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Research paper

Validation of the Lower Extremity Functional Scale in community-dwelling elderly people (LEFS-Greek); determination of functional status cut-off points using TUG test

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ABSTRACT

Purpose: The aim of this study was to evaluate structural and validity properties of the Greek version of the Lower Extremity Functional Scale (LEFS-Greek) in elderly individuals. Furthermore, to explore the ability of Timed Up & Go (TUG) test as an additional validation criterion.

Methods: Two hundred and two individuals were randomly selected from a large cohort of communitydwelling elderly people with lower extremity musculoskeletal disorders. The structural properties of LEFS-Greek were examined using exploratory and confirmatory factor analysis. The concurrent validity of the instrument was tested against the subscales of the physical functioning and role physical SF-36® Health Survey-Greek version and the TUG test. Known-groups validity was examined to assess questionnaire's ability to discriminate participants into subgroups according to their use of a cane. The cut-off points of the LEFS-Greek were obtained by ROC analysis using the TUG test as external criterion. Results: Factor analysis demonstrated that the scale has a single-factor structure. LEFS-Greek was strongly correlated with SF36-PF, SF36-RP and TUG test (0.93, 0.62, and -0.72, respectively; P < 0.001). The questionnaire was able to distinguish between the subgroups (LEFS-Greek subgroup scores 19.70 ± 14.43 vs. 51.03 ± 20.39 , respectively; P < 0.001). In ROC analysis the area under the curve for LEFS-Greek was 0.978 (95%CI 0.94-1.02, P < 0.001), with cut-off points at 53, and sensitivity and specificity of 92%

Conclusion: LEFS-Greek is a valid assessment tool that can be used to measure functional ability in individuals with lower extremity musculoskeletal disorders. This is the first study in which specific cutoff points were determined

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1. Introduction

The assessment of functional status is of major importance in patient-centered health care. An impairment in a patient's functional ability, indicates a declined well-being, and is directly proportional to a degraded quality of life. The patient's level of functional ability, or disability, influences the decision-making process and sets the goals for therapeutic intervention. A variety of rating scales and self-reported questionnaires are used for the

the objective documentation and recording of data. These tools are frequently used in large study populations, as they are noninvasive, inexpensive, and easy to administer. They are implemented as a means of comparing the findings of different interventions and/or as a functionality monitoring instrument.

evaluation of functional status in medical research, contributing to

Lower Extremity Functional Scale (LEFS), introduced in 1999 by Binkley et al. [1], is a well established evaluation tool for measuring the activity limitations and functional outcomes of patients with a wide spectrum of lower extremity disorders of musculoskeletal origin [2-10]. The original version of LEFS was cross-culturally adapted for Italian patients in 2010 [11], and in 2012 for Dutch [12], Taiwan-Chinese [13] and Brazilian [14] patients. Recently, after all the necessary technical, linguistic, and cultural adaptations, the Greek version of LEFS (LEFS-Greek) was tested for

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repeatability and found to be highly reliable in elderly individuals with lower extremity musculoskeletal disorders [15]. However, LEFS has not been validated in the Greek population yet.

The purpose of this study was to test the concurrent validity of LEFS-Greek against the subscales of physical functioning (SF36-PF) and role physical (SF36-RP) of the Greek version of the SF-36[®] Health Survey (version 1.0) [16,17] and the Timed Up & Go test (TUG) [18] in elderly individuals. Specifically, we set out to conduct factor analysis, to assess the questionnaire's known-group validity, and to define the cut-off points of the instrument.

2. Methods

2.1. Study population and procedures

Two hundred and fifty individuals, randomly selected from a population consisting of community-dwelling elderly people with lower extremity musculoskeletal disorders, participated in the present study. Based on the "rule of 10", for the factor analysis to be reliable, a minimum of 200 subjects is required [19]. Written informed consent was obtained from all participants. The study protocol followed the principles of the Helsinki Declaration and its later amendments and was approved by the Council of the Physical Therapy department of Technological Educational Institute of Athens.

The inclusion criteria were the age of the participants (greater than or equal to 65 years) and the existence of symptomatic lower extremity musculoskeletal disorder that affected only one limb. The term "symptomatic musculoskeletal disorder" is used to identify any functional limitation due to chronic bone or muscle pain and/or signs of limited motion in the affected hip, knee or ankle joint. The diagnosis confirming the existence of "musculoskeletal disorder" had to have been recorded in the individual's health card and confirmed by an orthopaedic-member of the research team. Exclusion criteria were the presence of rheumatic diseases leading to secondary osteoarthritis, musculoskeletal symptoms due to neurological aetiology, and metabolic diseases of the musculoskeletal system. None of the participants had undergone any prior osteotomy or joint replacement surgery. Forty-eight individuals were excluded on the basis of the exclusion criteria. Finally, 202 individuals (127 females) fulfilled the inclusion criteria and completed all assessment protocols. The non-participants' demographic characteristics were similar to those of the subjects participating in the study.

