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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 community-dwelling 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% and 96% respectively.
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 cut-off points were determined.

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 evaluation of functional status in medical research, contributing to the objective documentation and recording of data. These tools are frequently used in large study populations, as they are non-invasive, 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.

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:

- Chi^2 (χ^2), 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 Chi^2 degrees of freedom (χ^2/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 cut-off 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 $\leq$ 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