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R2

**THE STROKE AND APHASIA QUALITY OF LIFE SCALE- 39 (SAQOL-39): EVALUATION
OF ACCEPTABILITY, RELIABILITY AND VALIDITY**

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R2

Full title

**THE STROKE AND APHASIA QUALITY OF LIFE SCALE- 39 (SAQOL-39): EVALUATION
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Abstract

Background and purpose: Health-related quality of life (HRQL) is a key outcome in stroke clinical trials. Stroke-specific HRQL scales (e.g., SS-QOL, SIS) have generally been developed with samples of stroke survivors that exclude people with aphasia. We adapted the SS-QOL for use with people with aphasia to produce the Stroke and Aphasia Quality of Life Scale (SAQOL). We report results from the psychometric evaluation of the initial 53-item SAQOL and the item-reduced SAQOL-39.

Methods: We studied 95 people with long-term aphasia to evaluate the acceptability, reliability and validity of the SAQOL and the SAQOL-39 using standard psychometric methods.

Results: A total of 83/95 (87%) were able to complete the SAQOL by self-report and their results are reported here. Results supported the reliability and the validity of the overall score on the 53-item SAQOL, but there was little support for hypothesized subdomains. We derived a shorter version (SAQOL-39) using factor analysis, which identified four subdomains (physical, psychosocial, communication and energy). The SAQOL-39 demonstrated good acceptability, internal consistency (Cronbach's $\alpha=0.74-0.94$), test-retest reliability (ICC=0.89-0.98) and construct validity (corrected domain-total correlations $r=0.38-0.58$, convergent $r=0.55-0.67$ and discriminant $r=0.02-0.27$ validity).

Conclusions: The SAQOL-39 is an acceptable, reliable and valid measure of HRQL in people with long-term aphasia. Further testing is needed to evaluate the responsiveness of the SAQOL-39 and to investigate its usefulness in evaluative research and routine clinical practice.

Outcome measures which incorporate patients' views about health-related quality of life (HRQL) are now commonly used to evaluate health care interventions. HRQL refers to the impact of health on a person's ability to lead a fulfilling life¹ and generally incorporates the individual's perceptions of physical, mental/emotional, family and social functioning²⁻⁴. Measures of HRQL are particularly relevant in stroke where the key aims of rehabilitation are to facilitate adaptation to disability, to promote social and community integration and to maximize well-being/quality of life⁵. Although a number of stroke-specific quality of life scales have been developed,⁶⁻⁹ most exclude stroke survivors with aphasia and/or cognitive decline who are in fact those most prone to social isolation and exclusion^{10,11}. A stroke-specific HRQL scale that is appropriate for use with people with aphasia is needed for use in clinical trials and service evaluation.

We adapted the Stroke-Specific Quality of Life Scale (SS-QOL)⁹ for use with people with aphasia, producing the Stroke and Aphasia Quality of Life Scale (SAQOL). In this paper, we report results from the psychometric evaluation of the initial 53-item SAQOL and the item-reduced SAQOL-39.

Subjects and Methods

The SAQOL

The development of the SAQOL has been previously reported^{12,13}. In short, the SAQOL is an interview-administered self-report scale which comprises the 49 items of the SS-QOL (modified to be communicatively accessible to people with aphasia) and four additional items to increase its content validity with this population. These four items are on difficulties with understanding speech, difficulties with making decisions and on the impact of language problems on family life and social life. Changes to the SS-QOL to produce the SAQOL were made through consultation with expert professionals and pilot testing with people with aphasia. The SAQOL was then pre-tested with 18 people with aphasia with good results^{12,13}.

The 53 items of the SAQOL were hypothesized to group into 12 subdomains based on the SS-QOL: self-care, mobility, upper-extremity function, work, vision, language, thinking, personality, mood, energy, family and social roles. The SAQOL has two response formats, both based on a 5-point scale: 1='couldn't do it at all' to 5='no trouble at all' and 1='definitely yes' to 5='definitely no'. Overall and subdomain scores can range from 1-5: the overall SAQOL score is calculated by summing across the items and dividing by the number of items; subdomain scores are calculated the same way.

