Research Article

Reliability and Validity of the Lower Extremity Motor Activity Log in Persian People with Ankle Sprain

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Article info:
Received: 13 Apr 2025
Accepted: 10Jun 2025

Citation: Ahmadi AS, Lajevardi L, Taghizadeh Gh, Azad A. Reliability and Validity of the Lower Extremity Motor Activity Log in Persian People with Ankle Sprain. Journal of Modern Rehabilitation. 2025;19(4):?-?

Running title: LE-MAL's validity and reliability in ankle sprain

Abstract

Background: Ankle sprains are among the most common injuries and affect functional mobility, lower extremity function and health status. Accessing to a reliable measurement tool to assess diverse real-world lower extremity use in patients following ankle sprain seems essential. Researchers have developed number of measurements to determine rehabilitation goals and also measure the effects of therapeutic interventions. This study was conducted to translate the original English Lower Extremity Motor Activity Log (LE-MAL) to Persian and to investigate the psychometric properties of the Persian version.

Material and Methods: The LE-MAL was translated to Persian and adapted to the Persian culture. Then a total of 140 patients with ankle sprain filled out the Persian LE-MAL, Lower Extremity Functional Scale (LEFS) and Life Space Questionnaire (LSQ). The Persian LE-MAL was re-completed by participants with an interval of two weeks and internal consistency, test-retest reliability and construct validity were investigated.

Results: The Persian LE-MAL had good internal consistency (Cronbach's α =0.95) and test-retest reliability (ICC=0.76). The construct validity of the Persian LE-MAL was demonstrated to be acceptable as a result of its significantly strong correlations with LEFS and LSQ (0.74<r<0.77). Standard error of measurement was less than 10% of the total instrument score (SEM=0.43) and minimal detectable change was 1.2. No ceiling and floor effect observed.
Conclusion: Persian version of LE-MAL is a valid and reliable measurement to assess lower extremity function in people with ankle sprain.
Keywords: Reliability; validity; ankle injuries; self report; outcomes assessment

1. Introduction

Ankle sprain is one of the most common musculoskeletal injuries experienced by active young adults at least once during their lifetime and impacts their quality of life and health status(1). Ankle ligamentous injury are the one of the most frequent injuries in Iranian population and have different distribution patterns in specific age and sex groups(2). Ankle sprains lead to secondary deficits and impairments in the kinematic characteristics of the lower extremities, such as neuromuscular functions of the hip and trunk, resulting in limited mobility, functional instability and disability(3-5). Accurate assessment and proper treatment is very essential Following an ankle injury, otherwise we expect chronic ankle instability(4, 6-8). Obtaining comprehensive information about the performance of the lower limb following an ankle sprain is essential for implementing rehabilitative interventions(9, 10).

Previously, researchers and clinicians focused on assessing parameters such as muscle strength, joint range of motion, pain and balance in patients, while none of these measures evaluated how individuals use their lower limbs outside the clinical setting and in daily life(8, 11). Recently, the use of self-report tests has increased(12). Especially the tests that measure changes in the health status of individuals with ankle sprains(10). Several self-report tools have been developed to assess the performance of the lower limb in individuals with ankle sprains, but these tools have limitations(13). One of these limitations is lack of assessing an individual's use of assistive devices such as crutches, orthoses, and level of assistance from others. Another significant limitation of other available tools is their inability to assess lower extremity function in real-life activities. There is a need for the development of more precise assessment tools for patients.

The LE-MAL is a self-report test that assesses the use of the lower limb in real-life situations and evaluates 14 functional activities (such as walking indoors and outdoors, using stairs, getting into a car, etc.) across three subscales(14, 15). This tool not only assesses lower limb performance but also measures balance maintenance during occupations. And it also measures the amount of use from assistive devices in occupations and evaluates the level of assistance from caregivers. Since there was no accurate scale in the Persian language to assess the lower limb's real-world use in individuals with ankle sprains, the aim of this study was to translate and investigate the validity and reliability of the LE-MAL.

