·Investigation·

Development of an Arabic version of the National Eye Institute Visual Function Questionnaire as a tool to study eye diseases patients in Egypt

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Abstract

• AIM: To develop and test an Arabic version of the National Eye Institute Visual Function Questionnaire-25 (NEI-VFQ-25).

• METHODS: NEI-VFQ-25 was translated into Arabic according to WHO translation guidelines. We enrolled adult consenting patients with bilateral chronic eye diseases who presented to 14 hospitals across Egypt from October to December 2012, and documented their clinical findings. Psychometric properties were then tested using STATA.

• RESULTS: We recruited 379 patients, whose mean age was (54.5±15)y. Of 46.2% were males, 227 had cataract, 31 had glaucoma, 23 had retinal detachment, 37 had diabetic retinopathy, and 61 had miscellaneous visual defects. Non-response rate and the floor and ceiling numbers of the Arabic version (ARB-VFQ-25) were calculated. Internal consistency was high in all subscales (except general health), with Cronbach-α ranging from 0.702-0.911. Test-retest reliability was high (intraclass correlation coefficient 0.79).

• CONCLUSION: ARB-VFQ-25 is a reliable and valid tool for assessing visual functions of Arabic speaking patients. However, some questions had high non-response rates and should be substituted by available alternatives. Our results support the importance of including self-reported visual functions as part of routine ophthalmologic examination.

• **KEYWORDS:** Arabic; psychometrics; questionnaires; National Institutes of Health; visual function questionnaire
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INTRODUCTION

The National Eye Institute Visual Function Questionnaire-25 (NEI-VFQ-25) is a broad, vision-targeted questionnaire used in the assessment of visual impairment. It has initially been developed by the National Eye Institute in order to match the need for a new tool to assess the extent of visual impairment in patients with various chronic eye conditions of moderate to high severity [1]. The original 51-item questionnaire was later shortened into a 25-question version, the NEI-VFQ-25, by removing items that showed floor or ceiling effects or which were found to be redundant. The shorter version has been validated for convenience purposes and was shown to have similar psychometric properties to the original version [2]. After its initial development, the NEI-VFQ-25 has been translated and adapted for usage in many languages and populations, including Italian[3], Spanish[4], Chinese[5], French[6], Japanese[7],

Greek[8], Taiwan Chinese[9], Turkish[10], Danish[11], Brazilian[12] and Persian[13].

Several studies showed that visual impairment is associated with detrimental effects on the social functioning and emotional well-being of patients, that the reliance on visual acuity (VA) alone in the assessment of visual condition is fallacious, and that the inclusion of other tools was necessary [14-17]. Health-related quality of life (HRQoL) questionnaires are among these tools. The concept of assessing HRQoL has been incorporated into medical fields, including oncology [18], nephrology [19], gastroenterology [20], urology[21] and other medical fields[22]. HRQoL questionnaires may be general, vision-related or disease-related. Disease-specific questionnaires have been developed for a variety of visual impairments, including cataract, glaucoma, age-related macular degeneration and retinitis pigmentosa [23]. The NEI-VFQ-25 is a vision-specific questionnaire that has been used to assess visual impairment in age-related macular degeneration[24], glaucoma[25], blepharospasm[26], diabetic eye disease[27], retinitis pigmentosa[28] and dry eye syndrome[29]. It is composed of 12 subscales: general health (1 item), general vision (1 item), ocular pain (2 items), near activities (3 items), distance activities (3 items), vision-specific social functioning (2 items), vision-specific mental health (4 items), vision-specific role difficulties (2 items), vision-specific dependency (3 items), driving (3 items), color vision (1 item) and peripheral vision (1 item). The NEI-VFQ-25 may be more advantageous to use in some visual disorders, even those for which there are disease-specific questionnaires. Because of its wide scope, the NEI-VFQ-25 captures the physical, emotional and social aspects of visual disability. Thus, it assesses all aspects of quality of life (QoL) that have been put forward by Aaronson in 1988 [30]. Besides, the NEI-VFQ score may be used to compare the extent of visual impairment in different disorders on the same scale. Nevertheless, it is sometimes preferable to use disease-specific HRQoL questionnaires in some conditions. For example, the AS-20 questionnaire is demonstrably more sensitive than the NEI-VFQ-25 in detecting reduced QoL in strabismus patients [31].

