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Validity of the SS-QOL in Germany and in Survivors of Hemorrhagic or Ischemic Stroke

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Objective. The Stroke-Specific Quality of Life Scale (SS-QOL) is a recently developed measure to assess health-related quality of life in stroke patients. The objective of this study was to translate the American version of the SS-QOL and examine the validity of the German proxy version, in both ischemic and hemorrhagic stroke survivors. *Methods.* The translation was conducted according to published guidelines. The validation was performed in consecutive adult stroke survivors. Data were obtained 1 year after discharge. To examine the dimensionality of the SS-QOL, factor analyses were conducted. The validity was examined by the associations of the subscales with the Functional Independence Measure and Short Form 36. *Results.* The literal translation revealed no major changes between the American and the German versions of the SS-QOL. Three hundred seven stroke survivors were included in the study. Unlike the 1st validation study, most of the variance could be explained by 8 instead of 12 factors; therefore, the 8-factor solution was further examined. The validity of the SS-QOL total score and "observable" scales such as "activities" was shown. *Conclusions.* For the German proxy version of the SS-QOL, an 8-factor solution was found to be the most appropriate. The psychometric properties of these 8 subscales were good or excellent with respect to internal consistency. The validity of the total score was shown, but some subscales (energy, mood, and thinking) failed the hypothesized associations. Therefore, the SS-QOL needs to be further explored in other settings and populations.

Key Words: *Stroke—Validation—Health-related quality of life—Rehabilitation.*

Cerebrovascular diseases were found to be the 3rd leading cause of lost "disability-adjusted life years" (DALYs) in the developed countries. They accounted worldwide for 38.5 × 10^6 DALYs in 1990.[1] In Europe during 2000, these diseases were estimated to be the 2nd leading cause of DALYs.[2] Disability caused by neurological conditions affects several areas of function, for example, for stroke, they include motor and sensory deficits, limitations in activities,[3,4] and cognitive impairments such as reduced attention and memory and problems with language.[5,6] Patients may also present with psychiatric disorders, such as poststroke depression.[7] This wide range of possible effects caused by stroke makes measurement of the results of rehabilitation difficult.[8]

Health-related quality of life (HRQOL) measurements are commonly used to qualify the burden of disease,[9] to evaluate treatment methods,[10] and to facilitate benchmarking, for example, for rehabilitation programs.[11]

The Stroke-Specific Quality of Life Scale (SS-QOL),[12] the first HRQOL measure for stroke patients, was made available in 1999, and it has since been used in 3 studies.[13-15] The Stroke Impact Scale (SIS) was also published in 1999[16] but offers only 8 scales, whereas the SS-QOL offers 12. Furthermore, the SS-QOL offers a total score, which facilitates the comparison, that is, of different patient groups. However, only the 4 physical domains of the SIS can be summed up to create a combined score. The SS-QOL provides more detailed information, facilitated by its different scales, and makes it possible to summarize all the information within 1 total score.

Until now, the SS-QOL has only been translated into Danish[15] and was validated exclusively in patients affected by ischemic stroke, not in patients affected by hemorrhagic stroke.

The objective of this study was, therefore, to translate and examine the cross-cultural validity of the SS-QOL and to assess the validity of the German version in both ischemic and hemorrhagic stroke survivors.

The specific aims were

1. to translate the SS-QOL and produce a cultural adaptation
2. to examine the dimensionality of the SS-QOL
3. to assess its metric properties in terms of ceiling and floor effects, test-retest reliability, and internal consistency
4. to assess the validity of the SS-QOL

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METHODS

Study Design

This is a validation study on a sample of stroke survivors. It was performed in the context of a prospective, randomized trial of an outpatient management program, aimed to improve provision of health care for persons with acquired brain injuries.

Data Collection Procedures

All patients had been treated in a single specialized rehabilitation hospital in Germany between January 1998 and December 2002.

All consecutive patients were approached to be enrolled in the study if they suffered from ischemic or hemorrhagic stroke. Within the scope of the outpatient management program, all discharged patients and proxies were invited to participate in the study and complete questionnaires or agreed to home visits by specialized nurses.

