A Quality-of-Life Instrument for Young Hemorrhagic Stroke Patients

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Background and Purpose—Hemorrhagic stroke has a high initial mortality rate. While survivors often recover motor function, many experience significant changes in their quality of life (QOL). Available outcome measures assess neurological impairment, disability, or handicap, yet often inadequately characterize the full impact of a stroke on patients’ lives. In this study, we develop and validate a QOL instrument specific for young patients with hemorrhagic strokes.

Methods—Methodological guidelines for instrument development were initially established. Based on the content of 40 open-ended patient interviews, a 54-item instrument (HSQuale) was developed. The reliability (test-retest and internal consistency) and validity (content and construct) of HSQuale were assessed in another 71 patients (18 to 49 years of age, 63% women, 77% white), at 1 year after their hemorrhagic stroke. Comparisons were made between HSQuale and other commonly used outcome measures.

Results—HSQuale demonstrated reproducibility (test-retest \( \kappa \), 0.40 to 0.96) and internal consistency (Cronbach \( \alpha \) ≥0.80 for 5 of 7 domains). HSQuale scores had broad frequency distributions (≤33% of subjects scored in any single score decile), avoided ceiling effects found for other outcome measures (Barthel Index and Short Form-36), and discriminated among clinically distinct subject groups (eg, intracerebral versus subarachnoid hemorrhage patients).

Conclusions—HSQuale is a reliable and valid QOL instrument. Compared with other outcome measures, it assesses a broader range of deficits and is better able to discriminate among subgroups of hemorrhagic stroke survivors. (Stroke. 2001;32:687-695.)

Key Words cerebral hemorrhage ■ cerebrovascular disorders ■ outcome assessment ■ prognosis ■ quality of life

Among patients with hemorrhagic stroke, the community-based, 30-day case-fatality rate is 30% to 60%.1–4 Approximately 70% of survivors, however, are independent in their activities of daily living at 1 year.2,3 For this reason, some authors have concluded that hemorrhagic stroke patients who survive the first few weeks have a “good” prognosis.1,3,5 A favorable outcome for hemorrhagic stroke patients, however, has been questioned, as many patients with good motor recovery exhibit marked cognitive disturbances and difficulties with emotional adjustment.6–9 Furthermore, while stroke scales, the Barthel Index,10 and the modified Rankin Scale11 continue to be the most commonly used stroke outcome measures, these traditional measures do not capture the full range of deficits experienced by stroke survivors. The evaluation of a broader range of patient outcomes (eg, cognitive, occupational) has been advocated.12–15 Although the consensus classification system recently developed by the Classification of Stroke Outcome Task Force of the American Heart Association16 is useful for assessing neurological impairments, disabilities, and handicaps of patients, a consensus instrument for assessing quality-of-life (QOL) outcomes for stroke patients is still lacking.

The need for stroke-specific QOL instruments is widely acknowledged, and several ischemic stroke–specific instruments have been published.17–19 The epidemiology, pathophysiology, and mortality outcomes of hemorrhagic stroke patients differ from those of ischemic stroke patients (eg, younger patient with berry aneurysm versus older patient with atherosclerotic disease, global versus focal lesion, higher initial mortality versus higher long-term mortality), and evidence exists for different QOL outcomes.20 Therefore, a need for a hemorrhagic stroke–specific QOL instrument exists. While hemorrhagic strokes comprise 10% to 15% of all strokes, they account for half of strokes in younger patients.21 Because young adults are at the peak of their professional and reproductive years, QOL outcomes are particularly relevant for this group of patients.22,23
Our goal was to develop a reliable and valid instrument to measure QOL outcomes of young hemorrhagic stroke patients. Consistent with recommendations that disease-specific instruments be validated against existing measures,24 the content validity of HSQuale was compared with commonly used stroke outcome measures and a commonly used generic QOL instrument.

Subjects and Methods

Patient Population

Case subjects were recruited from the Hemorrhagic Stroke Project (HSP), a case-control study of risk factors for hemorrhagic stroke among young adults.24 The HSP enrolled men and women 18 to 49 years of age who were hospitalized for a primary, nontraumatic intracranial hemorrhage at 44 hospitals in 6 states (1994 to 1999). Case subjects were excluded if they were unable to communicate within 30 days of their stroke or if they had a history of prior stroke or other brain lesion predisposing to hemorrhage.

