

# ARTICLE Translation, cross-cultural adaptation, and analysis of the measurement properties of the Brazilian Portuguese version of the spinal cord injury pain instrument

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STUDY DESIGN: A questionnaire validity study.

**OBJECTIVES:** To perform the translation, cross-cultural adaptation, and analysis of the measurement properties of the Brazilian Portuguese version of the Spinal Cord Injury Pain Instrument (SCIPI) for the screening of neuropathic pain in spinal cord injury. **SETTING:** Neurorehabilitation hospital in north-eastern Brazil.

**METHODS:** We performed the translation and cross-cultural adaptation of the SCIPI. The pre-final version was applied in 10 patients with spinal cord injury sequelae and pain report. The final version of the SCIPI was applied to 100 patients. The measurement properties evaluated were structural validity, test-retest reliability, internal consistency, construct validity, and diagnostic accuracy. **RESULTS:** None of the items in the pre-final version of the SCIPI had any comprehension problems. The one-dimensional structure of the final version of the SCIPI was adequate. There were significant correlations between the SCIPI and the Douleur

Neuropathique 4 (rho = 0.546), as well as adequate test-retest reliability (intraclass correlation coefficient = 0.89, kappa  $\ge$  0.79), internal consistency (Cronbach's alpha  $\ge$  0.76), and diagnostic accuracy (area under the curve = 0.860).

**CONCLUSION:** The Brazilian version of the SCIPI presents measurement properties that are suitable for measuring neuropathic pain related to spinal cord injury.

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# INTRODUCTION

Spinal cord injury generates important impacts in terms of healthcare, disabilities, economic level, and quality of life [1]. Pain is a frequent problem in this population, with 70% presenting chronic pain symptoms [2] and approximately 57.6% of the pains having neuropathic characteristics [1].

The association between nociceptive pain and neuropathic pain is common in people with spinal cord injury sequelae [3]. The correct and accurate diagnosis of pain, taking into account the different pathophysiological mechanisms (nociceptive, neuropathic, and nociplastic), is of great importance for successful treatment, considering that conduction of the treatment of neuropathic pain is different from that of a nociceptive pain [4, 5].

Considering the current lack of a gold standard method to diagnose neuropathic pain, there are several instruments to perform this screening [6]. In Brazil, adapted and validated versions of the Douleur Neuropathique 4 (DN4), Leeds Assessment of Neuropathic Pain Questionnaire (LANSS), Neuropathic Pain Symptom Inventory (NPSI), and Pain Quality Assessment Scale (PQAS) are available [7].

These more generic neuropathic pain tracking instruments, which are widely used for peripheral causes of pain, have lower measurement properties when applied to homogeneous samples and from central causes of pain (as in the case of pain related to spinal cord injury), reaching indices of diagnostic accuracy from 55 to 88% depending on the instrument applied [8]. Another aspect to be considered is that these instruments are based on physical examination, in addition to the verbal descriptors of pain, as spinal cord injury has peculiarities inherent to the injury, such as changes in skin sensitivity, in which the items of these generic instruments cannot be sensitive, thus interfering with accuracy [8, 9].

The Spinal Cord Injury Pain Instrument (SCIPI) is a rapid, standardised and valid (for English and German) screening instrument to detect neuropathic pain manifestations in a population with spinal cord injury sequelae [8, 9]. Its differential is based on an updated review of the definition of neuropathic pain and updated guidelines for detecting this condition. It is administered in the form of an interview or self-report, does not require clinical physical examination, and can be applied when the patient is unavailable in person. In addition, the SCIPI has an item aimed at the changes in skin sensitivity caused by spinal cord injury [8, 9].

Thus, the aim of this study was to perform the translation, crosscultural adaptation, and analysis of the measurement properties of the Brazilian Portuguese version of the SCIPI for the screening of neuropathic pain in spinal cord injury.

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# METHODS

## Study design

This is a questionnaire validation study carried out according to the Guideline for the Process of Cross-cultural Adaptation of Self-Report Measures [10] and the Consensus-based Standards for the Selection of Health Measurement Instruments [11]. The authorisation to carry out the translation and adaptation of the SCIPI into Brazilian Portuguese was granted via email by one of the authors of the questionnaire (Dr. Thomas N. Bryce).

