Published in final edited form as:
Am J Ophthalmol. 2009 October ; 148(4): 558–562. doi:10.1016/j.ajo.2009.05.009.

Comparison of quality of life instruments in adults with strabismus

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Abstract

Purpose—To compare two health-related quality of life (HRQOL) questionnaires in adults with strabismus: the new AS-20 (developed specifically for adult strabismus) and the NEI VFQ-25 (VFQ-25).

Design—Cross-sectional study

Methods—84 adult patients with strabismus (median age 53, range 18-81 years) completed the AS-20 and VFQ-25 HRQOL questionnaires. Patients were categorized as diplopic (n=65), or non-diplopic (n=19). Subnormal HRQOL was defined as below the 5th percentile for adults with no visual impairment. The proportion of patients below normal was compared overall and by diplopia status.

Results—Overall, more patients scored below normal with the AS-20 than with the VFQ-25 (90% vs 29%, P <0.0001). Non-diplopic patients were more often below normal on AS-20 psychosocial subscale than function subscale (95% vs 42%, P=0.002), while diplopic patients were more often below normal on the function subscale (85% vs 68% and P=0.01). On the psychosocial subscale, more non-diplopic than diplopic patients scored below normal (95% vs 68%; P=0.01); on the function subscale more diplopic than non-diplopic patients scored below normal (85% vs 42%; P=0.0005). The VFQ-25 appeared insensitive to non-diplopic strabismus: no patients scored below normal on composite score and no more than 11% scored below normal on VFQ-25 subscales. Of diplopic patients, 37% scored below normal on VFQ-25 composite score. No more than 38% scored below normal on VFQ-25 subscales.

Conclusion—The new AS-20 appears more sensitive than the VFQ-25 for detecting reduced HRQOL in adult strabismus, and therefore may be a more useful tool for clinical assessment and clinical trials.

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B. Financial Disclosures: No conflicting financial relationships exist

C. Contributions of Authors: Design (SRH, DAL, EAB, SRC, JMH) and conduct (SRH, DAL, JMH) of the study; Collection (SRH, DAL, JMH), management (SRH, DAL, JMH), analysis (SRH, DAL, EAB, SRC, JMH), and interpretation (SRH, DAL, EAB, SRC, JMH) of the data; Preparation (SRH, DAL, JMH), review (SRH, DAL, EAB, SRC, JMH), or approval (SRH, DAL, EAB, SRC, JMH) of the manuscript

Introduction

Quantitative assessment of health related quality of life (HRQOL) provides a means of measuring specific effects of strabismus for an individual patient during everyday life. The NEI-VFQ-25 (VFQ-25) questionnaire[1] is commonly used for assessment of HRQOL in many ophthalmic conditions, but there are few data on the performance of such vision-related HRQOL instruments in adults with strabismus. Patient-derived, strabismus-specific HRQOL questionnaires have been recently developed[2-4] but there are no data comparing HRQOL assessment using strabismus-specific questionnaires with assessment using more general vision questionnaires. We compared quality of life scores using the VFQ-25[1] questionnaire and the recently developed Adult Strabismus (AS-20) questionnaire[4] to determine which instrument best detected subnormal HRQOL in adults with strabismus.

Patients and Methods

Institutional Review Board approval was obtained and each patient gave informed consent before participating. All procedures and data collection were conducted in a manner compliant with the Health Insurance Portability and Accountability Act.

The AS-20 consists of 20 questions with 2 established subscales: Psychosocial (10 items) and Function (10 items).[4] For each AS-20 questionnaire item a 5-point Likert type scale is used for responses: ‘never’ (score 100), ‘rarely’ (score 75), ‘sometimes’ (score 50), ‘often’ (score 25), and ‘always’ (score 0).[4] The VFQ-25 consists of 25 questions in 12 subscales: General health, General vision, Ocular pain, Near activities, Distance activities, Vision specific social function, Vision specific mental health, Vision specific role difficulties, Vision specific dependency, Driving, Color vision and Peripheral vision. As described in the instructions outlined in the manuscript first describing the VFQ-25,[1] composite scores were calculated from all subscales with the exception of the ‘General Health’ subscale. Different response options are used depending on the question (full questionnaire with user instructions available at: http://www.nei.nih.gov/resources/visionfunction/vfq_ia.pdf; accessed 23rd February 2009). For AS-20 and VFQ-25 questionnaires, scores range from 0 (worst HRQOL), to 100 (best HRQOL) overall and on predefined subscales.