The inclusion criteria were age of at least 18 years and a Functional Independence Measure (FIM)[17] total score at discharge of at least 60 (due to a pilot study calculated on data at time of the discharge).

The exclusion criteria were if the proxies were not fluent enough in German to follow an interview, did not complete the questionnaires, or were unwilling to participate.

At discharge, socioeconomic variables and the FIM were assessed. One year after discharge, the SS-QOL, FIM, and the Short Form 36 (SF-36)[18] were assessed. The SF-36 was collected on a convenience sample subset of 79 patients. The data were collected from March 2000 until July 2000 on patients with a discharge FIM over 59. Owing to a pilot study, we found that values below this level produce floor effects. At the time of the 1-year follow-up, information on patients with discharge FIM scores between 60 and 89 was collected by in-person interview and by mail for patients with discharge FIM scores over 89. All in-person interviews were conducted by specialized nurses during home visits. The allocation to the type of administration did not change owing to a different FIM score at the time of survey.

Data collection for the test-retest analyses was carried out with a convenience subset sample of 19 stable survivors from 10 ± 2 days after the 1st assessment of the SS-QOL. The 1st assessment was made at 1-year follow-up. A specialized nurse rated whether the patient was stable or not. We collected information only within the in-person interview administration mode.

Measurements

The SS-QOL was 1st published in 1999 by Williams and others.[12] It contains 49 items and covers 12 different areas of the quality of life that may be affected by stroke. The 12 areas of the SS-QOL are energy (E), family roles (FR), language (L), mobility (M), mood (MD), personality (P), self-care (SC), social roles (SR), thinking (T), upper extremity function (UE), vision (V), and work/productivity (W). Each area can be scored separately, but a total score is also available. The proxy version of the SS-QOL was used in this study. The possible range of all scales is from 1 to 5, where a lower value represents a lower HRQOL.

The SF-36[19] is the most widely used general HRQOL measure. The 8 scales cover areas of physical health (PFI), role functioning (ROLPH), pain, general health perception (GHP), vitality (VITAL), social functioning (SOCIAL), role emotional (ROLEM), and mental health (MHI). Additionally, it provides 2 summary scores, the Physical Component Score (PCS) and Mental Component Score (MCS). We used the German validated form by Bullinger and Kirchberger.[19]

The FIM[17] is very commonly used on patients with neurological conditions,[20] and it provides an overall score (FIMSU) as well as cognitive (COGFIM) and motor scores (MOTFIM). We used the German translation by De Langen.[21]

TRANSLATION AND CULTURAL ADAPTATION OF THE SS-QOL

The procedure was carried out according to published guidelines.[22] Two translators produced 2 independent forward translations from English to German. The main goal was to achieve the best idiomatic result, rather than a direct translation. The 2 forms were then merged into 1 by committee of 3 health professionals, all with a neurological background. This committee discussed and decided how to handle "questionable issues." Two native English-speaking health professionals then did the 2 independent back-translations. The 2 translators had no knowledge of the original version. The committee then prepared the 1st consensus version form of the German SS-QOL. This 1st version was applied in a pilot study to 20 stroke patients with the agreement of their proxies. On completion of the questionnaire, they were asked if any item, response category, or instruction was unclear or misleading. Three proxies were asked the probe question "What do you mean?" for each item to ensure that the items were fully understood as having the meaning of the English items.

The reported changes refer only to the proxy version. For the mobility, upper extremity function, self care, vision, language, and work/productivity scales in the English version, the options given in the answer categories are "Couldn't do it at all," "A lot of trouble," "Some trouble," "A little trouble," "No trouble at all." In German, this was changed to "was not able to do," "had great difficulties," "had some difficulties," "had little difficulties," and "had no difficulties." The meaning of *trouble* and *difficulty* in German is the same, but *difficulty* is more commonly used. This modification was made due to different back translations.

