

RESEARCH ARTICLE

Responsiveness and Minimally Important Changes for Persian-version of Patient-Rated Tennis Elbow Evaluation Questionnaire in Patients with Lateral Elbow Tendinopathy Following Physiotherapy Intervention

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Abstract

Background: Evaluating responsiveness and calculating minimally important change (MIC) for the Persian-version of the Patient-Rated Tennis Elbow Evaluation (PRTEE) questionnaire following physiotherapy in patients with lateral elbow tendinopathy (LET).

Methods: We enrolled 82 patients with LET to complete the PRTEE. After completing four weeks of physiotherapy, all patients were reevaluated by the PRTEE. The patients also rated their changes on a 7-point global rating of change scale (GRoC). The receiver operating characteristic (ROC) curve and correlation analysis were used for evaluating the responsiveness. The MIC was determined by determining a desirable cutoff on the ROC curve.

Results: The results showed a moderate relationship (Spearman's correlation coefficient= 0.43-0.56) of total PRTEE, pain subscale, and function subscale with the GRoC scale. The total PRTEE, pain subscale, and function subscale revealed an area under the curve of 0.87, 0.82, and 0.83, respectively. We found the MICs 31.33, 14.5, and 15.5 points for total PRTEE, pain subscale, and function subscale, respectively.

Conclusion: The Persian-version of the PRTEE questionnaire has acceptable responsiveness and can measure changes in patients with LET following physiotherapy. We advocate using the PRTEE questionnaire in both clinical settings and research.

Level of evidence: IV

Keywords: Lateral elbow tendinopathy, Measurement properties, Minimal important change, Patient-rated tennis elbow evaluation, Rehabilitation

Introduction

Lateral elbow tendinopathy (LET), also named tennis elbow, is a major elbow health problem.¹ Soft tissue injury of wrist extensor tendons origin, specifically the tendon of extensor carpi radialis brevis, results in lateral elbow pain, aggravated by strong gripping or repetitive wrist movements during sport or work.^{2,3} Pain and functional limitations are major problems that

restrict the performance of a daily task for patients with LET.⁴

Numerous management options have been used for this condition, including wait and see (no treatment), nonsteroidal anti-inflammatory drugs, injection, and physiotherapy.³ Most of clinicians support a conservative method as a solution of healing for LET. Physiotherapy

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is usually recommended as a routine therapy.^{5,6} In the late few years, there are increasing interests in applying patient-reported outcome measures for assessing the efficacy of physiotherapy management.⁶ Researchers have developed the Patient-Rated Tennis Elbow Evaluation (PRTEE) questionnaire to address the gap in outcome measures for LET disorder.^{7,8} The PRTEE questionnaire is one of the most widely-used outcome measures that appraise elbow pain and functional capacity in the activities of daily living in individuals with LET.⁹ Because this questionnaire is a brief and simple way to assess patients' pain and function, the goodness of the PRTEE questionnaire has been reported in several languages.¹⁰⁻¹² Clinicians and researchers are used to evaluate reliability, validity, and responsiveness as a prerequisite for patient-reported outcome measures. The reliability and validity of the Persian-version of the PRTEE questionnaire have been established in Iranian patients with LET.¹³⁻¹⁵ Responsiveness means 'the ability of a measurement instrument to find change during the time in the framework to be measured.'¹⁶ This measurement property must be examined in different patient groups, interventions, and settings because they may vary from situation to situation.¹⁷

There are two main definitions for responsiveness, each having own program for assessing.¹⁸ Initial definition, known as 'internal responsiveness', distinguishes the ability of an outcome measure to differ from a specific preset period. Most of clinicians recommend a conservative approach as the choice of therapy. Hence, the internal responsiveness of a measure will be determined by specific treatment. second aspect is 'external responsiveness', which we used in this study. External responsiveness refracts the number of changes in an outcome measure beyond a specified period related to relevant alters in a reference measure of health status. External responsiveness is the correlation between a change in the outcome measure and a change in the external standard. If this correlation is significant, the measurement records enough external standard changes. It is accepted that changes in the external standard indicate a change in the patient's condition. External responsiveness will only depend on the election of an external standard and not the treatment backup. Therefore, this type of responsiveness will be a property of the outcome measure.¹⁹

The research has focused on internal responsiveness rather than external responsiveness.¹⁰⁻¹² subsequently, in this study, we attempted to evaluate the correlation between changes in the PRTEE questionnaire and external standard using appropriate statistical methods. In the following, sensitivity and specificity for each value were used to plot a ROC curve for measurement of external responsiveness. Minimal clinically important change (MIC) that has got by external responsiveness, shows smallest score (number) or modify in a score that is valuable from patients belief.¹⁹ clinicians and researchers should know MIC scores when using outcome measures during physiotherapy to evaluate if the physiotherapy program reaches its goals or not.