Normal thresholds

For the purposes of this study we defined subnormal AS-20 and VFQ-25 scores as those below the 5th percentile for visually normal adults. To determine whether alternative definitions of subnormal would influence our findings, we also performed a secondary analysis setting thresholds using 1.96 standard deviations (SD) below mean values for normal non-strabismic adults for both VFQ-25 and AS-20. Using 1.96SD below the mean assumes a Gaussian distribution of the data but HRQOL data in a visually normal population do not follow a Gaussian distribution. Nevertheless, some available datasets only provide mean and SD data, and so percentiles cannot be calculated.

For the VFQ-25 questionnaire, we used previously published normative data, from studies by Varma et al[5] and Mangione et al.[1] For the percentile analysis we used individual scores, made available to us by Varma et al, on 1000 randomly selected, English speaking adults with no visual impairment (from the 4272 published in their manuscript[5]). We performed two secondary analyses, calculating normal thresholds as the mean minus 1.96 SD from: 1) data provided by Varma et al and 2) the published report by Mangione et al. Because the Mangione report did not include the composite VFQ-25 score, we computed a mean (SD) composite score as the mean of all the sub-scales with the exception of the General Health subscale as described in the VFQ-25 instructions.[1] Derived normal thresholds for VFQ-25 composite score and for each of the VFQ-25 subscales are shown in Table 1.

For the AS-20 questionnaire there were limited previously published normative data. Therefore, we calculated the 5th percentile from 31 visually-normal adults (median age 45, range 23 to 63 years). For the secondary analyses we calculated the normal threshold for the AS-20 using the mean minus 1.96SD from the same group of 31 visually normal adults. Nineteen (61%) were female and for 29 (94%) race was self-reported as 'White.' All subjects had no history of strabismus or amblyopia and underwent a full orthoptic examination. All were orthotropic at distance and near fixation, and had no more than 10 pd of horizontal phoria and no vertical heterophoria by prism and alternate cover test. Stereoacuity was 40 seconds of arc using the Frisby test, and best corrected visual acuity was at least 20/25 in each eye (median 20/20 in each eye). Of these 31 visually normal adults, data on 13 have been reported previously.[4] Derived normal thresholds for AS-20 composite score and for AS-20 subscales are shown in Table 1.

Patients

Ninety-six adults with strabismus (median 50.5, range 18-81 years) were prospectively recruited from outpatient clinics to complete the AS-20 and VFQ-25 HRQOL questionnaires. Patients were classified as 'diplopic,' 'non-diplopic' or 'rare diplopia' based on their history and clinical exam. The 12 patients classified as 'rare diplopia,' reported vague symptoms of occasional diplopia. For the purposes of this present study these patients were excluded from further analysis because our goal was to determine whether the questionnaires would discriminate between patients with and without true binocular diplopia. Of the 84 remaining patients, 65 were classified as diplopic and 19 as non-diplopic. 42 (50%) had undergone strabismus surgery historically (at least one year prior to assessment), and had residual or consecutive strabismus at the time of assessment.

Patients completed AS-20 and VFQ-25 questionnaires without assistance during the office visit, following simple verbal and written instructions.[4] (http://www.nei.nih.gov/resources/visionfunction/vfq_ia.pdf; accessed 23rd February 2009). For both questionnaires, written instructions indicated that the patient should answer each question based on their visual experience with habitual refractive correction in place, including any prism correction if this was worn habitually (26 (40%) of 65 diplopic patients). For the purposes of standardization, patients were asked to complete the AS-20 questionnaire first, followed by the VFQ-25.

Patients with diplopia

Of the 65 patients with diplopia 27 had neurogenic strabismus, 27 childhood onset / idiopathic strabismus, 10 had mechanical strabismus and 1 sensory strabismus. Twenty patients had a primary esodeviation; 24 patients had a primary exodeviation, 17 had a primary vertical deviation, and 4 were orthophoric in primary position following surgery over 1 year previously but had residual strabismus in eccentric gaze positions. Visual acuity ranged from 20/15 to 20/40 (median 20/20) in the better eye and from 20/15 to 20/80 (median 20/25) in the worst eye. 12 (18%) of 65 patients had ocular co-morbidity such as cataract, glaucoma or previous retinal detachment.

