The Stroke Impact Scale 3.0
Evaluation of Acceptability, Reliability, and Validity of the Brazilian Version
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Background and Purpose—We sought to assess the psychometric attributes of the Brazilian version of the Stroke Impact Scale (SIS) 3.0 in stroke survivors.

Methods—Patients were evaluated by the National Institutes of Health Stroke Scale, Mini-Mental State Examination, Barthel Index, Lawton Instrumental Activities of Daily Living Scale, modified Rankin Scale, Geriatric Depression Scale, and Hospital Anxiety and Depression Scale. Health-related quality of life was evaluated with the MOS–Short Form 36 and SIS 3.0.

Results—One hundred seventy-four stroke survivors were assessed (mean age, 56.9 years; 55.2% male). Hand function had a prominent floor effect (45.9%), whereas a ceiling effect was observed in the communication domain (17.3%). The internal consistency of SIS (Cronbach’s α=0.94) and SIS domains (item-dimension correlation, 0.17 to 0.89) were satisfactory; only the emotion domain had poor internal consistency (Cronbach’s α=0.49). Test-retest reliability was evaluated in 50 consecutive patients. Concerning the stability of the SIS, the weighted κ values ranged from 0.33 (item 3a) to 0.94 (item 7e). Intraclass correlation coefficient values for the SIS domains ranged from 0.48 (emotion) to 0.94 (hand function). Standard error of measurement values for SIS domains ranged from 6.85 (mobility) to 9.63 (social participation). Regarding convergent validity, a significant correlation (Spearman’s correlation coefficient, P<0.0001) was found between the SIS composite physical domain and the National Institutes of Health Stroke Scale (r=0.69), modified Rankin Scale (r=0.81), Barthel Index (r=0.87), Lawton Scale (r=0.76), and MOS–Short Form 36 physical component summary (r=0.61). SIS domain scores significantly decreased as modified Rankin Scale scores increased (discriminative validity; ANOVA, P<0.0001).

Conclusions—The Brazilian version of SIS 3.0 has satisfactory psychometric properties and can be used in stroke survivors to assess health-related quality of life. (Stroke. 2008;39:2477-2484.)

Key Words: health-related quality of life ■ reliability ■ stroke ■ Stroke Impact Scale ■ validity

Many developing countries are exhibiting increased life expectancy as well as changes in diet and other risk factors, such as smoking. This fact may contribute to a looming epidemic of stroke in these areas of the world. This demographic change will have a great effect on the profile of disease, as these regions will have to care for a larger number of patients with stroke. Brazil is the largest country in South America with >180 million people. The Brazilian population is becoming older, and the proportion of stroke survivors is expected to increase accordingly.

Health-related quality of life (HRQoL) and subjective well-being are 2 outcomes that are being increasingly incorporated into healthcare evaluation. Although functional outcome measures are important in stroke rehabilitation, patient-reported rating scales are increasingly used to measure several aspects of the patient’s health associated with therapeutic interventions. Suitable and psychometrically tested instruments to assess HRQoL in stroke patients are still lacking in Brazil and other Portuguese-speaking countries.

The MOS–Short Form 36 (SF-36) is a generic measure used to evaluate HRQoL in stroke survivors worldwide. Nevertheless, some SF-36 dimensions may have important floor (eg, physical role) and ceiling (eg, bodily pain and emotional role) effects in stroke patients. The Stroke Impact Scale (SIS) is a specific HRQoL tool that was developed by Duncan et al at the University of Kansas Medical Center to measure multidimensional consequences of stroke.

The primary objective of this study was to perform a validation and cross-cultural adaptation of SIS 3.0. The psychometric attributes of the Brazilian version of SIS 3.0 were assessed in a sample of stroke survivors.
Subjects and Methods

Patients
The reliability and validity study was conducted in the Sarah network of rehabilitation hospitals, a public institution dedicated to the treatment and rehabilitation of neurologic and orthopedic disorders in Brazil. Patients with a diagnosis of stroke who were consecutively admitted to the outpatient Neurology and Stroke Rehabilitation Clinics of the Sarah Hospital in Brasilia DF between July 2007 and December 2007 were included in the study. In addition, the first 50 consecutive patients returned to the clinic to again complete the SIS 3.0 ~15 days after the first evaluation to analyze test-retest reliability.

