Measuring quality of life in a way that is meaningful to stroke patients

Objective: To identify predictors of poststroke quality of life.

Background: Health-related quality of life (HRQOL) measures assess the impact of disease on the physical, emotional, and social aspects of patients' lives. Although HRQOL measures are used increasingly, factors associated with HRQOL poststroke and the ability of stroke-specific versus generic HRQOL measures to predict patient-reported HRQOL are not well known.

Methods: A total of 71 patients were evaluated 1 month postischemic stroke with a new stroke-specific HRQOL measure—the SS-QOL—and the SF-36, a generic HRQOL measure. Stroke severity, impairments, and functional limitations were also measured. Demographic variables and outcome measure scores were compared between patients rating their overall HRQOL the same as prestroke versus those with overall HRQOL worse than prestroke. Independent predictors of overall HRQOL were identified using multivariable modeling.

Results: Variables associated with better overall HRQOL were higher (better) SS-QOL and Barthel Index scores, and lower (better) NIH Stroke Scale and Beck Depression Inventory scores. Independent predictors of good overall HRQOL were the SS-QOL score (odds ratio [OR], 2.97; 95% CI, 1.3, 7.1; \( p = 0.01 \)) and NIH Stroke Scale score (OR, 0.69; 95% CI, 0.47, 0.99; \( p = 0.05 \)). Demographic factors and SF-36 scores were not associated with overall HRQOL ratings.

Conclusions: Stroke-specific quality of life score and patient impairments predict patient-reported overall health-related quality of life (HRQOL) poststroke. SF-36 scores were not associated with overall HRQOL ratings. Disease-specific HRQOL measures are more sensitive to meaningful changes in poststroke HRQOL and may thus aid in identifying specific aspects of poststroke function that clinicians and "trialists" can target to improve patients' HRQOL after stroke.

Health-related quality of life (HRQOL) refers to the constellation of physical, psychological, and social aspects of life that may be affected by changes in health states.\(^1\)\(^-\)\(^3\) It is important to incorporate patient-centered outcomes like HRQOL into clinical measures so that the impact of disease on the patient as a whole can be understood and quantified.\(^3\)\(^-\)\(^5\) This concept is especially relevant in stroke, when patients have both a broad range of impairments and a wide spectrum of symptom severity.

HRQOL outcomes are incorporated increasingly as an outcome in clinical trials, but knowing whether the treatment really made a difference in patients' HRQOL is often difficult. To date, most stroke trials have used generic HRQOL scales. Although generic HRQOL measures have the advantage of allowing comparisons of patients with different diseases, they are
less sensitive for exploring the effects of particular impairments on HRQOL or for assessing response to treatment in an individual with a specific disease.5,6 In stroke research, the disadvantages of generic HRQOL measures are particularly apparent.7 One critical question in evaluating HRQOL outcomes in a clinical trial is whether aspects of patients’ lives that patients consider important have been measured.8 If a generic HRQOL measure does not assess hand dexterity, communication, or vision, then how can the effects of these common stroke impairments on HRQOL be measured? By this practical criterion, most generic HRQOL measures have questionable validity poststroke. Although disease-specific scales are designed to have superior content validity and improved sensitivity to change compared with generic scales, no direct comparison of generic and stroke-specific HRQOL measures has been reported previously.

Because of the problems using generic HRQOL measures in specific diseases, we developed recently the SS-QOL—a new stroke-specific quality of life measure.9 Content validity of SS-QOL items was established by developing items from interviews of stroke survivors. The original item pool was tested in a prospective cohort of ischemic stroke patients. The resulting 49-item version (SS-QOL, version 2.0) showed promising initial psychometric characteristics, with internal reliability of each individual domain >=0.73 and no notable ceiling or floor effects.

The aims of this research are to use the SS-QOL to identify the predictors of poststroke HRQOL in patients with mild to moderate ischemic stroke and to compare the ability of the SS-QOL with that of a generic HRQOL scale for predicting overall HRQOL poststroke.

Methods. Study cohort. Patients older than 18 years with acute ischemic stroke were identified from three adult hospitals (a veterans administration hospital, a county hospital, and a tertiary referral hospital) to develop and to validate a new stroke-specific HRQOL measure, the SS-QOL. Because the primary aim in assembling the cohort was instrument development, patients were excluded if they met any of the following criteria: prior stroke with persistent deficit, intracerebral or subarachnoid hemorrhage, dysphasia at 1 month poststroke such that meaningful communication could not be established, and marked comorbidities likely to affect HRQOL concurrently (e.g., class III or IV heart failure, peritoneal or hemodialysis, preexisting musculoskeletal disease limiting physical function markedly, metastatic cancer, active psychiatric disease or dementia, and diagnosis of HIV infection or AIDS).

