Validation of the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25) in Age-Related Macular Degeneration

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Purpose. Patient-reported measures of visual function are increasingly incorporated into clinical trials of new treatments for age-related macular degeneration (AMD). Limited information is available regarding the associations between distance visual acuity (VA), reading speed, or contrast sensitivity and the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25) subscales judged relevant to these measures. This study's objective was to evaluate such associations along with questions on restricted activity days.

Methods. This cross-sectional study was conducted in patients with clinical diagnoses of neovascular AMD. Patient-reported outcome measures included the NEI VFQ-25 and restricted activity days. Clinical assessments included best-corrected visual acuity (BCVA), reading speed, and contrast sensitivity. The better-seeing eye was defined based on the BCVA of each patient. Psychometric properties of the NEI VFQ-25 were examined; analyses a priori focused on the Near Activities, Distance Activities, and Vision-Specific Dependency subscales.

Results. The final study group included 92 participants (mean age, 78 years). Cronbach's α for the subscales ranged from 0.67 to 0.92. The NEI VFQ-25 overall composite, Near Activities, Distance Activities, and Vision-Specific Dependency scores were correlated with BCVA ($r = -0.48$ to -0.54, all $P < 0.0001$), reading speed ($r = 0.43$ to 0.56, all $P < 0.0001$), and contrast sensitivity ($r = -0.39$ to -0.46, all $P < 0.001$) of the better-seeing eye and with restricted activity days ($r = -0.52$ to -0.55, all $P < 0.0001$).

Conclusions. This study provides additional evidence supporting the validity of the NEI VFQ-25 in neovascular AMD patients by demonstrating correlations with a spectrum of vision measurements and a daily function measure. (*Invest Ophthalmol Vis Sci.* 2011;52:3354–3359) DOI:10.1167/iovs.10-5645

Measurement of patient-reported outcomes (PROs) in ophthalmologic research has increased the understanding of the impact of visual impairment on activities and functioning in patients with eye diseases.[1–7] The visual impairment experienced by many patients with age-related macular degeneration (AMD) has been found to affect their ability to perform usual activities, cause psychological distress, and limit their participation in social events.[3,8,9] PROs of visual function provide a more comprehensive evaluation of the impact of, and the effects of treatment for, AMD.

The present study is intended to provide additional confirmation of the reliability and validity of the NEI VFQ-25 in AMD patients. Validity of the NEI VFQ-25 is examined through associations with measures of visual acuity (VA), reading speed, contrast sensitivity, and responses to a questionnaire on restricted activity days.

Methods

Participants

This cross-sectional, noninterventional, single-visit study was conducted with patients who had clinical diagnoses of neovascular AMD in at least one eye. Participants were recruited through ophthalmologist and retinal specialist offices from 15 sites in the United States.

To be eligible for participation, patients were required to have characteristics similar to those of patients enrolled in the MARINA, ANCHOR, and PIER studies, including subfoveal choroidal neovascular lesions with or without a classic choroidal neovascularization (CNV) component secondary to AMD in at least one eye, evidence of recent disease progression, and best-corrected VA (BCVA) letter score of 70 to 24 (Snellen equivalent of 20/30 to 20/320) in the study eye.[10–12] Patients who had received treatment for CNV within the previous 4 weeks or who had an acute illness or cognitive or other impairment that would interfere with study requirements were not eligible.

The study protocol and consent form were approved by each local institutional review board and met Health Insurance Portability and Accountability Act requirements. Patients with AMD who met the eligibility criteria were asked to participate in the study. If the patient was willing to participate, written informed consent was obtained.

Data Collection Procedures and Measures

After confirming eligibility and completing the informed consent process, a study staff member administered the PRO measures and performed clinical assessments. All study data were recorded for each participant on a study case report form.

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See the Appendix for a complete list of study sites and clinic staff members participating in this study.

