ORIGINAL ARTICLE

Psychometric validation of Visual Function Questionnaire (NEI VQF-25) under Local Conditions in Slovakia, E.U.

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SUMMARY

Aim: The aim of this study is to validate the Slovak version of the National Eye Institute Visual Function Questionnaire-25 (NEI VQF-25) in patients with chronic ocular diseases.
Material and methods: The questionnaire was tested on 211 responders. The first group consisted of 83 patients with age-related macular degeneration (AMD), the second group represented 68 patients with diabetic macular edema (DME), and the control group had 60 responders. The Questionnaire (NEI VQF-25) consists of the base of 25 vision-targeted questions representing 11 vision-related constructs, plus an additional single-item general health-rating question. The data – demographic data and information from the Visual Function Questionnaire were obtained during one single visit of the patients during the period November 1st, 2010 and February 20th, 2011. The internal consistency and safety of the test were evaluated using Cronbach's alpha reliability coefficient. For separate groups the standard score was evaluated.
Results: The coefficient higher than 0.7, evaluated as good reliability, was calculated in all constructs except the sub-scale "ocular pain". The validity, evaluated using multivariable analysis measuring convergence and discrimination analysis, in the end confirmed accomplishment of all circumstances. The composite score of NEI VQF-25 in the DME group was 69.9 ± 4.6, in the AMD group 68.5 ± 4.3, and the highest score had the control group 91 ± 1.8.
Conclusion: The questionnaire NEI VQF-25 in the Slovak version is useful and safe instrument to measure the quality of life in patients with DME and AMD.

Key words: quality of life, questionnaire NEI VQF-25, age-related macular degeneration (AMD), diabetic macular edema (DME)

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INTRODUCTION

The demographic indicators of developed countries point to a change in age structures of the population and an increase in chronic illnesses, including chronic eye disorders. Age-related macular degeneration, glaucoma and diabetic retinopathy are chronic eye disorders which are the most frequent causes of blindness in developed countries. The progression of chronic eye disorders leads to the development of functional disability, which in its final result has a negative influence on the quality of life of the individual. Assessment of quality of life appears as an appropriate indicator of health, although it is difficult to measure and fundamentally more complex. The condition of visual functions can be evaluated by objective measurements such as examination of central visual acuity (by ETDRS optotypes developed for the Early Treatment Diabetic Retinopathy Study), an assessment of the condition of peripheral vision (examination of the visual field), assessment of structural changes on the retina and disc of the optic nerve by display techniques. In the treatment and management of patients with a chronic eye disorder it is necessary to have a reliable, valid and sensitive method for measuring quality of life. The quality of life questionnaire is a tool which takes into account also subjective factors of the individual as an expression of the degree of satisfaction of life requirements in relation to the degree and stage of advancement of the disorder, and the impact on the individual's daily activities.

MATERIAL AND METHOD

Visual Function Questionnaire NEI VFQ 25

The questionnaire NEI VFQ 25 represents a reduced version of the 51-point questionnaire. NEI VFQ 25 is a validated questionnaire for measuring quality of life beyond the framework of standard clinical indicators developed by the RAND company in co-operation with the National Eye Institute (NEI). It was developed as a tool for assessing quality of life in relation to visual functions within the population of South America (6). It was introduced into practice in the English version. It became a component of several multicentric studies focusing on the treatment of chronic eye disorders, bringing an effect in the assessment of quality of life in the case of glaucoma (4), age-related macular degeneration (1), dry eye syndrome (7) and diabetes mellitus (2). As of today it has been validated for use in several languages (8, 9, 10, 11). In addition to objective indicators on the condition of the disorder, VFQ 25 makes a further parameter available, which reflects a complex evaluation of the disorder by

patients themselves. It thus enables an assessment of not only the present condition, but also the impact of treatment or the progression of the disorder with its impact on quality of life.

The NEI VFQ 25 questionnaire is composed of a basic set of 25 questions focusing on visual functions representing 11 configurations in direct connection with sight and a supplementary single-point question relating to an evaluation of overall health. This question, which is deliberately included in the questionnaire, has been demonstrated to be a predictor of the further development of condition of health within the framework of population studies. The NEI VFQ 25 questionnaire has the following sub-scales for the assessment of visual functions:

- overall assessment of sight (1),
- difficulties during activities with near vision (3),
- difficulties during activities with distance vision (3),
- restriction of social life due to vision (3),
- symptoms of mental health due to vision (4),
- difficulties with operation of motor vehicle (3),
- restriction of peripheral vision (1),
- restriction of colour vision (1),
- eye pain (2).

