OPEN

A Screening Tool to Identify Spasticity in Need of Treatment

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Objective: To develop a clinically useful patient-reported screening tool for health care providers to identify patients with spasticity in need of treatment regardless of etiology.

Design: Eleven spasticity experts participated in a modified Delphi panel and reviewed and revised 2 iterations of a screening tool designed to identify spasticity symptoms and impact on daily function and sleep. Spasticity expert panelists evaluated items pooled from existing questionnaires to gain consensus on the screening tool content. The study also included cognitive interviews of 20 patients with varying spasticity etiologies to determine if the draft screening tool was understandable and relevant to patients with spasticity.

Results: The Delphi panel reached an initial consensus on 21 of 47 items for the screening tool and determined that the tool should have no more than 11 to 15 items and a 1-month recall period for symptom and impact items. After 2 rounds of review, 13 items were selected and modified by the expert panelists. Most patients (n = 16 [80%]) completed the cognitive interview and interpreted the items as intended.

Conclusions: Through the use of a Delphi panel and patient interviews, a 13-item spasticity screening tool was developed that will be practical and easy to use in routine clinical practice.

Key Words: Delphi Technique, Patient Outcome Assessment, Screening, Muscle Spasticity

S pasticity is a disabling neurologic disorder with various etiologies that can lead to physical impairment and psychological difficulties. Optimal management of spasticity relies on early recognition and prompt treatment to yield the best potential for improved outcomes.[1,2] However, identifying and measuring disabling or painful spasticity pose clinical challenges for health care providers, stemming, in part, from ongoing discussion and debate regarding the definition of spasticity.[3,4] Whereas spasticity is classically defined as a velocity-dependent increase in muscle tone (hypertonia) accompanied by some form of increased reflex activity, a tendency to classify all stiffness as spasticity has led to ongoing modifications by various experts. None of these modifications have been universally accepted as "spasticity" or have completely differentiated it from other forms of muscle overactivity such as rigidity or dystonia.[3–5]

Various scales are available for assessing spasticity. Two that are commonly used, the Ashworth Scale and the Modified Ashworth Scale, have demonstrated varying levels of inter-rater reliability, possibly in part because of differing spasticity characteristics based on etiology, a number of uncontrolled patient and environmental factors, and a range of examiner techniques that may lead to scoring inconsistency.[6–9] Scales, such as the Penn Spasm Frequency Scale (a frequency count of muscle spasms, translating into a score on a scale ranging from 0

to 4), have also been used in assessing spasticity; however, it is recognized that the sensitivity of the scale varies across patient populations, with a paucity of reliability studies of such scales.[6] Others have shown that scales used in one setting may lose reliability when used in another. For example, the Modified Tardieu Scale that is used for assessing spasticity in children with cerebral palsy (CP) was generally found to have only moderate inter-rater reliability in assessing spasticity of the plantar-flexor muscle in poststroke adult patients.[10] Other assessments of spasticity may include electrophysiologic or biomechanical methods, which may be more quantitative but too complex for use in clinical practice.[6]

Overall, although assessment or evaluative measures exist for spasticity, the validity and reliability or practicality of the measures remain questionable. Furthermore, these patient rating scales were not initially designed for screening, but rather for monitoring/rating and thus have not been tested for screening. Moreover, the relationship between available measures and patient experience of disability has not been clearly established. From a therapeutic management standpoint, none of the available measures are specifically designed to identify or screen for spasticity requiring treatment; rather they are, generally, used on already selected patients, for research purposes and assessing treatment outcome.

With recognition of the absence of a criterion standard spasticity screening tool for detecting patients in need of treatment and the possibility of improving outcomes, we sought to develop a patient-reported screening tool for health care providers to identify such patients, regardless of etiology, for use in routine clinical practice. This tool has possible use in both general practice and specialist settings, and in addition to raising awareness of spasticity, may enhance the identification and appropriate referral of these patients to, potentially, improve patient quality of life.

METHODS

This study included 2 components: a Delphi panel and cognitive interviews. The objective of the Delphi panel was to enlist a group of experts in spasticity to develop and refine an initial pool of items that could be used to identify spasticity in need of treatment taken from existing spasticity questionnaires. The objective of the cognitive interviews was to evaluate whether the draft spasticity screening tool item pool was understandable and relevant to patients with spasticity.