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TABLE 1. Demographic and Clinical Characteristics of Study Participants

Characteristic	All Participants (n = 92)
Age in years, mean ± SD	78.3 ± 7.9
Men, *n* (%)	34 (37.0)
White, *n* (%)	88 (95.7)
Employment, *n* (%)	
Retired	73 (79.3)
Working full or part time	10 (10.8)
Other	9 (9.8)
Education, *n* (%)	
High school or less	46 (50.0)
Some college, college degree, postgraduate degree	43 (46.7)
Other	3 (3.3)
Years since diagnosis of AMD, mean ± SD	1.99 ± 2.78
Lesion composition of study eye, *n* (%)	
Predominantly classic	28 (30.4)
Minimally classic	18 (19.6)
Occult with no classic	46 (50.0)
Lesion size in study eye, mean ± SD disc areas	3.83 ± 3.25
Blood associated with CNV, *n* (%)	45 (48.9)
Median BCVA letter score of better-seeing eye (approximate Snellen equivalent)	70 (20/40)
Median BCVA letter score of worse-seeing eye (approximate Snellen equivalent)	45 (20/125)

Patient-Reported Outcomes

NEI VFQ-25. The NEI VFQ-25 was administered by the study coordinator and was scored according to the guidelines provided by the instrument developers.[13] Scores range from 0 to 100, with higher scores indicating better visual function.

Restricted Activity Days. After the NEI VFQ-25 was administered, the study coordinator asked, "Over the last 3 months, how many days were you restricted in your usual daily activities?"[14]

Clinical Assessments

Refraction and BCVA. After PROs were completed, refraction and BCVA were obtained in both eyes, as described in the study protocol. The refraction protocol was adapted from that used in the Early Treatment Diabetic Retinopathy Study.[15] All analyses were made using the letter score, though the letter score was converted to an approximate Snellen equivalent VA for reports.

Reading Speed. Next, reading speed was evaluated in a standardized manner using the Submacular Surgery Trial (SST) reading cards and reading speed testing protocol.[16] Reading speed for each eye was calculated as the number of words read correctly per minute in a 3-minute period.

Contrast Sensitivity. Contrast sensitivity was then measured in a standardized fashion according to the study protocol using commercial versions of the Pelli-Robson charts.[17] Scores range from 0.6 to 100; higher scores indicate worse contrast sensitivity. Ambient room lighting was measured between 75 and 125 foot candles, the recommended standard lighting.

Extended Ophthalmoscopic Examination, Stereoscopic Color Fundus Photography, and Fluorescein Angiography. Finally, dilated ophthalmoscopic examination, stereoscopic color fundus photography of the disc and macula, and fluorescein angiography of the study eye were performed on each participant.

Statistical Analysis

Regardless of study eye designation, the better- and worse-seeing eye for each patient were determined by BCVA letter score. The relationship between the NEI VFQ-25 and clinical measures was examined separately for the better- and worse-seeing eye. Demographic variables and clinical conditions were summarized by descriptive analyses. Although all subscales were included in the analyses, the focus was on the Near Activities, Distance Activities, and Vision-Specific Dependency subscales because these were specified a priori in the statistical analysis plans for the Genentech phase 3 trials of ranibizumab.

The internal consistency reliability of the NEI VFQ-25 was assessed using Cronbach's formula for coefficient α.[18] Values range from 0 to 1.0, with higher scores indicating a more reliable and homogeneous instrument. A Cronbach's α of $\geq$0.70 indicates acceptable internal consistency reliability for an instrument used with group data.[19]

Convergent validity was evaluated by correlations between the NEI VFQ-25 and BCVA, contrast sensitivity, reading speed, and number of restricted activity days. Convergent validity was supported when the NEI VFQ-25 scores were substantially correlated (absolute value of correlation >0.40), with items or scales measuring similar concepts.[20]

To assess known-groups validity, analysis of covariance models, adjusted for age and sex, were used to examine the mean NEI VFQ-25 scores by clinical severity based on BCVA, reading speed scores, and number of restricted activity days. All statistical analyses were performed using analysis software (SAS Institute, Cary, NC).

RESULTS

This study initially enrolled 115 patients with AMD from 15 sites in the United States. Five patients provided written informed consent but withdrew from the study before any procedures were performed. Eighteen patients were enrolled based on medical history but were later determined not to meet entry criteria because of lesion size or composition (n = 10) or VA (n = 8). The remaining 92 patients completed the NEI VFQ-25, composing the final study group analyzed.

