Observational Study

Medicine®

OPEN

Responsiveness of the modified lower extremity functional scale in patients with low back pain and sciatica

A comparison with pain intensity and the modified Roland-Morris Disability Scale

Yi-Shiung Horng, MD, PhD[a,b], Wen-Hsuan Hou, MD, PhD[c], Huey-Wen Liang, MD, PhD[d,*]

Abstract

We tested the responsiveness of the modified Lower Extremity Functional Scale (LEFS) for patients with low back pain (LBP) and sciatica and made a comparison with the modified Roland-Morris Disability Scale for sciatica (RMS-L) and self-reported pain intensity measured by visual analogue scale (VAS).

One hundred and forty-eight participants were recruited from 2 university hospitals. The evaluation included demographic data, LBP history, and the modified LEFS, RMS-L, and VAS, with a follow-up one month later. Several responsiveness statistics were calculated.

The study followed 132 participants, approximately 25% reported improvement. Guyatt responsiveness index (GRI) was 0.8 or higher for 3 measures, while standardized response means were 0.8 or higher for the RMS-L and VAS, but only 0.6 for the modified LEFS among improved group. According to ROC analysis, the modified LEFS had an area under curve (AUC) similar to that of the modified RMS-L, but significantly smaller than that of the VAS.

The responsiveness of the modified LEFS was moderate but not superior to the VAS or RMS-L. Although, the modified LEFS could not replace the RMS-L or VAS, it could still be used as a complementary measure since these three measurements covered different body function, activity and participation domains.

Abbreviations: AUC = area under curve, Cis = confidence intervals, GRI = Guyatt responsiveness index, ICC = intraclass correlation coefficient, LBP = low back pain, LEFS = the modified Lower Extremity Functional Scale, MCID = minimal clinically important difference, RMS = Roland-Morris Disability Scale, RMS-L = the modified Roland-Morris Disability Scale, ROC = receiver operating characteristic, SRM = standard response mean, VAS = visual analogue scale.

Keywords: low back pain, questionnaire, responsiveness, sciatica, visual analogue scale

1. Introduction

The musculoskeletal structures and nervous system of the low back and lower extremities are closely related and low back pain (LBP) patients often experience leg symptoms, including pain, numbness, claudication or even weakness. These symptoms lead to functional limitations that are even greater than those in patients with LBP alone.[1]

To apply a single questionnaire to facilitate comparisons among various different conditions of the low back and/or lower extremities, we validated a modified version of the Lower Extremity Functional Scale (LEFS) in LBP subjects.[1] The LEFS is a widely used and region-specific measure for lower extremity musculoskeletal disorders.[2] We tested its psychometric properties for LBP by substituting “lower limb problem” with “low back/lower limb problem” in the introductory sentence, and the results showed satisfactory reliability and validity among all LBP patients. Nevertheless, its responsiveness has not been explored until now, and the information is crucial for clinical application.

Responsiveness is defined as the ability of a measurement or instrument to detect change accurately when it has occurred.[3] It is an essential clinometric property of an outcome measure, especially for detecting the changes associated with interventions. There is no consensus on the most appropriate strategy for quantifying responsiveness, but most studies provide the information for both internal and external responsiveness.[4] Internal responsiveness can be obtained by paired *t* test or several effect size statistics and is mostly based on sample variability and measurement precision, while external responsiveness can be obtained through the receiver operating characteristic (ROC) method with an external measure of change, correlation, and

Editor: Dennis Enix.

This work was supported by National Taiwan University Hospital, Taiwan (Grant no. NTUH-101-S1846).

The authors report no conflicts of interest.

[a] Department of Rehabilitation Medicine, Taipei Tzuchi Hospital, The Buddhist Tzuchi Medical Foundation, New Taipei City, [b] Department of Medicine, Tzu Chi University, Hualien, [c] School of Gerontology Health Management and Master Program in Long-Term Care, College of Nursing, Taipei Medical University, [d] Department of Physical Medicine and Rehabilitation, National Taiwan University Hospital and National Taiwan University College of Medicine, Taipei, Taiwan, ROC.

[*] Correspondence: Huey-Wen Liang, Department of Physical Medicine and Rehabilitation, National Taiwan University Hospital and National Taiwan University College of Medicine, Taipei, Taiwan (e-mail: lianghw@ntu.edu.tw).

