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Original article

Sensitivity to change and minimal clinically important difference of the Locomotor Capabilities Index-5 in people with lower limb amputation undergoing prosthetic training

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ABSTRACT

Objective: To determine the sensitivity to change and minimal clinically important difference (MCID) for the self-administered Locomotor Capabilities Index-5 (LCI-5) in people with lower limb amputation undergoing prosthetic training.
Design: Prospective single-group observational study.
Methods: The LCI-5 was administered to 110 patients (69 males [63%]; median [interquartile range] age, 60 [48–69] years) before and after prosthetic training. The external anchor administered after the program was a 7-point Global Rating of Change Scale (GRCS) designed to quantify the effect (improvement or deterioration) of the intervention.
Results: Test–retest reliability of the LCI-5 ($n = 30$) was high (intraclass correlation coefficient [$ICC_{2,1}$] = 0.92). The minimum detectable change at the 95% confidence level was 5.66 points. After triangulating these results with those of the mean-change approach and receiver operating characteristic (ROC) curve analysis (area under the ROC curve $\geq$ 0.90), based on a different GRCS score splitting, we identified 2 cutoffs for the LCI-5: a change of 7 points, indicating the MCID, and 12 points, indicating "large improvement" in locomotor capabilities (12.5% and 21.4% of the maximum possible score, respectively).
Conclusions: The LCI-5 showed a high ability to detect change over time (responsiveness). The 2 proposed values (MCID of 7 points and large improvement of 12 points), based on a mix of distribution- and anchor-based approaches, represent cutoffs that can accurately identify 2 different levels of true change (as perceived by the patient) in locomotor capability after prosthetic training.

1. Introduction

Restoration of appropriate mobility is a major goal in people with lower-limb amputation (LLA). To monitor accurately the impact of therapeutic interventions, particularly in prosthetic trials, valid outcome measures of prosthetic mobility after LLA are greatly needed. The Locomotor Capabilities Index (LCI) was designed to evaluate ambulatory skills with a prosthesis, as part (item #11) of the Prosthetic Profile of the Amputee, a questionnaire for people with LLA [1,2]. The LCI assesses the patient's perceived capability in performing 14 different locomotor activities while wearing a prosthesis. It is available in several languages and is widely used, particularly its version with 5 rating categories (LCI-5), which has demonstrated similar psychometric properties to the original version but a lower ceiling effect and larger effect size [3–5]. These latter features signify that the LCI-5 has a greater ability to encompass the actual mobility range of individuals with LLA who undergo prosthetic training and to detect changes in functional limitations during rehabilitation.

Condie et al. [6] reported that the LCI-5 demonstrates good internal consistency, test–retest reliability, and construct validity and recommended it for clinical and research use. However, 2 recent reviews of lower limb prosthetic outcome measures [7,8]

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underlined the lack of evidence on its responsiveness/sensitivity to change. These areas represent an important drawback for a measurement tool, in that in daily practice and research, one needs to know, when examining the outcome, both the minimum detectable change (MDC) and the minimal clinically important difference (MCID). The MDC is the smallest change in score that can be detected beyond random error, whereas the MCID (also known as minimal important change) is the smallest improvement in score reflecting a clinically meaningful change as perceived by the clinician or patient.

For this reason, here we aimed to calculate, in a sample of individuals with LLA undergoing prosthetic training, the internal consistency, test–retest reliability, sensitivity to change (standard error of measurement [SEM] and MDC), and responsiveness (MCID) of the LCI-5, to enhance confidence in its use in clinical practice and research.

2. Methods

2.1. Participants

A convenience sample of individuals with LLA was consecutively recruited between January 2011 and June 2014 at 2 Italian free-standing rehabilitation centers (Lissone; Rome) for rehabilitation training. Inclusion criteria were unilateral transfemoral or transtibial LLA due to diabetes, peripheral artery disease, trauma or malignancy; age > 18 years; ability to read and write Italian; and use of a modular prosthesis. Exclusion criteria were presence of cognitive or language function deficits; any condition that prohibited prosthetic fitting and use; non-ambulation before LLA for reasons unrelated to peripheral artery disease or diabetes; and bilateral LLA.

