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TITLE PAGE

Adaptation and Transcultural Translation into Spanish of the Patient-Rated Tennis Elbow Evaluation Questionnaire

Running title: PRTEE transcultural translation into Spanish

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Author Contributions Statement

All authors contributed to the design, acquisition of data, analysis or writing. All authors have read and approved the final version.

Abstract

The purpose of this study was to perform the translation and cross-cultural adaptation of Patient-Rated Tennis Elbow Evaluation questionnaire to Spanish language and evaluate its reliability and validity. The translation and culturally adaptation into Spanish was done in accordance with the published guidelines.

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One-hundred and fifty Spanish-speaking patients with unilateral chronic lateral epicondylalgia competed the questionnaire. Test-retest reliability was established by the intraclass correlation coefficient. Internal consistency was established with Cronbach's α. To establish convergent validity, we used the Disabilities of the Arm, Shoulder and Hand questionnaire using the Spearman's correlation coefficient. Error estimation in the measurements was calculated with the standard error of measurement. Our results showed a high internal consistency (Cronbach's α=0.96) and high test-retest reliability (intra-class coefficient=0.9; 0.89-0.94; p <0.001). The Spearman's correlation coefficient (r=0.765; p <0.001) showed a good relationship between the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire and the Disabilities of the Arm, Shoulder and Hand questionnaire. The standard error of measurement (11.9%) showed little variability of measurements. In conclusion, the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire is a valid and reliable tool that can be used to assess lateral epicondylalgia in Spanish-speaking individuals in order to implement the best treatment and reduce time with pain and disability.

Level of evidence: Basic science Study.

Keywords: Spanish; questionnaire; PRTEE; Lateral Epicondylalgia; adaptation.

Introduction

Lateral epicondylalgia, also known as tennis elbow, is a common injury with a high prevalence, especially among the 40 to 50-year-old population [1,2]. The prevalence in the general working population (25–64 years) is 1.3% for males and 1.1% for females [3]. Lateral epicondylalgia is a costly musculoskeletal disorder, which has been linked to an overload injury. Different instruments have been introduced to evaluate many musculoskeletal conditions, where questionnaires have become an inherent component in the field of health care [4]. The Patient-Rated Elbow Evaluation questionnaire is one of the most commonly used elbow pain and disability outcome measures self-reports in clinical practice and research [5,6]. This questionnaire evaluates pain and functional ability in the previous week and has been translated into several languages [4,6,7,8,9,10,11]. Nevertheless, it had not been adapted into its Spanish version before.

Given that lateral epicondylalgia is a common cause of musculoskeletal pain in upper limbs and Spanish is the second most spoken language in the world, the aim of this study is to translate, adapt, validate and assess the responsiveness to change of a Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire to be used with a Spanish-speaking population.

Material and methods

The study was conducted in 2 phases. Phase 1 involved the translation and cross-cultural adaptation of the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire following the international recommendations [12], and Phase 2 entailed the validation of the Spanish version in subjects with lateral epicondylalgia.

Cross-cultural adaptation

In the first stage, two independent native bilingual Spanish translators (1 physiotherapist and 1 non-health care professional) translated the questionnaire from English to Spanish to produce two versions. Both versions were compared and synthesized into 1 preliminary Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire by a non-medical translator who was not familiar with the study. The discrepancies between the 2 initial translations were discussed and resolved in a consensus meeting. The preliminary Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire was then translated back into English by two independent English-speaking nonmedical translators to obtain a new English version and ensured that the translation was faithful to the original questionnaire and included the same concepts. This translation was subsequently compared to the original questionnaire by an expert committee and was found to be semantically and grammatically equivalent. In order to determine whether the participants understood the last version, we commenced a pilot test on 10 patients with chronic lateral epicondylalgia and 10 healthy individuals. After they were asked to comment on the items and their understanding of the meaning of the issues discussed was explored, the final Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire was validated.

Validation of Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire version

In the second stage, we evaluated the measurement properties of the Spanish version in patients with chronic lateral epicondylalgia.

Subjects

The Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire was administered to 150 Spanish-speaking participants (51% men and 49% women) with chronic unilateral lateral epicondylalgia. The patients were recruited from clinics and Mutual Insurance Companies in Valencia and Madrid. The medical diagnosis of the patients was lateral epicondylalgia.