Design and participants

The study design was a cross-sectional, interview-based psychometric study. Participants were recruited from three settings: two Speech and Language Therapy (SLT) service providers - one inner city and one semi-rural-, and one not-for-profit organization for people with aphasia. The target population was people with long-term aphasia. Inclusion criteria were: aphasia due to a stroke of at least 1-year duration, no known pre-stroke history of severe cognitive decline or mental health problems, and living at home prior to the stroke. Participants were identified through review of the SLT records at each site. Eligible participants were invited to take part in the study and written consent was obtained from those willing to take part. Test-retest reliability data were collected, within a period of 2-14 days, from the participants from the first recruitment site who agreed to have the SAQOL administered twice.

Procedure and measures

Participants were interviewed at home or at the SLT site. We used the Frenchay Aphasia Screening Test (FAST)¹⁴ to screen for aphasia. The total FAST score determined overall aphasia severity and the receptive FAST score determined which participants were able to self-report. A FAST receptive score of 7/15 was used as a cut-off score below which significant others provided proxy reports. Measures comprised the SAQOL, General Health Questionnaire (GHQ-12)¹⁵, Raven's Coloured Progressive Matrices (RCPM)¹⁶, Frenchay Activities Index

(FAI)¹⁷, and MOS Social Support Survey (SSS)¹⁸. Participants were also asked to rate their overall quality of life compared to before the stroke on a 5-point scale (1=a lot worse to 5=better than before the stroke). The American Speech and Hearing Association Functional Assessment of Communication Skills for Adults (ASHA-FACS)¹⁹ was also completed for each participant.

Psychometric analyses

We used gold standard methods^{20, 21} to evaluate the psychometric properties of the SAQOL using a strategy developed in previous work²². Table 1 summarizes the psychometric tests and criteria used to evaluate acceptability, reliability and validity. Data analyses were carried out using SPSS 10.0 for Windows²³.

[table 1 about here]

Results

Respondents

A total of 95 of 116 eligible participants (82%) agreed to take part. Of these, 12 were excluded from the analyses as they were unable to self-report on the questionnaires (<7/15 on the receptive domains of the FAST), leaving 83 subjects. The majority of the sample was male (62.7%), white (78.3%) and married/had partner (62.6%) and 43.4% were over 65 years of age.

[table 2 about here]

Stage 1: Psychometric evaluation of the 53-item SAQOL

Acceptability and reliability (table 3): The SAQOL had minimal missing data and floor/ceiling effects but 11 items (21%) showed unacceptable skew. The overall scale had good internal consistency (alpha= 0.93). Four of the hypothesized subdomains failed the criterion for internal consistency $\geq .70$ (work, vision, personality and family roles). Test-retest reliability data were

collected from 17 participants. Their characteristics were similar to the overall sample in terms of age, gender, marital status and overall and receptive FAST scores. The SAQOL showed excellent test-retest reliability for the overall score (ICC=0.98) and for the 12 subdomains (ICC=0.84-0.99).

[table 3 about here]

Validity

Within scale analyses: All hypothesized subscales were moderately to highly correlated ($r=0.39-0.73$) with the total score, except for vision ($r=0.26$). As expected, subscales measuring related constructs (e.g., self-care, mobility, work) were correlated ($r=0.73-0.78$), whereas correlations were lower between less related subscales (e.g., self-care and mood $r=0.29$). All intercorrelations between subscales were below the criterion of 0.80, except for self-care with upper extremities ($r=0.84$).

The results of Principal Components Analysis (PCA) indicated that 5 items did not load highly (<0.20) on the general component. Principal axis factor analysis (PAF) with varimax rotation was used to evaluate the 12 hypothesized subdomains. The results did not support the 12-subdomain structure of the SAQOL, and no clear alternative models were identified.

Comparisons with external criteria: Analysis of variance of mean SAQOL scores showed significant differences between respondents who were better/same, worse or a lot worse than before the stroke ($F(2, 80)=10.609$, $p<.001$, pairwise comparisons $p<.05$), thus supporting the construct validity of the SAQOL. Comparisons with external measures (table 4) provide further support for convergent ($r=0.44-0.59$) and discriminant ($r=0.26-0.29$) validity of the overall SAQOL. Results, however, do not support the construct validity of four of the tested subscales (thinking, mood, family roles and social roles).

