THE GERONTOLOGICAL SOCIETY OF AMERICA®

Journals of Gerontology: Medical Sciences
cite as: *J Gerontol A Biol Sci Med Sci*, 2019, Vol. 74, No. 4, 556–559
doi:10.1093/gerona/gly230
Advance Access publication October 4, 2018

OXFORD

Brief Report

Meaningful Change Estimates for the Late-Life Function and Disability Instrument in Older Adults

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Received: April 6, 2018; Editorial Decision Date: September 14, 2018

Decision Editor: Anne Newman, MD, MPH

Abstract

Background: The Late-Life Function and Disability Instrument (LLFDI) is a well-validated and frequently used patient-reported outcome for older adults. The aim of this study was to estimate the minimal clinically important difference (MCID) of the LLFDI-Function Component (LLFDI-FC) and its subscales among community-dwelling older adults with mobility limitations.

Methods: We performed a secondary analysis of the Boston Rehabilitative Impairment Study of the Elderly, a longitudinal cohort study of older adults with mobility limitations residing in the community. The MCID for each LLFDI-FC scale over 1 year of follow-up was estimated using both anchor- and distribution-based methods, including mean change scores on a patient-reported global rating of change in function scale, the standard error of measurement (SEM), and the minimal detectable change with 90% confidence (MDC_{90}).

Results: Data from 320 older adults were used in the analysis (mean age 76 years, 69% female, mean of four chronic conditions). Meaningful change estimates for "small change" based on the global rating of change and SEM were 2, 3, 4, and 4 points for the LLFDI-FC overall function scale and basic lower-extremity, advanced lower-extremity, and upper-extremity subscales, respectively. Estimates for "substantial change" based on the global rating of change and minimal detectable change with 90% confidence were 5, 6, 9, and 10 points for the overall function scale and basic lower-extremity, advanced lower-extremity, and upper-extremity subscales, respectively.

Conclusion: This study provides the first MCID estimates for the LLFDI-FC, a widely used patient-reported measure of function. These values can be used to interpret the outcomes of longitudinal investigations of functional status in similar populations of community-dwelling older adults.

Keywords: Clinically important difference, Minimal important change, Measurement, Responsiveness, Self-reported function

Deficits in physical function such as difficulty walking or rising from a chair are common among older adults and are especially strong predictors of adverse outcomes such as disability, hospitalization, and death (1–3). As such, physical function is an important and frequent focus of aging research. However, selecting the optimal measure of function is a critical design step; the ideal measure needs to reflect the construct of interest and have strong evidence for its psychometric properties and interpretability.

Patient-reported outcome measures (PROs) are frequently used to measure physical function in geriatric research as they provide a direct, patient-centered assessment of a large range of functional activities applicable to an older adult's daily life. Although many PROs are available, lack of conceptual clarity over the construct being measured and problems with responsiveness are common limitations, which can influence their usefulness (4). The Function Component of the Late-Life Function and Disability Instrument (LLFDI-FC) is a widely used PRO of physical function that was

specifically conceived to address these shortcomings (5–7). We have previously reported strong evidence supporting the LLFDI-FC's construct validity, reliability, and responsiveness to change (1,7). We have also shown that poor scores on the LLFDI-FC are predictive of adverse outcomes such as disability, falls, and hospitalizations in older adults with mobility limitations (1). However, increments of change in the LLFDI-FC that are most clinically meaningful remain unknown. This information is critical for interpreting results of both population-based studies and clinical interventions in older adults designed to target changes in function. Minimal important change values are also needed for rigorous sample size and power calculations in guiding study design. The LLFDI-FC may be particularly advantageous for this purpose, as it is a continuous measure (scored from 0 to 100) and would be expected to have smaller sample size requirements than some of the commonly used measures of function in the aging literature.

The objective of this study is to provide preliminary estimates of the minimal clinically important difference (MCID) of the LLFDI-FC and its subscales among community-dwelling older adults with mobility limitations. Given the inherent strengths and weaknesses of anchor- and distribution-based approaches for determining the MCID, this report will combine data drawing on both techniques to determine the most appropriate estimates of meaningful change for the LLFDI-FC (8,9).

