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TENDINopathy Severity Assessment-Achilles: a study protocol for cross-cultural adaptation and psychometric properties patient-reported outcome instrument in Persian athletes with Achilles tendinopathy

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ABSTRACT

Patient-reported outcome measurements (PROMs) are important to evaluate the impact of clinical practice in athletes with Achilles tendinopathy (AT). The TENDINopathy Severity assessment-Achilles (TENDINS-A) is a PROM that measures the pain, symptoms and physical function associated with AT. This study aims to translate, cross-culturally adapt and measure the properties of the Persian language version of the TENDINS-A (Persian-TENDINS-A) in athletes with AT.

According to the COnsensus-based Standards for selecting health Measurement INstruments guidelines, 100 athletes with AT will be required for test-retest reliability, construct validity and internal consistency. Analyses will include confirmatory factor analysis, internal consistency, construct validity, SE of measurement, agreement, smallest detectable change, and floor and ceiling effects. Test-retest reliability of the Persian-TENDINS-A will be evaluated within 2–3 days for the Persian-TENDINS-A. Hypothesis testing of the Persian-TENDINS-A will be determined using a Pearson correlation of a single point in time between Persian-TENDINS-A scores with the Victorian Institute of Sports Assessment-Achilles and Pain Self-Efficacy Questionnaires.

The study protocol was approved by the Ethics Committee of the University of Zabol (approval ID: IR.UOZ.REC.1403.004) based on the Declaration of Helsinki. Findings from this study will be disseminated to the athletes, clinicians and researchers through peer-reviewed journals and national and international conferences.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Assessment of the severity of pain and disability in Achilles tendinopathy (AT) should be based on the patient's perception using self-report questionnaires and similar instruments.
⇒ The TENDINopathy Severity Assessment-Achilles is a patient-reported instrument to assess pain, symptoms and physical function associated with AT.

WHAT THIS STUDY ADDS

⇒ This study protocol will follow the COnsensus-based Standards for selecting health Measurement INstruments (COSMIN) with permission from the scale developers.
⇒ This study involves translation, cross-cultural adaptation, reliability and validity of the TENDINopathy Severity Assessment-Achilles score in the Persian language.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study will be conducted on Persian-speaking males and females with insertional or midportion AT.
⇒ Psychometric properties will be explored, including construct validity, internal consistency, test-retest reliability, and floor and ceiling effects.
⇒ This study will also help assess and plan rehabilitation programmes for athletes with AT.

INTRODUCTION

Achilles tendinopathy (AT) is a chronic condition in the ankle and foot.[1 2] AT is characterised by localised pain over the Achilles tendon, usually associated with physical activity and sports.[3 4] Most patients with AT are active and involved in recreational or competitive sports.[5]

Various factors may be associated with pain in the Achilles tendon, including biomechanics,[6] muscular strength,[7] genetic and/or metabolic factors.[8 9] While Murakawa *et al* reported that psychological factors demonstrate a limited association with the severity of AT,[10] some studies indicated a correlation between psychological factors and outcome measures related to pain, disability and physical function in tendinopathy.[11 12] Thus, examination of pain and disability should be based on the patient's perception. Therefore,

pain and disability severity in AT should be examined through self-report questionnaires and similar instruments.

Several reliable self-reported questionnaires evaluating the pain, disability and activity limitation associated with chronic conditions in the ankle and foot exist.[13–15] However, these questionnaires do not have sufficient structural validity and do not evaluate the severity of the disability during physical activities. The TENDINopathy Severity Assessment-Achilles (TENDINS-A) was developed by Murphy *et al* and consists of questions covering subscales of pain, symptoms and physical function related to AT.[16] Nevertheless, for this questionnaire to be effective in multiple geographical regions, it requires translation and cross-cultural adaptation to ensure cultural relevance while maintaining the original measurement properties. Therefore, the main aims of this study are to translate and cross-culturally adapt the TENDINS-A questionnaire into the Persian language version (Persian-TENDINS-A) according to international guidelines and to evaluate the measurement properties of the Persian-TENDINS-A in athletes with AT.

METHODS

Study design and participants

Reporting of this cross-sectional study will follow the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)[17] guideline for observational studies and the Checklist for Reporting Results of Internet E-Surveys (CHERRIES).[18] Also, reporting will be further informed by the criteria of the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) Risk of Bias checklist[19 20] and the Guidelines for Reporting Reliability and Agreement Studies (GRRAS).[21]

The study will be performed per the ethical standards in the World Medical Association Declaration of Helsinki.[22] This study was approved by the Research Ethics Committee of the University of Zabol (approval ID: IR.UOZ. REC.1403.004).