Medicine (2019) 98:14(e15105)

Received: 4 September 2018 / Received in final form: 8 March 2019 / Accepted: 11 March 2019

http://dx.doi.org/10.1097/MD.0000000000015105

regression model. On the other hand, minimal clinically important difference (MCID) represents the smallest amount of change in an outcome that might be considered important by patients or clinicians. These responsiveness statistics are all important criteria for the validity of outcome measures.

Previous studies presented concurrent comparison of responsiveness among outcome measures for LBP to help in the choice of proper tools regarding functional level, disease duration, types of intervention or study setting.[5–7] Our goal is to assess the responsiveness of the modified LEFS, which we compare with 2 other outcome measures, self-reported pain intensity and the modified Roland-Morris Disability Scale for sciatica (RMS-L) for sciatic patients.[8] The results should be helpful in choosing appropriate instruments for functional outcome among LBP with sciatica.

2. Methods

2.1. Study population

This prospective and observational study recruited a convenience sample of patients who were receiving physical therapy in the physical medicine and rehabilitation clinics in 2 university hospitals. Eligible patients were 18 years of age or older, had experienced LBP with radiating pain to legs (sciatica), for at least 1 week, and had no other comorbidities such as cognitive impairment, neurological or cardiopulmonary disorders that would influence locomotion. The cases with LBP due to malignancy, infectious disease or visceral disorders were excluded. This study was approved by the ethics committee of our institutes. Each subject signed an informed consent before their enrollment.

2.2. Baseline data collection

The baseline questionnaire contained questions about the patients' demographic data (age, sex, occupation, and educational level) and characteristics related to LBP and sciatica (duration, any radiation of pain or leg numbness, and operative history). Overall pain severity was rated using a 0 to 100 mm and un-scaled visual analogue scale (VAS).[9] The modified LEFS and RMS-L were used to evaluate the functional limitations caused by LBP and sciatica.

2.3. Functional questionnaires

The LEFS contains 20 items to rate the degree of difficulty in performing different physical activities due to problems in the lower extremities; a 5-point scale is used, from 0 (extreme difficulty/unable to perform activity) to 4 (no difficulty).[2,10] The total score ranges from 0 to 80, with higher scores indicating better function. We adapted a modified version in which "low back/lower limb problem" was substituted for "lower limb problem" in the introductory sentence of the questionnaire for our present study.[1]

The Roland-Morris Disability Scale (RMS) contains 24 statements, and the patients are asked to place a check mark next to the statement if it applied to them on that day.[11,12] The score is calculated by adding up the number of statements checked; possible scores range from 0 (no disability) to 24 (maximum disability). This modified version changes "back pain" in the original questionnaire to "leg pain" to increase the sensitivity to change in sciatic patients and is referred to as the RMS-L.[8]

2.4. Follow up

For all the subjects, follow-up occurred at least 1 month later. Patients completed the modified LEFS, RMS-L and VAS for their current condition and rated the global change in their low back/sciatica condition between the 2 occasions as "much improved", "moderately improved", "slightly improved", "no change", "slightly worsened", "moderately worsened", or "much worsened". Those who reported slightly improved, no change or slightly worsened were classified as the "stable group", while those who reported moderately improved or much improved were classified as the "improved group". The classification was used as an external criterion for improvement in the data analysis.

2.5. Data analysis

The modified LEFS score was computed by summing the scores for each item while the RMS-L scores were calculated by adding up the numbers of positive response. The change scores of the modified LEFS, RMS-L and VAS were compared using a paired t test and the correlation was computed by Pearson correlation coefficient. The standard response mean (SRM) was calculated as the mean of score changes divided by the standard deviation of change scores for both the stable and improved groups. GRI was calculated by dividing the mean change of the patients who had improved by the standard deviation of change of the stable group classified by global change rating.[13] For all responsiveness statistics, values of 0.20, 0.50, and 0.80 or greater have been advocated to represent small, moderate, and large degree of responsiveness, respectively.[14–16] The receiver operative characteristic (ROC) curve was constructed based on the self-ratings of global change to separate the stable and improved groups. A value of 1 for the area under the curve (AUC) represents perfect (100%) accuracy, and a value of 0.5 represents chance alone. For each outcome, a cut-off point was calculated for which the sensitivity and specificity jointly minimize the total error in misclassification and was defined as the MCID of each instrument.[17] Additionally, a bootstrapping technique with the creation of 5000 bootstrap samples with replacement was used for comparisons between the AUC of the modified LEFS and the RMS-L.[18] In brief, this method obtains the sampling distributions of the outputs for the positive class and the negative class, respectively, and then creates a confidence bands for the ROC curve through this resampling procedure. Alternatively pairwise comparisons were made between ROC curves by varying the decision threshold over the whole range of the bootstrap sampling distributions.[19] The 95% confidence intervals (CIs) were computed using the 2.5th and 97.5th percentiles of the bootstrap distribution and P values were obtained by computing a series of CIs based on the bootstrap distribution with varying levels of confidence (e.g., 95%, 99%) until 1 endpoint of the CI crossed 0 (e.g., 99% CI corresponds to $P = .01$). All statistical analysis was performed with SAS 9.1 for Windows (SAS Institute, Cary, NC).