Among 132 individuals invited to participate in the study (completing a questionnaire), 18 declined and 4 returned an incomplete questionnaire. The remaining 110 individuals who gave valid answers to all items constituted the final study group. To assess the test–retest reliability, 30 participants (mean LCI score, 37.5; range, 25–47) who were randomly selected from the total sample were asked to complete the questionnaire twice, within a 72-hour interval.

The rehabilitation program consisted of prosthetic fitting (definitive prosthesis), instruction in skin care and prosthetic management, muscle strengthening and stretching exercises (as appropriate), gait training and functional training.

The study was approved by the local ethics committees of the two rehabilitation centers, and was undertaken in compliance with the Declaration of Helsinki. All participants signed an informed consent before enrolment.

2.2. Instruments and procedure

2.2.1. LCI-5

The LCI-5 is a self-administered scale designed for people with LLA. It contains 14 questions (phrased as "Would you say that you are able to do the following activities with your prosthesis on?") assessing locomotor skills and level of independence in using a lower-limb prosthesis. A 5-level ordinal scale (0–4 points, ranging from "not able" to "able to accomplish the activity alone, without ambulation aids") rates the person's perceived degree of independence in performing each of the 14 activities while wearing the prosthesis. The total score is the sum of the individual item scores, with a possible maximum score of 56. Higher scores indicate greater locomotor capability with the prosthesis and less dependence on assistance. Validity and other psychometric properties of the Italian version of LCI-5 have been extensively demonstrated [2,3]. In this study, participants completed the LCI-5 within the first 48 hours after admission to the rehabilitation centre and at the end of the training program.

2.2.2. Global Rating of Change Scale (GRCS)

The GRCS is a self-reporting questionnaire designed to quantify patients' perceived improvement or deterioration over time. It is used to assess the effect of an intervention or chart the clinical course of a condition. Participants completed the GRCS at the final assessment (end of inpatient rehabilitation). They were asked to rate the overall change in their prosthetic mobility from when they began treatment, by using a 7-point transition question with response options ranging from −3 ("much worse") to +3 ("much better"), 0 indicating "unchanged" [9].

2.3. Statistical analysis

Internal consistency was determined by calculating [10] the following:

- Cronbach alpha (α): the closer to 1, the higher the internal consistency of the scale's items; Cronbach α values > 0.70 are recommended for group-level comparisons, and a minimum of 0.85 to 0.90 is desirable for individual judgments;
- item-to-rest correlation (i.e., to what degree each item was correlated with the total score, omitting that item from the total), by using the Spearman's rank correlation, with values > 0.30 considered satisfactory;
- inter-item correlations, with correlations < 0.15–0.20 indicating that the items do not measure the same construct very well (if at all) and correlations > 0.70 indicating that the 2 items are so similar that they are redundant [11].

Test–retest reliability of global scores was examined by the intraclass correlation coefficient (ICC), with a "two-way mixed effects, single measurement" model ($ICC_{2,1}$) [10]. Responsiveness was investigated with both distribution-based and anchor-based methods.

For distribution-based methods (analysing the ability to detect change in general), we calculated the SEM based on the analysis of variance used to produce the test–retest ICC (Eq. (1)): the SEM links the reliability of the measurement instrument to the standard deviation (SD) of the population:

$$SEM = SD\sqrt{1-ICC_{2,1}} \quad (1)$$

On the basis of the SEM, we calculated the MDC by Eq. (2):

$$MDC = SEM{*}z\ \ value{*}\sqrt{2} \quad (2)$$

The MDC represents the smallest change in score that probably reflects true change and not simply measurement error. The 95% confidence level (CI) (MDC_{95}) corresponds to a z-value of 1.96 and the 90% CI (MDC_{90}) to a z-value of 1.64, which indicates that for an individual with a change score greater than or equal to the MDC_{95} threshold, one can state (with 95% or 90% confidence) that this change is real and not due to measurement error [10].