Ethical approval was not needed for the Delphi panel but was obtained for the cognitive interviews. This study was performed in accordance with ethical principles originating from the Declaration of Helsinki and is consistent with Good Clinical Practice and applicable regulatory requirements. The information provided by the patients who agreed to participate, and by their respective physicians, was used solely for the purposes of the study. This study conforms to all STROBE guidelines and reports the required information accordingly (see Supplementary Checklist, http://links.lww.com/PHM/A316).

Recruitment

Eleven experts were recruited to participate in the multinational Delphi panel. All efforts were made to recruit a geographically diverse group of experts who would be highly knowledgeable in assessing and treating spasticity.

For inclusion in the cognitive interviews, participating patients were required to be aged 18 to 65 years and have a confirmed clinical diagnosis of spasticity in need of treatment caused by stroke, multiple sclerosis (MS), traumatic brain injury (TBI), CP, or spinal cord injury (SCI), with the spasticity causing pain or affecting range, care, or function. Patients were also required to read and provide written consent on the subject informed consent form and Health Insurance Portability and Accountability Act authorization; read, write, and speak English fluently; and be willing and able to participate in a 60-minute interview. Patients with any medical or psychiatric condition or disorder that would interfere with their ability to effectively participate in a 60-minute interview were excluded.

Delphi Panel

Candidate items for the screening tool were selected based on a literature review of existing spasticity measures. The initial item bank for review by the Delphi panelists came from the following questionnaires: Arm Activity Measure,[11,12] Leeds Adult Spasticity Impact Scale,[13,14] 88-item Multiple Sclerosis Spasticity Scale,[15] Patient Reported Impact of Spasticity Measure,[16] Spasticity 0–10 Numeric Rating Scale,[17] Spasticity Impact Assessment Lower Limb,[18] Spasticity Impact Assessment Upper Limb,[18] Spasticity Symptom Assessment Lower Limb,[18] Spasticity Symptom Assessment Upper Limb,[18] and the spasticity subscale of the Performance Scales measure.[19] Four experts (who also participated in the Delphi panel) were asked to select items that were most likely to identify spasticity in need of treatment.

Using a modified Delphi process, spasticity specialists from the United States, Canada, Europe, and Australia were engaged to reach consensus on items that should be included in the screening tool. Under the modified Delphi panel approach, 2 iterations of the screening tool were reviewed before consensus was reached by the panelists.

During round 1, panelists were sent the Spasticity Screening Tool Delphi Survey, in which they were instructed to choose 1 of 4 options ("yes," "probably yes," "probably no," or "no") for each item that reflected their level of endorsement. Panelists were also asked to comment on the item list and provide suggestions for rewording or adding an entirely new item. Responses were then collected and analyzed, summarizing the results and sharing the anonymized responses of the entire group with all panelists.

During round 2, the group reviewed the anonymized results and made changes to their initial responses. Panelists were asked to provide additional feedback on the entire group's responses and comments. After the second round, the results were reviewed at a final meeting to reach a final consensus and allowed experts to draft a final scale for cognitive debriefing and validation. Given the limited time with a large number of participants, an item was discussed in detail only if it had a majority or split vote for inclusion in the screening tool in the round 2 Delphi Survey results (ie, items with clear consensus on exclusion were not discussed in detail).

Cognitive Interviews

Patient cognitive debriefing interviews were used to assess patients' understanding of items and response choices, as well

as the overall comprehensiveness and relevance of the screening tool items.

A sample size of 20 patients across multiple etiologies (n ≥ 4 per etiology of MS, TBI, CP, or SCI) was determined as a reasonable target for cognitively debriefing the spasticity screening tool. Adult men and women were recruited from a clinic's patient database, identifying patients who met the study eligibility criteria. Patients' demographic and medical characteristics were summarized.

Cognitive interviews were conducted by personnel who had undergone National Institutes of Health Human Participant Protection training, as well as internal data protection training to protect patient confidentiality and training for conducting interviews with patients. In addition, mock interviews were conducted to identify any potential issues with the interview guide and ensure good interviewing practices. Interviewers followed a semistructured Cognitive Debriefing Interview Guide, which included open-ended questions. Specific information was collected on the patients' perceptions of the content validity of the new instrument. Patients were asked to complete the measure using a think-aloud method, which consists of interviewers encouraging participants to verbalize their thoughts while answering questions. The interviews were conducted face-to-face and digitally audio recorded, lasting approximately 1 hour.

