Persian Version of the 25-item National Eye Institute Visual Functioning Questionnaire (NEI-VFQ 39): A Validation Study

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Abstract

<u>*Purpose*</u>: This study was performed in order to characterize the psychometric properties of the National Eye Institute visual functioning questionnaire in Iranians.

<u>Methods</u>: After forward and backward translation, examination of the translation quality and a pilot test, 80 patients with various chronic ophthalmic diseases and 30 healthy individuals completed the questionnaire. Internal consistency (IC) was measured using Cronbach's alpha coefficient and reproducibility was evaluated using the intraclass correlation coefficient (ICC) obtained through test-retests. Regarding construct validity, convergent, discriminant and known group comparison validities were evaluated. The standardized response mean index was used to assess responsiveness and sensitivity of the instrument to changes.

<u>**Results:**</u> Cronbach's alpha was above 0.7 for all of the subscales except for that of "driving", which had a value of 0.68. The ICC in all subscales was above 0.7. All items had correlations higher than 0.4 with their original subscales. About 70% of the items were correlated with their own subscale more than other subscales. Known group comparison showed that the healthy group scored significantly higher than the patients in all subscales and the composite score (P<0.001). Standardized response means ranged from 0.61 to 2.42, and was 1.19 in general health (GH), indicating the sensitivity of the instrument to changes.

<u>Conclusion</u>: The Persian version of the National Eye Institute visual functioning questionnaire 25 was valid, reliable, responsive to changes and could evaluate the results of therapeutic ophthalmic interventions and quality of life (QoL) of the Iranian patients.

<u>Keywords</u>: National Eye Institute Visual Functioning Questionnaire, Persian, Quality of Life, Reliability, Responsiveness, Validity

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Introduction

For many years, only objective indicators were used to assess medical treatments¹; for example, indices such as visual acuity (VA) and visual field assessment were more important in ophthalmology.²⁻⁴ Although these assessments indicated to what extent a treatment was successful, there was a lack of understanding of patients' feelings and their perception of their own disease.⁵ Hence, there was a difference between the evaluation of an ophthalmologist and the perception of patients regarding the disease, its treatment and cure.⁶ Increased life expectancy in patients with chronic diseases as an achievement of modern medicine necessitates more attention to their quality of life (QoL).⁶ Although there is no agreement on the definition of QoL, it has а been accepted as subjective and multi-dimensional construct. The World Health Organization (WHO) defines "guality of life" as "individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations. standards, and concerns". Hence, it is very subjective and personal and cannot be evaluated by others.⁷

The effects of ophthalmic diseases on the QoL of people are well known and there are various instruments to measure them. These instruments are either general vision (GV) specific or disease specific.8,9 One of the instruments used to assess the QoL in patients with chronic eye diseases is a questionnaire developed by the American National Eve Institute (National Eve Institute-Visual Functioning Questionnaire 51, NEI-VFQ 51). It was designed in the mid-1990s to show the effect of vision impairments on different aspects of health-related QoL. Feedback from users indicated that a shorter version was needed for researchers and clinicians and it was changed to a NEI-VFQ 25 guestionnaire.¹⁰

In comparison with the long version, the shorter version was more feasible for a clinical trial setting in which the duration of the interview was a critical consideration. The form is available at http://www.rand.org/health/surveys_tools/vfq.h tml.

Advantages of this questionnaire are as follows: using patients' experience in

developing its content, ability to compare the relative burden of one condition with another on the same scale, multi-dimensional nature of the questionnaire showing the effect of vision problems on physical and social functions and the feeling of well-being and, finally, the multi-conditional evaluation of the validity and reliability of the questionnaire.¹⁰

Since QoL instruments are culture related,¹¹ and according to our knowledge, there is no Persian instrument to measure QoL in patients with chronic eye diseases, validating this questionnaire in Persian could provide an appropriate instrument for evaluating patients speaking this language. The NEI-VFQ has already been standardized and translated into various languages.¹²⁻¹⁷ The psychometric properties of the questionnaire would enable us to compare our findings with other studies from different parts of the world.

