Development and validation of a functional disability index for chronic low back pain

Mehmet Tuncay Duruöz^{a,*}, Emel Özcan^b, Aysegül Ketenci^b and Ayse Karan^b

^aPhysical Medicine and Rehabilitation Department, Rheumatology Division, Celal Bayar University Medical School, Manisa, Turkey

^bPhysical Medicine and Rehabilitation Department, Istanbul University Istanbul Medical School, Istanbul, Turkey

Abstract.

OBJECTIVE: To develop a valid and reliable functional disability scale for chronic low back pain (CLBP).

METHODS: Inpatients and outpatients suffering from low back pain (LBP) for at least 3 months were selected randomly. Patients with inflammatory LBP were not recruited. Interrater reliability and Cronbach's α were examined. Face, content, convergent and divergent validities were investigated. Factor Analysis and pearson's correlation coefficients (r) were performed.

RESULTS: 112 patients (71 females) with a mean age of 39.93 (SD: 12.92) answered the 66 questions on the provisional scale. Elimination left 18 daily activity questions. The interrater reliability of the scale was 0.79 and Cronbach's α was 0.90. Face and content validities were determined. It showed good convergence with the Quebec Back Pain Disability Scale (r: 0.82), the Oswestry Disability Index (r: 0.76), Waddell's Functional Index (r: 0.68), and the Visual Analog Scale of Handicap (VAShandicap) (r: 0.49) The scale showed no significant or fair relationship (divergence) with VAS-lumbar, VAS-radicular, Beck Depression Inventory, morning stiffness, night pain, finger tip-ground distance, radicular pain duration, or modified Schöber's index. The scale had two main factors. First represents activities implicating forward bending and second represents standing activities.

CONCLUSION: A practical functional disability scale for CLBP was developed and validated.

Keywords: Chronic low back pain, functional disability, outcome assessment

1. Introduction

Low back pain (LBP) is a major cause of disability in developed countries, and is estimated to be the most prevalent type of pain [1]. It may be one of the major symptoms of some diseases and causes deterioration of the patients' daily activities and quality of life. Therefore, it is essential for clinicians to evaluate the LBP in patients accurately [2]. Although some scales to measure disability or QOL in patients with LBP are currently available, they are not always compatible with one another [3]. Epidemiological studies indicate that about 60-90% of the population experience back pain at some time during their active lives [4] and the annual incidence is 5 percent [5]. An individual's functional status has become increasingly important over past decades, reflecting the growing expectation by society of a life without disability or handicap [6]. Therefore, measurements such as laboratory tests, muscle strength, and spinal mobility, have no direct clinical importance to patients and they are not enough to reflect the functional status [7]. Functional status questionnaires seek to quantify function directly which is better to reflect the concerns of the patients. Accurate assessment of functional disability is important for evaluating treatment and the progress of disease. It is also important for establishing strategies to maximize an individual's functional potential and promote well being.

The severity of pain is used frequently in the clinical assessment of patients with low back pain; however, pain alone is not enough to assess general health of

^{*}Address for correspondence: Mehmet Tuncay Duruöz, MD., Physical Medicine and Rehabilitation Department, Rheumatology Division, Celal Bayar University Medical School, Evka 3 Mahallesi, 126/8 sokak, No: 3, Bornova, 35050 Izmir, Manisa, Turkey. Tel.: +90 533 512 1548; Fax: +90 232 375 5044; E-mail: tuncayduruoz@ gmail.com.

a person [8]. Since pain evaluates the physiological impairment of an individual, but not his/her functional status, indices of the functional status of a patient with LBP should be employed in clinical studies.

It is most important to assess the functional disability in LBP studies. The generic measures of health status, such as the Sickness Impact Profile (SIP) [9] or SF-36 [10] may not be sensitive enough to detect small but clinically important differences in function among patients with LBP [11]. Because of this reason, we need questionnaires to assess functional disability which is developed specifically for CLBP. Some indices, assessment charts, questionnaires and rating scales have been used over the past two decades to assess the functional status of patients with low back pain and sciatica, but only a few of them have been shown to be valid [12,13]. Choosing the best outcome measure often has been a difficult problem in back pain research.

