Psychometric Properties of the Croatian Version of the 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25)

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Abstract

Purpose: The purpose of study was to translate, adapt and validate the Croatian version of the 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25) in participants with visual impairment. This study also aims at evaluating the relationship between visual impairment and health-related quality of life (HRQoL).

Methods: The prospective observational study was conducted at the University Hospital Centre Zagreb, Department of Ophthalmology. The sample consisted of 175 patients with four chronic ocular diseases: cataract, glaucoma, diabetic retinopathy and age-related macular degeneration (ARMD). The translation of the NEI VFQ-25 to Croatian was conducted following the standardized procedure. All participants underwent an ophthalmological examination and completed the NEI VFQ-25 and the Medical Outcomes Study Short Form-36 Questionnaire (SF-36). In order to assess the psychometric properties of the NEI VFQ-25 we calculated Cronbach's α coefficient, intraclass correlation coefficient (ICC), convergent and discriminant validity, as well as criterion and concurrent validity.

Results: Results show high internal consistency (Cronbach α range 0.739-0.932) and high test-retest reliability (ICC 0.876-0.975) for all subscales. None of the items had failed either convergent or discriminant validity. Moderate to high Spearman's rho coefficients of correlations were found between best corrected visual acuity and 8 subscales in the NEI VFQ-25 ($0.430<\rho<0.631$). Moderate correlations were found between comparable domains in the NEI VFQ-25 and in the SF-36 questionnaire ($p<0.01$).

Conclusion: The Croatian version of the NEI VFQ-25 has very good psychometric properties and can be a useful instrument for assessing vision-related quality of life in Croatian population with chronic ophthalmic diseases.

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Introduction

Advances in modern medicine have enabled successful treatment of various chronic diseases thereby extending life expectancy, while at the same time bringing to the focus the importance of the notion of quality of life [1]. Health-related quality of life (HRQoL) is a subjective and multidimensional concept that integrates an individual's health condition with their perception of general quality of life depending on physical, mental, emotional and social functioning [2].

Ocular disease and potential blindness have been shown in previously conducted research to have an adverse impact on HRQoL [3, 4]. Impairment of the visual function has a significant impact on the functional status and physical capacity of patients as it reduces their functional performance and functional ability, as well as their working capacity [5–8]. Visual impairment may indirectly lead to social isolation, emotional and cognitive issues, and changes in an individual’s mental condition as well as increase an individual’s dependency on other people [5–9]. Therefore, the importance of assessment of patient-reported overview of visual functioning and treatment outcome for patients with visual impairment has been gaining in prominence in ophthalmology [10–11].

Self-administered HRQoL assessment instruments are being increasingly used in various fields of medicine and health care as a measurement for quantification of the impact of health condition on QoL and assessment of treatment outcome. The focus has been on patient experience which provides greater understanding of the patient and facilitates decision-making for physicians in the course of treatment [12, 13].

In daily clinical practice, ophthalmic condition is assessed through objective measurements such as visual acuity, visual field and contrast sensitivity. However, patients’ subjective perception of the degree of visual impairment does not always correlate highly with objective measurements because, when used exclusively, objective measurements are not always able

to assess binocular vision and functional capacity which is essential for visual functioning [4]. This concept describes activities in everyday life with respect to vision related operations [4].

There are several types of HRQoL questionnaires, either self-administered or administered by trained interviewers [12]. Discriminative instruments evaluate cross-sectional differences in QoL among participants at a point in time, while evaluative instruments measure longitudinal changes in HRQoL among patients during a period of time [12]. Furthermore, questionnaires are either generic, which provide a general summary of HRQoL, or specific instruments that focus on aspects of health that are specific to the area of primary interest such as vision-related or disease-related (cataract, glaucoma, ARMD) questionnaires [12, 14, 15].

Research has found that vision-related questionnaires are more responsive than general health-related questionnaires in the assessment of QoL in ocular disease patients [16]. One of the most widely used instruments for the assessment of the visual function on QoL is the National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25). The first version of the questionnaire was composed of 51 items [17, 18], but it has been subsequently reduced to 25 items with psychometric properties which correlate with the original version, in order to allow easier clinical and research application [19]. The NEI VFQ-25 questionnaire has been translated to many languages worldwide and adapted to be used in numerus populations [20, 30].

