CROSS-CULTURAL ADAPTATION OF THE ARABIC VERSION OF THE PATIENT REPORTED IMPACT OF SPASTICITY MEASURE IN ARABIC SPEAKING PEOPLE WITH SPINAL CORD INJURY IN SAUDI ARABIA

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DEDICATION

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ABSTRACT

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CROSS-CULTURAL ADAPTATION OF THE ARABIC VERSION OF THE PATIENT REPORTED IMPACT OF SPASTICITY MEASURE IN

ARABIC SPEAKING PEOPLE WITH SPINAL CORD

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Spasticity is present in 65 to 78% of people with spinal cord injury (SCI). Its impact on quality of life (QoL) can be perceived by patients with SCI and clinicians as either problematic or beneficial. Spasticity management practice can improve greatly using standardized assessments with an appropriate battery of tools, including patient reported measures. The Patient Reported Impact of Spasticity Measure (PRISM) is a tool used to measure the impact of abnormal muscle control or involuntary muscle movement in people with spastic SCI. The PRISM assesses both positive and negative effects of spasticity and provides the overall impact of spasticity on an individual. The purpose of this dissertation was to adapt the PRISM for Arabic-speaking people with SCI living in Saudi Arabia, a country with one of the highest incidences of SCI around the world. This dissertation is composed of three studies to achieve its purpose. The first study aimed to translate and cross-culturally adapt the PRISM into Arabic language (PRISM-Arabic). Thirty-five subjects with SCI, and five expert committee members participated in this cross-cultural adaptation process. The produced PRISM-Arabic was deemed valid in terms of face and content validity

and was ready to be evaluated further. The second study aimed to investigate the reliability and validity of the PRISM-Arabic in patients with SCI in Saudi Arabia. The results showed that the PRISM-Arabic had adequate internal consistency, test-retest reliability and construct validity. However, the Positive Impact subscale demonstrated poor measurement properties, and it should be interpreted cautiously when inferring the positive experience from spasticity on QoL. The third study investigated the PRISM-Arabic's responsiveness to change in patients with SCI reporting spasticity during their in-patient rehabilitation admission period. The results showed that PRISM-Arabic was not sensitive to changes in the subjective impact of spasticity after receiving treatment and lacks the ability to distinguish those patients who did and did not improve. This dissertation concluded that the PRISM-Arabic is an adequate assessment tool measuring the impact of spasticity for Arabic speakers with Spastic SCI. It enhances patient's communication with healthcare providers and promotes their participation in clinical decision making concerning spasticity management.

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CHAPTER I

PROSPECTUS

BACKGROUND

Spinal cord injury (SCI) is a devastating neurological condition worldwide. The annual incidence of traumatic SCI in developed countries is approximately 15 to 40 cases per million people.[1–3] The Kingdom of Saudi Arabia, however, has one of the highest incidences of SCI, with approximately 63 cases per million annually.[4] Consequently, the government of Saudi Arabia has assigned additional health care services for the treatment of SCI in the past few decades. However, health-related research in areas related to SCI is still limited.[5–11]

In individuals with SCI, multiple consequences of the loss of communication between the brain and spinal cord exist. Among these is the neural integrity to modulate spinal reflex circuitry. The consequence of this disrupted modulation is spastic hypertonia with increased reflex excitability and disordered motor output (i.e., spasticity, clonus, spastic gait patterns) that contribute to impaired motor function.[12] Several sources cite spasticity as one of the most difficult health complications after SCI.[12–16]

The spasticity can develop in both upper and lower extremities and trunk depending on the level of injury of the spinal cord.[12] In fact, spasticity in individuals who sustained an incomplete injury was almost always reported as problematic.[17] Its presence can lead to disturbance in the quality of life if there is a high degree of pain, a high disturbance in day-to-day activities, less range of motion, more contractures, or

more hospitalizations. Achieving an acceptable quality of life is considered by many to be the definitive goal of rehabilitation following SCI.[14,17]

Because spasticity is a major issue for patients after SCI, the assessment of its impact is worthy of concentrated and disciplined attention. Most commonly used assessment tools to evaluate spasticity are the Ashworth Scale or Modified Ashworth Scale (MAS), Spasm Frequency Score (SFS), and Reflex Score (RS).[18] Even though these tools may have adequate reliability for the SCI population, they do not cover all dimensions of the spasticity's impact on the whole person.

Lechner et al,[19] looked into the relationship between self- and clinician-rated spasticity in SCI, concluded that a single clinical assessment of spasticity is a poor indication of a patient's general spasticity. They also suggested that clinical measures of muscle tone–related spasticity should be complemented by self-rating that distinguishes muscle tone–related spasticity from spasticity as a complication that affects the individual as a whole.[19] In accordance to that, spasticity-related interventions need to be aimed at what matters most to the patient.[20–22] Understanding patients' experiences to make accurate assessments is an important practice to effectively evaluate treatment interventions and select appropriate management strategies.

The Patient Reported Impact of Spasticity (PRISM) is a new instrument that was developed by Cook et al,[23] specifically for individuals with SCI. The PRISM is a questionnaire that standardizes self-report information relevant to the clinical assessment of the impact of abnormal muscle control or involuntary muscle movement on quality of life. However, its use with patients with SCI is currently

limited to English speaking populations. Therefore, translating and cross-culturally adapting it to the Arabic language would increase its usability in Arabic speaking populations. The translated PRISM will provide informative data by including perspectives of patients with SCI for making decisions related to their spasticity management.

PURPOSES OF THE STUDY

The purposes of this study are to translate and cross-culturally adapt the PRISM into Arabic language and to determine the psychometric properties of reliability, validity, and responsiveness of the resulted Arabic version of PRISM (PRISM-Arabic) in Arabic-speaking adults with SCI.

SPECIFIC AIMS AND HYPOTHESES

This dissertation will be done in three studies. The aim of the first study is to translate and cross-culturally adapt the PRISM into the Arabic language. The translation process will include administration and evaluation of the Arabic-translated version of the PRISM in terms of clarity, meaning, and equivalency to the original PRISM. The resultant Arabic version will be pilot tested by engaging Arabic speakers with SCI to ensure that it is retaining its equivalence in an applied situation. We hypothesize that the final PRISM-Arabic will have to have no changes to the original PRISM's content-specific meanings nor to the conceptual idea of its questions other than the necessary cultural adaptation identified according to Beaton's guidelines for cross-cultural adaptation.[24]

The second study consists of three aims: The first aim is to assess the internal consistency of the PRISM-Arabic on Arabic-speaking people with SCI. The related

hypothesis is that there will be a significantly good correlation (Cronbach's coefficient $\alpha \geq 0.7$) between items in each subscale of the PRISM-Arabic.[25] This cutoff was determined based on the findings from the original article that developed the PRISM.[23] The second aim is to determine the test-retest reliability of the PRISM-Arabic on Arabic-speaking people with SCI. The related hypothesis is that the PRISM-Arabic will show, at least, an excellent reliability with Intraclass Correlation Coefficient ($ICC_{2,1}$) value > 0.80. This cutoff was chosen based on the results of the original version.[23,25] The third aim is to establish the construct validity of the PRISM-Arabic. Construct validity of the PRISM-Arabic will be assessed by correlating its subscales with the Arabic version of the Quality of Life Index – Spinal Cord Injury Version III (AQLI-SCI),[22,26] the Functional Independence Measure – Motor subscale (FIM-Motor)™,[27,28] Spinal Cord Injury Measure III (SCIM-III),[29] and the MAS.[30] Using Spearman rank correlation coefficient (r_s),[25] the related hypotheses are that the AQLI-SCI will have a significant negative correlation ($r_s \leq -0.3$) with the following PRISM-Arabic subscales - social avoidance/anxiety, psychological agitation, need for intervention, and social embarrassment. In addition, both the SCIM-III and the FIM-Motor™ will have significant negative correlations ($r_s \leq -0.3$) with the following PRISM-Arabic subscales – daily activities, need for assistance/positioning, positive impact (reversed scores). Finally, the MAS will significantly correlate positively with the total score of the PRISM-Arabic ($r_s \geq 0.3$).[25] The construct validity of the PRISM-Arabic as a measure of the impact of spasticity will be supported if the proposed hypotheses are confirmed.

The third study aims to establish the responsiveness of the Arabic version of the PRISM to clinical change. It will be studied in two folds:

1) The responsiveness to change will be assessed by correlating the PRISM-Arabic's subscales' change of score with the change of scores of the AQLI-SCI, the FIM-Motor™, the SCIM III, and the MAS. The related hypothesis is that the change of scores of the AQLI-SCI will have negative correlation ($r_s \leq$ -0.3) with the change of scores of the following PRISM-Arabic subscales: social avoidance/anxiety, psychological agitation, need for intervention, and social embarrassment. Also, the change of scores of both the SCIM-III and the FIM-Motor™ will have negative correlations ($r_s \leq$ -0.3) with the change of scores of the following PRISM-Arabic subscales: daily activities, need for assistance/positioning, positive impact (reversed scores). Finally, the change of score of the MAS will correlate positively with the total score of the PRISM-Arabic ($r_s \geq 0.3$).

2) The Effect Size Index (ES) and Minimal Clinically Important Difference (MCID) of the PRISM-Arabic total score will be calculated relative to the participants' assessment of change measured by the Global Rating of Change (GRC) scale.[25,31]

INSTRUMENTATION

PRISM: It is a subjective health-related quality of life measure that assesses the impact of altered motor control with respect to its seven sub-scales, which include social avoidance/anxiety, psychological agitation, daily activities, need for assistance/positioning, need for intervention, and social embarrassment. It accounts for both the negative and positive aspects associated with spasticity. It has 41 items

with a five-point Likert scale. Sub-scale scores are obtained by averaging item scores and multiplying by the number of items. The higher the score, the more negative impact is reported by the respondent.[23] The PRISM demonstrated good reliability in terms of internal consistency (Cronbach's α = 0.74-0.96) and reproducibility (ICC = 0.82-0.91). Further work is still required to establish psychometric properties for its use with the SCI population, especially with respect to validity (construct, discriminative, and convergent).[23]

AQLI-SCI: The QLI-SCI was developed specifically for people with SCI to measure both satisfaction with aspects of quality of life and the importance of these aspects to the person. It consists of 37 items that represent five subscales: total quality of life, health and functioning, social and economic, psychosocial/spiritual, and family subscales. The higher the score in each subscale, the better quality of life is indicated. The Arabic QLI for the generic version showed excellent test-retest reliability (ICC = 0.88), excellent internal consistency (Cronbach's α = 0.93), but no reports of reliability were established for the SCI version.[22,26,32] The construct validity, however, was reported with a good correlation between the QLI-SCI and the Reintegration to Normal Life Index (r_s = -0.65).

FIM-Motor™: It measures the level of a patient's disability and indicates how much assistance is required for the individual to carry out activities of daily living. It contains 13 items: eating, grooming, bathing, upper body dressing, lower body dressing, toileting, bladder management, bowel management, bed to chair transfer, toilet transfer, shower transfer, locomotion (ambulatory or wheelchair level), and stairs. The total FIM-Motor score ranges from 13 to 91 (the higher the score in the

FIM-Motor, the more functionally independent the patient is). It showed excellent test-retest reliability (ICC = 0.91), excellent interrater reliability (ICC = 0.90), excellent internal consistency for non-traumatic and traumatic SCI (Cronbach's alpha for motor-FIM = 0.91 and 0.94), respectively.[33,34] It was found to be valid with excellent correlation with the Walking Index for Spinal Cord Injury (r_s = 0.88-0.92), Berg Balance Scale (r_s = 0.86-0.89), and 50-Foot Walk Test at 3, 6, and 12 months (r_s = 0.66-0.80) at 3, 6, and 12 months.[35]

SCIM-III: The SCIM-III scale was developed specifically for people with SCI (traumatic and non-traumatic, acute and chronic) to evaluate their performance of activities of daily living (ADL) and to make functional assessments of this population. It consists of 19 items that assesses three domains: self-care (feeding, bathing, dressing, grooming), respiration and sphincter management (respiration, bladder management, bowel management, use of toilet), and mobility (tasks in the room and toilet, and tasks indoor and outdoor). The total SCIM-III scores ranges from 0 to 100.[29,36] It showed excellent interrater reliability for the SCIM III total score (ICC = 0.96) and subscale scores (ICC = 0.84-0.96), adequate to excellent internal consistency (Cronbach's alpha = 0.77-0.85). It was, also, shown to be valid with excellent correlation to the FIM scores (r_s = 0.84-0.84).[29,36,37]

The SCIM-III will be included in this study as a measure of function relative to spasticity. As a result, the respiration item of the respiration and sphincter management subscale of this measure will not be considered in this study for the lack of relevancy to the study purpose. The exclusion of the respiration item has been shown to increase the subscale's internal consistency of the SCIM-III in patients with

SCI (Cronbach's α after deleting respiration item have increased = 0.733 from the total respiration and sphincter management subscale α = 0.704), suggesting that these tasks may have a weak relationship with the other items in the respiration/sphincter management subscale. So, for the purpose of this study, the modified SCIM-III total score (excluding the respiration and sphincter management subscale) will range from 0 to 90 (the higher the score the more functionally independent the person is with his/her self-care and general mobility).

MAS: It measures muscle hypertonia in patients with lesions of the central nervous system, in general. It has been used commonly as an easy and fast administration of clinically measuring spasticity. It tests resistance to passive movement about a joint with varying degrees of velocity. Its score ranges from 0 to 4 (0, 1, 1+, 2, 3, 4). Where a score of 0 indicate no resistance throughout the joint movement, while a score of 4 indicate rigidity. The average MAS score from all affected muscles will be used.[30,38] It was found to have adequate test retest reliability for individual muscle groups' testing (ICC = 0.56), adequate interrater reliability (ICC = 0.56). It was found to have excellent construct validity correlating it with the Wartenberg Pendulum test (r_s = -0.69).[30,38,39]

GRC: It is a subjective numerical rating of change scale that asks a person to assess his or her current health status (the impact of spasticity) compared to his or her health status in a previous point of time. The magnitude of the improvement or change is then scored on an 11-point integer scale. It ranges from "a great deal worse (-5)" to "a great deal better (+5)" with zero indicating no change. Participants will be using this scale to rate their change of the impact of spasticity, in general.[40–42]

METHODS

Using a convenience (consecutive) sampling approach, 70 participants with SCI, who report spasticity, and have recently been admitted for rehabilitation as an inpatient in a hospital or a rehabilitation center in Riyadh, Saudi Arabia were recruited for the study. To be eligible for inclusion, participants had to be adults (≥ 18 years of age), and able to read, speak, and understand Arabic. In addition, they have to have sustained an SCI with a duration of injury of more than three months from the day of testing. Anticipated length of stay needs to be at least three to four weeks for inclusion in Studies 2 and 3. Those who are pregnant, or have been diagnosed with psychological- or cognitive-related complications that might interfere with their rehabilitation program or how they will respond to the questionnaire were excluded from the study. Other exclusion criteria include active infection, open wounds, heterotopic ossification/myositis ossificans, or other acute musculoskeletal injuries.

All participants read and signed a written informed consent for participation approved by the Institutional Review Board of Texas Woman's University – Houston Campus, and the corresponding hospital or center where the participant participated.

Study one. Translation and cross-cultural adaptation.

Based on the guidelines given by Beaton et al,[24] an Arabic translation and cultural adaptation of the PRISM will be employed. There are five steps to the translation and cultural adaption. The first step was to forward translate the PRISM from its original language of English into Arabic. In a forward translation, two bilingual translators, whose native language is Arabic and are proficient with English, will translate, independently, the original PRISM from English into Arabic. In the

second step, the two translators, working together, will synthesize their translated versions into a single translation of the PRISM. In this synthesis stage, the two translators reviewed and discussed their translated versions. They resolved discrepancies between the two versions and reached a consensus to produce a new synthesized version of the PRISM.

In the third step, to validate and consolidate the translation, two translators, who are fluent and proficient in both English and Arabic languages, performed a backward translation from the synthesized Arabic version to English. The fourth step included four people (at least one of them a health care professional and another a linguistic professional) proficient in both languages (English and Arabic) to serve as the expert committee for the translation process. Their role was to determine any discrepancies between the two versions that resulted from backward translation, resolve any questions related to the translation process, and reach a conclusion about the suitability of the Arabic version of the PRISM. They combined all the versions that resulted from the previous steps (forward translation, translation synthesis, and backward translation) and formed a pre-final version of the Arabic PRISM.

The fifth step in the process of cross-culturally adapting the PRISM to Arabic speakers is to perform a pilot (pre-testing) by including participants who meet the inclusion and exclusion criteria. Ten participants were asked to individually complete the newly translated version of the PRISM. After that, the principal investigator interviewed them and encouraged them to give their suggestions and thoughts about the pre-final Arabic PRISM. The participants' remarks were discussed between the principal investigator and the expert committee.

Data Analysis: Descriptive statistics were used to examine the distribution of missing or misunderstood scores. Any problematic items will be revised, leading to the final version of the PRISM-Arabic. This study will be Chapter Three of this dissertation.

Study two. Internal consistency, test-retest reliability, and construct validity of the PRISM-Arabic. **Study three.** The responsiveness of the PRISM-Arabic to clinical change.

Sixty participants who met the inclusion and exclusion criteria were recruited for both studies.[43] Their participation in the study was in three sessions:

Session 1: After signing the consent form, the participant completed the demographics sheet, which is expected to take no more than 10 minutes. The principal investigator screened the responses for inclusion and exclusion criteria. Participants meeting the criteria completed the PRISM-Arabic and the AQLI-SCI forms. Completing these forms will take no more than 40 minutes. The FIM-Motor™, the SCIM-III, and the MAS scores were collected from each participant's chart by the treating physical or occupational therapist. For consistency, therapists were asked to score their patients with the FIM-Motor™, SCIM-III, and MAS on the same day of the first session.

Session 2 (two days later): All participants completed the PRISM-Arabic for the second time, and GRC taking no more than 20 minutes. GRC was used to affirm that there were no changes on the impact of spasticity from Session 1. If a change was reported, the participant was removed from the study.

Session 3 (three weeks after Session 2): Participants completed the PRISM-Arabic (for the third time), the AQLI-SCI (for the second time) forms and the GRC scale. Completing these forms should take no more than 30 minutes. The FIM-Motor™, the SCIM-III, and the MAS final scores were collected from each participant's chart. Again, to have a consistent collection of data, therapists will be asked to score their patients with the FIM-Motor™, the SCIM-III, and the MAS on the same day of the third session.

Data Analyses: For Study Two, the internal consistency of the PRISM-Arabic will be analyzed by correlating its' items to their corresponding subscale using Cronbach alpha (α). In addition, the test-retest reliability of the Arabic PRISM was assessed by calculating the ICC from a two-way random effects model (participant X PRISM) analysis of variance (ANOVA). The strength of the reliability was interpreted based on the following criteria: > 0.75 good reliability, 0.50 to 0.74 moderate reliability, < 0.49 poor reliability.[25] Finally, the analysis of the construct validity will be measured by correlating the PRISM-Arabic's subscales with the AQLI-SCI, the FIM-Motor™, the SCIM-III, and the MAS at baseline using the Spearman rank correlation coefficient (r_s). All data analyses will be deemed significant at alpha (α) < 0.5.

For Study Three, the sensitivity of the PRISM-Arabic to change was determined by correlating the PRISM-Arabic's subscales change of score (third attempt – baseline) with the change of scores of the AQLI-SCI, the FIM-Motor™, the SCIM-III, and the MAS. After that, the ES was calculated by dividing the mean

change scores of the PRISM-Arabic by the standard deviation of the baseline scores. Again, all data analyses will be considered significant at alpha (α) < 0.5.

The MCID was calculated in relation to participants' responses to the GRC.[25,41] A cutoff of 2 (a little bit better) was used to identify subjects who had achieved minimal clinically important change from those who did not. Change scores on the PRISM-Arabic were entered into a logistic model to generate Receiver Operating Characteristic (ROC) curve. The area under the curve was calculated as an indication of the overall ability of the test measure (PRISM-Arabic change scores) to identify when a clinically important change had taken place.

Following a literature review in Chapter Two of the dissertation, studies one, two and three will comprise Chapters Three, Four and Five, respectively. A summarizing discussion of the findings and conclusions will be presented in Chapter Six.

CHAPTER II

REVIEW OF THE LITERATURE

EPIDEMIOLOGY

SCI is a devastating neurological condition that results in disability. It is described, mainly, by the loss of communication between the brain and parts of the body in an individual. It results in varying degrees of loss of sensory, motor, and autonomic function, all of which can impact an individual's medical and emotional status.[1–5]

People who sustain SCI may develop many secondary medical complications, such as spasticity, urinary tract infections, pressure sores, osteoporosis, formation of heterotopic ossification of soft tissues, autonomic dysreflexia, and cardiopulmonary dysfunction.[6–9] In addition to the medical complications, psychological consequences evolve, causing a significant negative impact on the individual's perception of himself or herself. These consequences result from the frustration and hard work associated with the daily activities for survival, stress on family relationships and traditional roles, the devaluation of the disabled person by society, and the loss of satisfaction from vocational and leisure time activities which may no longer be possible after SCI.[10–14]

Damage to the spinal cord may be traumatic or non-traumatic. Traumatic SCI has been described by the World Health Organization (WHO)[3] as any injury to the spinal cord that is caused by damage or trauma resulting from an external force. The causes of traumatic SCI include falls, road traffic accidents, occupational and sports

injuries, and violence. Non-traumatic SCI, on the other hand, usually involves an underlying pathology, such as infectious disease, tumor, musculoskeletal disease such as osteoarthritis, and congenital problems such as spina bifida.[15]

According to the WHO,[3] every year, between 250,000 and 500,000 people around the world sustain a SCI. The annual incidence of traumatic SCI in developed countries is approximately 15 to 40 cases per million population.[3,15–18] In the United States, for instance, 54 people out of every million Americans experience such an injury. Between 245,000 and 353,000 Americans were estimated to be living with a SCI in 2017, and approximately 17,000 people are added each year.[3]

SPINAL CORD INJURY IN SAUDI ARABIA

Incidence, Prevalence and Main Causes of SCI in Saudi Arabia

From an epidemiological perspective, there are no accurate figures available for the prevalence and incidence of SCI in Saudi Arabia. All published reports included both traumatic and non-traumatic SCIs, and were hospital-based, retrospective studies with small sample sizes.[19,20] The best representative data came from graduation thesis and dissertation projects. The first project was submitted by AboAbat[21] to the Department of Orthopedic Mechanics University of Salford, Salford, United Kingdom in 1999. He conducted a population-based survey in 1994. The survey included 78,130 individuals. At that time, the Saudi population was 12,779,930. His study included both traumatic and non-traumatic SCI. AboAbat reported prevalence and incidence of SCI to be 627 per million and 62.37 per million, respectively, during the time the study took place.[21] The second project was submitted by Alshammari[22] to University of Birmingham, Birmingham, United Kingdom. The

study was conducted in Riyadh city (capital of Saudi Arabia) and included only subjects who were involved in motor vehicle accidents (occupants or pedestrians). Alshammari reported prevalence of 960 per million and incidence of 38 per million during 2000-2010. The Saudi population was estimated at 25,634,675 in 2010.[22] The variation in prevalence and incidence in the two projects can be attributed to definition of SCI, inclusion criteria, and study location.[23]

Traumatic SCIs in Saudi Arabia were reported, rather extensively in the literature, compared with non-traumatic SCI, due to the collaborative research between the Saudi Ministry of Health and the Ministry of Interior. The highest incidence of traumatic SCI in Saudi Arabia was reported due to road traffic accidents (RTAs).[19,24,25] The high rate of RTAs in Saudi Arabia is not quite surprising. According to General Directorate of Traffic of Saudi Arabia, during 2015, the number of incidents that took place in Riyadh City alone was 518,795 traffic accidents.[26] A study in Saudi Arabia examined the causes and effects of RTAs in Saudi Arabia between 1971 and 1997. The study identified that 79.2% of traumatic SCIs were due to RTA and that 564,762 people died or were injured due to RTAs, a number equivalent to 3.5% of the total population of Saudi Arabia at that time.[25] Another study conducted by Al-Jadid in 2013[24] examined the prevalence and causes of traumatic SCI in the national Saudi referral trauma center. With 466 patients who have been admitted between the years 1982 and 2010, the researcher reported that 80.1% were due to RTAs. These reports demonstrate that Saudi Arabia has higher incidence rate of SCI compared with the United States (54 cases per million) and other developed countries.

