Development of a patient-centered questionnaire for post-stroke spasticity assessment: a reliability study

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Summary

In the emerging scenario of patient-centered medicine, it is becoming increasingly important to involve patients in the management of chronic diseases. The rehabilitation field currently has no assessment tool for evaluating the functional impact of post-stroke spasticity on activities of daily living.

The aim of this study was to identify a tool to fill this gap.

The “Spasticity Questionnaire in Real Life” (SPQR) was administered, twice, to 39 patients with post-stroke spasticity.

Statistical analysis showed internal consistency and reliability of the questionnaire, with values greater than 0.96 and 0.76, respectively. These results show that the SPQR is a promising tool for evaluating the functional impact of post-stroke spasticity.

KEY WORDS: botulinum toxin type A, muscle spasticity, patient-centered care, patient outcome assessment, stroke.
conditions (for example during self-care and dressing maneuvers).

The aim of this study was to evaluate the reliability of the SPasticity Questionnaire in Real life (SPQR), a new questionnaire developed to assess the extent to which spasticity negatively affects functional outcome and quality of life in patients whose condition requires a targeted treatment.

Materials and methods

The SPQR was created through a consensus procedure by a panel of Italian experts in the treatment of PSS. It is a self-administered patient questionnaire (patient-reported outcome), but it can be compiled either alone or with the help of the caregiver. It consists of two subscales: one for the upper limb, and the other for the lower limb. It has a total of 15 items with a four-point categorical response scale, where responses range from 0 (most favorable) to 4 (least favorable). The SPQR score can vary between 0 and 45, where 0 means that the degree of spasticity does not interfere with the performance of certain specific tasks, and 45 represents a degree of spasticity that severely impairs the patient's ability to perform these tasks.

In the period June 2017 - September 2017, a total of 39 patients was recruited in three different rehabilitation centers (the Maggiore della Carità University Hospital in Novara, Fondazione Santa Lucia in Rome, the Ospedali Riuniti University Hospital in Foggia). Inclusion criteria were a diagnosis of ischemic or hemorrhagic stroke, right or left hemiparesis, upper and/or lower limb spasticity (Modified Ashworth Scale, MAS, score > 1). We excluded patients with spasticity due to other causes and/or diseases, patients who had received treatment with botulinum toxin (BoNT-A) in the last 3 months, patients with a Mini-Mental State Examination score < 24, and those affected by neglect or apraxia, or musculoskeletal conditions in the lower limbs such as arthritis or fractures.

To assess the reliability of the SPQR, the assessment was repeated after one week. All statistical analyses were performed using Graphpad Prism 6 (Graphpad Software Inc., San Diego, California, USA) and Vassar Stats. A significance threshold of \( p < 0.05 \) was applied. Correlations between different items on the same test were analyzed using the Pearson correlation and total variability is related to patient variability (Cicchetti, 1994).

Results

The study included 39 subjects, whose demographic data are summarized in Table I. The mean time taken to complete the questionnaire was 4 minutes and no items were left unanswered.

The level of internal consistency was excellent: 0.95. The reproducibility showed a value between 0.84 and 0.98, resulting statistically significant (\( p < 0.05 \)). The total interrater reliability, obtained by calculating the Kappa coefficient, gave a score of 0.76 (95% CI 0.61-0.91). Also the variability (ICC2.1), with a value of 0.89, was statistically significant (95% CI 0.71-0.96).

