



Preliminary Validation of a Self-Reported Functional Outcomes Tool for Children with Extremity Tumors: Translation into Persian and Assessment of the Reliability and Validity of the pTESS-Leg Questionnaire

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Abstract

Background: With the advancements in treatment for limb sarcomas, including limb preservation and functional restoration, it is essential to assess the functional status of pediatric patients. This study aims to translate and validate the Pediatric Toronto Extremity Salvage Score (pTESS-Leg) questionnaire for children with extremity tumors into Persian.

Methods: The methodology involved a forward and backward translation process, followed by a review from an expert committee to ensure cultural relevance. Reliability was assessed using Cronbach's alpha for internal consistency and Spearman correlation for test-retest reliability. Validity was evaluated through the Content Validity Index (CVI) and Content Validity Ratio (CVR).

Results: The findings indicated acceptable internal consistency (Cronbach's alpha = 0.95) and significant test-retest reliability across all questions. The CVR reached 100% for all items, indicating adequate content validity. These results affirm that the Persian version of the pTESS-Leg tool is a reliable and valid measure for assessing functional outcomes in children following treatment for extremity tumors, facilitating improved evaluation and comparison of patient outcomes in clinical settings.

Conclusion: The Persian version of the pTESS-Leg questionnaire is a reliable and valid tool for assessing functional outcomes in children with extremity tumors. This study highlights the importance of culturally adapting assessment instruments to enhance treatment outcome evaluations and facilitate comparisons across studies.

Keywords: Extremity Tumors, pTESS-Leg Questionnaire, Children, Self-reported Outcomes

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Introduction

Sarcoma is a type of musculoskeletal tumor that primarily affects the long bones and soft tissues of the limbs, particularly the lower extremities (1, 2). Historically, patients with limb sarcomas were typically treated with amputation (3, 4). However, the focus has shifted towards limb preservation and maintaining functionality as key objectives in disease management. With the development of adjuvant therapies, including radiotherapy and chemo-

therapy, patients now have a greater opportunity to undergo limb salvage procedures. Functional improvement following limb salvage surgery has become a key outcome of interest for both physicians and patients (1, 5, 6). Outcome assessment utilizing relevant questionnaires aids physicians in evaluating pain and functionality in patients (7).

Today, the use of patient-reported outcome measures (PROMs) has become an integral component of clinical

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Key Messages:

↑What is “already known” in this topic:

Functional assessment following limb sarcoma treatment in children is crucial; however, no validated Persian tool currently exists for this purpose. This absence limits the accurate evaluation of functional outcomes and hinders cross-study comparisons in Iranian clinical settings.

→What this article adds:

This study translates and validates the Pediatric Toronto Extremity Salvage Score (pTESS-Leg) into Persian. It offers clinicians and researchers a culturally adapted, standardized tool for assessing functional outcomes in Persian-speaking children with extremity tumors.

studies and research. Measuring patient function post-surgery with appropriate questionnaires is essential for evaluating treatment success and enables standardized, reliable comparisons of outcomes across studies (7). The Toronto Extremity Salvage Score (TESS) (8) is a questionnaire designed to assess functional performance and the degree of physical disability in patients undergoing treatment for limb sarcoma. Initially developed in English, TESS has since been translated into several languages, including Chinese, Korean, Danish, Dutch, and Portuguese (7, 9-13). Most studies examining post-surgical outcomes in patients with lower limb tumors have focused on adults, while the average age of diagnosis for malignant bone tumors ranges from 14 to 16 years (14). Although it was once believed that children could not independently report their functional status, leading to proxy reports by parents or physicians, it is now recognized that children are capable of doing so (15). The present study aims to translate and culturally adapt the TESS for the lower limbs into Persian and to validate the translated version among children with bone or soft tissue tumors undergoing surgical treatment in Iran.