The study protocol was approved by the Institutional Review Board of the CEU Cardenal Herrera University (Valencia) (Spain). Prior to inclusion in the study all participants signed informed consent approved by "the University of Alcalá and the Cardenal Herrera University Institutional Review Board".

Procedures

All subjects completed a visual analog scale and the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire. The Patient-Rated Tennis Elbow Evaluation questionnaire assesses pain and functional ability in the previous week. It consists of 15 items, 5 items investigate pain, 6 items investigate the degree of difficulty in performing specific activities, and 4 items investigate the degree of difficulty in performing usual activities. Each item can be answer by no difficulty or unable to perform (0-10). The score ranging from 0 (best score) to 100 (worst score). Specific and usual activities scores are divided by 2. To establish convergent validity, we used the Disabilities of the Arm, Shoulder and Hand questionnaire. The Disabilities of the Arm, Shoulder and Hand questionnaire

assesses quality of life related to health [13]. It consists of 30 questions and 2 optional modules of 4 questions each. It deals with the upper extremity as a functional unit in various activities of daily life: sports, leisure or work, and asks the participant to indicate different symptoms (e.g., pain, stiffness, and loss of strength) for each activity. Each question is scored from 1 to 5 points, with increasing values denoting increased intensity of symptoms. The total score is calculated by adding the scores of each item (ranging from 30 to 150 points).

The Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire was administered a second time one week after the first administration to evaluate test-retest reliability.

Sensitivity to change is defined as the ability of a measure (or instrument) to reflect underlying change over time [14].

Sample-Size Determination

The calculation of the sample size was done according to the criteria established by Kline [15] in which between 5 and 10 subjects for each item of the questionnaire is recommended.

Statistical Analyses

The statistical analysis was carried out with the statistical program SPSS (SPSS Inc. Chicago, IL, USA) in its 22.0 version. The descriptive statistics for each variable were calculated to provide a profile of the participants in the study. Normality was assessed with the Kolmogorov-Smirnov test with significance correction of Lilliefors. Afterwards, a descriptive analysis of the results was carried out, using means and typical deviations (for those dependent variables that adjusted to the norm) and medians and first and third quartiles (for the dependent variables that did not adjust to the norm). Additionally, frequency values and percentages for each category were presented for the qualitative dependent variables.

The following psychometric properties were studied through statistical analysis:

Internal consistency. Test-retest reliability of the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire was estimated with the intraclass correlation coefficient (ICC) for all the items one by one and as a whole [16,17]. At the same time, Cronbach's Alpha was measured considering that a measure lower than 0.7 indicates low internal consistency, a rank value between 0.7 and 0.8 indicates moderate consistency and a value higher than 0.8 indicates good internal consistency [18].

Standard errors of measurement (SEM). SEM Were calculated to measure rank error. SEM is a quantitative expression of the rank error that can happen whenever the same participant repeats certain tests. SEM was calculated from the ICC and the SD for each session, using the highest of both SD measurements to determine the rank error attributed between the sessions. The formula SEM = SD × sqrt (1 - ICC) was used to calculate SEM, and for a better interpretation, SEM percentage of error (SEM%) was calculated with the formula SEM% = SEM / media * 100%, which provided error estimation or inherent variability normalized to the average.

Furthermore, to determine the smallest quantity of real change beyond the measurement limit of error, the minimum detectable change (MDC) was calculated with a 95% confidence level. The MDC values that reflect the magnitude of necessary change to ensure that change is not a result of a random variation or a measurement error, were calculated with the formula:[19] $MDC = \sqrt{2} \times 1.96 \times SEM$. In order to verify the existence of bias in the measurements, the regression line was calculated with a Bland and Altman plot [20].

Floor effect and ceiling effect. For its analysis, the percentage of patients that obtained the lowest and highest values in each dimension of the scale was factored in. Ceiling effect and /or floor effect are considered present if more than 15% of participants have obtained the highest or lowest possible values [21].

Convergent validity. It was carried out using Spearman's coefficient. The correlations were assessed with those items of the Patient-Rated Tennis Elbow Evaluation questionnaire corresponding with the items in the Disabilities of the Arm, Shoulder and Hand questionnaires validated into Spanish.

Factorial Analysis. Kaiser-Meyer-Olkin tests and Barlett's sphericity test were used to determine if the sample was adequate for the development of exploratory factorial analysis by the principal component's method. Regarding the number of factors that should be retained, a ≥ 1 minimum limit of proper values was established. Those elements that saturated the retained factors sufficiently were selected, establishing a limit of 0.30 or higher for the selection [22].