On the assessment day, all three questionnaires were completed on site by the participants, under the supervision of the same member of the research team. Participants were then performed the TUG test. Following one pilot trial, the average time of two successive trials was recorded using a timer with an accuracy of 1/100 s.

The structural properties of LEFS-Greek were examined using exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). The EFA was conducted to investigate the interrelatedness of the 20 items on the LEFS-Greek questionnaire. Specifically, EFA was used to explore whether the 20 items (observed variables) could be explained largely or entirely in terms of a smaller set of unobserved variables, termed "factors". The factor structure was selected by examining the magnitude and rate of change in eigenvalues. Subsequent to EFA, CFA was conducted to examine and confirm the latent factor structure of the LEFS-Greek questionnaire as suggested by the EFA results. The acceptance or rejection of the factor model was based on two parameters: both, the values of the global fit indices, and the magnitude of the variance explained by the resulting factors, to be acceptable. EFA and CFA were conducted against the same sample. The concurrent validity of LEFS-Greek was tested against the SF36-PF and SF36-RP. These

subscales were selected from the SF-36[®] Health Survey based on the results from other studies, which indicated that these physical components might be most relevant to outpatients with musculoskeletal disorders [20,21]. For additional concurrent validity analysis of the LEFS-Greek, TUG test was chosen as an additional objective criterion.

The TUG test was also used as the external criterion for the definition of the LEFS-Greek cut-off points. TUG's cut-off point was set at 12 s, as indicated by Rockwood et al. [22] and Bischoff et al. [23] for community-dwelling elderly people. Finally, the LEFS-Greek known-groups validity was examined in order to assess the questionnaire's ability to classify the participants into subgroups, defined by an objectively measured clinical variable [16]. The clinical variable that was chosen as an objective criterion of the participants' functional status was the use or not of a walking-aid (cane), regardless of the frequency of its use.

2.2. Data analysis

All analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 16.0 (SPSS Inc., Chicago, IL). The critical level for significance was set at P < 0.05.

The distribution and normality of the collected data were tested using the Kolmogorov–Smirnov test and probability-probability plots.

The latent factor structure of the LEFS-Greek questionnaire was investigated with an EFA using the principal component analysis method of extraction and *varimax rotation*, with eigenvalues greater than 1.0, estimation of scree plot test and factor loading greater than 0.30. The CFA was carried out using the analysis of moment structure program (AMOS), version 7.0. The considered global fit indices were:

- Chi² (χ²), which tests the fit of the observed covariance matrix obtained under the constraints of the model;
- the root mean square error of approximation (RMSEA);
- the comparative fit index (CFI).

The ${\rm Chi}^2$ degrees of freedom ($\chi^2/{\rm d.f.}$) ratio less than 2.0, RMSEA less than 0.05, and CFI greater than 0.95 indicated an acceptable fit. The CFA also included the goodness-of-fit index (GFI), the adjusted goodness-of-fit index (AGFI), the Tucker–Lewis index (TLI), the root mean square residual (RMR), the incremental fit index (IFI), and the expected cross-validation index (ECVI).

The concurrent validity of the LEFS-Greek questionnaire was tested by establishing its correlation with the SF36-PF, SF36-RP and the TUG test scores. The independent samples t-test was used for the examination of the LEFS-Greek known-groups validity. The participants who did not use a cane were characterised as independed (n = 156), whereas the users of a cane as aid-depended (n = 46).

ROC analysis was conducted to obtain the LEFS-Greek score cutoff points by calculating the respective areas under the curve (AUC) in order to discriminate between independed and aid-depended participants. The AUC together with their standard errors and confidence intervals (95%CI) were calculated using the maximum-likelihood estimation method, which has the advantage of being free of assumptions about the Gaussian distribution of underlying variables. In addition, the sensitivity and specificity of different cut-off points of LEFS-Greek total score were estimated using the TUG test as external criterion (TUG < 12; good functional status vs. TUG > 12; poor functional status).

3. Results

The LEFS-Greek inferential statistical analysis using the Kolmogorov-Smirnov test and probability-probability plots

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Table 1 Sociodemographic and personal characteristics of the sample population of the study participants (n = 202).