[table 4 about here]

Stage 2: development and psychometric evaluation of the SAQOL-39

PAF with varimax rotation was used to develop an item reduced version of the SAQOL, and to identify a conceptually clear and psychometrically sound subdomain structure. Results of the KMO test showed adequate sampling adequacy, and Bartlett's test of sphericity was significant for all models. Preliminary analyses produced a 7-factor model. A total of 14 items that did not load (<0.40) or which crossloaded were removed, and the analyses repeated on the remaining 39 items. The final model for the reduced 39-item SAQOL explained 48% of the variance and included four factors: physical, psychosocial, communication and energy (table 5).

[table 5 about here]

Acceptability and reliability (table 3): The acceptability of the SAQOL-39 is demonstrated by minimal missing data and floor ceiling effects and only 4 skewed items. It shows good internal consistency and test-retest reliability for scale ($\alpha=0.93$; $ICC=0.98$) and subscale scores ($\alpha=0.74-0.94$; $ICC=0.89-0.98$).

Validity

Within scale analyses: Intercorrelations between SAQOL-39 subscale scores ($r=.10-.47$) and correlations between subscale and total scores ($r=.38-.58$) are all acceptable. Results support the 4-factor model described above.

Comparisons with external criteria (table 4): Results provide good support for known groups ($F(2, 80)=10.609$, $p<.001$), convergent ($r=0.46-0.58$) and discriminant ($r=0.19-0.27$) validity. The physical, communication and energy subscales show good convergent ($r=0.39-0.67$, $r=0.55$, $r=0.32$, respectively) and discriminant ($r=0.10-0.26$, $r=0.08-0.21$, $r=-0.10-0.14$, respectively) validity. The psychosocial subdomain shows good discriminant ($r=0.12-0.20$) and

adequate convergent validity ($r=0.28-0.62$) with only one correlation lower than predicted ($r=0.28$ with the SSS).

Discussion

Existing quality of life scales are hard to use with people with aphasia who may have difficulty understanding some of the items or expressing their responses. We modified a stroke-specific scale, the SS-QOL, for use with people with aphasia and tested its psychometric properties in a group of people with long-term aphasia. The fact that 87% (83/95) of the respondents were able to self-report in an interview format suggests that use of the SAQOL would allow the majority of stroke survivors to be included in trials, thus minimizing the need for proxy respondents. This is important as there tends to be a significant difference in proxy- and self-reports of functional status and quality of life after stroke^{27, 28}.

Although our results confirm the acceptability, reliability and validity of the 53-item SAQOL, there is little support for its hypothesized subdomain structure. We therefore used factor analysis to develop a shorter 39-item version. The SAQOL-39 shows good acceptability, internal consistency, test-retest reliability and construct validity. Moreover, there is support for four conceptually clear and psychometrically robust subdomains (physical, psychosocial, communication and energy), which have been consistently identified by stroke survivors as among the areas of functioning most affected by stroke^{6,9,11}. The SAQOL-39 is therefore a highly relevant measure to stroke survivors which is relatively short and does not produce significant respondent burden.

An important consideration is the representativeness of our sample. Although there are no comparison data for stroke survivors with aphasia, respondents in this study are similar to stroke survivors in the UK. Stroke is more common in men and in older people²⁹; in our sample 63% were male and 44% were over 65 years old. In the study area, 24% of the population is Black or Asian³⁰ compared with 22% in our sample. There were, however, differences in social

class between our sample and the UK stroke population. Stroke is more prevalent in people from manual social classes²⁹, whereas 57% of our sample was from non-manual social classes. This may reflect the geographical area from which the sample was drawn. As it is possible that socioeconomic status has an effect on HRQL, we compared the SAQOL-39 scores of our different socioeconomic groups. We found no significant differences in the HRQL of the groups ($F(7,75) = .64, p \leq .72$), even when we collapsed them in broader social classes ($F(3,79) = .92, p \leq .43$).

