# Identifying and Classifying Quality of Life Tools for Assessing Spasticity After Spinal Cord Injury

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**Objective:** To identify and classify tools for assessing the influence of spasticity on quality of life (QOL) after spinal cord injury (SCI). **Methods:** Electronic databases (MEDLINE/PubMed, CINAHL, and PsycInfo) were searched for studies published between 1975 and 2012. Dijkers's theoretical framework on QOL was used to classify tools as either objective or subjective measures of QOL. **Results:** Sixteen studies met the inclusion criteria. Identified objective measures that were used to assess the influence of spasticity on QOL included the Short Form-36 (SF-36), the Sickness Impact Profile (SIP), and the Health Utilities Index-III (HUI-III). Subjective measures included the Quality of Life Index–SCI Version III (QLI-SCI), Life Situation Questionnaire–Revised (LSQ-R), Reciprocal Support Scale (RSS), Profile of Mood States (POMS), Spinal Cord Injury Spasticity Evaluation Tool (SCI-SET), and the Patient Reported Impact of Spasticity Measure (PRISM). A number of tools proved either to be insensitive to the presence of spasticity (QLI-SCI) or yielded mixed (SF-36) or weak (RSS, LSQ-R) results. Tools that were sensitive to spasticity had limited psychometric data for use in the SCI population (HUI-III, SIP, POMS), although 2 were developed specifically for assessing spasticity on daily life post SCI (SCI-SET, PRISM). **Conclusions:** Two condition-specific subjective measures, the SCI-SET and PRISM, emerged as the most promising tools for the assessment of spasticity impact on QOL after SCI. Further research should focus on establishing the psychometric properties of these measures for use in the SCI population. **Key words:** *outcome measurement*, *quality of life*, *spasticity*, *spinal cord injury* 

S pasticity of the upper limbs, trunk, or lower limbs is typically experienced by individuals with an upper motor neuron spinal cord injury (SCI) following spinal shock, and the resulting spasms often negatively impact quality of life (QOL).<sup>1</sup> Although there is great variability in definitions of spasticity, the most commonly cited definition is by Lance<sup>2(p485)</sup>: "Spasticity is a motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the upper motor neuron syndrome." A wider definition of spasticity includes increased exteroceptive reflexes, as well as loss of motor function (ie, muscle power and coordination).<sup>3</sup>

*Corresponding author:* Christina Balioussis, PhD, Toronto Rehabilitation Institute – University Health Network, Lyndhurst Centre, 520 Sutherland Drive, Toronto, Ontario, M4G 3V9, Canada; phone: 650-243-1534; fax: 416-425-9923; e-mail: cbalioussis@gmail. com The notion is that muscle weakness and impaired coordination are not part of the spasticity syndrome itself, but rather are associated with spasticity.<sup>3-6</sup> Spasticity following SCI is prevalent, with 65% to 78% of persons more than 1 year post injury reporting its occurence.<sup>7,8</sup>

The decision to treat spasticity largely depends on the frequency, severity, and impact of the spasms on a person's daily life.<sup>9,10</sup> Treatment may include conservative physical therapy,<sup>11</sup> with a possible combination of other modalities,<sup>1</sup> including pharmacological treatments (eg, diazepam,<sup>12,13</sup> baclofen,<sup>14</sup> clonidine,<sup>14,15</sup> tazanidine,<sup>12,13,16</sup> dantrolene sodium,<sup>12,17</sup> cyproheptadine,<sup>14,18</sup> and cannabis<sup>17</sup>). Persons who do not respond to oral administration of medications may be

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surgically implanted with a pump for intrathecal administration of baclofen<sup>19-21</sup> or receive injections of chemodenervation agents (phenol and ethanol<sup>22</sup> or botulinum toxin<sup>16,23</sup>). Severe recalcitrant cases require surgical intervention, including dorsal rhizotomy and cordotomy.<sup>24</sup> Continued improvements in the definition and management of spasticity are hampered by the development of valid and reliable tools for assessing spasticity impact.<sup>1</sup>

Relatedly, the valid and reliable assessment of QOL post SCI, which is an important outcome for understanding the additional burden of specific secondary health conditions that emerge post SCI and for gauging the success of rehabilitation interventions in minimizing their frequency and severity, is a challenge.<sup>25</sup> Symptoms of spasticity may have a profound influence on an individual's QOL,7,26 including lifestyle and sense of wellbeing,<sup>27</sup> by limiting workplace participation, adding to the cost of medication, and increasing attendant care requirements.<sup>8,21,28</sup> Despite these findings, there are problems with assessing the influence of spasticity on QOL that are related to the multidimensionality and breadth of spasticity definitions, the fluctuating nature of associated symptoms, and their clinical impact. It is therefore essential that health care professionals be made aware of available tools that are designed to assess the influence of spasticity on QOL after SCI.

Furthermore, investigators should possess a broader understanding of the different conceptualizations of QOL and which tools correspond to each of these. This will help to ensure that the objectives of a study are well aligned with the selected QOL tool. Gaining prominence in the field is the notion that QOL can be measured from an objective or subjective perspective.<sup>29</sup> Objective measures are based on the assumption that there is widespread agreement about what constitutes QOL.25 Such measures focus on external conditions and contain items that can be defined and quantified to reflect societal standards. Conversely, subjective measures are designed with the assumption that QOL can only be judged by the individuals experiencing it.30 Although there are advantages and disadvantages inherent in each measurement type,<sup>29</sup> subjective measures give patients a means of providing health professionals with a greater understanding of QOL and its connection to their health and well-being following SCI, whereas objective measures can be used to inform decision makers on how to allocate funds and resources for various interventions.

To date, no systematic reviews on the influence of spasticity on QOL, or on the appropriateness of QOL measures for assessing spasticity, have been conducted. Given the substantial influence spasticity has on QOL, there is a need to improve conceptual understandings of QOL to ensure that investigators employ appropriate research designs as well as suitable outcome measures to assess this prevalent secondary health condition. Hence, the purpose of this systematic literature review was to classify and evaluate outcome measures that are used to assess the influence of spasticity on QOL following SCI.

### Methods

A systematic review of the literature was conducted using multiple databases (MEDLINE/ PubMed, CINAHL, and PsycInfo). The key term "spinal cord injuries" and its variants, along with spasticity (or muscle spasms, muscle tone, or muscle spasticity), quality of life, participation, personal or life satisfaction, and activities of daily living, were used to identify relevant articles published between January 1975 and December 2012. Reference lists of identified articles were also reviewed. To be included, studies had to be in English and have adult (>18 years) participants with SCI comprising at least 50% of the sample. Abstracts were verified by 2 independent reviewers. Related constructs reflecting well-being were also incorporated into the review (eg, participation, social support, affect). Studies that examined global constructs of QOL post SCI and/or those that contained pediatric populations or pediatriconset SCI were excluded.

Dijkers's theoretical model<sup>25</sup> was used to categorize measures as objective or subjective and to provide a deeper understanding of the specific QOL constructs that are underlying the measures (see **Figure 1**). QOL as "utility" (Box A) reflects the desirability and preferences of life valuations and is

obtained by judging one's tradition, achievements, and status in terms of societal norms and standards (Box B). It is expressed as an outsider's viewpoint (objective) and typically provides a metric framing of QOL that is used in health economic analyses.<sup>25</sup> QOL as "achievements" (Box C), another objective QOL perspective, takes into account the individual's possessions, accomplishments, characteristics, and so on.<sup>25</sup> Therefore, QOL is predicted by what a person has obtained in his or her life (ie, good health, marriage), which society generally views as indicative of what is needed to have a good life. QOL as "subjective well-being" recognizes that humans develop individual priorities and wants (Box E), which may range in relative importance (Box D). When these needs and wants are compared to reality (Box C), the resulting reactions can range from positive to negative and are likely to affect morale, life satisfaction, and other expectations (Box E).25 QOL as "subjective well-being" can therefore be defined as "feelings of wellbeing as influenced by the good things in life."31(pS21)

### Results

Fifty-six studies (34 from MEDLINE/PubMed, 22 from CINAHL, and 0 from PsycInfo) were identified. Only 16 met the inclusion criteria: 7 pre-post intervention studies,<sup>27,32-37</sup> 8 crosssectional observational studies,<sup>9,38-44</sup> and 1 crosssectional and longitudinal study<sup>45</sup> (see **Table 1**). For each measure, we identified whether it assesses QOL from an objective or subjective perspective by linking it to the category of QOL (ie, QOL as a utility, achievements, or subjective well-being) as described by Dijkers's theoretical model.<sup>25</sup> To help illustrate these classifications, each identified measure is mapped onto the box(es) in **Figure 1**.