Patients without diplopia

Of the 19 patients without diplopia, 14 had childhood onset / idiopathic strabismus, 3 had sensory strabismus and 2 neurogenic strabismus. Two patients had a primary esodeviation; 15 patients had a primary exodeviation, and two had a primary vertical deviation. Visual acuity ranged from 20/15 to 20/40 (median 20/20) in the better eye and from 20/20 to 20/800 (median 20/30) in the worst eye. Five (26%) of 19 patients had ocular co-morbidity such as cataract, glaucoma or previous retinal detachment.

Analysis

For each patient, on each questionnaire, mean composite and subscale scores were calculated. The calculated normal thresholds are shown in Table 1. The lowest thresholds were found using the 5th percentile of the data provided by Varma and the highest using 1.96SD below the mean of the Mangione data. We therefore used these two extremes to calculate the proportion of subjects falling below defined normal thresholds across all patients and for sub-groups of patients with and without diplopia. The proportion of patients with below normal scores using the AS-20 was compared to the proportion of patients with below normal scores using the VFQ-25 with McNemar's tests. Proportions of below normal scores for patients with and without diplopia were compared using Fishers exact tests.

Results

Proportions of subnormal scores using 5th percentile threshold

All strabismus patients—More patients scored below normal on AS-20 than VFQ-25 composite scores (90% vs 29%; P<0.0001, Table 2). On AS-20 subscales, 74% scored below normal on the Psychosocial subscale and 75% on the Function subscale (Table 2). The VFQ-25 subscales with the highest proportion of subnormal scores were: Driving (32%), Distance activities (25%) and Vision specific role difficulties (21%) (Table 2).

Patients with diplopia—Of the 65 patients with diplopia, significantly more scored below normal on AS-20 composite score than on the VFQ-25 composite score (89% vs 37%, P<0.0001, Table 2). 85% of diplopic patients scored below normal on the AS-20 Function subscale and 68% on the Psychosocial subscale (P=0.01, Table 2). Of VFQ-25 subscales, the highest proportion of subnormal scores were: Driving (38%), Distance activities (31%) and Vision specific role difficulties (28%) (Table 2).

Patients without diplopia—Of the 19 patients without diplopia significantly more scored below normal on the AS-20 composite score than on the VFQ-25 composite score (95% vs 0%, Table 2). 95% of non-diplopic patients scored below normal on the AS-20 Psychosocial subscale and 42% on the AS-20 Function subscale (P=0.002, Table 2). Non-diplopic patients very rarely scored below normal on any of the VFQ-25 sub scales: the highest proportion of below normal scores was 11% on the Driving subscale and General health subscales (Table 2).

Comparison between patients with and without diplopia—On the AS-20 questionnaire, composite scores were comparable between diplopic and non-diplopic patients (Table 2). Nevertheless more non-diplopic than diplopic patients scored below normal on the Psychosocial subscale (95% vs 68%; P=0.01, Table 2) whereas more diplopic than non-diplopic patients scored below normal on the Function subscale (85% vs 42%; P=0.0005, Table 2). On the VFQ-25, more diplopic than non-diplopic patients scored below normal on the composite score (37% vs 0%; P=0.001, Table 2). More diplopic patients also scored below normal on 5 of the 11 subscales (Distance activities, Vision specific mental health, Vision specific role difficulties, Driving and Peripheral vision) (Table 2). There were no VFQ-25 subscales where non-diplopic patients scored below normal more often than diplopic patients.

Secondary analysis - proportions of subnormal scores using mean minus 1.96SD threshold

Using thresholds based on the mean minus 1.96 SD (Mangione et al VFQ-25 data and normal AS-20 data), we found very similar results to those obtained using the 5th percentile to define normal thresholds (Table 2). More patients (overall, diplopic and non-diplopic) scored below normal on the AS-20 than on the VFQ-25, on composite scores and on subscales.(Table 2).