The process for analyzing the interview findings was semiquantitative and semiqualitative. Qualitative data were analyzed using ATLAS.ti version 7.0 (ATLAS.ti GmbH, Berlin, Germany). A coding scheme was developed based on the semistructured Cognitive Debriefing Interview Guide and applied to all transcripts. Each of the items in the new screening tool was evaluated according to the following criteria: the clarity and ease of comprehension on first reading, the relevance of the question, and the absence of ambiguity in the question.

RESULTS

Delphi Panel

Demographic characteristics for the 11 panel members who participated in the Delphi process are presented in Table 1. All but one of the panelists were male, most specialized in physical medicine and rehabilitation or neurology, and

TABLE 1. Delphi panel demographics (N = 11)

Characteristic	
Sex, n (%)	
Female	1 (9)
Male	10 (91)
Specialty, n (%)	
Neurology	5 (45)
Physical medicine and rehabilitation	5 (45)
Physical therapy	1 (9)
Years treating spasticity patients, mean ± SD (range)	17 ± 9 (3–30)
No. spasticity patients treated per month,[a] mean ± SD (range)	35 ± 26 (0–80)
Academic affiliation with a university, n (%)	10 (91)

[a]One panelist saw patients only for research studies.

TABLE 2. Demographics of patients included in the cognitive debriefing interviews (N = 20)

Characteristic	
Age, mean ± SD (range), y	47 ± 15 (26–67)
Sex, n (%)	
Female	10 (50)
Male	10 (50)
Race, n (%)	
White	19 (95)
Black/African American	1 (5)
Spasticity etiology, n (%)	
Cerebral palsy	4 (20)
Multiple sclerosis	3 (15)
Spinal cord injury	6 (30)
Stroke	3 (15)
Traumatic brain injury	4 (20)

all but one had an academic university affiliation. Panelists had been in practice for an average of 17 years, seeing an average of 35 patients with spasticity per month. One panelist was not a medical doctor but had over 25 years of experience in clinical practice as a physical therapist with stroke patients and 10 years of experience in stroke research, with the past 5 years devoted solely to research.

A total of 47 candidate items were accumulated during the item bank development. During round 1, the responses of the panelists were distributed throughout the 47 items, with no items achieving a dominant majority (ie, 10 or 11 of the 11 total panelists). However, 7 of the 47 items had an agreement between 7 and 9 panelists (63.6% to 81.8%) for endorsing the inclusion of the item (ie, all with a "yes"). No items for exclusion had the same high-level agreement. Seven (63.6%) of the 11 panelists also agreed on the recall period of 1 month for items that capture symptoms of spasticity. Most panelists (8/11 [72.7%]) also identified missing items/domains in the current list of items, and 10 additional items were suggested and included in the round 2 survey.

During the second round, the Delphi panel reached an initial consensus on 21 of the 47 items for the screening tool. Panelists also expressed a preference for the screening tool to have a total of 11 to 15 items (63.6%) and a 1-month recall period for both symptom and impact items (72.7% and 45.5%, respectively). As a result of the final meeting, 13 items were selected and modified, covering perceived signs and symptoms of spasticity as well as impact of spasticity on functions of daily life.

Cognitive Interviews

A total of 20 patients with spasticity completed the patient interviews. Demographic data for these patients are shown in Table 2. Mean age was 47 years, with an even distribution based on sex (n = 10 female, 50%); most were Caucasian (n = 19, 95%). Although effort was made to recruit evenly across the 5 etiologies (target goal of n = 4 per etiology), only 3 patients were recruited each in MS and stroke etiologies, and the total patient number included 2 additional SCI patients (n = 6, 30.0%).

Instructions: Please answer the following questions thinking about your muscle stiffness, tightness, or spasms <u>over the past 1 month</u>

Item #	Question
1	How bad is the stiffness or tightness of your muscles, either at rest, when you move, or are being moved?