As a general rule, translating a questionnaire to another language can impact its validity due to linguistic, ethical and cultural characteristics of the population [12, 22]. It is therefore necessary to assess validity and reliability of the translated questionnaire and cross-reference it with the original questionnaire [20–30]. We are not aware of any developed or translated and standardised questionnaire in the Croatian language that assesses the impact of visual impairment on HRQoL.

The purpose of this study was to translate and adapt the NEI VFQ-25 questionnaire to Croatian and evaluate the psychometric properties of the questionnaire in patients with common chronic ocular disease.

Materials And Methods

Patients and study design. The prospective observational study was conducted at the University Hospital Centre Zagreb, Department of Ophthalmology in the period from October 2018 to December 2019. It was approved by the Ethics Committee of the University Hospital Centre Zagreb (class 8.1–18/37 – 2, reference number 02/21 AG) and it was carried out in line with the Helsinki Declaration.

All participants had been duly informed of the study purpose and procedures after which they had signed informed consent forms by which they consented to participation in the research. The sample included 4 groups of patients with ocular diseases: patients with cataract (C), glaucoma (G), diabetic retinopathy (DR) and age-related macular degeneration (AMRD). All diagnostics was carried out in accordance with valid international guidelines [33–36]. Eligibility criteria were Croatian language as mother tongue, age 50 and older, presenting BCVA 0.6 or worse in the better eye for patients with C, ARMD and DR, negative medical history of laser and surgical procedures on the eye within the prior 3 months. Non-inclusion criteria were cognitive, motion or hearing impairment, systemic comorbidity of the ocular function (e.g. neurological disease), psychiatric comorbidity, presence of more than one ocular disease and patients with visual loss to the level of light perception and/or projection or subject who were blind (no light perception). Exclusion criteria were more than 10% missing response in questionnaires.

A comprehensive ophthalmological examination (BCVA), slit lamp anterior segment examination, Goldmann Applanation Tonometry and funduscopic examination were carried out, demographic data for participants was collected (sex, age, educational attainment) and presence of comorbidity was established. The participants filled out the Croatian version of the NEI VFQ-25 questionnaire with additional questions in the Appendix and the previously validated Croatian version of the 36-Item Short Form Health Survey (SF-36) for general health assessment [38].

The final sample consisted of 175 patients, mean age 70.1 years ± 7.74, 71 (40.6%) of them were men. In order to assess test-retest reliability, 26 patients with glaucoma completed questionnaires at baseline and in surveys performed 2 weeks apart.

Questionnaires

The study used the NEI VFQ-25 questionnaire (version 2000) which was designed to capture the impact of vision impairment on multiple dimensions of HRQoL [19]. The questionnaire is composed of 25 items divided into 12 subscales. One subscale assesses general health (1 item), while the other 11 subscales are vision-related subscales: global vision rating (1 item), difficulty with near vision activities (3 items) and distance vision activities (3 items), limitations in social functioning due to vision (2 items), role limitations due to vision (2 item), dependency on others due to vision (3 items), mental health symptoms due to vision (4 items), driving difficulties (3 items), limitations with peripheral (1 item) and colour vision (1 item), and ocular pain (2 items). The result obtained from each scale is converted using a scoring algorithm to 0-100 scale, where the higher score represents better vision related HRQoL [19].

The SF-36 questionnaire is one of the globally most widely used instruments for assessing general health and it is composed of 36 items which asses the following 8 domains: physical functioning, role physical, role emotional, energy/fatigue, emotional well-being, social functioning, pain, general health [37]. This questionnaire was selected because it had been previously used in Croatia on several occasions and it contains very good psychometric properties [38].

Translation

The translation and adaptation of the original NEI VFQ-25 questionnaire to the Croatian language was conducted in accordance with internationally accepted guidelines with the aim of ensuring cross-cultural equivalence of the questionnaire [12, 39].

The initial translation of the questionnaire from English to Croatian had been carried by two experts in ophthalmology, who had each translated the questionnaire independently. Afterwards, they had discussed discrepancies in their translations and jointly drafted a new version. The new version was then referred to a professional translator who carried out a back translation to English, without access to the original version of the questionnaire. Following that, an expert group composed of two ophthalmologists, methodologist and a professional translator met to review all versions of the translation and established that there were no major discrepancies between them. A pilot study was carried out on a small sample (N = 15) in order to determine whether the respondents had any ambiguities related to questions or any suggestions how to improve the translation. The obtained results indicated that the questionnaire had been well received and that the content was easily understandable.