The anchor-based method involved using the GRCS score as an external criterion (anchor) to determine whether changes in outcome scores were clinically meaningful [11–13]. We analyzed 2 parameters:

- for the mean change approach, we calculated the mean change for participants graded on the GRCS as not/minimally improved (GRCS score = 0, "unchanged" or 1, "a little better"), moderately improved (GRCS score = 2, "better"), or largely improved (GRCS score = 3, "much better");

- and for the receiver operating characteristic (ROC) curve approach, we determined the best cutoff score and the area under the ROC curve (AUC) after dividing participants by 2 different cutoff points, indicating moderate change (GRCS score $\geq$ 2) and large change (GRCS score = 3).

An ROC curve plots sensitivity (*y*-axis) against 1-specificity (*x*-axis) [10]. In this context, sensitivity was calculated as the number of participants correctly identified as improved on the basis of the cutoff value divided by all participants identified as having undergone a meaningful change (GRCS score $\geq$ 2). Specificity refers to the number of participants who were correctly identified as not improved (on the basis of the cutoff value) divided by all participants who truly did not undergo a meaningful change (GRCS score $\leq$ 1). The optimal cutoff score was chosen as the point that jointly maximized sensitivity and specificity (associated with the least amount of misclassification), by using the bootstrap method to estimate its 95% CI. The AUC can be interpreted as the probability of correctly identifying, in randomly selected pairs of individuals who have and have not shown an improvement, the one with improvement. The greater the AUC, the greater a measure's ability to distinguish individuals with improvement from those without improvement. As a general rule, an AUC $>$ 0.80 is considered excellent discrimination [10].

3. Results

Their main clinical and demographic characteristics of the 110 participants are in the Table 1. The mean (SD) completion time of the LCI-5 (self-administered) was 9 min [2], which included short instructions and explanations by the healthcare personnel. All questionnaires were fully completed; on occasion, participants reported minor difficulty in estimating the capability for activities never performed with the prosthesis. The median LCI-5 score at admission was 28.5 (interquartile range [IQR] 23–32) and at discharge 41 (39–43) (Fig. 1A). The corresponding scores for participants with transfemoral LLA were 27.5 (23–32) and 39 (37–42) versus 33 (32–36) and 43 (40–46) for those with transtibial LLA.

The Cronbach α was 0.94 for the LCI-5, which indicates a high level of internal consistency for the questionnaire. Item-to-rest correlation ranged from 0.49 (“get up from a chair”) to 0.82 (“pick up an object from the floor”); the mean inter-item correlation for the questionnaire was 0.54 (95% CI 0.50–0.59). The test–retest reliability was high: $ICC_{2,1}$ = 0.92.

The correlation between the GRCS score and the score changes for the LCI-5 was r_s = 0.65 (95% CI 0.59–0.71).

According to the GRCS score, 10% of participants (n = 11) rated no or minimal improvement after prosthetic training, 26% (n = 29) moderate improvement, and 64% (n = 70) large improvement. No participant indicated any deterioration. The SEM for the LCI-5 was 2.04 and the MDC_{95} was 5.66 points. The median LCI-5 score changes according to GRCS score were as follows: 5 points for individuals rating no/minimal improvement (GRCS score $\leq$ 1; 10% of the sample), 10 points for those rating moderate improvement (GRCS score = 2; 26% of the sample), and 15.5 points for those rating large improvement (GRCS score = 3; 64% of the sample).

Splitting the GRCS data into no/minimal improvement versus moderate/large improvement after prosthetic training (GRCS score $\leq$ 1 vs 2 and 3), the AUC was 0.97 (95% CI 0.93–1.0). The cutoff score that best identified the MCID in locomotor capability (measured by GRCS score = 2 or 3) was a change of 7 points on the LCI-5 (95% CI 2.5–9.4). Among the 99 participants who perceived a moderate to large improvement in locomotor capability (GRCS score = 2 or 3), only one showed a change $<$ 7 points on the LCI-5.