Sensitivity to change. It is the ability to detect significant changes, both positive and negative, in the measured attribute. Sensitivity to change is a very important aspect of the questionnaire when this is used as a response variable. Sensitivity to change was evaluated by applying the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire to 32 subjects, before and after the specific program of isometric exercises. A parametric t-test for paired samples was used, since the data for both the pre and post measurements were normal.

Results

Profile of Participants

Table 1 shows information about the characteristics for the whole sample (n = 150). The age range of participants was 18-75, with an average age of 47.07 years. The sample consisted of a majority of men (51%), while women represented 49% of the sample (Table 1).

Table 2 collects individual descriptive data of the items in the questionnaire.

Internal Consistency

Good internal consistency was also obtained when considering all the items of the Patient-Rated Tennis Elbow Evaluation questionnaire in its Spanish version, with an ICC of 0.9 (IC 95% = 0.89-0.94); $p < 0.001$. Cronbach's alpha was considered very good, with a value of 0.9. The results obtained by dimensions can be considered very good: the section of the questionnaire dedicated to pain obtained a

Cronbach's alpha of 0.8 and in the functional disability section, daily life activities obtained 0.9 (Table 2).

The visual distributions of the Bland and Altman representations show that the average of the values does not predict the difference, which confirms that it lacks systematic errors and that, together with the Cronbach's alpha values and the total test-retest ICC, the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire can be considered reliable and repeatable (Figure 1).

Floor Effect and Ceiling Effect

Bearing in mind that the maximum score is 150 points and the minimum is 0, no floor or ceiling effects have been found in the studied sample for the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire.

Convergent Validity

In order to calculate the convergent construct validity, the total score of the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire was compared to the total scores obtained in the Disabilities of the Arm, Shoulder and Hand questionnaire. Spearman's correlation coefficient for non-parametric samples was used.

A good, directly proportional and statistically significant linear relationship was found between the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire and the Disabilities of the Arm, Shoulder and Hand questionnaire as a whole ($r = 0.765$, $p < 0.001$) (Table 2).

Factorial Analysis

The KMO measure for sampling adequacy was 0.90, higher than the recommended value of 0.60, and the Bartlett's test results were significant ($X^2 = 1410{,}21$; $p < 0.001$), indicating that data are adequate for principal component analysis.

Three components were isolated in the factorial analysis, corresponding to the three dimensions of the test, which explains the 78.9% variance. The first self-extracted factor explains 60.52% of the variance, which seems to indicate the unidimensionality of the test and implies that only one latent trait or construct is at the base of the entire set of items in the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire [22].

Standard errors of measurement and minimum detectable change

For the entire set of items, the SEM was 8, which is translated into an 11.9% error, indicating the small variability in the measurements. The MDC was determined to be 11 points, which means an MDC% of 16.4%. For the 3 parts of the questionnaire, the SEM and MDC are shown on Table 2.

Sensitivity of the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire

Statistically significant differences were found between the pre-treatment evaluation and the post-treatment evaluation [31.31 (21.66-40.96); p <0.001].

Discussion

The main finding of the present study was that the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire is a valid, reliable, and responsive tool that can be used to quantitatively measure outcomes in Spanish patients with chronic lateral epicondylalgia. The questionnaire also showed good psychometric properties, good reliability and good construct validity.

The Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire has been shown to be reliable. To assess the reliability of the questionnaire, we evaluated its internal consistency by using Cronbach's alpha, which indicates the extent to which test items covary. A Cronbach´s alpha value of 0.9 is considered to be excellent [23]. Nevertheless, a very high (over 0.96) value may reflect some items are redundant. Our results showed an excellent internal consistency ($\alpha = 0.96$). This high value is considered to be at the limit that allow an excellent internal consistency interpretation rather than element redundancy. Our results were equivalent to those of the Swedish [8] (0.94), Italian [11] (0.95), Dutch [10] (0.98), Greek [6] (0.95) and French [7] (0.98) versions of the Patient-Rated Tennis Elbow Evaluation questionnaire. Therefore, we consider the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire to be a well-designed questionnaire.