Reported Characteristics of SCI in Saudi Arabia

With the limited sources of information about SCI in Saudi Arabia, describing the characteristics of this population is difficult. There are only few articles found in the literature that studied SCI characteristics within local rehabilitation centers. Al-Jadid[24] in 2013 described the sample of 466 patients with traumatic SCI that aimed to determine the causes, age and gender differences, hospital length of stay, and prevalence of traumatic SCI in a Saudi referral trauma center at Prince Sultan Military Medical City. Al-Jadid's results showed that the mean age of the patients was 29.7 ± 0.73 years. Out of 466 patients with traumatic SCI, 398 were males (85.4%) and 68 were females (14.6%). The lower incidence of females compared with males was probably related to the social habit in Saudi Arabia where females were not allowed to drive cars at that time. The higher frequency of traumatic SCI was found in the 16-30 age group. Also, 80.1% of the studied sample sustained their injuries as a result from RTAs. Cervical cord was the most common site of injury accounting for 34% of cases in the male population, while 45.6% of cases in the female population had sustained upper thoracic cord injuries.[24]

A more recent study done by Alshehri et al[27] in 2016 aimed to estimate the characteristics and causes of traumatic SCI at King Fahad Medical City (KFMC) in Riyadh city, which is one of the largest rehabilitation hospitals in the country. Alshehri et al studied 216 patients with SCI who were admitted due to traumatic etiology between 2012 and 2015. During this period, the reported age upon injury was averaged at 28.94 years old, and most of them (54.6%) were between 14-25 years of age. Males were the majority comprising of 86.5% of the studied sample, and 71.7%

of them had a high school level of education or less. Also, 61.6 % of the patients experienced paraplegia (complete or incomplete), and 38.4% experienced tetraplegia. More than half of the patients (53.7%) had complete traumatic SCI (37% paraplegia and 16.7% tetraplegia). On the other hand, Alshehri et al reported that 24.5% of the patients who had incomplete SCI were paraplegic, and 21.7% had incomplete tetraplegia.[27]

SPASTICITY

Spasticity is a common complication after SCI. About 65–78% of the population with chronic SCI (more than one year post-injury) have symptoms of spasticity.[28,29] It is a condition related to neuromuscular dysfunction that is characterized by tight or stiff muscles and can interfere with normal movement and functions. Spasticity is usually associated with lesions involving the pyramidal, extrapyramidal (the cortico-reticular pathways at the level of the cortex or internal capsule, and the reticulospinal and vestibulospinal tracts at the level of the spinal cord), or both. It is a complex topic that is still poorly understood.[30,31] The most quoted definition of spasticity is the one described by Lance[32] in 1980 as: "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 motoneuron syndrome".[32(p1305)] His definition has been found to be too restrictive to some of the pathophysiologic features reported since his publication. Pandyan et al[33] revised Lance's definition to include the description of spasticity as "disordered sensori-motor control, resulting

from an upper motor neuron lesion, presenting as intermittent or sustained involuntary activation of muscles".[33(p5)]

The clinical presentation of spasticity, including hypertonicity, develops because of an imbalance that occurs in the excitatory and inhibitory inputs to α motor neurons which is caused by damage to the central nervous system (CNS) including the spinal cord. This damage then results in an imbalance between messages from the nervous system, because of alpha-gamma coactivation, to the muscles' extrafusal and intrafusal fibers. The resulted alterations cause an increased excitability referred by individuals with SCI as tightness, stiffness, or pull of muscles.[3,34,35]

Immediately following SCI, the spinal cord becomes areflexic causing a decrease in tendon reflexes, muscle paralysis, and flaccid muscle tone below the level of injury. After that, spasticity starts to develop gradually over several weeks and months, where the tendon reflex, the flexor withdrawal reflex, and the Babinski sign start to appear.[31] The threshold of these reflexes decreases causing the muscles to respond greatly by briefly evoked stimulations to cutaneous and proprioceptive receptors.[36,37]

IMPACT OF SPASTICITY

Negative Impact

In the literature, studies showed that problems that arise because of spasticity are numerous and are generally considered by patients and clinicians to have a negative impact.[28,29,38–45] In fact, spasticity in individuals who sustained an incomplete injury was almost always reported as problematic.[28] Limited joint movement, contractures, abnormal postures that can produce pain and pressure ulcers were all

associated with spasticity. It also interferes with functional capacity, limits activities of daily living (ADL) and gait, causes aesthetic or hygiene issues, and disturbs sleep.[28,46] Moreover, it complicates the role of the caretaker, hinders rehabilitation efforts, and adds to the cost of medications and attendant care.[29,38,39,43–45,47] Dijkers et al[9] investigated the factors complicating treatment sessions in SCI rehabilitation in a study published in 2013. They studied 1376 patients with SCI who received a total of 151,172 treatment sessions from 483 therapists. Therapists used a modified Pittsburg Rehabilitation Participation Scale (PRPS) to rate patient's level of participation during treatment sessions. The six-point scale ranges from none "refused entire session", to excellent "participated throughout the whole session." After that, therapists selected from a list, factors (if any) that, in their opinion, had affected the objective or content of the session. The results showed that pain, fatigue, and spasticity were commonly reported factors among other medical, behavioral, and logistical factors in affecting more that 30% of sessions. The frequency and occurrence of these factors have significantly affected the goals and content of the rehabilitation treatments causing an increased hospital length of stay. Spasticity, however, was found to comprise 17% of the sessions being affected.[9]

In 1995, Levi et al[43] worked on a national project in Sweden called the Stockholm SCI Study (SSCIS). They studied a group of people with SCI of traumatic etiology (n = 353) who were living in the Stockholm region. Levi et al examined the prevalence of spasticity among other medical complications, and whether spasticity constituted a significant problem by restricting ADL, causing pain, or both. About 68% of those recruited had a spastic paralysis, out of whom, 41.3% reported their

spasticity to be problematic. In 1999, Sköld et al[28] further studied the report published from the SSCIS. Among patients reporting spasticity, they found that spasticity could be elicited in up to 60% of the cases. Sköld et al also studied a possible association between elicitable spasticity and impaired Range of Motion (ROM). Calculations were performed both for patients reporting spasticity and for patients reporting no spasticity. Significant correlation values were found between elicitable spasticity and impaired ROM in hip abduction and extension (x^2 = 5.06-12.37), right knee flexion and extension (x^2 = 6.02-6.77), elbow flexion and extension (x^2 = 6.10-27.73).[28]

In 2017, Holtz et al[46] evaluated the prevalence and effect of spasticity after traumatic SCI in 465 subjects. The tools they used were Penn Spasm Frequency Scale, the SCI Health Questionnaire, plus the anti-spasticity medication use collected from patients' charts. Holtz et al found that the prevalence of spasticity at discharge to the community was 65%, and the prevalence of problematic spasticity (defined as discharged on anti-spasticity medication) was 35%. In community follow-up, the prevalence of patients reporting any problematic spasticity was 35% at one year, 41% at two years, and 31% at five years post-injury. Interference with function caused by spasticity was reported by 27% of patients at one year, 25% at two years, and 20% at five years postinjury.[46]

Van Cooten et al[48] assessed the functional hindrance due to spasticity in 203 individuals with recent SCI during inpatient rehabilitation, three months, and one year after discharge. Van Cooten et al's study focused on the influence of spasticity on activities using a functional hindrance scale that assessed the influence of spasticity on five domains: 1) sleeping; (2) transferring; (3) washing and clothing; (4)

wheelchair propulsion; (5) others. The results showed that the percentage of individuals that indicated functional hindrance due to spasticity ranged from 54 to 62% over time and did not change significantly over time. Also, the percentage of individuals who experienced hindrance due to spasticity during specific activities ranged from 4-27%. Moreover, the odds for experiencing functional hindrance due to spasticity were significantly higher for individuals with tetraplegia (OR = 2.17, $p < 0.01$), more severe spasticity (OR = 5.51, $p < 0.01$) and for those using anti-spasticity medication (OR = 4.18, $p < 0.01$).[48]

Many researchers have a reported spasticity's significant interference with a person's QoL and self-satisfaction. Spasticity was found to be associated with lower scores of all physical, emotional, and QoL domains measured by the 36-item Short Form Survey (SF-36), 12-item Short Form Survey (SF-12) and the Visual Analogue Scale (VAS).[2,42,49,50]

Westerkam et al[12] did a study on the association of spasticity and life satisfaction after SCI.[12] Their study was a cross-sectional survey of existing data (n = 1,549), where the outcome measures included: home life satisfaction, global satisfaction, vocational satisfaction, overall QoL, and three subscales from the PRISM. Westerkam et al found that spasticity had a negative association with QoL after SCI [*Beta* = (-0.56), (-0.93), and (-0.63), $p < 0.05$].[12]

Mahoney et al[10] studied the everyday life experience of persons who have spasticity associated with SCI in 2007. They used an applied ethnographic study design, which is a form of qualitative research used to understand the experience of living with a health condition. They did in-depth open-ended interviews with 24

people with SCI who experience spasticity to identify the domains that were impacted. Domain analysis revealed seven domains: physical, activity, emotional, economic, interpersonal, management, and cognitive domains. These areas were expressed and described as being impacted by spasticity in a way that is not consistent with the clinical definitions given by Lance[32(p1305)] and Pandyan.[33(p5)] As a result, one may confidently conclude that these clinical definitions have failed to address the impact of spasticity on the life of a person.[10]

Positive Impact

Although spasticity can have a negative impact on people with SCI, there are suggestions that symptoms of spasticity may increase stability in sitting and standing, facilitate the performance of some ADL and transfers, increase muscle bulk and strength of spastic muscles, and increase venous return (possibly avoiding edema and diminishing the incidence of deep vein thrombosis).[51–56] Moreover, light to moderate spasticity may have a positive effect on function and may enable patients with lower limb paresis to attain a standing position and have more ease of movement, for example, transferring from bed to chair.[57]

This potential for a beneficial effect of spasticity on QoL has a large impact upon decisions regarding its management. Additionally, no criterion standard for assessing the severity of spasticity exists. Spasticity must be clearly defined before it can be holistically measured. Assessing spasticity based on documenting its clinical presentations and severity has preoccupied investigators in most published articles, while measuring its impact on persons' daily lives may need and deserve more

attention. The way spasticity alters the life of a person with SCI should provide the basis for defining spasticity and improving its measurement.

SPASTICITY MANAGEMENT

The decision to treat spasticity should be goal-driven. Patients, their families, and the multi-disciplinary team may set these goals during the rehabilitation process. Spasticity management can be directed to deal with "passive problems" such as maintaining ROM, reducing pain, and enabling ease of care, or to solve "functional problems" such as improving gait and other ADL. However, that treatment decision should consider the positive and negative effects of spasticity.[57] The following questions can help direct the management: Does the patient need treatment? What are the aims of treatment? Do the patient and caregivers have the time required for treatment? Will treatment disrupt the life of the patient and caregivers?[58]

A wide range of treatment options from noninvasive to invasive procedures are currently used in spasticity management. Common procedures used for the management of spasticity are summarized in the following sections.

Physical modalities.

Physical techniques are considered the first line of defense in the management of spasticity. Usually the goal of physical techniques is to reduce spasticity to allow better control of movement or improve functional tasks.[57] Common techniques include: positioning, stretching, ROM, weight-bearing activities, strengthening, electrical stimulation, cold or heat application and application of splints and orthoses.[57]

Pharmacology.

Oral medications are commonly used to manage generalized spasticity. Anti-spastic medications can be divided into the following three groups:[57]

GABAergic medications work on interneurons that enhance the effect of gamma-aminobutyric acid (GABA) neurotransmitter. Common examples of this type of medication are baclofen and diazepam.[59]

Alpha-2-adrenergic medications interact with alpha-2 receptors in the CNS. Common examples are tizanidine and clonidine.[59]

Peripheral acting medications work at the neuromuscular junction. One of the common peripheral acting medications is dantrolene.[59]

All these medications can be used alone or in combination to achieve the desired effect. Side effects vary by medications and individuals. Common side effects for an anti-spasticity medication include dizziness, weakness, dry mouth, nausea, fatigue, diarrhea, hepatotoxicity, hypotension, ataxia, hallucinations, bradycardia, and constipation.[57,58,60] In addition, sudden discontinuation of relaxants might lead to withdrawal seizures and hallucinations.[60]

Injections.

Injections are used to manage focal spasticity. There are two types of injections that are commonly used to manage spasticity:[59]

Botulinum toxin, commonly referred to as Botox® (one of its trade names, and the one approved by the Saudi Food and Drug Authority), is used to inhibit acetylcholine release at the neuromuscular junction. The effect appears 24 to 72 hours

post injection, peaking at two to six weeks. The effect lasts between two to six months depending on the injected muscle(s) and administered dose.[57,58,60,61]

Ethanol or phenol injection is a procedure that is carried out percutaneously for peripheral nerve suppression to decrease muscle activation. However, this procedure causes irreversible damage to the nerve through protein coagulation. Common side effects of these injections are dysesthesia, pain, peripheral edema, skin sloughing, and wound infection.[57,58,61]

Surgeries.

Surgeries are used when oral medications and injections do not yield the required reduction in spasticity. There are three common surgical procedures used:

Surgeries performed on muscles or *tendons* to improve function, correct a deformity, or improve self-image. Common orthopedic procedures are tendon lengthening, release, and transfer.[62]

Intrathecal baclofen, the procedure of this type of surgery aims to deliver baclofen to the intrathecal space surrounding the spinal cord through a catheter attached to a programmable intrathecal pump implanted in the anterior abdominal wall. After surgery, the baclofen dose is adjusted gradually until the desired effect is reached. Pump refills can be done through outpatient visits. One of the advantages of the intrathecal baclofen is that much smaller doses of baclofen are used compared with its administration orally, leading to less side effects. Common problems are skin infection issues reported by patients, failure of the pump and displacement of the catheter. These complications may lead to under-dosage and withdrawal syndrome.[57,58,61]

Selective dorsal rhizotomy (SDR), is a procedure that interrupts motor nerve signal transduction to reduce spasms and pain. The dorsal nerve roots are cut to disrupt the reflex arc. This surgery is rarely used with adults. The biggest disadvantage with this type of surgery, like the orthopedic surgeries, is that the effect is irreversible.[57,58,60]

Electrical stimulation.

Spinal cord stimulation to manage spasticity was found to be most effective in patients with incomplete SCI. However, most studies report that its therapeutic effect declines with time.[63–67] Neuromodulation with an implanted epidural electrode and stimulator is one of the techniques of spinal stimulation. With epidural stimulation, the aim of stimulating the dorsal columns with frequencies that induce paresthesia through the neuromodulatory effects proposed by the gate theory.[64,68] This technique was initially used to alleviate intractable pain, but various applications were discovered other than pain control, including spasticity management. Although studies showed significant reduction in the severity of the spasticity in both the extremities and trunk, and there was even improvement in bladder and bowel function in a minority of patients,[64,67,68] the use of epidural stimulation for the treatment of spasticity has gradually declined. Midha el al[63] showed that epidural stimulation of the spinal cord lacks long-term efficacy for relieving spasticity and was not cost-effective.

The concept of *neuromuscular electrical stimulation* (functional electrical stimulation [FES]) is to apply surface electrical stimulation of the spastic muscle and/or their antagonists while the individual with spasticity is undergoing a functional

activity. The theory behind it is that stimulating the antagonist muscle was thought to inhibit the spastic muscle through the reciprocal inhibition mechanism.[69] Also, when used with the spastic muscle, the repeated electrical stimulation evoked contractions lead to muscle fatigue. Moreover, the excitation of the cutaneous afferents decreases the excitability of the propriospinal interneurons and motoneurons through the autogenic inhibition mechanism.[60]

A few studies found a decrease in spasticity after treatment with FES, effects were not longlasting,[69,70] and others found it to be insignificant.[71–73] In 2013, Ralston and colleagues[71] studied the effect of FES while cycling on lower limb spasticity measured by the Ashworth Scale (AS) and the PRISM. They found no clear effects on spasticity.[71]

Magnetic stimulation.

Transcranial magnetic stimulation is a neurostimulation and neuromodulation technique, based on the principle of electromagnetic induction of an electric field in discrete brain regions.[66] It is a noninvasive application that induces changes in cortical excitability and modulation of descending inputs, including inhibition.[74] Studies showed that spasticity in the lower extremities in incomplete SCI were significantly reduced according to modified Ashworth scale (MAS), visual analogue scale (VAS) for spasticity, spinal cord assessment tool for spasticity (SCAT), modified Penn spasm frequency scale (MPSFS), spinal cord injury spasticity evaluation tool (SCI-SET) by using a high frequency repetitive transcranial magnetic stimulation.[66] However, well-designed trials with larger sample sizes are still needed to confirm its clinical implications.[66]

Transthoracic magnetic stimulation is another form of magnetic stimulation that is applied to the thoracic spinal cord. Although it seems to have a promising effect on spasticity, it has only been studied on patients with multiple sclerosis and was found to have significant results with spasticity reduction that lasted for 24 hours.[75]

In general, no one treatment option will successfully manage spasticity in all individuals; the most conservative tactics are utilized first, with a progression from physical rehabilitation modalities, pharmacologic interventions, injection techniques, intrathecal baclofen, and lastly, surgery. Moreover, local treatments are used primarily in individuals with spasticity predominating in only certain muscle groups, such as in individuals with stroke or traumatic brain injury. In the case of SCI, the distribution of spasticity tends to be more diffuse, making regional or systemic treatments preferable.[76]

After reviewing the wide range of possibilities for treating spasticity, one can acknowledge the differences between them in terms of how invasive they can become, the applicability of utilizing one option over another, the time demands one may require, and how the ensuing plan of care may be altered. Clinicians must assess spasticity in order to make decisions whether or not to treat the spasticity, and if so, to carefully select the best treatment option that can be ultimately useful to enhance the QoL for those people with SCI. Furthermore, involving patients is imperative in the assessment and decision-making process.

ASSESSMENT OF SCI

There is an increasing demand among researchers for reliable, valid, and sensitive outcome measures that are specific to SCI. Researchers and clinicians have commonly believed that the default outcome measure used when dealing with SCI is the American Spinal Injury Association (ASIA) Impairment Scale (AIS),[1,6] which was originally designed as a clinician-administered scale to be used to classify the severity (completeness) of the injury in individuals with SCI. It identifies sensory and motor levels indicative of the highest spinal level demonstrating "unimpaired" function. However, the AIS does not assess functional ability, nor does it measure the QoL in an individual with SCI. While the goal of SCI care and clinical research is to improve the overall functional capacity of persons living with SCI, and because neurologic recovery and functional recovery do not always parallel each other, several functional measures and QoL assessment tools were studied in depth. The Modified Barthel Index, the Functional Independence Measure™ (FIM™), the Quadriplegia Index of Function (QIF) and the Spinal Cord Independence Measure (SCIM) were mentioned extensively in the literature. However, the FIM™ and SCIM were found to be more reliable and valid on the overall functional ability of a person with SCI compared with the others.[77–80] Also, worth mentioning are the Walking Index for Spinal Cord Injury (WISCI)[77] and the Wheelchair Skills Test (WST)[81] functional measures that are specific mobility functional measures. Yet, these specific functional scales will not be considered in this literature review because of their limited assessment of certain functions rather than holistic functional ability.

Functional Assessment Tools

Functional Independence Measure – Motor subscale (FIM-Motor™). The FIM measures the level of a patient's disability and indicates how much assistance is required for the individual to carry out ADL. It contains 13 items: eating, grooming, bathing, upper body dressing, lower body dressing, toileting, bladder management, bowel management, bed to chair transfer, toilet transfer, shower transfer, locomotion (ambulatory or wheelchair level), and stairs. The total FIM-Motor score ranges from 13 to 91 (the higher the score in the FIM-Motor, the more functionally independent). It showed excellent test-retest reliability (ICC = 0.91), excellent interrater reliability (ICC = 0.90), excellent internal consistency for non-traumatic and traumatic SCI (Cronbach's α for FIM-Motor = 0.91 and 0.94), respectively.[82,83] It was found to be valid with excellent correlation with the WISCI-II (r_s = 0.88-0.92), Berg Balance Scale (r_s = 0.86-0.89), and 50-Foot Walk Test at 3, 6, and 12 months (r_s = 0.66-0.80).[77]

Spinal Cord Independence Measure-III (SCIM-III). This scale was developed specifically for people with SCI (traumatic and non-traumatic, acute and chronic) to evaluate their performance of ADL and to make functional assessments of this population. It consists of 19 items that assesses three domains: self-care (feeding, bathing, dressing, grooming), respiration and sphincter management (respiration, bladder management, bowel management, use of toilet), and mobility (tasks in the room and toilet, and tasks indoor and outdoor). The total SCIM-III scores range from 0 to 100 (the higher the score in the SCIM-III, the more functionally independent).[78,79] It showed excellent interrater reliability for the SCIM-III total score (ICC = 0.96) and

subscale scores (ICC = 0.84-0.96), adequate to excellent internal consistency (Cronbach's α = 0.77-0.85). The SCIM-III was also shown to be valid with excellent correlation with the FIM total scores (r_s = 0.84), and was found to be responsive to functional changes (7.5 points, p = 0.01).[78–80]

Quality of Life Assessment Tools

Attaining an acceptable QoL is considered by many to be the ultimate goal of rehabilitation following SCI.[12,49,84–91] Additionally, measuring it is thought to be an essential compliment to measure the quality of care. In 1990, Ferrans and Powers[92] defined QoL as "a person's sense of well-being that stems from satisfaction or dis-satisfaction with the areas of life that are important to him/her".[93(p29)] Several QoL instruments have been discussed in the literature, including the Quality of Well-Being scale (QWB), the Short Form -36 and -12, the Quality of Life Index (QLI) and the World Health Organization Quality of Life –BREF scale (WHOQOL-BREF). This review will briefly discuss these scales in order to understand their statistical relationships with each other and how they can relate to understanding the impact of spasticity on the QoL of an individual with SCI.