The questionnaire contains an appendix with optional points, which users may add to a specific sub-scale. The inclusion of these questions may help the evaluation of the area of quality of life on which the specific study places emphasis. Scoring within the framework of the NEI VFQ 25 questionnaire with and/or without optional points represents a two-stage process:

1. numerical values from questionnaire survey are pre-coded according to scoring rules (table 1).
2. points within the framework of each sub-scale are averaged in such a manner as to create 12 scores of the sub-scale.

Each point is converted into a scale from 0 to 100, the lowest possible score being 0 points and the highest 100 points. A higher score represents better function (6).

A total of 211 patients were included and divided into 3 groups: patients with age-related macular degeneration (ARMD), patients with diabetic macular edema (DME) and a control group – healthy individuals with an identical age and demographic structure to the patients in the ARMD and DME groups.

All data – demographic indicators, clinical data and information from the visual function questionnaire – was obtained during a single visit of the patients in the period from 1 November 2010 to 20 February 2011. Patients with the inclusion criteria were included in the study: age >18 years, patients with ARMD and DME meeting the conditions of one of the observed groups. Patients with serious comorbidities which could markedly influence the result of the visual function questionnaire and which were not related to ARMD or DME, such as serious mental and systemic disorders, were not included in the study. All patients signed an informed consent form. The study passively observed the patient's condition of health (presence of comorbidities: hypertension disorder), duration of the eye disorder (year of determination of diagnosis), condition of visual functions (examination of central visual acuity by ETDRS optotypes expressed in decimal system). Best corrected visual acuity (BCVA) was analysed separately for the better and worse eye, since it is probable that it is the eye with better BCVA which is of benefit for quality of life. The study included a questionnaire for assessment of the patients' experience of completing the NEI VFQ 25 questionnaire.

Internal consistency and reliability were evaluated using Cronbach's alpha. A coefficient greater than 0.7 is considered to constitute good reliability. The average of the inter-question correlation coefficients for each sub-scale of the visual function questionnaire is presented as an auxiliary parameter. Its value is smaller than Cronbach's alpha, but is not influenced by the number of questions in each sub-scale. Validity was evaluated using a multivariate analysis for measurement of convergent (correlation with own sub-scale of > 0.4) and discriminatory validity (correlation with own sub-scale higher than with other sub-scales).

The standard methods of descriptive statistics were used for the other results. The standard score for each group is presented together with a 95% reliability interval. The standard methods of

Table 1. Scoring system of NEI VFQ 25

Item no.	Category of response	Pre-coded value
1, 3, 4, 15c	1	100
	2	75
	3	50
	4	25
	5	0
2	1	100
	2	80
	3	60
	4	40
	5	20
	6	0
5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, 16a A3, A4, A5, A6, A7, A8, A9	1	100
	2	75
	3	50
	4	25
	5	0
	6	*
17, 18, 19, 20, 21, 22, 23, 24, 25 A11a, A11b, A12, A13	1	0
	2	25
	3	50
	4	75
	5	100
A1, A2	0	0
	až	až
	10	100

testing hypotheses were used to verify the given hypotheses – tests on contingency table, ANOVA, t-test.

RESULTS

The data obtained by VFQ 25 was evaluated for 211 patients, 83 with ARMD, 68 patients with DME and 60 individuals in the control group. The characteristics of the patients are presented in table 2.

The average duration of the disorder is longer in the DME group (7.3 years) in comparison with the ARMD group (4.4 years, p = 0.003). Patients in the DME group are younger, the analysis indicates earlier onset of the disorder (graph 1).

In the case of chronic eye disorders there is a more frequent occurrence of comorbidities. From a statistical perspective for example, the occurrence of hypertension disorder was equal in the DME group (74%) and the ARMD group (72%). In the control group only 52% of individuals suffered from this disorder, which can be attributed to the younger age of the group.

Best corrected visual acuity (BCVA) was analysed separately in the better and worse eye. The control group had better BCVA for both the better and worse eye, which means that DME / ARMD usually afflicts both eyes in patients. The better eye had equal BCVA in the DME and ARMD groups (p = 0.519), whilst visual acuity of the worse eye was worse in the ARMD group than in the DME group (p = 0.002) (table 3).