Hence, main issues addressed in our paper were to estimate the external responsiveness and to determine the MIC values of the Persian-version of the PRTEE following physiotherapy intervention in patients having LET.

Materials and Methods

Patients

A total of 82 patients with LET between July 2018 and June 2019 were enrolled in some physiotherapy centers. For inclusion, at first session, the diagnosis was confirmed increasing pain in at least two of the following tests: (1) extension of wrist restricted (Tomson test), (2) resisted middle finger, (3) full passive flexion of the wrist (Mill's test), or 4) forceful gripping. In addition, the patients could complete the items of the patient-reported questionnaires independently.^{18,20} Exclusion criteria were: (1) neck pain with radicular symptoms for upper extremities, (2) pain for both elbows, or (3) indicating neurological or systemic arthritis.²¹ Ethical approval was received from the Research Ethics Committee of Mashhad University of Medical Sciences (approval number: IR.MUMS.REC.1398.069). Primarily written informed consent was filled by all of patients.²² Demographic and clinical characteristics of the enrolled patients are showed in table 1 [Table 1].

Procedure

The literature has shown that assessing external responsiveness does not related to the types of treatments. Therefore, we did not control the detailed treatment, but the overall treatment was the same among all patients.^{17,19} At first, a baseline questionnaire containing questions on demographic variables and the Persian-version of the PRTEE were completed by participations, and then the physiotherapy treatment was initiated for them.¹⁴ All patients received the physiotherapy intervention for 12 sessions in four weeks (i.e., three sessions per week).⁵ The physiotherapy

Table 1. Demographic and clinical characteristics of patients completing the PRTEE (n=82)

Demographic data	n (%) unless stated
Age (year), mean (SD)	44.31(10.63)
Height (m), mean (SD)	1.64 (0.93)
Weight (kg), mean (SD)	66.74 (9.10)
BMI, mean (SD)	24.90 (10.63)
Sex	
Men	13 (15.9)
Women	69 (84.1)
Duration of symptoms (month)	
< 6	46 (56.1)
6-12	28 (34.1)
> 12	8 (9.8)

SD: Standard deviation; BMI: Body mass index

intervention consisted of an exercise therapy program and electrotherapy according to observed clinical signs and symptoms, focusing on improvement in function and decrement in pain.^{21,23} The program also included home exercises.²⁴ After completing four weeks of physiotherapy intervention, all patients were reevaluated using the PRTEE.¹⁴ The patients also numbered their conditions on a 7-point global rating of change scale as an external standard. This 7-point Likert scale is a single-item self-reported assessment form in which patients number their perceived development since the starting of treatment.²⁵

Instruments

Persian-version of the PRTEE questionnaire contains two components: pain (five pieces) and function (15 pieces). The 20 pieces in the PRTEE questionnaire are processed to assess elbow pain and functional capacity during the ADLs. Each component score and the summary score range from zero (no pain and disability) to 100 (most pain imaginable and major functional disability).¹³ For each piece, the participant could only choose one reply choice. The scores that the individual gained from the different subscales were used to quantify total score. For each patient, the total score of zero displayed the ideal condition, and the total score of 100 displayed the worst-case scenario. For calculating total score, the sum of 15 items (specific activities include 11 items and usual activities include four items) related to function was divided by three Fields.¹⁰ Then, the total pain score was added to the resulting function subscale.^{13,14}

In addition, the patients were requested about their perception of amount of change in their health status postintervention by the 7-point global rating of change scale. This 7-point Likert scale was regulated as "How did your elbow condition change compared to the starting of the physiotherapy intervention?" and consisted of seven possible answers where very much worse = number 1, much worse = number 2, slightly worse = number 3, no change = number 4, slightly better = number 5, much better = number 6, and very much better = number 7. For this purpose, we considered the change scores of five or lower as unimproved participants and the scores of six and seven as improved participants.²⁵

Statistical analysis

We used SPSS, Version 19 for data analyzing. $P < 0.05$ was considered as level of statistical significance. The normal distribution of the data in the primary analysis examined by Kolmogorov-Smirnov test. Due to normally distributed data, paired t-test was applied to assess the differences between pre and postinterventions for the PRTEE questionnaire. Total sample and subsamples of improved (i.e., very much better and much better) and unimproved (i.e., slightly better, no change, slightly worse, much worse, and very much worse) patients directed for these analyses. To calculate score changes for the PRTEE questionnaire, the follow-up scores were lessened from the baseline scores. Hence, a positive change score was recognized as an improvement in a

patient's clinical condition, while a negative change score was noticed as an unimprovement in the patient's clinical condition.^{18,22,25}