We were presented with a need to slightly modify two questions in the translated questionnaire to account for Croatian habits and lifestyle. Item 13 (How much difficulty do you have visiting people at their homes, at parties, or in restaurants?) was translated as: How much difficulty do you have visiting people at their homes, gatherings or restaurants?. In the Appendix, item A7 was reformulated to: „Because of your eyesight, how much difficulty do you have taking part in active sports or other outdoor activities that you enjoy (like riding a bicycle, jogging, or walking)?“ due to low prevalence of golf and bowling in Croatia.

Statistics

Continuous variables are presented as mean ± standard deviation (SD), while discrete data is expressed as frequencies and percentage. Reliability of the NEI VFQ-25 was assessed by Cronbach's Alpha coefficient. The test-retest reliability was calculated using intraclass correlation coefficient (ICC). Construct validity was assessed with convergent and discriminant

validity. Concurrent validity was assessed by Spearman's rho coefficient of correlation between the NEI VFQ-25 subscales and BCVA. Construct validity was assessed by correlating the NEI VFQ-25 subscales with the SF-36 subscales. Significance level was set at $p < 0.05$. All statistical analyses were performed using the SPSS VERSION 23.0 software (SPSS, Inc., Chicago, IL, USA).

Results

Descriptive analysis and item analysis. The final analysis included the total of 175 patients and their characteristics are given in Table 1. Participants with DR (N = 49) and ARMD (N = 49) were the most prevalent, followed by glaucoma (N = 45) and cataract patients (N = 32). The mean age of participants was 70 years (SD = 7.74), 41% were men, more than half of them graduated from high school (54%). The average BCVA was 0.57 on the better and 0.39 on the worse eye. Mean scores and standard deviations of the total scores and subscales of the NEI VFQ-25 questionnaire are presented in Table 2. Glaucoma patients had the highest mean total score (M = 89.05), followed by patients with DR (M = 76.91). Cataract patients had a slightly lower score (M = 72.44), while the ARMD group had the lowest total score (M = 65.93). Furthermore, glaucoma patients scored highest on all subscales with the exception of ocular pain subscale.

Table 1
Demographic and clinical characteristics of patients

	Total N = 175	**Cataract N = 32**	**Glaucoma N = 45**	**DR N = 49**	**ARMD N = 49**
Age	70.1 ± 7.74	72.9 ± 6.41	65.0 ± 6.49	67.7 ± 7.58	75.2 ± 5.69
VA better eye	0.57 ± 0.267	0.53 ± 0.101	0.95 ± 0.094	0.45 ± 0.162	0.40 ± 0.201
VA worse eye	0.39 ± 0.327	0.32 ± 0.158	0.87 ± 0.154	0.27 ± 0.163	0.13 ± 0.156
			Frequencies (%)		
Gender (N = 175)	Men		71 (40.6%)		
	Women		104 (59.4%)		
Education (N = 173)	Elementary school (1–8 years)		34 (19.7%)		
	Secondary school		93 (53.8%)		
	Bachelor’s degree		22 (12.7%)		
	Master’s degree		22 (12.7%)		
	Post-master’s degree		2 (1.2%)		

Table 2
Mean score ± standard deviation of the NEI VFQ-25 total score and subscales