We report the translation, adaptation and validation of an Arabic version of the NEI-VFQ-25 among Egyptian patients who presented to 14 hospitals across Egypt with bilateral chronic eye diseases. The use of a cheap and yet reliable method for the assessment of visual impairment in conjunction with VA is arguably more important in developing countries and among individuals with low socioeconomic status. Hence, the NEI-VFQ-25 is very relevant in our study population and setting.

SUBJECTS AND METHODS

Subjects

Development of the Arabic version The Arabic version of NEI-VFQ-25 was developed according to the WHO translation guidelines for research instruments. The translation process involved six steps:

1) Forward translation of the NEI-VFQ-25 from English to Arabic was done by one professional non-medical translator and one medical translator.

2) Revision of both Arabic translations was done by a panel of three bi-lingual Egyptian ophthalmologists to produce a second draft of ARB-VFQ-25.

3) Two other translators, who were blinded to the original questionnaire, back-translated the drafted ARB-VFQ-25 into English.

4) The back-translated ARB-VFQ-25 was compared with the original English version to identify any discrepancies, which was revised by the panel.

5) Cognitive debriefing of the drafted ARB-VFQ-25 was performed on ten people with visual impairment and five normal people to test their understanding and interpretation of the questionnaire.

6) The final version of the ARB-VFQ-25 was established after minor revisions, taking into account the outcome of the cognitive debriefing.

The Arabic version of the instrument was pilot-tested in a sample of ten ophthalmic patients who visited the ophthalmology outpatient departments of four university hospitals for various visual concerns, as well as a sample of 5 normal subjects who were cleared to be visually competent. The results of the pilot-testing indicated that the instrument was well accepted, and all items were easy to understand. However, proper adaptation of the questionnaire to the experience of Arabian patients mandated slight modification of two questions.

Therefore, 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 or outdoors, to restaurants, or in mosques/churches?). Also, item "A7" [Because of your eyesight, how much difficulty do you have taking part in active sports or other outdoor activities that you enjoy (like golf, bowling, jogging, or walking)?] was translated as: [Because of your eyesight, how much difficulty do you have taking part in active sports or other outdoor activities that you enjoy (going long walks or jogging)?].

Study design and subject groups Patients presenting for follow-up or visual consultations that met the eligibility criteria were recruited from fourteen eye hospitals across Egypt; seven of which are tertiary centers. All investigations were performed according to the guidelines of the Declaration of Helsinki, informed consents were obtained from all patients, and Institutional Review Board approval was obtained for study execution.

Male and female patients whose mother tongue is Arabic, yet

with variable educational backgrounds were recruited. Eligibility criteria included a minimal age limit of 18y, absence of cognitive impairment or co-morbidities affecting visual QoL, bilateral disease affection at time of filling the questionnaire, and negative history of eye surgery related to the current disease during the preceding 3mo.

Excluded from this study were patients affected by more than one eye disease, serious mental or major systemic illness (affecting QoL), or having non-vision related eye disease. Purpose, methods, and significance of the study were fully explained to all study participants. Trained Arabic-speaking interviewers measured patients' visual acuity and administered the ARB-VFQ-25 to each patient face-to-face.

In total, 379 patients were enrolled and subdivided into 5 subject groups. Group 1 consisted of a random sample of 227 known cataract patients (103 males/124 females) who were recruited and scheduled for bilateral phacoemulsification with intraocular lens implantation.

Group 2 consisted of a random sample of 31 known glaucoma patients (14 males/17 females). Inclusion criteria for those patients were binocular primary open angle glaucoma evidenced by binocular abnormalities detected with Humphrey visual field analyzer, presence of glaucomatous defects in the optic nerve, and at least one documented instance in each eye of intraocular pressure greater than 21 mm Hg.

Group 3 consisted of a random sample of 37 known diabetic retinopathy patients (15 males/22 females) who have been diagnosed with proliferative (PDR), non-proliferative diabetic retinopathy (NPDR), or diabetic macular edema (DME).