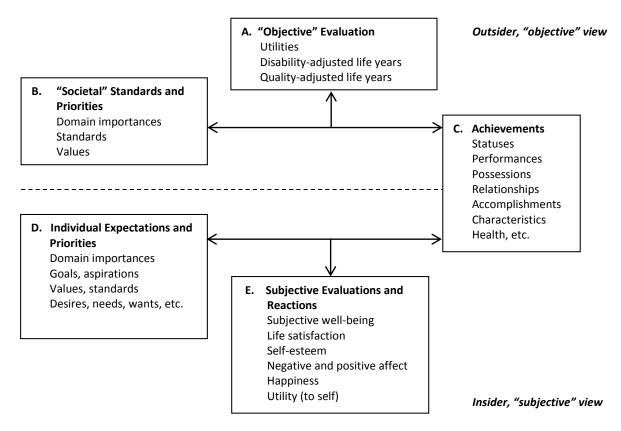
## Applicability of objective QOL measures on assessing spasticity

Five objective measures were identified: (1) the Short Form-36 (SF-36)<sup>46</sup>; (2) the Sickness Impact Profile (SIP); (3) the Health Utilities Index-III (HUI-III)<sup>47</sup>; (4) the Evaluation of Personal Independence (EPI); and (5) a survey comprised of questions from the Spinal Cord Independence Measure (SCIM),<sup>48</sup> Functional Independence Measure (FIM),<sup>49</sup> and the Barthel Index<sup>50</sup>(see **Tables 1** and **2**). The SF-36 (Boxes B and C, **Figure 1**) is the most commonly cited measure of objective QOL, with well-established psychometric properties for multiple health conditions.<sup>51</sup> The SF-36 is suitable for use in SCI,<sup>52</sup> with reliability being moderate to high ( $\alpha = 0.72-0.98$ ), with the exception of the general health item (see **Table 2**).

With regard to assessing the influence of spasticity on QOL, findings for the SF-36 have been inconsistent. The study by Noonan et al<sup>39</sup> found the SF-36 to be insensitive to the presence of spasticity once influencing factors (ie, demographics, years post injury) were controlled for. Conversely, Westgren and Levi42 found it sensitive to problematic spasticity. Similarly, Jones et al<sup>37</sup> found that the scores of persons with SCI who were implanted with a baclofen pump improved pre to post implantation, with the exception of scores on the SF-36 physical subscale. In the studies by Westgren and Levi42 and Noonan et al,<sup>39</sup> the severity of spasticity was not assessed. Jones and colleagues<sup>37</sup> used a spasticity self-perception scale developed by Schwartz et al53 rather than a validated clinical measure of spasticity (ie, Ashworth Scale).

In addition to the mixed findings, there are some controversies associated with the SF-36. Some reports by wheelchair users indicate that certain questions are offensive<sup>54,55</sup> because 5 of 10 items refer to climbing or walking. Some people with disabilities also perceive that the SF-36 (including other health-related QOL measures) has flawed underlying assumptions regarding their QOL (ie, disability equates poor health).<sup>52,55</sup> These limitations could potentially be minimized by pairing the SF-36 with a condition-specific tool.<sup>55</sup> The development of the SF-36V has addressed some of the noted problems of the SF-36, but the psychometric properties of this scale have not yet been fully established for the SCI population.<sup>56</sup>

The SIP<sup>57,58</sup> (Boxes B and C, **Figure 1**) is a generic health status measure of change in behavior as a consequence of illness. The SIP has been used in 2 studies,<sup>27,41</sup> and both found it to be sensitive to



**Figure 1.** Three conceptualizations of quality of life and their interrelations. Adapted, with permission, from Dijkers MP. Individualization in quality of life measurement: Instruments and approaches. *Arch Phys Med Rehabil.* 2003;84(4 Suppl 2):S3-14. Copyright © 2003 by Elsevier.

spasticity (see **Table 1**). Like the aforementioned studies,<sup>39,42</sup> no details were provided by Lundqvist et al<sup>41</sup> on the impact or severity of spasticity. However, the study by Gianino et al<sup>27</sup> did quantify spasticity with the Ashworth Scale, among other spasm scales, which is considered the current standard for assessing spasticity post SCI.<sup>59</sup> The SIP has been used in several SCI studies,<sup>41,60,61</sup> but psychometric data for use in the SCI population are lacking.<sup>62</sup> The SIP faces some of the same controversies as the SF-36 regarding its underlying assumptions.<sup>55</sup>

The HUI-III (Boxes A, B, and C, **Figure 1**) is a comprehensive system for describing the health status of individuals and for assigning a preference (or utility) score to them.<sup>47</sup> A preference score is a societal representation of well-being, which is typically reported as a single metric anchored at

0 (death) and 1 (perfect health), and represents a preference for a health state.<sup>63</sup> These health state morbidities are measured across a group of individuals and combined into a utility score, which can then be used as a quality weight for calculating the number of quality-adjusted lifeyears gained in cost utility analyses.<sup>64</sup>

Craven et al<sup>44</sup> used the HUI-III to ascribe the burden of various secondary health conditions, including spasticity, post SCI and found it to be sensitive to the presence of spasms. Although this study provided some evidence with regard to QOL as "utility" for spasticity, the HUI-III lacks psychometric validation for SCI. As well, presence and impact of spasticity were based on self-report via the Secondary Conditions Scale,<sup>65</sup> a validated measure that provides standardized definitions of secondary health conditions and records their

Spasticity results
Table 1.

Author(s) Study Design	Methods	Outcome
Gianino et al <sup>27</sup> Pre-post intervention and qualitative study	<b>Population:</b> 25 (40% males) subjects diagnosed with intractable spasticity of the spine, including subjects with MS (15), SCI (7), and neurological diseases (3); mean age 39.4 yrs (range, 21-70 yrs)	There were no significant changes in the QLI-SCI total or subscale scores for the different time points. However, there was a trend toward improvement for the health and function subscales.
	<b>Objective:</b> To explore the effect from intrathecal baclofen on spasticity and QOL <b>QOL outcome measures:</b> QLI-SCI, SIP, Ashworth Scale	There were significant differences between MS and SCI participants with respect to the SIP total score ( $P = .0358$ ) as well as the physical ( $P = .0026$ ) and psychological ( $P = .0037$ ) SIP subscores. After 3 months treatment with intrathecal baclofen, subjects reported less spasticity, improved ability to perform daily activities, greater mobility, and reduced pain.
Westgren & Levi <sup>42</sup> Cross-sectional survey	<b>Population:</b> 320 persons (261 men) with SCI; mean age 42 yrs (range, 17-78 yrs); YPI $\leq$ 4 yrs and $\geq$ 4 yrs <b>Objective:</b> To determine associations between major outcome variables after SCI and QOL <b>QOL outcome measures:</b> SF-36	Spasticity was associated with lower QOL. Problematic spasticity yielded significant medium effect sizes in all of the SF-36 subscales.
Noonan et al³ <sup>9</sup> Cross-sectional survey	<ul> <li>Population: 70 persons (81% male) with SCI; mean age at injury, 45 ± 18 (13-91 yrs); mean age at follow-up, 51 ± 18 (19-95 yrs)</li> <li>Objective: To determine the effect of associated SCI conditions on health status and QOL attaces. SF-36; Numeric QOL Rating</li> </ul>	Spasticity was significantly related to the physical functioning subscore of the SF-36 in the first 2 stages of analysis, but became nonsignificant once all confounding variables were controlled for.
Loubser et al <sup>34</sup> Pre-post intervention study	<b>Population:</b> 9 males with SCI and spasticity; mean age, 45.6 ± 12.35 (22-63 yrs) Objective: To explore the effect from intrathecal baclofen on spasticity <b>QOL outcome measures:</b> Occupational Therapy Evaluation of Personal Independence	All but one patient benefited markedly in terms of gaining independence, of reducing time and effort for care required by caregivers, or both. Persons with paraplegia and lower level tetraplegia gained independence in mobility and self-care. Persons with paraplegia with severe spasticity gained independence in driving. Although persons with high tetraplegia remained dependent in ADLs, caregiver time and effort for daily care decreased markedly.
Fleuren et al° Cross-sectional survey	<b>Population:</b> 26 patients 920 males) with SCI; mean age 41.0 $\pm$ 10.6 yrs; mean mos post injury 100.9 $\pm$ 76.5 mos. <b>Objective:</b> To study the manifestation of spasticity in daily life of patients with SCI, their perception of spasticity, and spasticity-related discomfort <b>QOL outcome measures:</b> Nonstandardized study-specific questionnaire	57.7% of patients found the perceived spasticity problematic, mostly due to decreasing function (73.3%) rather than pain. Spasticity impacted ability to change position (22.0%), make a transfer (20.7%), be active (17.1%), maintain a stable body position (12.2%), as well as ADLs (17.1%). Findings confirm that the impact of spasticity on daily life is related to the context in which it occurs. Positive effects include helping to get dressed and prevention of pressure sores and muscle atrophy. Negative effects include initial shame regarding spasms and initial time taken to understand the new body signals.