Internal consistency and reliability was evaluated using Cronbach's alpha. According to the study protocol, a coefficient of 0.7 and greater is considered to constitute good reliability (5, 6). In our sample Cronbach's alpha attained a value of > 0.7 in all cases with the exception of the sub-scale "eye pain" (table 4).

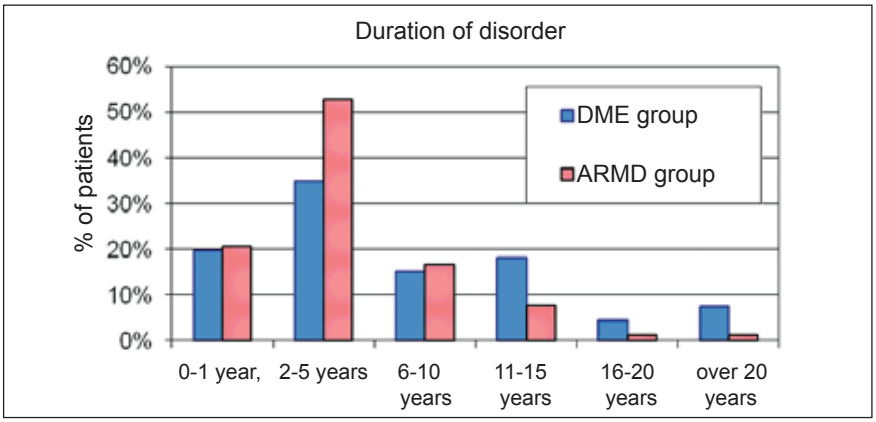
Validity was evaluated using a multivariate analysis for measurement of convergent (correlation with own sub-scale of > 0.4) and discriminatory validity (correlation with own sub-scale higher than with other sub-scales). All items met the conditions for convergent and discriminatory validity.

On the basis of these results we hereby assert that the Slovak version of the NEI VFQ 25 questionnaire is an effective tool for measuring quality of life of patients with a disorder of visual functions within the Slovak population.

The results of the NEI VFQ 25 questionnaire in the observed patients are presented in table 5. From an evaluation of the scoring system it ensues

Tab. 2. Demographic data

	ARMD	DME	Control group
Number	83	68	60
Men/women	36/47	31/37	15/45
Age (years)	73,9	64,1	59,9
SD (=standard deviation)	8,5	9,0	10,2
Min.	52	29	42
Max.	86	82	82



Graph 1. Duration of disorder

BCVA	DME group	ARMD group	Control group
Better eye			
Average	0.61	0.58	0,92
SD (=standard deviation)	0,31	0,32	0,11
Median	0,7	0,6	1
Worse eye			
Average	0,39	0,24	0,86
SD (=standard deviation)	0,33	0,22	0,19
Median	0,3	0,1	0,9

Tab. 4. Reliability and validity

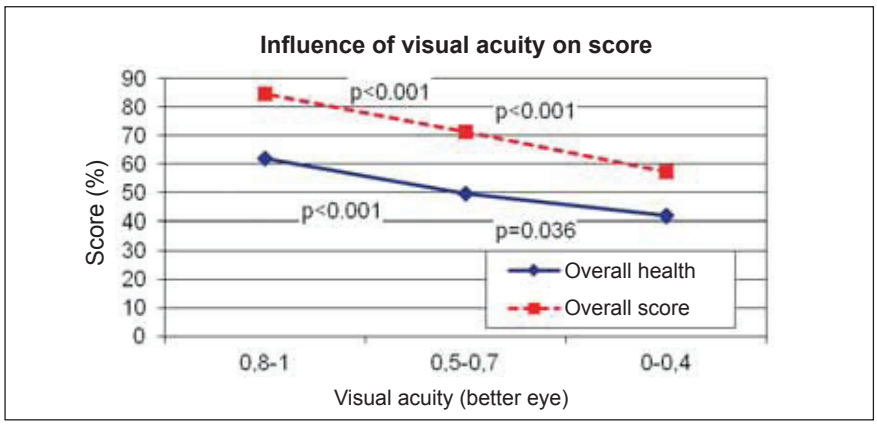
Sub-scale	Number of questions	Chronbach's α	Average of inter-question correlation coefficients
Overall health	2	0,809	0,693
Overall vision	2	0,810	0,682
Eye pain	2	0,675	0,525
Near vision	6	0,910	0,630
Distance vision	6	0,911	0,638
Social life	3	0,767	0,572
Feeling of life	5	0,880	0,587
Functional limitations	4	0,934	0,780
Dependency	4	0,931	0,773
Driving	3	0,755	0,547
Colour vision	1	NA	NA
Peripheral vision	1	NA	NA