Discussion

Both AS-20 and VFQ-25 questionnaires detected reduced HRQOL in adults with strabismus. The patient-derived, strabismus-specific AS-20 questionnaire detected subnormal HRQOL more often than the vision-specific VFQ-25 questionnaire. The AS-20 questionnaire and component subscales (Psychosocial and Function) were better able to detect the impact of strabismus on HRQOL, in patients both with and without diplopia.

Our finding that more patients scored below normal thresholds using the AS-20 than using the VFQ-25 suggests that the strabismus-specific AS-20 is better able to detect reduced HRQOL in adults with strabismus. This greater sensitivity of the AS-20 to the effects of strabismus may have been predicted given the expectation that condition-specific questionnaires address HRQOL concerns specific to the condition of interest.[6, 7] Future studies evaluating other aspects of validity such as test retest reliability and responsiveness (e.g. following treatment) will further help confirm the usefulness of these HRQOL instruments for clinical evaluation of adult strabismus.

The VFQ-25 questionnaire was more sensitive to the effects of strabismus in patients with diplopia than in those without diplopia. It is likely that this finding reflects the VFQ-25 emphasis on vision deficits in contrast to psychosocial concerns. There are few previous data on the performance of the VFQ-25 in adults with strabismus, but a study by Bradley et al[8] reported patients with Graves eye disease with diplopia scored lower (worse HRQOL) on the VFQ-25 than those with Graves disease but without diplopia, and presumably, also without strabismus. In our present study, VFQ-25 subscales such as Driving, Distance Activities and Vision specific role difficulties appeared somewhat sensitive to diplopic strabismus, but not non-diplopic strabismus. Nevertheless, the proportion of subnormal scores was greater using the AS-20, both Psychosocial and Function subscales detecting reduced HRQOL in strabismus patients with and without diplopia. Interestingly, specific topic areas in the VFQ-25 such as Driving, which are not covered in the AS-20, did not yield a very high proportion of below normal responses in this study population (32% overall, and 38% in patients with diplopia). This finding supports our previous decision, during the development of the AS-20, to exclude questions regarding driving.[4]

The two established subscales of the AS-20 (Function and Psychosocial)[4] appeared to discriminate well between patients with and without diplopia in the present study. As might be expected based on clinical experience, significantly more diplopic than non-diplopic patients scored below normal on the function subscale (85% vs 42%; P=0.0004, Table 2) and significantly more non-diplopic than diplopic patients scored below normal on the psychosocial subscale (95% vs 68%; P=0.02, Table 2). Nevertheless, as noted in our previous report,[4] while impact on function appears predominant for diplopic patients, the majority also report psychosocial concerns. Similarly, while psychosocial concerns dominate for non-diplopic patients, a large proportion also report impact on function. Identifying the type of HRQOL concerns present for an individual patient may be important in their clinical management.

There are several limitations to this study. First, the VFQ-25 was designed to measure HRQOL in adults with reduced visual acuity due to eye disease such as cataract, potentially making it more likely to detect reduced HRQOL in the few patients in our study who had reduced visual acuity. Nevertheless, such an effect would make the VFQ-25 more rather than less sensitive to reduced HRQOL, strengthening our finding of better detection of reduced HRQOL using the AS-20. Another limitation is that we recruited a relatively small number of non-diplopic patients. Nevertheless, it is noteworthy that the observed difference was large enough that we were still able to demonstrate statistically significant differences between proportions scoring below normal. Also, we defined normal thresholds on the AS-20 using a relatively small

number of racially homogeneous, visually normal adults, but the AS-20 normal thresholds based on the 5th percentile and the mean minus 1.96SD were very similar. An additional potential limitation is that our primary analysis is based on Latino visually normal adults,[5] but secondary analysis using a presumably different racial group[1] yielded similar results.

The new strabismus-specific, patient-derived AS-20 questionnaire is more sensitive than the VFQ-25 for detecting reduced HRQOL in adults with strabismus and discriminates between patients with and without diplopia. Further studies are needed to evaluate relationships between severity of strabismus and these measures of HRQOL.