Methods

We used data collected between years 2 and 3 of the Boston Rehabilitative Impairment Study of the Elderly (Boston RISE), a longitudinal cohort study of older primary care patients at risk for mobility decline. A total of 320 patients had complete outcome data at years 2 and 3 and were included in this analysis.

Methods for Boston RISE were approved by the relevant Institutional Review Boards. Study details have been published elsewhere (10). Patients were recruited from primary care practices who met the following criteria: age 65 years or older, ability to speak and understand English, difficulty or task modification with walking 1/2 mile and/or climbing one flight of stairs, no planned major surgery, and expectation of living in the area for two or more years. Exclusion criteria included significant visual impairment, uncontrolled hypertension, lower-extremity amputation, supplemental oxygen use, myocardial infarction or major surgery in the previous 6 months, Mini–Mental State Exam score of less than 18, and Short Physical Performance Battery score of less than 4.

Measures

Late-Life Function and Disability Instrument-Function Component

The LLFDI-FC is an interview-administered questionnaire that assesses a wide range of functional tasks, consistent with both the World Health Organization International Classification of Functioning, Disability and Health and Nagi disablement models (4,11). The LLFDI-FC asks patients to report their present degree of difficulty in performing 32 physical functional tasks on a usual day without assistance (ie, without the help of another person or assistive device). Response options are as follows: none, a little, some, quite a lot, cannot do. The LLFDI-FC comprises an overall function scale and three subscales: advanced lower-extremity function (eg, walking several blocks, getting up from the floor), basic lower-extremity function (eg, standing, stooping, walking inside the home), and upper-extremity function. Each LLFDI-FC scale is scored from 0 to 100, where 0 indicates poor function and 100 indicates good function.

Global Rating of Change in Function Scale

A global rating of change (GRC) in function scale was developed as a patient-reported anchor. During their year 3 follow-up interview, participants were asked to rate the amount of change they perceived in their functional ability according to the following question, "Over the past year, has your ability to move around in your home and in your community (such as walking, climbing stairs) become…" Responses were recorded on a 5-point Likert scale (much worse, a little bit worse, stayed about the same, a little bit better, much better).

Analysis

A combination of anchor-based methods (ie, external criterion that reflects a patient's perspective) and distribution-based methods (ie, statistical distributions of change and reliability) are recommended to optimally determine the MCID (8,9). The following methods were used to calculate meaningful change estimates for the LLFDI-FC scales:

1. The mean change scores on each of the LLFDI-FC scales were calculated for each answer on the GRC.
2. The standard error of measurement (SEM) was calculated as $S_b \times \sqrt{(1 - r)}$, where S_b is the *SD* at baseline and r is the test–retest reliability coefficient. Previously published data for the reliability coefficients were used (5). One SEM is equal to a 68% confidence interval around a single measured value (9,12).
3. The minimal detectable change with 90% confidence (MDC_{90}) refers to the smallest amount of change that falls outside of measurement error with 90% confidence, and was calculated as 1.645 × sqrt2 × SEM (8). Alternatively stated, 90% of truly unchanged patients will display random fluctuations equal to or less than the MDC_{90}.

Data were analyzed using SPSS version 24.0 for Windows (SPSS, Chicago, IL). Those at the floor (ie, those with a score of 0 on an LLFDI subscale at baseline and who could not decline) were excluded from the relevant analysis.

Results

Data from 320 older adults were used in the analysis. Their baseline characteristics are shown in Table 1. On average, patients were 76 years old, were 69% female, and had a mean of four chronic conditions. Their mean baseline SPPB score was 9 indicating mild to moderate mobility limitation. The advanced lower-extremity scale was the only scale with patients at the floor at baseline; 12 patients (3.8%) were therefore excluded from subsequent analyses for this subscale.

Over 1 year of aging, the majority of patients reported either no change in function or a small decline (Table 2). Spearman correlation coefficients between change in the LLFDI-FC and change in the GRC were 0.2 for upper-extremity and basic lower-extremity function, and 0.3 for overall and advanced lower-extremity function (all $p < .001$). Given that only a small proportion of patients reported an improvement (14%), the remainder of the anchor-based analysis is focused on estimates of clinically important decline.