Methods

The questionnaire

The 25 items in the NEI-VFQ are grouped in 12 subscales (including 11 items which are related to vision and 1 item that is related to general health [GH]). In addition to the original 25 items, the questionnaire contains an appendix section, which is optional and can be added to subscales or can even replace them according to research conditions. The optional section includes 12 items which are related to vision and 1 item which is related to GH. Generally, taking the optional items into account, the questionnaire has 39 items (NEI-VFQ 39).

The subscales of the questionnaire are as follows: GH (2 items); GV (2 items); ocular pain (OP, 2 items); near activities (NA, 6 items); distance activities (DA, 6 items); vision specific social function (VSSF, 3 items); vision specific mental health (VSMH, 5 items), vision specific role difficulties (VSRD, 4 items); vision specific dependency (VSD, 4 items); driving (3 items); color vision (CV, 1 item) and peripheral vision (PV, 1 item).

The score of each subscale is expressed on a scale from 0 (the worst function) to 100 (the best function). The items are averaged to form subscales and the means of subscales yield composite scores.¹⁸

Development of the Persian version and pilot study

The **NEI-VFQ** 39 questionnaire was independently translated into Persian by a translator and a general practitioner (GP) (forward translation). Then, in three sessions, the research team reviewed the quality and content of the questionnaires and after comparing the translated questionnaire with its original version, a single version was made. This version was slightly modified according to Iranian culture and lifestyle. Thus, in item "21" [frustration] was changed to [confused]. [Legal forms] was deleted from item "A3" and [golf, bowling] were changed to [walking, football] in item "A7". After that, a backward translation was done by another translator and GP, independently. The English translated versions and the original version were given to a native bilingual American physician to check the consistency of the content. In his opinion, the content of the translated questionnaire was consistent with the original version. The research team evaluated the comments of the reviewer and the translated versions (English and Persian) in two sessions and concluded that the final Persian version was valid and ready to use. Afterwards, the pilot study was conducted to confirm the content and face validity.

At this stage, and as a pilot study, the final version was tested on 15 individuals in Noor Eve Hospital in Tehran. These individuals had at least one of the following diseases: cataract, glaucoma, age-related macular degeneration (ARMD), diabetic retinopathy or low vision due to any cause. In addition to these patients, healthy individuals with none of the above mentioned diseases were included in the pilot study to maintain the combination of the field sample. In this stage, the administrative and interviewer problems were identified and resolved. Through a diagram (Figure 1) the process of development of the Persian questionnaire was summarized.

Study design and sampling

Tehran University of Medical Sciences ethic committee approved the study. After explaining the aims and nature of the study, participation in completing the questionnaire indicated participants' willingness to cooperate; however, they were free to leave the study even after completing the questionnaire. In the Noor Eye hospital, two main groups were studied. The first group included 80 patients who only had a single type of visual impairment, such as cataract, glaucoma, ARMD, diabetic retinopathy or low vision. The diseases were diagnosed by an ophthalmologist. The second group included 30 healthy individuals with none of the above mentioned diseases or who had their refractive errors corrected with glasses or contact lenses.¹⁸ A consecutive method was used for sampling. Data collection was done in three steps. In the first step, all 110 participants completed the questionnaires. Then, to evaluate reliability and perform test-retests, 20 patients with glaucoma, ARMD, diabetic retinopathy or low vision were selected to complete the questionnaire within the following 1-3 weeks. То assess responsiveness, all patients with cataract completed the questionnaire twice, once at time zero and then 2 months after surgery. Interviews were done by a member of the research team in one of the hospital clinics.