Inclusion criteria for severe NPDR were 4-quadrant hemorrhage, or 2-quadrant venous bleeding, or 1-quadrant intraretinal microvascular abnormalities. Criteria for PDR were detection of new blood vessels formation at the disc or elsewhere. Clinically significant macular edema (CSME) patients included were having retinal thickening at least 1 disc area in size, any part of which is located within 1 disc area of the foveal center or retinal thickening within 500 micrometers of the foveal center or hard lipid exudates within 500 micrometers of the foveal center associated with adjacent retinal thickening.

Group 4 consisted of a random sample of 23 retinal detachment patients (13 males/10 females) who were known to have rhegmatogenous retinal holes, tears, or dialyses *via* fundus photography camera (Visucam 500).

Group 5 consisted of a random sample of 61 patients with miscellaneous visually significant eye diseases.

Table 1 shows the distribution of different groups of patients included in the study.

Table 1 Demographic and clinical patient data

Diagnosis	*n* (%)
Cataract	227 (59.5)
Primary open angle glaucoma	31 (6.9)
Diabetic retinopathy	37 (9.5)
Retinal detachment	23 (6.1)
Miscellaneous diseases	61 (17.6)
Gender	
M	175 (46.2)
F	204 (53.8)
Education	
No schooling	224 (59.1)
Primary	62 (16.4)
Preparatory	17 (4.5)
High school	45 (11.9)
University or higher	31 (8.2)
Number of co-morbidities	
No co-morbidities	218 (57.2)
Hypertension	38 (10.2)
Diabetes	71 (18.7)
Hypertension and diabetes	30 (7.0)
Liver disease	5 (1.5)
Others	17 (5.4)

Methods

Data collection All surveys were administered by trained interviewers. The interviewers had no direct involvement in the medical care of the patients. The interviews included both the main questions as well as the optional questions of the Arabic version of the NEI-VFQ-25. Each interviewer recorded, on a structured form, the type of eye disease, best corrected visual acuity, ocular pressure, date of interview, hospital's name, patient's demographic data, and medical co morbidities. The data were managed by ID number, edited through interviewer-specific, password-protected filing system, and were analyzed in a way that maintained all participants' privacy.

Descriptive analysis and item analysis Data from the different subject groups were used for the item analysis. Missing values were estimated for each item. We also examined whether each item's distribution of responses was strongly skewed.

Reliability Reliability analysis was done by Cronbach's-α estimation as an index of internal consistency for each subscale. The optimal range of Cronbach-α is 0.70-0.90. To further determine scale homogeneity, the item-scale correlation coefficient was calculated. A coefficient greater than 0.40 is considered acceptable. A subgroup of patients (20%) was retested after 2wk to determine the test-retest reliability of the questionnaire. A time window of 2wk between two consecutive surveys was used for the assessment of reliability. The time point was set at 2wk as this was short enough to avoid changes in visual acuity and long enough for patients not to remember the answers. Quantification of test-retest reliability was done using intraclass correlation coefficients.

Table 2 Mean subscale and scores of ARB-VFQ-25 $\bar{x} \pm s$

Subscale	Cataract	POAG	Retinal detachment	Diabetic retinopathy	Dry eye disease	Other
General health	57.6±20.7	57.6±19.5	63.0±20.3	53.9±20.8	55.7±25.3	55.6±20.2
General vision	40.9±18.6	54.8±19.7	50.4±19.4	48.3±19.5	57.5±21.9	41.7±22.7
Ocular pain	72.1±29.9	67.7±29.6	77.7±26.6	66.0±25.6	50.9±32.7	63.3±30.5
Near activities	33.6±24.1	55.9±29.7	48.0±26.2	39.7±30.0	41.8±32.0	38.4±26.3
Distance activities	42.1±23.7	59.1±22.6	53.1±26.1	51.0±25.9	54.2±25.8	45.8±25.1
Social functioning	65.9±29.7	83.3±20.4	74.6±26.5	69.2±30.8	81.0±25.4	68.5±27.8
Mental health	42.0±28.2	44.1±29.1	40.7±22.8	39.6±26.6	60.0±24.0	43.8±21.9
Role difficulties	44.9±33.2	63.4±28.1	57.6±26.3	47.2±29.6	62.9±37.3	54.4±28.5
Dependency	53.9±33.6	73.1±26.4	63.3±26.5	58.0±31.2	78.6±29.6	58.3±30.7
Driving	13.6±21.3	33.7±30.9	12.0±25.1	33.7±29.2		18.2±21.4
Peripheral vision	60.2±36.3	70.7±32.8	67.4±27.6	61.8±33.5	78.6±27.5	69.0±38.0
Color vision	76.1±34.2	81.0±28.1	80.4±33.7	69.4±35.4	85.7±28.9	75.5±37.3
Composite score	52.7±21.3	64.8±18.5	60.0±18.6	54.9±22.6	65.1±21.2	55.3±20.8