	Cataract	Glaucoma	DR	ARMD
General Health	40.63 ± 22.67	48.89 ± 20.61	30.10 ± 21.03	37.24 ± 24.00
General Vision	54.38 ± 20.47	68.89 ± 13.18	49.80 ± 17.85	43.27 ± 15.99
Ocular Pain	75.00 ± 22.90	73.06 ± 19.02	84.95 ± 18.92	84.69 ± 18.80
Near Activities	60.68 ± 22.62	77.78 ± 15.59	57.45 ± 25.01	47.05 ± 23.22
Distance Activities	63.00 ± 28.88	88.45 ± 15.06	71.09 ± 26.01	54.03 ± 29.41
Social Functioning	77.34 ± 23.64	95.56 ± 10.71	86.01 ± 23.62	77.17 ± 26.26
Mental Health	64.45 ± 27.52	82.36 ± 15.95	65.43 ± 22.43	55.23 ± 22.33
Role Difficulties	63.67 ± 30.18	86.67 ± 16.73	58.16 ± 32.43	46.68 ± 32.35
Dependency	77.34 ± 25.51	94.81 ± 11.69	72.48 ± 32.76	64.46 ± 30.28
Driving	62.50 ± 18.63	86.36 ± 14.67	73.04 ± 17.06	61.25 ± 23.77
Color Vision	85.94 ± 4.54	97.78 ± 8.95	90.10 ± 22.32	88.78 ± 21.69
Peripheral Vision	73.44 ± 23.71	86.67 ± 19.66	81.12 ± 23.68	74.49 ± 26.26
Composite score	72.44 ± 19.32	89.05 ± 7.65	76.91 ± 14.49	65.93 ± 18.40

Reliability and construct validity. As demonstrated in Table 3, Cronbach's Alpha coefficient indicates high internal consistency for the NEI VFQ-25 in the range from 0.739 for ocular pain

Table 3
Cronbach's Alpha and ICC reliability

	Number of items	Cronbach's Alpha	ICC Test-retest	Item convergent validity [a] (success rate %)	Item discriminant validity [b] (success rate %)
General Health	1	N/A	0.934	N/A	N/A
General Vision	1	N/A	0.965	N/A	N/A
Ocular Pain	2	0.739	0.967	0.836–0.916	100%
Near Activities	3	0.804	0.880	0.804–0.890	100%
Distance Activities	3	0.869	0.951	0.854–0.894	100%
Social Functioning	2	0.837	0.908	0.842–0.953	100%
Mental Health	4	0.778	0.975	0.567–0.883	100%
Role Difficulties	2	0.932	0.895	0.954–0.968	100%
Dependency	3	0.889	0.930	0.871–0.914	100%
Driving	3	0.782	0.962	0.644–0.910	100%
Color Vision	1	N/A	0.936	N/A	N/A
Peripheral Vision	1	N/A	0.876	N/A	N/A
Composite score	25	0.956	0.960	N/A	N/A

a Percentage of correlation coefficients calculated between one item and its score higher than 0.4

b Every time an item is correlated higher to a scale other than the one it belongs to is calculated as a failure

to 0.932 for role difficulties subscale. Test-retest reliability was computed by the ICC and 26 glaucoma patients were included in the test-retest assessment 2 weeks after baseline. The obtained results indicate very good ICC reliability (0.876–0.975) in all subscales. None of the NEI VFQ-25 items in our study failed either convergent or discriminant validity.

Criterion validity. Correlations between the NEI VFQ-25 subscales and the total score with visual acuity are shown in Table 4. Strong correlations were found between BCVA better eye, BCVA worse eye and composite score on the NEI VFQ-25 ($r = 0.628$ and 0.664, respectively). Weak correlations were found between BCVA and subscales general health, ocular pain, colour vision and peripheral vision ($r < 0.4$). The other eight subscales showed moderate to high correlations with BCVA (r in a range from 0.4 to 0.6).

Table 4
Spearman's rho correlation of NEI VFQ-25 subscales with visual acuity

NEI VFQ-25 subscales	BCVA better eye (p-value)	BCVA worse eye (p-value)
General Health	0.300 (< 0.001)	0.294 (< 0.001)
General Vision	0.575 (< 0.001)	0.631 (< 0.001)
Ocular Pain	-0.264 (< 0.001)	-0.177 (< 0.05)
Near Activities	0.548 (< 0.001)	0.565 (< 0.001)
Distance Activit	0.601 (< 0.001)	0.587 (< 0.001)
Social Func	0.430 (< 0.001)	0.512 (< 0.001)
Mental Health	0.556 (< 0.001)	0.575 (< 0.001)
Role Difficulties	0.578 (< 0.001)	0.598 (< 0.001)
Dependency	0.572 (< 0.001)	0.563 (< 0.001)
Driving	0.435 (< 0.001)	0.480 (< 0.001)
Color Vision	0.232 (< 0.01)	0.350 (< 0.001)
Peripheral Vision	0.260 (< 0.001)	0.326 (< 0.001)
Composite score	0.628 (< 0.001)	0.664 (< 0.001)

Concurrent validity. To assess concurrent validity, correlation coefficients between the NEI VFQ-25 and the SF-36 subscales were calculated and shown in Table 5. Comparable domains have shown moderate statistically significant correlations ($r = 0.573$, $p < 0.01$, between subscale general health in the NEI VFQ-25 and general health subscale in the SF-36; $r = 0.530$, $p < 0.01$, between subscale social functioning in the NEI VFQ-25 and social functioning subscale in the SF-36; $r = 0.498$, $p < 0.01$, between subscale mental health in the NEI VFQ-25 and emotional well-being subscale in the SF-36).