2. Materials and Methods

This cross-sectional study was conducted on 140 patients referred to hospitals and rehabilitation centers in Shiraz, Iran, from January 2024 to July 2024. Inclusion criteria was grade 2 unilateral acute ankle sprains, diagnosed by an orthopedic physician and medical records such as X-Ray radiography, anterior drawer test and figure 8 measurement score. Age considered between 18 to 65, absence of no other injuries or concurrent diseases reported, and being able to read and write in Persian language was considered essential as other inclusion criteria. Patients who withdrew

from participation for any reason, did not attend the follow-up session on time, or experienced sudden changes in their health conditions were excluded from the study. Permission to translate the LE-MAL into Persian was obtained from the copyright holder (University of Alabama at Birmingham). Subsequently, the execution of the project was approved by the Ethics Committee of the Iran University of Medical Sciences (IR.IUMS.REC.1400.1238), and all study participants signed an informed consent form to participate in the study.

In the process of this study, the LE-MAL tool was first translated into Persian. Then, to assess the construct validity of the Persian LE-MAL, 140 participants were asked to complete the (LEFS) Lower Extremity Functional scale and the (LSQ) Life Space Questionnaire tests. Both of the LEFS and the LSQ are self-report, nearly have the same number of items, and assess functional mobility. To assess the test-retest reliability, the Persian LE-MAL was administered with a two-week interval to 80 of the participants.

The English version of the LEMAL was translated into Persian based on the standardized cross-cultural translation guidelines provided by the International Quality Of Life Assessment (IQOLA) project(16). Permission for translation was obtained from the developer, Prof. Uswatte. The translation process began with a forward translation from the original language (English) to the target language (Persian) by two bilingual translators whose native language was Persian. Each translator provided a list of possible alternative translations for each item to ensure clarity. Translations that closely matched the original test were selected by the researcher.

Subsequently, a backward translation was carried out by two other bilingual translators who were native English speakers and had no knowledge of the original English version of LE-MAL. They translated the Persian version into English. To assess the conception of the translations, the English version obtained by the primary researchers' group was discussed, and the opinion of the test developer was considered after correspondence.

The Persian LE-MAL was provided to 20 participants, including 10 patients and 10 occupational therapy and physiotherapy specialists with a minimum of 5 years of experience in the field of orthopedic patients. Questionnaires were completed face-to-face, and the comprehensibility of the questions was evaluated by the participants. There was no difficulties in understanding the questions, and the clarity, simplicity, and relevance of each question were indicated an acceptable face validity.

2.1. Tools

2.1.1. Lower Extremity Motor Activity Log (LEMAL)

The LE-MAL is a 14-item self-report questionnaire, and its psychometric properties have been evaluated in individuals with stroke, spinal cord injury, Multiple Sclerosis, and pelvic injuries in various countries, including United States and Brazil(15, 17-21). the LE-MAL was developed to assess a person's real-world performance such as walking indoors and outdoors, stepping over an object on the floor, rising from and sitting down in a chair and toilet, getting in and out of a bathtub, standing while washing hands and face. This questionnaire comprises three subscales:

1) Functional performance level
2) Confidence level (fear of falling during task execution).
3) Assistance level (need for assistance from others, use of a walker or cane, use of orthoses or modified shoes, use of handrails).

All subscales are scored using the Likert scale 0(inability to perform the task) to 10(fully able). In some studies, the LE-MAL has been used to collect data before and after treatment or as an entry criterion for study participants(22-35).

2.1.2. Lower Extremity Functional Scale (LEFS)

The LEFS (Lower Extremity Functional Scale) is an assessment tool designed for patients with musculoskeletal disorders, including ankle sprains. This self-report questionnaire assesses 20 different daily life activities, and each item is scored from 0 (complete inability to perform the activity) to 4 (complete ability to perform the activity). The maximum score is 80, and lower score indicates lower function(13). Persian version of this questionnaire is valid and reliable(36).

2.1.3. Life Space Questionnaire (LSQ)

This test was designed to assess the extent and frequency of a person's functional mobility in the community(37). This self-report questionnaire consists of 9 questions about a person's ability to leave their room, house, local community, and regional area. The minimum score is zero (bed-bound), and the maximum score is 9 (the ability to independently travel daily outside the city). The LSQ is a reliable and valid self-reported measure that captures the unique construct of real-world home and community mobility in people with lower extremity problems(38). LSQ has been used in many studies examining quality of life and functional mobility(39-41).