In this study, we used the same sample for item reduction and psychometric evaluation of the SAQOL-39. It is important that the psychometric properties of the SAQOL-39 are re-evaluated in an independent sample. Further psychometric testing should also evaluate the responsiveness of the SAQOL-39.

The SAQOL-39 is a psychometrically robust measure that can be used to assess HRQL in the majority of stroke survivors, including people with aphasia, in clinical practice and research. As is common with new measures, further research is needed to confirm its psychometric properties and to determine its appropriateness as a clinical outcome measure. The SAQOL-39 is a new and promising measure for use in treatment and service evaluation, clinical audit and treatment prioritisation.

Note: Copies of the SAQOL-39 and the Users' Manual are available from: k.hilari@city.ac.uk

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TABLE1. Psychometric Tests and Criteria

Psychometric property	Definition/Test	Criteria for Acceptability
1. Acceptability	The quality of data; assessed by completeness of data and score distributions	Applied to items: - missing data <10% - floor/ceiling effects <80% (i.e. high endorsement rates at the bottom and top ends of the response scale) - skewness between +1 to -1 for at least 75% of items. Some negative skewness is expected, but should not exceed 25% of items.
2. Reliability		
2.1 Internal consistency	The extent to which items comprising a scale measure the same construct (e.g. homogeneity of the scale); assessed by Cronbach's alphas and item-total correlations	- Cronbach's alphas > 0.70²⁰ - Item-total correlations $\geq$ 0.30²⁰
2.2 Test-retest reliability	The stability of a measuring instrument; assessed by administering the instrument to respondents on two different occasions and examining the correlation between test and retest scores (test-retest period 2-14 days ²¹)	Intraclass correlation coefficients (ICC) > 0.75²¹
3. Validity		
3.1 Construct validity		
3.1.1 Within-scale analyses	Evidence that a single entity (construct) is being measured and that items can be combined to form a summary score and that subscales are consistent with conceptual model; assessed on the basis of evidence of good internal consistency, intercorrelations between subdomains, correlations between subdomains and corrected total score (i.e., total score with relevant subdomain removed), and results from factor analysis.	- Internal consistency (Cronbach's alpha) > 0.70 - High correlations (0.50-0.80) between related subdomains (e.g., self-care and mobility) and lower correlations (<0.50) for less related subdomains (e.g., mood and self-care) - Moderate correlations between subdomains and total scores (0.30-0.80) - Evidence from factor analysis that a single construct is being measured and of a conceptually clear factor model: → Principal components analysis (PCA): items should load >.2 on the first component → Principal axis factoring (PAF): a sound factor model should be conceptually clear and meet the following criteria^{24, 25}: items should load $\geq$ 0.40 and should not crossload (i.e., load on 2 or more factors with values $\geq$ 0.4 and with a difference of <0.2 between them)²⁴; and at least 3 items per factor.

Psychometric property	Definition/Test	Criteria for Acceptability
3.1.2 Analyses against external criteria*		
3.1.2.1 Known group differences/ hypothesis testing	The ability of a scale to differentiate known groups; assessed by comparing mean SAQOL scores of 3 groups: respondents who rated their HRQL as the same or better (group 1), a little worse (group 2) or a lot worse (group 3) than before the stroke.	Significant differences in mean SAQOL scores between the three groups.
3.1.2.2 Convergent validity	Evidence that the SAQOL is correlated with measures of the same or similar constructs ; assessed on the basis of correlations between the SAQOL and the FAST, ASHA-FACS, RCPM, GHQ-12, FAI, SSS.	- Moderately high correlations (≥ 0.60) between the : → SAQOL Language with language and communication measures (FAST, ASHA-FACS) → SAQOL Thinking with cognition (RCPM) → SAQOL Mood with GHQ-12 → SAQOL Work with activities (FAI) - Moderate correlations (0.30-0.59) between: → SAQOL with GHQ-12, FAI, ASHA-FACS → SAQOL thinking, personality, energy, social roles, family roles and work with GHQ-12 → SAQOL personality, mood, social and family roles with social support (SSS) → SAQOL social and family roles with FAI → SAQOL work with FAST
3.1.2.3 Discriminant validity	Evidence that the scale is not correlated with measures of different constructs ; assessed on the basis of correlations with measures of different constructs	Low correlations (< 0.30) between SAQOL and measures of different constructs (see last column in table 4)

Adapted from Lamping et al., 2002

* The 'physical' subdomains of the SAQOL were not included in this part of the validation process as aphasia per se does not affect these domains. Validation of these domains would require administering several other measures of aspects of physical functioning (e.g., self-care, upper extremity function) which would have significantly increased respondent burden.