Stroke Definition and Inclusion/Exclusion Criteria
Stroke was defined as a focal neurologic deficit of sudden onset that lasted at least 24 hours with no known alternative to a vascular cause. Stroke was confirmed by clinical examination and radiologic findings on brain computed tomography and/or magnetic resonance imaging. Both ischemic and hemorrhagic strokes were included in the study, as well as first and recurrent strokes. Trial of ORG 10172 in Acute Stroke Treatment criteria10 were used to define ischemic stroke subtypes.

Exclusion criteria were as follows: (1) patients with transient ischemic attack; (2) severe disability caused by a previous neurologic disorder; (3) concomitant severe systemic illness; and (4) impaired ability to understand the questionnaires (eg, due to severe aphasia, dementia, or decreased level of consciousness). The institutional board reviewed the design and methods of the study. All patients included in the study gave their informed consent.

Assessments
Neurologist-based assessments were based on the National Institutes of Health Stroke Scale (NIHSS),11 the modified version of the Rankin Scale (mRS),12,13 Folstein’s Mini-Mental State Examination (MMSE),14 and the Geriatric Depression Scale (GDS).15 Activities of daily living (ADLs) were evaluated by means of the Barthel Index (BI),16 whereas instrumental activities of daily living (IADLs) were assessed with the Lawton and Brody Scale.17 HRQoL was evaluated with a generic instrument, the SF-36,6 and a specific HRQoL measure, the Brazilian version of SIS 3.0.8 Patients also answered the Hospital Anxiety and Depression Scale (HADS).18 The SIS 3.0 measures were administered by an interviewer and were answered by the patients during their visit to the clinic. Sociodemographic data and information about vascular risk factors were obtained during the interview.

The NIHSS is a 15-item stroke impairment scale11 that provides a quantitative measure of the key components of a standard neurologic examination. The NIHSS assesses level of consciousness, extrinsic ocular movements, visual fields, facial muscle function, arm and leg strength, coordination (limb ataxia), sensory function, language (aphasia), speech (dysarthria), extinction, and inattention. The scale has been widely used as a standard neurologic assessment tool in clinical trials.19 The maximum possible score is 42, and higher scores indicate greater impairment.

The mRS was used to measure global functional independence.13 The scale is defined categorically with 7 different grades: 0 (no symptoms), 1 (no significant disability despite symptoms), 2 (slight disability; unable to perform all previous activities but able to look after own affairs without assistance), 3 (moderate disability; patient requires some help but is able to walk without assistance), 4 (moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance), 5 (severe disability; patient is bedridden, incontinent, and requires constant nursing care and attention), and 6 (deceased). The validity and interrater reliability of the mRS has been well documented.13

The MMSE14 measures certain areas of cognitive functioning, including memory, orientation to place and time, naming, reading, copying (visuospatial orientation), writing, and the ability to follow a 3-stage command. This instrument has 19 items and is scored from 0 to 30 points. The cutoff point for cognitive impairment is 24/23.

Appraisal of the cognitive state was carried out by means of the Brazilian version of the MMSE.20 The BI has been widely used to evaluate ADLs in stroke patients. The BI16 measures 10 basic aspects of ADLs related to self-care and mobility: control of bowels and bladder, grooming, toilet use, feeding, transfer, mobility, dressing, stairs, and bathing. The BI score ranges from 0 to 100, and lower scores indicate greater dependency. Validity and reliability have been well established.21

The Lawton and Brody IADL scale17 was used to assess higher levels of IADLs. The scale ranges from 8 (completely unable to handle instrumental activities) to 24 (no help needed). The scale assesses the following functional abilities: using the telephone, getting to places beyond walking distance, grocery shopping, preparing meals, doing housework or handyman work, doing laundry, taking medications, and managing money.

Depression is an important determinant of HRQoL in stroke survivors.22 The HADS18 consists of 7 items for assessment of anxiety and 7 for depression, with each item scored from 0 (no problem) to 3 (severe problem). Scores on individual items can be summed to calculate a score for anxiety (HADS-Anx) and for depression (HADS-Dep). Scores ≥11 points on a subscale are indicative of mood disturbance. The GDS has been used for evaluation of depressive symptoms in cross-sectional studies in samples of elderly subjects.23 In the present study, the 15-item GDS, Brazilian version, was used.23 Scores range from 0 to 15, and higher scores (cutoff value ≥6) are associated with clinically important depressive symptoms.