Quality of Well-Being scale. The QWB questionnaire is a preference-weighted measure of health status and overall well-being of a person. It consists of four domains (mobility, physical activities, social activities, and symptom/problem complexes). It consists of 71 items ranging from 0.0 (indicating death) to 1.0 (indicating full function).

In a study done on veterans with chronic SCI in an in-patient setting and out in the community, the QWB showed adequate concurrent validity when correlated with

the SF-36 Physical Summary subscale score (r = 0.42), but was found to have poor validity when correlated with all other SF-36 domains (r = 0.04-0.29).[94]

Short Form -36. The SF-36 is a generic patient-reported outcome measure that quantifies health status and measures health-related QoL. It consists of eight domains (physical functioning, role limitation due to physical problems, general health perceptions, vitality, social functioning, role limitation due to emotional problems, general mental health, and health transition). Items within each domain are totaled to provide a score for their respected domain. Each domain can be used independently. The scoring ranges from 0 (indicating negative health) to 100 (indicating positive health).[95]

All domains of the SF-36 showed adequate to excellent test-retest reliability in patients with chronic SCI (intra-rater ICC = 0.71-0.99, inter-rater ICC = 0.52-0.98),[96] adequate to excellent internal consistency across all domains (Cronbach's α = 0.76-0.90).[97] Construct validity of the SF-36 was found to be poor to adequate when compared with the QWB questionnaire (r = 0.04-0.42).[94]

Quality of Life Index (QLI) – SCI version. The generic Ferrans and Powers[92] QLI was developed to measure QoL of healthy individuals. Specific versions of the index were developed for particular diseases, including SCI. It consists of two parts: satisfaction with different domains of life and the importance of each domain. Each of the two parts contains 37 items, giving a total of 74 items. The items cover a broad range of life aspects, including physical health and functioning, stress, leisure activities, future retirement, friends and social support, socioeconomic aspects, satisfaction with the persons' nation, peace of mind, personal faith, life goals, self-

acceptance, general happiness, general satisfaction, control over life, marriage, and family.[98]

The language of the SCI version of the instrument was well received by patients with SCI, and the satisfaction scores agreed with the overall score, (r = 0.98).[99] However, the correlation of the importance scores was low (r = 0.47).[100] As expected, QLI scores correlated to both community integration (r = -0.65) and self-esteem (r = 0.61) but not to body functions and structure or the level of activity. Moreover, the instrument's reliability was not examined.[100]

The World Health Organization Quality of Life -BREF scale. The WHOQOL-BREF is the short version of the WHOQOL-100 that was developed to assess the quality of life within the context of an individual's culture, value systems, personal goals, standards, and concerns. It is a self-report questionnaire that contains 26 items and addresses four domains (physical health, psychological health, social relationships, and environment. Items are rated on a 5-point Likert scale (low score of 1 to high score of 5). A score for each domain will be calculated from their respected items. Higher scores indicate high quality of life. This tool has been shown to be successful across many cultures, including Arabic speakers.[101]

Although the WHOQOL-BREF scale is not specific to SCI, it was shown that all four of its domains had excellent internal consistency in patients with chronic SCI (Cronbach α = 0.79-0.87). Each domain of the WHOQOL-BREF had adequate to excellent validity when correlated with the Global Rating of Change (GRC) scale (r = 0.54-0.73), and the eight domains of the SF-36 (r = 0.43-0.78).[96]

SPASTICITY-SPECIFIC ASSESSMENT

Clinical Assessment Tools

Spasticity does not always need treatment, particularly if there is no realistic proposition of functional gain.[61] However, assessing it is needed and should be documented. In most clinical practices, the decision to treat spasticity largely depends on the frequency, severity, and impact of the spasticity on a person's daily life.[102] Consequently, numerous clinical outcome measures have been used to assess SCI-related spasticity.

Ashworth and Modified Ashworth scales. The most clinically used tools to assess spasticity are the Ashworth Scale (AS) and the Modified Ashworth Scale (MAS).[4] Both are simple, require no tools to administer and are used routinely. AS is a five-point ordinal scale to describe muscle tone ranging from 0 ("no increases in tone") to 4 ("limb rigid in flexion or extension").[103] In 1987, Bohannon and Smith[104] added an extra category (1+) to make the scale more sensitive and accommodate patients with minimal spasticity. They also slightly modified the definitions.[104] These measures have since been adopted for assessing spasticity in a variety of conditions including SCI, although one should recognize the existence of the differences in the characteristics of spasticity with different CNS pathologies. These tools only address the velocity dependent aspect of spasticity across a single joint. The scale determines the amount of resistance felt during the passive displacement of a limb, but it does not account accurately for the dependence of the resistance to the velocity of the stretch, which can be highly variable from examiner to examiner.[105]

Tederko et al[106] found that MAS had a poor interrater reliability for individual muscle groups (ICC = 0.56) in patients with chronic cervical SCI. He suggested that the MAS might be a more appropriate measure of global muscle tone than measurement of tone in individual muscle groups.[106]

Haas et al[107] investigated the interrater reliability of AS and MAS in 30 patients with chronic SCI. He reported poor to adequate reliability depending on the muscle group and limbs (κ = 0.21-0.61). For example, reliability was worst for plantar flexors, followed by hip extensors and flexors and best for hip adductors.[107] However, there were no logical explanation for these inconsistent results.

Spinal Cord Assessment Tool for Spastic Reflexes (SCATS). SCATS was developed to quantify spasms and spastic hypertonia in patients with SCI. It is easy to administer and requires no equipment. The SCATS has three components: clonus, flexor spasms, and extensor spasms. Each component is rated on a four-point ordinal scale ranging from 0 to 3. Benz et al[108] reported excellent correlation between SCATS extensor spasms and AS for hip and knee flexors (r = 0.98 and r = 0.88, respectively) and moderate correlation with AS for ankle plantar flexors (r = 0.61). Only the SCATS clonus score correlated significantly with Penn Spasm Frequency Scale (PSFS) (r = 0.59), which is a self-report measure that assesses a patient's perception of spasticity frequency and severity.[108] They also noted that the SCATS provided additional information in comparison to the AS and MAS in assessing multi-joint spasticity, whereas the AS and MAS are limited to spasticity assessment over a single joint.[108]

Tardieu scale. Inspired by Lance's[32] definition of spasticity being a velocity-dependent phenomena resulted from UMNLs,[109] Tardieu scale was developed to assess the velocity component of spasticity taking into account the resistance to passive movement of the tested muscle group at both, slow and fast speed velocity.[110] It was modified by Boyd et al[111] in 1999 to include standardized joint positions and velocities. The scale is administered by applying passive stretch to a muscle group at two velocities. The first stretch is as slow as possible (equivalent to passive range of motion) and is used to determine angle of muscle reaction at slow velocity. The second stretch is to move the segment as fast as possible and is used to determine both the angle of muscle reaction and the quality of muscle reaction at the fast velocity. The angle at which the muscle reaction occurs is typically measured with a goniometer, and quality of muscle reaction is measured on a 6-point scale (where 0 indicates "no resistance through the course of the passive movement" and 5 indicates that "the joint is immobile".[111]

When compared with the AS and the MAS, Tardieu scale was found to correctly identify the presence of the spasticity better. Also, the Tardieu scale can differentiate spasticity from contractures, whereas the MAS was confounded by contractures.[112,113] In 2017, Akpinar et al[114] studied the reliability of the MAS and the Modified Tardieu Scale (MTS) on 65 adult patients with SCI. Muscle groups tested were hip adductors, hip extensors, knee extensors, knee flexors, and plantar flexors. The test-retest reliability of the MTS scores were adequate ($\boldsymbol{\kappa}$ = 0.69-0.92). Also, the inter-rater reliability of the MTS was excellent (*ICC* = 0.87-0.97) for all muscle

groups tested. They concluded that MTS could be utilized as a complementary tool for treatment decisions in patients with SCI.[114]

Electrophysiological Assessment

Electrophysiological measures provide quantitative, objective data that can be analyzed compared with qualitative clinical measures.[115] There is a potential in using these measures to assess SCI, predict functional outcomes, and inform clinicians about the planning and results of therapeutic interventions.[116] Despite the benefits of these measures, however, they have yet to be fully standardized and validated for routine clinic use, and there is a need for further research and detailed guidelines.

Electrophysiological measurements alone do not play any significant role in evaluating spasticity. Nevertheless, they contribute significantly in that they provide the most reliable way of determining the stretch reflex threshold in patients with spasticity. Thus, evaluation of spasticity using electrophysiological testing requires activation of the stretch reflex.[117] Several studies during the past 40 to 50 years have used electromyography (EMG) to measure the responses evoked by either stretching of the muscle (stretch reflex), tendon tap (T-reflex), or electrical stimulation of the peripheral nerve supplying the muscle, also called the Hoffman or H reflex, in order to evaluate whether these responses are exaggerated in individuals with spasticity and related to the degree of spasticity.[118–124]

One of the most used techniques in electrophysiological testing is the H-reflex. The H-reflex is generally considered a measure of motor neuron excitability. It can be elicited by low intensity (submaximal) electrical stimulation of the afferent fibers of a mixed peripheral nerve such as the tibial nerve or the common peroneal nerve.

Afferent nerve stimulation leads to activation of the α-motor neuron, which is recorded using a surface EMG electrode. The H-reflex amplitudes are increased after SCI.[116,118,119] However, no significant correlations were reported with other clinical measures (AS, MAS, Tardieu scale, SCATS).[117,118,125]

Self-Reported Assessment Tools

Penn Spasm Frequency Scale (PSFS). PSFS is a self-report measure that assesses a patient's perception of spasticity frequency and severity. It consists of two parts. The first part is a five-point scale that assesses the frequency of spasms ranging from (0 = No spasms) to (4 = Spasms occurring more than 10 times per hour). The second part is a three-point scale that assesses the severity of the spasms ranging from (1 = Mild) to (3 = Severe). If the person indicates "no spasms" in the first part, then they do not answer the second part. This measure is easy to use and requires no equipment. However, its reliability has not yet been established.[126]

Adams et al[127] reported that PSFS has excellent internal consistency (ICC = 0.90), adequate to excellent construct validity when correlated with the Spinal Cord Injury Spasticity Evaluation Tool (SCI-SET), Spasticity Severity, and Spasticity Impact (r = 0.66, 0.58, and 0.67, respectively). However, they reported a poor correlation with the Quality of Life Index (QLI)-Health and Functioning Subscale (r = 0.46).[127]

Visual Analog Scale (VAS). Another approach of patient self-report of spasticity involves the VAS, which is a graphical scale that allows the patient to select the degree in which a construct of interest is graded from one extreme to the opposite. It is a simple and quick method to establish a baseline and track progress after

interventions.[128] Two studies have been found in the literature that asked patients with SCI to rate their spasticity from “no spasticity” to “most imaginable spasticity”.[129]

Convergent validity was demonstrated with significant correlations between VAS and MAS.[128] However, it must be noted that this validation cannot be applied generally to all self-reports of spasticity recorded using VAS. For example, Lechner et al[129] found lower correlations between VAS and MAS, likely because patients scored their spasticity resulting from a specific activity rather than the general spasticity experienced.[129] As with the PSFS, the need to standardize the timing of measurements of the VAS is important.

The Numeric Rating Scale (NRS) is another approach with the same concept. However, instead of using a graphically visual scale, a numbering scale indicating the amount of spasticity felt is used. The NRS is an 11-point Likert scale ranging from 0 (indicating no spasticity) to 10 (indicating most imaginable spasticity). Anwar and Barnes[130] published a pilot study to assess the validity and reliability of the NRS for the measurement of spasticity in people with multiple sclerosis. The study showed a moderate test-retest reliability ($r = 0.67$), and a moderate construct validity when correlated with the MAS ($r = 0.45$), and the Tardieu scale ($r = 0.43$).[130]

Spinal Cord Injury Spasticity Evaluation Tool (SCI-SET). SCI-SET is a 7-day recall self-report questionnaire that assesses the impact of spasticity on aspects of daily life in people with SCI. It is composed of 35 items in which participants rate the impact of their spasticity on a 7-point Likert scale ranging from -3 (extremely problematic) to +3 (extremely helpful).[127]

Adams et al[127] reported that SCI-SET has excellent internal consistency (Cronbach's α = 0.90), excellent test-retest reliability (ICC – 0.91), adequate to excellent construct validity when correlated with the PSFS (*r* = -0.66), Spasticity severity (*r* = -0.48), Spasticity impact (*r* = -0.61), and QLI-SCI Version III (health and functioning subscale) (*r* = 0.68). However, a poor correlation was reported with the FIM™ (*r* = 21).[127]

Patient Reported Impact of Spasticity Measure (PRISM). PRISM is a self-report questionnaire developed and validated for measuring the impact of spasticity on QoL for persons with SCI.[131] It is a subjective health-related QoL measure that assesses the impact of altered motor control with respect to its seven sub-scales, which include social avoidance/anxiety, psychological agitation, daily activities, need for assistance/positioning, need for intervention, and social embarrassment. Participants respond to each item in the PRISM with "never true, rarely true, sometimes true, often true or very often true for me." It accounts for both the negative and positive aspects associated with spasticity. It has 41 items with a five-point Likert scale. Sub-scale scores are obtained by averaging item scores and multiplying by the number of items. The higher the score, the more negative impact is reported by the respondent.[131] The PRISM demonstrated good reliability in terms of internal consistency (Cronbach's α = 0.74 to 0.96) and reproducibility (ICC = 0.82 to 0 .91). Further work is still required to establish psychometric properties for its use with the SCI population, especially with respect to validity (construct, discriminative, and convergent).[131]

Clinician-Administered Tools versus Patients' Perception on the Impact of Spasticity

Most literature has focused on the quantification of spasticity symptoms.[8] Recent studies agree with the concept provided by Hsieh et al.[126] that spasticity may be better measured with an appropriate battery of tests. Spasticity as experienced by people who experience it is a complex phenomenon, involving a wide range of abnormal sensations in everyday life. Assessment of spasticity should incorporate patient reports. Learning about patient word choice used to describe spasticity can improve communication with healthcare providers. Ethical clinical practices require clinicians to incorporate patients' understanding of this phenomenon in their plan of care.[132] However, tools that assess the influence of spasticity on patient activities, participation and QoL are lacking.[126]

Lechner et al[129] investigated the relationship between self- and clinician-rated spasticity in SCI by correlating between clinicians' AS ratings with self-rated spasms severity. They reported a poor correlation (r_s = 0.36) between AS and general self-rated spasm severity (rating of spasms severity in general) and a moderate correlation (r_s = 0.70) between AS and present self-rated spasm severity (rating of spasm severity immediately upon the completion of AS). Their conclusion was that a single clinical assessment of spasticity is a poor indication of a patient's general spasticity.[129] Lechner et al also suggested that clinical measures of muscle tone–related spasticity should be complemented by self-rating that distinguishes muscle tone–related spasticity from spasticity as a complication that affects the individual as a whole.[129]

Accordingly, spasticity-related interventions need to be aimed at what matters most to the patient.[88,98,133] Understanding patients' experiences to make accurate assessments is an important practice to effectively evaluate treatment interventions and select appropriate management strategies. Moreover, the demand for subjective measures of the impact of spasticity on QoL is evident.

DEVELOPMENT OF THE PATIENT REPORTED IMPACT OF SPASTICITY MEASURE (PRISM)

Throughout the literature, researchers have made some effort to develop assessment tools that measure spasticity. Cook et al[131] believed that these efforts have failed to assess the experience of spasticity because of its multidimensional nature and broad scope, and that no tool has captured the true impact of spasticity on QoL. Cook et al developed the PRISM as a tool to measure the impact of abnormal muscle control or involuntary muscle movement.[131]

The study took place at four sites from the Department of Veterans Affairs medical centers (VAMCs) in Cleveland, Ohio; Dallas and Houston, Texas; and Palo Alto, California. They also recruited from TIRR Memorial Hermann Rehabilitation and Research in Houston, Texas. They started by developing an initial item pool by interviewing 24 participants. The interviews were semi-structured, audio-taped, transcribed, and then evaluated. The data were reviewed and summarized giving attention to identifying recurrent themes. Sixty-five candidate items were developed at this stage, and seven domains were identified that described participants' experiences: physical characteristics, impact on activities (positive and negative), psychological sequelae, financial costs, impact on interpersonal relations, functional

self-management, and attributes. Descriptive subcategories within each domain were identified.[10]

The introductory text for the questionnaire stated, “The following questions are about your experience of abnormal muscle control or involuntary muscle movement. Different people have different terms they use for abnormal muscle control and involuntary muscle movement. Some of these are (1) spasticity, (2) muscle stiffness (tone), (3) spasms, (4) clonus (bouncing), (5) when muscles don’t cooperate together like they’re supposed to, and (6) when trying to move one part of my body causes another part to move also.” The stem for the items stated, “Over the PAST WEEK, my abnormal muscle control or involuntary muscle movement …”. The items followed inquired respondents about both the positive and negative impacts of their spasticity. A 5-point Likert-type response scale was chosen (never true, rarely true, sometimes true, often true or very often true for me).[131]

Then, a refinement of the initial item pool was conducted using cognitive testing methods by including eight participants with SCI. These participants gave their comments and input whether the item content comprehensively captured their experiences with abnormal muscle control or involuntary muscle movement. As a result, the 65 items were revised accordingly and were ready for the administration and evaluation stage of the developmental PRISM.[131]

The developmental PRISM survey was then administered to a sample of 180 participants with SCI who reported abnormal muscle control or involuntary muscle movement. These individuals had sustained SCI, were over 18, spoke and read English, and stated that they had experienced spasticity. Thirty-three of the 180

participants returned a week later with responses to calculate the reliability of the instrument and underwent a clinical examination to classify their injuries based on the ASIA scale. This subsample also reported the global severity (mild, moderate, or severe) and frequency ("no spasms" to "spasms occurring more than 10 times per hour") of their spasms. The subsample also reported the degree to which spasms interfered with their function ("did not interfere", "made function difficult", or "prevented function").[131]

Results showed that the internal consistency for all subscales range between (Cronbach $\alpha = 0.74\text{-}0.96$). The reproducibility values were high for all subscales ranging between (ICC = 0.82-0.91) for the returned sample of 33 participants. Validity testing was performed by correlating PRISM subscales scores and responses to the severity and interference questions mentioned above. All the comparisons based on severity responses were statistically significant (Mann-Whitney U, $p < 0.05$, one-tailed). However, only two of the comparisons based on interference ratings were statistically significant "Daily Activities" ($p = 0.04$), and "Need for Intervention" ($p = 0.03$).[131]

Literature Related to PRISM

PRISM has been complimented in the literature as a well performed measure due to the clarity of results obtained from objective QoL measures specific to SCI populations.[84] Balioussis et al[102] conducted a study to identify and classify tools for assessing the influence of spasticity on QoL after SCI. Balioussis et al concluded that, along with the SCI-SET, the PRISM emerged as the most promising tool as an effective measure of spasticity impact, because it assesses both positive and negative

effects of spasticity and provides a more complete picture of the overall impact of spasticity on an individual.[102]

Further support for the PRISM comes from a study by Westerkam et al,[12] who used scales of the "home life satisfaction", "global satisfaction", "vocational satisfaction", "overall quality of life", as well as three 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.[12]

Moreover, two studies adopted some of the items found on the PRISM. Cheung et al[134] did a study in 2014 to study patient-identified factors that influence spasticity with stroke and multiple sclerosis populations. Cheung et al adopted six items from the Daily Activities subscale of the PRISM.[134] Another study done by Zorowitz et al[135] developed a 13-item spasticity screening tool for healthcare providers to identify patients with spasticity in need for treatment regardless of etiology. Zorowitz et al's initial item bank for review came from existing spasticity measure questionnaires, including the PRISM. However, Zorowitz et al did not specifically mentioned any details on the process of their review on the PRISM.[135]

McKay et al[136] conducted a study to understand how people with SCI characterize their experience of spasticity and the relationship between those characteristics and the perceived impact on daily life. They developed a 75-item questionnaire that included the 41-item PRISM and 34 more items related to the

characteristics of spasticity, including: stiffness presence, stiffness impact, spasm presence, endogenously triggered spasms, and exogenously triggered spasms. There were 113 participants with spastic SCI responded to the questionnaire. The study was designed to find relationships between PRISM subscales and spasticity characteristics.[136]

The study results showed that all negative impact subscales of the PRISM (social avoidance/anxiety, psychological agitation, daily activities, need for assistance/positioning, need for intervention, and social embarrassment) had moderate correlation with stiffness presence (ρ = 0.34-0.53, $p < 0.05$). Moreover, high to moderate correlations with stiffness impact (ρ = 0.55-0.84, $p < 0.05$), low to moderate correlation with spasm presence (ρ = 0.29-0.47, $p < 0.05$), low to moderate correlations with endogenously triggered spasms (ρ = 0.24-0.55, $p < 0.05$), and low to moderate correlations with exogenously triggered spasms (ρ = 0.16-0.58, $p < 0.05$) were reported. No correlations were found between spasticity characteristics and the PRISM positive impact subscale. The study also discussed that stiffness was the characteristic of spasticity that respondents indicated as being the most problematic. Stiffness had a higher prevalence compared with spasm and had the greatest negative impact on daily activities and psychological agitation.[136]

Serbian Version of the PRISM

The PRISM has been translated and culturally adapted to Serbian language to assess the impact of spasticity on Serbian people with multiple sclerosis (MS). The resultant Serbian version of the PRISM was produced after implementing the guidelines given by Beaton et al.[137] Their study also examined the validity (construct,

convergent, divergent) and reliability (internal consistency, test–retest reliability) in 48 patients with spasticity because of MS. The construct validity and convergent validity values were calculated by comparing the Serbian PRISM with the MAS and the NRS (range 0-10, where "0 = no spasticity", "10 = worst possible spasticity). The divergent validity testing was calculated by comparing the Serbian PRISM subscales scores between men and women, and between two educational level groups; high school, and college/university.[138]

The construct validity testing showed that all seven subscales of the Serbian PRISM correlated positively with the MAS, of which four were significant ($0.29 \leq r \leq 0.34$). Similarly, all Serbian PRISM subscales scores significantly and positively correlated with NRS ($0.32 \leq r \leq 0.51$), except one (Positive Impact), which was borderline significant (r= -0.28, negative because of reverse scoring). The strength of significant associations was small to medium for MAS and generally medium for NRS. For divergent validity, no Serbian PRISM subscale score was significantly different between men and women ($p \geq 0.104$) or between the groups with different education levels ($p \geq 0.139$).[138]

The results also showed that the internal consistency of the Serbian PRISM had a value of Cronbach α to be higher than 0.70 for all its subscales. Moreover, the observed test-retest reliability testing of the Serbian PRISM had ICC values of more than 0.75 for all its subscales.[138]

HEALTHCARE MEASURES IN ARABIC LANGUAGE

Arabic language is the fifth most widely spoken as well as the fastest growing language. Arabic speakers are more than 400 million people in 22 countries around

the world.[139] Generally, it is divided into three distinct categories: 1) Classical Arabic – which is the language of religion and of the Qur'an, 2) Modern Standard Arabic (MSA), also called fus'ha – which is the formal Arabic used in writing, education, and administration, and 3) the Regional Colloquial Arabic dialects (Lahja Ammeya) – which is used in everyday conversations, songs, movies, and on informal occasions.[140]

Arabic is widely considered as one of the most difficult languages to deal with in a localization context. Consequently, the MSA was perceived as the most common dialect widely used in most Arab countries.[141] Therefore, we would expect an instrument to have some degree of validity when used in other Arabic countries knowing that that Arabic language style used was the MSA. Nevertheless, a structured quantitative research study will be necessary to apply the instrument outside the targeted Arabic country where the cross-cultural translation took place.