Statistical analysis

The reliability of the questionnaire regarding internal consistency (IC) and reproducibility evaluated. The Cronbach's alpha was coefficient was used to assess IC¹⁹ and the intraclass correlation coefficient (ICC)²⁰ was used to assess reproducibility. Construct validity of the questionnaire in terms of convergent and discriminant validity was determined. To determine convergent validity, the correlation between each item and its own subscale was evaluated and for discriminant validity, the correlation between each item and its own subscale was compared to its correlation with other subscales.²¹ Convergent validity is considered to be acceptable when the correlation between one item and its original subscales is 0.4 or higher. Discriminant validity is considered to be acceptable when the correlation between one item and its own subscales is higher than the correlation between that item and other subscales.²¹ In calculating the correlation between each item and its subscale, the effect of the item was omitted from the subscale. Also, to analyze the correlation between subscales. Pearson's correlation coefficient was used. When the correlation between each

subscale and the composite score was calculated, the effect of the subscale was deleted. Known group comparison validity was also performed by simple linear regression to assess the ability of the questionnaire to discriminate vision related QoL in healthy participants and patients.²² Because the effect of age on QoL, linear regression was used to show age adjusting difference scores between patients and healthy group. The index of "standardized response mean" was used to assess responsiveness.⁷ To calculate the

index, the postoperative mean score of each subscale in all cataract patients was subtracted from the mean score of the same subscale before surgery and the result was then divided by the standard deviation of changes. This index was used to assess the sensitivity of the instrument in determining the impact of cataract surgery on the QoL of the patients. Values between 0.2-0.4 showed a small change, values between 0.4-0.8 showed a moderate and values of 0.8 or more showed a large change.⁷



*: Intraclass correlation coefficient

**: Standardized response mean

Figure 1. Diagram of the Persian questionnaire development

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Results

Participants' profile

Age of patients ranged between 24-88 years (66.95±14.7) and healthy group ranged between 22-67 years (39.24±13.15) (P<0.001). The patient group included patients with cataract, diabetic retinopathy, low vision, ARMD and glaucoma. Table 1 shows subscale mean scores and composite scores in the healthy group and patient group based on different etiologies.

The questionnaire

As shown in Table 2, the highest missing values were identified in question 14 regarding the subscale of DA and items 15c, 16 and 16a regarding the subscale of driving that was due to not driving or stopping driving because of other non-vision related reasons. There was also a high level of missing values in items 5, A3 and A4 regarding NA and question 8 regarding DA.

Reliability

Cronbach's alpha was above 0.7 for all of the subscales except for that of "driving", which had a value of 0.68. The ICC was above 0.7 in all subscales. Table 3 shows information on reliability.

Validity

Table 2 demonstrates the correlations obtained bv the Pearson's correlation coefficient. As an indication for convergent validity, correlations of more than 0.4 were observed between items and their original 12 items (30.8%), the subscales. For correlation between the item and its own subscale was equal to or bigger than the correlation between the same item and other subscales. As shown in Table 1, known group comparison showed that the healthy group scored significantly higher than the patients in all subscales and the composite score. Pearson's correlation coefficient was also used to analyze the correlations between correlations were all as subscales. The expected and significant. The highest correlation was found between activity oriented subscales such as NA and DA (r=0.92), but OP, which is a vision-targeted physical subscale, showed the weakest correlation as its correlations with 7 subscales were less than 0.4 (Table 4).

Responsiveness

Except for driving, CV and PV, which were subscales with a moderate change (0.4-0.8), large changes (0.8 or more) were observed in all subscales as shown in Table 5.

 Table 1. The 39-Item NEI-VFQ subscale and composite scores (mean±standard error)