TABLE 2. Respondent characteristics (N=83)

Variable	n (%)
Gender	
Female	31(37.3)
Male	52 (62.7)
Age	
Mean [SD]	61.67 [15.47]
Range	21-92
21-45	13 (15.7)
46-65	34 (41)
66+	36 (43.4)
Stroke type	
Ischaemic	36 (43.4)
Haemorrhagic	16 (19.3)
Unknown	31 (37.3)
Time post stroke	
Mean in years [SD]	3.5 [3.09]
Range	1y 1m-20y 10m
1-2 years post onset	26 (31.3)
>2-4 years post onset	31 (37.3)
>4 years post onset	26 (31.3)
Ethnic group	
Asian	7 (8.4)
Black	11 (13.3)
White	65 (78.3)
Marital status	
Married	42 (50.6)
Has partner	10 (12)
Single	14 (16.9)
Divorced or widowed	17 (20.5)
Socioeconomic status (revised SEC) ²⁶	
Professional/senior manager	23 (27.7)
Ass. Professional/ junior manager	6 (7.2)
Other admin. And clerical worker	13 (15.7)
Own account non-professional	5 (6)
Supervisor, technician and related worker	11 (13.3)
Intermediate worker	9 (10.8)
Other worker	12 (14.5)
Never worked/other inactive	4 (4.8)
Employment status	
Retired before stroke	31 (37.3)
Inactive because of stroke	47 (56.6)
Some p/t or voluntary work	3 (3.6)
Student	2 (2.4)
Cognition (RCPM scores converted to Standard Progressive Matrices scores/grades)	
Intellectually impaired ($\leq 5^{\text{th}}$ percentile)	3 (3.6)
Below average ($\leq 25^{\text{th}}$ percentile)	45 (54.2)
Average (25^{th} - 75^{th} percentile)	17 (20.5)
Above average ($\geq 75^{\text{th}}$ percentile)	15 (18.1)
Intellectually superior ($\geq 95^{\text{th}}$ percentile)	2 (2.4)
Aphasia severity (FAST score)	
Severe (1-10)	9 (10.8)
Moderate (11-20)	29 (34.9)
Mild (21-30)	45 (54.2)

TABLE 3: Acceptability and reliability of SAQOL and SAQOL-39 (N=83)

	SAQOL	SAQOL-39
Acceptability		
Missing data (%)	0-2.4	0-1.2
Scale score range	1-5	1-5
Sample score range	2.13-4.47	1.72-4.46
Mean (SD)	3.39 (.62)	3.27 (.70)
Floor/ceiling effects (%)	0/1.2	0/0
Skewness (>±1)	11 items affected (21%)	4 items affected (10.2%)
Reliability		
Internal consistency Cronbach's alpha		
Scale	.93	.93
Subdomains	.58-.90, with 4 domains <.70	.74-.94
Item-total correlations	.07-.67 (11 items <.30)	.22-.69 (4 items <.30)
Test-retest reliability ¹ Intraclass correlation coefficient (ICC)		
Scale	.98	.98
Subdomains	.84-.99	.89-.98