Discussion

Post-stroke spasticity significantly reduces the quality of life (QoL) of affected patients in various ways: physical, psychological and emotional. The International Classification of Functioning highlights the need for unified and standard language for describing health, functionality and disability in terms of activity and participation influenced by different environmental factors. This objective can be achieved through evaluation tools that provide objective data able to delineate changes in body structures and functions. In line with the biopsychosocial model of whole patient care, treatment goals should be patient-centered and the rehabilitation intervention must be commensurate with the patient's needs and functional limits (Pratt et al., 2015). Only by focusing on the possible correlation between patient-reported disability and PSS measured by the currently available assessment tools, it is possible to quantify the degree of limitation in the performance of specific tasks, and the impact on wellbeing and QoL; indeed, the latter are elements that cannot be reported by objective scale scores, only derived from outcome measures directly reported by patient (Sunnerhagen and Francisco, 2013). This means that clinical assessment is essential in order to understand patients' needs and to plan the treatment most likely to ensure functional recovery. Currently there is no validated tool capable of measuring spasticity, functional level and QoL. There is clearly a need for a spasticity assessment tool, able to measure progress and effectiveness of treatments (Wade, 1992). The most widely used spasticity assessment tool is the MAS, which, however, is only an ordinal measure of resistance to passive mobilization (Pandyan et al., 1999) and does not take into account the different elements that influence resistance, such as a voluntary reflex, viscoelastic properties of soft tissues and joints, and pain (Pymer and Katz, 1994). These components can affect muscle tone.

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Table I - Demographic data of included patients.

<table>
<thead>
<tr>
<th>Patients (n)</th>
<th>39</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) ± SD</td>
<td>60.5 ± 10.23</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female% (n)</td>
<td>41.0% (16)</td>
</tr>
<tr>
<td>Male% (n)</td>
<td>59.0% (23)</td>
</tr>
<tr>
<td>Time since stroke (months) ± SD</td>
<td>64.2 ± 46.7</td>
</tr>
<tr>
<td>Stroke type:</td>
<td></td>
</tr>
<tr>
<td>Ischemic% (n)</td>
<td>66.7% (26)</td>
</tr>
<tr>
<td>Hemorrhagic% (n)</td>
<td>33.3% (13)</td>
</tr>
<tr>
<td>Hemiparesis side:</td>
<td></td>
</tr>
<tr>
<td>Right% (n)</td>
<td>48.7% (19)</td>
</tr>
<tr>
<td>Left% (n)</td>
<td>51.3% (20)</td>
</tr>
</tbody>
</table>
(quantified by MAS), but also the ability to achieve functional goals, well-being and QoL, which cannot be quantified, but are nevertheless variables that contribute to the patient’s perception of the success of the treatment. Instrumental evaluations, such as dynamic electro-myography and multifactorial gait analysis, also remain key tools for the clinician, in order to evaluate muscle activation patterns and the biomechanical implications of spasticity. In view of the above considerations, it is necessary to establish the treatment goals with each individual, and adapt the rehabilitation program to individual patients’ specific needs, identifying how the PSS affects ADL and functional autonomy, as reported by patients themselves (Baricich et al., 2016). However, the objective of spasticity treatment should not merely be to reduce spasticity understood as a “clinical sign”, but rather to limit its negative impact on the functional framework of the patient. In line with these indications, the Guidelines of the Royal College of Physicians emphasize the importance of identifying an instrument capable of measuring the functional level and the need for treatment in patients with stroke outcomes (Ashford and Turner-Stokes, 2013). We have sought to address this need by developing a new tool for assessing the impact of PSS on the lives of patients. The tool created was found to be specific and suitable for evaluating the functional impact of spasticity on performance in patients with stroke. This tool thus addresses a current gap in the literature.

As for the technical and practical requirements, the SPQR seems to be a workable instrument, inexpensive, easy and quick to compile, and presenting no patient compliance problems. Indeed, it uses simple language that can be readily understood by patients. In view of these promising psychometric and practical characteristics, the SPQR could be proposed for use on a national scale to promote a uniform and more complete description of the conditions of patients with PSS and to promote uniform rehabilitation pathways, in terms of goals, costs and timing. The results of this study are of considerable clinical significance, as the SPQR is the first specifically designed questionnaire for the early identification of functionally relevant PSS, and it is suitable for use in normal clinical practice. Further studies on a larger sample could produce more significant results.

Acknowledgments

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References


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