This study was done to develop a practical, accurate, cost-effective, time-sparing and discriminative index that assesses the functional disability of patients that have chronic low back pain (CLBP) in their ordinary daily lives. The scale is based on questions about the activities commonly performed in a person's daily environment and it may help to decide on the appropriate therapeutic strategies to improve the function of patients with low back pain. The secondary objective was to evaluate the effectiveness of surgical, medical and rehabilitation treatment for patients with low back pain.

2. Material and methods

2.1. Patients

Out and inpatients aged 16–70 years who had had low back pain for at least three months (CLBP) were recruited randomly for the study. Patients were excluded based on the following criteria: 1. chronic inflammatory rheumatic diseases, severe OA of the lower limbs, spondyloarthropathies; 2. severe psychiatric disorders; 3. surgery or trauma of the lumbar region or/and lower limbs within the past 90 days; 4. neurological or neuromuscular disorders of lower limbs; 5. bedridden patients.

2.2. Instrument development

The scale was constructed in three stages. Firstly we made list of daily activities concerning with low back

movement and constructed a provisional scale. We then tested this provisional scale to identify the most relevant items. Lastly, we prepared the final scale and assessed its reliability and validity.

2.3. List of activities

The activities associated with low back were identified and used in the pilot study. We first questioned 10 patients suffering low back pain to determine the difficult activities during their daily living. Then examined 28 published quality of life and disability scales to establish a pool of questions covering 159 activities that were considered to be related to low back movements [7-10,13-36]. The authors of the study then selected and modified the questions. We selected the most clearly defined activity from among similar activities and eliminated specific activities associated with professional occupations (e.g. carrying 25-30 kg sacks to a second floor). We also eliminated activities that were not carried out routinely within the society (e.g., carrying a 5-year old child) and any questions about activities that we considered to be difficult to answer in our society (e.g. sex-related activities). Lastly we modified activities that we considered to be difficult for the patient to estimate correctly and easily (e.g. questions such as "Can you walk for 500 meters? or two blocks?" were changed to "Can you walk well enough at your regular pace to satisfy your needs, like going to the grocery, store, bus stop etc.?").

2.4. Pilot study

The pilot study used 36 low back activities selected from various functional indices. The questionnaires were completed by face-to-face method in 15 patients. The feasibility of the study, the clear descriptions of the activities and the ease with which patients responded were all evaluated by the doctors carrying out the study. Suggestions were also solicited from the patients and doctors to make the questions clearer. Some questions were modified and some new activities proposed by patients were added to the questionnaire. Explanatory statements were added to some questions. For example, the question "Can you watch a movie on TV from beginning to end without ever standing up while you are sitting on a soft seat (such as an armchair)?" was changed to "Can you watch a movie on TV from the beginning to the end without ever standing up if you are sitting on a soft seat (such as an armchair or, couch): a) without changing your position? b) by changing

your position? c) by extending your legs? Multiple activities in a single question were asked separately. For example, the question "Can you wear and take off your socks?" was changed to two questions. "Can you wear your socks? and "Can you take off your socks?" We added 19 new activities proposed by the patients. These included, "Can you wash your feet in the bathroom?", "Can you run across the street?", "Can you brush your teeth while bending over the sink?", "Can you bend over the sink and wash your face?", "Can you wipe your feet on the doormat?" and "Can you turn and look behind you while standing upright?".

The resulting provisional scale had 66 questions; each item was scored on a 7 point Likert scale (0 = without difficulty; 1 = with a little difficulty; 2 = with some difficulty; 3 = with much difficulty; 4 = nearly impossible to do; 5 = impossible; 6 = never done).

2.5. Testing the provisional scale

This step identified the best performing items in the "provisional scale" for use in the "definitive scale". The poorly performing items in the provisional questionnaire were eliminated. All questions with more than 5% "never done" responses were eliminated, because the activities were not part of the patients' daily lives (26 items). The questionnaire of any patient who was the only one to answer "never done" to an item was not included in the analysis. Questions with an interrater reliability of 0.45 or below were eliminated. Questions whose answer distribution was badly skewed were also eliminated. We also eliminated the low factor loaded item in activities that may be accepted as redundant in the same factor group after the factor analysis and the varimax rotation matrix. Similarly, questions with a factor loading of 0.45 or below after factor analysis were eliminated. Two interviewer doctors assessed the comprehensiveness of each item by patients on a four point Likert scale as: i - easily answered (no doubtful) by every patient, ii - few patients needed small explanation, iii - usually doubtful, iv - always doubtful. The question which was understood "usually or always doubtful" by patients was eliminated. The final scale was obtained after this process and it is called "Istanbul Low Back Pain Disability Index (ILBPDI)".