3. Results

A total of one hundred and forty-eight subjects were evaluated at baseline and 132 (89.2%) were followed up in an average of 31 days. The followed and un-followed subjects had similar demographic features, disease conditions and baseline assessment (Table 1). More than 70% of the participants had a disease duration of more than 6 months, and only 7% had undergone prior spinal surgeries. The average scores of the modified LEFS,

Table 1

Demographic characteristics of the participants. The results were shown as either number (%) or mean (standard deviation).

Variables	Follow up, n=132	Lost follow up, n=16	P
Man, n (%)	56 (42.4)	8 (50.0)	.60
Age (yr)	48.9±14.0	51.5±10.5	.38
Married	96 (72.8)	15 (93.7)	.07
Educational years ≧12 yr	97 (73.5)	10 (62.6)	.38
Employed	71 (54.2)	11 (68.7)	.30
Duration of symptoms			.62
0–4 weeks	8 (6.1)	2 (12.5)	
1–6 months	29 (22.0)	3 (18.8)	
>6 months	95 (72.0)	11 (68.7)	
Receiving surgery	9 (6.8)	2 (12.5)	.34
Assessment at baseline			
Lower Extremity Function Scale	60.3±13.7	62.7±13.7	.52
modified Roland-Morris Disability Scale for sciatica	10.0±5.3	7.4±5.5	.07
Pain by visual analogue scale	46.9±22.4	45.1±25.1	.77

RMS-L and VAS at baseline corresponded to approximately 75%, 58%, and 53%, respectively, of their own individual best function. None of the subjects had a ceiling or floor score on the VAS. In total, 0.8% of the subjects achieved floor scores for the RMS-L at baseline, and 1.5% of the subjects had ceiling scores. Additionally, 1.5% of the participants had a ceiling score for the modified LEFS and no participants had ceiling or floor scores for the VAS.

The mean change scores of the modified LEFS, RMS-L and VAS for all subjects were −9.7, −1.3 and 2.5, respectively (Table 2). At follow up, the improved group (25% of subjects) had mean score changes of 7.1 for the modified LEFS, −3.6 for the RMS-L, and −21.7 for the VAS, (Table 2). The correlation computed by Pearson correlation coefficient was −0.32 between the modified LEFS and VAS ($P<.01$), and −0.27 between the modified LEFS and RMS-L ($P<.01$) (Table 3). For the individual items in the LEFS (Table 4), most of the items had no significant change for the stable group, except for putting on shoes or socks. In contrast, 8 out of 24 items had significant change for the improved groups, mostly related to locomotion and heavy lifting. These items are also found mostly among those items with the lowest scores at baseline.

SRM was greater or equal to 0.8 for the RMS-L and VAS in the improved group, but not for the modified LEFS (Table 5), while GRI values were all above 0.8 for all 3 measures. Using the improved or stable groups with the global rating as a cut-off point, the AUCs among the 3 measures were the largest for the VAS (0.79), followed by the RMS-L (0.70) and the modified LEFS (0.66) (Table 6). In addition, the MCIDs of the modified LEFS, RMS-L and VAS equaled 2.5, 2.5, and 15.5 and corresponded to 3.1%, 16.7%, and 15% of individual maximal scores. The bootstrapping technique showed that the AUC was significantly different between the modified LEFS and VAS ($P=.04$), but not between the modified LEFS and RMS-L ($P=.49$).

Table 2

The mean and standard deviation of the change scores of the modified LEFS, RMS-L, and VAS, categorized by the self-rated global change.