(8 males) with SCI; mean age 37.6 $\pm$ 11.5 yrs;SCI-SET showed significant ( <i>P</i> <.001) moderate to strong associations with self- assested spasticity severity, self-assessed spasticity impact, QLI-SCI, and the PSFS. $\star$ 2. 19 persons (15 males) with SCI; mean age $\pm$ 11.5 yrs;SCI-SET showed significant ( <i>P</i> <.001) moderate to strong associations with self- assested spasticity severity, self-assessed spasticity impact, QLI-SCI, and the PSFS. $\star$ 2. 11.5 yrs;Study 3: 61 persons (45 males) yrs, mean YPI 10.2 $\pm$ 8.6 yrsyrs, mean YPI 10.2 $\pm$ 8.6 yrsWith regard to test-retest reliability, the intra-class correlation coefficients for SCI-SET was .91, and above the recommended minimum reliability values.of spasticity on daily life in people with SCIThe mean SCI-SET score indicated an overall negative impact of spasticity on daily life despite perceptions of some benefits.ET; QLI-SCI health and functioning subscaleSCI-SET score indicated an overall negative impact of spasticity on daily life	with chronic SCI; mean age 37.1 ± 7.7 yrs; Participation in 12 sessions of BWSTT or TTS did not result in group changes in scores on the SCI-SET. The 12 sessions of BWSTT resulted in a medium effect size (0.5) on cts of body-weight-supported treadmill QOL. standing (TTS) on spasticity, motor neuron is in individuals with chronic SCI	<ul> <li>I, mean age 44.12 yrs, YPI range 4 to the assistance of bracing or supports mic standing program using the my measurable physiological effects</li> <li>Although self-evaluations of spasticity using the SCI-SET showed improvement from the assistance of bracing or supports the initial visit (-0.57), differences were not statistically significant.</li> </ul>	CI; $\geq 18 \text{ yrs}$ ; and YPI > 1 yr cL; $\geq 18 \text{ yrs}$ ; and YPI > 1 yr ationships among social support, adjustment, persons with SCI; (2) to explore potential tribution to the social support of others and nothers SCI, RSS	SCI; mean age 33.5 yrs (16-72 yrs); Patients with spasticity problems scored significantly worse on the ambulation and feeding issues. ients – their physical, psychological,	<ul> <li>SCI; mean age 33.5 yrs (16-72 yrs), Patients demonstrated improvements in ADLs such as feeding ability (10), self-care (10), indoor and outdoor mobility (19), and driving (4).</li> <li>ecal baclofen on symptoms of a comprised of items from the</li> </ul>
<ul> <li>Population: <i>Study 1</i>: 9 persons (8 males) with SCl; mean age 37.6 ± 11.5 yrs; mean YPI 13.6 ± 11.5 yrs; <i>Study 2</i>: 19 persons (15 males) with SCl; mean age 45.7 ± 13.9 yrs; mean YPI 13.6 ± 11.5 yrs; <i>Study 3</i>: 61 persons (45 males) with SCl; mean age 41.9 ± 12.6 yrs, mean YPI 10.2 ± 8.6 yrs</li> <li>Objective: To develop and assess the reliability and validity of a new scale designed to measure the impact of spasticity on daily life in people with SCI QOL outcome measures: SCI-SET; QLI-SCI health and functioning subscale (satisfaction)</li> </ul>	<ul> <li>Population: 7 persons (6 males) mean YPI 5.0 ± 4.4 yrs.</li> <li>Objective: To determine the effetraining (BWSTT) and tilt-table excitability, and related construction OOL outcome measures: SCI-SI</li> </ul>	<ul> <li>Population: 8 persons (7 males) with SCI, mean age 44.12 yrs, YPI range 4 to 29 yrs, who could stand with or without the assistance of bracing or supports</li> <li>29 yrs, who could stand whether a dynamic standing program using the Segway Personal Transporter results in any measurable physiological effects in individuals with SCI.</li> <li>OOL outcome measures: SCI.SET</li> </ul>	<ul> <li>Population: 125 persons with SCI; ≥18 yrs; and YPI &gt; 1 yr</li> <li>Objective: (1) To investigate relationships among social support, adjustment, and secondary complications in persons with SCI; (2) to explore potential effects of persons' perceived contribution to the social support of others and reception of social support from others</li> <li>OOL outcome measures: OLI-SCI, RSS</li> </ul>	<ul> <li>Population: 98 (81 males) subjects with SCI; mean age 33.5 yrs (16-72 yrs);</li> <li>2.3 YPI (.1-22.7 yrs)</li> <li>2.3 YPI (.1-22.7 yrs)</li> <li>Objective: To define the QOL of SCI patients – their physical, psychological, and social functioning</li> <li>OOL outcome measures: SIP</li> </ul>	
Adams et al³ Cross-sectional survey	Adams & Hicks <sup>36</sup> Random cross-over, pre-post intervention study	Boutilier et al <sup>35</sup> Pilot prospective pre- and post-intervention study	Anson et al <sup>45</sup> Cross-sectional and longitudinal survey	Lundqvist et al <sup>41</sup> Cross-sectional survey	Jagatsinh <sup>32</sup> Pre-post intervention study

(Table 1 Continued)

Continued
 Table I.

Author(s) Study Design	Methods	Outcome
Kogel et al <sup>33</sup> Pre-post intervention study – case approach	Population: 5 male subjects with tetraplegia Objective: To assess the effects of dronabinol, a THC derivative, for the treatment of spasticity QOL outcome measures: POMS	Emotionally, all participants showed decreases in vigor. Test data also showed slight to significant increases in at least one dysphoric mood for each patient, although results were extremely variable. Consequently, dronabinol seems to produce a heightened emotionality, but in an extremely individualized manner.
Jones et al <sup>37</sup> Pre-post intervention study with a qualitative component	<ul> <li>Population: 7 males with SCI (AIS A or B); mean age 36.7 yrs (25-45 yrs); with positive bulbocavernous reflex</li> <li>Objective: To document changes in perceived sexual function and spasticity after implant of a baclofen pump</li> <li>QOL outcome measures: SF- 36; Schwartz et al's performance scale items for perception of spasticity severity</li> </ul>	Participants reported perceived improvement in spasticity severity and overall health- related QOL.
Westerkam et al <sup>43</sup> Cross-sectional survey	<ul> <li>Population: 1,549 participants with SCI; mean age 45.1 yrs; YPI &lt;1.</li> <li>Objective: To identify the relationship between spasticity and life satisfaction among participants with SCI</li> <li>QOL outcome measures: Home life satisfaction, global satisfaction, vocational satisfaction, overall QOL, 3 subscales of the PRISM</li> </ul>	Three aspects of spasticity (daily activities, positive impact, and spasticity at its worst) were negatively correlated with home life satisfaction, global satisfaction, and overall QOL. The daily activities scale and the spasticity at its worst rating were negatively correlated with vocational satisfaction. Spasticity is negatively associated with QOL after SCI, and this should be an important consideration throughout patient treatment and rehabilitation.
Craven et al <sup>44</sup> Cross-sectional telephone survey	Population: 357 (218 males) community-dwelling persons with chronic traumatic and non-traumatic SCI; mean age 54 yrs; mean YPI 19.3 (onset range, 2-65 yrs) Objective: To describe the relationships between secondary health conditions and health preference in a cohort of adults with chronic SCI QOL Outcome Measures: HUI-Mark III; SCS-M	HUI-Mark III scores were lower ( $P < .001$ ) in high impact groups for spasms compared to low/no impact groups.
Cook et al <sup>40</sup> Cross-sectional survey	<b>Population:</b> 180 persons (162 males) with SCI; mean age 52.12 $\pm$ 11 yrs; YPIrange, 2 mos to 56 yrs <b>Objective:Objective:</b> To develop an instrument that measures the impact of spasticityon QOL <b>QOL outcome measures:</b> PRISM	The intraclass correlation coefficient values for the PRISM's 7 subscales were all high (.82 to .91), and internal consistency was the lowest for the need for intervention scale ( $\alpha =.74$ ) and highest for social avoidance/anxiety scale ( $\alpha =.96$ ). The a priori hypotheses regarding abnormal and involuntary muscle movement were partially confirmed, and thus provided some content validity for the PRISM.