2.2. Statistical analysis

Descriptive statistics (including mean, standard deviation and frequency) were computed for demographic variables. SPSS version 26 analyzed the data. The Kolmogorov-Smirnov test was used to assess the normality of the data distribution. The ceiling and floor effects were calculated by measuring the percentage of participants who achieved the minimum and maximum possible scores (5% at the top and bottom of the score range), and values less than 15% were considered acceptable(42).

For the first phase of the test, the data obtained from 140 participants were used to assess internal consistency. Cronbach's alpha coefficient was used to investigate internal consistency. Cronbach's alpha coefficient greater than 0.80 indicates very good internal consistency, 0.70 to 0.79 indicates moderate internal consistency, and less than 0.70 indicates poor internal consistency(43).

Test-retest reliability for the first and second phases of LE-MAL sampling was conducted by using the Intraclass Correlation Coefficient ($ICC_{2,1}$). ICC values of 0.75 or higher indicate excellent reliability, 0.40 to 0.75 indicate moderate reliability, and less than 0.40 indicate poor reliability(44).

The following formula was used to calculate the absolute repeatability from SEM: $SEM = SD_{pooled} \times \sqrt{1 - ICC_{2,1}}$. SEM should be less than half of the pooled standard deviation or less than 10% of the total score and subscale scores(45).

The following formula was used to calculate the minimum detectable change (MDC): $MDC_{95\%}=1.96\times\sqrt{2}\times SEM$ (45). The MDC is the minimum amount of change considered following a measurement error, and it is used for the clinical interpretation of changes in questionnaire scores(46, 47).

To investigate construct validity, Pearson correlation coefficients was measured between the total score of LE-MAL and subscale scores of LE-MAL. Also the Pearson correlation coefficients was measured between the total score of LE-MAL and total scores of the LEFS and the LSQ. Correlation coefficient 0.90 or higher indicates very strong correlation; 0.68 to 0.89 is strong, 0.36 to 0.67 is moderate and less than 0.35 indicates a weak correlation(48).

3. Results

3.1. Translation, floor and ceiling effect

Totally 140 patients (57 males and 83 females) diagnosed with grade 2 ankle sprain participated in this study. Descriptive information for the variables is presented in Table 1. The data were normally distributed. All translated LE-MAL items were clearly understandable and no changes were made to the translated items. No ceiling and floor effects were observed for the total score and subscales of assistance, functional performance, and confidence of the Persian LE-MAL. Acceptable internal consistency was achieved for the total score (α=0.97) and all three subscales of the Persian LE-MAL (α=0.97-0.95) (Table2).

Table 1) Descriptive information of qualitative variables of patients with grade 2 acute ankle sprain (Number=140)

Variables			Frequency	Frequency%
1	**Sex**	**Male**	57	40.7
		Female	83	59.3
2	**Affected side**	**Right**	77	55
		Left	63	45
3	**Educational level**	**High school or less**	19	13.6
		diploma	67	47.8
		University degree	54	38.6
4	**Diagnosis**	**Medial ankle sprain**	38	27.1
		Lateral ankle sprain	102	72.9
5	**NSAID usage**	**Yes**	54	38.6
		No	86	61.4
Age (Mean): 35.2 years, Standard Deviation: 13.37 years				

Table 2: Test-retest reliability and internal consistency of the Persian LE-MAL

Construct	ICC (95%CI)	ICC Interpretation	Significance level	SEM	MDC	Test mean±SD	Retest mean±SD	Cronbach`s alpha
Assistance	0.44(0.1-0.66)	Moderate	0.000	0.55	1.52	9.2±0.81	9.7±0.54	0.96
Functional performance	0.75(0.41-0.85)	Excellent	0.000	0.57	1.58	7.41±1.4	8.32±0.96	0.95
Confidence	0.78(0.62-0.87)	Excellent	0.000	0.54	1.50	7.68±1.53	8.48±1.04	0.97
Total score	0.76(0.24-	Excellent	0.000	0.43	1.20	8.13±1.12	8.89±0.75	0.97