Instrument	Overall (n=132)	Worsen (n=3)	Stable (n=96)	Improved (n=33)
LEFS	2.5 (10.1)	−0.3 (4.0)	1.1 (9.2)	7.1 (11.6)
RMS-L	−1.3 (3.7)	−0.7 (5.5)	−0.6 (3.1)	−3.6 (4.5)
VAS	−9.7 (22.7)	21.7 (20.2)	−4.7 (19.6)	−27.0 (21.7)

LEFS=Lower Extremity Functional Scale, RMS-L=modified Roland-Morris Disability Scale for sciatica, VAS=visual analogue scale.

Table 3

Pearson's correlation coefficient between the score changes of the modified LEFS, RMS-L, and VAS.

	VAS	LEFS
RMS-L	0.25 ($P<.01$)	−0.27 ($P<.01$)
LEFS	−0.32 ($P<.01$)	–

LEFS=Lower Extremity Functional Scale, RMS-L=modified Roland-Morris Disability Scale for sciatica, SRM=standardized response mean, VAS=visual analogue scale.

4. Discussion

This study showed a moderate SMR and a large GRI the modified LEFS in patients with LBP with radiating leg pain (sciatica). The LEFS is a valid and reliable functional measure for lower limb conditions. This modified version, where we replaced "lower limb problem" with "low back/lower limb problem" in the introductory sentence, provided adequate reliability and concurrent validity for subjects with LBP either with or without leg pain.[1] It also had good internal consistency (Cronbach α: 0.94), high test-retest reliability ($ICC_{(2,1)}$: 0.86) and satisfactory correlations with RMS, and it discriminated well between the subgroups of LBP with or without leg pain. In the present study, we took further of examining its responsiveness and made comparisons with preexisting measurements, including self-reported pain and the RMS-L. Although the results showed a moderate SRM and a large GRI for the modified LEFS among sciatica patients, it does not confirm a superior responsiveness in comparison with the RMS-L or VAS. The clinical application warranted further interpretations.

The LEFS is sensitive to changes among patients with lower extremity conditions. As shown in previous studies, SRMs of the LEFS were between 0.92 and 1.76 for improved subjects and the AUC was between 0.76 and 0.97.[20–22] The results of this present study show lower SRMs for LBP with sciatica than did previous applications among lower limb extremity disorders. We attribute this to the less functional limitation of lower limb function in the current sample of LBP, which is reflected by a relatively high score of the modified LEFS at baseline. It is also consistent with the clinical observation that these patients often complain of pain, numbness and difficulties in locomotion, but mostly not to the extent of being unable to walk or stand in comparison with those patients with leg fractures or major trauma. It also renders a low mean change score (7.1) for the improved group. The large proportion of chronic cases in the current sample also contributes to the relatively small SRM since chronic LBP patients are reported to have lower SRMs and AUCs than acute cases.[6] It is possible to be more responsive in acute or severe cases, such as pre- and post-operative ones, and further studies are warranted.

Two common outcome measures for LBP were chosen for comparison with LEFS – self-reported pain by the VAS and the RMS-L. The RMS is a well-validated and widely accepted condition-specific measure of back pain-related disability and has been used for sciatica in its original form,[23] a short version,[9] or a modified version where all references to back pain are changed to "leg pain".[24] Some reports support its superiority regarding

Table 4

The average score change of respective items from modified LEFS.