Characteristics	Values
Age (years) ^a	74.42 ± 6.60
Height (m) ^a	1.66 ± 0.08
Weight (kg) ^a	78.4 ± 13.6
BMI (kg/m ²) ^a	28.3 ± 4.1
Gender	
Males (%)	37.5
Females (%)	62.5
Affected side	
Right (%)	54.5
Left (%)	45.5
Affected joint	
Hip (%)	38.6
Knee (%)	53.0
Ankle (%)	8.4
Use of cane	
No (%)	77.2
Yes (%)	22.8

BMI: body mass index.

showed normal data distribution (D[101] = 1.56, P = 0.015). Table 1 shows the sociodemographic and personal characteristics of the participants. The mean values of the four instruments used, were 43.89 (\pm 23.25) for LEFS-Greek, 47.38 (\pm 32.91) for SF36-PF, 32.92 (\pm 40.92) for SF36-RP, and 11.57 (\pm 5.75) for TUG test.

3.1. Factor analysis

In the EFA of LEFS-Greek, the Bartlett Test of Sphericity was 2276.82 (P < 0.0005). The Kaiser–Meyer–Olkin Measure of Sampling Adequacy was equal to 0.948, showing that the data were suitable for factor analysis. One factor was extracted (item 1) that explained 67.94% of the total variance with eigenvalue 13.59. Factor loadings, which are the correlation coefficients between the items and the factor, ranged from 0.304 to 0.934. EFA with a two-factor solution did not produce any additional interpretable factors. CFA confirmed EFA results, showing a single-factor model with acceptable global fit indices. Specifically, the global fit indices were: $\chi^2 = 341.3$ (P < 0.0005), χ^2/d .f.ratio = 2.03, RMSEA = 0.052, CFI = 0.94, RMR = 0.358, GFI = 0.856, AGFI = 0.772, IFI = 0.923 and TLI = 0.940.

3.2. Validation

The concurrent validity of LEFS-Greek was evaluated in relation to SF36-PF, SF36-PR and the TUG test; the results indicated strong correlation between the four assessment tools (Table 2). The results of known-groups validity showed that LEFS-Greek was able to discriminate the participants who used a cane from those who did not (Table 3).

In ROC analysis the AUC for LEFS-Greek total score was 0.978 (95%Cl 0.94–1.02, P < 0.0005), with cut-off point 53, and sensitivity and specificity 92% and 96%, respectively (Fig. 1).

Table 2
LEFS-Greek concurrent validity against SF36-PF, SF36-RP and TUG test.

	Pearson's coefficient	Significance F
LEFS-Greek vs. SF36-PF	0.926	< 0.001
LEFS-Greek vs. SF36-RP	0.619	< 0.001
LEFS-Greek vs. TUG	-0.723	< 0.001

LEFS-Greek: Greek version of the Lower Extremity Functional Scale; SF36-PF: Physical Functioning subscale of SF-36 18 ; SF36-RP: Role Physical subscale of SF-36 18 ; TUG: Timed Up & Go Test.

Table 3
Known-groups validity of LEFS-Greek.

Walking-aid (cane)	n	$Mean \pm SD$	Significance P
Independed	156	51.03 ± 20.39	< 0.001
Aid-depended	46	19.70 ± 14.43	< 0.001

LEFS-Greek: Greek version of the Lower Extremity Functional Scale; SD: standard deviation.

4. Discussion

This is the first study to examine the validity and structural properties of the LEFS questionnaire in Greek individuals with lower extremity musculoskeletal disorders. LEFS-Greek was found to have strong to excellent correlations with the TUG test, and the SF36-PF and SF36-RP subscales of the SF-36[®] Health Survey. In addition, factor analysis was performed and specific cut-off points for functional status were determined.

4.1. Factor analysis

Factor analysis of the LEFS-Greek confirmed the one factor model proposed by the authors of the original questionnaire, since all items loaded on a single-factor. In the present study, the factor loadings of each item ranged between 0.65 and 0.93 (item 16), with the exception of item 15 (0.30). Our results are similar to those of the Taiwan-Chinese version, where factor loadings ranged between 0.60 (item 15) and 0.93 (item 4) [13]. Factor loadings of the original version ranged between 0.44 (item 4) and 0.86 (item 9) [1]. The differences observed in the values of the factor loadings of each item for the studies mentioned, may be attributed to the personal (i.e. age) and functional characteristics of the participants.