	0.89)							

ICC: Intraclass Correlation Coefficient; CI: Confidence Interval; SEM: Standard Error of Measure; MDC: Minimal Detectable Change

3.2. Reliability

As shown in Table 2, the total score (ICC=0.76) and the subscales of LE-MAL (0.78>ICC>0.44) demonstrate moderate to excellent test-retest reliability. Mean and standard deviation of the total score and subscale scores of LE-MAL are also reported in Table 2(as well as the values of ICC, SEM, and MDC). The ICC values for the 14 items of the Persian LE-MAL in test-retest assessments ranged from 0.54 to 0.83. Items 1 to 5 and item 8 showed excellent reliability, while items 6, 7, and 9 to 14 demonstrated moderate reliability (Table 3).

Table 3. ICC value in test-retest times for each item of the Persian LE-MAL

Items	**Test-retest**		
	ICC	**Significance level**	**Interpretation of reliability**
1.Walking indoors	0.80	0.000	Excellent
2.Walking Outdoors	0.75	0.000	Excellent
3.Climbing stairs (up and down)	0.76	0.000	Excellent
4.Stepping over object	0.82	0.000	Excellent
5.Turning around when standing (whole body with movement of feet)	0.83	0.000	Excellent
6.Come to stand from a chair	0.61	0.000	Moderate
7.Come to stand from a toilet	0.67	0.001	Moderate
8.Getting in and out of bed	0.75	0.000	Excellent
9.Getting in and out of bath or shower	0.54	0.000	Moderate
10.Getting in and out of car	0.66	0.000	Moderate
11.Open a door with a door knob in standing and walking through the doorway	0.58	0.000	Moderate
12.Wash hands/grooming at the sink in standing	0.57	0.000	Moderate
12.Wash hands/grooming at the sink in standing	0.63	0.000	Moderate
14.Retrieving object from floor (from standing position)	0.58	0.000	Moderate

ICC; Intraclass Correlation Coefficient, LE-MAL; Lower Extremity Motor Activity Log

3.3. Validity

The results of construct validity are presented in Table 4. Researchers' hypothesis in this study was confirmed after finding a positive correlation between the total score and subscale scores of LE-MAL with the total scores of the LEFS and LSQ. There is an evident from the strong correlation between the total score of the Persian LE-MAL and the LEFS and LSQ ($0.74<r<0.77$). Additionally, strong correlations were observed between the subscales of Confidence and functional Performance of Persian LE-MAL with the total scores of the LEFS and LSQ ($0.68<r< 0.77$). Moderate correlation was found between the assistance subscale of LE-MAL and total scores of the LEFS and LSQ ($0.54<r<0.58$).

Table 4. The amount of correlation coefficient (significance level) between total scores and subscales of Persian LE-MAL using LEFS and LSQ

Tests / Persian LE-MAL	LSQ (sig)	LEFS (sig)
Assistance	0.58 (0.000)	0.54 (0.000)
Functional performance	0.73 (0.000)	0.68 (0.000)
Confidence	0.71 (0.000)	0.77 (0.000)
Total score	0.77 (0.000)	0.74 (0.000)
First number is Pearson’s correlation coefficient and following number in parenthesis is significance level		

LE-MAL; Lower Extremity Motor Activity Log, LEFS; Lower Extremity Functional Scale, LSQ; Life Space Questionnaire

4. Discussion

The aim of this study was to translate the LE-MAL into Persian and assess its validity and reliability in individuals with ankle sprains. The results of this study is similar with the Brazilian versions in terms of content validity and all activities in the questionnaire were culturally appropriate for Iranians, without changing any items(18, 19). Similar to the Brazilian version, no ceiling or floor effects were observed in the current study, indicating the sensitivity of the Persian LE-MAL to detect changes in a specific range of conditions(19).

High internal consistency was found in the Persian LE-MAL and its similar to the Brazilian and American versions, where Cronbach's alpha coefficients reported from 0.80 to 0.95(15, 17-19).