Table 5
Construct validity – correlation between NEI VFQ-25 and SF-36

NEI VFQ-25	SF-36							
	Physical func	Role phys	Role emot	Energy	Emot well-b	Social functi	Pain	General hea
General Health	0.462**	0.447**	0.200**	0.390**	0.200**	0.341**	0.367**	0.573**
General Vision	0.246**	0.291**	0.027	0.302**	0.298**	0.315**	0.118	0.341**
Ocular Pain	0.241**	0.358**	0.181*	0.110	0.155*	0.226**	0.412**	0.186*
Near Activities	0.259**	0.274**	0.098	0.291**	0.291**	0.379**	0.118	0.298**
Distance Activit	0.393**	0.433**	0.269**	0.472**	0.438**	0.569**	0.329**	0.447**
Social Func	0.388**	0.395**	0.202**	0.395**	0.411**	0.530**	0.301**	0.413**
Mental Health	0.392**	0.385**	0.285**	0.483**	0.498**	0.497**	0.241**	0.451**
Role Difficulties	0.382**	0.437**	0.171*	0.489**	0.449**	0.504**	0.151*	0.455**
Dependency	0.415**	0.384**	0.188*	0.455**	0.370**	0.502**	0.201**	0.455**
Driving	0.245*	0.256*	0.168	0.250*	0.307*	0.376**	0.087	0.347**
Color Vision	0.293**	0.285**	0.200**	0.219**	0.204**	0.422**	0.252**	0.285**
Peripheral Vis	0.349**	0.400**	0.314**	0.334**	0.333**	0.407**	0.344**	0.307**

Missing responses. As seen in Table 6, there is little missing data, with the exception of item 14 (“Because of your eyesight, how much difficulty do you have going out to see movies, plays, or sports events”) and driving subscale items (more than half of our sample does not drive). None of the items from our questionnaire had a high floor effect (less than 20%); however we have observed the ceiling effect for majority of the items.

Table 6
Missing responses, floor and ceiling effect

Item	Missing	Floor	Ceiling
1. General health	0 (0.0%)	21 (12%)	2 (1.1%)
2. General vision	0 (0.0%)	0 (0.0%)	1 (0.6%)
3. Mental health: How much of the time do you worry about your eyesight?	0 (0.0%)	24 (13.7%)	10 (5.7%)
4. Ocular pain: How much pain or discomfort have you had in and around your eyes (for example, burning, itching, or aching)?	0 (0.0%)	4 (2.3%)	80 (45.7%)
5. Near vision: How much difficulty do you have reading ordinary print in newspapers?	3 (1.7%)	30 (17.1%)	25 (14.3%)
6. Near vision: How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things around the house, or using hand tools?	0 (0.0%)	11 (6.3%)	30 (17.1%)
7. Near vision: Because of your eyesight, how much difficulty do you have finding something on a crowded shelf?	0 (0.0%)	1 (0.6%)	67 (38.3%)
8. Distance vision: How much difficulty do you have reading street signs or the names of stores?	0 (0.0%)	6 (3.4%)	73 (41.7%)
9. Distance vision: Because of your eyesight, how much difficulty do you have going down steps, stairs, or curbs in dim light or at night?	1 (0.6%)	3 (1.7%)	63 (36.0%)
10. Peripheral vision: Because of your eyesight, how much difficulty do you have noticing objects off to the side while you are walking along?	0 (0.0%)	1 (0.6%)	84 (48.0%)
11. Social function: Because of your eyesight, how much difficulty do you have seeing how people react to things you say?	2 (1.1%)	1 (0.6%)	103 (58.9%)
12. Color vision: Because of your eyesight, how much difficulty do you have picking out and matching your own clothes?	1 (0.6%)	2 (1.1%)	139 (79.4%)
13. Social function: Because of your eyesight, how much difficulty do you have visiting with people in their homes, at parties, or in restaurants?	9 (5.1%)	6 (3.4%)	117 (66.9%)
14. Distance vision: Because of your eyesight, how much difficulty do you have going out to see movies, plays, or sports events?	43 (24.6%)	15 (8.6%)	62 (35.4%)
15. Driving: How much difficulty do you have driving during the daytime in familiar places?	100 (57.1%)	1 (0.6%)	58 (33.1%)
16. Driving: How much difficulty do you have driving at night?	103 (58.9%)	5 (2.9%)	14 (8.0%)
17. Role limitation: Do you accomplish less than you would like because of your vision?	0 (0.0%)	19 (10.9%)	47 (26.9%)
18. Role limitation: Are you limited in how long you can work or do other activities because of your vision?	0 (0.0%)	16 (9.1%)	57 (32.6%)
19. Ocular pain: How much does pain or discomfort in or around your eyes, for example, burning, itching, or aching, keep you from doing what you'd like to be doing?	0 (0.0%)	1 (0.6%)	79 (45.1%)
20. Dependency: I stay home most of the time because of my eyesight.	0 (0.0%)	14 (8.0%)	92 (52.6%)
21. Mental health: I feel frustrated a lot of the time because of my eyesight.	0 (0.0%)	12 (6.9%)	71 (40.6%)