Most Arabic translated self-report measures were translated into Arabic language using the MSA version. However, the only QoL measure related to SCI that has been translated into Arabic language is the QLI measure – SCI version that was done by Halabi in 2006.[98] His translated Arabic QLI demonstrated a high degree of translation accuracy and content validity.[98]

Issues with Translation to Arabic Language

In general, literature showed five problem of equivalence associated with translating an instrument to Arabic language: conceptual, vocabulary, idiomatic, grammatical-syntactical, and experiential equivalences.[142,143] Researchers interested in translating instruments should have great knowledge about these problems of

equivalence. The following is a brief breakdown of these problems and how they can relate to translating the language of an instrument from English into Arabic:

1) Conceptual equivalence: It occurs when the two languages of interest have the same word, but each has a different meaning in a certain situation.[143]

2) Vocabulary equivalence: It occurs when a word from the original language does not exist or is defined by the dictionary in multiple ways or terms in the target language. This problem is usually solved by finding comparable word or group of words.[143] For example, the English word "pain" was found to have over 100 words when translated into Arabic language.[144]

3) Idiomatic equivalence: It occurs when employing a direct translation of an idiom that may result in a false translation that would not make sense. Therefore, translators must be familiar with the real meanings of idioms to maintain idiomatic equivalence.[140,143]

4) Grammatical-syntactical equivalence: Each language has its own unique rules of grammar, structure, and syntax. So, the grammatical-syntactical equivalence problem occurs with word order, comma usage, and verb nuance and tense.[143] For example, some instruments use capital letters to emphasize or highlight words. However, there are no capital letters in Arabic language. Therefore, researchers suggest rendering capitalized words with bold type font in the translated Arabic version.[140,145]

5) Experiential equivalence: It occurs when the two languages of interest differ greatly in cultural nature and overall way of life.[140,143] For example, the English word "caregiving" may be translated as "ilaj" in Arabic, which refers to giving

medical care, like administering medications. Therefore, researchers and translators should have great familiarization to the cultural differences and to distinguish between cultural translation and linguistic translation.

TRANSLATION AND CULTURAL ADAPTATION OF MEASURES

Clinicians commonly use questionnaires to assess treatment outcomes. These questionnaires provide a convenient way to assess how treatment has affected the interested outcomes such as health related QoL. Questionnaires can also be used by clinicians to screen for diseases, to estimate prognosis and to collect information on how their patients are thinking or feeling. For a questionnaire to be useful, a patient needs to be able to read and understand the text and the items need to make sense and be relevant to that person.[146]

With the increased diversity between populations worldwide, the need for multinational and multilingual measures that are cross-validated for clinicians and researchers has risen. Hence, the need for the translation and cross-cultural adaptation of original questionnaires would enable comparisons of different populations and permit the exchange of information across cultural and linguistic barriers. Also, this procedure would add an important value to researchers who conduct meta-analyses of data from eligible trials in populations around the world regardless of their differences in their languages and cultures.[147] Another important reason to adapt an existing questionnaire is that it is much more efficient than developing a new one. There is substantial work involved in developing and validating a questionnaire.[148]

The process of translation and adaptation of instruments has been studied extensively in the literature, leading to the development of several guidelines. These

guidelines aim to achieve different language versions of the original instrument that are conceptually equivalent in each of the target countries and cultures. That is, the instrument should be equally natural and acceptable and should practically perform in the same way.[148]

A clear distinction should be made between translation, adaptation, and cross-cultural validation. Translation is the single process of producing a document from a source version in the target language. Adaptation refers to the process of considering any differences between the source and the target culture to maintain equivalence in meaning. The cross-cultural validation of a questionnaire is a different process, however, as it aims to ensure that the new questionnaire functions as intended and has the same properties as the original and functions in the same way.[149] The most emphasis is given to the cross-cultural and conceptual, rather than on linguistic and literal equivalence that are achieved with translation only.[150]

An important aspect in translation and adaptation for a questionnaire of the source language is to be equivalent with the questionnaire of the target translation languages in four dimensions. These dimensions are to achieve semantic, idiomatic, experiential, and conceptual equivalence. Semantic equivalence identifies the similarity among the meanings of words of the source language and the target language. Idiomatic equivalence identifies the ways by which the idioms and colloquialisms of the source language can be translated to the target language. Experiential equivalence describes the similarity between the daily activities of the source culture and the targeted culture. Finally, conceptual equivalence determines the resemblance and identity between the concepts of the source and target culture.[137]

Guidelines and Steps Involved in Translation and Cross-Cultural Adaptation

As mentioned earlier, several guidelines were introduced in the literature.[137,150–152] Most of these guidelines have similar agreement to the steps, but differ in their definitions and some conceptual roles of the people involved in the process. Several WHO studies have refined the methodology of translation and adaptation of an instrument.[153] The resultant recommendation of implementation of this methodology includes the following steps:

Forward Translation. This step involves translating the original instrument to the target language. It is usually done by at least two independent translators whose native language is that of the target language. These translators must be bilingual (fluent in the source and the target language) and preferably bicultural (having in-depth experience in both cultures, the source and target language cultures). In addition, the translators must have distinct backgrounds. All translators involved in this step will generate two forward-translated versions of the original instrument.[137,154]

Synthesis. This step comprises the forward translators who played their role in step one to meet and compare their translations regarding ambiguities and discrepancies of words, sentences, and meanings. Any ambiguities or discrepancies must be discussed and resolved. This process will generate one synthesized translated version of the instrument, along with a report summarizing the challenges they had following their discussions.[137,154]

Backward Translation. The purpose of this step is to validate and consolidate the resulted synthesized version produced in step two. It involves two or more independent translators whose native language is that of the source language of the

original instrument. Again, these translators must be bilingual (fluent in the source and the target language) and preferably bicultural (having in-depth experience in both cultures). In addition, the translators must have distinct backgrounds. Their role is to back-translate the resulted synthesized translated version from Step Two to the source language. This step generates multiple backward translated versions from the synthesized version created from Step Two.[137,154] Some researchers argue that this step can be avoided, specifically when the original instrument is robust.[150]

Expert Committee Review. In this step, an expert committee will be formulated by the researcher to assure the achievement of cross-cultural equivalence. Experts recommend that this committee should include at least one methodologist (who can be the investigator, member of the research team, or both), one healthcare professional who is familiar with the content areas of the construct of the instrument, and all translators involved in Step One (forward translation) and Step Three (backward translation). The role of the methodologist is to ensure the translation's equivalence, cultural relevance, and the validity of the backward translation method. The role of the healthcare professional will be to give input on patients' perspectives about relevant wordings used in the questionnaire. The expert committee will review all translations done: forward translations from Step One, the synthesized translation from Step Two, backward translations from Step Three, and all reports and documentation done throughout the process. Their role is to discuss and resolve any ambiguities and discrepancies concerning cultural meaning and colloquialisms or idioms in words and sentences of the instructions, the items, and the response format between the forward translations and between each of the backward translations and

the original instrument. If ambiguities and discrepancies cannot be resolved, steps one through four may be repeated as many times as necessary.[137,148,150,155] Epstein et al[150] argued that this step has a large impact in the cross-cultural adaptation process, and that it helps ensuring accurate content. This process will generate the pre-final version of the target language of the instrument.[150]

Pilot Testing of the Pre-Final Version. At this step of the adaptation process, the pre-final version of the instrument, produced after Step Four, will be tested under pilot testing. This is done by field-testing it in subjects or patients from the target setting. Ideally, 10 to 40 subjects should be included in this pilot study.[154] The procedure is to ask these subjects to independently complete the pre-final version of the instrument. They are asked to respond freely and honestly to all items in the questionnaire. The distribution of responses is examined to look for a high proportion of missing items or single responses.[137] After that, subjects will be interviewed independently. In the interview, subjects will be probed about the meanings of each item and address those items that were difficult or just need to be changed. They will also be asked to take part in suggesting a better or easier form of language for difficult items in the questionnaire.[137,154] By the end of this step, a translated, adapted, and cross-validated version of the instrument will be generated. This version will be ready for psychometric evaluation and testing.[137,154]

Psychometric Evaluation. After the translation and adaptation process, the investigators ensure that the new version has demonstrated the measurement properties needed for the intended application. For this reason, the last step of the translation and adaptation process of the instrument is to establish the full

psychometric properties of the newly translated, adapted, and cross-validated instrument with a sample of the target population of interest. The new instrument should retain both the item-level characteristics such as item-to-scale correlations and internal consistency, and the score-level characteristics of reliability, construct validity, and responsiveness. The sample size for this step depends on the types of psychometric testing that will be used.[156] The most recommended and commonly used psychometric approaches in this step are as follows:

Internal consistency tests the homogeneity of the items in a questionnaire, as items should be addressing different domains of the same construct. Most questionnaires measure a single underlying construct by using multiple items, and these items should be moderately correlated with each other, and each item should correlate with the total scale score.[157] The internal consistency can be evaluated by calculating Cronbach's alpha.[156]

Reproducibility is the extent to which repeated measurement on stable subjects yields similar results.[158] Reproducibility testing is achieved by two related constructs: 1) agreement statistics that describe how close the scores for repeated measures are, and 2) reliability statistics which describe the correlation between repeated measures, often called test-retest reliability.[148,156]

Validity tests if the newly developed translated version is assessing the specific construct. This testing can be achieved by correlating the scores of the instrument with other tools that measure the same construct, preferably, using a gold standard. Using the correlation coefficient, a higher correlation value means that this instrument is valid for testing this construct.[148,156]

Responsiveness is the ability of a questionnaire to detect clinically important changes over time, even if these changes are small.[146] Different methodologies have been proposed in the attempt to determine the clinical importance of change. A typical approach is to test it using Cohen's effect size by dividing the mean change of scores by their standard deviations. Another approach is to use an external criterion of true change and investigate how well the measure can discriminate between subjects who have truly improved and those who did not.[148,156]

Testing a questionnaire is usually a very time-consuming task. A recommended guideline for evaluating an instrument's properties is to have at least 100 patients to analyze all psychometric tests. Also, patients should be under treatment and all of them should answer the questionnaire on three different occasions: 1) at baseline, 2) after some time and before the construct being measured is expected to change, and 3) after a true change is expected, usually at discharge.[149,159]

CONCLUSION

This literature review presents knowledge on how the impact of SCI can be devastating on a person's life.[3,10–14] Adding to that, spasticity was found to be one of the most common complications, and was deemed by many as one of the most difficult problems affecting individuals with SCI.[9,28,29,38,39,43–45,47] However, some discussed the positive impact caused by spasticity on people with SCI, as it has been found to facilitate ADL performance and increase functional capacity.[52,53,55–57] Therefore, the decision to manage spasticity may require extensive assessment including the measurement of its impact on persons' daily lives.

The literature also discussed the importance of assessing spasticity in this population, but although it is generally agreed to be easy to recognize, it is not easy to quantify.[135] Many spasticity-specific clinical assessment tools were developed looking at different dimensions of spasticity. However, these tools were found to be limited to assess the full representation of the spasticity phenomena. Consequently, researchers suggested that a single tool is not enough, but rather a battery of tools will be needed to assess the whole impact of spasticity. Adding to that, clinical assessment of muscle tone-related spasticity should be complimented by a spasticity-specific self-rating tool to capture negative physical, emotional, social and even, the positive impact of spasticity on an individual.[126,129,132]

The PRISM is an instrument that was developed by Cook et al[131] specifically for individuals with SCI. The PRISM is a questionnaire that standardizes the collection of self-report information relevant to the clinical assessment of the impact of abnormal muscle control or involuntary muscle movement on quality of life.[131] Consequently, it emerged as an effective and most promising tool measuring the impact of spasticity, because it assesses both positive and negative effects of spasticity and provide a more complete picture of the overall impact of spasticity on an individual.[102] Thus, its inclusion as part of the assessment process given to patients with spastic SCI will be an integral addition.

The PRISM, however, is currently limited to English speakers in the United States. Its use has not been spread worldwide except in Serbia where it has been translated to Serbian language and tested on Serbian patients with MS only.[138] To help

validating PRISM around the world, using it on other populations with spastic SCI who speak different languages and live in different cultures will be crucial.

Arabic language is the fifth most widely spoken as well as the fastest growing language.[139] Therefore, a reliable and validated Arabic tool for measuring the impact of spasticity among individuals with SCI, such as the PRISM, will not only add valuable addition to the assessment process given to those individuals living in a country such as Saudi Arabia which has one of the highest incidences of SCI around the world,[19,21,24,160,161] but will also provide further strength to the PRISM tool's psychometric properties and the generalization of its use in this population globally.

This dissertation translated, cross-culturally adapted the PRISM, and provided its quantitative estimates in Arabic speaking individuals with SCI in Saudi Arabia. First, The translation process was done in accordance with the guidelines recommended by Beaton et al.[137] Secondly, the newly translated Arabic PRISM underwent reliability and validity testing to be compared with the original PRISM. Thirdly, further testing of its sensitivity to change was conducted.

CHAPTER III

TRANSLATION, CROSS-CULTURAL ADAPTATION PROCESS AND PILOT TESTING OF THE ARABIC VERSION OF THE PATIENT REPORTED IMPACT OF SPASTICITY MEASURE (PRISM-ARABIC)

ABSTRACT

Context: The Patient Reported Impact of Spasticity Measure (PRISM) is a self-reported questionnaire that is used to assess the impact of spasticity on the quality of life of individuals with spinal cord injury (SCI). Its inclusion in the assessment process for patients living in a country such as Saudi Arabia, which has one of the highest incidences of SCI around the world, will be an integral addition. *Aims:* The aims for this study were to translate and cross-culturally adapt the PRISM into Arabic and pilot test the Arabic version on Arabic speakers with SCI in Saudi Arabia. *Settings and Design:* Translation process was administered according to the recommended guidelines used for cross-cultural adaptation of healthcare measures. *Methods and Material:* Pilot testing of the PRISM-Arabic was administered to 35 individuals with SCI presenting with spasticity. Participants were interviewed to assess the relevance of the questionnaire to the Arabic language and culture. Face and content validity of the PRISM-Arabic as well as its floor and ceiling effects were assessed. *Results:* During the translation process, the expert committee made changes in 14 occasions due to cultural equivalence differences. Pilot-testing showed eight items that needed further adaptation. After all were made, the cross-culturally adapted PRISM-Arabic showed adequate face and content validity and did not have flooring

and ceiling effects. *Conclusions:* The PRISM has been successfully translated and cross-culturally adapted into Arabic language. Further assessments of its psychometric properties are recommended. Implications for its use in clinical practice and research were presented.

INTRODUCTION

Spinal cord injury (SCI) is a devastating neurological condition that can result in significant disability. It results in varying degrees of loss of sensory, motor and autonomic function, all of which can have a great impact on the individual's medical and emotional status.[1–3] Spasticity is a sequela that is present in 65 to 78% of the population with chronic SCI.[4,5] This impairment results from an imbalance between messages from the central nervous system to the muscles causing an increased excitability referred by patients or clients as tightness, stiffness, or increased pull of muscles.[6–8]

Problems that arise because of spasticity are numerous, and it is generally considered by patients and clinicians to have a negative impact on limiting functional capacity and activities of daily living (ADL).[9–12] However, there are suggestions that symptoms of spasticity may facilitate the performance of some ADL and transfers, increase stability in sitting and standing, increase muscle bulk and strength of spastic muscles, and increase venous return.[13–15] This potential for a beneficial effect of spasticity on quality of life (QoL) has an impact upon decisions regarding its management.

Standardized clinical assessment tools for spasticity are often used to measure the clinical presentations, frequency, and severity of the spasticity. However, there

has been a change in recent years to focus on standardizing the measurements of the client's overall activity and functional status.[16] Therefore, researchers suggested that a single tool is not enough, but rather a battery of tools will be needed to assess the impact of spasticity. Additionally, clinical assessment of muscle tone-related spasticity should be complimented by a spasticity-specific self-rating tool to capture the physical, emotional, and social impact of spasticity on an individual.[17–19]

The Patient Reported Impact of Spasticity Measure (PRISM) is an instrument that was developed by Cook et al,[20] specifically for individuals with SCI. It is a questionnaire that standardizes the collection of self-report information relevant to the clinical assessment of the impact of abnormal muscle control or involuntary muscle movement on QoL.[20] Its assessment is done with respect to its seven subscales, which include social avoidance/anxiety, psychological agitation, daily activities, need for assistance/positioning, positive impact, need for intervention, and social embarrassment. It accounts for both the negative and positive aspects associated with spasticity. It has 41 items with a five-point Likert scale. Subscale scores are obtained by averaging item scores and multiplying by the number of items. The higher the score, the more negative the impact is reported by the respondent.[20]

The PRISM demonstrated good reliability in terms of internal consistency (Cronbach's $\alpha = 0.74\text{-}0.96$) and reproducibility (ICC = 0.82-0.91). Further work is still required to establish psychometric properties for its use with the SCI population, especially with respect to validity (construct, discriminative, and convergent).[20]

The PRISM's inclusion as part of the assessment process given to patients with spastic SCI will be an integral addition.[21] However, it is currently limited to

English speakers in the United States. Its use has not spread worldwide except in Serbia where it has been translated to the Serbian language and tested on Serbian patients with multiple sclerosis (MS) only.[22] Therefore, providing a version of the PRISM for use among an Arabic population will be a helpful step to the PRISM's generalizability and usability in a population with SCI. This study took place in Saudi Arabia, a country with one of the highest incidences of SCI around the world,[23–25] and applied the Modern Standard Arabic language (MSA) throughout the translation process to help generalize the use of the PRISM in all Arabic speakers with SCI.[26–28] The purpose of this study was to produce an Arabic version of the PRISM to be used with Arabic speaking individuals with SCI. The aims of the study were: 1) to translate and cross-culturally adapt the PRISM questionnaire into Arabic language, and 2) to pilot test the produced Arabic version with individuals with SCI.

PARTICIPANTS AND METHODS

This cross-cultural study was approved by the Institutional Review Board of the institutions.

Translation and Cross-Cultural Adaptation Process

The process of translation and cultural adaptation was planned and carefully implemented using the guidelines given by Beaton et al[29] for cross-cultural adaptation of self-reported measures. These were as follows:

1) **Forward translations.** In this stage, two bilingual translators whose native language was Arabic performed the forward translation of the original English version of the PRISM into Arabic using the MSA language. These two translators were independent and had different backgrounds. One of them had knowledge of the target

population (patients with SCI) and the purpose of this study. His role was to modify unexpected meanings to be recognized and understood by the population of interest during the second stage of the translation process. The other translator had knowledge about the purpose of the study only. Both translators produced two separate Arabic translated versions of the PRISM (T1 and T2).

2) Synthesis. In this stage, the two forward translators met together to synthesize the results of their translations. The process was done by reviewing, comparing and synthesizing the two resulting Arabic translated versions from stage one (T1 and T2) with the original (English version) PRISM. The purpose for this step was to produce one synthesized Arabic version of the PRISM (T3) with a report documenting the challenges they had following their discussion and consensus.

3) Back translations. The purpose of this stage in the cross-cultural adaptation process was to validate and consolidate the synthesized Arabic version of the PRISM produced in stage two (T3). Two independent bilingual translators performed the back translation to English language. The two back translators were independent and were unaware of the original English PRISM and purpose of this study. They both had no medical background to avoid information bias. This process produced two back-translated English versions of the PRISM (T4 and T5).

4) Expert committee. To assure the achievement of cross-cultural equivalence, the expert committee was formulated with two methodologists, a physical therapist (PT), a language professional, and the principal investigator (also a PT). One methodologist had previous experience in cross-cultural adaptation of tools to Arabic language in Saudi Arabia. The other methodologist has experience

developing patient satisfaction surveys within hospital settings. Both methodologists were experts in questionnaire development for Arabic speakers. Their role was to help in translation and to give input ensuring translation equivalence, cultural relevance, and the validity of the backward translation method followed during the translation stage. The PT has worked closely and extensively with patients with SCI. His role was to give input on patients' perspectives about relevant wording used in the questionnaire. The language professional is a translator who works closely with the targeted population. He translates between Arabic-speaking patients and English-speaking healthcare professionals. All experts were bilingual and had previous knowledge about the concept of this study and its purpose.