HSP case subjects from Connecticut, Massachusetts, Rhode Island, and Texas participated in the development and evaluation of HSQuale. HSP case subjects who had their stroke 1 year (±3 months) before the time of this study were interviewed, as neurological recovery and the psychosocial impact of a stroke have stabilized for patients by this time.25–27 For HSQuale development, the first 40 eligible HSP case subjects who were contacted and willing to participate were interviewed (1996). To assess the reliability and validity of HSQuale, an attempt was made to enroll all 98 eligible HSP case subjects in an evaluation study (1997 to 1998). There was no overlap of subjects in the development phase and evaluation study of HSQuale. Subjects were recruited and consent was obtained following approval of the Human Investigation Committee at Yale University School of Medicine.

Methodological Guidelines

Terms commonly used in QOL instrument development and assessment have been previously defined.28–29 To improve the face validity of HSQuale, the following guidelines were established.

1. Because assessment of patients’ subjective well-being is preferred over sole assessments of objective functioning,30–34 and in order to minimize between-subject variance (ie, 2 patients may value different aspects of life differently), QOL instruments should directly ask patients to evaluate their self-defined QOL.

2. Because status instruments cannot always assess the extent of deficits experienced by individual patients with varying premorbid states, QOL instruments should directly assess ‘change’ in function or well-being due to the medical event under study. Furthermore, QOL assessments by ‘before’ and ‘after’ administrations of status instruments are susceptible to within-subject variance (ie, the same patient may value different aspects of life differently in sickness than in health).35–37 Questions asked at one time point that focus on ‘change,” however, capture the impact of the medical event by holding constant the patient’s definition of QOL.

3. While QOL assessments attempt to assess the effect of a specific medical event on QOL, many other medical (eg, comorbidities) and nonmedical (eg, death of a loved one) factors can influence patients’ QOL. The use of specifying phrases (eg, “As a result of your stroke,” “Since your bypass surgery,” “”) reduce the impact of extraneous influences by asking patients to report QOL changes due (directly or indirectly) to the medical event under study.

4. Because patients have reported excellent or improved QOL despite serious and persistent disabilities,36,39 for a comprehensive assessment, QOL instruments should evaluate both positive and negative outcomes.

5. Because the clinical significance of QOL instrument scores is often difficult to determine, scores should readily convey direction and crude magnitude of change in patients’ QOL.35,36 Because the use of both generic and disease-specific instruments is advocated but seldom practiced,40,41 QOL instrument should include generic items that can be included in other studies, along with disease-specific items that are responsive to QOL changes of the patient population under study.

6. Because QOL instruments are increasingly used in patient populations dissimilar to those in which they were validated, to verify content validity, open-ended questions that ask patients to identify QOL concerns not addressed by domain items should be included.

HSQuale Development

Item and Domain Generation

Sixty-five domain items were written on the basis of the methodological guidelines above and the following: (1) individual, open-ended interviews with 30 HSP case subjects; (2) open-ended interviews with clinicians (2 neurologists and 2 neurovascular surgeons) involved in the care of hemorrhagic stroke patients; and (3) review of the hemorrhagic and ischemic stroke outcomes literature. An attempt was made to word items and response choices in phrases commonly used by subjects during interviews. On the basis of a review of content, the 65 items were grouped into the following 7 domains: General Outlook, Physical Functioning, Cognitive Functioning, Relationships, Social & Leisure Activities, Emotional Well-Being, and Work & Financial Status.

Modeled after summary questions included in the Functional Assessment of Cancer Therapy—General Scale,42 Domain Summary Questions (DSQs) were added as the last item in each of the 7 domains. An Overall Summary Question (OSQ) was also added to the end of the instrument. The DSQs and OSQ can be included in other QOL instruments to allow comparisons across medical events (DSQ: “Would you say changes you have noticed in your [domain name] resulting from your bleed have increased, decreased, or not changed the quality of your life? Slightly, somewhat, or greatly?”). OSQ: “As an overall question, would you say having had a bleed has increased, decreased, or not changed the quality of your life? Slightly, somewhat, or greatly?”.