Item	Missing	Floor	Ceiling
22. Mental health: I have much less control over what I do, because of my eyesight.	0 (0.0%)	16 (9.1%)	59 (33.7%)
23. Dependency: Because of my eyesight, I have to rely too much on what other people tell me.	0 (0.0%)	11 (6.3%)	93 (53.1%)
24. Dependency: I need a lot of help from others because of my eyesight.	0 (0.0%)	9 (5.1%)	97 (55.4%)
25. Mental health: I worry about doing things that will embarrass myself or others, because of my eyesight.	0 (0.0%)	7 (4.0%)	97 (55.4%)

Discussion

The primary objective of the presented study was to validate the NEI VFQ-25 in the native Croatian population to provide a useful evaluation instrument for QoL quantification in patients with visual impairment. The Croatian version was validated in 175 patients with four common chronic ocular diseases: cataract, glaucoma, DR and ARMD. In general, the overall results indicate adequate reliability and validity of the presented questionnaire. Furthermore, it was translated and adapted in line with recommended guidelines, with two items requiring minor modifications [39]. Due to cultural and linguistic differences, several changes to the content of some items during adaptations of the NEI VFQ-25 among other populations were proposed as well [20–32].

Boer et al. have conducted a systematic review of the literature to evaluate questionnaires for the assessment of vision related QoL on the basis of descriptive and psychometric criteria [40]. The review has concluded that among 31 analysed questionnaires the NEI VFQ-25 provides the best psychometric properties for the assessment of HRQoL for patients with visual impairment.

The NEI VFQ-25 is a questionnaire that is used worldwide and our data is comparable to validation studies among other populations, which have also found very good psychometric properties of the questionnaire [20–32].

Reliability analysis was assessed by Cronbach's Alpha and value greater than 0.7 is considered as adequate [41]. In our study, questionnaire subscales are in the range from 0.739 to 0.932. These findings are consistent with reports from previous studies [23, 24, 26, 28, 32]. The test-retest method is a measure of reliability and explains the extent to which scores remain stable over a period of time when no change in status has occurred. Correlation between two administrations of a questionnaire 2 weeks apart greater than 0.80 is considered to be satisfactory [42]. The test-retest reliability in our study was found to be adequate over a 2-week period, calculated by the ICC (ranged from 0.876 to 0.975) with comparable results in other studies [26, 28, 29, 30, 31]. This is a critical characteristic for a questionnaire that might be used in follow-up studies.

Pertaining to construct validity of the questionnaire, we calculated convergent and discriminant validity [43]. The ability to discriminate between levels of disease severity is important, particularly for visual function measurement, which would be expected to correlate strongly with disease severity. Convergent validity was assessed using correlation between an item and its own subscale. It is considered adequate when correlation coefficient is greater than 0.4. Discriminant validity was calculated by success rate. Each time an item is correlated higher with any other subscale other than one it belongs to, it is considered as a failure [26]. None of the items in our study failed either convergent or discriminant validity, comparable with other validation studies [26, 28].

