Eigenvalue	3.02	1.38		
% of variance	44	18		

 $\eta^2 = 0.08$, with the patients being on average slightly older than the controls (71.6 years of age vs 69.1 years of age).

Factor Structure

The Kaiser-Meyer-Olkin measure verified the sampling adequacy for the analysis (KMO = 0.72) and Bartlett's test of sphericity was significant, $\chi^2(15) =$ 1757, P < 0.001. The EFA on subsample 1 revealed two factors with an eigenvalue of greater than 1, explaining 44% and 18% of the variance. The scree plot was inspected and a parallel analysis was performed, both of which strongly supported a two-factor structure. Table 2 displays the results of the EFA with the rotated factor loadings of the items, eigenvalues, and explained variance of the respective two factors. The items of the factors were inspected for meaningful underlying constructs. Consequently, the two factors were interpreted as follows: vision-related limitations (visual limitations; items 3, 4, 5, and 6) and general health and quality of life (HOOL; items 1 and 2).

Table 3 presents the goodness of fit statistics from the CFA of the two-factor model and the competing one-factor model, both in subsample 2 and in the patient sample. Inspection of the fit indices revealed a good model of fit for the two-factor structure in the patient sample. In subsample 2, the SRMR did not meet the recommended value of less than 0.08. However, all other indices met the criteria for a good model of fit, including a nonsignificant P value for χ^2 , normed χ^2 of less than 3, RMSEA of less than 0.07, and CFI of greater than 0.95. Furthermore, although the one-factor model showed a satisfactory model of fit in the patient sample, a comparison of fit indices between the models indicated that the twofactor model clearly outperforms the one-factor model in both samples.

Table 3. Fit Indices of the CFA of the VQL-6 in Subsample 2 of the Population-Based Sample and the Patients

Model	χ2 (<i>df</i>)	P Value	χ^2/df	RMSEA	SRMR	CFI
Subsample 2 ($n = 671$)						
One-factor model	33.92 (9)	< 0.001	3.77	0.022	0.24	1.00
Two-factor model	5.26 (8)	0.73	0.66	0.000	0.11	1.00
Patient sample ($n = 203$)						
One-factor model	25.78 (9)	0.002	2.86	0.084	0.10	0.99
Two-factor model	8.31 (8)	0.40	1.04	0.000	0.03	1.00

df, degrees of freedom.

Table 4. Item Mean and SD, Floor/Ceiling Percentages, Internal Consistency, and Item-Rest Correlation in the Population-Based Sample and Patient Sample

Scale and Item	$Mean \pm SD$	Floor (%)	Ceiling (%)	Internal Consistency	Item-Rest Correlation
Population-based sample ($n = 1$	1342)				
HQOL					
1 - General health	7.60 ± 1.33	0.0	4.2	0.89*	0.81
2 - General quality of life	7.72 ± 1.35	0.0	5.4		0.81
Visual limitations					
3 - Limitations in daily life	8.34 ± 2.36	0.7	43.7	0.78 [†]	0.53
4 - Worry about the future	8.29 ± 2.05	0.4	51.9		0.56
5 - Accomplishments	8.80 ± 1.91	0.1	66.4		0.68
6 - Dependent of others	9.42 ± 1.41	0.1	82.5		0.65
Patient sample ($n = 203$)					
HQOL					
1 - General health	7.27 ± 1.23	0.0	3.0	0.83*	0.71
2 - General quality of life	7.54 ± 1.26	0.0	4.4		0.71
Visual limitations					
3 - Limitations in daily life	6.45 ± 2.86	2.0	14.3	0.87 [†]	0.73
4 - Worry about the future	5.25 ± 2.39	4.9	8.9		0.60
5 - Accomplishments	5.90 ± 2.88	7.4	18.2		0.78
6 - Dependent of others	7.20 ± 2.82	4.9	37.9		0.78

SD, standard deviation.

Item and Scale Evaluation

As shown in Table 4, among participants of the population-based sample ceiling effects were found for all items. In the patient sample meaningful ceiling effects were apparent for item 5 (18.2%) and item 6 (37.9%). No floor effects exceeding 15% were found. Within factors all item-rest correlations exceeded 0.3 in both samples. Inter-item correlations did not surpass 0.80 in the patient sample (range, 0.51–0.74). In the population-based sample, a correlation of 0.81 was found between item 1 and item 2, all other interitem correlations ranged from 0.41 to 0.61. The factors and

the entire VQL-6 revealed high reliability scores in both samples.

Validity

Convergent Validity

Subscale sum scores were created for each factor of the VQL-6. Higher scores indicated greater general health and quality of life (HQOL), and fewer vision-related limitations (visual limitations). A global composite score was calculated by summing up all items of the VQL-6. Table 5 depicts the results of Spearman's correlation analyses of the VQL-6 and

^{*}Established with Spearman Brown coefficient.