Note: ADLs = activities of daily living; AIS = American Spinal Injury Association Impairment Scale; BWSTT = body-weight-supported treadmill training; HUI-Mark III = Health Utilities Index-Mark Powers Quality of Life Index–SCI Version III; QOL = quality of life; RSS = Reciprocal Social Support; SCI = spinal cord injury; SCIM = Spinal Cord Independence Measure; SCI-SET = Spinal Cord Injury Spasticity Evaluation Tool; SCS-M = SCI Secondary Conditions Scale-Modified; SIP = Sickness Impact Profile; TTS = tilt-table standing; YPI = years post injury. III; mos = months: MS = multiple sclerosis; POMS = Profile of Mood States; PRISM = Patient Reported Impact of Spasticity Measure; PSFS = Penn Spasm Frequency Scale; QLI-SCI = Ferrans and

presence and perceived impact without assessing signs and symptoms.

Similar findings were obtained by Jones et al<sup>37</sup> in their study assessing the impact of an implantable intrathecal baclofen pump. They used a single item to ask respondents to assign a general utility rating (0 = worst health to 100 = perfect health) to their spasticity's impact on health and well-being. A significant improvement was detected on this item from pre to post implantation. However, the item lacks validation for SCI and the vigor typically associated with other direct utility measures (ie, standard gamble or time trade-off scenarios).

Jagatsinh<sup>32</sup> examined the effects of intrathecal baclofen pump implantation on activities of daily living in a pre-post intervention study using a survey derived from items in the Barthel Index,<sup>50</sup> FIM,<sup>49</sup> and SCIM<sup>48</sup> (Boxes B and C, Figure 1). The scores for each measure were not reported separately, but rather were amalgamated to identify whether improvements were achieved in a particular domain (eg, improved, no change, worsened). Results showed that the intrathecal baclofen pump improved symptoms; Jagatsinh<sup>32</sup> concluded that this indicated an improved QOL by allowing participants to live more independently. Similarly, Loubser et al<sup>34</sup> examined 9 patients who received an intrathecal baclofen infusion for treatment of spasticity using the EPI (Boxes B and C, Figure 1). The EPI assesses 4 dimensions of activities of daily living, including communications, hygiene, eating, and dressing, and was administered by occupational therapists from the clinical program.<sup>34</sup> Although the assessments revealed improvements in function and activities of daily living from pre to post intervention, the EPI is a study-specific measure and is therefore limited in scope as an outcome measure of QOL, much like the measure used by Jagatsinh.<sup>32</sup> Subsequent searches for the EPI in the literature yielded negative results. As such, there are no psychometric data supporting the use of the EPI for this population.

Study-specific measures, such as the one used by Jagatsinh<sup>32</sup> and Loubser et al,<sup>34</sup> are informative but tend not to be generalizable to the larger population. Moreover, effect sizes are not calculated, information on cross-cultural applications is not available, and the instruments typically cover a number of different dimensions.<sup>66</sup> Although the SCIM,<sup>48,67,68</sup> FIM,<sup>69,70</sup> and Barthel Index<sup>50,71</sup> all have data supporting their use in SCI, the amalgamation of these tools by Jagatsinh<sup>32</sup> negates their validity. Further, the SCIM and FIM could be classified under Dijkers's model (Boxes B and C, Figure 1), but they should not be viewed as QOL measures, given that their scope is too narrow to qualify as measures of health-related QOL and that their developers did not intend for these measures to be used in this fashion.<sup>25</sup> Rather, they are indexes of disability and should not be confounded with QOL. The description of the EPI in Loubser et al<sup>34</sup> might have strong clinical utility for SCI because it was administered by occupational therapists at a rehabilitation hospital for people with SCI, but there remain a number of questions regarding its psychometric properties. As well, the domains covered are similar to the SCIM and FIM. As such, use of the EPI is not strongly recommended as a measure of spasticity impact on QOL.

In summary, the objective measures of QOL (SF-36, SIP, HUI-III) appear to be sensitive to the presence of spasticity, but the psychometric properties of these scales are limited for use in SCI. Only 3 of the studies<sup>27,34,44</sup> adequately captured the severity of spasticity in their samples, but only 227,34 of those used the Ashworth Scale to do so. Although the Ashworth Scale is a clinical measure currently held as the standard in spasticity assessment, its use is considered problematic by researchers and clinicians due to its lack of psychometric rigor.59 It is essential that future studies use a test battery approach to assess spasticity or refine current spasticity measures for use in the SCI population. Two study-specific outcome measures, the EPI and one derived from items of the SCIM, FIM, and Barthel Index,32 were identified, but they are problematic on several fronts. Both the SF-36 and SIP assess QOL under the "achievements" category, whereas the HUI-III is classified as a measure of QOL as "utility." Further work is warranted to examine the applicability of the SIP. It is recommended that the SF-36 be used in conjunction with the HUI-III; the SF-36 could be used to provide some psychometric validation of the HUI-III, and it could further the understanding of the influence of spasticity on QOL as "utility."

Measure	QOLª	QOL construct	SCI psychometrics	Format/scoring	Administrative burden	Sensitive to spasticity impact <sup>b</sup>
Evaluation of Personal Independence (EP1)	0	SWB	٧N	Assesses 4 dimensions of activities of daily living: communications, hygiene, eating, and dressing. Scores are assigned through a grading key ranging from <i>normal performance to activity impossible</i> .	~5 min	+Loubser et al <sup>34</sup>
Ferrans and Powers Quality of Life Index- (SCI Version III)	S	SWB	Cronbach's $\alpha = .73$ 99 Validity established for SCI (see Hill et al <sup>57</sup> for further details)	74 items divided into 2 parts: satisfaction (37 items) and importance (37 items). Each item is ranked on a 6-pt scale ranging from 1 (very dissatisfied or unimportant) to 6 ( <i>very satisfied or</i> <i>important</i> ). The scale assesses the following domains: health and functioning, socioeconomic status, psychological and spiritual well-being, and family relationships. Scores range from 0 to 30, with higher scores indicating better QOL.	~ 10 min	-Gianino et al <sup>27</sup>
Health Utilities Index- III (HUI-II I)	0	SWB	Lacks psychometric validation	Assesses 8 attributes (vision, hearing, speech, ambulation, dexterity, $\sim$ 3-10 min emotion, cognition, and pain) in respondents over the 4 weeks prior to the administration date. Each attribute is assigned to 1 of the 5 or 6 levels of ability/disability. Scores for each attribute are combined using a multiplicative utility function and are reported as a single metric ranging from 0 ( <i>death</i> ) to 1 ( <i>perfect health</i> ). There is a 15- and a 40-item version of the HUI-III.	~3-10 min	+Craven et al <sup>44</sup>
Life Situation Questionnaire-Revised (LSQ-R)	S	SWB	High levels of reliability (Cronbach's $\alpha = 0.76-0.86$ )	Assesses current level of satisfaction with various domains of life (ie, employment, medical treatments, social activities, and subjective well-being). It is embedded into a larger survey, the LSQ, which measures a broad range of long-term SCI outcomes. It consists of 50 items divided into 2 parts. Part 1 consists of 20 items that measure satisfaction on scale ranging from 1 ( <i>very dissatisfied</i> ) to 5 ( <i>very satisfied</i> ). Part 2 consists of 30 items measuring problems on a scale ranging from 1 ( <i>no problem</i> ) to 5 ( <i>major problem</i> ). Scoring is achieved through 8 embedded subjective well-being scales.	~ 10 min	+Westerkam et al <sup>43</sup>
Patient Reported Impact of Spasticity Measure (PRISM)	S	SWB	Good internal consistency (Cronbach's $\alpha = .74$ to .96) and reproducibility (ICC range from .82 to .91). Validity still needs to be established.	41 items covering 7 subscales. Items are ranked on a 5-point scale ranging from 0 ( <i>never true for me</i> ) to 4 ( <i>very often true for me</i> ), with higher scores indicating great impact. The tool covers 7 subscales: Social Avoidance/Anxiety, Psychological Agitation, Daily Activities, Need for Assistance/ Positioning, Positive Impact, Need for Intervention, and Social Embarrassment.	~ 10 min	+Cook et al <sup>40</sup> +Westerkam et al <sup>43</sup>