NA: not calculated (more than one question in sub-scale is required for calculation)

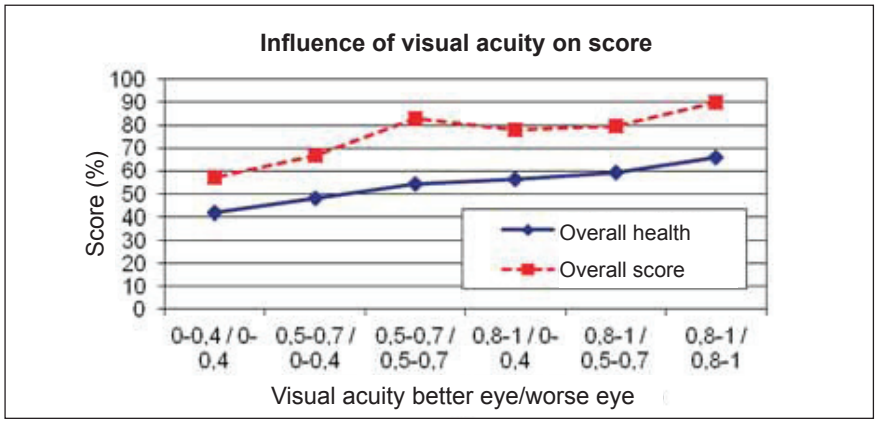
Table 5. NEI VFQ-25 score

Sub-scale	DME group			ARMD group			Control group	
	score	95% CI	p	score	95% CI	p	score	95% CI
Overall health	45.8	4.3	<0.001	52.8	3.9	<0.001	67.8	3.8
Overall vision	57.6	4.5	<0.001	51.9	3.9	<0.001	82.8	3.2
Eye pain	79.4	4.5	0.077	86.1	4.1	0.638	84.8	3.9
Near vision	59.7	6.0	<0.001	55.1	5.3	<0.001	85.9	3.4
Distance vision	68.3	5.4	<0.001	65.9	5.4	<0.001	92.8	2.4
Social life	83.0	5.2	<0.001	80.1	5.0	<0.001	98.4	1.0
Feeling of life	60.6	6.4	<0.001	57.6	5.8	<0.001	88.2	2.5
Functional limitations	60.9	6.4	<0.001	59.0	5.7	<0.001	91.4	3.0
Dependency	69.8	7.4	<0.001	66.6	7.0	<0.001	98.3	1.2
Driving	56.0	15.7	0.001	51.2	18.5	0.001	87.7	5.4
Colour vision	91.0	4.4	0.003	90.7	3.8	<0.001	98.3	1.6
Peripheral vision	75.7	6.1	<0.001	78.4	5.1	<0.001	93.3	4.9
Total score	69.9	4.6	<0.001	68.5	4.3	<0.001	91.2	1.8

95% reliability interval is created as score Ī 95% CI
p-values are the result of the t-test in comparison with the control group



Graph 2. BCVA v VFQ-25



Graph 3. BCVA v VFQ-25

that "overall health" is lower for the DME and ARMD groups than the overall score, which is in accordance with the finding that patients with a disorder "feel more ill". Patients with DME have a lower score for overall health than patients with ARMD.

Patients in the DME and ARMD group had a statistically lower score than the control group on all sub-scales with the exception of the sub-scale "eye pain". The t-tests between the DME and ARMD group indicated a difference on the sub-scale of "overall health" (p = 0.019) and the sub-scale "eye pain" (p = 0.031). The values are presented in table 5.

The questionnaire confirmed that disorders affect "near vision" more than "distance vision", whilst "colour vision" and "peripheral vision" retain high values, which confirmed the strong correlation of evaluation of quality of life (NEI VFQ 25) with clinical picture of disorder of observed patients.

The most frequent evaluation of visual functions is by means of best corrected visual acuity. This is the assumption that deterioration of visual acuity shall lead to a reduction of the score on the NEI VFQ 25 questionnaire. We confirmed this by means of a regression analysis for the overall score and for "overall health"

Result of linear regression:

Overall health = 37.7 + 15.7 * BCVA_better_eye + 13.3 * BCVA_worse_eye

Overall score = 51.0 + 22.8 * BCVA_better_eye + 18.6 * BCVA_worse_eye

with all various statistically significant parameters from 0. There is a significant drop in the overall score and "overall health" upon a deterioration of BCVA in both the better and the worse eye (graph 2, 3, table 6).