[†]Established with McDonalds omega.

Table 5. Spearman's Correlation Coefficients Between the VQL-6 and the NEI-VFQ-25 in the Population-Based Sample (n = 1342)

		VQL-6	
	Visual		VQL-6
	Limitations	HQOL	Composite
NEI-VFQ-25			
General health	0.35*	0.80*	0.59*
General vision	0.59 [*]	0.52*	0.65*
Ocular pain	0.44*	0.30*	0.44*
Near activities	0.56*	0.31*	0.55*
Distant activities	0.53 [*]	0.32*	0.53*
Social functioning	0.43*	0.25*	0.42*
Mental health	0.72*	0.38*	0.70*
Role difficulties	0.65*	0.31*	0.62*
Dependency	0.47*	0.26*	0.47*
Driving	0.33*	0.24*	0.36*
Color vision	0.30*	0.15*	0.28*
Peripheral vision	0.44*	0.24*	0.42*
NEI-VFQ-25 composite	0.73*	0.45*	0.74*

^{*}Significant after FDR multiple hypothesis testing adjustment

the NEI-VFQ-25 in the population-based sample. All correlations were significant after FDR multiple hypothesis testing adjustment ($P_{adj} < 0.001$) and ranged from weak to strong. Visual limitations and the VQL-6 composite score showed similar correlations with the NEI-VFQ-25, revealing mostly moderate to strong correlations with all NEI-VFQ-25 subscales. Strong correlations were found for HQOL with general health and general vision on the NEI-VFQ-25. All other correlations between HQOL and the NEI-VFQ-25 ranged from weak to moderate.

As shown in Table 6, among the patients all correlations were significant ($P_{adj} < 0.001$), except the correlation between HQOL on the VQL-6 and driving on the NEI-VFQ-25 ($P_{adj} = 0.059$). Visual limitations and the VQL-6 composite score showed notably strong correlations with the NEI-VFQ-25. Furthermore, the correlations between HQOL and the NEI-VFQ-25 ranged from weak to strong. Similar to the population-based sample, a particularly strong correlation was found between HQOL and general health.

Divergent Validity

In the population-based sample, all Spearman's correlation coefficients between the VQL-6 and the divergent measures were found to be significant (P_{adj} < 0.001). As shown in Table 7, the subscales of the VQL-6 revealed weak to moderate correlations, and the

Table 6. Spearman's Correlation Coefficients Between the VQL-6 and the NEI-VFQ-25 in the Patient Sample (n = 203)

		VQL-6	
	Visual		VQL-6
	Limitations	HQOL	Composite
NEI-VFQ-25			
General health	0.46*	0.76*	0.55*
General vision	0.75*	0.53*	0.76*
Ocular pain	0.39 [*]	0.35*	0.41*
Near activities	0.82*	0.49*	0.81*
Distant activities	0.81*	0.44*	0.79 [*]
Social functioning	0.68*	0.44*	0.67*
Mental health	0.88*	0.53*	0.86*
Role difficulties	0.88*	0.50*	0.86*
Dependency	0.79*	0.48*	0.77*
Driving	0.62 [*]	0.17	0.57*
Color vision	0.54 [*]	0.32*	0.52 [*]
Peripheral vision	0.60*	0.23*	0.56*
NEI-VFQ-25 composite	0.91*	0.52*	0.89*

^{*}Significant after FDR multiple hypothesis testing adjustment

Table 7. Spearman's Correlation Coefficients Between the VQL-6 and the DASS-21, FEDA, SIMS, and the BRIEF-A in the Population-Based Sample (n = 1342)

	Visual		VQL-6
	Limitations	HQOL	Composite
DASS-21 total	-0.31 [*]	-0.42^{*}	-0.41^{*}
FEDA total	-0.40^{*}	-0.46^{*}	-0.49^{*}
SIMS total	-0.29^{*}	-0.35^{*}	-0.37^{*}
BRIEF-A total	-0.28^{*}	-0.28^{*}	-0.32^{*}

^{*}Significant after FDR multiple hypothesis testing adjustment.

composite score correlated moderately with the divergent measures. Visual limitations correlated weakly with the SIMS and BRIEF-A. Moreover, a weak correlation was revealed between HQOL and the BRIEF-A.

Known-Groups Validity

Table 8 demonstrates the beta regression models for the VQL-6 subscales and composite score, adjusting for age and gender. Patients with MD and patients with GL reported lower subscale and composite scores than the controls. With regard to the controlled variables, being older was associated with lower subscale scores and composite scores. Gender was a significant predictor of HQOL.