Inasmuch as the environmental situation in the United States is similar in Germany, for example, taking a bath or a shower, and because items were verbalized only as basic activities, the literal translation revealed no major problems. The following modifications were made with regard to some items. "Did she/he have trouble zipping a zipper?" and "Did she/he have trouble buttoning buttons?" were changed to "Did she/he have difficulties buttoning up/unbuttoning buttons?" and "Did she/he have difficulties zipping/unzipping a zipper?" respectively, because there are no common words in German everyday speech for *zipping* and *buttoning*. The decision to change these items was made at the 1st committee meeting, referring to the forward German translations. The pilot study reveals 1 item as not as feasible as required. This item was "Did he/she have trouble putting on socks?" Three proxies of women said that they were unable to answer this question because their relatives did not wear socks, they wore tights. To make this item more generic, it was changed to "Did he/she have difficulties putting on socks or tights?" The committee was aware that the item may become more difficult, because putting on tights would require more effort. A higher impact of the ability was assumed, as putting on tights is a far more complex maneuver than putting on socks. The German form of the SS-QOL is available from the author.

ANALYSIS

To examine the dimensionality of the SS-QOL, we used the same method as that used in the original study factor analyses, with principal component analysis and varimax-rotation.[12,23]

To asses the metric properties for the SS-QOL ceiling effects, we counted the percentage of patients who scored 5 for each scale, and to determine floor effects, we counted the percentage of patients who scored 1. For the test-retest reliability, the intraclass correlation coefficient (ICC)[24] was chosen, because it accounts for constant differences. Additionally, a Bland & Altman plot[25] was used to detect systematic differences.

To examine the internal consistency, Cronbach's alpha was calculated. To assess the validity, the SS-QOL was correlated with SF-36 and FIM values using the Spearman's rank correlation coefficient, because of the unknown scales of measurement of the SS-QOL.

Hypothesis

According to our findings of a different factor structure, we built the hypothesis based on the new results. First, we suggested that we would find a similar strength of association between scales of the SS-QOL and the SF-36 as described in the original publication by Williams and others.[12]

Second, we hypothesized that there would be a moderate to high association between SS-QOL and SF-36 scales that measure a similar construct, for example, SS-QOL activities and SF-36 physical function. In contrast, we expected a low association between SF-36 scales and scales of the SS-QOL that measure constructs not covered by one of the measures. An example of this can be seen in the pain scale of the SF-36, which could be only indirectly associated with the SS-QOL total score, due to disability caused by pain, as pain is not directly covered by the SS-QOL. Similarly, we expected no essential association for the motor scale of the FIM and the personality scale of the SS-QOL, and a moderate to high association between mobility and activities from the SS-QOL and the FIM motor scale. More hypothesized associations and also those not expected to occur are shown in Table 1. All analyses were performed with SPSS 12.0 for Windows.

RESULTS

As factor analyses produced the same factor-loading patterns for ischemic and hemorrhagic stroke survivors, both groups were analyzed together.

Participants

Data from 307 out of 358 consecutive discharged stroke patients were collected 1 year after discharge. Loss of follow-up in 51 cases was due to the death of 18 patients, 20 refused to participate, 8 had a readmission to the hospital, and 5 patients changed their place of living and were untraceable. One hundred twenty-six of all patients were assessed by in-person interviews. The loss of follow-up in this subsample was 22. Eight patients

Table 1. Associations between Stroke-Specific Quality of Life Scales, Functional Independence Measure, and Short Form 36 1 Year after Discharge and Hypothesized Relationships

SS-QOL Domain	PFI	ROLPH	PAIN	GHP	VITAL	SOCIAL	ROLEM	MHI	PCS	MCS	FIMSU	COGFIM	MOTFIM
Energy*	0.556**	0.462**	0.357**	0.483**	0.322* +	0.525**	0.530**	0.213	0.501**	0.449** +	0.190**	0.119*	.208**
Activities*	0.835** +	0.766** +	0.422**	0.679**	0.559**	0.524**	0.718**	0.435**	0.808** +	0.542**	0.798** +	0.468**	.840** +
Language*	0.475**	0.355**	0.192 0	0.375**	0.224	0.283* +	0.372**	0.208	0.389**	0.304* +	0.451**	0.603** +	.364**
Mood*	0.520**	0.508**	0.199	0.411**	0.220 +	0.621**	0.436**	0.225	0.428**	0.459** +	0.266**	0.254**	.253**
Personality	0.007 0	0.192	0.208*	0.164	0.253*	0.492**	0.231	0.016	0.104 0	0.212	0.155**	0.185**	.137* 0
Social roles*	0.491**	0.632** +	0.286*	0.460**	0.402**	0.463** +	0.456** +	0.344*	0.481**	0.421**	0.356**	0.282**	.349**
Thinking	0.211 0	0.298*	0.169	0.163	0.169	0.239	0.285*	0.087	0.230 0	0.116	0.204**	0.376** +	.122* 0
Vision	0.350**	0.446**	0.234 0	0.486** +	0.421**	0.156	0.517**	0.079	0.435**	0.312*	0.213**	0.105	.239**
Total score*	0.838** +	0.753**	0.425** 0	0.687**	0.571**	0.630**	0.739**	0.405**	0.771** +	0.621** +	0.691** +	0.535** +	.688** +