The SF-36 is a generic HRQoL measure that includes 8 domains for assessment of physical functioning, role limitations due to physical problems, bodily pain, general health perception, vitality, social functioning, role limitations due to emotional problems, and emotional well-being.6 Scores for each domain range from 0 to 100, and higher values indicate better function. The Brazilian version of SF-36 was used.24

The SIS 3.025 is a 59-item self-report assessment of stroke outcome used to assess HRQoL. The SIS has 8 domains: strength, hand function, mobility, physical and instrumental activities of daily living (ie, ADLs and IADLs), memory and thinking, communication, emotion, and social participation. Scores for each domain range from 0 to 100, and higher scores indicate a better HRQoL. The strength items are rated in terms of strength; memory, communication, ADLs/IADLs, mobility, and hand function items are rated in terms of amount of difficulty; emotion and social participation items are rated in terms of frequency. Four of the subscales (strength, hand function, ADLs/IADLs, and mobility) can be combined into a composite physical domain.26 The SIS 3.0 also includes a question (item 50) to assess the patient’s global perception of recovery. The respondent is asked to rate his or her percentage of recovery on a visual analog scale of 0 to 100, with 0 meaning no recovery and 100 meaning full recovery. Permission for use and validation of the scale were obtained from Mapi Research Trust (Lyon, France).27

Translation and Back-Translation
The SIS 3.0 was translated into Portuguese by 4 independent native Portuguese speakers with excellent knowledge of English. Then, a first Portuguese version of the SIS was obtained by consensus. This version was back-translated into English by an English native who had very good knowledge of Portuguese without access to the original English version of the questionnaire. The first back-translation was compared with the original version, and modifications were made to eliminate all discrepancies between the original and the back-translated versions. The final joint translation was named the SIS 3.0 Brazilian version.

Data Analysis
The following psychometric attributes were explored: acceptability, scaling assumptions, reliability, precision, and construct and discriminant validity. Acceptability is the extent to which score distributions adequately represent the true distribution of health status in the sample. To establish acceptability, observed versus possible score ranges, floor and ceiling effects (proportion of patients who
obtained minimum and maximum scores, respectively; acceptable <15%), and skewness (criterion, −1 to +1) were determined. Scaling assumptions test the correct grouping of items and the appropriateness of a summed score. Scaling assumptions were checked by means of the item-domain correlation corrected for overlapping (each relevant item is removed from its domain for correlation). Values of 0.40 or higher were considered appropriate. Internal consistency of the SIS 3.0 and SIS domains was assessed by using Cronbach’s α. It was considered acceptable when this coefficient was 0.70 or higher. Correlations between the SIS domains were also calculated; Pearson’s coefficient values of 0.30 to 0.80 were deemed satisfactory.

Test-retest reliability for individual items was assessed by means of weighted κ (quadratic weights), whereas for SIS domains, an intraclass correlation coefficient (ICC) (2-way random model, agreement) was calculated. Weighted κ values >0.40 for items and an ICC ≥0.70 for SIS domain scores were taken as criteria of acceptable concordance and stability.

The SEM and the smallest real difference (SRD) were calculated to determine the precision and potential responsiveness of the SIS. SEM is an estimate of error in interpreting an individual’s test score, which is an estimate of a subject’s “true” test performance. SEM values were calculated with the following formula: SEM = SD × √(1 − reliability coefficient for test), and [SEM = SD/2] was taken as the criterion of acceptable precision. The SRD indicates thresholds for a true difference between 2 successive measurements at a 95% confidence level [SRD = 1.96 × √2 × SEM]. Lower the reliability, the greater the SEM and SRD, and the less precise the scale.

Convergent validity refers to the extent to which the measure (SIS 3.0) is related to other measures for related constructs (SF-36). It was explored by means of Spearman’s rank correlation coefficients (rS). Construct convergent validity with other functional measures for stroke (eg, NIHSS, BI, mRS, HADS, and GDS) was also assessed. The Spearman coefficient corrected for ties was also used to assess the correlation between the SIS domains and sociodemographic variables. It was hypothesized that coefficient values would be moderate (rS = 0.30 to 0.59) or high (rS ≥ 0.60) with the stroke rating scales and SF-36 dimensions and low (rS < 0.30) with respect to age and education.