			-					
	Cataract	Glaucoma	ARMD	Diabetic retinopathy	Low vision	Total patients	Healthy group	P [†]
General health	60.20±2.72	65.00±6.47	58.75±5.92	53.33±4.23	64.26±5.20	59.5±2.010	82.42±2.60	P<0.001
General vision	44.90±3.61	44.29±6.65	35.25±5.86	37.62±5.03	28.23±4.59	44.06±2.16	86.33±2.25	P<0.001
Ocular pain	75.00±4.84	92.86±4.61	72.50±9.46	81.55±4.92	86.76±2.72	80.47±2.46	97.5±1.26	P<0.001
Near activities	52.87±5.23	55.95±12.46	32.08±8.02	38.21±7.04	21.81±6.00	40.09±3.37	96±1.26	P<0.001
Distance activities	60.12±4.53	61.96±8.44	47.96±8.58	46.55±6.62	34.26±6.52	49.7±3.08	97.6±0.79	P<0.001
Vision-specific social functioning	69.67±4.90	64.29±10.71	50.00±11.04	51.19±7.95	35.29±7.88	54.58±3.71	100±0.0	P<0.001
Vision-specific mental health	53.60±5.10	41.43±7.05	37.00±9.31	32.38±6.66	31.76±6.65	40.25±3.16	96±0.97	P<0.001
Vision-specific role difficulties	65.75±5.34	54.46±11.71	53.12±8.65	42.56±7.12	37.87±7.43	51.17±3.47	95±1.44	P<0.001
Vision-specific dependency	65.75±6.81	60.71±11.94	55.62±13.92	48.81±9.33	41.54±8.40	54.45±4.25	99.37±0.34	P<0.001
Driving	39.58±12.21	69.44±7.30	27.78±27.82	20.83±13.24	8.33±8.30	32.97±7.17	92.03±1.80	P<0.001
Color vision	81.00±5.05	92.85±4.61	85.00±6.67	73.81±7.99	60.29±10.07	76.25±3.61	96.67±1.57	P<0.001
Peripheral vision	83.00±5.54	60.71±12.02	70.00±8.16	59.52±8.71	45.59±9.40	65.31±4.01	99.17±0.83	P<0.001
Composite score	64.56±3.71	62.96±6.35	53.07±6.91	50.53±6.01	41.90±5.72	54.49±2.65	96.05±0.72	P<0.001

ARMD: Age-related macular degeneration

[†]: Based on the difference between total patients and healthy group using simple linear regression

Subscale	Items	Item subscale correlation [†]	Missing
General vision			
	6-Level general vision	0.95	0
	0-10 vision rating	0.95	0
Ocular pain			
	Amount pain	0.62	0
	Amount time: pain	0.62	0
Near activity			
	Reading normal newsprint	0.97	19 (17.3%)
	Seeing well up close	0.93	3 (2.7%)
	Finding objects on crowded shelf [‡]	0.91	0
	Reading small print	0.96	18 (16.4%)
	Reading mail/bills accurately	0.96	18 (16.4%)
	Shaving/styling hair/makeup	0.95	7 (6.4%)
Distance activity			
-	Reading street signs	0.88	18 (16.4%)
	Going down stairs at night [‡]	0.83	3 (2.7%)
	Going out to movies/plays [‡]	0.94	72 (65.5%)
	Recognizing faces in room [‡]	0.88	Ò Ó
	Participating in sports/outdoors [‡]	0.89	9 (8.2%)
	Seeing television programs	0.89	0
Vision specific social functioning			
	Seeing how people react	0.89	0
	Visiting others	0.95	12 (10.9%)
	Normal social activities	0.95	13 (11.8%)
Vision specific mental health			10 (111070)
	Amount time: worrv [‡]	0.65	0
	Amount true: confused	0.82	0
	Amount true: no control [‡]	0.84	0
	Amount true: embarrassment [‡]	0.74	0
	Amount true: irritable	0.84	0
Vision specific role difficulties	A modific true. Initable	0.04	Ũ
vision specific role difficulties	Accomplish less	0.86	0
	Limited in endurance	0.83	0
	Have more help	0.85	0
	Limited in things can do [‡]	0.88	0
Vision specific dependency		0.08	0
vision specific dependency	Stav home most of time	0.87	0
	Bely too much on others" word	0.84	0
	Need much help from others	0.04	0
	Need much help from others	0.91	0
Driving	Do not leave nome alone	0.89	U
Driving	Devilent femilier +	0.74	
	Daylight familiar places*	0.74	64 (58.2%)
		0.75	76 (69.1%)
	Difficult conditions*	0.71	75 (68.2%)
Color vision			-
	Difficulty matching clothes	NA	0
Peripheral vision			
	Seeing objects off to side	NA	0

Table 2. Convergent and discriminant validity and missing values (all participants)

[†]: In evaluation of the correlation between each item and its subscale, the effect of the item itself has been omitted. [‡]: The correlation between the score of these items and their subscales was equal or more than the correlation between them and other subscales.