Criterion validity reflects correlation between the gold standard and a new questionnaire [12]. Strong correlations were found between visual acuity (better and worse eye) and composite score in the NEI VFQ-25. Weak correlations were found between BCVA and subscales general health, ocular pain, colour vision and peripheral vision. The remaining eight subscales showed moderate to high correlations with BCVA (ranging from 0.4 to 0.6) suggesting that corresponding subscales are associated

with degree of difficulty with central visual function. Comparable correlations between visual acuity and the NEI VFQ subscales have been detected by other authors in the process of validation [20, 28].

A study on patients with type 1 and type 2 diabetes was carried out to research whether there is a correlation between three clinical measures of the central visual function (visual acuity, central visual fields and contrast sensitivity) and the NEI VFQ-25 Near and Distance Activities subscale scores. The results indicated that low scores related to these HRQoL measures may reflect poor central visual fields and contrast sensitivity in addition to poor visual acuity. Thus, the NEI VFQ-25 Near and Distance Activities subscales demonstrate utility as measures of central visual function in these cohorts.

Concurrent validity was assessed correlating the NEI VFQ-25 subscales with the SF-36 that had been previously validated in Croatian. Moderate correlations were found between comparable domains in the NEI VFQ-25 and the SF-36 scores (correlation coefficient r = 0.573 for general health subscale in both questionnaires; r = 0.530 between subscale social functioning in NEI VFQ-25 and social functioning subscale in SF-36; r = 0.498 between mental health subscale in NEI VFQ-25 and emotional well-being subscale in SF-36). Comparable findings were observed in other studies [20, 27, 28].

Although we had recorded overall significantly lower missing rate than most other studies on this topic, higher missing values were nonetheless observed in items related to subscale driving, followed by item 14 related the subscale distance activities. Missing values on the driving subscale were due to never driving or stopped driving because of reasons other than vision. Comparable results have been detected in validation studies in other populations as well [20, 22, 26–29, 31].

For item 14, our missing value stands at 25%, which is considerably higher than the original version of the questionnaire as well as other validation studies [19, 26]. A possible explanation could be that participants in our study were not interested in going out to see movies, plays or sport events because of the high average age (M = 70.1 years). The other reason could be due to the economic situation in the country where the monthly average pension amounted to approximately EURO 360 as of March 2020 [44]. On the other hand, participants in Hong Kong had exceptionally high missing rates on items pertaining to driving, but equally for item 14 where the missing rate was over 60% [31]. Comparable observations have been recorded in other studies, and some authors have suggested the possibility of making these subscales optional [20, 26, 27, 29].

None of the items from our questionnaire had a high floor effect (less than 20%); however we have observed the ceiling effect for majority of the items [19, 20, 26].

Our study has demonstrated that glaucoma patients had the highest mean total score (M = 89.05) and the highest results on all subscales with the exception of ocular pain subscale. This can be explained by the fact that glaucoma in its clinical course does not produce symptoms, and causes impairment to peripheral vision that patients remain unaware of until noticeable visual field loss occurs. Additionally, eye drops that are used for long-term treatment of glaucoma may induce ocular discomfort and inconvenience which could explain lower scores on ocular pain subscale.

Interestingly, peripheral vision subscale is not among the items that were mostly affected (i.e., lowest score) in patients with glaucoma in most of the studies. Contrast sensitivity, glare sensitivity, and dark adaptation are potential items that could be added to the questionnaire to make it more responsive to changes in vision-related QoL in patients with glaucoma. This might help detect changes in vision-related QoL of patients with glaucoma in the early stages of the disease and with minor changes in disease severity.

With reference to correlation of the general score and visual acuity in cataract patients, cataract surgery indications are known to differ among countries depending on economic and health systems. Hence, the level of the visual function and the related impact on the visual functioning and, consequently vision related QoL at the time of surgery, varies even between centres. A systematic review of the questionnaire for the assessment of QoL in cataract patients has revealed the absence of items for the more able patients as a limitation in both the NEI VFQ-25 and most other questionnaires [11].