2.6. The final scale

The final scale contained 18 questions, which were tested on 112 patients. Each item was scored on a 6 point Likert (0–5) scale, as the "never done" answer

was dropped. Patients answered the questions based on their experience during the past month. Global raw scores were calculated (sum of scores for each item); they ranged from 0–90. In compliance with the standards published by the American Psychological Association [37], the reliability and validity properties of the scale were assessed.

2.7. Reliability

The "interrater reliability" was assessed after the questionnaires had been answered twice, 2–5 days apart, by each patient, monitored by two independent doctors (face to face questionnaire). The internal consistency of the scale was tested to determine whether the activities within the scale were closely related.

2.8. Validity

Validity was assessed by four methods.

2.8.1. Face validity

The approval of the items and answer choices by experienced doctors as ways assessing functional disability of the low back pain. We also determine whether the activities and answer choices were easily understood and whether they needed any extra explanation by the patients. We modified questions to make them more clear during provisional process.

2.8.2. Content validity

We used two methods. Firstly, the doctors determined whether the questionnaire includes items relevant to the topic [38] and items related to other areas of everyday life.

2.8.3. Construct validity

This was investigated in three ways. Internal Construct Validity: Factor analysis was used to determine the internal structure of the instrument. Factor analysis places the parameters that were correlated together in the same group. However, the activities within one group were usually poorly correlated with the activity in group. Factor analysis placed the closely inter-related activities together in a group and determined the structural factors of the scale [39]. Convergent Validity was assessed by correlating the global scale score with variables that should have converging relationships. These variables were the Quebec Back Pain Disability Scale (QBPDS); the Revised Oswestry Disability Index (RODI) and Waddell's Functional In-

Demographic and clinical characteristics of the participants $(n = 112)$			
39.86; SD: 2.73 (18–70)			
63.40			
25.10; SD: 3.89 (17.3-35.2)			
18.75; 11.61; 25; 36.61 ; 8.04			
93.13; SD: 88.72 (3-359)			
10.96; SD: 13.98			
11.61			
3.57; 17.86; 48.21 ; 30.36			

dex (WFI). Divergent Validity: The scale should not be well correlated with parameters other than functional low back scales. We assessed divergent validity by looking for a correlation between the scale and parameters that are not associated with functional disability. These were the short form of Beck Depression Inventory (BDI) [40]; morning stiffness, pain at night, finger tip-ground distance, assessment of functional handicap by Visual Analogue Scale, VAS-handicap), VAS value of lumbar pain (VAS-lumbar), VAS value of radicular pain (VAS-radicular), modified Schöber (MacRae) value, duration of the LBP, duration of the recent LBP, the age, weight, height, Body Mass Index (BMI), weekly working hours, number of wake up at night because of LBP, duration of daily sleep and right and left straight leg raising degrees.

2.9. Statistical analysis

Statgraphics Plus Version 7 software was used for all statistical analysis [41]. We calculated the means, standard deviations, minimum and maximum values, quartile values and 95% confidence intervals of the means for quantitative variants and the proportions and percentages for qualitative variants. The correlation of two quantitative variants was assessed using Pearson's parametric correlation coefficient method because the sample populations had bivariate normal distribution. The "p" values of < 0.05 were considered significant. Correlation results were interpreted according to the Fermanian method [42]: very good correlation ≤ 0.91 ; good correlation 0.90-0.71; moderate correlation 0.70-0.51; poor correlation 0.50-0.31; very poor or insignificant correlation ≤ 0.30 . Interrater reliability was assessed using the intraclass correlation coefficient (ICC) under their corresponding random effect models. We estimate the components of total variance by analysis of variance (two way ANOVA), and calculated the ICC as usual [43]. Internal consistency was calculated by using the Cronbach- α [44]. Factor analysis was performed using principal component analysis to extract

factors. The Orthogonal Varimax Rotation matrix was obtained and, the factors with eigenvalue ≥ 1.5 because of Scree Test results were considered to be factors of the scale [39].