Discriminant validity refers to the ability of the measure to discriminate between stroke patients at different stages of severity determined by the mRS. The ANOVA test was used to compare SIS mean scores subdivided by mRS stages. SPSS 13.0 for Windows (SPSS, Chicago, Ill) was used for data analysis.

### Results

#### Patient Sample

Most patients who were approached consented to participate, and only 2 patients refused to participate in the study. The metric attributes of SIS 3.0 were evaluated in 174 stroke survivors (55.2% male; mean age, 56.9 years). Demographic and vascular risk factors of the study population are shown in Table 1. The great majority of patients (89.6%) had an ischemic infarction. Motor and functional evaluations of stroke patients are shown in Table 2. The NIHSS mean score was 6.6 (range, 0 to 16), and 45.4% of stroke patients had a mRS score ≥2. The median BI score was 80 (interquartile range 40; limits of 10 and 100), and 62.2% of survivors had had a stroke in the previous 12 months.

#### Acceptability

The acceptability and reliability of SIS 3.0 and the distribution of scores on the 8 SIS domains are displayed in Table 3. The mean score of the composite physical domain was 45.5 (SD = 23.9). The mean scores of the SIS domains ranged from 25.1 (hand function) to 77.2 (communication). The mean score of the SIS visual analog scale was 54.3, with a median of 50 and an interquartile range of 40. Skewness ranged from −0.87 (communication) to 1.1 (hand function). A prominent floor effect (45.9%) was observed in the hand function domain, whereas a ceiling effect was observed in the communication domain (17.3%).

#### Reliability

The internal consistency of SIS 3.0 (Cronbach’s α = 0.94), the composite physical domain (Cronbach’s α = 0.96), and the SIS domains (Cronbach’s α from 0.81, strength to 0.95, hand function) was satisfactory. Only the emotion domain (Cronbach’s α = 0.49) did not attain the α value of 0.70.

Most corrected item-domain correlation coefficients obtained values higher than the criterion (0.40). Corrected item-domain coefficients were unsatisfactory in 4 items of the emotion domain (item 3e, blame, 0.17; item 3f, enjoy things, 0.33; item 3h, life is worth living, 0.25; and item 3i, smile, 0.25) and in 1 item of the ADL/IADL domain (item 5g, bowel control, 0.28). Removal of this last item did not lead to a reduction in internal consistency for its domain (Cronbach’s α = 0.89 with and Cronbach’s α = 0.90 without the bowel item).
Concerning the interdomain correlation of SIS 3.0, the closest association was observed for mobility and ADL/IADL domains ($r_s = 0.80$), strength and hand function ($r_s = 0.61$), ADL/IADL and hand function ($r_s = 0.61$), and memory and communication ($r_s = 0.58$). The weakest association ($r_s = 0.04$ to 0.30) was obtained for the memory domain and the remaining SIS domains. Patients’ global assessment of recovery was significantly correlated with the SIS composite physical domain (0.43) and with ADL/IADL (0.43), mobility (0.41), and strength (0.30) domains.

The test-retest reliability of SIS 3.0 was acceptable. The weighted $r_s$ values for the SIS items ranged from 0.33 (item 3a) to 0.94 (item 7e). Items 3a (feel sad, 0.33), 2c (remember to do things, 0.38), 3c (feel to be a burden to others, 0.37), and 8b (social activities, 0.38) had weighted $r_s$ values lower than the limit of 0.40. Concerning the stability of the SIS, ICC values for the SIS domains ranged from 0.48 (emotion) to 0.94 (hand function).

### Precision

The SEM value for the SIS composite physical domain was 4.77 (upper limit 95% CI 11.0). SEM values for each SIS domain ranged from 6.85 (mobility) to 11.4 (strength) and attained the criterion (SEM = SD/2) with the exception of the emotion domain (SD = 12.2, SEM = 8.64). The SRD for the SIS domains ranged from 18.99 (mobility) to 26.70 (social participation).

### Validity

SIS 3.0 was shown to have adequate convergent validity. Tables 4 and 5 display the correlations between SIS domains, SF-36 dimensions, and stroke functional scales. The SIS composite physical domain was correlated at a high level with the physical component summary of the SF-36 ($r_s = 0.61$, $P < 0.0001$). Significant correlations ($P < 0.0001$) were observed between the SF-36 physical component summary and the following SIS domains: mobility ($r_s = 0.58$), ADL/IADL ($r_s = 0.58$), strength ($r_s = 0.50$), and hand function ($r_s = 0.48$). Concerning the SF-36 categories, the highest association ($P < 0.0001$) was obtained between SF-36 physical function and the following SIS domains: mobility ($r_s = 0.83$), ADL/IADL ($r_s = 0.78$), strength.

