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Psychometric Properties of the Italian Version of the Total Disability Index in Patients with Spine Pain and Disability: An Italian Cross-Cultural Adaptation, Validation and Translation

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SUMMARY

Background. Low back pain and neck pain are musculoskeletal disorders with the highest prevalence in the adult population. Spinal practices usually use formal questionnaires to asses and quantify pain and disability in people that suffer from back and neck pain, the aim of this study was to describe the translation and cross-cultural adaptation process of the English Total Disability Index (TDI) – which is a more universal disability assessment – into Italian version.

Methods. The English version of the TDI has been translated according to international guidelines. The measurement properties (construct validity and reliability) have been tested according to COSMIN checklists. Exploratory Factor Analysis (EFA) was used to analyze structural validity. Cronbach's α was calculated to assess the internal consistency and the Intraclass Correlation Coefficient (ICC) was calculated to estimate the reliability. The Functional Rating Index (FRI), the EuroQol Health Questionnaire 5 Dimensions (EQ-5D) and a Visual Analogue Scale (VAS) were used to assess the validity of the construct.

Results. All the items were similar in meaning to the originals. EFA showed a mono-factorial structure. Cronbach's α was 0.857 and the ICC was 0.821. The Pearson's Correlation Coefficient showed significant correlations ($p < 0.01$) between SFI and FRI, EQ-5D and VAS items.

Conclusions. Based on the results obtained, we suggest the use of TDI in daily clinical practice, also promoting its continuation in the field of scientific research.

KEY WORDS

Health care; spine; low back pain; neck pain; assessment; psychometrics; rehabilitation.

INTRODUCTION

The low back pain and neck pain are musculoskeletal disorders with the highest prevalence in the adult population and they cause considerable disability and costs for the society (1, 2). It has been estimated that between 49% and 90% of people will experience at least one episode of low back pain during their lifetime (3) and studies have shown a high neck pain prevalence which ranges from 16% to 75% (2). Therefore, spinal practices usually use formal questionnaires to asses and quantify pain and disability in people that suffer from back and neck pain. The Oswestry Disability index (ODI) is the most common assessment scale used

to evaluate low back pain. Instead, the Neck disability Index (NDI), which is a modified version of the ODI, is used to evaluate patients with neck problems (4). These forms are completed by the patients when they first arrive at the practice when insurance documentation, demographic questionnaires and other clinical evaluation are performed. Few studies have investigated associations between back and neck pain, psychological factors and health behaviors, and how the combination of back and neck pain affects a significant proportion of the population (5, 6). In a retrospective proof-of-concept study Spiegel *et al*. have consolidated the ODI and NDI into a single questionnaire, the Total Disability Index (TDI), which is a more universal disability assessment and allows the patients registration to be easier and quicker as it provides a global assessment of pain and disability correlated to the spine using a single questionnaire (7). The TDI consists of 14 items that were selected from the ODI and NDI based on overlap and disability-state specificity. The items that were chosen are indicators that assess either back or neck functionality or were broadly applicable and correlated to both the neck and back (4). Since it is a recent study, the TDI has not yet been validated in other languages. This work was conducted during the quarantine caused by the Coronavirus and for this reason we collected patients data through Google Forms which were sent by email or WhatsApp.
The aim of this study was to describe the translation and cross-cultural adaptation process of the English TDI version into Italian.

METHODS

Authors certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed consent was obtained from all participants for being included in the study. Institutional Review Board approval was not required because the administration of these tool was part of the usual process of assessment of these individuals in clinical practice, the research involved the analysis of data collected such that individual subjects cannot be identified in any way (8).