Conversely, on splitting the GRCS data into minimal/moderate improvement versus large improvement (GRCS score $\leq$ 2 vs 3), the AUC was 0.90 (95% CI 0.85–0.96) (Fig. 2), and the cutoff score that best identified this large improvement in clinical status was 12 points (95% CI 10.2–13.8) on the LCI-5. Among the 70 participants who perceived a large improvement in locomotor capability (GRCS score = 3), 58 (83%) showed a change $\geq$ 12 points on the LCI-5 after prosthetic training.

Table 1
Clinical and demographic characteristics of individuals with lower-limb amputation undergoing prosthetic training (n = 110).

Age, years, median (IQR)	60 (48–69)
Sex, male/female, *n*	69/41
Cause of amputation, *n* (%)	
Peripheral vascular disease and/or diabetes mellitus	77 (70)
Trauma	29 (26)
Malignancy	4 (4)
Amputation level, *n* (%)	
Unilateral, transfemoral	68 (62)
Unilateral, transtibial	42 (38)
Time since amputation at admission, months, median (IQR)	9 (7–11)
Length of stay, days, median (IQR)	32 (18–40)

IQR: interquartile range.

4. Discussion

The assessment of patient outcome is a fundamental part of clinical practice, and meaningful threshold change values of outcome measures play a key role in clinical decision-making and in facilitating the communication of results in a concise and comprehensible manner [14]. The present study is the first to examine the MCID threshold (the smallest improvement considered worthwhile by a patient) for the LCI-5, thus increasing the interpretability of score changes for the scale at the individual level in both clinical practice and research.

Our study confirmed the high reliability values of the LCI-5 (Cronbach α = 0.93; test–retest reliability with $ICC_{2,1}$ = 0.92). Our results agree with the literature for the LCI-5 [3], but, even though similar, they cannot be properly compared with the literature on the earlier LCI version (with 4 scoring options, 0–3) [15] because of a different metric structure. For the LCI-5, a recent Finnish study reported a Cronbach α of 0.96 and ICC of 0.95 for internal consistency, with an SEM of 3.4 (unfortunately, no MDC was calculated) [16], and in the validation study of the Persian version of the LCI-5 [17], Cronbach α values were 0.87 and 0.92 for the basic activities subscale and advanced activities subscale, respectively.

The ability of participants to estimate a change in their prosthetic mobility during the course of rehabilitation was confirmed by the good correlation of their GRCS score with the change in LCI-5 score. Our anchor-based method was based on a patient global perceived effect assessment, the most common external criterion. As recommended [9], we used a 7-point transition question focusing on change in the topic of interest. Because of inconsistency in the literature regarding the definition of the cutoff for dichotomizing a “clinically important” versus unimportant change, we considered our participants who rated their condition as “unchanged” or “a little better” as not having significantly changed over time, then examined the 2 remaining ways of clustering the outcome (considered to represent “minimal clinically important change” and “large improvement” in locomotor skills, respectively).

Thus, an MCID of 7 points (12.5% of the maximum LCI-5 score) represented a meaningful triangulation of our results for defining a minimal clinically important change in locomotor capability that could be achieved after prosthetic training. In particular, this value

