VALUE IN HEALTH REGIONAL ISSUES 2 (2013) 392–397

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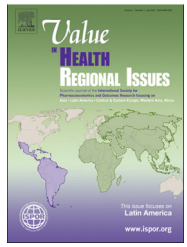

PATIENT-REPORTED OUTCOMES (PRO)

Evaluation of the Stroke-Specific Quality-of-Life (SSQOL) Scale in Mexico: A Preliminary Approach

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ABSTRACT

Objectives: The prevalence of stroke survivors with incomplete recovery in society has been estimated at 460/100,000 people, and one third of them require help in at least one daily activity. Two thirds of all deaths related to stroke in the world occur in low- and middle-income countries. The objective of the present work was to assess the reliability and validity of the previously translated Spanish Stroke-Specific Quality-of-Life (SSQOL) version 2.0 scales in Mexican stroke survivors. **Methods:** An observational and cross-sectional pilot study was conducted. Thirty-one patients who suffered stroke up to 1 year prior to the present study were included. Patients were interviewed twice in a 7-day period; other indexes and scales were applied. The reliability was assessed by using Cronbach's alpha (internal consistency) and test-retest by using Spearman's rho scores; the acceptability was evaluated by the floor and ceiling effects. **Results:** Ceiling and floor effects were observed for fewer than 20% of the patients. The overall internal consistency of the questionnaire was greater than 0.7 (Cronbach's α), with only two domains (family roles and personality) having lower internal consistency values. The results displayed high test-retest reliability: all domains had Spearman's rho scores of over 0.8. The questionnaire has adequate construct validity. **Conclusions:** Our preliminary results showed that the psychometric properties (acceptability and reliability) of the Spanish SSQOL questionnaire are good, encouraging, and comparable to those of other similar studies. This study is the first approach to validate the Spanish version of the SSQOL questionnaire in Mexican stroke survivors.

Keywords: Mexico, stroke-specific quality-of-life, questionnaire, stroke, validation.

Introduction

Stroke is the leading cause of disability and death in the world [1]. Each year, 15 million people worldwide suffer strokes. Of these, 5 million die and 5 million survive with disabilities, becoming a burden for their families and communities [2]. Two thirds of all deaths related to stroke in the world occur in low- and middle-income countries [1].

The risk of death due to stroke in Argentina, Chile, and Uruguay is double that in the United States and Europe [1–4]. Hispanics are the largest minority population in the United States, and Mexican Americans are the largest subgroup of Hispanics [5]. It has been documented that Mexican Americans experience a substantially greater incidence of ischemic stroke and intracerebral hemorrhage than do non-Hispanic white people, even though social and biological risk factors associated with stroke are similar between Mexican Americans and non-Hispanic white people [6]. Mexicans living in the United States have a high prevalence of diabetes mellitus, low socioeconomic status, and limited access to quality health care [6].

Ischemic heart disease and stroke are two of the main public health problems in Mexico [7]. According to data from the Health Ministry of Mexico, 5.6% of general mortality is due to stroke, with a rate of 25.6/100,000 inhabitants per year. This represents over 25,000 deaths from 2000 to 2004 [8]. It has been demonstrated that stroke is more prevalent in Mexico in people older than 55 years. Hypertension, diabetes mellitus, and excessive alcohol ingestion are the main risk factors for the recurrence of stroke, contributing to 70.1%, 38.9%, and 16.1% of cases, respectively [9].

In recent years, continuing advances in medical interventions have increased the survival rate of patients who suffer strokes. Therefore, the number of patients living with chronic degenerative diseases due to strokes, as well as the prevalence of disabilities among this population, has increased. Hence, significant interest has arisen in health-related quality of life (HRQOL) as a tool to assess changes in patient health throughout the length of a patient's life [10,11]. Patients usually lose functionality after

Conflict of Interest: There is no conflict of interest to declare.

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http://dx.doi.org/10.1016/j.vhri.2013.04.002

suffering strokes, and social, emotional, physical, and occupational impairments arise. The measurement of HRQOL is crucial to obtain a complete understanding of the actual status of the patient after a health care intervention. There are conventional clinical scales that measure the functionality of poststroke patients, but these do not evaluate limitations in work reintegration, emotional adjustment, or capacity for leisure or recreation [12].

Various specific instruments for assessing poststroke HRQOL offer the advantage of assessing domains relevant to stroke, such as vision or language. These, however, are not available in all languages, and some are proxy versions (addressed to the primary caregiver) [3]. Among these tools is the Stroke-Specific Quality-of-Life (SSQOL) scale, which was developed as a comprehensive measure of multiple effects in poststroke patients. The scale consists of 49 questions grouped into 12 domains [13]. The SSQOL questionnaire has been translated into Danish and German, but only the Danish version has been appropriately validated [14–16]. The SSQOL questionnaire is an appropriate tool to measure the HRQOL of poststroke patients.