Methods

This study was conducted in 2021 at Shafa Yahyaean Hospital, affiliated with Iran University of Medical Sciences, which is one of the primary referral centers for patients with tumors in Iran. The questionnaire was translated from English to Persian using a forward and backward translation approach. An expert committee, comprising five specialists and fellowship-trained tumor experts, reviewed the translations to ensure accuracy and cultural relevance. The forward-backward translation process followed the ISPOR and WHO guidelines. Two independent forward translators (both physicians fluent in English and Persian) translated the original questionnaire from English to Persian. A consensus meeting was held to resolve discrepancies and produce a reconciled Persian version. Subsequently, two independent back-translators (both physicians fluent in English and Persian, blinded to the original English version and with no affiliation to the forward translators) translated the Persian version back into English. The back-translated versions were compared with the original by a committee consisting of the forward translators, the back-translators, and an epidemiologist as an independent arbiter to confirm conceptual equivalence. Preliminary pilot testing was conducted with a sample of participants, followed by initial validation to assess the questionnaire's reliability and content validity based on the collected data. Both sets of questionnaires were completed by the patients with an interval of 72 hours between them. This interval was selected because functional status was expected to remain stable during this short period while still allowing sufficient time to reduce recall bias. Despite the small sample size, there were no missing data.

1. *Total sample size:* The final validation sample consisted of 23 participants (n = 23).

2. *Sampling method:* Convenience (availability) sampling was used.

3. *Recruitment and setting:* Participants were recruited from Shafa Yahyaean Hospital among pediatric patients (age < 18 years) who had undergone limb-salvage surgery for lower extremity malignant tumors between 2011 and 2016 (1390–1395 Persian calendar) and were attending the hospital for routine follow-up visits.

4. *Consecutive or not:* This was not a consecutive series; rather, eligible patients who were available and consented during the study period were included consecutively as they presented, but due to the rarity of the condition and the pilot/preliminary nature of the study, we report it as a convenience sample.

Reliability Internal consistency

Cronbach's alpha coefficient was used to assess the internal consistency of the questionnaire items in both test administrations.

Test-retest reliability

To evaluate the reliability of the test administered to respondents at two different time points, the Spearman correlation coefficient was used. The correlation coefficient between each question and its subsequent repetition was reported.

Note: Spearman correlation coefficients are reported for per-item (item-by-item) test-retest reliability.

Content Validity

Content Validity Index (CVI), Content Validity Ratio (CVR) and Construct Validity

The CVI and CVR indices were assessed for the Persian questionnaire developed with input from five specialists and fellows in bone tumors. The CVR for each question was determined by evaluating whether the question was essential, not essential, or useful but not essential. For the CVI, a four-point Likert scale (completely relevant, relevant but needs revision, needs substantial revision, irrelevant) was employed for each question (16).

Construct Validity

To assess construct validity, an a priori hypothesis was tested: older children would report lower functional scores on the Persian version of the pTESS-Leg. To evaluate the hypothesis that the questionnaire does not discriminate between boys and girls, the mean pTESS-Leg scores were compared between the two sexes. Due to the sample size being less than 30, non-parametric Mann-Whitney U tests were used.

Results

The Cronbach's alpha coefficient, used to assess the internal consistency of the questionnaire items, was determined to be 0.95 in both test administrations (Table 1).

The reliability results from the test-retest evaluation are also presented in Table 2, which includes the Spearman correlation coefficient for each question and its repetition, along with the corresponding p-value. The CVR score for each question reached 100%. The CVI score was 100% for all questions, except for item 9, which received a score of 80%.

Table 1. Internal consistency assessment and Cronbach's alpha report

Test number	Number of items in the scale	Scale reliability coefficient
1	30	0.953
2	30	0.952

Table 2. Calculation of Reliability and Content Validity Indices of the Questionnaire

