Development of a disease-specific health-related quality of life questionnaire for patients with post-stroke spasticity

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Abstract

Objective: This study was designed to develop a disease-specific health-related quality of life (HR-QOL) measure for patients with post-stroke spasticity.

Methods: Based on responses from 20 patients with post-stroke spasticity and an extensive literature search, items potentially used to measure these patients’ recovery status were identified and the Apoplexy Spastic-Paralysis Questionnaire (ASPQ) was formed. A sample of 106 patients was then tested twice using the ASPQ, the Self-rating Depression Scale (SDS) and the Stroke-specific Quality of Life (SS-QOL). Clinicians also examined all the patients using the Ashworth Scale (AS). Internal reliability was assessed using Cronbach’s coefficient α, while construct validity was determined using principal component analysis (PCA). Empirical validity was evaluated between patients with depression and those without depression by single factor analysis. Sensitivity was examined by calculating the Spearman correlation coefficient between the changes in scores of the ASPQ, the AS and the SS-QOL.

Results: The ASPQ had adequate internal consistency reliability (α=0.874) and sensitivity, with significant correlations between the changes in scores of the AS, the SS-QOL and the ASPQ, with three domains. In a construct validity test, six factors were extracted; the overall variance explained by all factors was 72.6%. For empirical validity, mean values of 19 items and 3 domains were all higher in the depressive patients than in the non-depressive patients.

Conclusion: The ASPQ is a reliable and valid self-rating scale for measuring the HR-QOL in patients with post-stroke spasticity.

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Key words: Questionnaires; Stroke; Hemiplegia; Quality of life; Sensitivity and specificity
INTRODUCTION

There are four sources of patient outcomes assessment: clinician-reported, physiological, caregiver-reported and patient-reported. Health can be investigated microscopically in terms of organs, cells, molecules or genes, but it also involves psychological, mental and social factors. Integrating the human body and its outer environment requires not only physiological and biochemical outcomes, but the patient’s perspective on clinical practices and research. In recent years, research on patient-reported outcomes (PROs) has attracted more attention, and its use has become increasingly prevalent and widespread. Spasticity, as one of the sequelae of a stroke, results from an upper motor neuron lesion, presenting as intense muscular tension and voluntary movement impairment. With the increase in China’s aging population, stroke has become common among middle-aged and elderly people, posing a serious public health danger. Many stroke patients experience spastic limbs about two weeks after falling ill, and their rehabilitation is a long process. Patients experience a variety of symptoms that have profound, negative effects on their ability to remain active and on their emotional well-being. Many interventions for stroke patients are integrative treatment methods designed to improve their physical condition and help them feel better. New types of stroke units are enhancing their efficiency and effectiveness with the use of Traditional Chinese Medicine treatment modalities. Although health-related quality of life (HR-QOL) measures have been an important part of evaluating the impact of strokes and stroke interventions, no systematic assessment of the symptoms and suffering of patients with post-stroke spasticity is currently available. At present, there are many measures by which to evaluate stroke patients, most of which assess physical function and daily activities, such as the National Institutes of Health Stroke Scale (NIHSS), European Stroke Scale (ESS), Fugl-Meyer Assessment (FMA), Barthel Index (BI), Functional Independence Measure (FIM) and the Activities of Daily Living (ADL), to name a few. Few HR-QOL measures assess post-stroke spasticity exclusively or include subjective internal states, such as symptoms or feelings that are unobservable by others. Hence, the objective of the current study was to describe the development of a disease-specific questionnaire for patients with post-stroke spasticity.

METHODS

Study design

In 1946, the World Health Organization (WHO) defined health in its broader sense as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity". This study’s proposed hypothesis is based on this definition of health. HR-QOL in patients with post-stroke spasticity should be measured in the following three aspects of their lives: physical symptoms, altered emotional states and social activity impairment. It is essential that the items on the final questionnaire reflect these areas of suffering that are most important to this type of patient. The questionnaire should show sensitivity, reliability, and validity, and be as brief as possible to minimize response burden.