We carried out this research at the Sarah Network of Rehabilitation Hospitals (São Luís, MA, Brazil); all study procedures were previously approved by the institution's research ethics committee (opinion number 3.714.777).

#### Participants

All participants included in the research were treated under the Hospital's Spinal Cord Injury Program. Patients of both sex, aged over 18 years, and with painful complaints arising after spinal cord injury were included. We consider the following exclusion criteria: Patients diagnosed with severe cognitive and/or psychiatric disorders (by the team of doctors and psychologists of the hospital during routine assessments); pain above the level of spinal cord injury (since pain above the level of spinal cord injury may be related to another cause, e.g., musculoskeletal disorders); and patients who did not speak Brazilian Portuguese as their native language.

A minimum sample size of 100 patients was used for validity analyses [11]. For reliability analyses, we used a sub-sample composed of 50 patients; the questionnaire was applied at two timepoints by one of the physiotherapists from the spinal cord injury program team, with an interval of 4 to 7 days between assessments [11].

### Spinal Cord Injury Pain Instrument (SCIPI)

The SCIPI is a 4-item instrument that investigates the pain characteristics of patients with spinal cord injury. For each item, a dichotomous answer is possible (yes = 1, no = 0). The total score ranges from 0 to 4; a score  $\ge 2$  indicates the presence of neuropathic pain.

#### Translation and cross-cultural adaptation

The SCIPI translation and cross-cultural adaptation process into Brazilian Portuguese followed the criteria of Beaton et al.[10]; however, the pre-final version test was applied to 10 patients [9, 12]. The stages for the translation and cross-cultural adaptation of the SCIPI are described below.

- Translation: Two independent translators (both with Brazilian Portuguese as their mother tongue and who were fluent in English) translated the original version of the SCIPI into Brazilian Portuguese.
- Synthesis of translations: After discussions and revisions, the two translators (under observation by one of the researchers) synthesized the two versions of the questionnaire translated independently and produced a single version of the SCIPI in a consensual manner.
- 3. Back-translation: Two independent translators (without technical knowledge of subjects in the health area), both with English as their mother tongue and who was fluent in Portuguese, translated the Brazilian Portuguese version of the SCIPI back into English, with no prior knowledge of the original version of the questionnaire.
- 4. Analysis by the expert committee: Two specialists in the field of pain and rehabilitation, together with the four translators involved in the adaptation process, defined the pre-final version of SCIPI in a manner agreed upon by all members of the committee.
- 5. Pre-final version test: Considering the characteristics of the population with spinal cord injury sequelae, we applied the pre-final version of the SCIPI in a sample size of 10 individuals [9, 12], according to the same inclusion criteria established here. Participants answered the SCIPI questions in the form of an interview (carried out by the interviewer without receiving any kind of influence); at the end of the interview, answered "yes" or "no" about the understanding of each question in the questionnaire. Questions that were not understood by more than 20% of the participants would be reformulated and tested again in a new sample of 10 participants until the desired level of understanding was reached [13], thus establishing the final version of the SCIPI in Brazilian Portuguese.

Test of the final version: In order to verify the measurement properties of the instrument, the cross-culturally adapted final version of the SCIPI was applied to 100 patients.

#### Other clinical measurements

In addition to the final version of the SCIPI, we applied the instruments DN4, LANSS, Numerical Pain Scale (NPS), and the anamnesis form containing information on sociodemographic, clinical, and spinal cord injury characteristics. The DN4 was used to validate the construct, and the LANSS, and NPS were used to characterize the pain of the sample; the assessments were performed by a physiotherapist from the neurorehabilitation team in spinal cord injury.

### Statistical analysis

In descriptive analysis, we used mean, standard deviation (SD), frequency and percentage. These data were processed using the Excel program (Microsoft, Redmond, WA, USA).

Internal consistency was obtained using Cronbach's alpha, with an acceptable value above 0.70 [14]. Test-retest reliability was assessed via intraclass correlation coefficient (ICC) with a 2-way random-effects model and acceptable values above 0.75 [15]. Also, the standard error of measurement (SEM) was calculated [16]. For each item of the SCIPI, the kappa value was calculated, with acceptable values above 0.60 [17].

For the correlations between the questionnaires, the normality of the data was initially verified using the Kolmogorov-Smirnov test. For the construct validity, Spearman's correlation coefficient (rho) was used to determine the magnitude of correlation between the SCIPI and the DN4. Our hypothesis is that the SCIPI demonstrates a good correlation, with a correlation magnitude greater than 0.50 with DN4, as it presents similar constructs [11, 18].