Table 1 shows the characteristics of the study group. The mean age of the participants was 78.3 (SD, 7.9) years; 63% were women, and 96% were Caucasian. Very few data were missing, with the exception of Driving subscale items ("Difficulty driving at night" and "Driving in difficult conditions"), which had 33% (30/92) and 32% (29/92) missing rates, respectively, reflecting the skip pattern of the questionnaire. The mean NEI VFQ-25 subscale scores ranged from 57.7 (SD, 35.0) for the Driving subscale to 87.8 (SD, 22.6) for the Color Vision subscale (Table 2 and Supplementary Table S1, http://www.iovs.org/lookup/suppl/doi:10.1167/iovs.10-5645/-/DCSupplemental).

TABLE 2. Descriptive Statistics and Internal Consistency Reliability (Cronbach's α) of NEI VFQ-25 Subscales

NEI VFQ-25 Subscale*	Score (mean ± SD)	Cronbach's α†
Overall composite score	72.7 ± 19.7	NA
Near activities	63.8 ± 25.7	0.91
Distance activities	70.2 ± 24.4	0.90
Vision-specific dependency	76.6 ± 31.3	0.92
General health	59.0 ± 20.5	NA
General vision	60.9 ± 18.3	NA
Driving	57.7 ± 35.0	0.74
Peripheral vision	79.9 ± 25.2	NA
Color vision	87.8 ± 22.6	NA
Ocular pain	86.1 ± 15.8	0.67
Vision-specific role difficulties	68.5 ± 29.1	0.79
Vision-specific social functioning	85.5 ± 20.2	0.72
Vision-specific mental health	68.5 ± 29.1	0.82

NA, not applicable.

* n = 92 for all subscales except driving (n = 80) and color vision (n = 90).

† Cronbach's α can be calculated only for multi-item scales.

TABLE 3. Correlations between NEI VFQ-25 Subscale Scores and BCVA, Reading Speed, and Restricted Activity Days

	Spearman Rank-Order Correlation Coefficient (*r*)				
	BCVA (Snellen Equivalent)		Reading Speed		
NEI VFQ-25 Subscale	Better-Seeing Eye (*n* = 92)	Worse-Seeing Eye (*n* = 92)	Better-Seeing Eye (*n* = 89)	Worse-Seeing Eye (*n* = 88)	Restricted Activity Days (*n* = 91)
Overall composite score	−0.50*	−0.21†	0.50*	0.35‡	−0.53*
Near activities	−0.48*	−0.17	0.43*	0.29§	−0.52*
Distance activities	−0.54*	−0.20	0.56*	0.36‡	−0.54*
Vision-specific dependency	−0.49*	−0.20	0.49*	0.37‡	−0.55*
General health	−0.01	−0.04	0.02	0.04	−0.04
General vision	−0.43*	−0.14	0.41*	0.32§	−0.34§
Driving	−0.58* (*n* = 80)	−0.28† (*n* = 80)	0.44* (*n* = 77)	0.27† (*n* = 76)	−0.52* (*n* = 79)
Peripheral vision	−0.21†	−0.07	0.33†	0.25†	−0.33§
Color vision	−0.28§ (*n* = 90)	−0.02 (*n* = 90)	0.21† (*n* = 87)	0.09 (*n* = 86)	−0.29§ (*n* = 89)
Ocular pain	0.14	−0.01	0.03	0.02	−0.07
Vision-specific role difficulties	−0.39‡	−0.23†	0.46*	0.33§	−0.53*
Vision-specific social functioning	−0.50*	−0.24†	0.45*	0.34§	−0.45*
Vision-specific mental health	−0.46*	−0.23†	0.34‡	0.28§	−0.44*

* $P < 0.0001$; † $P < 0.05$; ‡ $P < 0.001$; § $P < 0.01$.

Internal Consistency Reliability

Internal consistency reliabilities (Cronbach's α) for the multi-item subscales ranged from 0.67 to 0.92 (Table 2).