LEFS items	Improved group Before	Improved group After	Improved group Change scores	*Stable group* Before	*Stable group* After	*Stable group* Change scores
1. Work, housework, or school activities	3.33 (0.65)	3.39 (0.66)	0.06 (0.86)	3.16 (0.84)	3.23 (0.74)	0.07 (0.84)
2. Hobbies, re creational or sporting activities	3.36 (0.78)	3.36 (0.70)	0.00 (1.00)	3.10 (0.88)	3.08 (0.82)	−0.02 (1.03)
3. Getting into or out of the bath	3.64 (0.55)	3.85 (0.57)	0.21 (0.78)	3.48 (0.78)	3.52 (0.75)	0.04 (0.65)
4. Walking between rooms	3.66 (0.63)	3.94 (0.24)	0.12 (0.55)	3.66 (0.63)	3.71 (0.56)	0.03 (0.68)
5. Putting on your shoes or socks	3.55 (0.62)	3.73 (0.57)	0.18 (0.58)	3.34 (0.84)	3.51 (0.79)	0.17* (0.68)
6. Squatting	3.21 (0.89)	3.45 (0.79)	0.24 (0.83)	2.84 (1.12)	2.96 (1.12)	0.11 (0.93)
7. Lifting an object	3.03 (0.88)	3.36 (0.74)	0.33 (1.05)	2.69 (1.08)	2.73 (0.92)	0.04 (0.86)
8. Light activities	3.61 (0.66)	3.85 (0.44)	0.24 (0.71)	3.65 (0.65)	3.74 (0.49)	0.09 (0.70)
9. Heavy activities	2.48 (1.00)	3.06 (0.90)	0.58* (1.20)	2.29 (1.23)	2.40 (1.06)	0.10 (1.03)
10. Getting into or out of a car	3.48 (0.71)	3.70 (0.59)	0.21 (0.93)	3.47 (0.79)	3.50 (0.74)	0.03 (0.81)
11. Walking 2 blocks	3.42 (0.66)	3.67 (0.65)	0.24 (0.83)	3.28 (0.97)	3.31 (0.94)	0.03 (0.70)
12. Walking a mile	2.82 (1.16)	3.48 (0.76)	0.67* (1.08)	2.96 (1.00)	2.81 (1.16)	−0.15 (0.78)
13. Going up or down 10 stairs	3.45 (0.79)	3.72 (0.67)	0.27* (0.72)	3.31 (0.89)	3.45 (0.72)	0.14 (0.73)
14. Standing	2.64 (1.08)	3.18 (0.85)	0.55* (1.00)	2.58 (1.18)	2.67 (1.18)	0.08 (0.89)
15. Sitting	3.12 (1.14)	3.45 (0.75)	0.33 (1.08)	3.15 (0.86)	3.19 (0.87)	0.04 (0.89)
16. Running on even ground	2.61 (1.27)	3.39 (0.79)	0.79* (1.14)	2.67 (1.26)	2.68 (1.20)	0.01 (0.88)
17. Running on uneven ground	2.24 (1.23)	2.97 (1.13)	0.73* (1.10)	2.27 (1.29)	2.33 (1.21)	0.06 (0.97)
18. Making sharp turns while running fast	2.24 (1.25)	2.76 (1.17)	0.52* (1.00)	2.20 (1.37)	2.27 (1.27)	0.07 (0.95)
19. Hopping	2.39 (1.22)	2.88 (1.07)	0.50* (1.14)	2.35 (1.39)	2.45 (1.35)	0.09 (1.06)
20. Rolling over in bed	3.55 (0.75)	3.79 (0.48)	0.24 (0.79)	3.44 (0.77)	3.55 (0.66)	0.11 (0.86)

* *P* value less than .05 by paired *t* test.

responsiveness in comparison with other functional outcome measures for LBP, such as the Oswestry Disability Index.[25] Its responsiveness statistics for LBP range from 0.5 to 1.6 for SRM,[23] and 0.64 to 0.93 for the AUCs.[23,25–27] The SRM and AUC of the RMS-L are 0.8 and 0.70, respectively, in present study and both are within the reported ranges. Meanwhile, self-reported pain is an important chief complaint for LBP and/or sciatica and is a major outcome measurement for interventions.[28] Our results document that the VAS has the largest SRM, GRI and AUC among 3 measures. This is consistent with previous studies showing that self-reported pain might yield an equal or greater treatment effect size or responsiveness than physical variables, generic instruments and even condition-specific instruments.[25,29,30]

The responsiveness of these three outcome measures can also be compared with ROC analysis using a clinical global rating as the anchor; this method is considered to be another preferable approach in terms of patient perspectives.[17] The modified LEFS demonstrates a slightly lower but not significantly different AUC in comparison with the RMS-L (0.66 vs 0.72, $P=.49$). It also has a significantly lower AUC than the VAS (0.66 vs 0.79, $P=.04$). This difference in responsiveness is consistent with other research findings about generic, region-specific and condition-specific outcomes measures. The disease or condition-specific measures are more sensitive to change,[31,32] but their application would be limited in cases with mixed diagnoses. Therefore, the region-specific measures may still produce superior responsiveness compared with the generic instruments, but not necessarily show inferior responsiveness compared with the disease-specific outcome measurements.[33,34] We also derive the MCID from ROC analysis to estimate the "the smallest difference in a score that is considered to be worthwhile or important".[35] The score changes necessary to be considered important are 15% to 16% for the RMS-L and VAS, but only 3% in the modified LEFS. The values of the RMS-L and VAS are similar to previous studies,[36] but the value of the modified LEFS was much lower than those previously published for the LEFS.[2] Smaller MCIDs are observed in chronic cases and are possibly related to baseline scores.[5,37] Some studies report a large increase in MCID with an increasing raw baseline score (more severely affected) for the Rolland-Morris Questionnaire.[37] The baseline data of the modified LEFS in the current sample is up to 75% of their best function, which may contribute to the small MCID. Previous researchers have suggested that the variability of the MCID is large and a single MCID value of an instrument seems unlikely to be applicable across all contexts.[37] Since the LEFS has not yet been widely tested for sciatica patients, the results should be carefully interpreted and retested in future studies.