SS-QOL = Stroke-Specific Quality of Life Scale; PFI = physical health; ROLPH = role functioning; PAIN = pain; GHP = general health perception; VITAL = vitality; SOCIAL = social functioning; ROLEM = role emotional; MHI = mental health; PCS = Physical Component Score; MCS = Mental Component Score; FIMSU = overall FIM score; COGFIM = cognitive FIM score; MOTFIM = motor FIM score; FIM = Functional Independence Measure.

**Correlation is significant at the 0.01 level; * = Correlation is significant at the 0.05 level 2-tailed. *N* for Short Form 36 comparisons varied between 77 and 79, for the Functional Independence Measure from 281 and 307. + = a moderate to high association was assumed; 0 = no or only a low association was assumed.

Table 2. Patient's Characteristics at Discharge

N = 307	%
Male	53.5
Family status	
Living alone	30.9
Living not alone	69.1
Work status	
Blue collar	29.0
White collar	20.8
Retiree	32.6
Housewife	11.1
Other	6.5
Discharge at	
Home	78.2
Not home (e.g., nursing home or rehabilitation center)	21.8

died, 4 refused to participate, 6 had a readmission to the hospital, and 4 were untraceable. One hundred eighty-three participants suffered from hemorrhagic stroke and 124 from ischemic stroke. Table 2 presents the patient's characteristics at discharge from the hospital. The average age was 55.9 years (*SD* = 13.5), and the mean length of stay in the hospital was 93.5 days (*SD* = 61.3). The mean discharge FIM was 92.3 (*SD* = 23.3). At the time of the survey, the mean FIM was 96.5 (*SD* = 24.67). Twenty-four of the 307 patients had FIM values below 60 at 1 year after discharge, and 2 of them had FIM values below 40. Spearman's rho was 0.69, and the ICC was 0.54 (CI 0.41–0.63) between the discharge FIM and 1 year later. Of the patients, 73.6% lived at home, 6.6% of them attended a day care nursing center but slept at home, and 26.4% lived not at home. The levels of care the patients received, according to German health insurance, were 2.3% level 1 (at least 90 min care/day), 3.9% level 2 (at least 180 min), and 0.6% level 3 (at least 300 min).

In factor analyses, all items of the SS-QOL showed good or excellent measurement of sample adequacy values (not reported). The KMO (Kaiser Maier Olkin) criterion was 0.92. In the 1st factor analysis, we forced a 12-factor solution as found in the original study. The total variance explained by the 12 extracted factors was 77.2%.

The main result of the 12-factor solution was a single common factor for different activities, including the self care, mobility, and upper extremity function scales, and the item doing the work used to do (W3).* The energy, personality, thinking, and vision scales were reproduced as found by Williams and others[12]; language and social roles were somewhat modified. Five factors were not interpretable (with factor loadings below 0.50 or consisting of a maximum of 2 items). Three items, family life (FR8), not interested in food (MD8), and finishing things started (W2), did not load clearly to any of the factors (>0.50). Therefore, we conducted further analyses.