Table 8. Beta Regression Models Predicting Proportion Scores of the VQL-6 Composite, and the Subscales Visual Limitations and HQOL

	В	SE B	Z	<i>P</i> Value
Visual limitations				
Intercept	3.05	0.41	7.54	< 0.001
Gender - female	-0.10	0.12	-0.81	0.42
Age	-0.01	0.01	-2.71	0.007
MD vs C	-1.52	0.16	-9.72	< 0.001
GL vs C	-1.43	0.16	-9.19	< 0.001
HQOL				
Intercept	1.88	0.29	6.55	< 0.001
Gender - female	0.18	0.09	2.15	0.032
Age	-0.01	0.00	-2.06	0.040
MD vs C	-0.33	0.11	-3.05	0.002
GL vs C	-0.30	0.11	-2.78	0.005
VQL-6 composite				
Intercept	2.70	0.30	8.88	< 0.001
Gender - female	0.02	0.09	0.17	0.86
Age	-0.01	0.00	-3.44	< 0.001
MD vs C	-1.05	0.12	-8.97	< 0.001
GL vs C	-0.97	0.12	-8.15	< 0.001

B, beta coefficient; C, control; SE, standard error.

The Kruskal–Wallis H tests revealed there was a significant difference on the visual limitations and HQOL subscales, $\chi^2 = 107.85$, P < 0.001; $\chi^2 = 25.26$, P < 0.001 respectively, and the composite score, $\chi^2 = 100.41$, P < 0.001, between the patients and controls. Post hoc Dunn tests showed that all pairwise comparisons between patients with MD and patients with GL were nonsignificant. Therefore, the patient groups were merged and the additional comparisons were performed using Mann–Whitney U tests between one combined patient group and the controls (Table 9). Patients scored significantly lower on the VQL-6 than the controls, both for the subscales and the composite score. Effect sizes were calculated and the magnitude of group differences on the visual limitations subscale

and the composite score was considered large, whereas a small to medium effect was revealed for HQOL.

Discussion

The present study evaluated the psychometric properties of the VQL-6 in a Dutch population-based sample and among patients with chronic ophthalmic diseases. EFA on subsample 1 of the population-based sample suggested a two-factor model, which was supported by CFA on subsample 2 and the patient sample. The two-factor model outperformed a single-factor model. The VQL-6 demonstrated good internal consistency within each factor, good known-groups validity, along with sufficient convergent and divergent validity. The factors derived from the factor analyses were summarized as visual limitations and HQOL, explaining 44% and 18% of the variance, respectively.

Evaluation of the item responses showed ceiling effects of items 5 and 6 in the patient sample, suggesting limited sensitivity of these items in capturing variability among individuals with fewer visionrelated limitations. The observed ceiling effects in the population-based sample were considered less significant, considering the VQL-6 specifically targets patients with an ophthalmic disease and it is reasonable to expect such effects in a population-based sample. In addition, excessive interitem correlation was found for item 1 and item 2 in the population-based sample indicating potential item redundancy, although this effect was not found in the patient sample. Furthermore, although a low number of items can be a threat for scale reliability, the factor analyses and high reliability scores provided no indications that undermined the robustness of our results.

Among patients with an ophthalmic disease, the VQL-6 demonstrated good convergent validity. Reports of higher vision-related quality of life on the VQL-6 corresponded with higher vision-related quality of life on the NEI-VFQ-25. Regarding the

Table 9. Median and Interquartile Range of the VQL-6 Composite and Subscale Scores for Patients (n = 203) and Controls (n = 98)

	Pa	tients Con		ontrols			
	Median	IQR	Median	IQR	P Value	r	
Visual limitations	25.50	19.00–31.50	37.50	32.50-40.00	<0.001*	0.59	
HQOL	15.00	14.00-16.00	16.00	15.00-17.25	<0.001*	0.29	
VQL-6 composite	40.50	32.50-47.50	53.50	48.38–56.13	<0.001 [*]	0.57	

IQR, interquartile range.

^{*}Significant after FDR multiple hypothesis testing adjustment.

VQL-6 subscales, visual limitations showed mostly strong correlations with the vision-related subscales of the NEI-VFQ-25. In addition, HQOL of the VQL-6 revealed a particularly strong correlation with the NEI-VFQ-25's general health subscale, but weak to strong correlations with the vision-related subscales of the NEI-VFQ-25. Although Spearman's correlation coefficients were generally smaller in the population-based sample, a similar pattern was found. These results are in accordance with previous studies that have demonstrated low correlations between the visionspecific NEI-VFQ-25 subscales and self-ratings of health on the 36-item Short Form Survey, 44 and strong associations between the general health subscale of the NEI-VFQ-25 and the 36-item Short Form Survey. 45,46 Therefore, we concluded that the subscales of the VQL-6 proved sufficient convergent validity as well.