Table 5

Responsiveness of the modified LEFS, RMS-L and VAS.

Instrument	SRM Improved	SRM Stable	GRI
LEFS	0.6	0.1	0.8
RMS-L	0.8	0.2	1.2
VAS pain	1.6	0.2	1.4

GRI = Guyatt responsiveness index, LEFS = Lower Extremity Functional Scale, RMS-L = modified Roland-Morris Disability Scale for sciatica, SRM = standardized response mean, VAS = visual analogue scale.

Table 6

Sensitivity to change estimated using receiver operating characteristic analysis.

Instrument	AUC	95% CI	ROC cut -point	Sensitivity	Specificity
LEFS	0.66	0.54–0.77	2.5	0.66	0.64
RMS-L	0.70	0.59–0.81	2.5	0.79	0.52
VAS	0.79	0.70–0.88	15.5	0.77	0.76

AUC = area under curve, CI = confidence interval, LEFS = Lower Extremity Functional Scale, RMS-L = modified Roland-Morris Disability Scale for sciatica, ROC = receivers' operative curve, SRM = standardized response mean, VAS = visual analogue scale.

We gain a low correlation of change scores between the modified LEFS, RMS-L and VAS, which is similar to previous work finding little correlation between the change in self-reported pain and the health-related quality of life outcomes measures for post-surgery patients.[38] One explanation is the different constructs reflected by these measures. According to the International Classification of Functioning, Disability and Health (ICF) model, self-reported pain is related to the "body function and structure" domain and the 20 items on the LEFS are related to the "activity and participation" categories, including walking, locomotion or maintaining postures, self-care, extended activities of daily living and leisure activities. In contrast, the RMS-L measures walking, locomotion, posture, self-care, extended activities of daily living, emotion, general health, and sensory function, all of which fit into a broader spectrum of body function, activity, and participation categories. Several activities are covered by both the LEFS and RMS-L, including climbing stairs, standing, rolling on a bed, putting on socks, walking, and household chores this could explain the higher correlation between the modified LEFS and RMS-L when compared with the correlation between the modified LEFS and the VAS in a previous cross-sectional study.[1] However, as we observed from individual items of the LEFS, only a selected set of activities have significant change during follow up, which are mostly related to locomotion or heavy duties. This studied population has mostly chronic LBP and receives outpatient physical therapy; this, it is likely that the effects of the intervention could be reflected more by the improvement of pain than by the functional activities. This is similar to previous findings showing a strong treatment effect in pain-related disability but low to medium effect sizes after a multidisciplinary treatment for patients with chronic LBP.[39]

Several limitations of the present study should be addressed. First, the patient population influences the responsiveness,[6] and the current sample had relative chronic LBP and with mild to moderate functional limitation. Therefore, a generalization of the results would be impossible for other subjects, such as those with acute and markedly disabled cases. This selection bias will probably reduce the sensitivity or responsiveness as seen in the present study, but the magnitude needs to be verified by further studies. Inclusion of LBP patient with not only leg pain and numbness, but also weakness or significant intermittent claudication will likely broaden the representativeness. Moreover, the follow-up period of present study is only one month, which may not be long enough to demonstrate a remarkable improvement for a sample with relatively chronic disease.

5. Conclusion

In conclusion, our results show a moderate responsiveness for the modified LEFS in a sample of patients with chronic LBP with sciatica but no superior responsiveness to the existing outcome measures, such as self-reported pain or the RMS-L. Although the modified LEFS could not replace the RMS-L or self-reported pain, it could still be used as a complementary measure since these 3 measures cover different body function, activity and participation categories. As a region-specific outcome measure, the modified LEFS also has the potential for clinical application for LBP patients with coexisting functional limitations related to other musculoskeletal disorders, but further studies are warranted.