This study evaluated external responsiveness applying the correlation analysis and the receiver operating characteristics (ROC, 95% confidence interval [CI]). A Spearman's correlation coefficient (rs) was used to determine the correlation between the score changes of the PRTEE questionnaire and the global rating of change scale. Higher correlation coefficients show a stronger association between the measurements and the external standard.¹⁹ Correlation coefficients greater than 0.60, between 0.30 and 0.60, and less than 0.30 were investigated strong, moderate, and weak, respectively.²⁶ The ROC curve is designed by plotting the true positive rate against the false positive rate at different threshold settings as cutoff points. The ROC curve is designed by plotting the "sensitivity" on the y-axis against the "1-specificity" on the x-axis for each cutoff point in change scores of the tool.^{19, 27} The area under the curve (AUC) and the optimal cutoff point (MIC) were helpful statistics extracted from the ROC curve. The AUC shows the external responsiveness of a questionnaire.²² An AUC value of 1.0 indicates the optimal discriminatory capability of the instrument to diagnose between improved and unimproved patients. The AUC values of <0.70, 0.70–0.79, and ≥ 0.80 are considered suboptimal external responsiveness, optimal external responsiveness, and excellent external responsiveness, along with the accurate discriminating ability of an outcome measure, respectively. Youden Index determined the MIC as the desirable cutoff point on the ROC curve.²⁸ The Youden Index provides a criterion for choosing the optimal cutoff value, the threshold for which 'sensitivity+ specificity- 1' is maximized. The MIC shows the score of ideal change, an important change from the patient's perspective.²⁹

Results

Means and standard deviations of preintervention, postintervention, and change scores for PRTEE as descriptive statistics are shown in Table 2. Based on the 7-point global rating of change scale, 50 (61%) patients were allocated as improved patients, including a total of 14 (17.1%) patients showed very much better, and 36 (43.9%) cases showed much better. Furthermore, 32 (39%) patients were allocated as unimproved patients, including 0 (0%), 27 (32.9%), 0 (0%), 5 (6.1%), 0 (0%) patients showed slightly worse, slightly better, very much worse, no change, and much worse, respectively.

The correlation analysis showed a moderate relationship between the PRTEE questionnaire (including total PRTEE, Pain subscale, and Function subscale) and the global rating scale (rs= 0.43-0.56) [Table 2]. In addition, the total PRTEE, Pain subscale, and Function subscale disclosed AUC of 0.87, 0.82, and 0.83, appropriately [Table 3]. As the findings demonstrated, the desirable cutoff scores that found nearest to the upper-left corner of the ROC were the best combination of sensitivity and specificity. They equal to 31.33

Table 2. Mean (SD) of pre-intervention, post-intervention and change scores for PRTEE subscales (n=82)

Questionnaires		Pre-intervention Mean (SD)	Post-intervention Mean (SD)	Change Mean (SD)	P-value
PRTEE subscales					
PRTEE Total	Total (n=82)	58.48 (20.10)	26.45 (18.04)	32.02 (17.82)	<0.001
	Improved (n=50)	60.82(19.63)	20.20 (13.57)	40.61 (14.22)	<0.001
	Not improved (n=32)	54.82 (20.58)	36.21 (19.94)	18.60 (14.34)	<0.001
PRTEE Pain	Total (n=82)	30.67 (9.55)	14.84 (9.02)	15.82 (9.48)	<0.001
	Improved (n=50)	32.10 (8.90)	12.16 (7.97)	19.94 (7.73)	<0.001
	Not improved (n=32)	28.43 (10.23)	19.03 (9.08)	9.40 (8.40)	<0.001
PRTEE Function	Total (n=82)	27.80 (13.10)	11.61 (10.22)	16.19 (11.25)	<0.001
	Improved (n=50)	28.72 (13.54)	8.04 (6.87)	20.67 (10.61)	<0.001
	Not improved (n=32)	26.38 (12.47)	17.18 (12.08)	9.19 (8.34)	<0.001

PRTEE: Patient-Rated Tennis Elbow Evaluation

(sensitivity= 0.78, specificity= 0.84), 14.5 (sensitivity= 0.74, specificity= 0.75), and 15.5 (sensitivity= 0.72,

specificity= 0.81) points for the total PRTEE, Pain, and Function, respectively.