Finally, the following open-ended question was added as a final item to allow verification of the content validity of the instrument in new study populations: “In what ways, other than those discussed in the above questions, has your bleed affected the quality of your life?”.

Wordings of revisions of HSQuale items were made on the basis of administration of the instrument to another 10 HSP case subjects.

Item Reduction

HSQuale (74 items: 65 domain items, 7 DSQs, 1 OSQ, and 1 open-ended question) was administered in an evaluation study. Subjects’ responses to the 65 domain items were used to eliminate items that failed to fulfill the following item-performance criteria: (1) ordinal response choices, in order to allow scoring (7 items eliminated); (2) strong correlation ($r \geq 0.50$) with at least one third of domain items or the domain’s DSQ, in order to maintain domain homogeneity (10 items eliminated); and (3) less than a two-thirds response frequency for any single response choice, in order to allow discrimination among patients (6 items eliminated). Five additional, frequently misunderstood items were eliminated. Because QOL assessments rely on thoughtful personal responses, 8 of 28 eliminated items were included in HSQuale for their value in familiarizing patients with QOL assessments and helping establish an introspective tone for the interviews. The questions did not add to patient burden, as patients often enjoyed sharing their responses to these questions. These 8 items are not included in HSQuale scores and can be eliminated. The final version of HSQuale, therefore, consists of 54 (38 scored, 16 unscoring) items (Figure 1).

Scoring

Individual HSQuale items were scored such that direction and magnitude of change in patients’ QOL would be readily conveyed. A response choice indicating “no change” from a patient’s premorbid status is awarded 50 points; response choices indicating maximum deterioration or improvement are awarded 0 and 100 points, respectively; and all other response choices are awarded points on the basis of the number of response choices available. For example, in the
Figure 1. HSQuale comprises 54 (38 scored, 16 unscored) items.
Relationships domain, a response of “much less close” would be awarded 0 points; “somewhat less close,” 25 points; “same as before,” 50 points; “somewhat more close,” 75 points; and “much closer,” 100 points. In the Cognitive Functioning domain, “much more difficult” would be awarded 0 points; “somewhat more difficult,” 17 points; “slightly more difficult,” 33 points; and “no more difficult than before,” 50 points.

Domain scores are determined by averaging item scores for items included in a domain (excluding the domain’s DSQ). Because the maximum score for each individual item varies according to the available response choices, the maximum domain scores vary depending on the included items. For comparison, Spearman rank correlation coefficients for calculated domain scores and respective DSQ scores were determined (General Outlook, 0.52; Physical Functioning, 0.73; Cognitive Functioning, 0.68; Relationships, 0.62; Social & Leisure Activities, 0.86; Emotional Well-Being, 0.63; and Work & Financial Status, 0.85).

QOL is greater than the sum of individual life domains. Furthermore, in arriving at their response to the OSQ, subjects often completed a mental exercise tantamount to using a personal QOL formula with individualized domain weights. Therefore, the OSQ score was used as an overall score for subsequent analyses. For comparison, Spearman rank correlation coefficient for OSQ scores and calculated overall scores (based on an average of calculated domain scores) was determined (r=0.76).

Regardless of whether a score represents an item, domain, DSQ, or OSQ score, direction and crude magnitude of QOL changes can be determined by comparison with the “no change” score of 50.

HSQuale Evaluation
For the evaluation study, telephone interviews were scheduled for a 2-hour time period identified by subjects. During the interviews, the following sociodemographic and clinical data were collected: age, gender, race, marital status, highest education level completed, occupation prior to stroke, and comorbidities. Stroke subtype was determined from subjects’ medical records. If a subject’s stroke had components of both intracerebral hemorrhage (ICH) and subarachnoid hemorrhage (SAH), it was labeled as an ICH.