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**Table 2. Functional Evaluation of Stroke Patients**

<table>
<thead>
<tr>
<th>SIS Domains</th>
<th>No. of Items</th>
<th>Mean ± SD</th>
<th>Observed Score Range</th>
<th>Skewness</th>
<th>Floor Effect, %</th>
<th>Ceiling Effect, %</th>
<th>Item-Domain Correlation</th>
<th>Cronbach’s $\alpha$</th>
<th>ICC</th>
<th>Weighted $\kappa$</th>
<th>SEM</th>
<th>SRD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength</td>
<td>4</td>
<td>46.7 ± 26.9</td>
<td>0–100</td>
<td>0.4</td>
<td>1.7</td>
<td>6.3</td>
<td>0.60–0.69</td>
<td>0.81</td>
<td>0.81</td>
<td>0.56–0.75</td>
<td>11.4</td>
<td>31.7</td>
</tr>
<tr>
<td>Hand function</td>
<td>5</td>
<td>25.1 ± 32.9</td>
<td>0–100</td>
<td>1.1</td>
<td>45.9</td>
<td>6.3</td>
<td>0.82–0.90</td>
<td>0.95</td>
<td>0.94</td>
<td>0.72–0.94</td>
<td>7.34</td>
<td>20.36</td>
</tr>
<tr>
<td>Mobility</td>
<td>10</td>
<td>49.4 ± 27.9</td>
<td>0–100</td>
<td>0.0</td>
<td>1.7</td>
<td>4.6</td>
<td>0.49–0.89</td>
<td>0.94</td>
<td>0.89</td>
<td>0.66–0.88</td>
<td>6.85</td>
<td>18.99</td>
</tr>
<tr>
<td>ADL/IADL</td>
<td>12</td>
<td>51.7 ± 25.3</td>
<td>5–100</td>
<td>0.3</td>
<td>0</td>
<td>5.8</td>
<td>0.28–0.77</td>
<td>0.89</td>
<td>0.83</td>
<td>0.59–0.89</td>
<td>8.38</td>
<td>23.22</td>
</tr>
<tr>
<td>Memory</td>
<td>8</td>
<td>70.8 ± 22.4</td>
<td>71–100</td>
<td>−0.6</td>
<td>0</td>
<td>12.6</td>
<td>0.58–0.77</td>
<td>0.88</td>
<td>0.87</td>
<td>0.38–0.67</td>
<td>7.76</td>
<td>21.52</td>
</tr>
<tr>
<td>Communication</td>
<td>7</td>
<td>77.2 ± 20.5</td>
<td>14.3–100</td>
<td>−0.9</td>
<td>0</td>
<td>17.3</td>
<td>0.48–0.68</td>
<td>0.82</td>
<td>0.81</td>
<td>0.56–0.74</td>
<td>8.68</td>
<td>24.05</td>
</tr>
<tr>
<td>Emotion</td>
<td>9</td>
<td>51.9 ± 12.2</td>
<td>22.2–80.6</td>
<td>−0.3</td>
<td>0</td>
<td>0</td>
<td>0.17–0.47</td>
<td>0.49</td>
<td>0.48</td>
<td>0.33–0.74</td>
<td>8.64</td>
<td>24.09</td>
</tr>
<tr>
<td>Social participation</td>
<td>9</td>
<td>50.6 ± 22.7</td>
<td>0–100</td>
<td>0.2</td>
<td>1.2</td>
<td>4.0</td>
<td>0.47–0.62</td>
<td>0.82</td>
<td>0.79</td>
<td>0.38–0.68</td>
<td>9.63</td>
<td>26.70</td>
</tr>
<tr>
<td>Patient’s global assessment of recovery</td>
<td>54.3 ± 20.9</td>
<td>0–100</td>
<td>0.5</td>
<td>2.9</td>
<td>6.3</td>
<td>0.47–0.62</td>
<td>0.82</td>
<td>0.79</td>
<td>0.38–0.68</td>
<td>9.63</td>
<td>26.70</td>
<td></td>
</tr>
<tr>
<td>Composite physical domain</td>
<td>45.5 ± 23.9</td>
<td>6.3–100</td>
<td>−0.1</td>
<td>0</td>
<td>1.7</td>
<td>0.40–0.78</td>
<td>0.96</td>
<td>0.94</td>
<td>0.56–0.94</td>
<td>4.77</td>
<td>13.23</td>
<td></td>
</tr>
</tbody>
</table>