Study instruments and follow-up. The following data were collected 1 month ± 1 week poststroke: demographic information, location and size of stroke, ischemic stroke subtype according to Trial of ORG-10172 in Acute Stroke Treatment (TOAST) criteria,10 and length of stay and discharge disposition. Initial stroke severity was determined retrospectively in a previously validated fashion with the Canadian Neurologic Scale.11 An interviewer administered the following measures in random order: the SS-QOL,9 the SF-36 (a generic HRQOL measure),12 and the Beck Depression Inventory (BDI; a depression symptom scale).13 Stroke-related impairments were measured with the NIH Stroke Scale (NIHSS),14 and disability was measured with the Barthel Index.15

The SS-QOL was developed using standard psychometric techniques from interviews with stroke survivors, and it includes 49 items encompassing 12 domains: energy, family roles, language, mobility, mood, personality, self-care, social roles, thinking, vision, upper extremity function, and work/productivity. Each item is ranked on a 5-point Likert scale, with higher scores indicating better function. Domain scores are unweighted averages of the items comprising that domain, and the summary SS-QOL score is an unweighted average of the 12 domain scores. In addition to the SS-QOL items, patients also rated independently each SS-QOL domain and their overall HRQOL compared with prestroke as the same, a little worse, or a lot worse. For this analysis, overall HRQOL was dichotomized (the same versus worse than prestroke HRQOL). Patients were considered depressed if their BDI score was >=10.16

Analyses. Demographic variables and SS-QOL, SF-36, NIHSS, and Barthel Index scores were compared in those with overall HRQOL the same and in those with overall HRQOL worse than prestroke using Student’s t-test or the chi square test. Logistic regression modeling with overall HRQOL as the dependent variable, and variables with p values <0.1 as independent variables, was used to identify the independent predictors of poststroke HRQOL. Interactions between candidate independent variables were considered in the model.

Results. Between August 1, 1997, and June 1, 1998, 71 patients were enrolled in the study. The mean age of the subjects was 61 years, 63% were male, 25% were African-American, and 18% had no health insurance (table 1). Most patients had mild stroke with a mean Canadian Neurologic Scale score on admission of 9.2 ± 1.9 (SD; range, 2.0 to 11.5; best possible score, 11.5). NIHSS scores were >=1 in 43% of patients, and the Barthel Indexes were >=95 in 81% of patients. The mean SF-36 score was 56 ± 16, and the mean SS-QOL score was 3.8 ± 0.7. HRQOL was rated the same as prestroke by 48% of subjects. A total of 39% of the subjects met criteria for at least mild depression. By TOAST criteria, 51% had lacunar stroke, 61% had stroke <=1 cm on CT or MRI, and 58% of strokes were in the deep gray or subcortical
white matter.

Table 1 Cohort demographics and stroke data (n = 71)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>61 (1)</td>
</tr>
<tr>
<td>Male, %</td>
<td>56</td>
</tr>
<tr>
<td>African American, %</td>
<td>25</td>
</tr>
<tr>
<td>Re-infarction, %</td>
<td>38</td>
</tr>
<tr>
<td>Initial Canadian Neurologic Index</td>
<td>9.2 (1.3)</td>
</tr>
<tr>
<td>Initial stroke subtype, %</td>
<td>57</td>
</tr>
<tr>
<td>Discharged stroke, %</td>
<td>73</td>
</tr>
<tr>
<td>Length of rehab, days</td>
<td>43 (14)</td>
</tr>
</tbody>
</table>

Table 2 Demographic and outcome measure scores by overall HRQOL group

Variables associated significantly with patients' overall HRQOL rating were SS-QOL, NIHSS, and BDI scores (table 2). Age, gender, ethnicity, stroke size, and SF-36 scores were not associated with overall HRQOL rating. Multivariable modeling with NIHSS, Barthel Index, BDI, and SSQOL scores as independent variables showed that the odds of HRQOL being the same as prestroke were associated with higher (better) SS-QOL scores (OR, 2.97; 95% CI, 1.3, 7.1) and lower (better) NIHSS scores (OR, 0.69; 95% CI, 0.47, 0.99; table 3). No significant interactions were seen between candidate variables.

Table 3 Independent predictors of overall HRQOL the same as prestroke

To determine whether only a few specific domains of the SS-QOL were responsible for the overall HRQOL rating, domain scores were compared in the two overall HRQOL groups (table 4). Although all domains except upper extremity were either the same or higher in the group with better HRQOL, only the family roles domain was significantly different, with higher (better) scores in those with better overall HRQOL (mean score, 4.0 versus 3.4; p = 0.04).
Discussion. In this sample of patients with mild to moderate ischemic stroke, the summary SS-QOL score was associated significantly with patient ratings of overall HRQOL 1 month poststroke. Of interest is that this association was not observed with the SF-36. In our patients, the SF-36 physical function and physical role scores did not exhibit a ceiling effect (scores were <=51 in both groups), but rather failed to discriminate patient-reported differences in overall HRQOL. As in other conditions, generic HRQOL measures may be less sensitive to meaningful HRQOL changes after ischemic stroke because either the domains or the specific items lack relevance to stroke survivors—a hypothesis supported by the inability of some SF-36 scale scores to discriminate markedly between the health status of patients with TIA and minor stroke.17

