Abstract. [Purpose] The purpose of this study was to establish the reliability and validity of the Korean-translated version of the Lower Limb Functional Index (LLFI) in the assessment of patients with lower-limb disorders. [Subjects and Methods] Fifty-six subjects with lower-limb disorders, 24 men and 32 women, participated in this study. Reliability was determined by using the intra-class correlation coefficient and Cronbach’s α for internal consistency. Validity was examined by correlating the LLFI scores with the Lower Extremity Functional Scale (LEFS) and Short Form 36 (SF-36) scores. [Results] The test-retest reliability was 0.95. The criterion-related validity was established through a comparison with the Korean versions of the LEFS and SF-36. [Conclusion] The Korean version of the LLFI was shown to be a reliable and valid instrument for assessing lower-limb complaints.

Key words: Lower Limb Functional Index (LLFI), Reliability, Validity

INTRODUCTION

Function refers to the ability to perform activities required for daily life[1]. Patient-reported outcome measures can confirm the effect of an intervention and provide guidance for decision making on further treatment[2]. As joint- or disease-specific outcome measures focus on a specific joint or disease, such measures are difficult to use for assessing health outcomes in patients with functional impairment and pain associated with multiple joints[3–7]. Alternatively, region-specific measures are suitable for patients who complain of dysfunction of various joints within a single kinetic chain, such as the upper and lower spine[5].

Measurements that can evaluate the function of the lower limb as a single regional kinetic chain include the Lower Extremity Functional Scale (LEFS)[9] and the Foot and Ankle Ability Measure (FAAM)[10]. However, the FAAM focuses on the lower leg below the knee joint; moreover, the most commonly used LEFS is characterized by excessive internal consistency, which indicates item redundancy, as well as a lack of sensitivity and long-term responsiveness[11].

The Lower Limb Functional Index (LLFI), developed based on the World Health Organization’s International Classification of Functioning, encompasses body structures, body function, activities, participation, and environmental factors. The LLFI questionnaire is easy and fast to complete and offers suitable readability with almost no missing responses[12]. The LLFI has been translated into different languages, including Spanish[13] and Turkish[14], and its high reliability and...
validity have been verified. However, the reliability and validity of the Korean version of the LLFI (K-LLFI) for patients with lower-limb disorders has not been determined. This study therefore aimed to identify the reliability and validity of the K-LLFI.

SUBJECTS AND METHODS

A total of 56 outpatients with lower-limb disorders receiving physical therapy at C Orthopedic Clinic in Gyeonggi province were recruited for this study. The subject inclusion criterion was a referral by a medical practitioner for musculoskeletal lower-limb symptoms classified as chronic (≥12 months). The exclusion criteria included difficulty in comprehending written Korean language, cognitive disorder, and neurological or cardiopulmonary comorbidities. After being informed about the study, the subjects agreed to participate and signed consent forms. The study was approved by the Institutional Review Board of Gachon University (1044396-201706-HR-098-01).

The LLFI is a 25-item region-specific patient-reported outcome measure. It has response options of “yes” (1 point), “partly” (0.5 point), or “no” (0 point) questions. The score is calculated by summing the response items, then multiplying the sum by 4. The total score is subtracted from 100 to provide a score of 0% to 100% (0%=maximum function).

Forward translations from English to Korean were performed by two native Korean-speaking translators. Then, back-translation to English was done by two native English-speaking translators. The translated questionnaire was understood without any difficulty by the participants.

To evaluate for reliability, the test–retest method was used. The questionnaire was completed during the initial visits. For test–retest reliability, all patients completed the questionnaires after 7 days. The 7-day test–retest reliability was analyzed according to the intra-class correlation (ICC) coefficient (2,1) and the internal consistency with Cronbach’s α. The criterion-related validity was evaluated by correlating the Korean LEFS and Short Form 36 (SF-36).

RESULTS

The general characteristics of the 56 subjects are shown in Table 1.

| Subregion | Hip | Knee |
|-----------|-----|------|
| Osteoarthritis | 2   | 32   |
| Total joint replacement | 3   |       |
| Osteoarthritis |       | 5    |
| Meniscal injury |       | 4    |
| Ligament injury |       | 10   |

The ICC was used for assessing test-retest reliability, and the ICC (2,1) of the K-LLFI was 0.95 (90% confidence interval, 0.89–0.97), showing a very high level of reliability (Table 2).

| ICC (95% CI) | Internal consistency (α) |
|------------|--------------------------|
| LLFI       | 0.95                     | 0.87                      |

All correlations are significant at the 0.05 level.

The K-LLFI values showed significant correlations with the Korean versions of the LEFS and SF-36. The correlation between the K-LLFI and the LEFS and SF-36 was high (r=0.86, r=0.78, respectively, p<0.05) (Table 3).

DISCUSSION

In this study, the test–retest reliability of the K-LLFI was assessed in patients with a lower-limb injury, and a high reliability was obtained. For the English and Turkish versions, reliability was assessed at an interval of 2 and 3 days, respectively, in patients with acute conditions. It was assessed at an interval of 7 days for the Spanish version in patients with chronic conditions. The resulting reliability of the three versions was high. In this study, the test–retest reliability was assessed at an interval of 7 days in patients with a chronic condition that had lasted for >12 months, and the reliability was high (r=0.95). The Spanish and Turkish versions demonstrated good internal consistency without item redundancy. The results of this study showed a Cronbach’s α coefficient of 0.87, which was consistent with those of the Spanish and Turkish versions.

For the original English version, the validity of the LLFI was examined by assessing its correlation with the LEFS, another region-specific measure, and good validity was identified. The Spanish version demonstrated a moderate correlation with
the Western Ontario and McMaster Universities Osteoarthritis Index when a validity test was performed\textsuperscript{(11)}. Although the LEFS is the most ideal measure for a Turkish version, it was not available. When correlation with the SF-36 was instead assessed for the Turkish version, the validity was fair\textsuperscript{(12)}. In this study, to measure the validity of the LLFI, correlations with the LEFS and SF-36 were assessed, and a high validity was observed with the LEFS and a fair validity was observed with the SF-36, which are similar to the results of the Turkish version.

An error value indicates the sensitivity in detecting changes with time. When a difference in the actual score exceeds the error value, changes can be detected, meaning that a lower error value indicates a higher sensitivity \textsuperscript{(15)}. In the English versions, the LLFI showed a lower error value than the LEFS\textsuperscript{(2)}. The study on the Turkish version stated the need for further investigations to determine a clinically important difference in relation to the error value\textsuperscript{(12)}.

Both the English and Turkish versions showed almost no missing responses compared with the LEFS. Furthermore, the Turkish version had fewer half-mark users than the English version, and suggested a format modification to include the three boxes consisting of “yes”, “half”, and “no” answers in order to promote the use of this option\textsuperscript{(12)}. In this study, there were neither missing responses nor items reported as difficult to understand. Therefore, the readability of the version was suitable.

This study confirmed the high reliability and validity of the K-LLFI. However, the results cannot be generalized because of the small sample size and because responsiveness in detecting changes with time was not evaluated. Therefore, further studies are necessary to assess the reliability of the version with a broader range of patients with lower-limb injuries.

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