2.10. English translation of the scale

The scale was translated into English by the backtranslation method [6] to provide an idea of the content for English-speaking reader: Questions were translated from Turkish to English by two independent Englishspeaking persons and were translated back into Turkish by another two independent persons. The translators lived in USA before and they knew very well the cultural structure of the two populations. The backtranslations were then compared with the original questionnaire and any discrepancies documented. Two experts on the questions reviewed the back-translations.

3. Results

3.1. Demographic and clinical data

The performance of the scale was assessed using 112 patients (71 men). Table 1 shows their demographic and clinical characteristics. Table 2 shows the patient scores of this scale, RODI, QBPDS, WFI, VAShandicap, VASlumbar, VASradicular and BDI.

3.2. Reliability

The interrater reliability of the scale was assessed in 96 patients and was found to be 0.79. The internal consistency of the scale was 0.90.

3.3. Validity

3.3.1. Face validity

The doctors and the patients determined that the questions and answer choices of the scale did assess the functional disability due to chronic low back pain and the questions were easily understood by the patients. Thus, the scale has a face validity.

Patient scores $(n = 112)$								
				Quartiles		%95 CI	for mean	
Parameter (range)	Mean	SD	Min	Max	Lower	Upper	Lower	Upper
Our Scale (0–90)	21.04	14.93	1	62	8	30.5	18.25	23.84
Oswestry (0-50)	22.13	8.28	1	41	16	28	20.57	23.68
Quebec (0-100)	35.25	17.37	476	23	47		32.00	38.50
Waddell (0-9)	4.85	6.99	0	9	2.5	7	4.35	5.35
VAShandicap (0-100)	46.23	24.41	0	100	28	62	41.66	50.80
VASlumbar (0-100)	39.90	21.58	0	100	27	53	35	86
VASradicular (0-100)	27.31	29.70	0	100	0	52	21.75	32.87
Beck (BDI) (0-39)	5.63	3.63	0	15	3	8	4.94	6.31

Table 2 Patient scores (n = 112)

SD: Standard deviation; Min: Minimum; Max: Maximum; CI: Confidence Interval.

Table 3			
Factor analyses:	Varimax rotated factor matrix		

Question	Factor 1	Factor 2
1	0.05526	0.74550
2	0.30015	0.73157
3	0.20673	0.76567
4	0.06960	0.78636
5	0.40338	0.65613
6	0.66768	0.24822
7	0.57730	0.32277
8	0.55017	0.41578
9	0.52883	0.28498
10	0.60090	0.08676
11	0.55999	0.12280
12	0.73360	0.04818
13	0.56260	0.19788
14	0.60578	0.39391
15	0.43575	0.48890
16	0.30800	0.62798
17	0.69739	0.14357
18	0.74518	0.25277

The highest loading of each item is underlined.

3.3.2. Content validity

The items in the questionnaire were found to be related to the everyday living activities of low back function and not related to professional or personal activities. Therefore, they are relevant to functional disability. The questions were related to different areas of daily life such as transport, sitting, standing, dressing, and hygiene. These results indicate that the scale has good content validity.

3.3.3. Construct validity

Internal construct validity: Factor analysis showed that the scale had two factor groups. Factors with eigenvalue of ≥ 1.5 according to the Scree test result were considered to be scale factors. The eigenvalues of first and second factors were respectively 7.19 and 1.78. Two factors represented 49.8% of the total variance. The factor group for each question was determined after orthogonal varimax rotation of factor analysis matrix (Table 3). The first group included 11 ac-

Construct validity of ILBPDI (Correlation coefficient with other parameters)

	Pearson (r)	р
Convergent Validity:		
Quebec Back Pain Disability Scale	0.82	< 0.00001
Revised Oswestry Disability Index	0.76	< 0.00001
Waddell's Functional Index	0.68	< 0.00001
Divergent Validity:		
VAS-handicap	0.49	< 0.00001
VAS-radicular	0.48	< 0.00001
VAS-lumbar	0.18	0.0533
Beck Depression Inventory (BDI)	0.38	< 0.00001
Age	0.29	0.0018
Body Mass Index (BMI)	0.06	0.5281
Schöber	-0.31	0.0008
Duration of LBP	0.21	0.0247

tivities (Questions 6-14, 17, 18) and these activities all involved bending forward. The second factor group included 7 questions (Questions 1-5, 15, 16) on standing activities.