The committee reviewed all the translations: two forward translations (T1 and T2), the synthesized translation from the forward translation stage (T3), and the two back translations (T4 and T5). They discussed the challenges and discrepancies that were found that did not reflect the original version of the PRISM. After significant modifications, the committee came up with critical decisions made to achieve semantic, idiomatic, experiential, and conceptual equivalence between the original PRISM and the Arabic-translated PRISM (PRISM-Arabic). Questionable words and phrases were replaced with ones believed to be reasonable adaptations into the Saudi Arabian culture. This process created the pre-final version of the PRISM-Arabic (T6) and was ready to be field tested (see Appendix A).

Pilot Testing of the Pre-Final Version of the PRISM-Arabic

Participants

Thirty-five participants were recruited for this pilot study. Using convenience (consecutive) sampling approach, individuals with SCI who reported spasticity and had been admitted for rehabilitation as an in-patient or out-patient in the hospitals were recruited. These two hospitals are the largest rehabilitation centers in Saudi Arabia, serving patients from all over Saudi Arabia and its neighboring countries. Inclusion criteria were an age minimum of 18 years and ability to read, speak, and understand Arabic. In addition, they must have sustained a SCI more than three months prior to the day of testing. Those who were pregnant or had been diagnosed with psychological- or cognitive-related complications that might interfere with their rehabilitation program or how they will respond to the questionnaire were excluded from the study. Other exclusion criteria included active infection, open wounds, heterotopic ossification/myositis ossificans, or other acute musculoskeletal injuries.

All participants read and signed a written informed consent in Arabic for participation approved by the Institutional Review Board of the university and the corresponding hospital or center where the participant was being treated.

Procedure

Participants were asked to independently complete the pre-final version of the PRISM-Arabic (T6) produced from stage four of the translation and adaptation process. They were asked to respond freely and honestly to all items in the questionnaire and then were interviewed independently (see Appendix B). In the interview, participants were probed about the meanings of each item, and to address

those items that were difficult or needed to be changed. They were also asked to suggest a better or easier form of language for difficult items in the questionnaire. Lastly, they were asked if they thought that the questionnaire was relevant and appropriate to their experience with spasticity.

Data Analysis

All data analyses were calculated using SPSS® for windows, version 25 (IBM Corp. Armonk, NY). The means and standard deviations of the demographic variables (including the American Spinal Injury Association (ASIA) Scale,[1] employment status, marital status, and level of education) were calculated to describe study participants. Independent sample *t*-tests were used to analyze the differences between demographic groups on the number of difficult or misunderstood items reported by participants. Face validity was determined upon participants' responses to the interview questioning on relevance and appropriateness of the scale to their experience with spasticity. The content validity was determined if the expert committee members reached a consensus concerning the relevance and appropriateness of the scale to those Arabic speaking individuals with SCI affected by spasticity. The floor and ceiling effects of the PRISM were determined by computing the percentage of participants scoring lowest or highest. The scale was considered to have flooring or ceiling effect when more than 15% of the participants had the lowest or highest possible score.

RESULTS

Translation and Adaptation Process

The two forward translations in stage one (T1 and T2) had noteworthy differences between them. In fact, the title of the tool (Patient Reported Impact of Spasticity Measure) was significantly different after translating it to Arabic language. The term "spasticity" has no Arabic equivalent, and both translators had to describe the phenomenon to make it meaningful for readers. They produced one synthesized Arabic version of the PRISM (T3) from their individual translations. The two back translations in stage three failed to make sense in multiple occasions due to literal translation from the synthesized Arabic version of the PRISM to English language. The two produced English versions (T4 and T5) did not convey the content of the original PRISM in numerous items. After reviewing all versions throughout the translation process, the expert committee changed the language of some of the contexts in 14 occasions used in T3. Table 3.1 explains the translation process followed on all major contexts and items in the pre-final PRISM-Arabic that were deemed unclear.

Results from the Pilot Study

Using descriptive analyses, the means and standard deviations of the demographic variables were calculated (see Table 3.2). Eight (22%) out of the 35 participants in this study reported difficulty in understanding 10 items from the questionnaire. Independent sample *t*-tests between the demographic groups showed that participants with lower level of education (high school and below) reported larger number of misunderstood items (19 items) compared to those with university level

education and above (6 items) (p = 0.02). Also, there was a significant difference between those who were employed (18 items) and those who were not (11 items) (p = 0.03) (see Table 3.3).

Adaptations After the Pilot Testing of the Pre-Final Version of the PRISM-Arabic

Four items out of all the 41-item pre-final PRISM-Arabic were most frequently thought to be unclear by participants (see Table 3.4). Item Number 5, "Helped me keep my muscles exercised," was reported by six participants to be unclear or difficult to understand because of a translation vocational equivalence issue. The word *exercised* (ممرنة) was perceived by these participants as the word *trained* or *under training task*. Consequently, the Arabic-translated word of "exercised" was re-adapted by expressing the conceptual meaning with more words. The resulted re-adaptation was (ساعدتني في الحفاظ على نشاط وقوة عضلاتي), which means "Help me keep my muscles in an exercised manner".

Also, Item Number 14, "Caused me to increase the amount of prescription medication I took", and Item Number 30, "Caused me to use over-the-counter medication", were reported difficult by three and four participants, respectively. This difficulty was because of the relationship between the two items that resulted in a translation experiential equivalence issue. Participants reported that they cannot distinguish between the two items and that the medication prescription process was never experienced the same way that the questionnaire is describing, because medication in Saudi Arabia usually can only be obtained from pharmacists with a prescription given by their physicians. Therefore, Item 14 was re-adapted to (جعلني

أقوم بزيادة جرعة الدواء المسجل بالوصفة الطبية), which means "Caused me to increase the amount of medication listed in the prescription".

Lastly, Item Number 38, "Made transfers hard for me or my attendant", that was translated in Arabic into "جعلت الانتقال صعبا" was reported by four participants to be unclear or vague because of a translation vocabulary issue. The word *transfers* "الانتقال" is a vague and an indefinite word. Therefore, a few words, "transfers **from chair**" were added to give an indication to the actual physical function of making transfers. The resulted re-adaptation was "جعل الانتقال من الكرسي صعباً", which means "Made transferring from chair hard".

Face and Content Validity of the PRISM-Arabic

All 35 participants reported that the PRISM-Arabic items were relevant and appropriate to their experience with spasticity, thus supporting the face validity of the cross-culturally adapted PRISM. Also, all expert committee members reached a consensus concerning the relevance and appropriateness of the PRISM-Arabic to those Arabic speaking individuals with SCI affected by spasticity. Furthermore, the completeness of the PRISM-Arabic items was satisfactory and the absence of floor and ceiling effects in the analysis further support adequate content validity (see appendix C).[30]

DISCUSSION

The purpose of the study was to translate and cross-culturally adapt the PRISM questionnaire into Arabic language and pilot test the PRISM-Arabic with individuals with SCI who complain of spasticity. The study followed the guidelines for cross-cultural adaptation for self-reported measures given by Beaton et al.[29] The

resulted translation had some minor changes that were proposed by the participating expert committee members. Although the expert committee handled the linguistic, cultural, and technical issues prior to the pre-final administration stage, the process of pilot-testing the pre-final Arabic PRISM was essential in identifying further issues that could not be explored within the previous stages. Thirty-five participants with SCI reporting spasticity in the cross-cultural adaptation process helped recognize, analyze and re-adapt four items of the pre-final PRISM-Arabic after the pilot study.

Lack of clarification and ambiguity of the written language can negatively affect the performance of the translated questionnaire and thus jeopardize the original intent. The pilot study analysis revealed significantly more reported misunderstood items in participants with lower education. This finding may suggest that the pre-final PRISM-Arabic was written at a too high of a level for persons with less education. The noted items with difficulties were re-adapted further to simplify them more by using additional words to explain them better. The pilot study also revealed significantly more reported unclear items with those who were unemployed. This may suggest the experiential factor affecting the clarity of some items. Thus, items with experiential issues were re-adapted to fit the target population's cultural differences. In general, this exploration analysis helped in modifying the pre-final PRISM-Arabic to minimize confusion, facilitate better understanding of the items, ensure clarity, and thus maintain and reflect the integrity and purpose of the original PRISM.

The translation and cross-culture adaptation process followed in the PRISM-Arabic in our study has thoroughly implemented the Beaton[29] guidelines involving all stages. The reported Serbian version[22] had no expert panel involvement, while in our

study, the expert committee played an integral part in the adaptation process. Further psychometric properties comparisons may be studied between the two versions (Arabic and Serbian) along with the original PRISM.

The study also examined the PRISM-Arabic's face and content validity. After changes were made, the PRISM-Arabic was finalized and ready to be tested in a larger scale for psychometric properties including the evaluation of test-retest reliability, construct validity, internal consistency and sensitivity to change to support the utility of the PRISM-Arabic in spasticity-related care

Implications for Rehabilitation and Research

Due to the high incidence of SCI in Saudi Arabia and the lack of a self-reported spasticity assessment tool in dealing with such a complication, the cross-cultural adaptation of the PRISM supports the use of standardized assessments. The use of standardized assessments can improve spasticity management practice, help identify patient's needs and serve as a basis for treatment planning. Furthermore, active participation of the patient in his/her own examination and evaluation will also be facilitated in such standardized assessment approach.

To the author's knowledge, the introduction of a spasticity-specific self-reported outcome measure such as the PRISM into clinics in Saudi Arabia will be the first of its kind. The use of the PRISM-Arabic would introduce and support a new area of research and clinical assessment related to patients with SCI reporting spasticity.

Limitations

Although participating hospitals in this study received patients with SCI from all over the country, the limited data collection to one geographical area within Saudi Arabia may threaten its generalizability. Also, although the translation process adopted the MSA language, it should not be broadly assumed that all Arabic speakers would respond to the PRISM-Arabic consistently. Future studies should examine its usability and applicability in other Arabic-speaking countries.

CONCLUSION

The PRISM was successfully translated and cross-culturally adapted into Arabic language for Arabic speakers with SCI reporting spasticity. Further testing of the PRISM-Arabic's psychometric properties is a necessary next step in future studies to strengthen its utility in spasticity-related care.

Table 3.1. Arabic Adaptation of Words and Sentences from the Original Patient Reported Impact of Spasticity Measure*

Item	Context from the original PRISM	Context from the Arabic-translated synthesized version of the PRISM	Issue with translation equivalence	Expert committee decision
Name of the tool	PATIENT REPORTED IMPACT OF **SPASTICITY** MEASURE	**الشلل التشنجي** spasticity has no equivalent term in Arabic Language	Vocabulary Equivalence	Changed to: الشد العضلي العصبي
Introductory context	**abnormal** muscle control	**الخلل** abnormal has many equivalent terms in Arabic language	Vocabulary Equivalence	Changed to: الاضطراب
Items: 3,10,17, 21,33,38	Difficult for (or helped) me or my **attendant**	**أحد** Back translated to: *"someone"*	Conceptual Equivalence	Changed to: مساعدي
Item: 4	**need someone** to reposition me	**لمساعده شخص اخر** Back translated to: *"need the help of someone"*	Vocabulary Equivalence	Retained
Item: 5	**keep my muscles exercised**	**اداء تمارين رياضية لعضلاتي** Back translated to: *"perform athletic exercises to my muscles"*	Vocabulary Equivalence	Change to: إبقاء عضلاتي ممرنة
Item: 14	**prescription medication**	**الأدوية** Back translated to: *"medication"*	Experiential Equivalence	Changed to: الأدوية الموصوفة
Item: 23	feel **powerless**	**بالضعف** Back translated to: *"weak"*	Vocabulary Equivalence	Changed to: بانعدام القوة
Item: 30	use **over-the-counter medication**	**أتناول بعض الأدوية بدون وصفة طبية** Back translated to: *"use medication without prescription"*	Experiential & Idiomatic Equivalence	Changed to: أتناول أدوية لا تحتاج إلى وصفة طبية
Item: 35	ability to **exercise**	**تمارين رياضية** Back translated to: *"athletic exercises"*	Vocabulary Equivalence	Changed to: أداء التمارين

***** The process of translation and cross-cultural adaptation followed recommendations from the expert committee members producing the pre-final Patient Reported Impact of Spasticity Measure – Arabic (PRISM-Arabic).
Words in **Bold** font are those of interest in the adaptation process.
Words and sentences in *italic* style are the resulted backward translation from the forward translation synthesized version of the PRISM

Table 3.2. Demographic and Spinal Cord Injury-Related Characteristics of the Pilot Group [*n* , (%)], N=35

Age (mean ± *SD*)	30.8 ± 8.8
Gender	
Male	27 (77.1%)
Female	8 (22.9%)
No. of Years Injured (mean ± *SD*)	4.9 ± 3.6
Level of Injury	
Quadriplegic	9 (25.7%)
Paraplegic	26 (74.3%)
ASIA Classification	
A	14 (40%)
B	10 (28.6%)
C	9 (25.7%)
D	2 (5.7%)
Employment Status	
Employed	18 (51.4%)
Unemployed	17 (48.6%)
Marital Status	
Single	20 (57.1%)
Married	11 (31.4%)
Separated	3 (8.6%)
Widowed	1 (2.9%)
Education Completed	
High School and Below	19 (54.4%)
University and Higher Education	16 (45.8%)

n: Sample size, *SD*: Standard Deviation values

Table 3.3. Demographic Groups' Differences on the Number of Misunderstood Items Reported*

Groups	*Mean*	*SD*	*p*
Gender			
Male	0.33	1.18	0.14
Female	2	2.78	
Educational Level			
High School and below	1.25	2.22	0.02†
University or Higher Education	0	0	
Employment Status			
Employed	0.06	0.24	0.03†
Unemployed	1.41	2.37	
Level of Injury			
Quadriplegic	1	2	0.58
Paraplegic	0.62	1.7	
Type of Injury			
Complete Injury	1.36	2.59	0.16
Incomplete Injury	0.3	0.73	

***** This table represents the differences between groups within a demographical category. Means differences were analyzed using independent sample t-tests

† Significant difference ($p < .05$)

Table 3.4. Results from Pilot Testing Pre-Final Version of the PRISM-Arabic and Related Adaptation*

Item	Context from the original PRISM	No. of participants who reported unclear	Context from the pre-final version of the PRISM-Arabic and related issue of translational equivalence	Solution	Resulted change
5	Helped me keep my muscles **exercised**	6 participants	ساعدتني على إبقاء عضلاتي **ممرنه** Perceived as **trained** *Issue of vocabulary equivalence*	Added group of words	ساعدتني في الحفاظ **على نشاط وقوة عضلاتي**
14	Caused me to increase the amount of **prescription medication** I took	3 participants	**تسبب في زيادة كمية الأدوية الموصوفة التي أتناولها** Difficult to be distinguished from item 30 *Issue of experiential equivalence*	Rewording the whole sentence	جعلني أقوم بزيادة جرعة الدواء المسجل بالوصفة الطبية
30	Caused me to use **over-the-counter medications**	4 participants	جعلني أتناول أدوية لا تحتاج إلى وصفة طبية Difficulty to be distinguished from item 14 *Issue of experiential equivalence*	Rewording item 14 to clarify the differences between item 30 and item 14	No Change
38	Made **transfers** hard for me or my attendant	4 participants	جعلت **الانتقال** صعبا عليّ أو على مساعدي The word **transfer** alone in Arabic is broad and diffused *Issue of vocabulary equivalence*	Added **"from/to chair"** to refer to the actual transfer function	جعل الانتقال **من/إلى الكرسي** صعباً عليّ أو على مساعدي

*Frequencies of items that were sought to be unclear by participants, and how they have been linguistically and culturally adapted into Arabic language.
Words in **bold** style font are of interest in the translation and adaptation process.
Words in *italic* style font are issues of translational equivalence

CHAPTER IV

RELIABILITY AND VALIDITY OF THE ARABIC VERSION OF THE PATIENT REPORTED IMPACT OF SPASTICITY MEASURE (PRISM-ARABIC) IN SAUDIS WITH SPINAL CORD INJURY

ABSTRACT

Purpose: Psychometric properties of the Arabic version of the Patient Reported Impact of Spasticity Measure (PRISM-Arabic) were investigated in patients with spinal cord injury (SCI) presenting with spasticity in Saudi Arabia.

Materials and methods: Eighty-three Arabic-speaking patients completed the PRISM-Arabic and the Arabic Quality of Life Index-SCI (AQLI-SCI). Data were collected from participants' charts, including scores on the Functional Independence Measure–Motor subscale (FIM-Motor), Spinal Cord Injury Measure–III (SCIM-III), and Modified Ashworth Scale (MAS).

Results: Fifty-nine participants completed the PRISM-Arabic a second time. The PRISM-Arabic subscales showed adequate internal consistency (Cronbach's α = 0.73–0.95) for all subscales except for the Positive Impact and Need for Intervention subscales (0.64 and 0.61). All subscales showed adequate test-retest reliability ($ICC_{2,1}$ = 0.84–0.94), while the standard error of measurement ranged from 1.19–2.84 points, and the minimal detectable change ranged from 3.3–7.9 points. All subscales, except the Positive Impact subscale, correlated as hypothesized with AQLI-SCI, FIM-Motor, SCIM-III, and MAS scores (r_s absolute value = 0.3–0.6). PRISM-Arabic subscales,

except for the Positive Impact subscale, showed sound reliability and validity for assessing quality of life affected by spasticity in people with SCI. Factor analysis and responsiveness measurements are recommended for future studies.

INTRODUCTION

With no accurate figures available, all spinal cord injury (SCI) studies from Saudi Arabia have reported high prevalence and incidence rates compared with other nations.[1–7] Following SCI, patients present with a variety of sensorimotor complications including but not limited to spasticity. The frequency of spasticity after SCI has been observed to be 65–78% of individuals with chronic SCI.[8,9] Effects of spasticity can be perceived as both problematic and beneficial by persons with SCI.[10–13] Consequently, decisions regarding the treatment of spasticity must be based on the goal of achieving a balance between the positive and negative effects on a person's quality of life (QoL).[14–16]

Attempts have been made to standardize spasticity assessment in individuals with SCI, suggesting the use of a battery of tools to comprehensively evaluate the impact of spasticity. This may include clinician assessment tools and patient self-report tools to capture all aspects affected by spasticity. Therefore, Cook et al[17] developed the Patient Reported Impact of Spasticity Measure (PRISM) as a tool to measure the impact of abnormal muscle control or involuntary muscle movement in people with SCI complaining of spasticity. The PRISM assesses both positive and negative effects of spasticity and provides a more complete picture of the overall impact of spasticity on an individual.[15] It has been praised for its clear results as an objective QoL measure specific to SCI.[15,18–22]

To date, the PRISM has been translated and cross-culturally adapted into the Serbian language and used on individuals with multiple sclerosis[23] and into Arabic for people with SCI in Saudi Arabia (Chapter III – Study One). The Serbian-PRISM (PRISMSR) was deemed valid when correlated with the Modified Ashworth Scale (MAS) and Numerical Rating Scale (NRS) (r = 0.29-0.51) as well as reliable (Cronbach's α = 0.78-0.93 and test-retest $ICC_{2,1}$ = 0.82-0.90) for assessing the impact of spasticity in Serbian people with MS.[23] However, the psychometric properties of the PRISM-Arabic were not examined, diminishing its clinical utility and generalizability in those individuals living in a nation with one of the highest incidences of SCI around the world.[1,4,24–26]

The purpose of this study was to investigate the psychometric properties (internal consistency, test-retest reliability, measurement error, and construct validity) of the PRISM-Arabic in Arabic speakers with SCI presenting with spasticity in Saudi Arabia. Our hypotheses were that the PRISM-Arabic would show adequate internal consistency, test-retest reliability, and evidence of construct validity when correlated with functional, clinical, and self-report scales measuring different areas affected by spasticity.

PARTICIPANTS AND METHODS

Participants

Using a convenience sampling approach, patients who had recently been admitted for in-patient rehabilitation at King Fahad Medical City – Rehabilitation Hospital or Sultan Bin Abdulaziz Humanitarian City in Riyadh, Saudi Arabia were recruited for the study. Participants with SCI were included if they were adults (≥ 18

years of age), reported spasticity, were able to read, speak, and understand Arabic, had SCI onset that was more than three months from the day of testing, and their anticipated length of stay would be at least three weeks. Those who were pregnant or had SCI-related complications that might have interfered with their responses to the questionnaire were excluded from the study. All participants read and signed a written informed consent form for participation in the study that was approved by the Institutional Review Board of Texas Woman's University in Houston, Texas, USA, and the corresponding hospital where the participant was being treated.

Outcome Measures

Arabic Version of the Patient Reported Impact of Spasticity Measure. The PRISM-Arabic (see Appendix C) was adapted into Arabic language by addressing both linguistic and cultural factors while maintaining the integrity of the original English version developed by Cook et al.[17] It is a subjective health-related QoL measure that assesses the impact of altered motor control with respect to its seven subscales, which include Social Avoidance/Anxiety, Psychological Agitation, Daily Activities, Need for Assistance/Positioning, Positive Impact, Need for Intervention, and Social Embarrassment. There are 41 items that are responded to using a five-point Likert scale. Subscale scores are obtained by averaging item scores and multiplying by the number of items. The higher the score, the higher the negative impact reported by the respondent. The seven subscales can be scored independently because the impact of spasticity is considered multidimensional.[17] The PRISM demonstrated good reliability in terms of internal consistency (Cronbach's $\alpha = 0.74–0.96$) and reproducibility (*ICC* = 0.82–0.91). Further work is still required to establish

psychometric properties for its use with the SCI population, especially with respect to validity.[17]

Arabic Version of the Quality of Life Index – Spinal Cord Injury. Arabic Quality of Life Index – Spinal Cord Injury version (AQLI-SCI)[28–30] was developed specifically for people with SCI to measure both satisfaction with aspects of QoL and the importance of these aspects to an individual. There are four subscales: Health and Functioning, Social and Economic, Psychosocial/Spiritual, and Family. The higher the score, the better the QoL in the relevant domain. A total score can also be calculated. The AQLI-SCI has demonstrated sound psychometric properties and has been deemed to be clinically useful with Arabic speakers.[28–30]

Functional Independence Measure – Motor Subscale (FIM-Motor). The FIM-Motor[31–33] measures the level of a patient's disability and indicates how much assistance is required for the individual to carry out activities of transferring, locomotion, and navigating stairs. FIM-Motor scores can range from 13 to 91 with higher scores indicating more functional independence. The FIM-Motor shows excellent reliability and validity values when used in patients with SCI.[31–33]

The Spinal Cord Injury Measure-III (SCIM-III). The SCIM-III was developed specifically for people with SCI to evaluate their performance in activities of daily living. It consists of 19 items to assess three domains: self-care (feeding, bathing, dressing, grooming), respiration and sphincter management (respiration, bladder management, bowel management, use of toilet), and mobility (transfers and locomotion, indoor and outdoor). Scores range from 0 to 100.[34–36] In the present study, the subscales assessing respiration and sphincter management were excluded

due to the lack of relevancy. Therefore, the total score ranged from 0 to 90, with higher scores indicating more functional independence in self-care and general mobility.