Participants and data collection

We included patients who met the diagnostic criteria set by the fourth Cerebra-vascular Disease Conference in 1995, and who presented high-limb muscle spasticity, as evaluated with the Ashworth Scale (AS) (Grade 1). The AS uses a five-point scale for grading resistance encountered during passive muscle stretching. We excluded patients if they had difficulties with consciousness, language or cognition that would prevent reliable completion of the questionnaire. From December 2006 to February 2007, patients were recruited at 5 locations in Beijing: Guan’anmen Hospital, affiliated with the China Academy of Chinese Medical Sciences; Huguosi Hospital, affiliated with the Beijing University of Chinese Medicine; Beijing Electric Power Hospital; Guangwai Hospital and Baizhifang Community Health Service Center, both in the West City District of Beijing. Twenty patients were interviewed to help with item selection and questionnaire construction. Another 106 patients were asked to complete the initial and the data obtained from that query were used to examine its reliability and construct validity. The patients also completed the Stroke-Specific Quality of Life (SS-QOL), a measure developed to assess HR-QOL in stroke patients, and the Self-rating Depression Scale (SDS). Scores were ranked from 1 to 5, with higher scores indicating better HR-QOL. In the 49-item scale, all 12 domains of the SS-QOL demonstrated excellent internal reliability (Cronbach’s α values for each domain was ≥0.73). The 106 patients completed all the measures twice and the recall period was two to three weeks. Additionally, each time a patient completed the instruments, a clinician with more than five years of clinical experience examined him or her using the AS to assess spasticity. The longitudinal data obtained were used to assess the sensitivity of the questionnaire. Informed consent was obtained from all participants prior to enrollment in the study.

Statistical analysis

Internal reliability was assessed using both Cronbach’s coefficient α and the corrected item-total correlation coefficient. Construct validity was determined using principal component extraction with varimax rotation. In accordance with China’s SDS norms, we defined the standard score above 53 as depression.
validity was evaluated to examine differences in scores on each item and domain of the ASPQ between patients with depression and non-depression by single factor analysis (T test for the numerical variable data of the Gaussian distribution, rank sum test for the numerical variable data of the non-normal distribution). Sensitivity was evaluated by calculating the Spearman correlation coefficient between the score changes of the ASPQ, the AS and the SS-QOL. All statistical analyses were performed with SPSS 16.0 for Windows and \( P \leq 0.01 \) was taken to indicate statistical significance.

**RESULTS**

**Questionnaire construction**

Beginning with the literature review, we analyzed the symptoms of stroke in limbs and the impact on patients' lives. Face-to-face interviews with 20 patients were conducted to determine their discomfort and disability and collect their opinions on the questionnaire item stems and response options, such as establishing an order of importance, marking the doubts beyond comprehension and giving their proposition. Finally, 19 items were selected to form the initial ASPQ, including nine for physical symptoms, six for altered emotional states and four for social activity impairment.

The content of three domains was as follows:
- Physical symptoms: pain, numbness, stiffness, heaviness, trembling, weakness, swelling, cramps, sweating;
- Altered emotional states: crying, upset, anger, sadness, lack of confidence, worrying;
- Social activity impairment: inactivity, disinterest, lack of interaction, loss of income.

Each item was rated on a five-point Likert scale: "Never", "Sometimes", "On average", "Often", "Always", "Not at all", "A little bit", "Moderately", "Quite a bit", "Extremely". The questionnaire is closed-ended with responses ranked on a five-point scale (ranging from 1 to 5). On average, it takes about 15 min to complete.

**Descriptive characteristics of the participants**

Of the 106 patients who completed the ASPQ, 60.4% were men with an average age of 62.5 (SD=13.5). Nineteen percent (19%) of these patients reported having a primary school degree or less education. Of the 106 patients, 83 (78.3%) reported having no depression while 23 (21.7%) reported having depression.

**Internal consistency**

The Cronbach coefficient \( \alpha \) was 0.874 for the 19 items. However, the Cronbach \( \alpha \) increased to 0.878 when "sweating" was removed. This item also showed a corrected item-total correlation below 0.3 (0.293, 0.307). Internal consistency reliability estimates were adequate for physical symptoms (9 items, \( \alpha=0.825 \)), altered emotional states (6 items, \( \alpha=0.759 \)) and social activity impairment (4 items, \( \alpha=0.865 \)).

**Construct validity**

To examine construct validity, 19 items were factorized using principal component analysis (PCA). The following six factors were identified and the total percentage of variance was 72.6% (Table 1): Factor 1 consisted of seven items related to physical symptoms and "confidence" level; Factor 2 was made up of four items related to altered emotional states; Factor 3 consisted of four items related to social activity impairment; Factor 4 consisted of two items related to physical symptoms; Factor 5 consisted of the three items "crying", "worrying" and "lack of income"; and Factor 6 consisted of the two items "sweating" and "lack of confidence".

**Empirical validity**

The four points along the SDS scale stand for "None or occasionally; Sometimes; Usually; and Always", in which <50 points is normal (non-depressive), the index of depressive severity is equal to the sum of all the item scores divided by 80 and the higher the score, the severer the depression. The mean values of the 19 items and three domains were all higher in the depressive patients than in the non-depressive patients (all \( P \leq 0.01 \)).

Table 2 lists the mean values of each domain of the ASPQ in depressive and non-depressive patients.

**Sensitivity analysis**

Table 3 lists the Spearman correlation coefficients between the score changes of the AS, the SS-QOL and the ASPQ, along with the three domains. The score changes of the ASPQ in three domains were positively correlated with the AS scores and negatively with the SS-QOL scores.