Similar to the Brazilian version of the LE-MAL, this study also assessed the test-retest reliability by retesting 80 out of the 140 participants after a 2-week interval(18). Test-retest reliability for

the Persian version of the LE-MAL was excellent, with ICC values ranging from 0.75 to 0.78 for the total score and the subscales, as shown in Table 2. This level of reliability is similar to the Brazilian and American versions of the LE-MAL, where ICC values for the total score ranged from 0.76 to 0.96, and ICC values for the subscales of performance and confidence ranged from 0.80 to 0.97(15, 17-19).In contrast to the Brazilian LE-MAL, where the ICC values for the assistance subscale ranged from 0.81 to 0.91, the test-retest reliability for the assistance subscale in the present study was found to be at a moderate level (ICC = 0.44). There are potential reasons for the lower "assistance" subscale scores in this study. Unlike previous studies that focused on individuals with neurological conditions, the present study involved orthopedic patients. The 2-week interval used for retesting might have provided sufficient time for orthopedic patients to improve and potentially require less assistance. This could explain why the assistance subscale scores in this study were lower compared to the Brazilian LE-MAL.

Based on Table 2, the SEM values for the total score and subscales of the Persian LE-MAL ranged from 0.43 to 0.57. These results are similar to the Brazilian LE-MAL, demonstrating that both Persian and Brazilian versions of LE-MAL exhibit acceptable absolute reliability since the SEM score is less than 10% of the total score and subscale scores(18). MDC for the total score in the Persian LE-MAL was 2.1, indicating that changes greater than 2.1, with 95% confidence, are not due to measurement error but rather represent real improvements. In contrast, MDC for the total score was reported as 0.58 and 3.14 in the Brazilian versions of LE-MAL(18, 19). This substantial difference in MDC scores between the Persian and Brazilian versions may be due to the noticeable variation in participant size between the two studies. Persian LE-MAL showed strong correlations between the total score ($r=0.77$) and the subscales of confidence and performance ($0.71<r<0.73$) with the LEFS. There was also a moderate correlation ($r=0.58$) between the assistance subscale and the LEFS. In the American version of LE-MAL, both total score and scores of all three subscales had a strong relationship with the tool for assessing lower limb function(15). In another American study involving stroke patients, a moderate to strong relationship was found between the total score and the subscales of LE-MAL with tools assessing lower limb function(17). However, in Brazilian versions, a weak to moderate relationship between the total score of LE-MAL and tools assessing lower limb function was reported(18, 19). In the Persian LE-MAL, a strong correlation was observed between the total score ($r=0.77$) and the confidence and functional performance subscales ($0.71<r<0.73$) with the LSQ, which assesses functional mobility. A moderate correlation ($r=0.58$) was found between the assistance subscale and the LSQ. Similarly, in the American version, strong correlations between the total score of LE-MAL and tools measuring functional mobility were reported(15). However, in the Brazilian versions, weak to moderate correlations between the total score of LE-MAL and tools assessing functional mobility were observed(18, 19).

. LE-MAL can also be used by clinicians and researchers to determine the effects of rehabilitation and treatment on individuals with ankle sprain. Although this study did not specifically examine the sensitivity of Persian LE-MAL to changes, it is recommended that future studies focus on its responsiveness with the aim of assessing the tool's ability to detect changes following surgical or rehabilitation interventions.

5. Conclusion

The results of this study indicate that the Persian LE-MAL is clinically appropriate, and is a valid and reliable tool for assessing lower limb function in individuals with ankle sprains.

Acknowledgements:
The authors of this study express their gratitude to the copyright holder (University of Alabama at Birmingham) for providing the questionnaire and to all the patients who participated in the study.

Disclosure statement

Funding:
This research was supported by rehabilitation research center of Iran university of medical sciences (project code: 1401-3-6-24015).

Conflicts of interest:
The authors report there are no competing interests to declare.

Ethics approval:
The execution of the project was approved by the Ethics Committee of the Iran University of Medical Sciences (IR.IUMS.REC.1400.1238), and all study participants signed an informed consent form to participate in the study.

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