Of 98 consecutively enrolled HSP case subjects from participating sites who were 1 year (±3 months) post-hemorrhagic stroke, 72% (71/98) agreed to participate in the HSQuale Study. The following instruments were administered to subjects during the interviews: Pfeiffer Short Portable Mental Status Questionnaire (SPMSQ)44, Barthel Index, modified Rankin Scale, Short Form-36 (SF-3645), HSQuale (74-item version), Duke-UNC Functional Social Support (DUFSS) Questionnaire,46 Center for Epidemiologic Studies Depression Scale (CES-D47), and Revised Life Orientation Test (LOT-R48). Although the 74-item version of HSQuale was administered, only the 38 items remaining after item reduction, the DSQs, and the OSQ were used for subsequent analyses.

Reliability
To assess test-retest reliability, HSQuale was readministered to one half of the subjects after a 2-week interval. Cicchetti weighted κ statistics48 were calculated for individual items, the DSQs, and the OSQ. To assess internal consistency, Cronbach α coefficients were determined for the 7 domains.49

Content Validity
An instrument is assumed to have adequate content validity if patient and expert input is incorporated into its development and/or if their review of the instrument fails to identify omission of important content. A more quantitative evaluation of content validity involves examining the distribution of patient scores across the available range,50,51 ie, the discriminatory power of an instrument.52 Ceiling and floor effects (the extremes of a skewed score distribution) are undesirable because they do not allow discrimination among patients or allow documentation of further patient improvement or deterioration.

The discriminatory power of HSQuale was evaluated and then compared with that of the most commonly used stroke outcome measures (Barthel Index, modified Rankin scale) and the most commonly used generic QOL instrument (SF-36). For this study, an instrument was considered to have poor discriminatory power if its frequency distribution of patients scores was >33% for any given score decile. Score deciles were determined by dividing the full range of possible scores by 10.

Construct Validity
An instrument’s construct validity can be established by demonstrating convergent validity (ie, the extent to which the instrument correlates with other instruments that measure similar constructs) and/or discriminant validity (the extent to which the instrument is able to discriminate among clinically distinct patient groups).

Convergent validity for HSQuale domains was evaluated by determining Pearson correlation coefficients for the following continuous variables: (1) HSQuale domain scores and relevant unidimensional instrument scores and (2) HSQuale domain scores and comparable SF-36 domain scores. The following criteria for the strength of correlation are supported by the literature: r≥0.50, strong; r=0.40 to 0.49, moderate; and r=0.30 to 0.39, weak.53

The discriminant validity of HSQuale’s OSQ was evaluated by Student t test comparisons of mean OSQ scores for subjects dichotomized into the following clinical groups: (1) stroke subtype (ICH versus SAH), (2) residual physical symptoms (≥1 versus none), (3) depressive symptoms (CES-D ≥16 versus <16), (4) poststroke seizures (≥1 versus none), and (5) comorbidity (>1 versus none).

Results
Characterization of Study Population
Of 98 consecutively enrolled HSP case subjects from participating sites who were 1 year (±3 months) post-hemorrhagic stroke, 72% (71/98) agreed to participate in the HSQuale Study.

### TABLE 1. Baseline Characteristics of Study Sample (n=71)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Percent (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female gender</td>
<td>63.4 (45)</td>
</tr>
<tr>
<td>Age, y</td>
<td></td>
</tr>
<tr>
<td>0–29</td>
<td>8.4 (6)</td>
</tr>
<tr>
<td>30–39</td>
<td>29.6 (21)</td>
</tr>
<tr>
<td>40–49</td>
<td>62.0 (44)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>77.5 (55)</td>
</tr>
<tr>
<td>Black</td>
<td>14.1 (10)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>08.5 (6)</td>
</tr>
<tr>
<td>Married</td>
<td>60.6 (43)</td>
</tr>
<tr>
<td>Highest education</td>
<td></td>
</tr>
<tr>
<td>&lt;High school</td>
<td>12.7 (9)</td>
</tr>
<tr>
<td>High school</td>
<td>63.4 (45)</td>
</tr>
<tr>
<td>&gt;High school</td>
<td>23.9 (17)</td>
</tr>
<tr>
<td>Occupation*</td>
<td></td>
</tr>
<tr>
<td>Professional, managerial</td>
<td>38.0 (27)</td>
</tr>
<tr>
<td>Sales, service, labor, clerical, technical</td>
<td>46.3 (33)</td>
</tr>
<tr>
<td>Other*</td>
<td>15.5 (11)</td>
</tr>
<tr>
<td>Stroke subtype†</td>
<td></td>
</tr>
<tr>
<td>ICH</td>
<td>42.3 (30)</td>
</tr>
<tr>
<td>SAH</td>
<td>57.7 (41)</td>
</tr>
</tbody>
</table>