POAG: Primary open angle glaucoma.

Construct validity The use of multi-trait analysis to evaluate convergent and discriminant validity has been described previously in detail [32]. What follows is a brief summary of the method: each item is hypothesized to belong to only one multi-item subscale. For each item, correlations between the score on that item and the scores on all the subscales are computed. Then, for each item, if the correlation between the score on that item and the score on the subscale to which that item belongs is 0.4 or higher, that item is said to have "passed" the test of convergent validity. Also for each item, if the correlation between the score on that item and the score on the subscale to which that item belongs is greater than the correlations between the score on that item and the scores on all the subscales to which it that item does not belong, then that item is said to have "passed" the test of discriminant validity[33].

Statistical Analysis Statistical analyses were performed with Stata Statistical Software: Release 12. StataCorp. 2011. College Station, TX: StataCorp LP.

RESULTS

Item Analysis The mean age of the 379 participants was 54.53 (±15.03); 175 (46.2%) were male. Demographics and clinical data for the participants are presented in Table 1. Mean subscale and overall ARB-VFQ scores for the different groups of subjects are presented in Table 2. Mean ARB-VFQ scores ranged from 12.0 ±25.1 for the retinal detachment patient group to 83.3±20.4 for the POAG group.

Correlation The item-scale correlations coefficients were generally high, ranging from 0.60 to 0.80 (Table 3), except for items in "general health", "ocular pain", and "driving" subscales, which had a correlation coefficient less than 0.50. Table 4 shows the correlation between all subscales.

Reliability Cronbach-α of the ARB-VFQ-25 ranged from 0.70 to 0.91. Except for the general health and driving subscales, Cronbach-α values were greater than or equal to 0.74. Table 5 includes the Cronbach-α of the full expanded 38-questions version of the ARB-VFQ, as well as that of the short 25 questions version. Test-retest reliability was high, with an intraclass correlation coefficient 0.79 in all subscales (Table 5).

Table 3 Item-scale correlation coefficients to ARB-VFQ-25

Subscale	No. of items	Item-scale correlation
General health	2	0.3374
General vision	2	0.6773
Ocular pain	2	0.4013
Near activities	6	0.7926
Distance activities	6	0.8691
Vision specific Social Functioning	3	0.8152
Mental Health	5	0.7218
Role Difficulties	4	0.7218
Dependency	4	0.8327
Driving	3	0.3347
Color Vision	1	0.6618
Peripheral Vision	1	0.673

DISCUSSION

Our study showed that the Arabic version of the NEI-VFQ-25 questionnaire was of adequate reliability and validity to be used for the assessment of ophthalmic disorders. We had to make some minor modifications to adapt to the Egyptian setting. As mentioned earlier, we changed questions 13 and A7. According to the UNICEF, Egypt has a total adult literacy rate of only 66% [34], which could explain the poor response rate to the "reading" questions. Moreover, the underdeveloped nature of Egypt's economy and the readily-available public transportation system may explain why questions related to driving also had a relatively poor response rate. A similar situation has been encountered by