This increased sensitivity of stroke-specific measures has important implications for both the clinician and the "trialist." Clinically, stroke-specific assessments can aid in identifying what is helping or hindering the patient's overall function, allowing the clinician to target interventions that are patient and situation specific. For example, if a patient's mood or energy score is low, then consideration of an antidepressant may be warranted, or if the upper extremity score is low, then referral to occupational therapy may be considered. In stroke trials, the benefit of a stroke-specific measure is that it can assess change across the spectrum of stroke symptoms and severity, thus allowing a broader range of stroke patients to be studied, requiring fewer subjects to detect differences, and providing a greater ability to detect differences that are truly meaningful to patients.

Prior studies of the predictors of generic HRQOL poststroke have used different HRQOL measures and a wide variety of candidate predictor variables in populations that sometimes included patients with TIA or hemorrhagic stroke types. Despite these difficulties, some variables associated frequently with impaired poststroke HRQOL include more impairments, functional disability, and depression. One reason that the SS-QOL may be most predictive of overall HRQOL ratings in our patients is that it incorporates a wide variety of impairments, disabilities, and handicaps, and thus has more explanatory power than an assessment of only one of these outcome categories. This limitation of single outcome measures is exemplified by the Barthel Index, which has a marked ceiling effect in patients with less severe stroke, as demonstrated in our cohort.

It is well-known that nonstroke-related depression may affect HRQOL more than other common chronic conditions. In our patients, depressive symptoms were associated with overall HRQOL in bivariate analyses, but were not associated independently with overall HRQOL. One potential explanation is that, although no significant interaction between SS-QOL and BDI scores were found, the inclusion of a mood domain in the overall SS-QOL score may already account for the effect of depressive symptoms on HRQOL. Some studies have reported that poststroke depression is more common in patients with more severe stroke. Even though our patients had mild to moderate stroke, a similar proportion (39%) were depressed 1 month poststroke, as in other hospital and community samples. Thus, our ability to assess depression as a potential independent predictor of HRQOL was not limited by a low rate of depression in our cohort.

Because the SS-QOL score was the strongest predictor of overall poststroke HRQOL, we were interested in knowing whether certain SS-QOL domains explained most of this association. We found only the family roles domain to be significantly different, however, with higher scores in those with better overall HRQOL. Although we cannot discount the potential impact of multiple tests, this finding may underscore the importance of assessing handicap after stroke, because difficulty in assuming prestroke family or social roles may influence strongly patients' HRQOL. The finding that 10 of the 12 domain scores were higher (better) in those with better overall HRQOL supports both the construct of the SSQOL as an HRQOL measure and the concept of poststroke HRQOL as more than just the sum of individual impairments or disabilities.
This study has several important limitations. Because there is no established gold-standard HRQOL outcome measure in stroke, we used a single question about overall HRQOL as the dependent variable in our model. Although a single question would not be expected to be responsive to change, this type of measure can categorize successfully individual patients with various stroke outcomes. Additional construct validity of our single question is demonstrated by the observation that all outcome measures except the SF-36 had better scores in patients reporting better overall HRQOL. Other limitations are that the cohort is small, represents a relatively homogeneous group of stroke patients with mild to moderate stroke, and does not include patients with marked cognitive or language dysfunction. Until proxy measures of stroke-specific quality of life are validated, the effects of language and cognitive changes on stroke-specific HRQOL are difficult to assess. Because relatively few patients with severe stroke were studied, it may be that other variables are also associated with overall stroke-specific HRQOL in these patients. We are currently conducting a study to address this question.

The important consideration in choosing an HRQOL measure for stroke research is to define the primary research question. This usually leads to the selection of a generic HRQOL measure when the aim is to compare stroke patients with patients with other diseases, and also leads to the selection of a disease-specific measure when the aim is to assess therapeutic response or to identify specific predictors of poststroke HRQOL. Because even patients with mild to moderate stroke have a marked decrease in HRQOL poststroke, measures like the SS-QOL may be especially valuable because they are more sensitive than generic measures to meaningful changes in poststroke HRQOL. Ongoing research will serve to determine the clinically meaningful difference in SS-QOL scores for both research and clinical practice applications and to validate further the SS-QOL in other populations. This work will provide a better understanding of the factors associated with poststroke HRQOL and thus will aid in designing interventions aimed at improving patients' HRQOL after ischemic stroke.

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Key words: Stroke; Quality of life; Outcomes

Accession Number: 00006114-199911100-00039

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Version: rel10.4.1, SourceID 1.12596.1.143