*Corrected for overlapping.
### Table 4. Convergent Validity Between SIS 3.0 Domains and SF-36 Dimensions: Spearman’s ρ Correlation Coefficients*

<table>
<thead>
<tr>
<th>SIS Domains</th>
<th>SF-36 Dimensions</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>PCS</th>
<th>MCS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Physical</td>
<td>Role</td>
<td>Physical</td>
<td>Pain</td>
<td>Social Function</td>
<td>Mental Health</td>
<td>Role Emotional</td>
</tr>
<tr>
<td>Strength</td>
<td>0.55</td>
<td>0.34</td>
<td>0.30</td>
<td>0.20</td>
<td>0.29</td>
<td>0.19</td>
<td>0.14</td>
</tr>
<tr>
<td>Hand function</td>
<td>0.48</td>
<td>0.32</td>
<td>0.09</td>
<td>0.11</td>
<td>0.10</td>
<td>0.06</td>
<td>0.04</td>
</tr>
<tr>
<td>Mobility</td>
<td>0.83</td>
<td>0.31</td>
<td>0.21</td>
<td>0.32</td>
<td>0.25</td>
<td>0.18</td>
<td>0.22</td>
</tr>
<tr>
<td>ADL/IADL</td>
<td>0.78</td>
<td>0.34</td>
<td>0.18</td>
<td>0.27</td>
<td>0.35</td>
<td>0.07</td>
<td>0.18</td>
</tr>
<tr>
<td>Memory and thinking</td>
<td>0.11</td>
<td>0.24</td>
<td>0.35</td>
<td>0.38</td>
<td>0.35</td>
<td>0.23</td>
<td>0.40</td>
</tr>
<tr>
<td>Communication</td>
<td>0.17</td>
<td>0.04</td>
<td>0.22</td>
<td>0.28</td>
<td>0.35</td>
<td>0.17</td>
<td>0.28</td>
</tr>
<tr>
<td>Emotion</td>
<td>0.13</td>
<td>0.05</td>
<td>0.29</td>
<td>0.33</td>
<td>0.55</td>
<td>0.29</td>
<td>0.38</td>
</tr>
<tr>
<td>Social participation</td>
<td>0.55</td>
<td>0.44</td>
<td>0.22</td>
<td>0.41</td>
<td>0.32</td>
<td>0.27</td>
<td>0.24</td>
</tr>
<tr>
<td>Patient’s global assessment of recovery</td>
<td>0.41</td>
<td>0.18</td>
<td>0.14</td>
<td>0.27</td>
<td>0.28</td>
<td>0.19</td>
<td>0.30</td>
</tr>
<tr>
<td>Composite physical domain</td>
<td>0.83</td>
<td>0.35</td>
<td>0.27</td>
<td>0.29</td>
<td>0.26</td>
<td>0.11</td>
<td>0.17</td>
</tr>
</tbody>
</table>

PCS indicates physical component summary; MCS, mental component summary.

*Spearman’s ρ correlation coefficient >0.16, P<0.05; ρ>0.28, P<0.001; ρ>0.32, P<0.0001.

### Table 5. Convergent Validity Between SIS 3.0 Domains and Stroke Functional Scales: Spearman’s ρ Correlation Coefficients*