Table 4 Correlation between subscales

Subscale	General health	General vision	Ocular pain	Near activities	Distance activities	Social functioning	Mental health	Role difficulties	Dependency	Driving	Color vision	Peripheral vision
General health	1											
General vision	0.262	1										
Ocular pain	0.048	0.0764	1									
Near activities	0.126	0.5449	0.2434	1								
Distance activities	0.167	0.57	0.2553	0.8217	1							
Social functioning	0.133	0.527	0.2118	0.6401	0.7574	1						
Mental health	0.25	0.4819	0.338	0.487	0.5335	0.5274	1					
Role difficulties	0.243	0.5288	0.3133	0.621	0.6622	0.6381	0.6661	1				
Dependency	0.216	0.4788	0.2567	0.6237	0.6863	0.6697	0.5971	0.7723	1			
Driving	0.085	0.1604	0.1035	0.1916	0.2864	0.1679	0.1002	0.1533	0.1819	1		
Color vision	0.037	0.3634	0.1848	0.4907	0.5684	0.635	0.3437	0.496	0.4919	0.1179	1	
Peripheral vision	0.109	0.3788	0.1524	0.4975	0.5864	0.5593	0.4016	0.5114	0.4968	0.107	0.538	1

Table 5 Internal reliability of ARB-VFQ (25 and 38 questions version)

Subscale	No. of items	Items	Chronbach-α[38]	Chronbach-α[25]
General health	2	1, A1	-0.006	N/A
General vision	2	2, A2	0.744	N/A
Ocular pain	2	4, 19	0.794	0.794
Near activities	6	5, 6, 7, A3, A4, A5	0.881	0.762
Distance activities	6	8, 9, 14, A6, A7, A8	0.911	0.866
Social functioning	3	11, 13, A9	0.779	0.814
Mental health	5	3, 21, 22, 25, A12	0.791	0.726
Role difficulties	4	17, 18, A11a, A11b	0.874	0.881
Dependency	4	20, 23, 24, A13	0.872	0.836
Driving	3	15c, 16, 16a	0.702	0.702
Color vision	1	12	N/A	N/A
Peripheral vision	1	10	N/A	N/A

the developers of the Chinese version of the NEI-VFQ-25[5]. Depending on subjects' responses, each subscale of the NEI-VFQ-25 was given a score from 0 to 100, where lower scores indicated poorer vision-related QoL. With the exception of the "general health" item, the mean score of all subscales is considered the composite NEI-VFQ-25 score.

This simple analysis relied on "Classical Test Theory" (CTT), and had inherent limitations and drawbacks. It was based on the assumption that all survey items were of equal importance and, therefore, were given equal weight upon calculating the composite score. It also assumed that the differences between response categories were uniform; *i.e.* it assumed that the difference between "extreme difficulty" and "moderate difficulty" was the same as that between "moderate difficulty" and "a little difficulty". Moreover, it assumed that the same response category carried the same weight in different questions. Of course this was not true, since "extreme difficulty" driving was not the same as "extreme difficulty" in a social functioning context[35]. For this reason Rasch analysis has been deployed in some NEI-VFQ translations[7,8]. Rasch analysis has the advantage of relying on "Item Response Theory" (IRT), which analyses ordinal variables in such a way that their scores are converted into interval scales. Inherent assumptions of Rasch analysis include: that only one variable (visual impairment) is measured by the questionnaire; that responses are only affected by that variable which is being measured; that the odds of performing an activity increase linearly with visual functions[35,36].

In 2004, de Boer *et al*[23] conducted a comprehensive systematic review and quality assessment analysis of all vision-related QoL questionnaire reported in the literature. A total of 31 questionnaires were assessed, which were either disease-specific, related to vision impairment in general or aimed at subject with low vision in particular. They assessed the following psychometric qualities of the questionnaires: content validity (item selection and reduction, subscale checking and internal consistency); reproducibility (reliability and agreement); construct validity; responsiveness; interpretability; respondent burden; true linear scaling.

Among the negative aspects of NEI-VFQ-25 was the fact that neither agreement nor inter-interviewer reliability was reported. Moreover, the NEI-VFQ-25 did not provide a true linear scale. Indeed, when Marella *et al*[37] performed Rasch analysis to assess the dimensionality of NEI-VFQ-25, two factors resulted: visual functioning and socio-emotional traits. Similarly, a key study by Massof and Fletcher [38] assessed 27 items of the 52-item NEI-VFQ version and had to remove 10

of them due to misfits to the model. Their study provided a demonstrably uni-dimensional 17-item version NEI-VFQ, although the validity of this reduced version is yet to be addressed. Despite these drawbacks, de Boer *et al*[23] concluded that the VCM1 (Core Questionnaire of Vision-related QoL Measure) and NEI-VFQ-25 showed the best psychometric quality when used for people with visual impairment.