Convergent and divergent validities: The scale was significantly good or very good correlation (Pearson's) with other functional disability scales associated with low back pain (Table 4). Thus, our scale has convergent validity. We found that the scale was poorly or insignificantly correlated with some parameters that are not directly associated with functional disability. These parameters were: VAS-handicap (r: 0.49; p < 0.00001), VAS-radicular (r: 0.48; p < 0.00001), BDI (r: 0.38; p < 0.00001). The scale was not good correlated, according to Fermanian criteria, with the non-functional parameters. These results show the divergent validity of our scale.

3.4. English translation of the scale

Changes required by cultural differences had no effect on the meaning of items. The English version was comparable to the original version (Tables 5 and 6).

Table 5
Istanbul Low Back Pain Disability Index - ILBPDI (Turkish)

Son bir ay içerisinde aşağıdaki aktiviteleri hiç bir yardımcı aletin veya kişinin yardımı olmadan yapıldığında bel ve siyatik ağrısından dolayı karşılaşılan zorluk derecesi belirtilmelidir. Süre ve mesafe belirtilmeyen sorularda (durakta beklemek veya arabayla yolculuk yapmak gibi), cevaplar hastanın günlük yaşantısındaki ihtiyacı göz önünde bulundurarak verilmelidir. Cevaplar: Hiç zorluk çekmeden = 0

Hıç zorluk çekmeden	= 0
Çok az zorlukla	= 1 puan
Biraz zorlukla	= 2 puan
Çok zorlukla	= 3 puan
Hemen hemen imkansız	= 4 puan
İmkansız	= 5 puan

Sorular:

1. Bir kat merdiven inebiliyor musunuz?

2. Bir kat merdiven çıkabiliyor musunuz?

* (Soru 3-4) İhtiyaçlarınızı gidermek için dışarda (pazara, bakkala, otobüs duraına gitmek gibi)

3.* Normal hızınızla yürüyebiliyor musunuz?

4.* Yava" yava" yürüyebiliyor musunuz?

5. Caddeyi karþıdan karþıya koşarak geçebiliyor musunuz?

6. Arabada oturarak şehir içinde yolculuk yapabiliyor musunuz?

* (Soru 7, 8, 9) Televizyonda bir filmi başından sonuna kadar yumuşak bir yerde oturarak (koltuk, kanape gibi) yerinizden kalkmadan:

7. * Pozisyonunuzu değiştirmeden seyredebiliyor musunuz?

8. * Pozisyonunuzu değiştirerek seyredebiliyor musunuz?

9. * Ayaklarınızı uzatarak seyredebiliyor musunuz?

10. Bir öğün yemeği başından sonuna kadar sandalyede oturarak yiyebiliyor musunuz?

11. Koltuk veya kanapede bir sure oturduktan sonra kalkabiliyor musunuz?

12. Yerden eğilip elbiseleriniz alabiliyor musunuz?

13. Lavaboya eğilip dişlerinizi fırçalayabiliyor musunuz?

14. Ayaklarınızı banyoda yıkayabiliyor musunuz?

15. Normal bir sandalyeyi kaldırarak odanın içindeki yerini değiştirebiliyor musunuz?

16. Baþinizin hizasından yukarıda bulunan bir yere çeşitli hafif eşyalar (tabak, kavanoz, kitap gibi) koyup alabiliyor musunuz?

17. Çoraplarınızı giyinebiliyor musunuz?

18. Pantalonunuzu giyinebiliyor musunuz?

4. Discussion

Disability questionnaires are not only suitable for routine clinical use, but also provide high-quality information for research. Reliable and validated scales are needed by clinicians to measure clinical evolution and patients' limitations before they can propose or evaluate treatment. The questionnaires are more consistent and reliable than interviews because they present the questions in exactly the same way to every patient, every time. Although there are many kinds of indices, previous studies indicate that simple indices are better than complex ones [2,6,45]. We have therefore developed a practical scale to assess functional disability caused by chronic low back pain.