The number of factors obtained using the Eigenvalue >1.0 criterion was 8. This solution explained 69.8% of the variance, which is close to the variance of the 12-factor solution. We have therefore presented the 8-factor solution in more detail. Four scales loaded onto the same factor. This factor could be named *activities* and encompasses the scales of self care, mobility, upper extremity function (with the exception of UE1 writing), work (with the exception of W2 finishing things started), and the item family life (FR8) of the family roles scale. The personality, thinking, and vision scales were reproduced as published. All original items of the energy, language, and social roles scales loaded on the specified factors but were added each for 1 more item. Withdrawn from others (MD6) had the highest loading on the social roles scale, not interested in food (MD8) loaded higher on energy, writing (UE1) loaded higher on language, and not participating in family activities out of pleasure (FR5) loaded higher on mood. The family roles scale was spread over different factors. Two items, finishing things started (W2) and felt as a burden (FR7) did not load clearly to any of the factors (>0.50) and were excluded from further analysis.

To look at possible effects of the different administration modes, we conducted separate factor analyses for the in-person interview and the mail administration groups. In the factor loading matrixes, some slight differences occur between both groups, but no clear different pattern could be identified. As a result of the insufficient item-to-person ratio within the subgroups, we have not reported the results in detail.

Psychometric Properties

Ceiling and floor effects are reported in Table 3. In general, the ceiling effects were much higher than floor effects. Table 3 also shows test-retest reliability as calculated with the ICC and ranged from 0.53 (personality) to 0.96 (activities) and was 0.83 (*n* = 19) for the summary scale. A Bland & Altman plot showed no systematic differences for the test-retest values. The internal consistency of the SS-QOL and its subscales had good or excellent reliability.

Validation

The criterion validity of the SS-QOL total score and also that of the subscales was examined by comparison of

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*Whereas W denotes the 3rd item of the work scale. The number denotes more precisely the original numbering of items used by Williams and others.[12]

Table 3. Descriptive and Reliability Statistics of the Stroke-Specific Quality of Life Scale

SS-QOL Domain	No. of Items	*n*	Mean (*SD*)	Ceiling %	Floor %	Cronbach's α	Test-retest (*n* = 19)
Energy*	4	299	3.44 (1.14)	11.1	1.3	0.84	0.67
Activities*	18	293	3.23 (1.16)	7.5	0.0	0.97	0.96
Language*	6	300	3.73 (1.22)	27.4	3.2	0.94	0.87
Mood*	4	290	3.66 (1.07)	17.4	1.6	0.83	0.76
Personality	3	292	3.45 (1.19)	19.0	2.1	0.79	0.53
Social roles*	6	291	2.96 (1.04)	6.9	1.0	0.86	0.64
Thinking	3	283	3.38 (1.14)	17.1	1.4	0.78	0.73
Vision	3	296	4.40 (0.89)	51.9	0.9	0.81	0.57
Total score*	47	307	3.45 (0.77)	1.3	0.0	0.96	0.83

*Indicates a modified scale.

the associations to the SF-36 and the FIM. All associations with the SF-36 and the FIM are shown in Table 1. The total SS-QOL scores have moderate to high associations between the 2 SF-36 component scales as well as the FIM scales. For some associations' subscales of the SS-QOL, such as the association of the mood or energy scales with the SF-36 vitality scale were not as strong as hypothesized.

In comparison to the original validation study,[12] the association between social roles and social functioning from the SF-36 seems to be higher, whereas the association between energy and vitality (SF-36) is somewhat lower.

Another interesting aspect is the predictive value of measurements. We examined the association between the FIM discharge score and some SS-QOL scales. The Spearman's correlation coefficient between the total FIM score at discharge and the total SS-QOL score 1 year later was 0.402 ($P < 0.000$). The correlation of FIM score at discharge and activities and thinking was 0.538 ($P < 0.000$) and 0.067 ($P = 0.342$), respectively.

DISCUSSION

Based on our finding that 8 factors may explain almost as much variance as 12 factors and that the subject-to-item ratio was low in the original study,[26] the reported factor structure by Williams and others[12] may not be stable. Therefore, we were in favor of the 8-factor solution, whereas the 4 mobility, upper extremity function, self care, and work/productivity scales may be combined. The content covered by the 1st 3 scales is highly related, as they measure activities of daily living (ADLs) and also another 2 items if the work/productivity scale were to be loaded onto this factor. We assume, despite the cognitive component of the 2 work/productivity items, that it may work as an overall estimation of functioning as the item family life. However, from a rehabilitation perspective, it may remain interesting to have a separate look at the different aspects of this scale. The new activity factor consists of 13 items and shows excellent consistency and test-retest reliability. Therefore, we assume that this scale may be shortening in further studies. A possible reason for the different factor structure found in our study is that it includes sample characteristic or cross-cultural differences that will need to be examined further in other settings and populations.