Author contributions

Conceptualization: Yi-Shiung Horng, Wen-Hsuan Hou, Huey-Wen Liang.
Data curation: Wen-Hsuan Hou, Huey-Wen Liang.
Formal analysis: Yi-Shiung Horng, Wen-Hsuan Hou, Huey-Wen Liang.
Funding acquisition: Huey-Wen Liang.
Investigation: Wen-Hsuan Hou, Huey-Wen Liang.
Methodology: Yi-Shiung Horng, Wen-Hsuan Hou, Huey-Wen Liang.
Resources: Yi-Shiung Horng, Wen-Hsuan Hou, Huey-Wen Liang.
Software: Huey-Wen Liang.
Supervision: Huey-Wen Liang.
Validation: Yi-Shiung Horng, Huey-Wen Liang.
Writing – Original Draft: Yi-Shiung Horng, Wen-Hsuan Hou, Huey-Wen Liang.
Writing – Review & Editing: Yi-Shiung Horng, Wen-Hsuan Hou, Huey-Wen Liang.
Huey-Wen Liang orcid: 0000-0003-0186-3126.

References

[1] Liang HW, Hou WH, Chang KS. Application of the Modified Lower Extremity Functional Scale in low back pain. Spine 2013;38:2043–8.
[2] Binkley JM, Stratford PW, Lott SA, et al. The Lower Extremity Functional Scale (LEFS): scale development, measurement properties, and clinical application. North American Orthopaedic Rehabilitation Research Network. Phys Ther 1999;79:371–83.
[3] Guyatt H, Deyo RA, Charlson M, et al. Responsiveness and validity in health status measurement: a clarification. J Clin Epidemiol 1989;42:403–8.
[4] Husted JA, Cook RJ, Farewell VT, et al. Methods for assessing responsiveness: a critical review and recommendations. J Clin Epidemiol 2000;53:459–68.
[5] Lauridsen HH, Hartvigsen J, Manniche C, et al. Responsiveness and minimal clinically important difference for pain and disability instruments in low back pain patients. BMC Musculoskelet Disord 2006;7:82.
[6] Grotle M, Brox JI, Vollestad NK. Concurrent comparison of responsiveness in pain and functional status measurements used for patients with low back pain. Spine 2004;29:E492–501.
[7] Bombardier C, Hayden J, Beaton DE. Minimal clinically important difference. Low back pain: outcome measures. J Rheumatol 2001;28:431–8.
[8] Kim M, Guilfoyle MR, Seeley HM, et al. A modified Roland-Morris disability scale for the assessment of sciatica. Acta Neurochir 2010;152:1549–53.
[9] Atlas SJ, Deyo RA, van den Ancker M, et al. The Maine-Seattle back questionnaire: a 12-item disability questionnaire for evaluating patients with lumbar sciatica or stenosis: results of a derivation and validation cohort analysis. Spine 2003;28:1869–76.
[10] Hou WH, Yeh TS, Liang HW. Reliability and validity of Taiwan Chinese version of Lower Extremity Functional Scale. J Formos Med Assoc 2014;113:313–20.
[11] Roland M, Morris R. A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. Spine (Phila Pa 1976) 1983;8:141–4.
[12] Chen SM, Liu MF, Wang BM, et al. Chinese translation and adaptation of the Roland-Morris low back pain disability questionnaire. Formos J Phys Ther 2003;28:324–32.
[13] Guyatt G, Walter S, Norman G. Measuring change over time: assessing the usefulness of evaluative instruments. J Chronic Dis 1987;40:171–8.
[14] Norman GR, Stratford P, Regehr G. Methodological problems in the retrospective computation of responsiveness to change: the lesson of Cronbach. J Clin Epidemiol 1997;50:869–79.
[15] Stucki G, Liang MH, Fossel AH, et al. Relative responsiveness of condition-specific and generic health status measures in degenerative lumbar spinal stenosis. J Clin Epidemiol 1995;48:1369–78.
[16] Cohen J. Statistical Power Analysis for the Social Sciences. Hillsdale: Lawrence Erlbaum; 1988.
[17] Crosby RD, Kolotkin RL, Williams GR. Defining clinically meaningful change in health-related quality of life. J Clin Epidemiol 2003;56:395–407.
[18] Efron B, Tibshirani RJ. An Introduction to the Bootstrap. New York, N. Y., London: Chapman & Hall; 1993.