The nature of low back pain is complex and multidimensional. There are some kinds of functional scales in the literature and they assess different dimensions of low back pain. The characteristics and outcomes are different in chronic low back pain, inflammatory back pain, acute back pain, sciatica etc. If we are able to assess the different characteristics of low back pain we may achieve more specific treatments. The Oswestry Disability Index assesses the intensity of pain and restrictions in activities. Rolland Morris Disability Questionnaire was developed to assess the disability for patients with acute low back pain [46-48]. In this study the scale was developed specifically to assess functional disability for chronic mechanical low back pain. Disease specific indices are superior than the general indices to identify specific troubles. Many scales contain pain questions (impairment), activity of daily living questions (disability) and questions about social or sexual life disadvantages (handicap) in the same index. Because impairment, disability and handicap are different dimentions of disease outcomes, they have to be evaluated separately to assess the diseases' impacts on subjects and to manage the accurate treatment strategy. Methodologically the study is somewhat limited by the subject sample, which would appear to be showing mild to borderline moderate overall impairment, with no normal control group comparisons. Inclusion of a normal control group to demonstrate additional discriminative validity would have been helpful. Kirshner and Guyatt [49] state that the development of a scale should have 6 steps: selection of item pool, item scaling, item reduction, reliability, validity and responsiveness. We followed this advice, and the responsiveness of the scale is currently under investigation.

Table 6 Istanbul Low Back Pain Disability Index – ILBPDI (English)

Please select the appropriate option to specify the degree of difficulty you have experienced during the past month when performing these activities without getting help from anyone or any assistive device. For questions that do not indicate a time period and distance (i.e., waiting at a bus stop or traveling by car) mark your answers based on your daily activities and needs.

Answers: No difficulty= 0With little difficulty= 1 pointWith some difficulty= 2 pointsWith great difficulty= 3 pointsAlmost impossible= 4 pointsImpossible= 5 points

Questions:

1. Can you walk down one flight of stairs?

2. Can you climb one flight of stairs?

* (Questions 3-4) In order to meet your needs such as going to the grocery, store, bus stop etc.

3.* Can you walk at your regular pace?

4.* Can you walk slowly?

5. Can you run across the street?

6. Can you travel around town while seated in a car?

*(Questions 7-8-9) Can you watch a movie in its entirety on TV while sitting on a soft couch or a sofa without getting up:

7. * Without changing your position?

8. * By changing your position?

9. * By stretching your legs?

10. Can you eat an entire meal seated in a chair?

11. Can you get up from a chair or sofa on your own after having been seated a while?

12. Can you bend forward to pick up your clothes from the floor?

13. Can you bend over the sink to brush your teeth?

14. Can you wash your feet in the bath?

15. Can you lift a regular size chair and move it around the room?

16. Can you put to and retrieve light items (i.e. books, plates, jars) from a shelf above your head?

17. Can you put your socks on?18. Can you put your trousers on?

The questionnaire was administered by the interviewers (physiatrists), enabling them to provide additional explanations to patients about the meaning of functional handicap and thus helped avoid missing

ditional explanations to patients about the meaning of functional handicap and thus helped avoid missing questions. The question of geriatric degeneration of joints and muscles was avoided by excluding all patients over 70 years old.

The practical advantages of this scale are clarity, comprehensiveness, simplicity and a minimum requirement of professional time and money. It takes about 3 ± 1 minutes to complete, and six levels of answers provide a sensitive grading of functional disability [50].

The interrater reliability of the scale was adequate. The patients were asked by two independent interviewers to complete the whole questionnaire (16 pages) twice in 2–5 days. They found it difficult to remember their previous answers the second time around. Any visual memory of the questions was eliminated as the questionnaires were filled out by two independent interviewers. Published studies have generally assessed the intrarater or test- retest reliabilities for functional scales and they are usually higher than interrater reliability. To assess the test-retest reliability the questionnaire should be filled out twice by the patients. To assess the intrarater reliability the questionnaire should be filled out twice by the same interviewer. Test-retest reliabilities for other scales reported in the literature were 0.63–0.99 [7,51]. However, the very high coefficients were obtained in studies in which the retest was performed on the same day as the initial evaluation, or on the following day. Some of these studies reported only Pearson's correlation coefficients, which are usually higher than the intraclass correlation coefficients (ICC) [6,38].