Acknowledgments

A. Funding / Support: Supported by National Institutes of Health Grants EY015799 (JMH), EY013844 (EAB), Research to Prevent Blindness, New York, NY (JMH as Olga Keith Weiss Scholar and an unrestricted grant to the Department of Ophthalmology, Mayo Clinic), and Mayo Foundation, Rochester, MN.

D. Conformity with Author Information: Institutional Review Board/Ethics Committee approval was obtained by the Institutional Review Board at the Mayo Clinic, Rochester MN. All experiments and data collection were conducted in a manner compliant with the Health Insurance Portability and Accountability Act.

E. Other Acknowledgments: Rohit Varma MD, MPH very kindly provided individual scores on 1000 randomly selected English speaking subjects with no visual impairment from the Los Angeles Latino Eye Study (Reference #5: Varma R, Wu J, Chong K, Azen SP, Hays RD. Impact of severity and bilaterality of visual impairment on health-related quality of life. Ophthalmology 2006;113:1846-1853) for us to calculate normal thresholds.

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Table 1

Normal thresholds on the Adult Strabismus (AS-20) and National Eye Institute Vision Function questionnaire (VFQ-25) health related quality of life questionnaires, based on the 5th percentile and mean minus 1.96 standard deviations in visually normal adults.

	Normal threshold based on 5th percentile	**Normal threshold based on mean minus 1.96 SD**	
	AS-20 (N=31 visually normal adults)	**AS-20 (N=31 visually normal adults)**	
AS-20 composite score	84	84	
Psychosocial subscale score	93	89	
Function subscale score	70	75	
	VFQ-25 (N=1000, Varma et al[5])	**VFQ-25** (N=1000, Varma et al[5])	**VFQ-25** (N=122, Mangione et al[1])
VFQ-25 composite score	64	66	71
General health	25	9	22
General vision	40	41	54
Ocular pain	50	45	61
Near activities	50	48	67
Distance activities	58	63	71
Vision specific social functioning	75	76	93
Vision specific mental health	44	46	68
Vision specific role difficulties	50	59	66
Vision specific dependency	67	67	87
Driving	63	66	52
Color vision	75	75	82
Peripheral vision	50	58	77

Table 2

Proportion of adult strabismus patients scoring below normal thresholds on the AS-20 and VFQ-25 health related quality of life questionnaires. Bold numbers indicate a significant difference between diplopic and non-diplopic patients (P<0.05 for each comparison)

	Proportion of strabismus patients scoring below normal based on 5th percentile thresholds in visually normal adults			**Proportion of strabismus patients scoring below normal based on mean minus 1.96 standard deviations in visually normal adults**		
	Overall (n=84)	**Diplopia (n=65)**	**No diplopia (n=19)**	**Overall (n=84)**	**Diplopia (n=65)**	**No diplopia (n=19)**
	AS-20 questionnaire (normals: N=31)			**AS-20 questionnaire (normals: N=31)**		
AS-20 composite score	90%	89%	95%	90%	89%	95%
Psychosocial subscale	74%	**68%**	**95%**	70%	**63%**	**95%**
Function subscale	75%	**85%**	**42%**	81%	**91%**	**47%**
	VFQ-25 questionnaire (normals: N=1000, Varma et al[5])			**VFQ-25 questionnaire** (normals: N=122, Mangione et al[1])		
VFQ-25 composite score	29%	**37%**	**0%**	37%	**45%**	**11%**
General health	2%	**0%**	**11%**	2%	**0%**	**11%**
General vision	5%	6%	0%	18%	**23%**	**0%**
Ocular pain	5%	5%	5%	15%	18%	5%
Near activities	17%	20%	5%	39%	**46%**	**16%**
Distance activities	25%	**31%**	**5%**	40%	**49%**	**11%**
Vision specific social functioning	18%	22%	5%	49%	**57%**	**21%**
Vision specific mental health	18%	**23%**	**0%**	45%	51%	26%
Vision specific role difficulties	21%	**28%**	**0%**	45%	**54%**	**16%**
Vision specific dependency	20%	25%	5%	43%	**51%**	**16%**
Driving	32%	**38%**	**11%**	25%	29%	11%
Color vision	6%	8%	0%	18%	**23%**	**0%**
Peripheral vision	17%	**22%**	**0%**	64%	**72%**	**37%**