Questions in English	Questions in Persian	Spearman's rank correlation (95% CI)
1. Putting on a pair of pants	پوشیدن شلوار	0.68 (0.37, 0.86)
2. Putting on shoes Tying shoelaces	پوشیدن کفش و بستن بند کفش ها	0.77 (0.52, 0.90)
3. Putting on socks	پوشیدن جوراب ها	0.89 (0.76, 0.95)
4. Showering	دوش گرفتن و حمام رفتن	0.86 (0.71, 0.94)
5. Cleaning up your room	تمیز کردن اتاق شما را رتیب کردن وسایل اتاق و جارو کشیدن	0.91 (0.80, 0.96)
6. Jumping	بالا و پایین پریدن : تل ای بازی کردن	0.89 (0.76, 0.95)
7. Helping with the shopping	کمک به خریدن	0.89 (0.76, 0.95)
8. Moving heavy things	جابجایی وسایل سنگین	0.95 (0.88, 0.98)
9. Getting in and out of the bathtub	نشستن و بلند شدن از صندلی حمام	0.64 (0.32, 0.83)
10. Getting out of bed	بلند شدن از رختخواب	0.87 (0.72, 0.94)
11. Getting up out of a chair	بلند شدن از روی صندلی	0.98 (0.95, 0.99)
12. Bending down on your knees	خم شدن روی زانو	0.71 (0.42, 0.87)
13. Bending to pick something up off the floor	خم شدن برای برداشتن چیزی از روی زمین	0.96 (0.90, 0.98)
14. Walking upstairs	بالا رفتن از پله ها	0.95 (0.88, 0.98)
15. Walking downstairs	پایین آمدن از پله ها	0.89 (0.76, 0.95)
16. Riding a bike	دوچرخه سواری	0.92 (0.82, 0.97)
17. Walking in your house	قدم زدن در خانه	0.75 (0.49, 0.89)
18. Walking outside	پیاده روی بیرون از خانه	0.77 (0.52, 0.90)
19. Walking up or down a hill	بالا یا پایین رفتن از سرانشیبی و یا تپه	0.89 (0.76, 0.95)
20. Standing straight	صاف ایستادن	0.86 (0.71, 0.94)
21. Getting up from your knees	بلند شدن از زمین بدون استفاده از تکیه گاه	0.76 (0.51, 0.89)
22. Getting in and out of a car	سوار و پیاده شدن از ماشین	0.80 (0.57, 0.91)
23. Participating in activities at school	شرکت در فعالیت های مدرسه	0.84 (0.67, 0.93)
24. Going to school every day, all day	رفتن و آمدن در مدرسه هر روز به صورت تمام وقت	0.73 (0.46, 0.88)
25. Playing favorite games	انجام بازی های مورد علاقه	0.92 (0.82, 0.97)
26. Playing with friends and family	بازی با دوستان و خانواده	0.82 (0.62, 0.92)
27. Playing usual sports Running	انجام ورزش های معمول	0.75 (0.49, 0.89)
28. Running	دویدن	0.83 (0.64, 0.93)
29. Keeping up with friends	شرکت در جمع دوستان و همراهی کردن با دوستان	0.80 (0.57, 0.91)
30. Walking for a long time (> 1 hour)	پیاده روی طولانی مدت (بیش از یک ساعت)	0.96 (0.90, 0.98)

*. The *P*-value associated with this correlation was ≤ 0.001 for all questions

Table 3. Comparison of Mean Age and pTESS-Leg Scores Between Boys and Girls Participants

Variable	Mean (SD) of the whole sample	Sex	<i>P</i> -value
Sex; Frequency (%)		Boy; 13 (56.52)	Girl; 10 (43.48)
pTESS-Leg; Mean (SD)	79.74 (28.83)	80.92 (31.02)	78.20 (27.27)
Age; Mean (SD)	15.62 (2.59)	15.77 (2.80)	15.50 (2.42)

The results indicate that the mean age of boys (15.77 years) and girls (15.50 years) is approximately similar. Additionally, the pTESS-Leg scores reveal that both groups have nearly equal scores, with boys averaging 80.92 and girls averaging 78.20, highlighting comparable assessments between the two sexes (Table 3). The hypothesis related to construct validity was tested, and the results were as follows: Age correlated moderately, but not statistically significantly, with lower pTESS-Leg scores ($r = -0.34$; $P = 0.115$). The resulting *p*-value exceeded 0.05, indicating no statistically significant difference between the groups.

Discussion

In this study, the Persian version of the pTESS-Leg tool was evaluated for reliability and content validity in children. Internal consistency was above 0.95, and test-retest reliability yielded significant *p*-values for all questions. Based on the results of the CVI and CVR, content validity was deemed adequate. Additionally,

construct validity was supported by acceptable performance against both age- and sex-related hypotheses.