The Cronbach's α coefficient of this scale was 0.90. It indicates that all questions in the scale were highly correlated with each other and provided assurance that random errors were minimized. Previously reported alpha coefficients for low back pain questionnaires ranged from 0.77 for the Oswestry scale [52] to 0.96 for the Quebec [7].

The items of the scale represent not only the activities that are essential for everyday living but also activities that are necessary for the person to adapt independently to the environment. One of the superiority of this scale is to assess patient' functional disability due to limitations of daily necessities. For example, we preferred to ask "Can you run across the street?" rather than "Can you run 15 meters?". Running 15 meters is not necessary in daily life activities and often patients do not know the answer, but we need to run across the street to catch the bus or to escape from cars etc. These kinds of questions may give us more detailed information about patients' limitations in daily living, and provide a broader and more discriminating approach for policy-making and planning treatment and rehabilitation [53]. This kind of scale maintains and extends the characteristics of usefulness to practitioners, consumers and educators and it is one of the advantages of this scale.

This scale includes activities with different necessities of daily life such as transport, sitting, standing, dressing, hygiene and they are done in different places (room, kitchen, car, street etc.). We used the suggestions of experienced clinicians and the patients plus factor analysis to group the items according to the low back movements. These results show that the items in the scale represent many dimensions and therefore it has good content validity. Because the Roland-Morris scale does not have any questions asking specifically about lifting, carrying, pulling or pushing objects, and the Oswestry does not have any questions pertaining to bending or body movement.

Two factors were extracted by factor analysis. The first was activities requiring bending forward. They seem to be the most important type of disability for our patients. The second factor was activities requiring the standing position. In factor analysis after orthogonal rotation, the items of the scale were grouped in factors according to the values of their correlation coefficients. Thus, the correlations between the items in the same factor group were high, while the correlations with items from other factors were low.

We assessed construct validity because there is no gold standard for assessing functional disability [54]. Our scale was well correlated with WFI, RODI and QBPDS. These results suggested that the developed scale has excellent convergence with other functional disability scales for low back pain but it is not exactly the same with others. Our scale has the highest correlation coefficient with QBPDS because its questions are related to functional disability. Some questions in the RODI are related to impairment (pain questions) and some questions in the WFI are related to handicap (e.g. item about "missing some social activities"). Because of this reason the total scores of RODI and WFI do not reflect the pure disability level. Although these scales have good correlation with the developed scale, they do not assess the exact same outcome with our scale which has items based on a conceptual model of disability.

Our scale has little or no relationship with variables not related to function, reflecting its good divergence and discriminative properties. There may be little correlation between health status instruments and disease activity measurements [6,13,34,35]. Our scale has fair (0.3 < r < 0.5) but significant relation with the VAShandicap, VAS-radicular, BMI, and Schöber test. It has not significant relationship with VASlumbar (r = 0.18; p = 0.0533). The functional disability due to LBP seems to be especially related to radicular pain, rather than lumbar pain. The back pain patients with radicular pain reported previously had significantly higher levels of disability than patients with back pain alone [55] and LBP patients with radiating leg pain below the knee are significantly more likely to undergo back surgery [56].

The limitation of our study is the subject sample, which would appear to be showing mild to borderline moderate overall impairment, with no normal control group comparisons. Thus, the actual utility of the proposed new scale across the continuum of impairment is not demonstrated. Although all questions are about the daily activities of normal subjects, the inclusion of a normal control group to demonstrate additional discriminative validity would have been helpful. Also, the study would have been stronger with some cross validation data. While responsiveness data are not required for an introductory article, they would also be helpful to fully determine the scale's actual utility and contribution

5. Conclusion

Our scale is a practical, accurate and inexpensive way to assess patient functional disability due to chronic low back pain. It has good psychometric properties. It has several advantages: it is user-friendly, cost-effective, time sparing, does not need additional equipment, and is reliable and valid in various aspects. Pending further demonstration of discriminative and predictive validity, this scale might be useful to discriminate between subjects or predict prognosis. The responsiveness of the scale to clinical changes, surgical, rehabilitation and local injection treatments are under investigation.

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