The internal structure of the SCIPI was evaluated through confirmatory factor analysis (CFA), with tetrachoric correlations and the robust diagonally weighted least squares (RDWLS) extraction method [19]. CFA processing was performed in R Studio (version 1.1.453, Boston, MA, USA), using the lavaan and semPlot packages. The Model fit had the following classification: values greater than 0.90 were considered adequate for comparative fit index (CFI) and Tucker-Lewis index (TLI), while values less than 0.08 were considered adequate for root mean square error of approximation (RMSEA) and standardised root mean square residual (SRMR). Values below 3.00 were considered adequate in the interpretation of the chi-square/degree of freedom (DF). In the CFA, factor loadings equal to or greater than 0.40 were considered adequate for the domain [14, 20].

We used the ROC curve to determine the diagnostic accuracy, with the following interpretation of the area under the curve (AUC):[21, 22] 0.5 (due to chance); > 0.5 to 0.7 (low degree of precision), > 0.7 to 0.9 (moderate degree of precision); > 0.9 and < 1.0 (high degree of accuracy); and 1.0 (perfect test). Determination of the best cut-off point was based on the lowest value obtained from the equation  $(1 - \text{sensitivity})^2 + (1 - \text{specificity})^2$  [22]. In addition, positive and negative predictive values and positive and negative likelihood ratios were calculated [23]. Data were processed by SPSS (version 17, Chicago, IL, USA).

# RESULTS

# Sample characteristics

The sample consisted of 100 patients, 69% male, with a mean age of 41 years (SD = 12.16); in addition, 53% were married, 45% had completed/incomplete secondary education, and 81% had no occupational activity. Details of the characteristics of spinal cord injury and pain are described in Table 1.

Regarding the characteristics of spinal cord injury, 67% had a cause of injury of traumatic origin. In total, 58% of patients presented a neurological level of thoracic spinal cord injury and 58% of spinal cord injuries were incomplete (ASIA-AIS Deficiency Scale classified as B, C, or D). The mean duration of spinal cord injury was 7 years (SD = 8.55); pain complaints at the neurological level of spinal cord injury were reported in 60% of patients, with mean pain duration of 60 months (SD = 74.32). The number of medications used on average was 4.24 (SD = 2.25), including several categories of medications for the management of

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Table 1.	Characteristics of spinal cord injury and pain of patients ( $n =$
100).	

Characteristics	n
Non-traumatic cause of spinal cord injury	
Myelopathy or Myelitis	20
Spastic paraparesis	9
Arnold Chiari I	2
Neoplasm	2
Traumatic cause of spinal cord injury	
Motorcycle accident	23
Firearm projectile	20
High drop	10
Car accident	7
Dropped object on the back	3
Shallow water dive	3
Knife Injury	1
Spinal cord injury level	
C2 to T1	33
T2 to T12	58
L1 to L5	9
ASIA Impairment Scale (AIS)	
A	42
В	13
C	26
D	19
Spinal cord injury time (years)	
Up to 2	35
3 to 10	49
11 to 20	8
21 or more	8
Presence of pain	
At the level of spinal cord injury	60
Below the level of spinal cord injury	40
Pain site	
Lower limb	20
Low back	14
Dorsal region	14
Hip	10
Knee	8
Leg	7
Shoulder	6
Gluteal region	5
Hand	3
Foot	3
Upper limb	3
Abdomen	3
Thigh	2
Perineum	2
Pain time (months)	
Up to 3	2
4–6	6
7–12	17
13–24	10
25 or more	65
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secondary dysfunctions (caused by spinal cord injury or previous comorbidities).

Regarding to the questionnaires used in the study, we observed the following mean scores: 2.47 (SD = 1.11) for SCIPI, 5.48 (SD =

2.34) for DN4, 11.28 (SD = 5.95) for LANSS and 6.16 (SD = 2.40) for the NPS.

## **Cross-cultural adaptation**

In the stage of translation and cross-cultural adaptation, there was no need to adapt any specific term. The pre-final version of the SCIPI was applied to 10 patients with spinal cord injury sequelae and who had pain complaints; no item in the questionnaire reached a misunderstanding rate greater than 20%. Thus, the final version of the SCIPI was established in the Brazilian Portuguese language (Supplement 1).