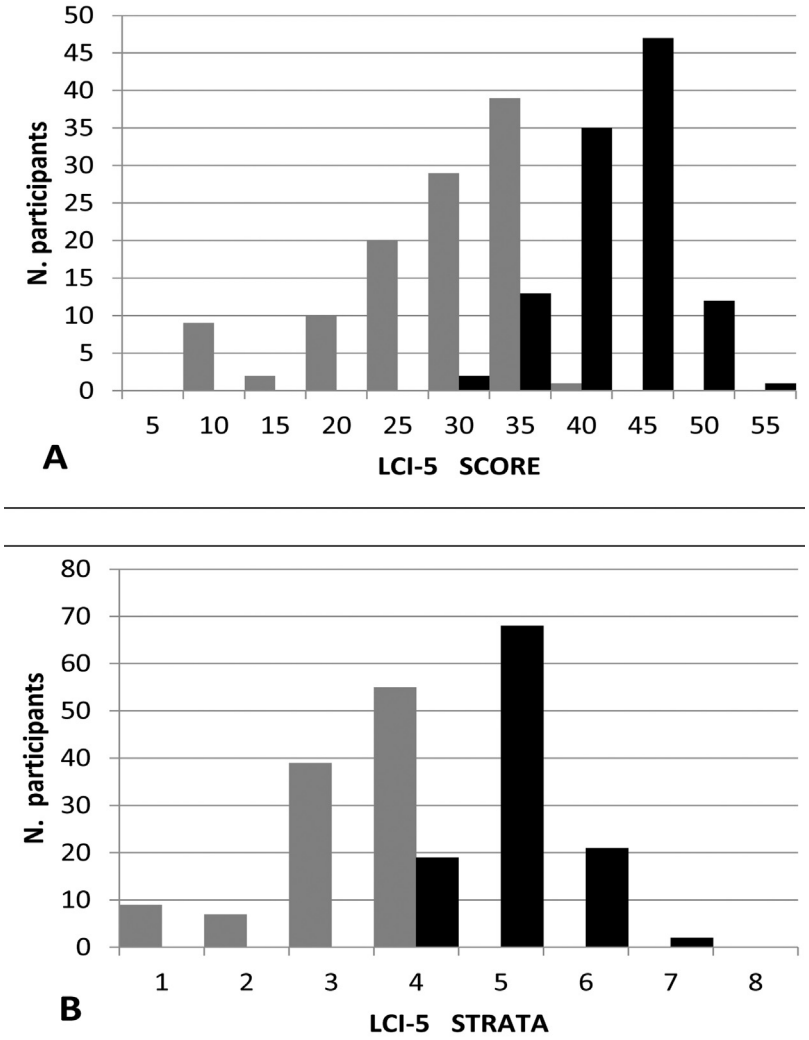

Fig. 1. Distribution of participant ability on the Locomotor Capabilities Index-5 (LCI-5) questionnaire before (grey columns) and after (black columns) prosthetic training. A. Distribution according to LCI-5 raw scores (higher values indicate greater locomotor capability). B. Distribution according to 8 LCI-5 ability strata obtained with Rasch analysis [17]: 1, very poor ability: 0–10 points; 2, poor ability: 11–18 points; 3, fair ability: 19–27 points; 4, moderately good ability: 28–36 points; 5, good ability: 37–43 points; 6, very good ability: 44–48 points; 7, excellent ability: 49–53 points; 8, top ability: 54–56 points.

is higher than our MDC_{95} value for LCI-5 (5.66 points). However, a change in LCI-5 of 12 points (about 21% of the maximum score) indicated a large change, as perceived by participants. Both values showed high discrimination (AUC for at least moderate improvement = 0.97; AUC for large improvement = 0.90), that is, the ability to correctly classify individuals with improvement or not according to the preset cutoff.

In general, caution is needed in interpreting change at the individual level. The choice of which of our 2 proposed thresholds (MCID: $>$ 7 points; large improvement: $>$ 12 points) to apply for a given individual should be clinically driven, knowing that using higher thresholds could reduce, for example, the risk of a too-early discharge in the clinical context. In addition, we point out that our MCID threshold identifies LLA individuals with clinically important improvement but not necessarily those who have reached a high mobility level. For this reason, to better understand the effects of treatment in specific contexts, different constructs should be taken into account. One such construct is the attainment of higher levels (statistically defined strata) of locomotor capability, according to Rasch analysis [18] (Fig. 1B). Another construct is the pre-defined personal rehabilitation potential (also considering mobility level before amputation), coupled with measures of ambulation performance [19], or, again, the assessment of individual restrictions and satisfaction with the prosthesis.