Because Mexican Americans have a high risk of stroke, evaluation of the reliability and validity of the SSQOL questionnaire in Mexican stroke survivors is an important health objective for both nations.

The objective of the present work was to assess the reliability and validity of the previously translated Spanish SSQOL version 2.0 scales in Mexican stroke survivors.

Methods

This was an observational, longitudinal, cross-sectional validation study in patients who had a stroke and were treated with dapsone during the acute phase of their stroke. The present study was performed at the National Institute of Neurology and Neurosurgery (NINN) in Mexico City. The recruitment period was from June until September of 2010. The cross-cultural adaptation of the SSQOL questionnaire into Spanish was done by Linda S. Williams and colleagues. They used the translation and back translation methods. The Spanish version of the SSQOL questionnaire was reviewed by medical staff at the NINN and by poststroke patients [13].

The SSQOL questionnaire consists of 49 questions grouped into 12 domains [13]; each individual domain consists of 3 to 10 items that are averaged to generate an overall score, with a minimum value of 1 (meaning the worst outcome) and a maximum value of 5 (meaning the best outcome). Any translated questionnaire test method needs to be assessed for validity and reliability as if it were a new instrument. The validity and reliability of the Spanish version of the SSQOL questionnaire in Mexican subjects were assessed by using different statistical tests further described in the "Data Analysis" section [15].

Subjects and Data Collection Procedures

Thirty-one ambulatory poststroke patients who had received treatment at the NINN in Mexico City were included in this study. The recruitment period was from June until September of 2010.

We included patients of both genders, who were older than 18 years and who had been diagnosed with a stroke up to 1 year prior to the present study and were willing to be visited at home. Exclusion criteria were inability to speak, dementia, verified psychiatric disorders, failure to complete the questionnaire and/or to understand its contents, and an elapsed time of over 1 year since stroke diagnosis. Elimination criteria were death of the patient and an inability to locate the patient during the study period.

All participants provided informed consent to participate in the study, in accordance with Mexican laws [17]. Ethical approval was obtained from the NINN Review Board before study initiation. Patient data, such as sociodemographic characteristics (age, gender, and employment status), stroke type, and vascular risk factors, were collected at the hospital from patient medical records. Patients were interviewed considering a minimum of 6 months after the stroke was diagnosed. During the patient interview, the Spanish version of the SSQOL questionnaire and conventional functionality scales including the Barthel index (IB), short-form 36 health survey (SF-36), Beck's Depression Index (EDB), and the National Institutes of Health Stroke Scale (NIHSS) were applied to assess convergent validity. We performed retests by providing copies of the SSQOL questionnaire to each patient and instructed patients to complete and return the questionnaires 1 week later [13,18–21]. All tools used in this study were in Spanish, and all measurements were rendered under the supervision of the study's primary investigator.

Data Analysis

The following statistical tests were used to validate the Spanish version of the SSQOL questionnaire:

The acceptability of the questionnaire was assessed by determining the ceiling and floor effects. Acceptable ceiling and floor effects are those under 20% [22].

Internal consistency and reliability were assessed by Cronbach's alpha tests. Cronbach's alpha values above 0.70 were considered acceptable [23,24].

The stability of the questionnaire was evaluated by measuring its test-retest reliability. The correlation between the test and the retest was assessed by Spearman's rho (r_s). An r_s value of above 0.80 was considered to be a satisfactory level of stability. A Wilcoxon test for dependent groups was also performed to reinforce the assessment [15].

The construct validity was assessed by comparing the linear association scores on specific domains of the SSQOL questionnaire with results from the SF-36, EDB, NIHSS, and IB scales via Spearman's rho tests. An r_s score between 0.30 and 0.60 indicated moderate association, and an r_s score greater than 0.60 denoted a strong association. The correlation coefficient (r^2) was also assessed; a score close to 0.5 on this measure was considered acceptable [15].

Convergent and discriminant validity were assessed by using the Pearson's correlation (r_p) for each item in relation to its domain. Convergent validity (as opposed to discriminant validity) was considered to be present when the item was moderately correlated with its domain ($r_p \geq 0.40$) [15,25].

All the before-mentioned thresholds hereby used are acceptable in the literature for validation [15,22–25].

The aforementioned statistical analyses were performed by using the SPSS version 13 statistical software package.

Results

Participants

Thirty-one patients who had suffered a stroke were included in the pilot study. Table 1 shows the sociodemographic characteristics of the participants. The average age of the population was 57.42 years (range 19–86 years). The number of male and female participants was similar. Most were married, and 54.8% had not completed basic education (junior high school). The main subtypes of stroke suffered by participants were atherothrombotic (38.7%) and cardioembolic (29.0%). The main concomitant diseases among these patients were hypertension (five patients,