The test–retest reliability was determined using the ICC with 7 days between each administration of the questionnaire. In our case, the ICC for total score, and functional disability and daily life activities subscales was 0.9, which is a similar value to Patient-Rated Tennis Elbow Evaluation questionnaires translated into other languages. The Swedish [8] version has an ICC=0.95, Turkish [9] ICC=0.92, Italian [11] ICC=0.95, Dutch [10] ICC=0.98 and Greek [6] ICC=0.94. Nevertheless, the pain subscale ICC was 0.8. This could be related to pain been a parameter that may change during the acute phases. However, we included chronic pain patients and participant achieved ICC scores during a 7-day period to ensure clinical stability. To have a better interpretation of the data reliability, the SEM also needs to be examined [24]. The SEM value found in this study was 11.9%.

The convergent validity is an important characteristic of questionnaires. It allows to corroborate the construct validity, by demonstrating a correlation between two measures. The Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire convergent validity was calculated by comparing the items in our questionnaire with the items in the Spanish Disabilities of the Arm, Shoulder and Hand questionnaire. The Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire had a good correlation with the Spanish Disabilities of the Arm, Shoulder and Hand questionnaire (r=0.765). These results met the requirements published by Terwee et al. [21], which recommend *r* values over 0.7 for questionnaires evaluating the same construct. Our correlation at baseline was close to those of the Greek [6] and Italian [11] versions but was found lower than the Swedish [8] and higher than the Dutch [10] versions.

Sensitivity to change, also called longitudinal construct validity [25], is considered an integral part of the analysis of the questionnaire's validity. Assessment of the sensitivity to change showed that the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire has good sensitivity to change and may be useful in objectively assessing changes during the use to the 4-week specific isometric exercise program.

The Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire did not reflect any floor or ceiling effect. This was not reported in the original questionnaire [26]. Nevertheless, the Canadian French also reported no floor or ceiling effect [27].

Our study has several limitations that need to be addressed. The data collection was specific to a geographical area. A larger sample from a wider range of Spanish-speaking countries would make the results more extensible. As in the Dutch [10] and the Italian [11] studies, we used 10 patients at the pre-test stage, while Beaton et al. [12] suggest that 30-40 patients are necessary at this stage.

In conclusion, the results of this study provide evidence of the validity, reliability and responsiveness of the Spanish version of the Patient-Rated Tennis Elbow Evaluation questionnaire showing it can be used as a tool to measure outcome in the studied population.

Author's Contribution

All authors contributed to the design, acquisition of data, analysis or writing. All authors have read and approved the final version.

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Disclosure statement

The authors report no conflict of interest.

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Tables

Table 1. Subject characteristics and descriptive statistics of the PRTEE-D, DASH and VAS pain scores.

Measure	Participants construct validity n = 150 (mean, SD)	Participants Sensitivity to change
Sex:		
Men	78 (52%)	17 (53.1%)
Women	72 (48%)	15 (46.9%)
Age (years)	47.45 ± 11.84	45.9 ± 9.1
Height (m)	1.70 ± 0.07	1.6 ± 0.07
Weight (kg)	71.59 ± 8.70	68.4 ± 11.6
BMI	24.93 ± 2.30	24.35 ± 2.58
Duration of symptoms (months)	3.10 ± 0.91	3.7 ± 1.1
Occupation:		
Soldiers	1 (0.7%)	8 (25%)
Directors/Managers	4 (2.6%)	2 (6.3%)
Professionals	30 (20%)	3 (9.4%)
Advanced Technicians	2 (1.4%)	6 (18.8%)
Technicians	31 (20.6%)	1 (3.1%)
Administrative assistants	14 (9.4%)	8 (25%)
Service workers	4 (2.6%)	1 (3.1%)
Farmers	1 (0.7 %)	3 (9.4%)
Qualified workers	18 (12%)	
Installation workers	35 (23.4%)	
Students	3 (2%)	
Retirees	7 (4.6%)	
PRTEE-S[a]	71.40 ± 29.78	79.32 ± 34.19
PRTEE-S pain subscore[a]	25.36 ± 9.15	28.59 ± 9.05
PRTEE-S Function subscore[a]	21.65 ± 11.95	24.53 ± 13.78

PRTEE-S function specific subscore[a]	24.40 ± 11.17	26.68 ± 13.62
DASH score	40.8 ± 7.9	42.9 ± 19.5
VAS pain score	5.0 ± 2.1	6.4 ± 1.6

[a]The first PRTEE-S measurement is used to calculate the mean score. PRTEE-S= Patient Rated Tennis Elbow Evaluation-Spanish, DASH = Disabilities for the Arm, Shoulder and Hand questionnaire, VAS = Visual Analogue Scale, LE = Lateral Epicondylalgia, SD = Standard Deviation, BMI = Body Mass Index.