In our study, the extracted factor (item 1) explained 67.94% of the total variance in the items, in agreement with the results reported by Hou et al. for the Taiwan-Chinese version, where the single-factor model explained 75.7% of the total variance [13]. Similar findings were reported by Hoogeboom et al. [12], and Gabel et al. [24], where the extracted factor (item 1) explained 54.18% and 53.42% of the total variance, respectively. In all the reported

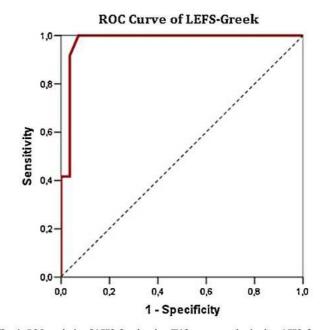


Fig. 1. ROC analysis of LEFS-Greek using TUG as external criterion. LEFS-Greek: Greek version of the Lower Extremity Functional Scale; TUG: Timed Up & Go Test.

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a The values are expressed as mean ± standard deviation.

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studies, factor analysis showed that the extracted factors explained more than 50% of the total variance, as suggested by Netemeyer et al. In particular, the authors reported that, when factor analysis is implemented, "the number of factors extracted should account for 50% to 60% of the variance in the items" [25]. Therefore, our results verify that the set of 20 items on the LEFS scale is adequate for the aspect it was designed to measure [26]. In addition, it may be concluded that LEFS is a single-factor assessment tool, whose major factor can be labelled as "daily-life functionality" (item 1), able to evaluate individuals' functional ability during daily-life activities.

4.2. Validation study

In the present study, the concurrent validity of LEFS-Greek was tested by exploring the correlation between LEFS-Greek the SF36-PF and SF36-RP SF-36[®] subscales. Our results were similar to those of the original version (0.80 and 0.64) [1], Italian version (0.77 and 0.59) [11], Taiwan-Chinese version (0.90 and 0.57) [13], and the Dutch version of LEFS (0.82 for LEFS vs. SF36-PF) [12], thus confirming the instrument's concurrent validity. Our results are not comparable to those of the Brazilian Portuguese version, because its clinimetric properties were assessed against different components (PCS and MCS) of the SF-36® health survey. It is worth mentioning that, in all validation studies where LEFS was tested against SF36-PF and SF36-RP subscales, the correlations between LEFS and SF36-PF were strong to excellent (0.77-0.93), whereas the correlations between LEFS and SF36-RP were found to be lower and moderate in quality (0.59-0.62). The stronger correlations found between LEFS and SF36-PF may be explained by the fact that both instruments are ordinal 5-point and 3-point Likert scales, whereas SF36-RP is a simple nominal scale.

To our knowledge, this is the first validation study of the LEFS scale where the TUG test was used as an additional objective validation criterion. Our results demonstrated a strong inverted association between the LEFS-Greek total score and the performance time of the TUG test. The negative sign of the correlation between LEFS and TUG test can be explained by the fact that higher scoring in LEFS implies better functional status, whereas longer performance time in TUG test is equivalent to poorer functional status.

Known-group analysis of the data showed that LEFS-Greek could detect statistically significant differences in the mean scores between the study's groups, based on the functional level of the participants, according to the use of a cane. These findings provide additional evidence for the validity of the scale.

This is also the first study of the LEFS scale in which specific cutoff points for functional status were determined. Our results indicated that patients with a LEFS-Greek total score higher than 53 had a 92% probability of really having good functional status. On the other hand, patients with a LEFS-Greek total score lower than 53 had a 96% probability of really having poor functional status. Therefore, a LEFS-Greek total score equal to 53 may be used as a cut-off value for the determination of functional status of individuals with similar characteristics in our study population group. Establishing an optimal threshold value for LEFS-Greek was one of the targets of our study, which is the reason why an objective physical performance measure (TUG test), with its own specific cut-off points, was used as an external criterion. On the other hand, in other studies no specific cut-off points for functional status were determined, possibly because ordinal scales, such as pain scales or Likert-type health status instruments, were used as external criteria. Establishing accurate functional cut-off points is of significant clinical importance, given that the level of functional ability, or disability, influences the decision-making process and sets the goals of therapeutic intervention [27].

4.3. Strengths and limitations

The random selection of the participants from a well-defined target population is an important strength of this study. In addition, testing the validity properties of LEFS-Greek using three standardised statistical measures added statistical power to our results. However, there are two potential limitations associated with the present study. The sample size for LEFS-Greek factor analysis was marginal, since our study population consisted of 202 participants, being near the lower acceptable sample size of 200 subjects. Furthermore, the study design did not include the examination of the responsiveness of LEFS-Greek.

In conclusion, LEFS-Greek is a single-factor structure questionnaire with high concurrent validity that can be used to evaluate function in elderly individuals with lower extremity musculoskeletal disorders. Both, known-groups validity and ROC analysis, confirmed the ability of LEFS to distinguish the cut-off point between different functional levels.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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