Table 2.Summary of outcome measures

+Kogel et al <sup>33</sup>	+Anson et al <sup>45</sup>	–Noonan et al <sup>39</sup> +Westgren & Levi <sup>42</sup>	+Gianino et al <sup>27</sup> +Lundqvist et al <sup>41</sup>	+Adams et al <sup>38</sup>
~ 5-10 min	~ 10-15 min	~ 5-10 min	~ 20-30 min for +Gianino et al <sup>27</sup> SIP +Lundqvist et al ~ 15-20 min for SIP 68	~ 10 min
65 items measuring 6 mood states on a 5-point scale ranging from 0 ( <i>not at all</i> ) to 4 ( <i>extremely</i> ). Total score ranges from 0 to 200, with higher scores indicating greater mood disturbance. The POMS yields score on the following dimensions: tension- anxiety, depression-dejection, anger-hostility, vigor-activity, fatigue-inertia, and confusion-bewilderment	Eight questions rating types of support received from families, friends, and the community. Responses are ranked on a 7-point scale ranging from 1 ( <i>never</i> ) to 7 ( <i>always</i> ). Higher scores indicate greater levels of support.	36 items covering 8 domains related to functioning and health. Scoring is norm-based, with a general population mean score of 50 and a SD of 10. Higher scores indicate higher levels of health.	136 severity-weighted negative health impact statements to which a respondent answers only if the statement is true based on the day the SIP is completed. Twelve domains of functioning assessed: sleep and rest, eating, work, home management, recreation and pastimes, ambulation, mobility, body care and movement, social interaction, alertness behavior, emotional behavior, and communication.	35 items ranked on a 7-point scale ranging from -3 ( <i>extremely problematic</i> ) to 3 ( <i>extremely helpful</i> ). The total score is the sum of all applicable responses divided by the number of applicable items.
N/A	Alpha coefficients ranged from .70 to .76 for the 4 types of support, with an average of .73. The alpha for the subsets was .55, but is expected as it sums 3 types of support.	Reliability and validity established for SCI (see Noonan et al <sup>39</sup> for further details)	Limited. Data and norms for the SCI population do exist for the SIP 68.	High internal consistency (Cronbach's $\alpha = .90$ ) and test-retest reliability (ICC = .91)
SWB	SWB	A; HRQOL	SWB	SWB
S	S	0	0	s
Profile of Mood States (POMS)	Reciprocal Social Support (RSS)	Short-Form Health Survey (SF-36)	Sickness Impact Profile O (SIP)	Spinal Cord Injury Spaticity Evaluation Tool (SCI-SET)

*Note:* A = Achievement; HRQOL = health-related quality of life; ICC = intercorrelation coefficient; N/A = not available; SCI = spinal cord injury; SWB = subjective well-being.  ${}^{a}O = objective; S = subjective.$  ${}^{b}+ = sensitive to spasticity impact; - = not sensitive to spasticity impact$ 

Specifically, scores on the SF-36 can be converted into SF-6D scores, which is a preference-based single-index measure for health from data using general population values. As with the HUI-III, the SF-6D can be used to obtain quality-adjusted life-years (QALYs) from the SF-36 for use in cost utility analysis.<sup>72</sup> Further, use of the SF-36V for investigating the influence of spasticity might be warranted, because it appears to have qualities that are more appropriate to studying SCI-related outcomes than does its predecessor.

### Applicability of subjective QOL measures on assessing spasticity

Six subjective measures were identified: the Ferrans and Powers Quality of Life Index–SCI Version III (QLI-SCI),<sup>59,73</sup> the Reciprocal Support Scale (RSS),<sup>45</sup> the Profile of Mood States (POMS),<sup>74</sup> the Life Situation Questionnaire–Revised (LSQ-R),<sup>75,76</sup> and 2 condition-specific measures: the Spinal Cord Injury Spasticity Evaluation Tool (SCI-SET)<sup>38</sup> and the Patient Reported Impact of Spasticity Measure (PRISM).<sup>40</sup>

The QLI-SCI<sup>59,73</sup> (Boxes C, D, and E, Figure 1) measures satisfaction in and the relative importance of several life domains. The QLI-SCI has been used in other SCI-related studies examining QOL,<sup>24,77,78</sup> and it has good underlying psychometric properties.78,79 The homogeneity reliability of the scale is good, with Cronbach's alpha scores of 0.73 to 0.99.77,80 Factorial analysis of the scale, however, revealed that the domain structure did not fit with subject interpretations.77 As well, the correlation of the importance of scores was very low (r = 0.47). With regard to sensitivity to spasticity, the QLI-SCI did not detect improvements over time in persons with SCI in a study by Gianino et al.27 The lack of effects on the QLI-SCI was partly attributed to the fact that for some patients, the benefits of spasticity may have taken longer to achieve than the duration of the study.<sup>27</sup> Also, the alleviation of one symptom of a complex injury may not affect non-health-related domains.<sup>27</sup> These interpretations are reasonable. A longer follow-up may have provided a clearer picture of the impact of reduced spasticity. It has also been noted that the structure of the

importance scale scoring on the QLI-SCI might require alteration and the scale may require domain rearrangement.<sup>56</sup> It is therefore possible that this may have influenced the findings in the study by Gianino et al.<sup>27</sup>

Conversely, Adams and Hicks<sup>36</sup> found that the QLI-SCI is sensitive to changes in spasticity over time. They conducted a body-weightsupported treadmill training (BWSTT) and tilttable standing (TTS) study on spasticity and obtained a moderate effect size for the QLI-SCI.<sup>36</sup> Although patients' scores on the QLI-SCI improved after undergoing BWSTT, it is difficult to attribute the changes in QOL to reduced spasticity. The authors acknowledge that changes in QOL may have resulted in increases in function due to the BWSTT.<sup>36</sup> Overall, further work is needed to conclusively show this relationship between the QLI-SCI and spasticity.

The LSQ-R (Boxes C-E, Figure 1) measures a broad range of long-term SCI outcomes<sup>81,82</sup> and has undergone major revisions to increase its core content coverage, particularly for items relating to subjective well-being.45,83 Factor analysis of the scale by Krause and Reed<sup>84</sup> yielded 3 satisfaction factors, which were identified as home life satisfaction, vocational satisfaction, and global satisfaction. Each satisfaction factor indicates a subscale of the measure. Westerkam and colleagues43 examined the influence of spasticity on QOL using the 3 satisfaction factors of the LSQ-R and found that spasticity was negatively associated with life satisfaction. Although significant, the models for these satisfaction scales accounted for a small proportion of the variance (10% or less).

Hallin et al<sup>66</sup> noted that the LSQ or its revised form have not been used consistently; there are discrepancies in the number of items used and the scales that were developed. The LSQ uses a mix of both objective and subjective items, although later versions emphasize the items that affect subjective well-being.<sup>66</sup> In their meta-analysis of QOL measures used in SCI research, Hallin et al<sup>66</sup> found that the LSQ-R has a high level of reliability (Cronbach's  $\alpha = 0.76-0.86$ ), despite the variety in its application.

The RSS<sup>45</sup> (Boxes C and E, Figure 1) rates the frequency with which respondents receive 4

types of support (social, material, emotional, and nonpaid personal) and the frequency with which upsetting things happen between respondents and members of their family, their friends, or the community. Some reliability for the scale was obtained in a sample of persons who were American Indians with SCI,<sup>85</sup> which yielded alpha coefficients that ranged from 0.70 to 0.76 for the 4 types of support, with an average of 0.73. The alpha for the upsets scale was 0.55; however, low internal consistency is expected given that the scale sums the evaluations that were made by 3 groups: family, friends, and community.<sup>85</sup>

With regard to spasticity, Anson et al<sup>45</sup> provided evidence that spasticity was negatively, though weakly, associated with giving advice and social support as measured by the RSS. One possibility for the weak associations detected by Anson et al<sup>45</sup> might be due to the fact that the health status of the sample was obtained through a section of the QLI-SCI.<sup>73</sup> Additionally, the focus was on a multitude of health conditions and not on spasticity per se. Despite the limitations of this study, the RSS appears to be a viable measure of social support for the SCI population, but further work is warranted to establish its psychometric properties and clinical utility for assessing spasticity impact.

The POMS<sup>74</sup> (Box E, **Figure 1**) is a measure of mood states. Kogel et al<sup>33</sup> evaluated the effects of dronabinol, a derivative of tetrahydrocannabinol (THC), on memory and spasticity in 5 males with tetraplegia. Results were mixed with respect to the effects of dronabinol on spasticity. The POMS indicated that participants experienced decreased vigor and emotional changes related to variations in drug dosage. Although the POMS has been used in other SCI studies,<sup>86</sup> Kogel et al<sup>33</sup> used it to assess treatment effects and not spasticity per se.

The demand for subjective measures of the impact of spasticity on QOL is evident, because new measures have been developed that ensure that the individual's experience is taken into consideration, specifically, the SCI-SET and the PRISM. The SCI-SET (Boxes C and E, **Figure 1**) was developed by Adams et al<sup>38</sup> and assesses the impact of spasticity on various activities of daily living and social participation after SCI. The SCI-SET was validated in 61 participants with chronic

SCI against self-assessed spasticity severity and impact scores on the Penn Spasm Frequency Scale (PSFS), the FIM motor subscale, and the health and functioning subscale from the QLI-SCI. The SCI-SET was found to be significantly moderately to strongly associated with self-assessed spasticity impact (r = -.61) and spasticity severity (r = -.48), as well as the QLI-SCI health and functioning subscale (r = .68) and the PSFS (r = -.66). The SCI-SET also showed high internal consistency ( $\alpha$ = .90) and test-retest reliability (intercorrelation coefficient [ICC] = .91).