*Included in this category are subjects who reported being unemployed or students before their stroke.
†If a subject’s stroke had components of both an ICH and an SAH, it was labeled as an ICH.
evaluation study. Of the 27 subjects who were not inter-
viewed, 15 were unreachable because of a change in tele-
phone number; 8 were contacted but declined participation; 3
were non-English, non-Spanish speaking; and 1 had died of a
recurrent hemorrhagic stroke. Participants and nonpartic-
ipants were similar in age and gender but differed in stroke
subtype (58% of participants had an SAH compared with
70% of nonparticipants; \( P < 0.05 \)).

Of the 71 study participants, 63% (45/71) were female,
62.0% (44/71) were aged \( \geq 40 \) years (mean age \( 41.0 \pm 7.4 \) years), 77% (55/71) were white, 61% (43/71) were married at
follow-up, 87% (62/71) had at least a high school education,
and 61.8% (44/71) reported holding nonprofessional and
nonmanagerial positions before their hemorrhagic stroke
(Table 1). One year after their hemorrhagic stroke, 55%
(39/71) of the 71 study participants reported no other comor-
bid condition, 94.4% (67/71) showed no cognitive impair-
ment on the SPMSQ, and 65% (46/71) did not have depres-
sive symptoms based on the CES-D scale.

### HSQuale Evaluation

#### Reliability

Of the 37 scored HSQuale items, 12 had “fair” (\( \kappa = 0.40 \) to
0.59), 20 had “good” (\( \kappa = 0.60 \) to 0.79), and 5 had “excellent”
(\( \kappa = 0.80 \) to 1.00) Cicchetti weighted \( \kappa \) statistics ratings. The
OSQ had excellent test-retest reliability (\( \kappa = 0.833 \)). Six
HSQuale domains had calculated Cronbach \( \alpha \) coefficients
(General Outlook, 0.78; Physical Functioning, 0.89; Cogni-
tive Functioning, 0.88; Social & Leisure Activities, 0.85;
Emotional Well-Being, 0.83; and Work & Financial Status,
0.89) greater than the recommended 0.70 for group compar-
isons.53 The Cronbach \( \alpha \) for the Relationship domain was
calculated to be 0.56.

#### Content Validity

Qualitatively, HSQuale’s content validity was established by
inclusion of patient and expert input in development. In
addition, a review of responses to the open-ended item at the
end of HSQuale failed to identify neglected content areas.
Quantitatively, HSQuale content validity was examined by
evaluating its discriminatory power. Frequency distribution
of domain scores were <33% for any given score decile
(Figure 2). Similarly, <33% of subjects chose any 1 of the 7
response choices for the OSQ (Figure 3). In comparison, 94%
of subjects scored in the top score decile for the Barthel Index
(Figure 4). Additionally, >33% of subjects scored in the top
score decile for 5 of 8 SF-36 domains: Physical Functioning, 43% (31/71); Role Limitations–Physical, 41% (29/71); Bodily Pain, 42% (30/71); Social Functioning, 39% (28/71); and Role Limitations–Emotional, 58% (41/71) (Figure 5). Fewer than 33% of subjects chose any 1 of the 5 response choices for the modified Rankin Scale.

**Construct Validity**

Moderate evidence exists for HSQuale’s convergent validity (Table 2). HSQuale’s General Outlook, Physical Functioning, and Emotional Well-Being domains correlate moderately or strongly with corresponding unidimensional instruments; HSQuale Cognitive Functioning and Social & Leisure Activities domains correlate less well. Appropriate unidimensional instruments for comparison purposes were not found for the HSQuale Relationships and Work & Financial Status domains.