☐0 *I don't have stiffness or tightness* ☐1 *A little stiff or tight* ☐2 *Somewhat stiff or tight* ☐3 *Very stiff or tight* ☐4 *Extremely stiff or tight*

2 How difficult is it for you to straighten, bend, or flex your limb(s) (leg[s] or arm[s]) due to stiffness or tightness in your muscles?

☐0 *Not difficult at all* ☐1 *A little difficult* ☐2 *Somewhat difficult* ☐3 *Very difficult* ☐4 *I am unable to straighten, bend, or flex my limbs*

3 How bad are your spasms that occur unpredictably or are caused by movement?

☐0 *I don't have spasms* ☐1 *A little bad* ☐2 *Somewhat bad* ☐3 *Very bad* ☐4 *Extremely bad*

4 Are any of the above stiffness, tightness, or spasms associated with pain?
Please specify the location of the pain: _____

☐0 *No, I don't have any pain* ☐1 *Yes, a little bit of pain* ☐2 *Yes, some pain* ☐3 *Yes, quite a bit of pain* ☐4 *Yes, a lot of pain*

5 Over the past month, how often was your sleep disrupted because of stiffness, tightness, or spasms in your muscles?

☐0 *Never* ☐1 *Rarely* ☐2 *Sometimes* ☐3 *Often* ☐4 *Every night*

6 Over the last month, how bothersome was your muscle stiffness, tightness, or spasms?

☐0 *Not bothersome at all* ☐1 *A little bothersome* ☐2 *Somewhat bothersome* ☐3 *Very bothersome* ☐4 *Extremely bothersome*

Upper Limb Specific

7 How bad is your hand clenching on its own?

☐0 *I don't have any hand clenching* ☐1 *It clenches a little* ☐2 *It clenches somewhat* ☐3 *It clenches quite a bit* ☐4 *It clenches all the way*

8 How difficult is it for you or your caregiver to clean the <u>palm of your hand</u> or <u>between the fingers</u> due to the tightness or clenching of the thumb, fingers, or hand?

☐0 *Not difficult at all* ☐1 *A little difficult* ☐2 *Somewhat difficult* ☐3 *Very difficult* ☐4 *Extremely difficult*

9 How difficult is it for you or your caregiver to clean your armpit due to stiffness or tightness in your arm?

☐0 *Not difficult at all* ☐1 *A little difficult* ☐2 *Somewhat difficult* ☐3 *Very difficult* ☐4 *Extremely difficult*

10 How difficult is it for you or your caregiver to put your arm through the <u>sleeve of your coat</u> or <u>shirt</u> due to stiffness or tightness in your arm?

☐0 *Not difficult at all* ☐1 *A little difficult* ☐2 *Somewhat difficult* ☐3 *Very difficult* ☐4 *Extremely difficult*

Lower Limb Specific

11 How bad is your foot and/or toes <u>pulling in</u>, <u>curling</u>, <u>sticking up</u>, or otherwise <u>getting</u> stuck on their own when you try to move?

☐0 *My foot and/or toes do not <u>pull in</u>, <u>curl</u>, <u>stick up</u> or otherwise get <u>stuck on their own</u>* ☐1 *A little bad* ☐2 *Somewhat bad* ☐3 *Very bad* ☐4 *Extremely bad*

12 How difficult is it to walk or move your leg(s) due to stiffness or tightness in your leg(s)?

☐0 *Not difficult at all* ☐1 *A little difficult* ☐2 *Somewhat difficult* ☐3 *Very difficult* ☐4 *I am unable to walk or move my legs*

13 How difficult is it for you or your caregiver to put on your pants or your shoes due to stiffness or tightness in your leg(s) or feet?

☐0 *Not difficult at all* ☐1 *A little difficult* ☐2 *Somewhat difficult* ☐3 *Very difficult* ☐4 *Extremely difficult*

FIGURE 1. Spasticity screening tool items: final version.