The MCID values determined by anchor- and distribution-based approaches for each of the LLFDI-FC scales are summarized

in Table 3. In general, anchor-based MCID estimates for small decline aligned well with the distribution-based SEM estimate, whereas anchor-based estimates for "substantial decline" were more closely aligned with estimates of the MDC_{90} for each of the scales. Recommended MCID values for both small and substantial change for the LLFDI-FC based on triangulation of the methods are also shown in Table 3.

Discussion

This study provides preliminary estimates of clinically important change for the LLFDI-FC, a frequently used patient-reported measure of function in aging research. Our analysis combines use of both anchor- and distribution-based techniques for determining the MCID, which strengthens the confidence in our estimates of meaningful increments of change that are both perceptible to patients and above measurement error. Our findings add to the growing body of evidence supporting the psychometric properties of the LLFDI-FC (1,5,7,13) and its usefulness as a patient-reported measure of function for older adults.

The selection of an appropriate MCID value depends on how it is defined. When a GRC scale is used as an anchor, minimal change is often described as a "small" or "slight" change on the anchor, whereas others have used descriptors corresponding to "much" or "substantial" change (14). Consequently, a critical issue when using anchor-based approaches lies in defining what constitutes a minimally important improvement—should the MCID be based on the amount of change or on its perceived importance? In light of this challenge and the well-established limitation of using an un-validated GRC scale as a gold standard, we support the recommendation of also using a distribution-based approach, such as the MDC_{90}, as a complementary method for estimating the MCID for different levels of change (8,9). As shown in Table 3, triangulating the estimates from anchor- and distribution-based methods results in recommended MCID values for small and substantial change for the LLFDI-FC that are both perceptible to patients and detectable beyond some level of measurement error. The ultimate choice of MCID will depend on the specific research/clinical context; for example, the MCID for "small change" may be preferred when considering group differences, where detecting small changes may be of interest. Smaller change thresholds are particularly relevant for informing conservative sample size estimations in study planning; detecting smaller changes requires larger sample sizes. On the other hand, our MCID estimates for "substantial change" are recognized as considerable by patients and are confidently beyond measurement error; these estimates are most relevant for interpreting within-patient changes, for example, after a clinical intervention or onset of illness.

The Boston RISE cohort study included patients at risk for mobility decline; therefore, it was not unexpected that only a small proportion of patients reported improvements in function on the GRC after 1 year of follow-up. As a result, we are only able to comment on anchor-based estimates of small and substantial decline, which may differ from estimates of improvement. Nevertheless, our distribution-based meaningful change estimates are independent of direction and are in line with our estimates of patient-rated change

Table 1. Baseline Characteristics of Patients ($N = 320$)

Characteristic	Mean ± *SD* or %
Age	76.2 ± 6.9
BMI	29.5 ± 6.1
Sex: women	68.5
Race: white	82.7
Chronic conditions (*n*)	3.9 ± 1.8
MMSE	27.6 ± 2.3
SPPB	9.0 ± 2.1
LLFDI overall function	56.1 ± 7.9
LLFDI basic lower-extremity function	66.5 ± 12.0
LLFDI advanced lower-extremity function	43.2 ± 14.0
LLFDI upper-extremity function	73.3 ± 14

Notes: BMI = body mass index; MMSE = Mini–Mental State Exam; SPPB = Short Physical Performance Battery; LLFDI = Late-Life Function and Disability Instrument.

Table 2. Patient-Reported Changes in Function Over 1 Y on the Global Rating of Change Scale

GRC Response	*n*, %
Patients "much worse"	33, 10
Patients "a little worse"	126, 39
Patients unchanged	115, 36
Patients "a little better"	34, 11
Patients "much better"	12, 4

Note: GRC = global rating of change.