The original version of this questionnaire is designed to align with the fundamental needs of children undergoing treatment for limb tumors. The use of simple and clear language in the original questionnaire facilitated a straightforward translation process, ensuring that the Persian version remains largely consistent with the original. The following sentence is the ninth question of the questionnaire: "Getting in and out of the bathtub." We made a slight modification to this question. In Iran, bathtubs are typically not used; instead, individuals usually sit on a chair in the bathroom. Therefore, this question was changed to "Sitting down and getting up from the bathroom chair." This modification was approved by the researchers at the beginning of the study and was also validated by them at the end of the study based on the results obtained from the CVI and CVR.

The pTESS questionnaire has been employed in various studies. The Persian version of the TESS questionnaire is

available for adults (17). This availability and its utility in assessing the functional outcomes of children have enabled researchers to evaluate children's performance following the treatment of malignant tumors. Furthermore, it has facilitated the comparison of functional improvement between pediatric and adult groups (18).

The duration of follow-up for participants assessing their performance on the TESS questionnaire varies across different studies. Our findings specifically pertain to patients who have undergone surgery at least two years prior (15, 19, 20). In this study, the physical performance score exhibits an inverse relationship with the age of the children; as age increases, the score decreases. The distribution of gender and the mean age by gender were comparable, and there was no significant difference in the average pTESS-Leg scores between girls and boys. However, this comparison has not been conducted in other studies.

Although the correlation between age and functional scores did not reach statistical significance ($r = -0.34$, $p = 0.115$), the direction of the association was consistent with our theoretical expectation that physical function decreases with increasing age. This finding may be considered as preliminary evidence, and future studies with larger samples are recommended to further clarify the role of age as a potential determinant of functional outcomes in this population. One limitation of this study is the presence of various dialects and cultural differences among the participants. This limitation is commonly observed in studies conducted in referral hospitals involving populations affected by rare diseases (21). It is important to note that full psychometric validation necessitates a substantially larger sample size, generally recommended to be 5–10 participants per item. Therefore, the present findings should be interpreted as preliminary. Although we assessed construct validity based on two hypotheses, further evaluations are required for a definitive determination of construct validity. In the interim, we recommend that researchers utilize this standardized tool and pay attention to patient feedback following surveys. Based on this feedback, they should aim to improve, add, or modify questions that may require adjustments over time. Structural validity (factor analysis) was not examined in this study, which is a limitation per COSMIN recommendations for cross-cultural validation. This was primarily due to the insufficient sample size, particularly for the pTESS-Arm. Future research with larger samples is needed to assess the factor structure and complete the validation of the instrument.

Conclusion

As a preliminary validation study, the Persian version of the pTESS-Leg questionnaire has demonstrated acceptable reliability and adequate content validity for assessing functional outcomes in children with extremity tumors. This study highlights the importance of culturally adapting assessment tools for diverse populations. The validated pTESS-Leg will enhance the evaluation of treatment outcomes and facilitate comparisons across studies. Future research should further investigate its application in

clinical settings to confirm its effectiveness in pediatric oncology.

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Conflict of Interests

The authors declare that they have no competing interests.

Authors' Contributions

K. Jamshidi conceived and designed the study (Conceptualization). B. Zareie performed the formal analysis and developed the methodology (Formal Analysis & Methodology). Kh. Kargar Shooroki was responsible for project administration and supervision (Project Administration). M. Mohammadi conducted the investigation and data collection (Investigation). S. Hajjaliloo Sami, B. Toloue Ghamari, S.S. Khabiri, and Sh. Beheshti Fard served as the scientific committee, contributing to the review of the questionnaire items and the translation process (Validation & Writing – Review & Editing). All authors reviewed and approved the final manuscript.

Ethical Considerations

This study was approved by the Iran University of Medical Sciences under ethics code IR.IUMS.REC.1401.727. Written informed consent was obtained from all parents or legal guardians of the participants.

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This research received no external funding.

Data Availability

The datasets generated and/or analyzed during the current study are not publicly available but are available from the corresponding author upon reasonable request via email.

AI Use Statement

The authors used ChatGPT, a Generative AI tool, to assist with the translation of the manuscript from English to Persian. All AI-generated content was critically reviewed and validated by the authors. No AI tools were employed in data collection, analysis, interpretation, or the writing and editing of this manuscript.

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