<table>
<thead>
<tr>
<th>SIS Domains</th>
<th>NIHSS</th>
<th>BI</th>
<th>Lawton Scale</th>
<th>Rankin</th>
<th>HADS-Anx</th>
<th>HADS-Dep</th>
<th>GDS</th>
<th>MMSE</th>
<th>SIS Patient’s Global Assessment of Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength</td>
<td>−0.56</td>
<td>0.53</td>
<td>0.43</td>
<td>−0.53</td>
<td>−0.20</td>
<td>−0.24</td>
<td>−0.06</td>
<td>0.15</td>
<td>0.30</td>
</tr>
<tr>
<td>Hand function</td>
<td>−0.60</td>
<td>0.55</td>
<td>0.50</td>
<td>−0.56</td>
<td>−0.09</td>
<td>−0.15</td>
<td>0.03</td>
<td>0.17</td>
<td>0.21</td>
</tr>
<tr>
<td>Mobility</td>
<td>−0.54</td>
<td>0.79</td>
<td>0.68</td>
<td>−0.74</td>
<td>−0.23</td>
<td>−0.28</td>
<td>−0.19</td>
<td>0.27</td>
<td>0.41</td>
</tr>
<tr>
<td>ADL/IADL</td>
<td>−0.64</td>
<td>0.85</td>
<td>0.78</td>
<td>−0.77</td>
<td>−0.23</td>
<td>−0.32</td>
<td>−0.18</td>
<td>0.25</td>
<td>0.43</td>
</tr>
<tr>
<td>Memory and thinking</td>
<td>−0.09</td>
<td>0.07</td>
<td>0.18</td>
<td>−0.04</td>
<td>−0.46</td>
<td>−0.43</td>
<td>−0.28</td>
<td>0.33</td>
<td>0.11</td>
</tr>
<tr>
<td>Communication</td>
<td>−0.15</td>
<td>0.10</td>
<td>0.24</td>
<td>−0.09</td>
<td>−0.39</td>
<td>−0.52</td>
<td>−0.23</td>
<td>0.40</td>
<td>0.20</td>
</tr>
<tr>
<td>Emotion</td>
<td>−0.05</td>
<td>0.04</td>
<td>0.08</td>
<td>0.02</td>
<td>−0.43</td>
<td>−0.39</td>
<td>−0.41</td>
<td>0.22</td>
<td>0.13</td>
</tr>
<tr>
<td>Social participation</td>
<td>−0.38</td>
<td>0.47</td>
<td>0.45</td>
<td>−0.47</td>
<td>−0.21</td>
<td>−0.33</td>
<td>−0.20</td>
<td>0.28</td>
<td>0.35</td>
</tr>
<tr>
<td>Patient’s global assessment of recovery</td>
<td>−0.19</td>
<td>0.35</td>
<td>0.36</td>
<td>−0.36</td>
<td>−0.23</td>
<td>−0.32</td>
<td>−0.17</td>
<td>0.20</td>
<td></td>
</tr>
<tr>
<td>Composite physical domain</td>
<td>−0.69</td>
<td>0.87</td>
<td>0.76</td>
<td>−0.81</td>
<td>−0.23</td>
<td>−0.29</td>
<td>−0.14</td>
<td>0.28</td>
<td>0.43</td>
</tr>
</tbody>
</table>

*Spearman’s ρ correlation coefficient >0.16, P<0.05; ρ>0.28, P<0.001; ρ>0.32, P<0.0001.

(r8=0.55), and social participation (r8=0.55). A moderate correlation (P<0.0001) was observed between the SIS emotion domain and the SF-36 mental health category (r8=0.55).

The SIS composite physical domain was significantly (P<0.0001) correlated at a high level with NIHSS (r8=−0.69), BI (r8=87), Lawton scale (r8=0.76), and mRS (r8=−0.81). Moderate correlations were observed between the SIS memory domain and HADS-Anx and HADS-Dep subscales (r8=−0.46 and r8=−0.43, respectively) and between the SIS communication domain and HADS-Dep (r8=−0.52). The SIS emotion domain was moderately correlated with HADS-Anx (r8=−0.43) and HADS-Dep (r8=−0.39) subscales and GDS (r8=−0.41). A low but still significant correlation was observed between years of education and the communication domain (r8=0.28), whereas age was moderately correlated with mobility (r8=−0.24).

SIS composite physical domain mean scores tended to significantly decrease as the severity of disease, based on
mRS, increased (ANOVA, \(P<0.0001\)). Concerning the SIS domains, the discriminant validity was poor for the memory domain and proved to be barely significant for communication (\(P=0.04\)). The highest discriminant values were obtained with strength, hand function, mobility, and ADL/IADL domains (\(P<0.0001\)). Table 6 shows the SIS domain mean scores subdivided by mRS scores.