# Structural validity

Based on the structure presented in the study by Franz et al. [9], we performed CFA considering the 4 items and one-dimensional structure. Thus, the fit indices with adequate values were found: Chi-square/DF = 0.808, CFI = 1.000, TLI = 1.000, RMSEA (90% CI) = 0.000 (0.000-0.187), and SRMR = 0.061. Regarding the factor loading, as shown in Fig. 1, only item 4 presented a value lower than 0.40; however, considering the good fit indices, we chose to keep the original SCIPI structure.

#### **Construct validity**

The SCIPI score was correlated with the DN4 score. Significant correlation was found with correlation magnitude greater than 0.50 (rho = 0.546, *p*-value < 0.001).

# **Reliability and internal consistency**

Table 2 shows the appropriate values for test-retest reliability and internal consistency, with ICC = 0.89 (*p*-value < 0.001), kappa  $\ge$  0.79 (*p*-value < 0.001), and Cronbach's alpha  $\ge$  0.76.

#### Accuracy

For this analysis, we considered DN4 to be a reference instrument to classify patients into two categories (with or without neuropathic pain) due to its higher correlation magnitude. The distribution of volunteers with and without neuropathic pain according to the DN4 and SCPI instruments is shown in Table 3. The SCIPI had moderate diagnostic accuracy, as described in Fig. 2 and Table 4, with an AUC value of 0.86, sensitivity of 93.8%, and specificity of 65%.

## DISCUSSION

We observed that the Brazilian version of the SCIPI has a reliable, one-dimensional structure, and a valid construct. We used the CFA to verify the internal structure of SCIPI, which allowed the theoretical factor structure of the observed data to be tested [24] and demonstrated that the instrument has a one-dimensional structure with observed variables is related to the latent variable. Only item 4 of the SCIPI in the Brazilian version had a factor loading of less than 0.40 (this item investigates whether the pain occurs in a region of the skin that is not sensitive). Our hypothesis for this aspect is that regions with partial changes in sensitivity were not considered, such as hypoesthesia, a frequent condition in incomplete spinal cord injury or spinal cord injuries from nontraumatic causes.

Our study demonstrated that the SCIPI has a good correlation with the DN4 (rho = 0.546). As there is no gold standard tool/ method for neuropathic pain assessment, construct validity was verified by correlating the SCIPI score with the DN4 score. We chose to use DN4 for two reasons: it is an instrument recommended by the Neuropathic Pain Special Interest Group for neuropathic pain screening [6], and it has suitable measurement properties into the Brazilian Portuguese language [25, 26].

The DN4 was translated, adapted, and validated for 11 languages, including Brazilian Portuguese. All adaptations demonstrated low levels of cross-cultural validity, as shown in the

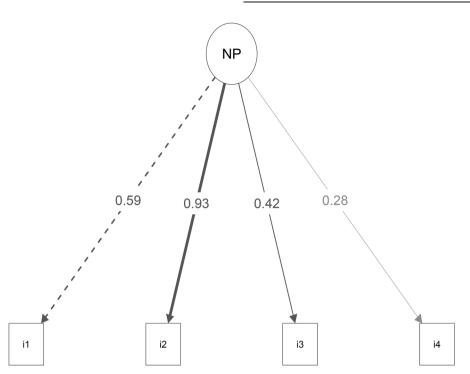


Fig. 1 Path diagram of the Spinal Cord Injury Pain Instrument. NP Neuropathic pain, i1 Pain sensation like electric shock, i2 Pain sensation like pins and needles, i3 Sensation of thermal pain, i4 Pain sensation in an area without sensitivity.

Table 2.	Reliability and internal consistency of the Spinal Cord Injury		
Pain Instrument (SCIPI) ( $n = 50$ ).			