Comparable HSQuale and SF-36 domains were thought to be HSQuale’s Physical Functioning domain and SF-36’s Physical Functioning and Role Limitations–Physical domains, HSQuale’s Social & Leisure Activities domain and SF-36’s Social & Leisure domain, and HSQuale’s Emotional Well-Being domain and SF-36’s Role Limitations–Emotional and Mental Health domains. Of the 5 possible correlations, 4 were found to be strong (Table 3). Unexpectedly strong correlations among other HSQuale and SF-36 domains were also found.

Strong evidence exists for the discriminant validity of HSQuale OSQ, because mean OSQ scores significantly differed ($P<0.05$) for patients dichotomized into clinically distinct groups on the basis of stroke subtype, presence of residual physical symptoms, presence of depressive symptoms, and presence of poststroke seizures (Table 4).

**Discussion**

HSQuale is a reliable (test-retest, internal consistency) and valid (face, content, construct) 54-item, hemorrhagic stroke–specific QOL instrument that takes 15 minutes to administer to patients. Because of its assessment of a broader range of patient outcomes and its greater discriminatory power, it outperforms currently available outcome measures.

HSQuale was found to have acceptable test-retest reliability (all $k>“fair”$ rating) and internal consistency (6 domains with Cronbach $\alpha$ coefficient $>0.70$). Its face validity among clinicians may be due to its thematic adherence to the familiar clinical question, “Do you feel better or worse?” HSQuale content validity was established qualitatively (because open-ended questioning failed to identify potentially missed content areas) and quantitatively (because a broad frequency distribution of patient scores was found for all HSQuale domains and the OSQ). HSQuale construct validity was established separately for the 7 domains and the OSQ. Convergent validity with unidimensional instruments was found for the HSQuale General Outlook, Physical Functioning, and Emotional Well-Being domains. The skewed frequency distribution of patient scores found for the Pfeiffer Short Portable Mental Status Questionnaire (>90% of subjects scored perfectly) and the Duke–UNC Functional Social Support Questionnaire (nearly 50% of subjects scored ≥38 of 40 points) imply these instruments are inappropriate for

<table>
<thead>
<tr>
<th>HSQuale Domain</th>
<th>Unidimensional Instrument</th>
<th>Correlation Coefficient†</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Outlook</td>
<td>Revised-Life Orientation Test</td>
<td>0.46</td>
</tr>
<tr>
<td>Physical Functioning</td>
<td>Barthel Index</td>
<td>0.49</td>
</tr>
<tr>
<td>Cognitive Functioning</td>
<td>Pfeiffer Short Portable Mental Status Questionnaire</td>
<td>0.33</td>
</tr>
<tr>
<td>Relationships</td>
<td>. . .</td>
<td>. . .</td>
</tr>
<tr>
<td>Social &amp; Leisure Activities</td>
<td>Duke–UNC Functional Social Support Questionnaire</td>
<td>0.33</td>
</tr>
<tr>
<td>Emotional Well-Being</td>
<td>Center for Epidemiologic Studies Depression Scale</td>
<td>0.63</td>
</tr>
<tr>
<td>Work &amp; Financial Status</td>
<td>. . .</td>
<td>. . .</td>
</tr>
</tbody>
</table>

*Pearson correlation coefficients, $r$.
†$r>0.50$, strong; $r=0.40–0.49$, moderate; $r=0.30–0.39$, weak.
assessing outcomes in this study population. Therefore, convergent validity is not expected with the HSQuale Cognitive Functioning and Social & Leisure Activities domains. Strong correlations between similar HSQuale and SF-36 domains also support HSQuale construct validity. Of note, the HSQuale Physical Functioning domain strongly correlated with 6 of 8 SF-36 domains. The emphasis of SF-36 on functioning has been noted before and it may account for some of the overlapping strong correlations.