Modified Ashworth Scale (MAS). The MAS[37–39] measures muscle hypertonia in patients with lesions of the central nervous system and has been commonly used to clinically measure spasticity. It tests resistance to passive joint movement with varying degrees of velocity. Scores range from 0 to 4 (0, 1, 1+, 2, 3, 4). A score of 0 indicates no resistance throughout the joint movement, while a score of 4 indicates rigidity. The average MAS score from all affected muscles was used in this study.[37–39]

Global Rating of Change (GRC). The GRC scale[40–42] is a subjective numerical rating of change scale that asks a person to assess his or her current health status (the impact of spasticity for this study) compared to his or her health status at a previous point in time. The magnitude of change is then scored on an 11-point integer scale ranging from -5 (*a great deal worse*) to +5 (*a great deal better*), with zero indicating no change. Participants used this scale to rate their perceived change in the impact of spasticity.[40–42]

Procedures

Data were collected in two sessions: at the initial rehabilitation assessment after admission and two to three days later. In the first session, 83 participants completed a questionnaire that included a demographic information sheet, the PRISM-Arabic, and the AQLI-SCI. FIM-Motor, SCIM-III, and MAS scores were also collected from each participant's chart by the treating physical or occupational

therapist. Therapists (seven physical therapists and three occupational therapists) were trained by the principal investigator and were asked to score their patients with the FIM-Motor, SCIM-III, and MAS on the same day of the first session. Fifty-nine participants completed the PRISM-Arabic a second time with 48 to 72 hours between administrations. They were also asked to rate the perceived change in their condition since the first session using the GRC. Patients with a GRC score of +1 (*tiny bit better, almost the same*), 0 (*no change*), and -1 (*tiny bit worse, almost the same*) were considered unchanged. Patients with an unchanged condition were included in the test-retest reliability assessment. For consistency, the same therapist was responsible for the administration and collection of all outcome measures in both sessions.

Data analyses

All data collected were used in the analysis and deemed to be free from outliers. Descriptive statistics for the demographic variables and PRISM-Arabic subscales were calculated. Cronbach's α was used to evaluate internal consistency reliability, where 0.70 to 0.95 was considered adequate reliability.[43]

The intraclass correlation coefficient for absolute agreement ($ICC_{2,1}$) was used to evaluate test-retest reliability; a minimum ICC level of 0.70 was considered adequate.[44] The standard error of measurement (SEM) was used to examine the measurement error associated with the test-retest, which was computed using the formula, $SEM = SD \times \sqrt{1 - ICC}$, where *SD* is the sample standard deviation and *ICC* is the test-retest interclass correlation coefficient.[44] The minimal detectable change with 95% confidence (MDC_{95}) was quantified to measure the true change in scores

that is beyond the measurement error. MDC_{95} was computed using the formula, $MDC_{95} = SEM \times 1.96 \times \sqrt{2}$.[44]

Spearman rank correlation coefficients were used to examine 11 correlational hypotheses for construct validation: (1) the AQLI-SCI would negatively correlate with Social Avoidance/Anxiety, Psychological Agitation, Need for Intervention, and Social Embarrassment of the PRISM-Arabic; (2) the SCIM-III and FIM-Motor would negatively correlate with Daily Activities, Need for Assistance/Positioning, and Positive Impact of the PRISM-Arabic; (3) the MAS would positively correlate with the PRISM-Arabic total scale. Correlation coefficients ≥ 0.30 were considered adequate,[45] while the construct validity was considered adequate when at least 75% (9 correlations) of the results corresponded with the hypotheses.[43] All data analyses were calculated using IBM SPSS Statistics for windows, version 25 (IBM Corp. Armonk, NY) and were deemed significant at $\alpha < 0.05$.

RESULTS

Table 4.1 provides details on the demographics and SCI-related characteristics of the participants. Forty-seven percent were classified as "A" based on the American Spinal Injury Association (ASIA) Impairment Scale, representing no sensory or motor function below the level of injury. Those classified as B, C, or D are deemed to have incomplete injuries with some amount of sensory and/or motor preservation present.[46] Table 4.2 provides descriptive information (number of items, potential range, mean score, and standard deviation) of all outcome measures used during admission.

Internal consistency reliability coefficients for most of the PRISM-Arabic subscales had adequate Cronbach's alpha levels ranging from 0.73 to 0.95, except for

the Positive Impact and the Need for Intervention subscales (α = 0.64 and 0.61, respectively). Regarding stability, results indicated good to excellent test-retest reliability for all subscales ($ICC_{2,1}$ = 0.84–0.94) (see Table 4.3). The subscales had a SEM ranging between 1.19 and 2.85 points, and a MDC_{95} ranging between 3.30 and 7.90 points.

Spearman rank correlation coefficients between the PRISM-Arabic subscales and the AQLI-SCI, FIM-Motor, SCIM-III, and MAS scores are reported in Table 4.4. All hypothesized correlations were significant (r_s absolute value = 0.30–0.60, $p <$ 0.05), except for the Positive Impact subscale, which showed no significant correlations with FIM-Motor (r = -0.14, p = 0.15) and SCIM-III (r = -0.20, p = 0.06) scores. Of the 11 hypothesized correlations, nine were supported (82%), which exceeds the 75% threshold set for evaluating the validity of the PRISM-Arabic.

DISCUSSION

The purpose of this study was to investigate the psychometric properties of the PRISM-Arabic in Arabic speakers with SCI who presented with spasticity in Saudi Arabia. The findings of this study may guide further development and clinical application of the PRISM in this population. The internal consistency of the PRISM-Arabic, as assessed by Cronbach's α, was acceptable to excellent for five of the seven subscales. However, the Positive Impact and Need for Intervention subscales had coefficients that were in the low range. Cronbach's alpha was the highest for Social Avoidance/Anxiety (11 items) and the lowest for Positive Impact (4 items) and Need for Intervention (5 items). Thus, the lower reliability is partly explained by scales with

fewer items often yielding a lower Cronbach's alpha.[47] The values also correspond to the Cronbach's alpha values found with the Serbian version of the PRISM.[23]

Good to excellent test-retest reliability of the PRISM-Arabic scores were also found. This result is consistent with the findings from the original PRISM.[17] In the current study, participants who were retested were asked to complete the GRC scale. This step was necessary to ensure that their condition in the retest part of the study remained unchanged, and therefore, they were appropriate for the analysis. Moreover, the SEM of the subscales ranged between 1.19 and 2.85 points, while the MDC_{95} ranged between 3.3 and 7.9 points. These values seem to be clinically applicable. However, further testing of the PRISM-Arabic's sensitivity to change over time while patients are under treatment and estimating its minimal clinically important difference (MCID) would further enhance the clinical interpretation of the change in scores.

The study examined the construct validity of the PRISM-Arabic with the most common scales used with this population measuring the same constructs of different areas impacted by spasticity. Construct validity was determined by correlating the subscales with the AQLI-SCI, FIM-Motor, SCIM-III, and MAS. The resultant correlation analyses showed significant results that support the construct validity of the PRISM-Arabic. The Positive Impact subscale, however, did not correlate with any of the four scales. As previously mentioned with regard to internal consistency reliability, with so few items, one would expect low correlation values.[47]

The correlation analyses as part of construct validation used in this study were different from the analyses done to test the validity of the Serbian version of the PRISM. The researchers correlated the subscales with the MAS and the Numeric

Rating Scale (NRS) as a measure of spasticity. Four subscales significantly correlated with the MAS (i.e., Psychological Agitation, Daily Activities, Need for Assistance/Positioning, and Need for Intervention). All subscales, except for Positive Impact, significantly correlated with the NRS.[23] Regardless of the differences between the two approaches, these findings agree with our results in that the Positive Impact subscale did not correlate significantly with the other scales. Therefore, the beneficial impact of spasticity may be a new area of interest measured by the PRISM that may have no similar scale measuring the same construct, in attempting to describe the positive experience of a person with SCI presenting with spasticity.

Study Limitations

The current study has limitations that warrant consideration. Construct validity was evaluated using correlational analysis,[48] while confirmatory factor analysis would be desired as well to evaluate structural validity whenever a scale is translated into another language or validated in a new population.[49] Additionally, one must note that the construct validity of the PRISM-Arabic is not optimal because patient-reported outcomes have no gold standard (criterion). Finally, all participants were Saudi Arabian citizens; thus, recommendations to use the PRISM-Arabic in different Arabic countries may require additional formal measurement properties testing.

Clinical Implementation and Future Studies

The PRISM-Arabic demonstrated sound psychometric properties, and therefore, can be used as an assessment tool measuring the impact of spasticity on Arabic speakers with SCI. However, the Positive Impact subscale should be used cautiously when interpreting the positive experience of a person with spastic SCI

given the subscale's questionable reliability and validity. The structural validity of the PRISM-Arabic needs to be examined in future studies. Additionally, for the PRISM-Arabic to be useful in clinical practice, it should be able to detect change in patients' status during treatment. Therefore, establishing the magnitude of change in scores on the PRISM-Arabic considered by patients is important, as with the MCID, will enhance the clinical relevance of the scale and will help clinicians in deciding whether the change in a patient's score is clinically relevant.

CONCLUSION

The PRISM-Arabic showed adequate reliability and validity for assessing the subjective impact of spasticity on quality of life in people with SCI. Future studies should confirm its factor structure using factor analysis and determine its responsiveness to change.

Table 4.1. Demographic and Spinal Cord Injury-Related Characteristics [*n* (%)], *N* = 83

Age (mean ± *SD*)	30.18 ± 12
Gender	
Male	53 (63.9%)
Female	30 (36.1%)
No. of Years Injured (mean ± *SD*)	5.12 ± 4.37
Level of Injury	
Quadriplegic	28 (33.7%)
Paraplegic	55 (66.3%)
ASIA Classification	
A	39 (47%)
B	18 (21.7%)
C	13 (15.7%)
D	13 (15.7%)
Employment Status	
Employed	36 (43.4%)
Unemployed	47 (56.6%)
Marital Status	
Single	43 (51.8%)
Married	31 (37.3%)
Separated	5 (6%)
Widowed	4 (4.8%)
Education Completed	
High School and Below	48 (57.8%)
University and Higher Education	35 (42.2%)

SD, standard deviation.

Table 4.2. Descriptive Statistics During Admission for PRISM-Arabic Subscales, AQLI-SCI, FIM-Motor, SCIM-III, and MAS: Number of Items, Range, Mean, and Standard Deviation

Outcome Measure	Number of Items	Potential Range	Mean ± *SD*
PRISM-Arabic			
Social Avoidance/Anxiety	11	0-44	11.24 ± 11.63
Psychological Agitation	5	0-20	7.09 ± 5.13
Daily Activities	6	0-24	7.10 ± 5.23
Need for Assistance/Positioning	5	0-20	6.54 ± 4.66
Positive Impact[a]	4	0-16	10.52 ± 3.62
Need for Intervention	5	0-20	6.03 ± 3.98
Social Embarrassment	5	0-20	6.26 ± 5.38
AQLI-SCI	37	0-30	17.70 ± 2.80
FIM-Motor	13	13-91	49.29 ± 19.91
SCIM-III	14	0-90	50.86 ± 22.31
MAS	N/A	0-4	2.47 ± 1.18

SD, Standard Deviation.

[a]Reverse scored (0 = very often true for me; 4 = never true for me)

Table 4.3. Cronbach's Alpha, Interclass Coefficients ($ICC_{2,1}$), 95% Confidence Interval, Standard Error of Measurement (SEM), and Minimal Detectable Change (MDC_{95}) for Each Subscale in The Arabic Version of The Patient Reported Impact of Spasticity Measure (PRISM-Arabic)

PRISM-Arabic subscale	Cronbach's α	*ICC*	95% Confidence Interval	*SEM*	MDC_{95}
Social Avoidance/Anxiety	0.95	0.94	0.89 - 0.96	2.85	7.90
Psychological Agitation	0.82	0.90	0.84 - 0.94	1.62	4.49
Daily Activities	0.83	0.93	0.88 - 0.96	1.39	3.85
Need for Assistance/Positioning	0.73	0.87	0.78 - 0.92	1.68	4.66
Positive Impact[a]	0.64	0.84	0.73 - 0.91	1.45	4.02
Need for Intervention	0.61	0.91	0.85 - 0.95	1.19	3.30
Social Embarrassment	0.86	0.91	0.85 - 0.95	1.64	4.55

ICC, interclass correlation coefficient; *SEM*, standard error of measurement; MDC_{95}, minimal detectable change with 95% confidence.
[a]Reverse scored (0 = very often true for me; 4 = never true for me)

Table 4.4. Construct validity correlations of the PRISM-Arabic and its subscales with the AQLI-SCI, FIM-Motor, SCIM-III, and MAS

	AQLI-SCI		FIM-Motor		SCIM-III		MAS	
PRISM-Arabic scales	*r*	*p*-value	*r*	*p*-value	*r*	*p*-value	*r*	*p*-value
Social Avoidance/Anxiety	**-0.56***	**< 0.01**	-0.19	0.07	-0.12	0.19	0.25*	0.03
Psychological Agitation	**-0.46***	**< 0.01**	-0.34*	< 0.01	-0.27*	0.02	0.38*	< 0.01
Daily Activities	-0.41*	< 0.01	**-0.42***	**< 0.01**	**-0.3***	**0.01**	0.32*	< 0.01
Need for Assistance/Positioning	-0.21*	0.05	**-0.59***	**< 0.01**	**-0.51***	**< 0.01**	0.31*	< 0.01
Positive Impact[a]	0.027	0.42	**-0.14**	**0.15**	**-0.2**	**0.06**	-0.17	0.10
Need for Intervention	**-0.30***	**0.01**	-0.17	0.09	-0.10	0.22	0.22*	0.05
Social Embarrassment	**-0.47***	**< 0.01**	-0.22*	0.05	-0.14	0.15	0.39*	< 0.01
PRISM-Arabic Total Scale	-0.48*	< 0.01	-0.4*	< 0.01	-0.32*	< 0.01	**0.30***	**0.01**

PRISM-Arabic, Arabic Version of the Patient Reported Impact of Spasticity Measure; AQLI-SCI, Arabic Version of the Quality of Life Index-Spinal Cord Injury Version (III); FIM-Motor, Functional Independence Measure-Motor subscale; SCIM-III, Spinal Cord Injury Measure (III); MAS, Modified Ashworth Scale; *r*, Spearman rank correlation coefficient.
[a]Reverse scored (0 = very often true for me; 4 = never true for me)
Bold values are correlations of interest (hypothesized).
*Significant at 0.05

CHAPTER V

RESPONSIVENESS TO CHANGE OF THE ARABIC VERSION OF THE PATIENT REPORTED IMPACT OF SPASTICITY MEASURE(PRISM-ARABIC) IN SAUDIS WITH SPINAL CORD INJURY

ABSTRACT

Purpose: To investigate responsiveness to change of the Patient Reported Impact of Spasticity Measure (PRISM-Arabic) of patients with spinal cord injury (SCI) with spasticity in Saudi Arabia.

Materials and methods: Fifty Arabic-speaking in-patients completed the PRISM-Arabic and Arabic Quality of Life Index-SCI (AQLI-SCI). Functional Independence Measure–Motor subscale (FIM-Motor), Spinal Cord Injury Measure–III (SCIM-III), and Modified Ashworth Scale (MAS) scores were collected from charts. All data were collected twice, at admission and discharge.

Results: There were no significant changes in any PRISM-Arabic subscale mean scores between admission and discharge using paired sample *t*-tests ($p < 0.05$) that reflected small effect sizes (*ES* = 0-0.17). No subscales, except for the AQLI-SCI with the Social Avoidance/Anxiety subscale of the PRISM-Arabic (r_s = -0.29, p = 0.02), were significantly correlated with the AQLI-SCI, FIM-Motor, SCIM-III, MAS, and GRC scores. The receiver operating characteristic (ROC) curve showed that the PRISM-Arabic total score did not distinguish between those patients who had improved impact of spasticity and those who did not.

Conclusion: The PRISM-Arabic is not sensitive to changes in the subjective impact of spasticity on quality of life in people with SCI over time after rehabilitation. Future research should study its structural validity.

INTRODUCTION

Spasticity is a complication that is observed in 65-78% of individuals with chronic SCI.[1,2] It is a changing phenomenon that makes it difficult to be measured accurately with a clear and consistent objective measure, particularly in the clinical field.[3] Healthcare professionals attempt to assess it comprehensively using a battery of tools, including clinician-rated and patient-reported outcome measures. However, there is a discrepancy between patient-reported and clinician-rated outcomes that measure spasticity.[4] Standardizing spasticity assessment by using both approaches is an imperative clinical practice to detect, analyze, and understand its severity and impact, and to determine the effectiveness of treatment techniques.

Cook et al[5] developed the Patient Reported Impact of Spasticity Measure (PRISM) in 2007. It is an objective quality of life (QoL) measure specific to people with SCI who report spasticity. It assesses the overall impact of spasticity with clear results including negative and positive effects caused by the spasticity.[6–11] The PRISM has shown good reliability and validity values when used in patients with SCI. It has been translated and culturally adapted into Serbian and Arabic languages.[12,13] Both translated versions have also showed sound psychometric properties, including internal consistency, test-retest reliability, and construct validity. However, no study has evaluated the PRISM's (or any of its other translated versions) ability to detect changes over time (responsiveness) in its respective construct.[14]

For some researchers, responsiveness is considered to be the most essential property of an evaluative instrument and should be considered as a stand-alone property when selecting a QoL measuring tool.[14,15] However, a clear and thorough methodology of its assessment is still arguable. Husted et al[16] provided a guideline to investigate an instrument's sensitivity to change by assessing its internal responsiveness (the ability of an instrument to change in response to interventions over time with regard to the statistical significance of the change of scores), and external responsiveness (comparing changes in an instrument to a valid reference tool in the construct to be measured). The Consensus-based Standards for selection of Health Measurement Instruments (COSMIN) recommended the use of a correlational approach with pre-defined hypotheses to measure external responsiveness.[17–19]

The researchers of this study believe that using a thorough design to measure the responsiveness of the PRISM-Arabic will add important information regarding its clinical applicability. Therefore, the purpose of this study was to investigate the PRISM-Arabic's responsiveness in patients with SCI reporting spasticity using the two approaches discussed (internal and external).

METHODS AND MATERIALS

A prospective, within-group cohort study design was used. The study was approved by the Institutional Review Boards of Texas Woman's University – Houston Campus, and the corresponding hospital where the participant was being treated. All participants provided written informed consent prior to participation in the study.

Participants

Patients with SCI who reported spasticity were recruited using convenience sampling from Sultan Bin Abdulaziz Humanitarian City and King Fahad Medical City in Riyadh, Saudi Arabia, where they received in-patient rehabilitation services. The inclusion criteria were: 1) adult (≥18 years of age); 2) able to read, speak and understand Arabic; 3) at least three months post onset; and 4) anticipated length of stay to be at least three weeks. Participants were excluded from the study if they were pregnant or had any complication that might interfere with their responses to the questionnaire. The sample size was determined based on the recommendations given by the COSMIN checklist[20] for a good responsiveness analysis.

Procedures

Data were collected in two sessions, during the three-day initial evaluation period from admission and before discharge. At the baseline session, demographic data were collected, and participants completed the PRISM-Arabic and the Arabic Quality of Life Index-SCI version (AQLI-SCI). The Functional Independence Measure-Motor subscale (FIM-Motor), Spinal Cord Injury Measure-III (SCIM-III), and Modified Ashworth Scale (MAS) scores were collected from each participant's chart by the treating therapist. All participants received in-patient traditional rehabilitation therapy services (including physical therapy and occupational therapy). Depending on the goals set by the rehabilitation team, some participants received oral anti-spastic medications (baclofen and/or dantrolene) for their spasticity. None of the study participants had received anti-spastic injections, surgeries or other types of aggressive spasticity management.

At discharge, participants completed the PRISM-Arabic and the AQLI-SCI, while FIM-Motor, SCIM-III and MAS scores were collected from their charts. Also, participants were asked to rate the change in their condition (impact of spasticity) since the first session using the Global Rating of Change (GRC) scale.

Outcome measures

Arabic version of the Patient Reported Impact of Spasticity Measure. The PRISM-Arabic[13] (Chapter Three) is a patient-reported measure that subjectively assesses the impact of altered motor control on QoL. It consists of seven subscales; Social Avoidance/Anxiety, Psychological Agitation, Daily Activities, Need for Assistance/Positioning, Positive Impact, Need for Intervention, and Social Embarrassment.[21] It has 41 items with a five-point Likert scale. Subscale scores are obtained by averaging item scores and multiplying by the number of items. Higher scores on the PRISM corresponds to more negative impact reported by the respondent. The seven subscales of the PRISM can be scored independently since the impact of spasticity is considered multidimensional [5].