Measure	Value
Mean (standard deviation)	
Test	2.54 (1.21)
Retest	2.60 (1.22)
ICC	0.89
CI 95%	0.82 to 0.94
SEM (score)	0.40
SEM (%)	15.68
Карра	
Item 1	0.80
ltem 2	0.82
ltem 3	0.80
ltem 4	0.79
Cronbach's alpha	0.78
Cronbach's alpha if item deleted	
ltem 1	0.76
ltem 2	0.76
Item 3	0.78
ltem 4	0.76

*ICC* Intraclass correlation coefficient, *CI* Confidence interval, *SEM* Standard error of measurement.

systematic review conducted by Mathieson et al. [6], although this review emphasises that the Brazilian Portuguese version has more satisfactory evidence among all other versions. In the validation of the Brazilian Portuguese version carried out by Santos et al. [24], the DN4 obtained a Cronbach's alpha of 0.713 (considered reasonable), ICC of 0.62 (considered moderate), and factor loadings between 0.502 and 0.817 in the factor analysis.

 
 Table 3.
 Cross-tabulation on the presence and absence of neuropathic pain according to the Douleur Neuropathique 4 (DN4) and Spinal Cord Injury Pain Instrument (SCIPI).

SCIPI	DN4			
	Neuropathic pain	No neuropathic pain		
Neuropathic pain	76	6		
No neuropathic pain	5	13		

Regarding diagnostic accuracy, the Brazilian version of the SCIPI had a sensitivity value of 84%, similar to the German version (86%), and higher than the original version (72%). The Brazilian version of the SCIPI proved to be less specific (65%) when compared to the original (78%) and the German (84%) versions [8, 9]. The assessment of the diagnostic accuracy of the original and German version SCIPI used the diagnosis issued by a committee of medical experts as the gold standard, while our study used the DN4 as a reference. We also verified other forms of accuracy, such as predictive values and likelihood ratio, but these data were not presented in other SCIPI validation studies.

Although the DN4 has adequate measurement properties, SCIPI was developed based on the clinical peculiarities of a person with spinal cord injury, validated in its original version according to revised definitions and guidelines for the clinical detection of neuropathic pain.

This study has limitations that must be described. The diagnostic evaluation during the performance of the accuracy was not performed by physicians' team specializing in neuropathic pain. Inter-examiner reliability was not tested, as we considered that assessments performed by two examiners in sequence using a self-report instrument with only 4 items would likely generate equal responses due to the patient's memory. Finally, considering the COVID-19 pandemic period, we performed the pre-final test phase in only 10 patients, although there was 100% understanding for all items.

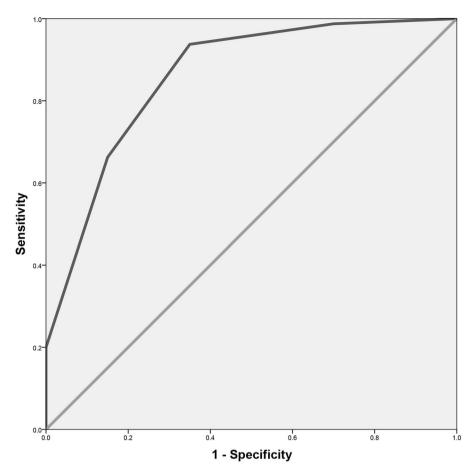


Fig. 2 ROC curve of the Spinal Cord Injury Pain Instrument (SCIPI).

Table 4. Area under the ROC curve, best cut-off point, sensitivity, specificity, predictive values and likelihood ratios of the Spinal Cord Injury Pain Instrument (SICPI).

Area (95% CI)	Cut-off point	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	PLR	NLR	Accuracy
0.860 (0.763, 0.956)	1.5	93.8	65.0	93	72	2.97	0.09	89%

CI Confidence interval, PPV Positive predictive value, NPV Negative predictive value, PLR Positive likelihood ratio, NLR Negative likelihood ratio.

#### CONCLUSION

The Brazilian version of the SCIPI presents measurement properties suitable for measuring neuropathic pain related to spinal cord injury.

#### DATA AVAILABILITY

The database of the present study is available in Supplement 2.

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# AUTHOR CONTRIBUTIONS

AVDF designed the study; MC and collected the data; MC, AVDF and CAFPG analyzed and interpreted the data; All authors read and approved the final manuscript.

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### **COMPETING INTERESTS**

The authors declare no competing interests.

# ETHICAL APPROVAL

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards (opinion number 3.714.777).

# CONSENT FOR PUBLICATION

The consent for publication was obtained from all individual participants included in the study.

## CONSENT TO PARTICIPATE

Informed consent was obtained from all individual participants included in the study.

## ADDITIONAL INFORMATION

**Supplementary information** The online version contains supplementary material available at https://doi.org/10.1038/s41393-022-00800-2.

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