[19] Pepe M, Longton G, Janes H. Estimation and comparison of receiver operating characteristic curves. Stata J 2009;9:1.
[20] Cacchio A, De Blasis E, Necozione S, et al. The Italian version of the lower extremity functional scale was reliable, valid, and responsive. J Clin Epidemiol 2010;63:550–7.
[21] Hoogeboom TJ, de Bie RA, den Broeder AA, et al. The Dutch Lower Extremity Functional Scale was highly reliable, valid and responsive in individuals with hip/knee osteoarthritis: a validation study. BMC Musculoskelet Disord 2012;13:117.
[22] Yeung TS, Wessel J, Stratford P, et al. Reliability, validity, and responsiveness of the lower extremity functional scale for inpatients of an orthopaedic rehabilitation ward. J Orthop Sports Phys Ther 2009;39:468–77.
[23] Davidson M, Keating JL. A comparison of five low back disability questionnaires: reliability and responsiveness. Phys Ther 2002;82:8–24.
[24] Patrick DL, Deyo RA, Atlas SJ, et al. Assessing health-related quality of life in patients with sciatica. Spine 1995;20:1899–908. discussion 1909.
[25] Beurskens AJ, de Vet HC, Koke AJ. Responsiveness of functional status in low back pain: a comparison of different instruments. Pain 1996;65:71–6.
[26] Stratford PW, Binkley JM, Riddle DL, et al. Sensitivity to change of the Roland-Morris Back Pain Questionnaire: part 1. Phys Ther 1998;78:1186–96.
[27] Maughan EF, Lewis JS. Outcome measures in chronic low back pain. Eur Spine J 2010;19:1484–94.
[28] Chapman JR, Norvell DC, Hermsmeyer JT, et al. Evaluating common outcomes for measuring treatment success for chronic low back pain. Spine 2011;36:S54–68.
[29] Pengel LH, Refshauge KM, Maher CG. Responsiveness of pain, disability, and physical impairment outcomes in patients with low back pain. Spine 2004;29:879–83.
[30] Walsh TL, Hanscom B, Lurie JD, et al. Is a condition-specific instrument for patients with low back pain/leg symptoms really necessary? The responsiveness of the Oswestry Disability Index, MODEMS, and the SF-36. Spine (Phila Pa 1976) 2003;28:607–15.
[31] Garratt AM, Klaber Moffett J, Farrin AJ. Responsiveness of generic and specific measures of health outcome in low back pain. Spine 2001;26:71–7. discussion 77.
[32] Horng YS, Lin MC, Feng CT, et al. Responsiveness of the Michigan Hand Outcomes Questionnaire and the Disabilities of the Arm, Shoulder, and Hand Questionnaire in patients with hand injury. J Hand Surg Am 2010;35:430–6.
[33] MacDermid JC, Richards RS, Donner A, et al. Responsiveness of the short form-36, disability of the arm, shoulder, and hand questionnaire, patient-rated wrist evaluation, and physical impairment measurements in evaluating recovery after a distal radius fracture. J Hand Surg Am 2000;25:330–40.
[34] Stratford PW, Kennedy DM, Hanna SE. Condition-specific Western Ontario McMaster Osteoarthritis Index was not superior to region-specific Lower Extremity Functional Scale at detecting change. J Clin Epidemiol 2004;57:1025–32.
[35] Beaton DE, Schemitsch E. Measures of health-related quality of life and physical function. Clin Orthop Relat Res 2003;413:90–105.
[36] Katz NP, Paillard FC, Ekman E. Determining the clinical importance of treatment benefits for interventions for painful orthopedic conditions. J Orthop Surg Res 2015;10:24.
[37] Beaton DE, Boers M, Wells GA. Many faces of the minimal clinically important difference (MCID): a literature review and directions for future research. Curr Opin Rheumatol 2002;14:109–14.
[38] DeVine J, Norvell DC, Ecker E, et al. Evaluating the correlation and responsiveness of patient-reported pain with function and quality-of-life outcomes after spine surgery. Spine 2011;36:S69–74.
[39] Moradi B, Hagmann S, Zahlten-Hinguranage A, et al. Efficacy of multidisciplinary treatment for patients with chronic low back pain: a prospective clinical study in 395 patients. J Clin Rheumatol 2012;18:76–82.