Construct validity of the OSQ was established by showing appropriate discriminant validity. OSQ scores differed significantly between subjects dichotomized into distinct clinical groups on the basis of stroke subtype, presence of residual physical symptoms, presence of depressive symptoms, and presence of poststroke seizures. The ability of the OSQ to discriminate between patients on the basis of their physical and mental health supports its construct as a global assessment of QOL outcome. Perhaps the difference in the injury pattern associated with ICH and SAH (ie, localized versus diffuse lesion) accounts for the difference in QOL outcomes noted. The difference in QOL outcomes of patients with and without poststroke seizure(s) was expected. The negative ramifications of even 1 poststroke seizure (eg, driving limitations, side effects of antiepileptic medications) were strongly emphasized by patients during interviews. Finally, because specifying phrases were specifically used to limit subjects’ assessments of QOL changes to those resulting from their hemorrhagic stroke, the weaker ability of the OSQ to discriminate between those with and without comorbid conditions was expected.

Comparison of Instruments

In addition to establishing the reliability and validity of the HSQuale, the study compared HSQuale content validity with that of other commonly used instruments. Although the Barthel Index is the most commonly used stroke outcome measure, as a disability scale its limitations are well recognized. Furthermore, it has exhibited significant ceiling effects in this and other stroke populations.

Kappelle et al. found that 92% of their study sample of young adults with ischemic strokes had nearly perfect scores on the Barthel Index (ie, ≥ 95), but half reported important QOL decline and only 42% returned to work.

Although available in its standard form only since the early 1990s, the SF-36 has rapidly become the most commonly used generic QOL instrument. To date, it has been used in numerous stroke studies. With greater use, however, the limitations of the SF-36 (eg, ceiling and floor effects, limited content validity) as a generic QOL instrument for stroke and other patients have become recognized. In this study, ceiling effects were found for 5 of 8 SF-36 domains (Physical Functioning, Role Limitations—Physical, Bodily Pain, Social Functioning, and Role Limitations—Emotional). Among elderly stroke patients, Anderson et al. found that the SF-36 Physical Functioning domain showed a “uniform distribution of scores that reflected a broad range of physical disability.” However, as Hobson et al. have pointed out, prominent ceiling effects are present in 4 of 8 SF-36 domains in the study of Anderson et al. Furthermore, the observation of Duncan et al. that SF-36 scores of patients with strokes are similar to those of patients with transient ischemic attacks “raises questions about the ability of the SF-36 to discriminate and to be responsive to clinical changes in stroke patients.”

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**TABLE 3. HSQuale Convergent Validity: Correlations Between HSQuale and SF-36 Domains***

<table>
<thead>
<tr>
<th>HSQuale Domain</th>
<th>SF-36 Domain</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Physical Functioning</td>
</tr>
<tr>
<td>General Outlook</td>
<td>0.55</td>
</tr>
<tr>
<td>Physical Functioning</td>
<td>0.84†</td>
</tr>
<tr>
<td>Cognitive Functioning</td>
<td>0.61</td>
</tr>
<tr>
<td>Relationships</td>
<td>0.60</td>
</tr>
<tr>
<td>Social &amp; Leisure</td>
<td>0.60</td>
</tr>
<tr>
<td>Activities</td>
<td>0.59</td>
</tr>
<tr>
<td>Emotional Well-Being</td>
<td>0.59</td>
</tr>
<tr>
<td>Work &amp; Financial Status</td>
<td>0.74</td>
</tr>
</tbody>
</table>

*Only Pearson correlation coefficients ≥0.50 are shown. †Expected strong (r>0.50) correlations.

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**TABLE 4. HSQuale Discriminant Validity: Mean OSQ Scores for Clinically Distinct Patient Groups**

<table>
<thead>
<tr>
<th>Clinical Group</th>
<th>Mean OSQ Score (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke subtype*</td>
<td></td>
</tr>
<tr>
<td>ICH</td>
<td>30 (30)</td>
</tr>
<tr>
<td>SAH</td>
<td>50 (41)</td>
</tr>
<tr>
<td>Residual physical symptoms(s)*</td>
<td></td>
</tr>
<tr>
<td>&gt;1</td>
<td>24 (40)</td>
</tr>
<tr>
<td>None</td>
<td>64 (31)</td>
</tr>
<tr>
<td>Depressive symptoms*</td>
<td></td>
</tr>
<tr>
<td>CES-D&gt;16</td>
<td>19 (25)</td>
</tr>
<tr>
<td>CES-D&lt;16</td>
<td>54 (46)</td>
</tr>
<tr>
<td>Poststroke seizures*</td>
<td></td>
</tr>
<tr>
<td>≥1</td>
<td>17 (7)</td>
</tr>
<tr>
<td>None</td>
<td>48 (39)</td>
</tr>
<tr>
<td>Comorbidity†</td>
<td></td>
</tr>
<tr>
<td>≥1</td>
<td>34 (32)</td>
</tr>
<tr>
<td>None</td>
<td>48 (39)</td>
</tr>
</tbody>
</table>