The PRISM-Arabic[22] (Chapter Four) has demonstrated adequate internal consistency (Cronbach's α = 0.73-0.95) in all its subscales except for the Positive Impact and Need for Intervention subscales (0.64 and 0.61, respectively). Also, all its subscales showed adequate reproducibility ($ICC_{2,1}$ = 0.84-0.94) with a standard error of measurement ranging from 1.19-2.85 points and a minimal detectable change ranging from 3.3-7.9 points. Also, the construct validity of all its subscales, except for the Positive Impact, were found to be adequate when correlated with the AQLI-SCI, FIM-Motor, SCIM-III and MAS scores (r_s = 0.3-0.6).[22]

Arabic version of the Quality of Life Index–Spinal Cord Injury (AQLI-SCI). The AQLI-SCI[23] is a questionnaire that was developed specifically for people with SCI to measure the satisfaction and importance levels in an individual with respect to five domains: overall QoL; health and functioning; social and economic; psychosocial/spiritual; and family subscales. The total AQLI-SCI score ranges from 0-30 (higher scores indicate better QoL). The Arabic QLI showed sound psychometric properties and was deemed to be clinically useful with Arabic speakers[24,25]

Functional Independence Measure™ – Motor Subscale (FIM-Motor). The FIM-Motor[26] measures the level of independence of a patient's functional transfers, locomotion, and stairs activities. The total FIM-Motor™ score ranges from 13-91 (higher FIM-Motor scores indicate greater functional independence). Researchers reported excellent reliability and validity values when used with SCI.[27–29]

The Spinal Cord Injury Measure-III (SCIM-III). The SCIM-III[30] assesses the performance of a patient's activities of daily living including self-care; respiration and sphincter management; and mobility. For the purpose of this study's objectives, the respiration and sphincter management domain of the SCIM-III was excluded. The resulting partial SCIM-III total score ranged from 0-90 (higher scores indicated greater functional independence in self-care and general mobility).[30–32] Still, with the exclusion of the respiration and sphincter management domain, the SCIM-III was shown to have excellent reliability and validity values when used with patients with SCI.[30]

Modified Ashworth Scale (MAS). The MAS[33] is a commonly used clinical assessment tool to measure muscle hypertonia in patients with lesions of the central

nervous system. It tests resistance to passive movement about a joint with varying degrees of velocity using a 6-point scale (0, 1, 1+, 2, 3, 4), where a score of 0 indicates no resistance throughout the joint movement and a score of 4 indicates rigidity. For the purpose of this study, the average MAS score from all affected muscles was used.[33–35]

Global Rating of Change (GRC). The GRC[36] scale is a subjective numerical scale used to assess patient-rated perception of any change in the impact of spasticity after rehabilitation. The magnitude of the improvement, no change, or deterioration is then scored on an 11-point Likert scale. It ranges from "a great deal worse (-5)" to "a great deal better (+5)" with zero indicating no change.[36–38]

Statistical Procedures and Data Analysis

Descriptive statistics, including means, percentages and/or standard deviations for demographic data for all participants were calculated to describe the study sample (see Table 5.1). Change scores in all measures after treatment were calculated by subtracting the scores from admission from those obtained at discharge (see Table 5.2).

The internal responsiveness of the PRISM-Arabic was evaluated by using a paired sample *t*-test between its subscale admission scores and discharge scores and by calculating the effect size (ES) (see Table 5.2). The ES calculation was done by dividing the mean change scores of the PRISM-Arabic subscales by the standard deviation of their corresponding baseline score. ES values of ≤0.2, 0.5, and ≥0.8 were considered small, medium, and large effects, respectively.[16,39]

The external responsiveness of the PRISM-Arabic was assessed using a hypothesis testing approach. This was done by treating the responsiveness as a longitudinal form of construct validity.[40] Thus, we formulated pre-defined correlation hypotheses between the changes in the PRISM-Arabic scores and the changes observed in the AQLI-SCI, the FIM-Motor, the SCIM-III, and the MAS scores. Hypotheses were formulated based on the similarity in the construct of the different domains and previously found results for the construct validity of the PRISM-Arabic.[22] The Spearmen rank correlation coefficient (r_s) was used to analyze the relationships between scales. Twelve correlation hypotheses were formulated as follows: 1) correlating the AQLI-SCI score change with the score changes in the following PRISM-Arabic subscales: Social Avoidance/Anxiety, Psychological Agitation, Need for Intervention, and Social Embarrassment (expecting a negative relationship); 2) correlating the score changes of both the SCIM-III and the FIM-Motor™ with the score changes of the following PRISM-Arabic subscales – Daily Activities, Need for Assistance/Positioning, Positive Impact (expecting negative relationship); 3) correlating the total score change of the PRISM-Arabic with the score change of the MAS and the GRC scale (expecting negative relationship).

To evaluate the results of the hypothesis testing, we used the following criteria: high responsiveness when less than 25% (2 correlations out of 12) of hypotheses are refuted, moderate responsiveness when 25–50% (3-6 correlations) are refuted and poor responsiveness when more than 50% (more than 6 correlations) are refuted.[41]

Additionally, the external responsiveness of the PRISM-Arabic was determined using the receiver-operating characteristic (ROC) curve to distinguish those who have improved from those who remained the same or worsened based on the GRC. A cutoff of ≥ 2 in the GRC was selected to classify patients as improved (had clinically meaningful change) and < 2 as not improved (no clinically meaningful change). An area under the curve (AUC) of at least 0.7 was considered adequate.[42] The point on the ROC curve nearest to the upper-left corner of the curve, representing the highest sensitivity and (1− specificity) values, was used to estimate the minimum clinically important difference (MCID) for the total score of the PRISM-Arabic.

All data analyses were calculated using IBM® SPSS® Statistics for windows, version 25 (IBM Corp. Armonk, NY), and were deemed significant at $\alpha < 0.05$.

RESULTS

Fifty patients with SCI who reported spasticity participated in this study. Their demographic and SCI-related characteristics are reported in Table 5.1. Forty participants (80%) received oral anti-spastic medications (baclofen and/or dantrolene) for their spasticity during their time in the study. Mean admission scores, discharge scores, and score change, along with their corresponding standard deviations for all outcome measures, are shown in Table 5.2. Paired sample *t*-tests of mean scores over time between admission and discharge showed no significant changes in both patient-reported outcome measures (PRISM-Arabic subscales and AQLI-SCI). However, statistical differences were found in all clinician-rated outcomes (FIM-Motor, SCIM-III, and MAS) ($p < 0.05$). ES values for all outcome measures are also reported in table 5.2.

Table 5.3 shows the correlation matrix for all outcome variables included in this study to evaluate the responsiveness to change of the PRISM-Arabic. None of the hypothesized correlations were significant, except for the AQLI-SCI with the Social Avoidance/Anxiety subscale of the PRISM-Arabic (r_s = -0.29, p = 0.02).

The GRC on the impact of spasticity in general identified 36 (72%) participants who reported a clinically meaningful improvement compared with 14 (28%) who reported no improvement. Using these two groups, a ROC curve was plotted for the PRISM-Arabic total change of scores against the GRC scores (see Figure 1-A). The result was not significant (AUC = 0.57, p = 0.44, 95% *CI* = 0.40-0.75). A subsequent ROC curve was plotted for the PRISM-Arabic total change of scores against the GRC scores only for those who received oral medication along with the traditional rehabilitation (see Figure 1-B). Still, a non-significant result was found (AUC = 0.55, p = 0.67, 95% *CI* = 0.35-0.74).

DISCUSSION

The purpose of this study was to evaluate the responsiveness to change of the PRISM-Arabic in patients with SCI reporting spasticity in Saudi Arabia who received in-patient rehabilitation. In the present study, the responsiveness of the PRISM-Arabic was assessed by examining its internal and external responsiveness statistics according to the guidelines suggested by Husted et al.[16]

In the current study, the internal responsiveness was assessed using paired sample *t*-tests of the PRISM-Arabic subscale score differences between admission and discharge. The results showed no significant changes between the two periods. These findings suggest that the PRISM-Arabic did not detect any patient-reported changes

on the impact of spasticity after rehabilitation. Also, the small ES values reported for PRISM-Arabic subscales (ES = 0-0.17) may provide further information that an actual lack of treatment effect can be seen using these scales on patients with SCI reporting spasticity.

The external responsiveness was evaluated using a correlation approach as a method of longitudinal construct validity. Pre-defined correlation hypotheses were formulated to assess how changes in PRISM-Arabic subscales over time were related to corresponding changes in reference measures of a construct. The AQLI-SCI, FIM-Motor, SCIM-III, and MAS were chosen to represent these reference measures of construct because they are commonly used with SCI. The GRC score was used as an external anchor for the construct of interest (overall change in the impact of spasticity). The results showed only one significant relationship (out of 11 hypothesized) between the Social Avoidance/Anxiety subscale of the PRISM-Arabic and the AQLI-SCI. These findings suggest that the PRISM-Arabic may not detect changes in the impact of spasticity over time.

Also, the ROC curve was plotted for the PRISM-Arabic total scores against all study participants' responses to the GRC scale. The resultant AUC score was not significant, indicating inability of the PRISM-Arabic to distinguish those patients who improved and those who did not. As a result, an optimal efficient cutoff point of improvement could not be determined. Even after removing participants who were not on anti-spastic medication, the result of the secondary analysis was not much different.

Although not intended, patients recruited for this study, received traditional rehabilitation and oral anti-spastic medication. For such conservative treatment, one would not expect to have large variations in the impact of spasticity on QoL. However, a more aggressive type of spasticity management (e.g.; botox injections, baclofen pump transplant, or spinal stimulation) may have a tendency to cause more obvious perception of spasticity release by patients.[43–45]

The results reveal another point of discussion when comparing patient-reported measures (PRISM-Arabic and AQLI-SCI) with clinician-rated measures (FIM-Motor, SCIM-III, and MAS) used in this study. While both patient-reported measures had non-significant results throughout all statistical analyses used to evaluate responsiveness, clinician-rated outcome measures (FIM-Motor, SCIM-III, MAS) were found to be significantly sensitive to capture changes that occurred in these patients following rehabilitation. These findings (excluding the MAS) fall in line with the literature reporting the sensitivity to change of these outcomes with respect to their constructs to be measured.[46,47]

Self-report instruments are typically the most preferred and valid form of measurement when assessing a person's opinion.[48] However, subjects' responses may not be a valid indicator of the concept that one is intending to measure.[17] Research has identified response problems and misclassification errors that may bias credibility. One in particular is the response fatigue that is associated with long questionnaires. Hyland[49] argued that in a longitudinal study, a relatively short scale (not more than 30-40 items) is most likely to be used. In the current study, patients responded to two questionnaires that had a total of 115 items both times data were collected (at

admission and before discharge). Although not tested, the longevity of the responding period may have led respondents to answer in such a way (not providing truthful or consistent responses) as to reduce the length of the survey.[50] Hence, researchers should consider how the length of the survey questionnaire over time can impact inferences.

Measuring the responsiveness in QoL may require a longer period between responses in order for a change to become more prominent to responders.[51] In this study, the time between data collection sessions in this study were relatively short (approximately 40 days) for a sensible change on the impact of spasticity to be detected. Consequently, an optimal evaluation to the PRISM-Arabic's responsiveness was hindered.

The PRISM-Arabic had good psychometric values when tested in cross-sectional studies.[22] This evidence demonstrates its suitability to discriminate patients with great impact of spasticity from those less impacted.[49] However, its sensitivity to changes over time is questionable given the need for longer and more aggressive spasticity management to cause greater changes to be perceived.

Clinical Implementation and Future Studies

An outcome measure is preferred to be reliable, valid, and responsive to change. The PRISM-Arabic has been previously evaluated in Arabic speakers with SCI reporting spasticity and showed good reliability and validity.[22] However, the current study showed its poor responsiveness to changes in the impact of spasticity. Thus, in clinical settings, the PRISM-Arabic is helpful for deciding whether or not to treat spasticity, or to assist in clinical decision making when choosing the best

practical spasticity management. Yet, the PRISM-Arabic may not detect changes in the impact of spasticity that occur over time after treatment.

In research trials, the PRISM-Arabic can be helpful in cross-sectional studies because it consists of a full and varied range of items describing relevant issues affected by spasticity (positively and negatively), which apply to the kind of discrimination needed. In longitudinal studies, however, the PRISM-Arabic may fail to produce a meaningful implication.

Future studies should evaluate the PRISM-Arabic's structural validity and the possibility that a shorter list of items may be valid and reliable in measuring its construct. We believe that doing so may not only confirm its factor structure but may also improve its clinical applicability by preventing the response fatigue phenomena that may have affected our sample. Also, examining the responsiveness of the PRISM-Arabic with patients receiving more aggressive spasticity management may provide larger effect sizes that can lead to better patients' perception of spasticity release.

CONCLUSION

The PRISM-Arabic is not sensitive to changes over time in the subjective impact of spasticity on quality of life in people with SCI after rehabilitation. Future research should study its structural validity.

Table 5.1. Demographic and Spinal Cord Injury-Related Characteristics of the Sample [*n* , (%)], N=50

Age (mean ± *SD*)	30.42 ± 14.12
Gender	
Male	22 (44%)
Female	28 (56%)
No. of Years Injured (mean ± *SD*)	4.98 ± 4.86
Length of Stay in Days (mean ± *SD*)	40.86 ± 8.06
Level of Injury	
Tetraplegic	17 (34%)
Paraplegic	33 (66%)
ASIA Classification	
A	27 (54%)
B	8 (16%)
C	6 (12%)
D	9 (18%)
Employment Status	
Employed	14 (28%)
Unemployed	36 (72%)
Social Status	
Single	26 (52%)
Married	17 (34%)
Separated	3 (6%)
Widowed	4 (8%)
Education Completed	
High School and Below	31 (62%)
University and Higher Education	19 (38%)
Spasticity Medication	
Oral medication Non-received	10 (20%)
Oral medication received	40 (80%)

n: Sample size, *SD*: Standard Deviation values

Table 5.2. Change of Scores in Outcome Measures and Related Subscales

Outcome Measure and Subscales	Range of Scores	Admission Scores Mean ±*SD*	Discharge Scores Mean ±*SD*	Change of Scores Mean ±*SD*	Paired Sample *t*-value	*p*-value	Standardized Effect Size
PRISM-Arabic							
Social Avoidance/Anxiety	0-44	11.64 ±13.04	11.14 ±12.10	-0.48 ±7.12	0.50	0.62	-0.04
Psychological Agitation	0-20	7.39 ±5.30	6.58 ±5.26	-0.89 ±3.58	1.57	0.12	-0.17
Daily Activities	0-24	7.77 ±6.24	7.46 ±6.55	0.02 ±4.84	0.50	0.62	0.00
Need for Assistance/Positioning	0-20	7.85 ±5.24	7.44 ±4.96	-0.43 ±4.16	0.70	0.49	-0.08
Positive Impact	0-16	10.26 ±4.42	10.31 ±4.18	0.13 ±3.77	-0.09	0.93	0.03
Need for Intervention	0-20	6.57 ±5.15	6.73 ±5.32	0.41 ±3.00	-0.34	0.74	0.08
Social Embarrassment	0-20	6.72 ±6.19	6.27 ±6.28	-0.21 ±3.85	1.01	0.32	-0.03
Total PRISM-Arabic	0-205	55.66 ±34.83	53.28 ±35.14	-2.39 ±17.79	0.97	0.34	-0.07
AQLI-SCI	0-30	17.74 ±3.07	17.75 ±3.90	0.53 ±3.22	-0.02	0.98	0.17
FIM-Motor	13-91	46.10 ±18.53	54.75 ±18.95	8.75 ±7.58	-7.95	<0.05*	0.47
SCIM-III	0-90	48.54 ±21.93	56.34 ±21.25	7.92 ±7.77	-7.26	<0.05*	0.36
MAS[b]	0-5	2.51 ±1.17	2.26 ±1.35	-0.24 ±0.96	-2.68[c]	<0.05*	-0.21

PRISM-Arabic: Arabic Version of the Patient Reported Impact of Spasticity Measure
[a] Reverse scoring (0 = very often true for me; 4 = never true for me)
AQLI-SCI: Arabic Version of the Quality of Life Index-Spinal Cord Injury Version (III), FIM-Motor: Functional Independence Measure-Motor Subscale
SCIM-III: Spinal Cord Injury Measure (III), MAS: Modified Ashworth Scale
[b] MAS scores ranked from 0 to 5 as follows (sore of 0 = 0 in MAS, score of 1 = 1 in MAS, score of 2 = 1.5 in MAS, score of 3 = 2 in MAS, score of 4 = 3 in MAS, score of 5 = 4 in MAS)
[c] Wilcoxon Signed Ranks Test (*z*-statistic)
* Significant at $\alpha = 0.05$

Table 5.3. Correlations of the change of scores in the Arabic version of the Patient Reported Impact of Spasticity Measure and Its Subscales with the Change of Scores in the Arabic Version of the Quality of Life Index-Spinal Cord Injury Version (III), Functional Independence Measure-Motor Subscale, Spinal Cord Injury Measure (III), Modified Ashworth Scale, and Global Rating of Change.

PRISM-Arabic Subscale	AQLI-SCI		FIM-Motor		SCIM-III		MAS		GRC	
Change of Scores	*r*	*p*-value	*r*	*p*-value	*r*	*p*-value	*r*	*p*-value	*r*	*p*-value
Social Avoidance/Anxiety	**-0.29***	**0.02**	-0.07	0.31	0.09	0.26	-0.15	0.15	0.13	0.38
Psychological Agitation	**-0.09**	**0.27**	0.01	0.49	0.08	0.29	-0.03	0.42	-0.07	0.64
Daily Activities	-0.04	0.39	**-0.21**	**0.07**	**-0.07**	**0.32**	0.08	0.29	0.10	0.50
Need for Assistance/Positioning	-0.07	0.32	**-0.02**	**0.44**	**0.09**	**0.28**	-0.15	0.15	-0.16	0.28
Positive Impact[a]	-0.11	0.22	**-0.11**	**0.22**	**0.05**	**0.38**	0.39*	< 0.01	0.04	0.81
Need for Intervention	**0.09**	**0.26**	-0.05	0.37	-0.05	0.36	-0.14	0.16	-0.14	0.35
Social Embarrassment	**-0.07**	**0.33**	-0.06	0.33	-0.07	0.31	0.07	0.32	-0.15	0.29
PRISM-Arabic Total	-0.19	0.10	-0.12	0.20	-0.02	0.46	**-0.09**	**0.27**	**-0.11**	**0.45**

PRISM-Arabic: Arabic Version of the Patient Reported Impact of Spasticity Measure
AQLI-SCI: Arabic Version of the Quality of Life Index-Spinal Cord Injury Version (III)
FIM-Motor: Functional Independence Measure-Motor Subscale
SCIM-III: Spinal Cord Injury Measure (III)
MAS: Modified Ashworth Scale
GRC: Global Rating of Change
[a]Reverse scores (0 = very often true for me; 4 = never true for me)
*Significant at $\alpha = 0.05$
Bold values are correlations of interest

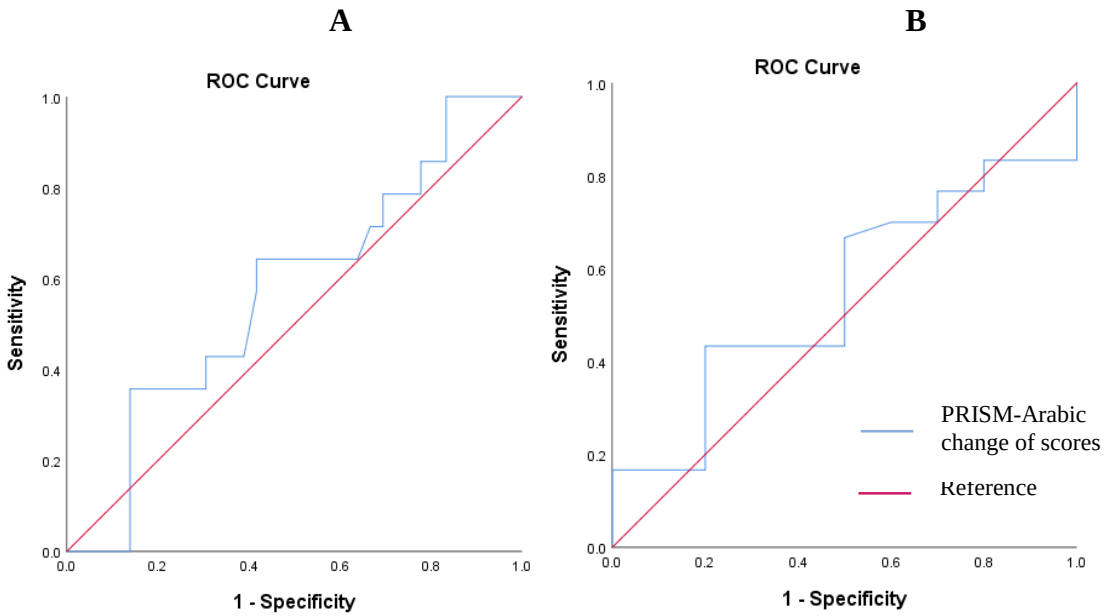

Figure 5.1. Receiver Operator Characteristic Curve (ROC) of the Arabic Version of the Patient Reported Impact of Spasticity Measure (PRISM-Arabic) Total Change of Scores Using the External Criterion of Global Rating of Change Scale Dichotomized as Improved and Non-improved. **A)** Receiver Operating Characteristic (ROC) curve for all participants in the study (n=50). **B)** Receiver Operating Characteristic (ROC) curve for participants who received oral anti-spastic medication (n=40).

CHAPTER VI

SUMMARY OF FINDINGS AND CONCLUSION

The main purpose of this dissertation was to translate and cross-culturally adapt the Patient Reported Impact of Spasticity Measure into Arabic language (PRISM-Arabic) for Arabic speaking people with SCI in Saudi Arabia. The PRISM was developed by Cook et al in 2007[1] as a self-report scale to measure the subjective overall impact of spasticity in people with SCI. For a self-reporting scale to be used in a different culture, it has the potential to be misrepresented due to many factors, including language and cultural differences, social desirability, concealment, and response style. Therefore, an appropriate adaptation and measuring evaluation should be implemented thoroughly.[2,3]

To achieve the purpose of this dissertation, three separate, yet related, studies were conducted. The first study, described in detail in chapter three, produced an Arabic version of the PRISM (PRISM-Arabic) to be used with Arabic speaking individuals with SCI. This study was done in two parts: 1) translating and cross-culturally adapting the PRISM questionnaire into the Arabic language following comprehensive guidelines used for such purposes,[2,4] and 2) pilot testing the produced Arabic version with individuals with SCI. The second study, described in detail in chapter four, evaluated the psychometric properties (internal consistency, test-retest reliability, measurement error, and construct validity) of the PRISM-Arabic. Finally, the third study, described in detail in chapter five, investigated the PRISM-Arabic's responsiveness to change in patients with SCI reporting spasticity. This study assessed

the internal responsiveness (change in PRISM-Arabic's response to interventions over time involving statistical significance of the change of scores), and the external responsiveness (correlating change of the PRISM-Arabic to changes in other valid reference tools measuring the PRISMs different constructs).

The first study concluded with the PRISM being successfully translated and cross-culturally adapted into the Arabic language. The translation and adaptation process thoroughly followed the guidelines given by Beaton et al[4] for cross-cultural adaptation. The resulted pre-final version of the PRISM-Arabic was pilot-tested in a sample of 35 Arabic speakers with SCI reporting spasticity. The study also examined the PRISM-Arabic's face and content validity where the participants revealed that the scale was relevant and appropriate to the experience of spasticity. The PRISM-Arabic was finalized and was ready to be tested on a larger scale for psychometric properties.

The results from the second study showed that all PRISM-Arabic subscales showed adequate internal consistency (Cronbach's $\alpha = 0.73–0.95$), except for the Positive Impact and Need for Intervention subscales (0.64 and 0.61). Also, all subscales showed adequate test-retest reliability ($ICC_{2,1} = 0.84–0.94$), while the standard error of measurement ranged from 1.19–2.84 points, and the minimal detectable change ranged from 3.3–7.9 points.