Translation and cultural adaptation

Once the consent of the developers of the Total Disability Index (TDI) was received the original tool was translated from English into Italian following the "Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures" (9) and the "Principles of good practice for the translation and cultural adaptation process for patient reported outcome (PRO) measures: report of the ISPOR Task Force for Translation and Cultural Adaptation" (10).
The original English version of the TDI was translated into Italian by two independent Italian translators fluent in the English language. The results were then synthesized, and no necessary changes or issues were identified. Then two English translators re-translated the Italian questionnaire back to English. The original version and the back-translated version of the tool were then compared. Finally, the translated version was checked by three physiotherapists fluent in the English language to make cultural adaptations and correct any remaining spelling, diacritical or grammatical errors.

Study design and eligibility criteria

This is a translation and validation study. At the beginning the original TDI was translated and culturally adapted into Italian and afterwards tested for its validity and reliability in patients with back or neck pain, or even with both. The study was conducted by a group of rehabilitation professionals from the Sapienza University of Rome and professionals from the Aerospace Medicine Department of the Italian Air Force of the Diagnostic Therapeutic Center and Aero-Medical Rehabilitation, between March and July 2020.
Following the "Consensus-Based Standards for the Selection of Health Status Measurement Instrument" (11, 12) (COSMIN) checklist, the reliability and construct validity of the culturally adapted scale were assessed.
Patients included in the study were 18 years or older and suffering from at least one of the following conditions: back pain, neck pain, self-reported history of spinal deformity, or other spine-related complaints. Exclusion criteria were the no eligibility for the survey completion and patients who were expected to undergo a surgical or an interventional procedure before their retest time.

Data collection

For the demographic and patient-reported outcomes (given the quarantine situation forced by the COVID-19 outbreak), the questionnaires were delivered as a Google Form questionnaire that were sent to individuals via social networks (WhatsApp) and emails. The retesting was repeated within 21 days using the same method. The form required around 20 minutes to complete as it was divided in more than one section. The first section included the consent for the use of personal data and a series of demographic questions (including age, sex, height and weight). The other sections of the form included patient reported outcome metrics (TDI, FRI, EQ-5D and the pain visual analog scale (VAS)). The Google Form used for the retest only included the TDI questionnaire. In the Total Disability Index questionnaire section patients were first asked to specify

their complaint of back pain only, neck pain only, back and neck pain, spinal deformity, or other. The diagnosis of spinal deformity was defined as patient-reported history of deformity. Data was collected from the Google Forms on an Excel sheet.

The 14 items included in the TDI were derived from the combined items of the ODI and NDI. The first 9 items were directly taken from the ODI version and four of these (pain intensity, personal care, lifting, and sleeping) are also included in the NDI questionnaire. The last 5 items were instead taken from the NDI assessment scale, and they do not appear on the ODI. The TDI questionnaire structure is very similar to the ODI and NDI, as every item has 6 choices reflecting a range from none to severe disability (0-5), with the highest scores representing increasing disability. The total of the scores is expressed as a percentage of 70 which is the maximum total score (4).

Other questionnaires

VAS

Visual analog scale (VAS) are psychometric measurement tools designed to document the severity of the symptoms of the patients and achieve a rapid, statistically measurable and reproducible classification of the symptoms perceived by the subject (13). The VAS is represented as a horizontal or vertical line (100 mm long) at the ends of which it presents descriptive expressions (usually "no pain" on the left and "extreme pain" on the right). The score is calculated by measuring the distance between the "no pain" point and the one marked by the patient with a ruler (14).

EQ-5D

The EQ-5D is a standardized questionnaire for measuring the "Health-related quality of life" (HRQL), or quality of life related to health. The questionnaire is divided into two distinct sections. The first asks for a subjective evaluation of five dimensions where each item provides the possibility to choose a level of severity (level 1 represents "no problem" while level 3 represents "extreme limitation"):

- mobility;
- self-care;
- daily activities;
- pain/discomfort;
- anxiety/depression.

The responses are then aggregated which then form a five-digit number that represents the patient's state of health. The second section of the EQ-5D uses an assessment using a visual analog scale (VAS) graphically represented by a graduated scale ranging from 0 to 100 (15).