¹ N=17

TABLE 4: Convergent and discriminant validity of SAQOL and SAQOL-39

Instrument		Validity		
		Convergent		Discriminant
		Same construct (correlations $\geq .60$ predicted)	Similar construct (correlations .30-.59 predicted)	(correlations $< .30$ predicted)
SAQOL	Mean		GHQ-12: .58** FAI: .59** ASHA-FACS: .44**	FAST: .29** RCPM: .29** SSS: .26**
	Subdomains			
	Language	FAST: .63** ASHA-FACS: .61**		RCPM: .11 FAI: .31** SSS: .10
	Thinking	RCPM: .06	GHQ-12: .41**	FAST: .03 ASHA-FACS: .09 FAI: .18 SSS: .20
	Personality		GHQ-12: .57** SSS: .40**	FAST: .03 ASHA-FACS: -.04 RCPM: .18 FAI: .18
	Energy		GHQ-12: .32**	FAST: -.09 ASHA-FACS: .02 RCPM: .19 SSS: .13
	Mood	GHQ-12: .57**	SSS: .24*	FAST: .11 ASHA-FACS: .18 RCPM: .27* FAI: .20
	Family Roles		FAI: .29** SSS: .24* GHQ-12: .41**	FAST: .12 ASHA-FACS: .21 RCPM: .31**
	Social Roles		FAI: .37** SSS: .18 GHQ-12: .41**	FAST: .24* ASHA-FACS: .34** RCPM: .31**
	Work	FAI: .61**	FAST: .32** GHQ-12: .34**	SSS: .07
SAQOL-39	Mean		GHQ-12: .53** FAI: .58** ASHA-FACS: .46**	RCPM: .27* SSS: .19
	Subdomains			

Instrument		Validity	
		Convergent	Discriminant
Physical	FAI: .67**	GHQ-12: .39** ASHA-FACS: .42**	FAST: .26* RCPM: .20 SSS: .10
Psychosocial	GHQ-12: .62**	SSS: <u>.28*</u> FAI: .31**	FAST: .12 ASHA-FACS: .20
Communication		FAST: .55** ASHA-FACS: .55**	RCPM: .16 FAI: .21 SSS: .08
Energy		GHQ-12: .32**	FAST: -.10 ASHA-FACS: .02 RCPM: .14 SSS: .12

* probability significant at the .05 level ** probability significant at the .01 level

¹ values not supporting set hypotheses are underlined

TABLE 5. Factor structure of the SAQOL-39

Factors	SAQOL-39 items		Item loadings (no items crossloading)	Original SS-QOL domain
Physical	SC1	Trouble with preparing food	.639	Self care
	SC4	Trouble with getting dressed	.762	
	SC5	Trouble with taking a bath/shower	.748	
	M1	Trouble with walking	.750	Mobility
	M4	Trouble with keeping balance	.576	
	M6	Trouble with stairs	.722	
	M7	Trouble with walking with no rest	.751	
	M8	Trouble with standing	.533	
	M9	Trouble with getting out of chair	.616	Work
	W1	Trouble with doing daily work	.805	
	W2	Trouble with finishing jobs	.473	Upper extremities
	UE1	Trouble with writing	.610	
	UE2	Trouble with putting on socks	.721	
	UE4	Trouble with doing buttons	.695	
	UE5	Trouble with doing a zip	.636	
	UE6	Trouble with opening a jar	.669	
	SR7	Physical problems effect on social life	.566	Social roles
Psychosocial	T5	Finding it hard to make decisions	.421	N/A, added item
	P1	Feeling irritable	.527	Personality
	P3	Feeling that your personality has changed	.421	
	MD2	Feeling discouraged	.484	Mood
	MD3	Having no interest in people	.486	
	MD6	Feeling withdrawn	.781	
	MD7	Having little confidence	.628	
	FR7	Feeling a burden to family	.526	Family roles
	SR1	Going out less	.553	Social roles
	SR4	Doing hobbies less	.511	
	SR5	Seeing friends less	.414	
Communication	L2	Trouble with speaking	.799	Language
	L3	Trouble with using the phone	.788	
	L5	Trouble with being understood	.785	
	L6	Trouble with finding words	.445	
	L7	Trouble with repetition	.722	
	FR9	Language problems effect on family life	.553	N/A, added item
	SR8	Language problems effect on social life	.564	N/A, added item
Energy	T4	Having to write things down to remember	.425	Thinking Energy
	E2	Feeling tired often	.694	
	E3	Having the need to stop and rest often	.705	
	E4	Feeling too tired to do what you want	.589	