The SCI-SET takes into account both the positive and negative effects of spasticity. Given its recent development, more testing is required to thoroughly assess its clinical utility. This is particularly important given the number of items, the need for posttest analysis, and the fact that it contains a 7-day recall component, which is too long of a period for accurate symptom recall.87 Although the tool shows promise as a reputable measure of spasticity impact on QOL, the use of the QLI-SCI58,87 for validation in the study by Adams et al<sup>38</sup> is potentially problematic given the issues noted above (ie, QLI potentially requiring domain rearrangement). The use of a noncontentious measure for validation would strengthen the argument for the use of the SCI-SET in QOL measurement within the context of spasticity impact. In a study using BWSTT and TTS to improve spasticity in a sample of persons with SCI, Adams and Hicks<sup>36</sup> found that the scores on the SCI-SET did not change over time, which might be partly attributable to the intervention not being intensive or long enough. An intervention study by Boutilier et al also found no change in SCI-SET scores.35

In a similar vein, Cook et al<sup>40</sup> developed an instrument for assessing the impact of spasticity on QOL from the patient's perspective, called the PRISM (Boxes C and E, **Figure 1**). They administered a developmental form of the instrument to 180 participants, with a subsample of 36 participants recruited to provide validation for the completed form. The intraclass correlation coefficient (ICC) values for its 7 subscales were high, ranging from .82 to .91, and internal consistency was the lowest for the need for intervention scale and highest for the social avoidance/anxiety scale. The a priori hypotheses regarding abnormal and involuntary muscle movement were partially confirmed and thus provided some content validity for the PRISM. Despite this, the inclusion of a more established measure as a comparator in this study would have provided greater insight into the tool's psychometric properties and clinical utility. In addition, the PRISM's scoring system does not take into account the ordinal nature of the scores, which is a considerable limitation of this tool.<sup>40</sup> The PRISM does show promise, however, as an effective measure of spasticity impact.

Further support for the PRISM comes from a study by Westerkam et al.43 As described above, these authors used scales of the LSQ-R (home life satisfaction, global satisfaction, vocational satisfaction), as well as 3 subscales of the PRISM (daily activities, positive impact, and spasticity at its worst) to determine the relationship between spasticity and life satisfaction post SCI. Daily activities, positive impact, and spasticity at its worst were all negatively correlated with home life satisfaction, global satisfaction, and overall QOL. Daily activities and spasticity at its worst were also negatively correlated with vocational satisfaction. Again, Westerkam et al's43 findings indicate that spasticity is negatively related with QOL after SCI, but the models only accounted for a small proportion of the variance.

Fleuren et al<sup>9</sup> used a study-specific and nonstandardized measure to assess activities of daily living, participation, and functional domains (Boxes C and E, Figure 1) in 26 participants with complete SCI. This measure was informed by the World Health Organization's International Classification of Functioning, Disability and Health.<sup>88</sup> Given that the scale was designed to assess the influence of spasticity on life activities and perceived degree of spasticity and resulting discomfort, it holds some good clinical utility for providing an understanding of patients' perceptions related to this health condition. Based on its theoretical underpinnings, the scale assesses the construct of participation. Further work is needed, however, to establish its psychometric properties for persons with SCI.

In summary, there are a number of potential subjective measures for assessing spasticity. In terms of more global domains of well-being, further work with the QLI-SCI and LSQ-R would be beneficial for refinement and to determine their viability as measures of spasticity impact on QOL.<sup>80</sup> Further work with the RSS is also needed to investigate how social support is affected by spasticity. No strong recommendations can be made regarding the POMS given the focus of the study in which it was used. Although their psychometric properties require further investigation, the more promising subjective measures are the SCI-SET and PRISM because they assess both positive and negative effects of spasticity and provide a more complete picture of the overall effect of spasticity on an individual.

### Discussion

The purpose of this systematic review was to highlight the influence of spasticity on QOL in the SCI population and to identify and classify appropriate measures for assessing this relationship. Identified measures from this review were representative of all 3 domains of QOL as indicated by Dijkers's model<sup>25</sup>: QOL as utility (HUI-III), as achievements (SF-36; SIP), and as subjective well-being. For QOL as subjective wellbeing, measures of social support (RSS), mood states (POMS), and specific life domains (QLI-SCI), including condition-specific surveys (PRISM, SCI-SET), were assessed. Although some of these measures appeared to be sensitive to spasticity, few had adequate levels of psychometric evidence for use in the SCI population (HUI-III, QLI-SCI, RSS, PRISM). There is some evidence that supports the use of the SCI-SET in the SCI population, however further work is recommended to establish the psychometric properties of this measure given its mixed face validity. Based on the findings, the PRISM might have greater sensitivity to spasticity than the SCI-SET, because it has items that take into account affective reactions to the presence of spasticity. The importance of accounting for the affective reactions of spasticity are illustrated by a qualitative study<sup>89</sup> that examined how persons with SCI (N = 24) experienced their spasticity

on a daily basis and provided some evidence on its positive aspects. As such, the PRISM contains a number of items that tap into these concepts. The SCI-SET taps into some of the issues noted above, but the PRISM also assesses the positive benefits of spasticity, such as opportunities for muscle exertion. Both the PRISM and SCI-SET are promising measures and their continued use is recommended, but there is a need to further establish their reliability and validity.

A number of the identified articles used obscure or nonstandardized study-specific outcome measures.<sup>9,32,34,89</sup> Given the issues noted, such as psychometric adequacy, it is essential that investigators attempt to adopt valid and reliable QOL scales for SCI. If use of a widely established measure is not possible, then there needs to be a strong justification for developing a new scale. Although some of the QOL measures demonstrated sensitivity to spasticity, it is recommended that, if used, they be paired with more established tools in order to help determine their clinical utility and psychometric properties for SCI.

Only 2 of the identified studies<sup>27,34</sup> used the Ashworth Scale of spasticity to measure spasticity in their sample. The Ashworth Scale<sup>90</sup> and Modified Ashworth Scale<sup>91</sup> are the leading clinical tools to quantify spasticity by measuring resistance during passive soft-tissue stretching. These measures are quick and easy to administer, are well tolerated by patients,<sup>87</sup> and are the most common scales used in SCI studies.<sup>92</sup> Despite these attributes, the poor interrater and intersession reliability associated with these tools has shed doubt on their applicability for SCI.<sup>59</sup>

As noted, the multitude of available definitions and conceptualizations of spasticity<sup>2-6</sup> poses a number of challenges for its assessment. Thus, it is possible that this issue (using the Ashworth Scale versus self-report) might have affected the sensitivity and specificity of some of the identified tools used to assess spasticity's influence on QOL. Regardless, the use of QOL measures, both global (QLI-SCI, HUI-III) and condition-specific (PRISM, SCI-SET), along with the designs of some of the studies clearly indicate how QOL improves when spasticity is better managed<sup>27,34,37</sup> and how QOL is better in persons with no to mild spasticity compared to those with moderate to severe spasticity.<sup>38,41,42,44</sup> Moreover, framing QOL within a theoretical framework (ie, Dijkers's model<sup>25</sup>) contributes to a better understanding of what concepts QOL measures are purported to assess. This understanding will help to ensure that the selected measures are congruent with the intended goals and outcomes of the project and are meaningful to the target audience.93 Further work is needed to develop more appropriate assessment measures of spasticity. Future studies should ensure that a clinical measure of the presence, frequency, and severity of spasticity be added, when possible, to quantify spasticity. Along with providing an enhanced understanding of QOL measurement, this would enable a more refined understanding of the impact of spasticity in people with SCI and would facilitate comparisons of findings across studies, thus advancing the state of knowledge in the field.

### Conclusions

The assessment of the impact of spasticity on QOL should be an important consideration in rehabilitation practice, as it influences the extent and nature of the treatment(s) applied. Based on this review, the SCI-SET and the PRISM emerged as promising measures for assessing the impact of spasticity on subjective QOL in persons with SCI. Further work is recommended, however, to improve their psychometric properties and clinical utility.

Although the literature includes studies that assess the influence of spasticity on QOL using both objective and subjective measures, more work using both types of measures in the same study is needed to illustrate its impact from multiple perspectives. In particular, more studies should focus on quantifying the impact of spasticity from the view of QOL as utility in tandem with subjective outcomes. This would inform recommendations for resource allocation within the health care system and would emphasize both the societal and patient perspectives on the burden of spasticity, while potentially improving clinical practices related to its treatment. Concurrent development of a psychometrically robust tool

for quantification of the clinical phenomena associated with spasticity would accelerate care and advance the field.