FRI

The FRI is a tool specifically designed to quantitatively measure the subjective perception of the function and pain of the spinal musculoskeletal system in a clinical setting (16). The scale currently consists of 10 items divided into 4 sections – Pain, Sleep, Work, Daily Activity – which fall into 3 domains:

1. limits in daily living activity, represented by 6 items (personal care, traveling, recreational activities, lifting weights, walking, and standing);
2. disability, represented by 3 items (frequency of pain, intensity of pain and sleep);
3. limitation in participation represented by one item (work) (17).

The score for each item ranges from 0 to 4 points where 0 indicates no pain or full ability to function and 4 indicates worst possible pain or inability to perform a certain function. The maximum total score is 40. Therefore the scale has a total score range from 0% (no disability) to 100% (maximum disability) (18).

Statistical analysis

Statistical analysis was performed to evaluate the internal consistency, reliability and validity of the questionnaire. The TDI validity was assessed by calculating the Scree Plot and the Pearson's Correlation Coefficient. The Scree Plot is used to determine the number of factors to retain in an exploratory factor analysis. The Pearson's Correlation Coefficient evaluates the correlations between TDI and VAS, EQ-5D and FRI. The significance level has been set for P-value less than or equal to 0.05.

To determine the internal consistency of the scale the Cronbach's α coefficient was calculated. Intraclass correlation coefficients (ICCs) and their associated 95% confidence intervals (CIs) were selected to calculate the test–retest reliability of TDI. Following the COSMIN checklist, the Cronbach alpha and the ICC values of >0.70 were considered to be acceptable. All statistical analysis was performed using IBM SPSS version 20.0.

RESULTS

Patient demographics

The study included 109 patients who met all the inclusion criteria for this work. Of this sample, 54.1% of the patients were female and the average patient age was 39 years old (range 18-88). The answers showed that 52 patients had isolated back pain, 24 had isolated neck pain, 26 suffered both back and neck pain, 5 self-reported spinal deformity and only two patients had other complaints. Following the COSMIN checklist, of those included only 37 completed re-test within 21 days.

Reliability and internal consistency

The statistical analysis showed a good internal consistency of the TDI questionnaire since Cronbach's Alpha was equal to 0.857 (**table I**), therefore higher than 0.7. This shows that

there is a good inter relation between all the items of the scale and therefore a good internal consistency. As **table II** shows, all the items of the scale are relevant. If you delete an item the value of Cronbach's Alpha tends to decrease. TDI test-retest reliability was also found to be good with an Intraclass Correlation Coefficient (ICC) of 0.821, as can be seen in **table III**. Even in this case the value is higher than 0.7 therefore demonstrating good reliability of the tool.

Validity

The Scree Plot was studied to assess the construct validity of the TDI. **Figure 1** demonstrates that the TDI has a good construct validity as all items are valid. All participants also completed a copy of the FRI, the VAS and of the EQ-5D. The values of the Pearson's Correlation Coefficient between the TDI and these questionnaires were statistically significant with a P-value less than 0.01.

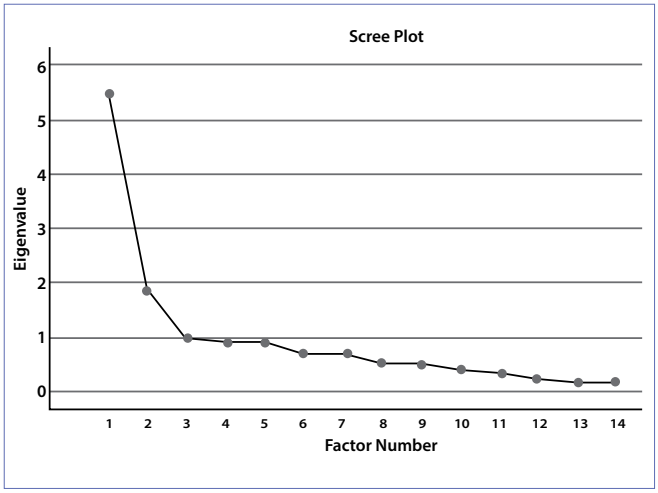

Figure 1. Construct validity – Scree plot.