The second study also examined the PRISM-Arabic's construct validity using the correlation hypothesis testing approach by correlating its subscales with the AQLI-SCI, FIM-Motor, SCIM-III, and MAS. These measuring tools were selected as reference measures for their similarity in the constructs measured in the different domains as measured by the PRISM-Arabic, and because they are commonly used

with SCI assessment. Nine (82%) of 11 pre-defined correlational hypotheses had significant results that support the construct validity of the PRISM-Arabic. Again, the Positive Impact subscale was found not to respond as hypothesized. A possible explanation is that the Positive Impact subscale had fewer items compared with the other subscales in the PRISM, and fewer items usually lead to lower internal consistency and may affect its ability to correlate significantly with other measures. Another possible explanation is that the beneficial impact of spasticity measured by the Positive Impact subscale may be a new area of interest in the PRISM that may have no similar scale measuring its construct.

The findings from the third study revealed that PRISM-Arabic was not sensitive to changes in the subjective impact of spasticity after receiving in-patient rehabilitation treatment. The results from examining the internal responsiveness using paired sample *t*-tests showed that all PRISM-Arabic subscales' mean scores had not changed significantly between admission and discharge ($p < 0.05$). Moreover, the mean score changes of PRISM-Arabic subscales between admission and discharge reflected very small effect sizes ($ES = 0–0.17$), providing additional information that an actual lack of treatment effect can be seen using these scales on patients with SCI reporting spasticity. A conceivable reason was that spasticity did not significantly change largely in our study, therefore, no changes in the PRISM would be anticipated.

Moreover, the third study evaluated the external responsiveness of the PRISM-Arabic using hypothesis testing approach in treating the responsiveness as a longitudinal form of construct validity. Using correlational hypothesis testing, PRISM-Arabic subscales were tested against the AQLI-SCI, FIM-Motor, SCIM-III,

and MAS. These measuring tools were selected as reference measures of construct of the different domains measured by the PRISM-Arabic because they are commonly used with SCI assessment and were found to have sound correlational values with PRISM-Arabic subscales from the second study. Adding to these scales, the PRISM-Arabic was correlated against the GRC scale as an external anchor assessing the overall change in the impact of spasticity. Only one hypothesis (out of 12 hypothesized) between the Social Avoidance/Anxiety subscale of the PRISM-Arabic and the AQLI-SCI was found to be significantly correlated (r_s = -0.29, p = 0.02). These findings suggest that PRISM-Arabic may not detect changes in the impact of spasticity over time. Again, a possible explanation was that spasticity itself did not change significantly in our sample throughout the given period of rehabilitation, and thus, no change would be expected.

Further, the ROC curve was plotted for the total scores of PRISM-Arabic against patients' responses to the GRC scale. The resultant area under the curve (AUC) score was not significant, indicating a lack of ability of the PRISM-Arabic to distinguish those patients who improved and those who did not. These findings lead to the inability to determine an optimal efficient cut-off point of improvement.

LIMITATIONS OF THE STUDIES

Samples recruited for all studies in this dissertation were collected from one geographical area and all participants were Saudi Arabian citizens which may threaten its generalizability. Thus, the PRISM-Arabic should not be generalized to all Arabic speakers.

Also, the construct validity testing of the PRISM-Arabic used in the second study was evaluated with correlational hypothesis testing analyses, whereas a confirmatory factor analysis, which requires more participants, would be preferred whenever a scale is translated into another language or validated in a new population.[5] Moreover, the construct validity of the PRISM-Arabic was not ideal since it was evaluated with outcome measures that were believed to serve as reference instruments of constructs measured by its domains. Because patient-reported outcomes, similar to the PRISM, have no comparable gold standard. Thus, the next best thing is to estimate the construct validity instead.[6–8]

A possible limitation in the third study was that the follow up survey for testing the responsiveness of the PRISM-Arabic was limited to the time participants spent during their in-patient rehabilitation period, consequently, restricting the detection of changes in the impact of spasticity. Measuring the responsiveness in QoL scales may require a longer period between responses in order for a change to become more perceptible to responders.[9]

CLINICAL RELEVANCE

Spasticity management practice can improve greatly using standardized assessments with an appropriate battery of tools, including patient-reported measures. Acknowledging patients' word choice used to describe spasticity can identify their needs and serve as a basis for treatment planning. Furthermore, active participation of patients in their own examination and evaluation will also be facilitated in such a standardized assessment approach.

The introduction of a spasticity-specific self-reported outcome measure such as the PRISM into clinics in Saudi Arabia is the first of its kind. The PRISM-Arabic is a reliable and valid assessment tool measuring the subjective impact of spasticity on Arabic speakers with SCI living in a country with one of the highest incidences of SCI around the world.[10–14] It can be helpful in making clinical decisions when choosing the most practical and appropriate spasticity management.

Although generalizing the use of PRISM-Arabic in all Arabic-speaking countries should be preceded by formal measurement properties testing, the translation to the Modern Standard Arabic (MSA) language style should enhance the applicability of the scale in most Arabic-speaking countries who can understand such style; use of the MSA style should be considered a strength of these studies.[15–17]

Nevertheless, there are certain negative findings in the clinical applicability of the PRISM-Arabic that warrant consideration. The Positive Impact subscale should be interpreted cautiously when inferring the positive experience of a person with spastic SCI given the subscale's uncertain reliability and validity. Also, clinicians should be aware about the potential inability of that PRISM-Arabic to detect changes in the impact of spasticity occurring over time after conventional rehabilitation treatment is given.

RECOMMENDATIONS FOR FUTURE RESEARCH

In this dissertation, the translation process adopted the MSA language to enhance the use of the scale in other Arabic speaking countries. However, future studies should examine the PRISM-Arabic's utility and applicability in other Arabic-speaking countries with additional formal measurement property testing.

Also, the responsiveness of the PRISM-Arabic was evaluated with participants who had conservative rehabilitation with minimal effectiveness on treating spasticity.[18,19] Therefore, future studies should focus on examining the responsiveness of the PRISM-Arabic with patients receiving more aggressive spasticity management that may allow enhanced patients' perception of spasticity improvement.[20–22]

Furthermore, future studies should evaluate the PRISM-Arabic's structural validity with a confirmatory factor analysis to confirm its factor structure and to possibly shorten the list of items since the tool may cause response fatigue, and thus, bias its credibility.

Finally, the PRISM-Arabic can be helpful in cross-sectional research studying people with SCI, because it comprises varied items explaining relevant issues influenced by spasticity, either positively or negatively. Future research can utilize the PRISM-Arabic for observational studies to estimate the impact of spasticity in this population which can be valuable in public health related research.[23,24]

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Chapter VI

1. Cook KF, Teal CR, Engebretson JC, et al. Development and validation of Patient Reported Impact of Spasticity Measure (PRISM). *J Rehabil Res Dev*. 2007;44(3):363-371. doi:10.1682/JRRD.2006.04.0036.

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Appendix A

Pre-Final Version of the PRISM-Arabic

Subject #: _____

Session #: _____

قياس إفادة المريض عن أثر الشد العضلي العصبي

الاسئلة التالية تتعلق بتجربتك مع الاضطراب في التحكم العضلي او الحركات اللاإرادية. يستخدم الناس مصطلحات مختلفة للتعبير عن الاضطراب في التحكم العضلي والحركات اللاإرادية، ومنها:

- الشد العضلي العصبي
- التيبس العضلي
- التقلصات العضلية.
- رعشة عضلية.
- عندما لا تعمل العضلات بتناسق كما هو متوقع.
- عندما تحاول تحريك جزء من الجسم ويتسبب ذلك في تحريك جزء آخر.

- الرجاء وضع دائرة حول أحد الأرقام أدناه بما يعكس تجربتك خلال **الأسبوع الماضي**.

الاضطراب في التحكم العضلي او الحركات اللاإرادية خلال الاسبوع الماضي:	غير صحيح تماماً	نادراً ما يكون صحيحاً	بعض الاحيان يكون صحيحاً	في كثير من الاحيان يكون صحيحاً	في أغلب الأحيان يكون صحيحاً
1- جعلني قلقاً من الخروج في الأماكن العامة.	0	1	2	3	4
2- يزعجني كثيرا.	0	1	2	3	4
3- جعل العناية الشخصية (مثل تسريح الشعر وتنظيف الأسنان) صعباً عليّ أو على مساعدي.	0	1	2	3	4
4- جعلني في احتياج لمساعده شخص اخر لتعديل وضع جسمي.	0	1	2	3	4
5- ساعدتني على إبقاء عضلاتي ممرنه.	0	1	2	3	4
6- جعلني احتاج لعلاج أكثر مما أستطيع توفيره.	0	1	2	3	4
7- منعني من الخروج وسط الأشخاص الغرباء.	0	1	2	3	4
8- جعلني أشعر بفقدان الأمل.	0	1	2	3	4
9- جعلني أشعر بعدم التحكم في جسمي.	0	1	2	3	4
10-جعلت ارتدائي للملابس صعباً عليّ أو على مساعدي.	0	1	2	3	4
11-منعني من أن أكون سعيداً بالقدر الممكن.	0	1	2	3	4
12-جعلتني اعتمد على الاخريين.	0	1	2	3	4
13-ساعدتني على استطالة عضلاتي.	0	1	2	3	4
14-تسبب في زيادة كمية الأدوية الموصوفة التي أتناولها.	0	1	2	3	4
15-جعلتني غير راغب في الخروج للأماكن العامة.	0	1	2	3	4
16-جعلتني اشعر بالإحباط.	0	1	2	3	4

الاضطراب في التحكم العضلي او الحركات اللاإرادية خلال الاسبوع الماضي:	غير صحيح تماماً	نادراً ما يكون صحيحاً	بعض الاحيان يكون صحيحاً	في كثير من الاحيان يكون صحيحاً	في أغلب الأحيان يكون صحيحاً
17-جعل النظافة الشخصية (قضاء الحاجة، تنظيف الجسم) صعبة عليّ أو على مساعدي.	0	1	2	3	4
18-جعلتني أرغب في الحصول على علاج بديل غير طبي.	0	1	2	3	4
19-جعلني قلقاً من الخروج مع الأصدقاء.	0	1	2	3	4
20-جعلني أحتاج لأجهزة سلامة (مثل حاجز للسرير، أربطة للقدم).	0	1	2	3	4
21-جعل تناول الطعام صعباً عليّ أو على مساعدي.	0	1	2	3	4
22-أثرت على العلاقات الرومنسية.	0	1	2	3	4
23-جعلتني أشعر بانعدام القوة.	0	1	2	3	4
24-سببت لي الإحراج.	0	1	2	3	4
25-جعلني أرغب في الحصول على التشجيع أو الدعم المعنوي من الأصدقاء والعائلة.	0	1	2	3	4
26-أثرت على النشاط الجنسي.	0	1	2	3	4
27-جعلتني ألفت انتباه الغرباء.	0	1	2	3	4
28-ساعد على الانتقال (مثال: من الكرسي للسرير).	0	1	2	3	4
29-جعلني أتجنب التواصل الجسدي مع الناس.	0	1	2	3	4
30- جعلني أتناول أدوية لا تحتاج إلى وصفة طبية.	0	1	2	3	4
31- جعل الآخرين يتجنبون لمسي.	0	1	2	3	4
32-جعلني بمزاج سيء.	0	1	2	3	4
33- سهل عليّ أو على مساعدي تغيير وضعية جسمي.	0	1	2	3	4
34-جعلتني أشعر بالإكتئاب.	0	1	2	3	4
35- اثرت على قدرتي على أداء التمارين.	0	1	2	3	4
36- غيرت وضعية جسمي بشكل كبير.	0	1	2	3	4
37- جعلني خائفاً من أن أتسبب لنفسي بإصابة جسدية.	0	1	2	3	4
38-جعلت الانتقال صعباً عليّ أو على مساعدي.	0	1	2	3	4
39- جعلت الغرباء يحدقون بي.	0	1	2	3	4
40- منعني من الخروج مع الأصدقاء.	0	1	2	3	4
41-جعل من الصعب إبقاء الذراعين أو الساقين داخل الكرسي.	0	1	2	3	4

Appendix B

Interview Questions

Subject #: _____

Date: _____

أسئلة المقابلة

	نعم	لا
بشكل عام، هل الاستبانة واضحة؟	☐	☐
هل تعتقد بأن أسئلتها شملت جميع المجالات التي ممكن أن تتأثر بالشلل التشنجي؟	☐	☐
هل فهمت المعنى لجميع الأسئلة في الاستبانة؟	☐	☐

أي من الأسئلة تعتقد بأنه غير **واضح؟** عددهم. _____

_____

أي من الأسئلة تعتقد بأنه صيغ بطريقة **صعبة؟** عددهم. _____

_____

اقتراحات: _____

_____

_____

_____

_____

_____

_____

_____

Appendix C

Final PRISM-Arabic

قياس إفادة المريض عن أثر الشد العضلي العصبي

الاسئلة التالية تتعلق بتجربتك مع الاضطراب في التحكم العضلي او الحركات اللاإرادية. يستخدم الناس مصطلحات مختلفة للتعبير عن الاضطراب في التحكم العضلي والحركات اللاإرادية، ومنها:

- الشد العضلي العصبي
- التيبس العضلي
- التقلصات العضلية.
- رعشة عضلية.
- عندما لا تعمل العضلات بتناسق كما هو متوقع.
- عندما تحاول تحريك جزء من الجسم ويتسبب ذلك في تحريك جزء آخر.

- الرجاء وضع دائرة حول أحد الأرقام أدناه بما يعكس تجربتك خلال **الأسبوع الماضي**.

الاضطراب في الشد العضلي العصبي أو الحركات اللاإرادية خلال الاسبوع الماضي:	غير صحيح تماماً	نادراً ما يكون صحيحاً	بعض الاحيان يكون صحيحاً	في كثير من الاحيان يكون صحيحاً	في أغلب الأحيان يكون صحيحاً
1- جعلني قلقاً من الخروج في الأماكن العامة.	0	1	2	3	4
2- يزعجني كثيرا.	0	1	2	3	4
3- جعل العناية الشخصية (مثل تسريح الشعر وتنظيف الأسنان) صعباً عليّ أو على مساعدي.	0	1	2	3	4
4- جعلني في احتياج لمساعده شخص اخر لتعديل وضع جسمي.	0	1	2	3	4
5- ساعدتني في الحفاظ على نشاط وقوة عضلاتي.	0	1	2	3	4
6- جعلني أحتاج لعلاج أكثر مما أستطيع توفيره.	0	1	2	3	4
7- منعني من الخروج وسط الأشخاص الغرباء.	0	1	2	3	4
8- جعلني أشعر بفقدان الأمل.	0	1	2	3	4
9- جعلني أشعر بعدم التحكم في جسمي.	0	1	2	3	4
10-جعلت ارتدائي للملابس صعباً عليّ أو على مساعدي.	0	1	2	3	4
11-منعني من أن أكون سعيداً بالقدر الممكن.	0	1	2	3	4
12-جعلتني اعتمد على الاخريين.	0	1	2	3	4
13-ساعدني على استطالة عضلاتي.	0	1	2	3	4
14-جعلني أقوم بزيادة جرعة الدواء المسجل بالوصفة الطبية.	0	1	2	3	4
15-جعلني غير راغب في الخروج للأماكن العامة.	0	1	2	3	4
16-جعلني اشعر بالإحباط.	0	1	2	3	4

الاضطراب في الشد العضلي العصبي أو الحركات اللاإرادية خلال الاسبوع الماضي:	غير صحيح تماماً	نادراً ما يكون صحيحاً	بعض الاحيان يكون صحيحاً	في كثير من الاحيان يكون صحيحاً	في أغلب الأحيان يكون صحيحاً
17-جعل النظافة الشخصية (قضاء الحاجة، تنظيف الجسم) صعبة عليّ أو على مساعدي.	0	1	2	3	4
18-جعلني أرغب في الحصول على علاج بديل غير طبي (مثل علاجات الطب البديل).	0	1	2	3	4
19-جعلني قلقاً من الخروج مع الأصدقاء.	0	1	2	3	4
20-جعلني أحتاج لأجهزة سلامة (مثل حاجز للسرير، أربطة للقدم).	0	1	2	3	4
21-جعل تناول الطعام صعباً عليّ أو على مساعدي.	0	1	2	3	4
22-أثرت على العلاقات الرومنسية.	0	1	2	3	4
23-جعلتني أشعر بانعدام القوة الجسدية.	0	1	2	3	4
24-سببت لي الإحراج.	0	1	2	3	4
25-جعلني أرغب في الحصول على التشجيع أو الدعم المعنوي من الأصدقاء والعائلة.	0	1	2	3	4
26-أثرت على النشاط الجنسي.	0	1	2	3	4
27-جعلتني ألفت انتباه الغرباء.	0	1	2	3	4
28-ساعد على الانتقال (مثال: من الكرسي للسرير).	0	1	2	3	4
29-جعلني أتجنب التواصل الجسدي مع الناس.	0	1	2	3	4
30- جعلني أتناول أدوية لا تحتاج إلى وصفة طبية.	0	1	2	3	4
31- جعل الآخرين يتجنبون لمسي.	0	1	2	3	4
32-جعلني بمزاج سيء.	0	1	2	3	4
33- سهل عليّ أو على مساعدي تغيير وضعية جسمي.	0	1	2	3	4
34-جعلتني أشعر بالإكتاب.	0	1	2	3	4
35- اثرت على قدرتي على أداء التمارين.	0	1	2	3	4
36- غيّر وضعية جسمي بشكل كبير.	0	1	2	3	4
37- جعلني خائفاً من أن أتسبب لنفسي بإصابة جسدية.	0	1	2	3	4
38-جعل الانتقال من الكرسي صعباً عليّ أو على مساعدي.	0	1	2	3	4
39- جعل الغرباء يحدقون بي.	0	1	2	3	4
40- منعني من الخروج مع الأصدقاء.	0	1	2	3	4
41-جعل من الصعب عليّ إبقاء الذراعين أو الساقين داخل الكرسي.	0	1	2	3	4

Appendix D

Institutional Review Board Approvals

Institutional Review Board
Office of Research
6700 Fannin, Houston, TX 77030
713-794-2480
irb-houston@twu.edu
http://www.twu.edu/irb.html

DATE: November 18, 2015

TO: Mr. Mishal Aldaihan
Physical Therapy - Houston

FROM: Institutional Review Board (IRB) - Houston

Re: Exemption for Cross-Cultural Adaptation of the Arabic Version of the Patient-Reported Impact of Spasticity Measure (PRISM) in Arabic Speaking People with Spinal Cord Injury in Saudi Arabia. (Protocol #: 18778)

The above referenced study has been reviewed by the TWU IRB (operating under FWA00000178) and was determined to be exempt from further review.

If applicable, agency approval letters must be submitted to the IRB upon receipt PRIOR to any data collection at that agency. Because a signed consent form is not required for exempt studies, the filing of signatures of participants with the TWU IRB is not necessary.

Although your protocol has been exempted from further IRB review and your protocol file has been closed, any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any adverse events or unanticipated problems. All forms are located on the IRB website. If you have any questions, please contact the TWU IRB.

cc. Dr. Peggy Gleeson, Physical Therapy - Houston
Dr. Carolyn Da Silva, Physical Therapy - Houston
Graduate School

مدينة سلطان بن عبد العزيز للخدمات الإنسانية
SULTAN BIN ABDULAZIZ HUMANITARIAN CITY

RESEARCH & ETHICS COMMITTEE

23rd November 2015

MR. MISHAL ALDAIHAN, DPT
Principal Investigator
Texas Woman's University
School of Physical Therapy
Carolyn Da Silva
Houston Campus
Houston Texas, U.S.A.

Subject : **"Cross-Cultural Adaptation of the Arabic Version of the Patient-Reported Impact of Spasticity Measure (PRISM) in Arabic Speaking People with Spinal Cord Injury in Saudi Arabia"**

Dear Mr. Mishal:

Thank you for submitting your research proposal.

The above mentioned proposal had been reviewed by the assigned members of the Research and Ethics Committee of the Sultan bin Abdulaziz Humanitarian City, Riyadh. I am pleased to inform you that this project has been approved by Research and Ethics Committee (Chairman Action).

Your research protocol has now been documented under:

Project Number : 005/2015/23rd November 2015
Series of : 2015 November 23rd

Kindly quote the project number indicated herein in all transactions and communications. You are advised to submit a progress report, this time after three (3) months from approval of your research proposal, in relation to this research schemed we need you also to send us a Final report after your research will be completed in relation to this research schemed to update the committee of its results.

I trust your research scheme proves fruitful and beneficial to you, the patients and this institution.

Thank you.

Best regards,

Dr. Sadi Al Zahrani, SLP Cons.
Chairman of Research & Ethics Committee
Sultan Bin Abdulaziz Humanitarian City
P.O. Box 64399, Riyadh 11536
Kingdom of Saudi Arabia

Kingdom of Saudi Arabia
Ministry of Health
King Fahad Medical City
(162)

وزارة الصحة
مدينة الملك فهد الطبية
King Fahad Medical City

المملكة العربية السعودية
وزارة الصحة
مدينة الملك فهد الطبية
(١٦٢)

IRB Registration Number with KACST, KSA: H-01-R-012
IRB Registration Number with OHRP/NIH, USA: IRB00008644
Approval Number Federal Wide Assurance NIH, USA: FWA00018774

October 20, 2015
IRB Log Number: 15-358E
Department: External
Category of Approval: EXEMPT

Dear Mishal Aldaihan,

I am pleased to inform you that your submission dated October 15, 2015 for the study titled '**Cross-Cultural Adaptation of the Arabic Version of the Patient-Reported Impact of Spasticity Measure (PRISM) on Arabic Speaking People with Spinal Cord Injury in Saudi Arabia**' was reviewed and was approved. Please note that this approval is from the research ethics perspective only. You will still need to get permission from the head of department or unit in KFMC or an external institution to commence data collection.

We wish you well as you proceed with the study and request you to keep the IRB informed of the progress on a regular basis, using the IRB log number shown above.

Please be advised that regulations require that you submit a progress report on your research every 6 months. You are also required to submit any manuscript resulting from this research for approval by IRB before submission to journals for publication.

If you have any further questions feel free to contact me.

Sincerely yours,

F M
Approved
20 OCT 2015
I R B

Prof. Omar H. Kasule
Chairman Institutional Review Board--IRB.
King Fahad Medical City, Riyadh, KSA.
Tel: + 966 1 288 9999 Ext. 26913
E-mail: okasule@kfmc.med.sa