Divergent validity was assessed on the assumption that the VQL-6 and the divergent questionnaires measure different psychological constructs. Hence, the magnitude of correlation with the convergent measures should be higher than the divergent measures. In the population-based sample, lower vision-related quality of life reported on the VQL-6 was associated with higher levels of emotional distress, attentional deficits, executive dysfunction, and symptoms of noncredible symptom reporting. These findings are in agreement with previous studies that demonstrated that visual impairment is often accompanied by greater symptoms of depression and anxiety.^{47,48} Moreover, in older adults loss of visual functions is associated with cognitive decline in the domains of attention and executive functioning. 49-51 Nevertheless, in the populationbased sample the VOL-6 shared 11% to 24% of the variance with the divergent measures and 55% with the NEI-VFQ-25, indicating a sufficient divergent validity. In the patient sample, the divergent measures were not conducted. Hence, a comparison between the convergent and divergent correlation coefficients for the patients was not possible.

In support of known-groups validity, the results of the beta regression indicated that patients with an ophthalmic disease reported significantly lower vision-related quality of life on the VQL-6 compared with individuals without an ophthalmic disease, controlling for age and gender. Further inspection of the pairwise comparisons revealed that the differences on visual limitations between patients and controls were larger than the differences on HQOL. Mangione et al²³ compared NEI-VFQ-25 scores between ophthalmic patients and controls and found significant results for all group comparisons, with smaller effect sizes on general health scores when compared with the vision-specific subscales. This result is in agreement with our

VQL-6 findings. A review by Mitchell and Bradley⁵² did not find converging evidence on the association between a visual impairment and health status. The authors concluded that a patient may be severely affected by their visual impairment, yet, they may still report their general health as excellent. This finding is in support of the view that vision-related quality of life and quality of health are different matters and should be evaluated individually.

This study has some strengths and limitations. A strength is that we used multiple validated questionnaires in the field of ophthalmology and psychology to evaluate the convergent, as well as the divergent validity. A second strength is that the psychometric properties were evaluated following a priori chosen criteria.²⁶ However, in the absence of test-retest data we did not evaluate the reproducibility and responsiveness of the VOL-6. A limitation of this study is that our sample included patients with MD and patients with GL, recruited from a single university medical center. This factor might hamper generalizability, something that should be explored in other settings in the future. Furthermore, some validity measures, including divergent validity and EFA, were solely examined in participants of the population-based sample. It is unknown if these psychometric properties can be generalized to patients with an ophthalmic disease. Moreover, we (partly) used the NEI-VFQ-25 as a foundation for our instrument and as a convergent measure. This choice was motivated by the NEI-VFQ-25's recognition, based on traditional quality criteria, as one of the better questionnaires for assessing vision-related quality of life. 19,53 However, the NEI-VFQ-25 was developed using classical test theory (CTT) methods. Recently, various studies have stressed the limitations of CTT and (re-)evaluated questionnaires with Rasch measurement theory or item response theory. 12,54-57 These modern methods have revealed validity issues in the NEI-VFQ-25, such as multidimensionality and item-misfit.^{57,58} Considering the potential limitations of CTT, we examined the possibilities of applying item response theory methods to our questionnaire. However, our instrument comprises a multidimensional questionnaire of six items. Given our questionnaire's short length, and the violated assumptions of unidimensionality and local independence (determined by inspecting the residual correlation matrix of the EFA for excessive correlations)⁵⁹ for item response theory methods, we determined that CTT was the most appropriate choice for the psychometric evaluation of the VQL-6. To solve these issues finally, the association with a true outside criterion representing a need for additional care is important for further validation of the VQL-6.

Based on the initial psychometric evaluations, the VQL-6 seems to have basic measurement properties. The VQL-6 could be of benefit to patients, ophthalmologists, and other professionals within integrated care. Compared with more comprehensive questionnaires, such as the NEI-VFQ-25, it may offer a quick and easyto-administer method to evaluate the patients' perspective with items specifically defined to screen for a need for additional care. In addition, it does not require complex analyses or special software for administration or scoring, like computer adaptive testing. The VQL-6 can be best interpreted by the defined subscale scores. A composite score of all items of the VQL-6 can be determined when a global indication of health and quality of life (HOOL), and vision-related limitations is desired. However, for use in clinical practice additional work is needed to establish the clinical value of the VQL-6. In follow-up research, we aim to evaluate item and subscale sensitivity and specificity, and establish an appropriate cut-off criterion to screen for patients with chronic ophthalmic diseases in need of additional care.

In conclusion, the VQL-6 underlies a robust two-factor structure and was shown to be a valid tool to assess the vision-related quality of life in a population sample and patients with chronic ophthalmic diseases. Additional work is needed to further validate the VQL-6 as a screening instrument and to assess its potential in enhancing communication between patients and ophthalmologists. Specifically, it is warranted to determine the clinical utility of the VQL-6 in identifying chronic ophthalmic patients in need of additional care, aiming to facilitate a timely referral to low vision services, visual rehabilitation, or support for the visual impairment.

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