	No of item	Cronbach's alpha	Intraclass correlation	95% confidence interval
General health	2	0.96	0.95	0.88-0.98
General vision	2	0.97	0.99	0.98-0.997
Ocular pain	2	0.72	0.84	0.59-0.94
Near activities	6	0.97	0.98	0.94-0.99
Distance activities	6	0.98	0.98	0.95-0.99
Vision specific social functioning	3	0.95	0.98	0.96-0.99
Vision specific mental health	5	0.82	0.91	0.78-0.97
Vision specific role difficulties	4	0.92	0.98	0.94-0.99
Vision specific dependency	4	0.93	0.99	0.97-0.996
Driving	3	0.68	0.99	0.98-1.0
Color vision	1	NA	0.98	0.96-0.99
Peripheral vision	1	NA	0.99	0.98-0.997
Composite score	39	0.91	0.99	0.98-0.998

Table 3. Internal consistency (Cronbach's alpha), and reproducibility (intraclass correlation / ICC) for NEI-VFQ subscales in patients

 Table 4. Correlations between NEI-VFQ subscales (all participants)

	GV	OP	NA	DA	VSSF	VSMH	VSRD	VSD	Driving	CV	PV	Composite score
General vision	1											
Ocular pain	0.34	1										
Near activities	0.81	0.40	1									
Distance activities	0.82	0.38	0.93	1								
Vision-specific social functioning	0.79	0.26	0.88	0.92	1							
Vision-specific mental health	0.80	0.34	0.85	0.87	0.81	1						
Vision-specific role difficulties	0.77	0.38	0.87	0.91	0.88	0.85	1					
Vision-specific dependency	0.70	0.32	0.80	0.84	0.81	0.86	0.89	1				
Driving	0.89	0.46	0.86	0.89	0.81	0.86	0.81	0.78	1			
Color vision	0.57	0.29	0.59	0.65	0.64	0.45	0.65	0.57	0.55	1		
Peripheral vision	0.68	0.15	0.62	0.67	0.72	0.63	0.64	0.64	0.59	0.58	1	
Composite score [†]	0.86	0.36	0.92	0.95	0.90	0.88	0.93	0.88	0.89	0.64	0.69	1

[†]: In evaluation of the correlation between each subscale with the composite score, the effect of subscale itself has been omitted. GH subscale, which is different from visual subscales, has not been included in the matrix.

GV: General vision, OP: Ocular pain, NA: Near activities, DA: Distance activities, VSSF: Vision specific social functioning, VSMH: Vision specific mental health, VSRD: Vision specific role difficulties, VSD: Vision specific dependency, CV: Color vision, PV: Peripheral vision

	Mean of change	SD of change	Standardized response mean
General health	21.33	17.95	1.19
General vision	35.67	18.50	1.93
Ocular pain	30.83	21.58	1.43
Near activities	50.78	24.27	2.09
Distance activities	45.14	18.62	2.42
Vision specific social functioning	28.33	22.67	1.25
Vision specific mental health	46.33	21.25	2.18
Vision specific role difficulties	34.58	24.53	1.41
Vision specific dependency	37.50	30.07	1.25
Driving	16.67	23.57	0.7
Color vision	21.67	31.15	0.7
Peripheral vision	15.00	24.64	0.61
Composite score	35.92	15.91	2.26

Table 5. Standardized response mean in cataract patients

Discussion

This study was performed to evaluate the psychometric properties of the NEI-VFQ 39 questionnaire. Our study showed that the Persian version had an acceptable validity, reliability and responsiveness. Some slight changes in the questionnaire were made in order to standardize it; therefore, no major changes were made in the content of the questionnaire. As shown in Table 2, the highest missing values were observed in guestion 14 regarding the subscale of DA and items 15c, 16 and 16a regarding the subscale of driving. A reason for missing values in item 14 [going out to movies/plays] could be due to the high mean age of the subjects and their unwillingness to go to the cinema or to watch sports events. In a study carried out in Japan,¹⁵ the same question also had high missing values. It seems that this question should be replaced with optional items such as [watching programs on TV]. Missing values of 3 items regarding the driving subscale were due to not driving or stopping driving because of reasons other than vision. Most studies have reported similar problems^{12,15,16} and it has even been proposed that this subscale should be optional.¹⁵ Missing values of items 5, A3 and A4 regarding NA and item 8 regarding DA were mainly due to the fact that some of subjects were either illiterate or could

only read numbers and were not in the habit of reading newspapers.