**DISCUSSION**

We have developed the disease-specific HR-QOL measure for patients with post-stroke spasticity using a comprehensive methodological framework based on the World Health Organization’s definition of health. Our approach to item selection and questionnaire construction used a variety of sources, including patient input and a comprehensive literature review to ensure we captured all the important items. The ASPQ exhibited adequate internal consistency and reliability. The results of the PCA revealed that the ASPQ items were loaded into six factors. In terms of empirical validity, as measured by the ASPQ, our data show that as depression becomes more severe, patients' perceptions deteriorate. The score of the ASPQ with three domains
In our study, it was suggested that the three items of the Apoplexy Spastic-Paralysis Questionnaire (ASPQ) represent sensitivity well.

The correlation coefficients among the three domains of the ASPQ and the HR-QOL (for patients with post-stroke spasticity) are given in Table 3. Correlation coefficients that were significant at the 0.01 level (2-tailed) are shown.

Table 2: Mean values of each item and domain of the Apoplexy Spastic-Paralysis Questionnaire (n=23)

<table>
<thead>
<tr>
<th>Domain</th>
<th>Patients with depression (n=23)</th>
<th>Patients without depression (n=83)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical symptoms</td>
<td>28±8*</td>
<td>22±7*</td>
</tr>
<tr>
<td>Altered emotional states</td>
<td>20±5*</td>
<td>13±3*</td>
</tr>
<tr>
<td>Social activity impairment</td>
<td>17±3*</td>
<td>13±4*</td>
</tr>
</tbody>
</table>

Table 3: Correlation coefficients (r) between the score changes of the AS, SS-QOL, ASPQ and three domains. (n=23)

<table>
<thead>
<tr>
<th>Score change</th>
<th>AS</th>
<th>SS-QOL</th>
<th>ASPQ</th>
<th>Physical symptoms</th>
<th>Altered emotional states</th>
<th>Social activity impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS</td>
<td>1.000</td>
<td>-0.322*</td>
<td>0.380*</td>
<td>0.438*</td>
<td>0.304*</td>
<td>0.053</td>
</tr>
<tr>
<td>SS-QOL</td>
<td>-1.000</td>
<td>-0.459*</td>
<td>-0.324*</td>
<td>-0.402*</td>
<td>-0.362*</td>
<td></td>
</tr>
<tr>
<td>ASPQ</td>
<td>-</td>
<td>-</td>
<td>1.000</td>
<td>0.833*</td>
<td>0.715*</td>
<td>0.630</td>
</tr>
<tr>
<td>Physical symptoms</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1.000</td>
<td>0.352*</td>
<td>0.285*</td>
</tr>
<tr>
<td>Altered emotional states</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1.000</td>
<td>0.503*</td>
</tr>
<tr>
<td>Social activity impairment</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1.000</td>
</tr>
</tbody>
</table>

Notes: AS: Ashworth Scale; SS-QOL: Stroke-specific Quality of Life; ASPQ: Apoplexy Spastic-Paralysis Questionnaire. *Correlation is significant at the 0.01 level (2-tailed).

showed significant correlations with that of the AS and the SS-QOL, which indicates that the ASPQ represents sensitivity well.

In our study, it was suggested that the three items "sweating", "lack of confidence" and "worrying" either have very high variability or do not measure the same thing as the other items, thus raising a concern. We have not yet investigated the questionnaire's responsiveness, i.e., its ability to detect even small but important changes over time. Further studies are needed to address these issues, both in broader settings and in efficacy trials of patients with post-stroke spasticity.

Limitations of our study include our decision to focus on items that were important to the stroke patients.
and relevant to spastic limbs. Thus, it is possible we excluded items that are important to stroke patients but not specific to spastic limbs. We also paid more attention to the patients’ perspective and perhaps neglected other symptoms that affect not just the patients, but the lives of those surrounding them. Our pragmatic goal of creating a specific, applicable and efficient instrument suitable for clinical trials brings with it this inevitable limitation. The ASPQ is designed to assess the physical symptoms, altered emotional states and social activity impairment caused specifically by post-stroke spasticity. It could provide unique information on post-stroke spasticity from the patients’ perspective. In summary, the ASPQ is the first disease-specific health-related quality of life measure for patients with post-stroke spasticity. A 19-item ASPQ was developed, consisting of nine items relating to physical symptoms, six items relating to altered emotional states and four items relating to social activity impairment caused by post-stroke spasticity. Using this instrument, we can discern a patient’s perspective on the development of post-stroke spasticity. Using this instrument, we can discern a patient’s perspective on the development of their illness and provide meaningful guidance for clinical practice and decision-making. Further studies are needed to overcome limitations regarding a few individual items and to examine important changes over time. The generalizability may be clarified and the questionnaire refined after additional sample groups are tested using the polytomous Rasch Model.

REFERENCES