Based on the final Delphi panel discussion, the 13-item screening tool was used in the cognitive interviews with most of the patients (n = 16 [80%]) completing the tool and interpreting the items as intended. Most items (10/13) were interpreted as intended by 90% or more of the respondents. The remaining 3 items were interpreted correctly by 80% (1 item) or 85% (2 items) of the respondents. Specifically, the item "over the past month, how often was your sleep disrupted because of stiffness, tightness, or spasms in your muscles?" was interpreted correctly by 80% of respondents. The items "How difficult is it for you to straighten, bend, or flex your limb(s) (leg[s] or arm[s]) due to stiffness or tightness in your muscles?" and "How difficult is it to walk or move your leg(s) due to stiffness or tightness in your leg(s)?" were interpreted correctly by 85% of respondents. One patient had difficulty interpreting the word "stiffness"; otherwise, no major issues arose from the interviews. Based on the cognitive debriefing interviews, some minor wording changes (ie, reinforcing recall in each question, rewording of a response option on select questions, adding examples to a couple of questions to improve relevance) were recommended and incorporated into the final spasticity screening tool (Fig. 1).

DISCUSSION

A short, simple, valid screening tool dedicated to spasticity is a much needed resource in the medical field, offering the potential for improving quality of life and health outcomes for patients. Spasticity is underserved and underrecognized globally, partly because it is unclear whose responsibility (ie, which provider) it is to recognize spasticity. Because spasticity can occur early,[20–22] the development of a screening tool that can be used during routine clinical practice, and that allows for early identification and intervention, has the potential to provide better outcomes.[1] Focal spasticity treatment not only improves function but may also have beneficial effects on central brain activity.[23]

The shortcomings of existing spasticity assessments have been described in the literature with regard to their propensity to measure differing aspects of the condition, as well as inherent confounding factors, dependence on variable assessor training, and reliability and reproducibility issues as quantitative tools.[6] Measures of functional impairment, such as the Disability Assessment Scale,[24] focus specifically on the functional impairment associated with poststroke spasticity and have been used for evaluation of treatment effects in a clinical trial.[25] The 13-item spasticity tool described here is one of the first practical tools for spasticity that complements the previously described Ashworth and Tardieu scales. If the Ashworth and Tardieu scales are used to assess the level of spasticity, this 13-item spasticity tool was developed to recognize spasticity needing treatment that can improve patient outcomes. The current screening tool provides a brief, patient-reported questionnaire that covers common spasticity symptoms such as stiffness, tightness, spasms, pain, clenching, and curling, as well as spasticity impacts such as hygiene, dressing, and walking. It should be noted that the screening tool is completed by the patient and therefore does not capture the perspectives of caregivers. In all, 4 upper-limb, 3 lower-limb, and 6 non-specific limb items were captured. Subsequently, the items selected were found to be relevant, clear, and easy to understand by patients with spasticity, with only minor changes being made as a result of the interviews.

Although this spasticity screening tool may aid in the identification of patients with spasticity in need of treatment, it is not intended to take the place of comprehensive evaluation and treatment planning. Tools such as the Goal Attainment Scale[26] are important for individualizing care goals and establishing realistic treatment objectives in patients with spasticity. Furthermore, discussion of the risks and benefits of treatment is essential before the initiation of treatment. It should also be considered that the spasticity screening tool may not be sufficient to detect some complex situations.

The development of this spasticity screening tool was based on existing validated measures of spasticity and followed a rigorous, systematic method. Most existing measures used for the selection of candidate items were developed based on more than 60 patient interviews and validated in more than 600 patients.[15,16,18] The cognitive debriefing of the proposed tool followed the US Food and Drug Administration's guidance of patient-reported outcomes, ultimately confirming the understandability and relevance of the tool. The result is an easy-to-use, short, content-valid patient-reported tool for health care providers to identify patients with spasticity in need of treatment.

However, further validation work is needed to assess the psychometric properties of the screening tool (eg, positive and negative predictive values, sensitivity, and specificity) in different etiologies. Once finalized and fully validated, this tool may be used routinely in general and specialist clinical practices. Such a tool may be used by any family member or health care provider (paramedical or medical) to maximize identification of this undertreated disorder. Additionally, finalization of the screening tool will allow for its clinical use to be assessed by evaluation of its impact on health care resource use and patient outcomes. A validation framework is provided in the online supplemental digital content (Appendix A, http://links.lww.com/PHM/A317).

CONCLUSIONS

A 13-item spasticity screening tool was developed to be practical and easy to use in routine clinical practice. Psychometric validation of the tool is planned among spasticity patients experiencing a variety of underlying etiologies.

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