Convergent Validity

BCVA and Contrast Sensitivity. The NEI VFQ-25 overall composite, Near Activities, Distance Activities, and Vision-Specific Dependency subscale scores were moderately correlated with BCVA (Snellen equivalent) of the better-seeing eye ($r = -0.50$, -0.48, -0.54, and -0.49, respectively; all $P < 0.0001$; Table 3 and Supplementary Table S2, http://www.iovs.org/lookup/suppl/doi:10.1167/iovs.10-5645/-/DCSupplemental).

The NEI VFQ-25 overall composite, Near Activities, Distance Activities, and Vision-Specific Dependency subscale scores were moderately correlated with contrast sensitivity of the better-seeing eye ($r = -0.46$, -0.45, -0.44, and -0.39, respectively; all $P < 0.001$; Supplementary Table S2, http://www.iovs.org/lookup/suppl/doi:10.1167/iovs.10-5645/-/DCSupplemental).

Restricted Activity Days. The participants reported that they had a mean of 13.0 (SD, 29.6; median, 0) restricted activity days over the past 3 months, with a range of 0.0 to 90.0 days.

Reading Speed. Mean reading speed for the better-seeing eye was 105.1 (SD, 53.1) words per minute (wpm) and 75.7 (SD, 46.2) wpm for the worse-seeing eye. The NEI VFQ-25 overall composite score, Near Activities, Distance Activities, and Vision-Specific Dependency subscale scores were moderately correlated with reading speed of the better-seeing eye ($r = 0.50$, 0.43, 0.56, and 0.49, respectively; all $P < 0.0001$; Table 3).

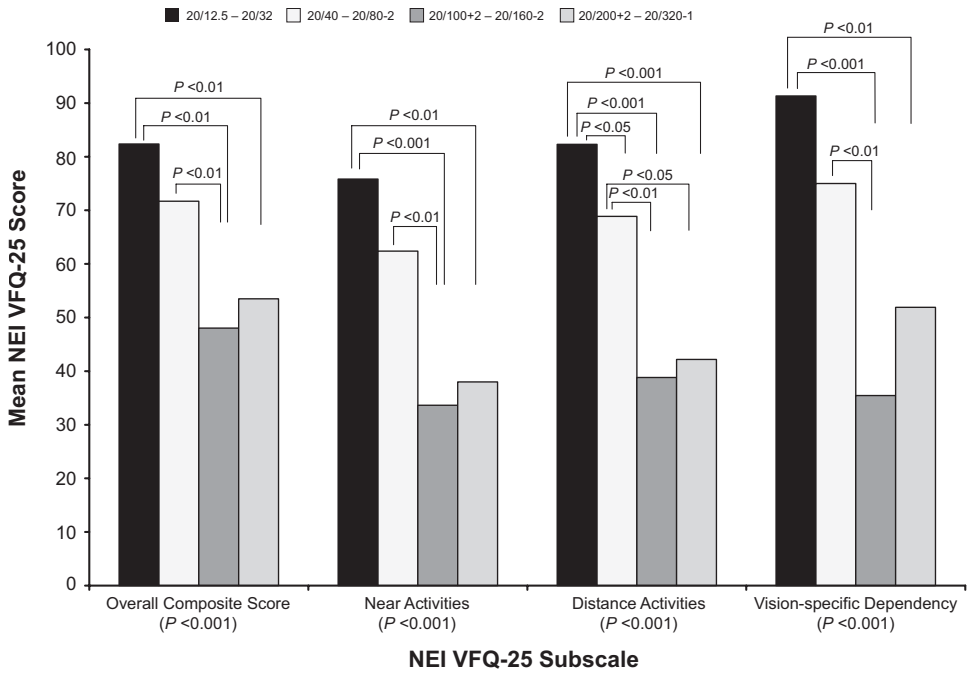

FIGURE 1. NEI VFQ-25 scores by BCVA letter score (Snellen equivalent) of the better-seeing eye (covariates were age and sex).