*P<0.05, †P<0.10.
Developers of the SF-36 have acknowledged the limitations of the instrument. The group notes “substantial” ceiling effects for the Social Functioning, Role Limitations—Physical, and Role Limitations—Emotional SF-36 domains, particularly for “younger and relatively well patients.”65 In addition, the omission of important health concepts (eg, cognitive functioning) from the instrument is recognized.64 Therefore, the past recommendation of Ware64 has been to rely on the instrument as a “generic core” rather than the principle measure of outcome.

Although the modified Rankin Scale did not exhibit a ceiling effect in this study, as a single-item instrument its use as an outcome measure is limited by its inability to identify specific areas of handicap.

General Observations

Three general observations can be made about QOL outcomes for young adults with hemorrhagic stroke. First, SAH survivors fare as well as or better than ICH survivors in all HSQuale domains (data not shown) and the OSQ. Second, perhaps because they survived an acute, life-threatening event, hemorrhagic stroke survivors can experience an improvement in QOL. In this study, 39% (16/41) of SAH and 23% (7/30) of ICH patients reported improvement in overall QOL compared with their premorbid status. Hop et al4 found that some patients with Rankin scores of zero (ie, no handicap) reported improvements in QOL on visual analogue scales. Similarly, Niemi et al20 found QOL improvements for 15% of their sample of middle-aged (≤65 years old) ischemic and hemorrhagic stroke patients. More specifically, they noted, “patients with SAH significantly more frequently had a restored or improved quality of life than patients with brain infarction.” Third, the strength of correlation between the HSQuale Work & Financial Status domain scores and the OSQ scores is noteworthy (r=0.80). The importance of occupational outcomes, especially in young adult stroke patients, is intuitive. Niemi et al20 found that “all previously employed [stroke] patients who were unable to return to work had a deteriorated quality of life.” King65 found that despite favorable overall QOL scores for their study patients, “not having a job is a major source of dissatisfaction” for patients.

Future Directions

Not having been administered in its shortened form in the evaluation study is a limitation of HSQuale. Although unlikely, it is possible that the deletion of items will change HSQuale performance on future administrations. Future studies should attempt to replicate the results found in this study on different patient populations, using the shortened HSQuale. If the instrument continues to prove reliable and valid, it should be used in outcome studies that aim to identify baseline variables (eg, lesion location) that are predictive of QOL outcomes.

While HSQuale DSQs and OSQ are readily generalizable, the individual domain items may limit the instrument’s generalizability, because they were developed on the basis of interviews with young, relatively healthy hemorrhagic stroke survivors. As mentioned, however, the generalizability of HSQuale to other stroke populations (eg, older hemorrhagic stroke patients) can easily be evaluated by administering the instrument to a small number of patients and reviewing their responses to the final, open-ended question of the instrument.

Guyatt et al28 note that “distilling the measurement of [QOL] into a few key questions is a goal of clinical investigators.” Therefore, there may be merit in pursuing psychometric evaluation of only the DSQs and the OSQ for QOL assessment. Such a mini-HSQuale would be beneficial in view of its ease of administration and the generalizability of DSQs and the OSQ to other medical events for which QOL outcomes are of interest.

Finally, HSQuale may be criticized for its susceptibility to recall bias, especially in patients who have suffered a central nervous system insult. It could be argued, however, that recall bias is inconsequential in subjective assessments because it is the patients’ perception of their premorbid status compared with their present status that determines their present QOL.

In summary, HSQuale is the first attempt at the development of an instrument to comprehensively characterize QOL outcomes in young hemorrhagic stroke patients. Its favorable performance in this study suggests it may serve an important role in evaluating patient outcomes after hemorrhagic stroke.

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