Table 3. Meaningful Change Estimates for the Late-Life Function and Disability Instrument From Anchor- and Distribution-Based Methods

LLFDI Scale	Change Scores for "About the Same" ($n = 115$)	Change Scores for "a Little Bit Worse" ($n = 126$)	Change Scores for "Much Worse" ($n = 33$)	SEM	MDC_{90}	MCID Small Change[a]	MCID Substantial Change[a]
Overall function	0.2 ± 5.2	2.0 ± 4.3	4.5 ± 8.4	1.6	3.7	2	5
Basic lower-extremity function	1.1 ± 10.3	2.9 ± 7.6	6.2 ± 11.9	1.9	4.3	3	6
Advanced lower-extremity function	1.2 ± 8.4	3.8 ± 8.4	9.2 ± 16.9	2.6	6.0	4	9
Upper-extremity function	1.2 ± 10.6	2.5 ± 10.4	3.9 ± 13.5	4.2	9.8	4	10

Notes: LLFDI = Late-Life Function and Disability Instrument; MCID = minimal clinically important difference; SEM = standard error of measurement; MDC_{90} = minimal detectable change with 90% confidence.

[a]The MCID value for small change was selected as the larger of either the anchor-based estimate for small change or the distribution-based SEM, rounded to the nearest whole number. The MCID value for substantial change was selected as the larger of either the anchor-based estimate for substantial change or the distribution-based MDC_{90}, rounded to the nearest whole number.

using the GRC. That is, the distribution-based calculations based on the SEM and MDC yielded estimates of similar magnitude to change in the LLFDI-FC among patients who rated themselves "a little bit worse" and "much worse," respectively. In addition, these anchor-based meaningful change values are also of similar magnitude to intervention studies where improvements in function were observed (7). For example, the anchor-based change estimate for "a little bit worse" for the LLFDI-FC overall function scale was 2 points in this study; in a previous trial showing improvement in self-reported function following testosterone therapy in older men, an improvement of 2.7 points on the LLFDI-FC was deemed important based on participants' self-reported rating of "better physical function" at 6 months (15). Future investigations specifically examining improvement will be necessary to have confidence in estimates of minimal important change for improvement on the LLFDI-FC.

One of the strengths of this study is that we developed an anchor specifically designed to measure change in the construct of interest: self-reported physical function. As such, our patient-reported anchor had strong face validity for our outcome which is often not the case in studies attempting to establish increments of important change. However, our approach also had several drawbacks. As we asked patients to recall change over a 1-year period, a possible limitation is recall bias, which has been identified as limiting the validity of a 6-month retrospective GRC when compared with change on a prospective global measure (16). In addition, although the correlations between change in anchor and change in outcome are seldom reported in the literature, it has been recommended that an r of at least 0.3 is needed for a GRC scale to be valid (9). The associations between change in the upper-extremity and basic lower-extremity scales of the LLFDI-FC and the GRC were below this threshold (0.2). These lower correlations may be a result of the wording of our GRC (in particular for upper-extremity function), recall bias, or simply the nature of the tasks in these scales. Nonetheless, the anchor-based change estimates obtained for upper-extremity and basic lower-extremity scales aligned fairly well with the distribution-based estimates, which suggest they may be useful as a starting point. Future studies will be necessary to refine the MCID estimates for these subscales as well for establishing the optimal MCID values for improvement on the LLFDI-FC. Finally, although this study includes a fairly large sample of community-dwelling older adults, the MCID values may not be generalizable to primary care patients living outside the Boston area and to those without mobility limitation.

In summary, our findings suggest that for mobility-limited older adults with multimorbidity, a change of 2 points for the overall function scale, 3 points for the basic lower-extremity subscale, and 4 points for both the advanced lower-extremity and upper-extremity subscales, is required for a small but meaningful change on the LLFDI-FC. For substantial change, the corresponding MCID values were 5, 6, 9, and 10 points. These values can be used as preliminary MCID estimates for the LLFDI-FC to guide study design and to help interpret the outcomes of longitudinal investigations of functional status in similar populations of community-dwelling older adults.

Funding

This study was supported by the National Institute on Aging (R01 AG032052-03) and the National Center for Research Resources in a grant to the Harvard Clinical and Translational Science Center (1 UL1 RR025758-01); in part by the Canadian Institutes of Health Research (to M.B.); a National Institutes of Health K24 award (4K24HD070966-05 to J.B.); and in part by the National Institute on Disability and Rehabilitation Research (H133P120001 to A.J.).

Conflict of Interest

AMJ has stock holdings in CREcare, LLC, a small business created to disseminate outcome instruments such as the LLFDI.

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