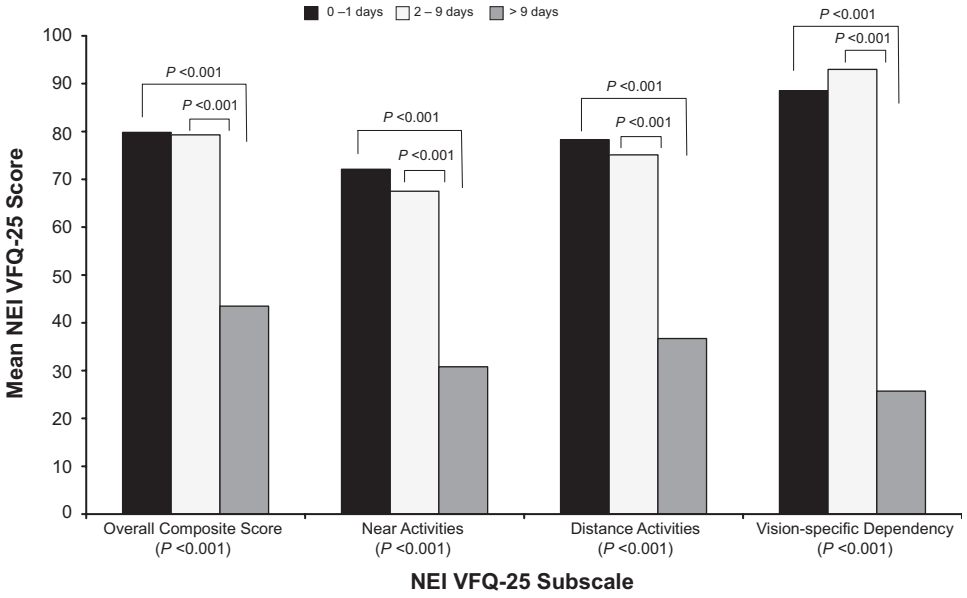

FIGURE 2. NEI VFQ-25 scores by the number of restricted activity days (covariates were age and sex).

Known-Groups Validity

BCVA. Mean NEI VFQ-25 overall composite scores were higher (indicating better visual function) in participants with BCVA of 20/12.5 to 20/32 (letter score, 95–73) than in those with BCVA of $20/100^{+2}$ to $20/160^{-2}$ (letter score, 52–38) and BCVA of $20/200^{+2}$ to $20/320^{-1}$ (letter score, 37–24) in the better-seeing eye (both $P < 0.001$ and $P < 0.01$, respectively; P values reflected pairwise comparison of NEI VFQ-25 overall composite scores between BCVA groups [Fig. 1, Supplementary Fig. S1, http://www.iovs.org/lookup/suppl/doi:10.1167/iovs.10-5645/-/DCSupplemental]). Mean NEI VFQ-25 overall composite scores were also higher in participants with BCVA of 20/40 to $20/80^{-2}$ (letter score, 72–53) compared with the group with BCVA of $20/100^{+2}$ to $20/160^{-2}$ (letter score, 52–38; $P < 0.01$).

Restricted Activity Days. Participants who reported 0 or 1 days of restricted activity had a mean NEI VFQ-25 overall composite score of 79.8 (SEM, 1.7) compared with a score of 43.5 (SEM, 3.4) in those reporting >9 restricted activity days ($P < 0.001$; Fig. 2, Supplementary Fig. S2, http://www.iovs.org/lookup/suppl/doi:10.1167/iovs.10-5645/-/DCSupplemental).

Reading Speed. Participants who read ≤80 wpm with the better-seeing eye had a mean NEI VFQ-25 overall composite score of 59.7 (SEM, 3.3) compared with a mean overall composite score of 79.3 (SEM, 2.4) in those who read >80 wpm (overall F-test $P < 0.001$; Fig. 3 and Supplementary Fig. S3, http://www.iovs.org/lookup/suppl/doi:10.1167/iovs.10-5645/-/DCSupplemental).