Inclusion criteria

The inclusion criteria will be as follows: Persian-native speaker, patient age older than 18 years, voluntarily came to the physical therapy centres to seek treatment or consultation for AT, and willing to fill in the questionnaire.

Exclusion criteria

Patients will be excluded if their injury is unrelated to AT, if they have a history of Achilles tendon rupture or previous lower limb surgery, and if they cannot communicate in Persian.

Participant characteristics and assessments (including sex, age, height, body mass, body mass index, sports experience, neuropathic pain (painDETECT questionnaire),[23] location of Achilles tendon pain (insertional/midportion),[2] symptomatic limbs (unilateral/bilateral), education level, pain duration, pain intensity (Visual Analogue Scale (VAS))) will be used at baseline are shown in table 1.

Translation and cross-cultural adaptation

This study will be divided into two parts. Part I will involve the adaptation process of TENDINS-A into the standard Persian language according to a standardised procedure. Part II will focus on analysing the adapted inventory's measurement properties. The translation and cultural adaptation of the Persian-TENDINS-A follow the method described by Beaton *et al*.[24]

Step 1. Consent: The original index authors of the project were contacted and informed, and consent was obtained to create a validated Persian-TENDINS-A.

Step 2. Forward translation: This forward translation will be undertaken by two bilingual native Persian translators who translate the original TENDINS-A English version into a Persian version.

Step 3. Synthesis of the translations: Synthesis of version 1 and version 2 to create version 3 with input from the original author and translator.

Step 4. Back translation: Back translation version 3 from Persian to English by two bilingual native English translators.

Step 5. Expert Committee Review: Committee members comprise the two translators, two research athletic trainers, an expert biostatistics researcher, two sports physiotherapists and a linguist who will meet to discuss all translated versions to approve and create a pre-final Persian-TENDINS-A version.

Step 6. Test of the Pre-Final TENDINS-A-Persian Version: A pre-final (pilot test) will be performed with 30 athletes with a history of AT to check whether the Persian-TENDINS-A has acceptable relevance, comprehensiveness and comprehensibility.

Step 7. Expert Committee Approval: Measurement properties of Persian-TENDINS-A will be evaluated. The components of each step are shown in figure 1.

Self-report questionnaires

TENDINopathy Severity Assessment-Achilles (TENDINS-A)

The TENDINS-A is a PROM with a 13-item (scorable items numbered 3, 4, 6, 7, 8, 10, 11, 12, 13A, 13B, 13C, 13D, 13E and 4 non-scorable items numbered 1, 2, 5, 9) that assesses the severity of the disability. The score ranges from 0 to 100 (0 representing a perfect score (no disability) and 100 representing (complete disability)).[25] Each subscale (pain; symptoms; physical function) is scored individually; a total score is not recommended.[16] If patients could not perform one of the pain with loading tests, they were instructed to leave it blank, and a score of 10 was provided.

Victorian Institute of Sports Assessment-Achilles questionnaire (VISA-A)

The VISA-A questionnaire contained eight questions that covered the three subscales of pain (questions

Table 1 Sociodemographic variables of athletes with Achilles tendinopathy

Participant characteristics and assessments	Construct validity test (n=XXX)	Reliability test (n=XXX)
Age, years	$\bar{x}$±SD	$\bar{x}$±SD
Body mass, kg	$\bar{x}$±SD	$\bar{x}$±SD
Body height, cm	$\bar{x}$±SD	$\bar{x}$±SD
Body mass index, kg/m^2	$\bar{x}$±SD	$\bar{x}$±SD
Sport experience, years	$\bar{x}$±SD	$\bar{x}$±SD
Pain intensity (0–100)	$\bar{x}$±SD	$\bar{x}$±SD
Pain duration (months)	$\bar{x}$±SD	$\bar{x}$±SD
TENDINS-A (0–100)	$\bar{x}$±SD	$\bar{x}$±SD
VISA-A (0–100)	$\bar{x}$±SD	$\bar{x}$±SD
PSEQ (0–60)	$\bar{x}$±SD	$\bar{x}$±SD
Sex, n (%)		
Female	n (%)	n (%)
Male	n (%)	n (%)
Neuropathic pain (PD-Q)		
Total score of PD-Q (0–38)	$\bar{x}$±SD	$\bar{x}$±SD
Neuropathic pain (≥19), n (%)	n (%)	n (%)
Indicated unclear pain (13 to ≤18), n (%)	n (%)	n (%)
Unlikely neuropathic pain (score ≤12), n (%)	n (%)	n (%)
Physical activity level, n (%)		
Recreational athlete	n (%)	n (%)
Novice athlete	n (%)	n (%)
Elite athlete	n (%)	n (%)
Competitive athlete	n (%)	n (%)
Education level, n (%)		
Master's degree or higher	n (%)	n (%)
Bachelor's degree	n (%)	n (%)
High school or less	n (%)	n (%)
Location of Achilles tendon pain, n (%)		
Insertional	n (%)	n (%)
Midportion	n (%)	n (%)
Symptomatic limbs, n (%)		
Unilateral	n (%)	n (%)
Bilateral	n (%)	n (%)