In studies on samples with low levels of education, it might be better to use 3 main questions, i.e. items 5, 6 and 7, or at least A5 [shaving/styling hair/make-up] for evaluating NA and optional items such as [watching programs on TV] or [recognizing faces in the room] and [participating in outdoor activities] instead of question 8 [reading street signs] for evaluating DA. The mentioned missing values have not been reported in other studies. The differences could be due to the different levels of education. The reason for missing values in items 13 and A9 [visiting others] and [entertaining at home] in the VSSF subscale might be that the elderly in Iran mostly live with family members and if they have guests, usually other family members take care of the guest, and for those who live alone, they do not attend the party due to physical inability rather than vision problems. Missing values of other items were either not seen or were trivial.

Concerning reliability, Cronbach's alpha ranged from 0.7 to 0.98 for IC and was reported to be 0.91 for the composite score of patients, except for the subscale of "driving" with an alpha of 0.68. Regarding the subscale of "driving", [daylight familiar places] was www.SID.ir

grouped with [nighttime places] and [difficult conditions]. Considering the differences between driving conditions in city streets and roads outside the city in Iran, and the insufficient light of roads at night, they seem to be two separate issues. It might be better to ask these items separately for city streets and intercity roads in Iran. The alpha for the same subscales in studies carried out in Japan and France was 0.58 and 0.12, respectively; however, they did not discuss the potential reasons.^{15,17} In other subscales, the alpha values indicated that the subscales were homogenous. According to the results reported in table 3, reproducibility of the questionnaire in each subscale was suitable (0.99 to 0.84) with a total of 0.99. Our results were similar to results of other studies.¹²⁻¹⁶

As for the validity, similar to the Japanese study,¹⁵ 100% of the items showed convergent validity but 70% showed discriminant validity. Univariate linear regression (Table 1) indicated a significant difference between the patient group and the healthy group in all subscales. Known group comparison showed an acceptable discriminant validity of the questionnaire in all subscales as well as the GH subscale, so that the subscale and total score of healthy individuals were significantly more than patients. In a study performed in Turkey, since there was no control group, the discriminant validity of the questionnaire was evaluated through the differences of the scores of the subscales at different levels of VA. In this study, the subscale scores and the total score were lower in patients with a worse VA than in those with a better VA.¹³ Regarding correlations between the subscales of the questionnaire, and similar to other studies, correlations between subscales were optimal and as expected.^{12,14} For example, similar to a study in Italy, the highest correlation was seen between activity oriented subscales such as NA and DA. But OP, as a vision-targeted physical subscale, showed the weakest correlation with other subscales.¹⁴

Because of the effect of sample size on the paired t-test, this test is not recommended to evaluate changes in scores of the QoL7; therefore, the standardized response mean was used to show responsiveness of the questionnaire. Responsiveness measures the longitudinal validity of the questionnaire and indicates an important part of the validity. Since cataract surgery influences the QoL of patients,²³ it is used the to check responsiveness. Reports on responsiveness of the NEI-VFQ 25 questionnaire are very limited. The standardized response mean was used in developing the Japanese version of the questionnaire for those undergoing cataract surgery. Its range, between 1.91 and 7.35, was reported to be as excellent.¹⁵ In the Brazilian version of the questionnaire, the difference between the scores of the subscales before and after surgery was considered to be very important and the differences in the subscales of GV, OP, NA, DA, VSSF, VSMH, VSRD, VSD and PV were significant.¹² According to table 5, this index had moderate and large values in all subscales. Since cataract surgery affects all visual functions, the obtained changes were congruent with our expectations.

Conclusion

Finally, it can be said that the Persian version of the NEI-VFQ 39 questionnaire was valid, reliable and responsive to changes and could evaluate the results of therapeutic ophthalmic interventions and the QoL of patients speaking in Persian.

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