Table 2. Descriptive Items and Test-Retest reliability of the PRTEE questionnaire and Convergent correlations between the PRTEE questionnaire and the DASH.

No.	**Test Med. * (n = 150)**	**Retest Med. * (n = 150)**	**CCI (n = 150)**	**CI (95%)**	**p**
Item 1, 0-10	3.00 (1.00-5.00)	2.00 (1.00-4.00)	0.8	0.79-0.89	<0.001
Item 2, 0-10	6.00 (5.00-8.00)	5.00 (4.00-7.00)	0.8	0.78-0.88	<0.001
Item 3, 0-10	6.00 (5.00-8.00)	5.00 (4.00-7.00)	0.8	0.77-0.86	<0.001
Item 4, 0-10	2.00 (0.00-3.00)	1.00 (0.00-3.00)	0.9	0.86-0.93	<0.001
Item 5, 0-10	8.00 (7.00-9.00)	8.00 (7.00-9.00)	0.8	0.75-0.87	<0.001
Item 6, 0-10	3.00 (2.00-6.00)	3.00 (2.00-5.00)	0.8	0.80-0.89	<0.001
Item 7, 0-10	5.00 (4.00-8.00)	5.00 (4.00-7.00)	0.8	0.79-0.88	<0.001
Item 8, 0-10	3.00 (1.00-6.00)	3.00 (1.00-5.00)	0.9	0.88-0.94	<0.001
Item 9, 0-10	6.00 (4.00-8.00)	6.00 (5.00-9.00)	0.8	0.80-0.89	<0.001
Item 10, 0-10	2.00 (2.00-5.00)	2.00 (1.00-5.00)	0.8	0.78-0.88	<0.001
Item 11, 0-10	5.00 (3.00-8.00)	5.00 (3.00-6.00)	0.9	0.86-0.93	<0.001
Item 12, 0-10	3.00 (2.00-5.00)	3.00 (2.00-5.00)	0.8	0.84-0.92	<0.001
Item 13, 0-10	5.00 (3.00-7.00)	5.00 (3.00-6.00)	0.9	0.89-0.94	<0.001
Item 14, 0-10	5.00 (4.00-7.00)	5.00 (4.00-7.00)	0.8	0.82-0.91	<0.001
Item 15, 0-10	6.00 (4.00-8.00)	6.00 (3.00-8.00)	0.9	0.91-0.95	<0.001

PRTEE questionnaire, 0-150		Mean ± DS IC (95%) (n = 150)	α	ICC CI (95%)	p	SEM SEM(%)	MDC MDC(%)
Overall	test	71.40±29.78 (66.15-76.66)	0.96	0.9 (0.89-0.94)	<0.001	8 (11.9 %)	11 (16.4 %)
	retest	62.75±23.65 (58.58-66.93)					
Pain	test	25.36±9.15 (23.74-26.97)	0.94	0.8 (0.85-0.92)	<0.001	2 (8.2 %)	5 (20.7 %)
	retest	22.94±8.01 (21.52-24.35)					
Functional Disability	test	21.65±11.95 (19.54-23.76)	0.95	0.9 (0.88-0.94)	<0.001	3 (13.9 %)	8 (11.9 %)
	retest	21.49±9.91 (19.74-23.24)					
Daily Life Activities	test	24.40±11.17 (22.43-26.37)	0.96	0.9 (0.91-0.95)	<0.001	2 (8.30 %)	5 (20.7 %)
	retest	23.76 ±9.51 (22.08-25.44)					
Convergent correlations between the PRTEE questionnaire and the DASH							
rho= 0.765; p<0.001							

*Nº: item number of the questionnaire, * Median, 1st and 3rd quartile, p = statistical significance.*

ICC = Intraclass Correlation Coefficient (of a 2-way mixed-effects model, with absolute agreement)

α = alpha of Cronbach

SEM = Standard Error of Mean; SEM =SD × sqrt (1 - ICC)

*SEM% = (SEM / mean) * 100%*

MCD = Minimum Detectable Change; MDC = √2 × 1.96 × SEM

*MDC% = (DCM / Average) * 100*

DASH= Disabilities of Arm, Shoulder and Hand

Figures

Figure 1. Bland and Altman representation between first PRTEE measurement and PRTEE retest.