DISCUSSION

PROs and functional status measures are increasingly used in addition to traditional measures of VA in clinical trials to examine the effectiveness of new therapies for AMD. The NEI VFQ-25 is the most frequently used measure of patient-re-

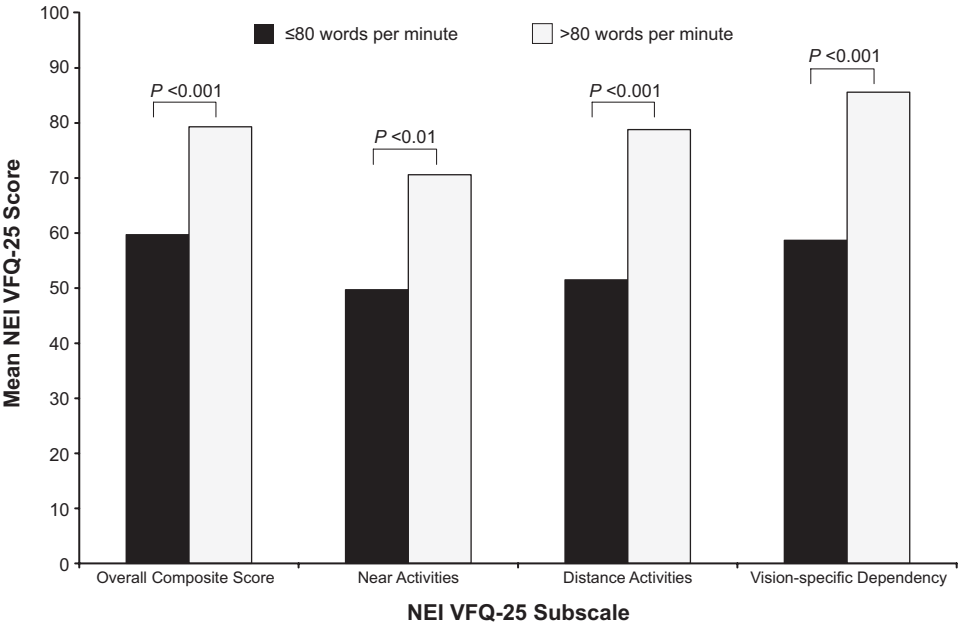

FIGURE 3. NEI VFQ-25) scores by reading speed of the better-seeing eye (covariates were age and sex).

ported, vision-related function in AMD studies.[3,4,6,7,21–24] This study demonstrates that the NEI VFQ-25 overall composite, Near Activities, Distance Activities, and Vision-Specific Dependency scores are at least moderately associated with objective clinical measures of visual function in the better-seeing eye—including BCVA, reading speed, contrast sensitivity, and number of restricted activity days—in patients with neovascular AMD.

The construct validity of the NEI VFQ-25 overall composite and subscale scores is supported by moderate to strong correlations observed with objective clinical and performance-based measures such as VA, reading speed, and contrast sensitivity. We also observed moderate correlations between NEI VFQ-25 scores and the number of patient-reported restricted activity days (Table 3). These findings suggest that impairments in visual function in AMD patients result in substantial problems and restrictions in everyday activities, which is consistent with previous research.[25] Based on this study, there is good evidence supporting the internal consistency reliability of the multi-item NEI VFQ-25 subscales in neovascular AMD populations.

There may be concerns about the generalizability of this sample to larger populations of neovascular AMD patients. Based on comparisons with the SST patient groups[4] and the ranibizumab clinical trials,[10,11] the present study has similar demographic (e.g., age and sex) and clinical characteristics. Reading performance and NEI VFQ-25 subscale and overall composite scores are within a similar range reported in the SST[4] and other AMD patient populations.[3,22] In addition, participants were recruited from a range of settings and locations, including university and community-based practices across the United States. Therefore, we believe that the findings of this psychometric evaluation study are likely to be applicable to other neovascular AMD patient populations.

A growing body of evidence supports the reliability, validity, and responsiveness of the NEI VFQ-25 in patients with AMD.[22] The study is unique in that the research participants were patients with neovascular AMD recruited from community settings and not included in a clinical trial. BCVA, contrast sensitivity, reading speed, and restricted activity days were all assessed in the same patients. The results of this study further confirm that the NEI VFQ-25 is a reliable and valid measure of vision-related function in patients with neovascular AMD.

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APPENDIX

Study sites and clinic staff members participating in this study were as follows: Kevin Blinder and Pam Light, Barnes Retina Institute, St. Louis, MO; David S. Boyer, Jackie Sanguinet, and

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