Table 3. Spearman (rs) correlation coefficient and area under the receiver operating characteristic (AUC) curve for PRTEE Questionnaire according to external, dichotomized measure of global rating of change scale (improved versus unimproved) (n=82)

Measure	Spearman coefficient (P-value)	AUC (95% CI)	Optimal cutoff value	Sensitivity (95% CI)	Specificity (95% CI)
PRTEE Total	0.56 (<0.001)	0.87 (0.79-0.95)	31.33	0.78 (0.63-0.88)	0.84 (0.66-0.94)
PRTEE Pain subscale	0.43 (<0.001)	0.82 (0.72-0.91)	14.5	0.74 (0.59-0.84)	0.75 (0.56-0.87)
PRTEE Function subscale	0.52 (<0.001)	0.83 (0.73-0.93)	15.5	0.72 (0.57-0.83)	0.81 (0.62-0.92)

PRTEE: Patient-Rated Tennis Elbow Evaluation; CI: Confidence interval
AUC (area under curve) equal or greater than 0.70 are in bold.

Discussion

The first aim of this study was to assess the external responsiveness of PRTEE subscales. Generally, the results of this study reveal that all subscales of PRTEE attained acceptable responsiveness in patients with LET with physiotherapy intervention. The second aim was to estimate the MIC value using the ROC for PRTEE subscales.

The external responsiveness for outcome measure

was examined through correlation analysis with the 7-point Likert scale and calculating the AUC. Our findings identified a moderate correlation between the PRTEE questionnaire and external standards. In addition, the results showed the AUC=0.87 for the total score and demonstrated an accurately discriminating ability to differentiate LET patients recovering from those who did not. The AUC for the pain subscale was 0.82, and for the function, and subscale was 0.83. These are

interesting results for both clinical practice and clinical research that the pain/function subscales identified changes important to the patients after physiotherapy intervention.

The findings of the current study were in agreement with a previous responsiveness study in the UK, in which Poltawski et al. studied the responsiveness of the PRTEE in a group of patients with LET. Their sample size (N=57) was lesser than that in the present study (N=82). Patients completed the PRTEE before and after receiving therapy for ten sessions. These researchers found the AUC approximately 0.86, 0.84, and 0.83 for Total, pain, and p function, respectively.³⁰ In addition, the responsiveness of the PRTEE was previously assessed by Hanyu et al. and by Cacchio et al., and the acceptable effect size (ES) and standardized response means (SRM) were demonstrated by them (ES= 1.12 and 2, SRM= 1.28 and 2.3, respectively).^{10,12}

It should be noted that ES and SRM are measures of the magnitude of change scores, not the validity of change scores. These studies demonstrated internal responsiveness through the traditional distribution-based methods. Therefore, differences in SRM and ES between studies probably reflect differences in treatment effects rather than differences in the responsiveness of the PRTEE. Regardless of the differences in the methods of evaluating responsiveness between our analysis and these two original validation studies, our findings were in line with those of these studies.

A recent systematic review with the meta-analysis by Shafiee et al. (2021) was conducted on the psychometric properties and cross-cultural adaptation of the PRTEE. Interestingly, Shafiee et al. (2021) obtained the same pattern of findings as they showed that two studies reported excellent AUC (more than 0.8) for the total score and subscales of the PRTEE, suggesting acceptable discrimination of important change with treatment.³¹

Another point for discussion is the use of MICs in this research. The MIC powerfully demonstrate the necessary scores for clinically desirable change in the health condition of patients. We calculated the MIC score of the PRTEE to be 31.33 points after 12 sessions of physiotherapy treatment in this study. Additionally, the MIC was 14.5 and 15.5 points for the PRTEE pain and function, respectively. This means that a patient with LET had to change at least 31.33 points on the Total score, 14.5 points on the PRTEE pain, and 15.5 points on the PRTEE function to be judged as having clinically important changes. The MIC value for the total score of PRTEE in this study can be compared with the smallest detectable change (SDC) of 20 points for total score calculated in Farazd et al. study in patients with LET with very similar characteristics.^{13,32} Ideally, the MIC should be larger than or equal to the measurement error (SDC).³³ We found the optimal cutoff point as the MIC equal to 31.33 points for the total score of the PRTEE after 12 sessions of physiotherapy intervention

in our study. This shows that if patients had a change value above 20 points, it could be distinguished with 95% confidence from measurement error.

The results showed that the Persian-version of the PRTEE questionnaire has acceptable responsiveness to changes in health status due to physiotherapy. Therefore, we advocate using the Persian-version of the PRTEE questionnaire in both clinical settings and research. In addition, clinicians can potentially use the MIC values reported in this study to determine if their patients with LET and similar demographics to this cohort of patients have experienced a true improvement in their status following physiotherapy intervention.

Limitations

A few limitations of present study must be considered by researchers. Several researchers have remembered using a retrospective global rating scale as an external standard due to recall bias. However, the short follow-up in the current study (i.e., four weeks) might suppressed the probably of recall bias associated with the global rating scale.³⁴⁻³⁶ Additionally, since no tennis players participated in this study, our findings could not be generalized to this patient population.

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