Table I. Cronbach's Alpha.

Cronbach's Alpha	n of items
0.857	14

Table II. Cronbach's Alpha if you delete an item.

	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Cronbach's Alpha if item deleted
1 Item	10.29	55.154	0.439	0.852
2 Item	11.39	56.648	0.554	0.849
3 Item	10.56	50.823	0.601	0.842
4 Item	11.31	53.902	0.627	0.843
5 Item	10.44	55.915	0.331	0.859
6 Item	10.73	51.512	0.648	0.839
7 Item	10.80	57.903	0.365	0.855
8 Item	11.01	51.268	0.673	0.838
9 Item	10.98	50.963	0.759	0.833
10 Item	10.84	57.559	0.287	0.859
11 Item	10.15	56.163	0.233	0.869
12 Item	10.87	57.354	0.328	0.857
13 Item	11.05	49.952	0.731	0.834
14 Item	10.92	51.188	0.642	0.839

Table III. Intraclass Correlation Coefficient (ICC).

	Intraclass Correlation[a]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Average measures	0.821[b]	0.644	0.909	6.121	36	36	0.000

Two-way mixed effects model where people effects are random and measures effects are fixed; [a]type A intraclass correlation coefficients using an absolute agreement definition; [b]this estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

DISCUSSION

The aim of the study was to translate and culturally adapt the TDI into Italian to produce an Italian version of the scale whit good validity and reliability. As the results show, the TDI is a good tool for the evaluation of spinal disorders, because of its shortness and its capacity to investigate simultaneously pain in the back and in the cervical area. Recent studies support a more global approach to musculoskeletal disorders by analyzing the extent of musculoskeletal (MS) symptoms. In particular they analyze the number of symptomatic anatomical sites rather than a particular site, both in the general population and in the working population. Other back's questionnaires analyze chronic and acute pain too for a wider use in the population, is the case of the Back Pain Functional Scale (19), already validated in Italian language. The results of these studies indicate a moderate prevalence of symptoms strictly confined to a specific anatomical site (prevalence estimated from 15 to 30%, depending on the study) and instead a higher prevalence of multi-site musculoskeletal disorders (20). In fact, the data obtained from the Google Forms showed that most of the patients involved in the study suffered from back pain, while a good part had both back and neck pain. The statistical analysis indicated a good validity and reliability of the tool. The internal consistency of the scale was assessed by calculating the Cronbach's Alpha, which is equal to 0.857, just a little bit less than the original version one. The retest data, collected within 21 days, attested a good test – retest reliability of the scale, with a ICC equal to 0.821. The original version of the TDI has an ICC score of 0.96 by repeating the test within two weeks. To assess the construct validity of the TDI, the Pearson's Correlation Coefficient was measured. The correlations between the tools are statistically significance with a P-value less than 0.01.

CONCLUSIONS

This study consists of the translation, cultural adaptation and validation of the Total Disability Index (TDI). The Italian version of the TDI has good psychometric properties as the results have shown a good validity and reliability of the tool. The brevity of the administration makes the TDI an important tool for assisting the clinician for the planning and management of the best therapeutic plan.
Rating scales, scoring systems, and questionnaires have been used for many years to assess the patient's subjective pain and degree of disability, as the Spine Functional Index scale, already validated in Italian language (21), the use of this scale can help the therapist to obtain more information about the patient's symptoms, since it simultaneously examines various disorders that may occur in the spine. In conclusion, based on the results obtained, we suggest the use of TDI in daily clinical practice, also promoting its continuation in the field of scientific research.

FUNDINGS

None

DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

All authors contributed equally to this work.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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