Upon completion of the questionnaire we evaluated patients' feedback with regard to its completion. 96% of all patients considered the questions to be comprehensible, but only 49% of patients regarded the questionnaire as commensurate in terms of time required for completion. 43% of patients with disorders (DME and ARMD groups) required assistance upon completion (0% in the control group) and 18% of patients with disorders did not consider the questionnaire to be easy (5% in the control group). 59% of patients considered the questionnaire to be beneficial for the care of their disorder and 1/3 of respondents felt a greater responsibility for their condition of health after completing the questionnaire.

DISCUSSION

The aim of the publication was a psychometric validation of the questionnaire NEI VFQ 25 within the Slovak population in the case of chronic eye disorders. A translation from the English version was secured by means of two independent translations via a translation agency. As upon validation of the Greek or French version, we made minimal alterations to the translation. In the Slovak version, after consultation

Tab. 6. NEI VFQ-25 score v visual acuity

BCVA (better eye)	BCVA (worse eye)	Number of patients	Overall health	Overall score
0-0.4	0-0.4	49	42.0	57.3
0.5-0.7	0-0.4	32	48.0	66.9
	0.5-0.7	12	54.2	82.7
0.8-1	0-0.4	31	56.5	78.0
	0.5-0.7	25	59.1	79.5
	0.8-1	61	66.0	90.0

with the translator, for question A7 in the supplementary section we gave priority to outdoor activities: walks, cycling, hiking, working in garden, in contrast with the activities: bowling, jogging, golf.

In our version reliability according to Cronbach's alpha was attained in all sub-scales, with the exception of the sub-scale "eye pain" (Cronbach's alpha 0.65), but the conditions of convergent and discriminatory analysis were met. The lower value can be explained by the fact that eye pain is not a pathognomonic symptom for chronic eye disorder (DME, ARMD). The results of our testing of the validity are comparable with the results of the French, Greek and Japanese versions. In the Japanese and French versions Chronbach's alpha was lower for the sub-scale of driving, in which the authors explained the connection in relation to the homogeneity of the tested patients. For example, 77% of patients with a cataract had difficulties driving in the evening. The authors also emphasise that certain findings within the group must be evaluated separately (5, 8, 9, 10). In our patients the majority of women aged over 60 had never driven at all in the past, which ensues from the social characteristics of the older population in Slovakia.

Assessment of quality of life is strictly individual. There are various forms of questionnaire evaluation of quality of life, focusing more or less on overall condition of health, ability to perform activities in daily life or tests assessing psychological aspects upon impairment of health, for example reduction of ability to see. For example, the ADVS (Activity of Daily Vision Scale) questionnaire assesses individuals' abilities to perform daily activities, and is thus more effective for evaluation of the impact on vision following a surgical procedure (3). However, if we require a more complex view of several aspects of life, on social and emotional well-being, then precisely the NEI VFQ 25 questionnaire identifies the impact of loss of vision within wider contexts, such as inclusion of the individual within social life (visits to restaurant, theatre, sporting events, meetings with people etc.).

CONCLUSION

The Slovak version of the NEI VFQ 25 questionnaire is a valid and reliable tool for measuring quality of life of patients with DME and ARMD. The internal consistency and reliability evaluated using Cronbach's alpha and the meeting of the conditions of convergent and discriminatory validity within the observed group of patients with chronic eye disorders (DME and ARMD) and the control group confirmed the validity of the questionnaire. The standard score for DME is 69.9 ± 4.6; for the ARMD group 68.5 ± 4.3 and in the control group 91.2 ± 1.8. The NEI VFQ 25 questionnaire has its application in practice. Upon an analysis of evaluation of the questionnaire by patients, we determined that the questionnaire is easily comprehensible, simple to complete and also serves to help a better understanding of the patient's condition of health. The fact that 43% of patients from the DME group and 33% of patients from the ARMD group required assistance upon completion of the questionnaires and almost one half of all respondents considered completion of the questionnaire to be disproportionately demanding in terms of time can however be considered to constitute a certain problem upon everyday use.

Workplaces in which validation of the questionnaire took place:
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