Continuous variables were expressed as mean±SD (minimal value and maximum value) and categorical variables as number (n) and percentage (%).
PD-Q, painDETECT questionnaire: scores range from 0 to 38; PSEQ, Pain Self-Efficacy Questionnaire: scores range from 0 to 60; TENDINS-A, TENDINopathy Severity Assessment-Achilles: scores range from 0 to 100; VISA-A, Victorian Institute of Sports Assessment-Achilles questionnaire: scores range from 0 to 100.

1–3), function (questions 4–6) and activity (questions 7 and 8). Questions 1 to 7 are scored out of 10, and question 8 carries a maximum of 30. Scores are summed to give a total out of 100. An asymptomatic person would score 100. A symptomatic person with AT would, on the other hand, be expected to score significantly lower. Persian version of VISA-A has been previously reported as valid and reliable (intraclass correlation coefficient (ICC)=90).[26]

Pain Self-Efficacy Questionnaire (PSEQ)

The Persian language version of the PSEQ will assess self-efficacy as a valid and reliable questionnaire (ICC=0.92). The PSEQ consists of 10 items scored on a 7-point Likert scale (0–6 points).[27] Scores range from 0 to 60, with the higher scores indicating stronger self-efficacy beliefs.

Pain intensity

A Visual Analogue Scale (VAS) will evaluate patients' pain intensity, where 0 signifies no pain and 10 signifies the worst imaginable pain.[28]

The painDETECT questionnaire

Neuropathic pain as identified by the painDETECT questionnaire (PD-Q) may be common in patients with chronic lower limb tendinopathy conditions such as AT.[23] Persian-translated PD-Q with acceptable

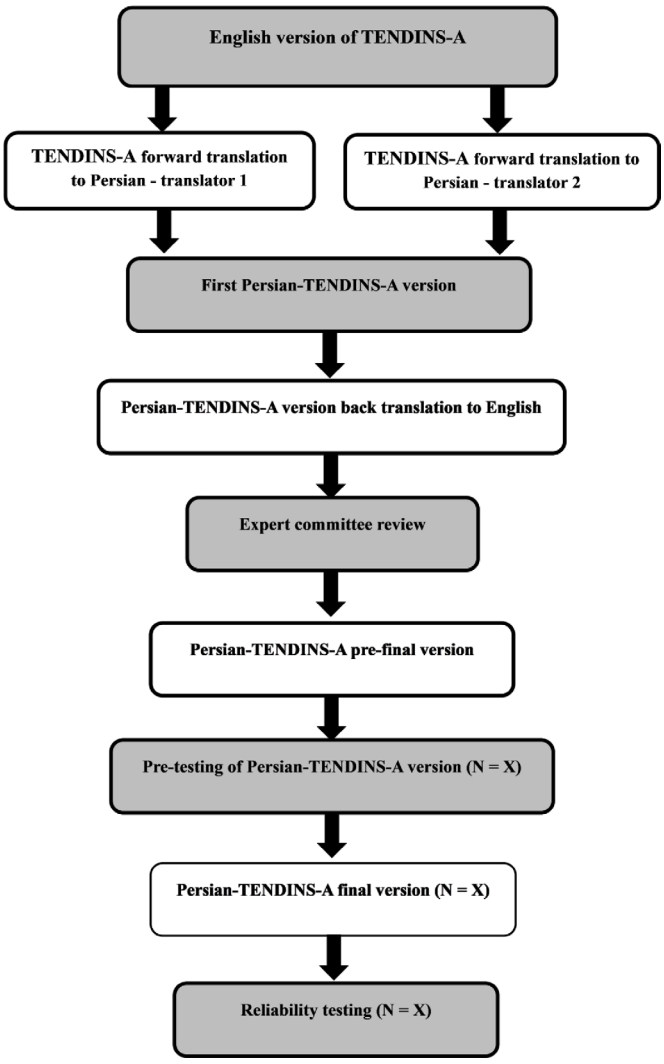

Figure 1 Flow diagram showing the process of cross-cultural adaptation to Persian of the TENDINS-A (TENDINopathy Severity Assessment-Achilles).