In contrast, patients with DR and ARMD had very poor QoL. In fact, these patients have the poorest visual acuity, as evident in Table 1. A multicentre study has been conducted to evaluate the impact of visual acuity of the better and the worse eye (BE and WE, respectively) on HRQoL and utility in patients with exudative ARMD. The results have shown that BE and WE visual acuity contributed to the vision-related QoL independently, as measured by the NEI VFQ-25 and the Macular Disease Quality of Life Scale [3]. Moreover, these patients have often had background comorbidity and distinct clinical complications, most notably patients with diabetes which certainly affects functional limitation and impacts HRQoL.

The NEI VFQ-25 has been validated in numerous other ocular pathological conditions apart from the above listed, such as dry eye syndrome, retinitis pigmentosa, blepharospasm and patents with low vision of various cause [26]. There have been studies which have attempted to comprehend self-reported visual disability in patients with certain ophthalmic impairments. Raphael et al. have conducted a study on validation of a 10-item neuro-ophthalmic supplement to the NEI VFQ-25 [45]. The results of this study have supported validity for this new scale and data have shown that adding the supplement to the NEI VFQ-25 has a capacity to capture self-reported visual dysfunction beyond that of the NEI VFQ-25 alone in neuroophthalmologic populations [45].

The advantages of our study are strict inclusion criteria, determined to assess how much HRQoL is in effect impacted by ocular disease and visual impartment rather than certain system comorbidity. Conditions associated with age such as arthritis, for patients with ocular diseases, further compromise their ability and confidence in performing daily activities and the impact may reduce their QoL. Additionally, patients with psychiatric comorbidity were excluded as it is known that conditions such as depression and anxiety impact HRQoL in patients with visual impairment [9].

Interpretation of these results is limited in at least several ways. Firstly, participants were recruited from a single hospital, which is a tertiary centre in the capital of Croatia, and therefore the sample might not be representative of the entire population in Croatia. The only clinical measurement we have considered for evaluating vision impairment was visual acuity. However, other factors such as visual field defects, diminishing of contrast sensitivity or glare may also impact visual functions. The mode of administration in the study was self-administered and our results do not apply to surveys that were interviewer administered. Finally, participants with multiple ocular diseases have not been included in the study, and it is thus not known what type of impact and to what extent multiple ocular diseases have on the results.

On balance, it might be suggested that, taking into consideration the dynamics of our time and changes to our daily lives, the content of the questionnaire should be periodically revised and adapted to capture new lifestyles. For example, use of computers and digital technologies (IT) has been increasing in our patients.

In conclusion, our study has included common ocular diseases (cataract, glaucoma, diabetic retinopathy, ARMD) and demonstrated that visual impairment is an important factor that impacts QoL. Psychometric testing indicates that data obtained with the Croatian version of the NEI VFQ-25 is sufficiently reliable, valid and responsive in the Croatian-speaking community. It provides a complement instrument for clinicians in clinical measures for the assessment of vision-related QoL and will contribute to a better understanding of our patients. A better understanding of patient-reported health status and QoL can improve patient-physician interaction and, consequently, enhance treatment adherence. It would also facilitate researchers in comparison of results of clinical trials.

Declarations

This submission has not been published anywhere previously and is not simultaneously being considered for any other publication.

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Conflicts of interest:

The authors have no relevant financial or non-financial interests to disclose.

Ethics approval:

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Ethics Committee of the University Clinical Centre Zagreb (class 8.1 – 18/37-2, reference number 02/21 AG).

Consent to participate:

Informed consent was obtained from all individual participants included in the study.

Availability of data and material (data transparency)

The data that support the findings of this study are available in Zenedoo at DOI 10.5281/zenodo.4624688.

Code availability

N/A

Authors' contributions

Conceptualization: [Dina Lešin Gaćina] Methodology: [Bernarda Škegro]; Formal analysis and investigation: [Bernarda Škegro, Iva Bešlić, Marija Bukvić, Dina Lešin Gaćina]; Writing - original draft preparation: [Dina Lešin Gaćina]; Writing - review and editing: [Sonja Jandroković, Ivan Škegro, Bernarda Škegro], Funding acquisition: [Dina Lešin Gaćina]; Resources: [Dina Lešin Gaćina, Bernarda Škegro]; Supervision: [Sonja Jandroković]

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