### Discussion

The SIS was developed from the perspective of patients and caregivers to detect persistent consequences of stroke, primarily in patients with mild to moderate stroke.\(^8\) Initial validation of SIS 2.0 was performed in the United States in a sample of stroke survivors 1 to 3 months after stroke.\(^8\) Rasch analysis further identified and removed misfitting items from the 8 domains that composed SIS 2.0 and established the validity of SIS 3.0.\(^{25}\) The same group of investigators validated SIS 3.0 in a sample of patients with moderate to severe stroke.\(^{24}\) The ceiling effect observed in the hand function domain (45.9%), a finding also detected in the original version (0.70 for most domains of the SIS. Nevertheless, internal consistency was inadequate for the emotion domain (Cronbach’s \(\alpha=0.49\)). This domain also had insufficient internal consistency (0.40) in the original SIS version (0.53).\(^8\)

Most item-domain correlation coefficient values were higher than the established criterion of 0.40; nevertheless, almost half of the items from the emotion domain did not attain this value. The item “control your bowels” had a low item-domain correlation in both the Brazilian and Australian\(^{44}\) versions of the SIS. As calculated, removal of this item did not lead to a reduction in internal consistency for the SIS ADL domain.

Test-retest reliability was satisfactory for the SIS 3.0 domains. Most of the composite physical domain items showed high reliability (weighted \(\kappa>0.61\)), whereas only 4 items had values <0.40 (mild concordance). Most items from memory, emotion, communication, and participation domains showed moderate reliability (\(\kappa=0.41\) to 0.60). Items related to cognitive and emotional functions were less reliable than items from physical domains of SIS 3.0. In addition, SIS domains attained ICC values higher than the ICC limit of 0.70, with the exception of the emotion domain (0.48; original version, 0.57). The ICC values (0.79 to 0.94) were similar to those in the original version (0.70 to 0.92).\(^8\)

This study provides additional psychometric information regarding the precision of the scale based on the SEM. The SEM and the SRD provide information about the threshold of within-subject variability that has to be surpassed for a change to be deemed relevant. In this study, the within-subject score variation on 2 replicate tests ranged from 6.4 to 11 points for the different SIS domains. A change of 4.77 (SEM) to 13.23 (SRD) points (≈5% to 15% of the maximum possible score, at a 95% CI) in the composite physical domain score can be considered a real change and a minimal important difference for the stroke population.
Evidence of adequate convergent validity has been shown for the SIS 3.0 Brazilian version. As hypothesized, the SIS composite physical domain was correlated at a high level with the SF-36 physical component summary and the SF-36 physical function. Hand function, ADL/IADL, and mobility domains also showed a moderate association with the functional scales used in the study (NIHSS, BI, Lawton Scale, and mRS). A less robust association between SIS domains and age, years of education, and time from stroke onset was also detected.

Mean scores of the SIS domains were significantly higher in the group of more severely affected stroke patients (mRS 3 and 4), thereby showing that SIS 3.0 has the ability to distinguish between patients with different health conditions. The memory domain lacked discriminant validity, as occurred in the original version of the SIS. Scores on the patient’s global assessment of recovery also displayed good discriminant validity among mild, moderate, and severe stroke patients.

This study was performed in a reference stroke rehabilitation center, and its generalizability to other populations may be uncertain. Nevertheless, validation of the SIS 3.0 Brazilian version was performed in a sample of 174 stroke survivors with all degrees of stroke severity. Although the psychometric analysis was performed in the chronic phase of stroke, the time from stroke onset to administration of the SIS has little effect on item functioning.

Our data suggest that the Brazilian version of SIS 3.0 is a valid instrument to assess the HRQoL of stroke patients. Additional psychometric evaluations are needed to assess responsiveness, the psychometric quality of the proxy version, and suitability of SIS 3.0 for specific stroke subgroups and to examine the factor structure of SIS 3.0. The reliability of the emotion domain was low, and a more stable and responsive measure of emotion is needed. However, the weak association between the emotion domain and the other SIS 3.0 domains supports the independence of this construct.

In conclusion, the SIS 3.0 Brazilian version has satisfactory internal consistency, test-retest reliability, construct convergent validity, and discriminant validity in stroke patients. SIS 3.0 is a psychometrically robust specific HRQoL measure that may be useful to evaluate the consequences of stroke in different cultural contexts.

Disclosures

None.

References


The Stroke Impact Scale 3.0: Evaluation of Acceptability, Reliability, and Validity of the Brazilian Version
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