The family roles scale was not supported by our analyses. First, approximately 26% of the participants did not live at home, which makes it difficult to assess the family roles in these survivors. Second, some scales such as family roles or social roles may have a different meaning for participants depending on whether they reside in a nursing home or live at home. Third, the information of all SS-QOL forms was collected by proxies. Proxy information may differ from directly assessed information.[27] Proxies may have a different view than the stroke survivors would have. In comparison, Duncan and others[28] showed that the strength of the agreement between proxy and patient generally differ. Agreement was best for the observable physical domains.

The validity of the SS-QOL is given for the activities scale. The high association of FIM motor and the SF-36 physical function scale and SS-QOL activities are plausible. In these scales, the items used are similar. The associations between scales encompassing cognitive or mental aspects, with external standards covering a similar construct, were not as high as expected. More precisely, the associations of mood and energy with vitality (SF-36) as well as thinking and the FIM cognitive scale have to be addressed. In general, there was a better fit for the hypothesis with the FIM scores than with the SF-36 scores, which often tend to be weaker. Acknowledging for the different sample sizes for the FIM and SF-36 correlations with the SS-QOL and the confidence intervals for the SF-36 makes different values in other studies probable. There is some evidence that the different methods of data collection (in-person interviews and questionnaires via mail) contribute to the weaker associations.[29,30] We assume that a bias of desirable response is more likely to be provoked by interview than by questionnaire,[31] even when referring to questions containing cognitive or mental constructs, as for those referring to

ADLs. This may account for the particularly low association. As mentioned above, the use of the proxy version could also be a cause for the lower association, as it may be more difficult for the proxy to assess cognitive and mental scopes of the stroke survivor than assessing straight forward ADLs.[32]

The loading of the item typing or writing from upper extremity function scale on the language factor is plausible because writing requires both functioning of the upper extremity and cognitive language functions.

The ceiling effects are unexpected because the SS-QOL contains more specific items than, for example, the FIM. For example, vision is an important issue that has been addressed whenever stroke patient's HRQOL is assessed; however, only a subgroup of stroke survivors is affected by vision problems.[33] In our study, we found small to moderate floor effects. Due to the inclusion criteria, we had no severely disabled patients in our study. If mildly to moderately disabled stroke survivors cause some amount of floor effects, we hypothesize that more severely disabled survivors may not be well represented by this measure. However, the challenge of how to measure HRQOL in severely disabled survivors remains unresolved, because until now no questionnaire was validated for such a sample. The common cognitive impairments in stoke patients also raise the ethical question as to whether an adequate response is possible either by the survivors themselves or their proxies.

Our study has some potential limitations. We have no information about relevant comorbidities that may affect the scores of the measures.[34] With respect to the great proportion of survivors suffering a hemorrhagic stroke[35] in our study, it is important to recognize that ischemic and hemorrhagic stroke patients may have had different outcomes influenced by the severity of the disease.[36,37] This fact may limit the generalizability of the results. In respect to the factor analyses, it is important to keep in mind that the item-to-person ratio was not high, especially because the values of test-retest reliability are based on a small sample size and the true values may differ.

The SS-QOL encompasses components of functioning that differ from other measures, such as the SF-36 or the SIS. Some of those components, such as vision, were recommended by ICF Core Sets for stroke patients published by Geyh and others[38]; others, such as changes in personality, are not yet covered by the ICF Classification.[39] Therefore, the SS-QOL remains an interesting measure, which may enrich the HRQOL perspective of stroke survivors.

In conclusion, for the German proxy version of the SS-QOL, an 8-factor solution was found to be the most appropriate. The psychometric properties of subscales were good or excellent with respect to internal consistency. The validity of the total score was shown, but some subscales—energy, mood, and thinking—failed the hypothesized associations. Therefore, the SS-QOL needs to be further explored in other settings and populations.

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