Our study has some potential limitations. Caution is required when interpreting and using MCID values, particularly considering the intrinsic weaknesses of the GRCS [20,21]. First, the GRCS (and the MCID values derived from it) may imply subjective retrospective judgments of change (e.g., due to recall bias or patient difficulty in understanding the context of improvement). However, problems of recall should not have been a significant issue in our sample, because the treatment period was quite short (about 4 weeks) and featured periodic discussions with the participants about their functional health status. Furthermore, a patient's GRCS score is likely to include constructs additional to those measured by the specific questionnaire. Thus, concurrently collecting a clinician-rated estimation of change, backed up by performance measures of mobility (distance/timed walking tests) [8], would have provided a more balanced change criterion. Regardless, in studies reporting such data, the clinician- and patient-reported GRCS score showed acceptable agreement [12,20].

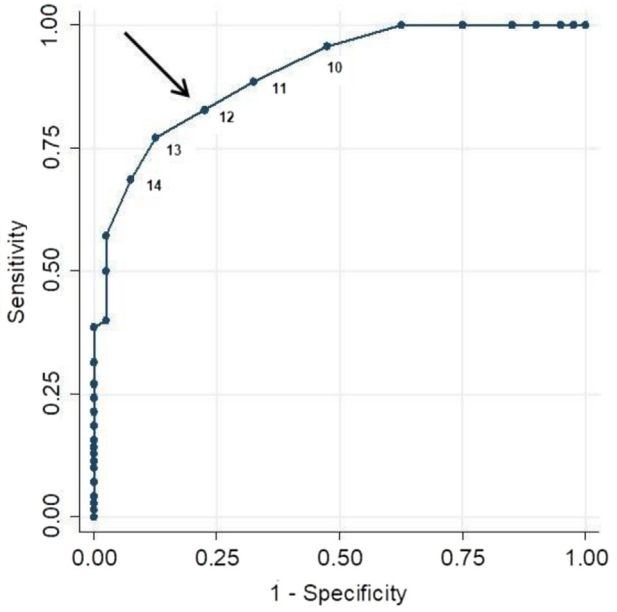

Fig. 2. Receiver operating characteristic curve of the LCI-5, showing its overall accuracy in identifying large improvement according to the Global Rating of Change Scale (score ≤ 2 vs 3). Arrow shows the related minimal clinically important difference (MCID) value (12 points).

One must also consider that:

- measurement error and parameters derived from it are often not constant across different levels of function and related scores [22];
- and MCID values can depend on selected characteristics of the sample (e.g., age, disease group, baseline functional status, potential for change) as well as treatment features [23].

Thus, the selection criteria of the present study could have threatened the study's external validity. The sample was a cross-section of adults with LLA and different clinical characteristics, recruited by a consecutive sampling method in 2 rehabilitation facilities. Different populations, interventions and methodological and statistical approaches (anchor, cutoffs, time between tests, etc.) could lead to quite different results. For this reason, the MCID should be considered a "context-specific concept," and studies should progressively define a (reasonably small) range of MCID values for a given measure [24].

In conclusion, this is the first study to examine in detail the ability of the LCI-5 to detect change over time, and it has demonstrated a high responsiveness of this scale. The 2 proposed values (based on a triangulation of distribution- and anchor-based approaches) represent cutoffs that identify with great accuracy, according to the patient, 2 different levels of true change ("minimal clinically important change" and "large improvement") in locomotor capability after prosthetic training. Further research is needed to enhance confidence in interpreting change scores of the LCI-5 as an outcome measure, but our study represents a useful step toward the ultimate goal of accurately classifying a meaningful response to rehabilitation when using this tool in individuals with LLA who wear a prosthesis.

Disclosure of interest

The authors declare that they have no competing interest.

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