Because the NEI-VFQ-25 was initially developed and tested on North American patients with moderate to severe eye disease. Concerns have been raised about its sensitivity to milder forms of visual impairments or as a screening method for visual disorders. However, later studies investigating this issue found the NEI-VFQ-25 to be a reliable screening method of visual impairment among elderly populations, with a detection rate of 69% and a false positive rate of 18%[39].

One important issue to consider is how an ophthalmologist should react when discrepancy arises between the NEI-VFQ-25 score of a patient and objective tests such as visual acuity. An interesting study by Yanagisawa *et al*[40] tested the correlation between vision-related QoL (measured by NEI-VFQ-25 score) and objective methods used to assess the visual field. The NEI-VFQ-25 score was only correlated with the Esterman disability score (EDS) method, and was not correlated with AMA method of dynamic visual field assessment. Despite the fact that the NEI-VFQ-25 contained only one item about visual field, it was good enough to question existing guidelines. Perhaps it would advisable to develop guidelines which include the NEI-VFQ-25 in routine ophthalmologic examination assessment and which advise ophthalmologists on how to react were significant discrepancies to arise between objective tests and NEI-VFQ-25 score. There are several factors that may explain potential discrepancies between VA and NEI-VFQ-25 scores. Firstly, it is known that VA alone may not be enough to assess visual impairment. It may be true that the inclusion of tests such as contrast sensitivity tests, tests of color vision and visual field examination to the ophthalmic assessment would be more indicative of the extent of visual impairment. In fact, Hirneiss *et al* [41] showed that the combination of refraction tests, intraocular pressure, cup/disc ratio and the ocular pain subscale of the NEI-VFQ-25 could be used to exclude prevalent eye diseases. The NEI-VFQ-25 score, however, was found to be an inadequate screening method if used alone. Secondly, psychological factors may sometimes explain discrepancies that are otherwise unexplained by objective tests. Patients may overreact to simple pathologies or -as is true in the Egyptian culture- fail to report impairment of visual or social functioning for religious reasons. For example, some of the patients we interviewed were difficult to convince to assess their health, stating that "Whatever God brings is satisfactory" and "Who are we to judge God's deeds?"

Having said that, perhaps it would be useful to include items assessing spiritual, personal and religious well-being to the NEI-VFQ, especially in Middle Eastern societies such as this study's population, where religion plays a pivotal role in the psychology of individuals. Indeed, the WHO QoL-SPRB BREF has been developed to be used in adjunction with HRQoL questionnaires and may be relevant to the assessment of vision-related QoL as well[42].

Many patients were having more than one eye disease at the time of presentation, which raised the question of whether the scores of multiple eye diseases have an additive detrimental effect on their QoL, a synergistic detrimental effect or more interestingly if they had a less-than-additive effect. It is probably true that patients with new diseases on top of existing ones will respond differently than the way their responded to their first pathology and that QoL is not proportionally related to physical injuries. For example, someone with a new pathology might respond with a disproportionate depression that he's been "infested with diseases", while someone in the same condition might take it from the perspective of "I got used to it, one more disease will not make such a big difference". Perhaps it not even possible to measure the worsening of QoL in each disease separately in a co-morbid patient.

Our study contained a number of limitations. Firstly, our study population was only composed of diseased individuals, so it questionable whether the ARB-VFQ-25 could be used for people with milder of visual impairment or for screening purposes. Other studies are needed to address this question. Secondly, our study did not include any general health related QoL questionnaires, such as SF-36 to generate a general physical and mental health component scores for validation of NEI-VFQ scales. Nonetheless, the fact that we found high correlation between visual impairment and low scores may invalidate this point. The third limitation of our study was its cross-sectional nature. Our study does not answer the question of whether the ARB-VFQ-25 could be used longitudinally and for continuous assessment of visual functions over time.

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