validity and reliability (ICC=0.97)[29] will be used to distinguish signs of neuropathic pain. It consists of one item about the pain course pattern, one about radiating pain and seven about the gradation of pain. There are three items about pain severity (current, strongest and average pain). The overall score is generated via a 38-point numerical rating scale. The rating is as follows: 0–12: neuropathic pain is unlikely <15%; 13–18: it is ambiguous, however, neuropathic pain can be present; and 19–38: neuropathic pain is likely >90%.[29]

Statistical analysis

Statistical data analysis will be performed using the SPSS, V.26. Descriptive statistics will be calculated to determine patient characteristics. Kolmogorov-Smirnov tests will be conducted to meet the normality of the data assumption of both tests.

Sample

Statistical analyses will comply with the COSMIN guidelines.[19 20] Based on the recommendations of the COSMIN checklist, the sample size should consist of at least 100 athletes with AT (respondents) for test-retest reliability, structural validity and hypothesis testing.[19 20] Statistical significance will be set at $p<0.05$.

Internal consistency

Internal consistency for the Persian-TENDINS-A will be examined using Cronbach's alpha (α). The α values range from 0 (no internal consistency) to 1 (perfect internal consistency). The grading system described by Bland and Altman[30] will be used for internal consistency as excellent (higher than 0.90), good (between 0.70 and 0.90), acceptable (between 0.60 and 0.70), poor (between 0.50 and 0.60) and unacceptable (<0.50).

Reliability

The ICC between test and retest Persian-TENDINS-A scores will be calculated to assess test-retest reliability.[20] The standard error of measurement (SEM and minimal detectable change (MDC) will be calculated according to Eq (1) and Eq (2), respectively. The MDC is the smallest change in scores that is not attributed to measurement errors.[31]

$$\text{Eq}\ (1): \quad \text{SEM} = \text{SD pooled} \times \sqrt{1 - ICC} \qquad (1)$$

$$\text{Eq}\ (2): \quad MDC_{95\%} = \text{SEM} \times 1.96 \times \sqrt{2} \qquad (2)$$

Test-retest reliability of the Persian-TENDINS-A will be assessed with a 2–3 day gap between two rounds of measurements.

Structural validity

IBM SPSS AMOS (V.24) will be used to run the confirmatory factor analysis. The construct validity of the Persian-TENDINS-A will be evaluated with exploratory factor analysis (EFA) using varimax rotation. Item adequacy and sampling will be performed using Bartlett's test of sphericity and Kaiser-Meyer-Olkin (KMO) criterion (≥0.50). Floor and ceiling effects will be evaluated. Floor and ceiling effects are considered present when 15% of patients report the minimum or maximum score.

Hypothesis testing

The Persian-TENDINS-A, VISA-A and PSEQ questionnaires will be used for hypothesis testing and measured according to Beaton's guidelines.[24] Hypothesis testing of the Persian-TENDINS-A will be determined using a single point-in-time correlation between Persian-TENDINS-A scores with VISA-A and PSEQ. The estimate will be expressed by assessing Pearson's correlation coefficients (or the non-parametric alternative). The strength of the correlations will be interpreted as

weak (r=0.10–0.30), moderate (r=0.31–0.50) or strong (r=0.51–1.00).

DISCUSSION

What does this study add?

Evaluating pain and disability severity in athletes with AT through PROM is important. Therefore, this study aims to translate and cross-culturally adapt the TENDINS-A questionnaire into the Persian language version (Persian-TENDINS-A) according to international guidelines and to evaluate the measurement properties of the Persian-TENDINS-A in athletes with AT. This study will also help assess and plan rehabilitation programmes for athletes with AT.

Description of risks

There will be no risks for included patients.

Patient informed consent

Written informed consent will be obtained from all participants, and their demographic data and consent forms will be kept.

Legal principles

The clinical data will be recorded and entered electronically into a secured computer system. This study adheres to accepted clinical practices to safeguard patients' rights and benefits.[22] All data collected will be validated against the source documents and stored in a secured computer system for 5 years after the publication of the results. Participants will be informed that they may withdraw their consent during the study, and their legal rights will not be affected.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Participants gave informed consent to participate in the study before taking part.

Ethics approval This study was assessed and approved by the Research Ethics Committee of the University of Zabol (Approval ID: IR.UOZ. REC.1403.004) prior to data collection.

Provenance and peer review Not commissioned; internally peer reviewed.

Data availability statement No data are available.

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