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#### REFERENCES

- Adams MM, Hicks AL. Spasticity after spinal cord 1. injury. Spinal Cord. 2005;43:577-586.
- Lance JW. Symposium synopsis. In: Young RR, Koeila WE, eds. Spasticity: Disordered Motor Control. Chicago: Yearbook Medical Publishers; 2 1980:485-494.
- 3. Young RR, Shahani BT. Spasticity in spinal cord injured patients. In: Bloch RE, Basbaum M, eds. Management of Spinal Cord Injuries. Baltimore: Williams & Wilkins; 1986:241-283.
- Katz RT, Royal GP, Brait C, Rymer Z. Objective quantification of spastic hypertonia: Correlation with clinical findings. Arch Phys Med Rehabil. 1992;73:339-347.
- Thilmann AF, Burke DJ, Rymer WZ. Preface. In: Thilmann AF, Burke DJ, Rymer WZ, eds. *Spasticity:* 5. Mechanisms and Management. Berlin: Springer-Verlag; 1993:v-vi.
- 6. O'Dwyer NJ, Ada L, Neilson PD. Spasticity and muscle contracture following stroke. Brain. 1996;119:1737-1749.
- 7. Skold C, Levi R, Seiger A. Spasticity after traumatic spinal cord injury: Nature, severity, and location. Arch Phys Med Rehabil. 1999;80:1548-1557.
- Maynard FM, Karunas RS, Waring WP. Epidemiology of spasticity following traumatic spinal cord injury. Arch Phys Med Rehabil. 1990;71:566-569.
- Fleuren JF, Voerman GE, Snoek GJ, Nene AV, Rietman JS, Hermens HJ. Perception of lower limb spasticity in patients with spinal cord injury. Spinal Cord. 2009;47:396-400.
- 10. Phadke CP, Balasubramanian CK, Ismail F, Boulias C. Revisiting physiologic and psychologic triggers that increase spasticity. Am J Phys Med Rehabil. 2013;92(4):357-369.
- 11. Albert T, Yelnik A. Physiotherapy for spasticity. Neurochirurgie. 2003;49:239-246.
- 12. Elovic E. Principles of pharmaceutical management of spastic hypertonia. Phys Med Rehabil Clin N Am. 2001;12:793-816. 13. Kita M, Goodkin DE. Drugs used to treat spasticity.
- Drugs. 2000;59:487-495.

- 14. Norman KE, Pepin A, Barbeau H. Effects of drugs on walking after spinal cord injury. Spinal Cord. 1998;36:699-715.
- 15. Stewart JE, Barbeau H, Gauthier S. Modulation of locomotor patterns and spasticity with clonidine in spinal cord injured patients. Can J Neurol Sci. 1991;18:321-332.
- 16. Kirshblum S. Treatment alternatives for spinal cord injury related spasticity. J Spinal Cord Med. 1999;22:199-217.
- 17. Gracies JM, Nance P, Elovic E, McGuire J, Simpson DM. Traditional pharmacological treatments for spasticity. Part II: General and regional treatments. Muscle Nerve. 1997;6:S92-S120.
- 18. Fung J, Stewart JE, Barbeau H. The combined effects of clonidine and cyproheptadine with interactive training on the modulation of locomotion in spinal cord injured subjects. J Neurol Sci. 1990;100:85-93.
- 19. Levi R, Hultling C, Seiger A. The Stockholm Spinal Cord Injury Study: 2. Associations between clinical patient characteristics and post-acute medical problems. Paraplegia. 1995;33:585-594.
- 20. Sheean G. The pathophysiology of spasticity. Eur J Neurol. 2002;9(Suppl 1):3-9.
- 21. Walter JS, Sacks J, Othman R, et al. A database of self-reported secondary medical problems among VA spinal cord injury patients: Its role in clinical care and management. J Rehabil Res Dev. 2002;79:53-61.
- 22. Gracies JM, Elovic E, McGuire J, Simpson DM. Traditional pharmacological treatments for spasticity. Part I: Local treatments. Muscle Nerve. 1997;6:S61-S91.
- 23. Barnes M. Botulinum toxin mechanisms of action and clinical use in spasticity. J Rehabil Med. 2003; (41 Suppl):56-59
- 24. Chambers HG. The surgical treatment of spasticity. Muscle Nerve. 1997;6:S121-S8.
- 25. Dijkers MP. Quality of life of individuals with spinal cord injury: A review of conceptualization, measurement, and research findings. J Rehabil Res Dev. 2005;42 (3 Suppl 1):87-110.
- 26. Anderson KD, Borisoff JF, Johnson RD, Stiens SA, Elliott SL. Spinal cord injury influences psychogenic as

well as physical components of female sexual ability. *Spinal Cord.* 2007;45:349-359.

- Gianino JM, York MM, Paice JA, Shott S. Quality of life: Effect of reduced spasticity from intrathecal baclofen. J Neurosci Nurs. 1998;30:47-54.
- Spinal Cord Injury British Columbia. Workforce participation survey of Canadians with spinal cord injuries. Spinal Cord Injury British Columbia; 2006. http://sci-bc-database.ca/wp-content/uploads/ workplace-participation-survey-of-canadians-withspinal-cord-injuries.pdf
- 29. Dijkers MP. Individualization in quality of life measurement: Instruments and approaches. Arch Phys Med Rehabil. 2003;84(4 Suppl 2):S3-14.
- Dijkers MPJM. Quality of life of individuals with spinal cord injury: A review of conceptualization, measurement, and research findings. J Rehabil Res Dev. 2005;42(3 Suppl 1):87-110.
- Dijkers MP. Quality of life after traumatic brain injury: A review of research approaches and findings. Arch Phys Med Rehabil. 2004;85(4 Suppl 2):S21-35.
- Jagatsinh Y. Intrathecal baclofen: Its effect on symptoms and activities of daily living in severe spasticity due to spinal cord injuries: A pilot study. Indian J Orthop. 2009;43:46-49.
- Kogel RW, Johnson PB, Chintam R, Robinson CJ, Nemchausky BA. Treatment of spasticity in spinal cord injury with Dronabinol, a tetrahydrocannabinol derivative. Am J Ther. 1995;10:799-805.
- Loubser PG, Narayan RK, Sandin KJ, Donovan WH, Russell KD. Continuous infusion of intrathecal baclofen: Long-term effects on spasticity in spinal cord injury. *Paraplegia*. 1991;29:48-64.
- Boutilier G, Sawatzky BJ, Grant C, Wiefelspuett S, Finlayson H. Spasticity changes in SCI following a dynamic standing program using the Segway. *Spinal Cord.* 2012;50(8):595-598.
- Adams MM, Hicks AL. Comparison of the effects of body-weight-supported treadmill training and tilt-table standing on spasticity in individuals with chronic spinal cord injury. J Spinal Cord Med. 2011;34(5):488-494.
- Jones ML, Leslie DP, Bilsky G, Bowman B. Effects of intrathecal baclofen on perceived sexual functioning in men with spinal cord injury. J Spinal Cord Med. 2008;31:97-102.
- Adams MM, Martin Ginis KA, Hicks AL. The Spinal Cord Injury Spasticity Evaluation Tool: Development and evaluation. Arch Phys Med Rehabil. 2007;88:1185-1192.
- Noonan VK, Kopec JA, Zhang H, Dvorak MF. Impact of associated conditions resulting from spinal cord injury on health status and quality of life in people with traumatic central cord syndrome. *Arch Phys Med Rehabil.* 2008;89:1074-1082.
- Cook KF, Teal CR, Engebretson JC, et al. Development and validity of patient reported impact of spasticity measure (PRISM). J Rehabil Res Dev. 2007;44:363-372.
- Lundqvist C, Siosteen A, Sullivan L, Blomstrand C, Lind B, Sullivan M. Spinal cord injuries: Clinical, functional and emotional status. *Spine*. 1991;16:78-83.

- Westgren N, Levi R. Quality of life and traumatic spinal cord injury. Arch Phys Med Rehabil. 1998;79:1433-1439.
- Westerkam D, Saunders LL, Krause JS. Association of spasticity and life satisfaction after spinal cord injury. Spinal Cord. 2011;49:990-994.
- Craven BC, Hitzig SL, Mittmann N. Impact of impairment and secondary health conditions on health preference among individuals with chronic spinal cord injury. J Spinal Cord Med. 2012;35:361-370.
- Anson CA, Stanwyck DJ, Krause JS. Social support and health status in spinal cord injury. Int J Paraplegia. 1993;31:632-638.
- Ware JEJ, Kosinski M, Gandek B. SF-36 Health Survey: Manual and Interpretation Guide. Lincoln, RI: QualityMetric Inc; 2001.
- Feeny D, Furlong W, Torrance GW, et al. Multiattribute and single attribute utility functions for the Health Utilities Index Mark 3 System. *Med Care.* 2002;40(2):113-128.
- Catz A, Itzkovich M, Agranov E, Ring H, Tamir A. SCIM-spinal cord independence measure: A new disability scale for patients with spinal cord lesions. *Spinal Cord*. 1997;35(12):850-856.
- Wright J. The FIM. The Center for Outcome Measurement in Brain Injury; 2000. http://tbims.org/combi/FIM. Accessed June 3, 2013.
- Mahoney FI, Barthel DW. Functional evaluation: The Barthel Index. Md State Med J. 1965;14:61-65.
- McHorney C, Ware JJ, Lu R, Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36) III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. *Med Care*. 1994;32(1):40-66.
- Hays RD, Hahn H, Marshall G. Use of the SF-36 and other health-related quality of life measures to assess persons with disabilities. *Arch Phys Med Rehabil*. 2002;83:S4-S9.
- Schwartz C, Vollmer T, Lee H. Reliability and validity of two self-report measures of impairment and disability for MS. *Neurology*. 1999;79:494-496.
- Andresen EM, Fouts BS, Romeis JC, Brownson CA. Performance of health-related quality-of-life instruments in a spinal cord injured population. Arch Phys Med Rehabil. 1999;80:877-884.
- Andresen EM, Meyers AR. Health-related quality of life outcomes measures. Arch Phys Med Rehabil. 2000;81:S30-S45.
- Hill MR, Noonan VK, Sakakibara BM, Miller WC, SCIRE Research Team. Quality of life instruments and definitions in individuals with spinal cord injury: A systematic review. *Spinal Cord.* 2010;48(6):438-450.
- Bergner M, Bobbitt RA, Carter WB, Gilson BS. The Sickness Impact Profile: Development and final revision of a health status measure. *Med Care.* 1981;19:787-805.
- Meyers AR, Andresen EM, Hagglund KJ. A model of outcomes research: Spinal cord injury. Arch Phys Med Rehabil. 2000;81:S81-S90.
- Craven BC, Morris AR. Modified Ashworth scale reliability for measurement of lower extremity spasticity among patients with SCI. Spinal Cord. 2010;48:207-213.

- Post MWM, deWitte LP, van Asbeck FWA, van Dijk AJ, Schrijvers AJP. Predictors of health status and life satisfaction in spinal cord injury. Arch Phys Med Rehabil. 1998;78:395-402.
- Post MWM, Van Asbeck FWA, van Dijk AJ, Schrijvers AJP. Services for spinal cord injured: Availability and satisfaction. Spinal Cord. 1997;35:109-115.
- Wood-Dauphinée S, Exner G, Group. SC. Quality of life in patients with spinal cord injury-basic issues, assessment, and recommendations. *Restorative Neurol Neurosci*. 2002;20:135-149.
- 63. Robinson R. Cost-utility analysis. Br Med J. 1993;307(6908):859-862.
- Boyle M, Furlong W, Feeny D, et al. Reliability of the Health Utilities Index- Mark III used in the 1991 cycle
   Canadian General Survey Health Questionnaire. Qual Life Res. 1995;4(3):249-257.
- Kalpakjian CZ, Scelza WM, Forchhemimer MB, Toussaint LL. Preliminary reliability and validity of a Spinal Cord Injury Secondary Conditions Scale. J Spinal Cord Med. 2007;30(2):131-139.
- Hallin P, Sullivan M, Kreuter M. Spinal cord injury and quality of life measures: A review of instrument psychometric quality. *Spinal Cord*. 2000;38:509-523.
- Catz A, Itzkovich M, Tesio L, et al. A multicenter international study of the Spinal Cord Independence Measure, version III: Rasch psychometric validation. *Spinal Cord*. 2007;45(4):275-291.
- Rudhe C, van Hedel HJ. Upper extremity function in persons with tetraplegia: Relationships between strength, capacity, and the spinal cord independence measure. *Neurorehabil Neural Repair*. 2009;23(5):413-421.
- Graves D. The construct validity and explanatory power of the ASIA Motor Score and the FIM: Implications for theoretical models of spinal cord injury. *Top Spinal Cord Inj Rehabil.* 2005;10:65-74.
   Hall KM, Cohen ME, Wright J, Call M, Werner
- Hall KM, Cohen ME, Wright J, Call M, Werner P. Characteristics of the Functional Independence Measure in traumatic spinal cord injury. Arch Phys Med Rehabil. 1999;80:1471-1476.
- Granger CV, Albrecht GL, Hamilton BB. Outcome of comprehensive medical rehabilitation: Measurement by PULSES profile and the Barthel Index. Arch Phys Med Rehabil. 1979;60:145-154.
- 72. Brazier J, Roberts J, Deverill M. The estimation of a preference-based measure of health from the SF-36. J Health Econ. 2002;21:271-292.
- 73. Ferrans CE, Powers MJ. Psychometric assessment of the Quality of Life Index. *Res Nurs Health*. 1992;15:29-38
- McNair DM, Lorr M, Droppleman LF. Manual for the Profile of Mood States. San Diego, CA: Educational and Industrial Testing Service; 1992.
- Krause JS. Dimensions of subjective well-being after spinal cord injury: An empirical analysis by gender and race/ethnicity. Arch Phys Med Rehabil. 1998;79(8):900-909.
- Krause JS. Subjective well being after spinal cord injury: Relationships to gender, race/ethnicity, and

chronological age. Rehabil Psychol. 1998;43(4):282-296.

- May L, Warren S. Measuring quality of life of persons with spinal cord injury: Substantive and structural validation. *Qual Life Res.* 2001;10:503-515.
- Lin KH, Chuang CC, Kao MJ, Lien IN, Tsauo JY. Quality of life of spinal cord injured patients in Taiwan: A subgroup study. *Spinal Cord*. 1997;35(12):841-849.
- Lyons S, Sorenson M. Quality of life in spinal cord injury patients with pressure ulcers. SCI Nurs. 2009;26:13-18.
- May LA, Warren S. Measuring quality of life of persons with spinal cord injury: External and structural validity. *Spinal Cord*. 2002;40(7):341-350.
- Crewe NM, Athelstan GT, Krumberger J. Spinal cord injury: A comparison of pre-injury and post-injury marriages. Arch Phys Med Rehabil. 1979;60(6):252-256.
- Crewe NM, Krause JS. An eleven year follow-up of adjustment to spinal cord injury. *Rehabil Psychol.* 1990;35(4):205-210.
- Krause JS, Crewe NM. Long-term prediction of selfreported problems following spinal cord injury. *Paraplegia*. 1990;28(3):186-202.
- Krause JS, Reed KS. Life satisfaction and self-reported problems after spinal cord injury: Measurement of underlying dimensions. *Rehabil Psychol.* 2009;54(3):343-350.
- Krause JS, Coker JL, Charlifue S, Whiteneck GG. Health outcomes among American Indians with spinal cord injury. Arch Phys Med Rehabil. 2000;81(7):924-931.
- Craig A, Tran Y, Lovas J, Middleton J. Spinal cord injury and its association with negative psychological states. Int J Psychosocial Rehabil. 2008;12:115-121.
- Hsieh JTC, Wolfe DL, Miller WC, Curt A, and the SCIRE Research Team. Spasticity outcome measures in spinal cord injury: Psychometric properties and clinical utility. *Spinal Cord.* 2007;46:86-95.
- World Health Organization. International Classification of Functioning, Disability and Health (ICF). Geneva: World Health Organization; 2001:18-19.
- Mahoney JS, Engebretson JC, Cook KF, Hart KA, Robinson-Whelen S, Sherwood AM. Spasticity experience domains in persons with spinal cord injury. Arch Phys Med Rehabil. 2007;88:287-294.
- 90. Ashworth B. Preliminary trial of carisoprodal in multiple sclerosis. *Practitioner*. 1964;192:540-542.
- Bohannon R, Smith M. Interrater reliability of a Modified Ashworth Scale of muscle spasticity. *Phys Ther.* 1987;67(2):206.
- Haas BM, Bergstrom E, Jamous A, Bennie A. The inter rater reliability of the original and Modified Ashworth Scale for the assessment of spasticity in patients with spinal cord injury. *Spinal Cord.* 1996;34:560-564.
- Hitzig SL, Noreau L, Balioussis C, Routhier F, Kairy D, Craven BC. The development of the spinal cord injury participation and quality of life (PAR-QoL) tool-kit. *Disabil Rehabil.* 2013;35:1408-1414.