

Reliability and validity of the Turkish version of the CDC HRQOL-4 scale in patients with chronic low back pain

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ABSTRACT

Objective: This study investigates reliability and validity of Turkish version of CDC Core Healthy Days Measures assessing health related quality of life (CDC HRQOL-4) in chronic low back pain (CLBP) patients.

Methodology: One hundred eighty nine CLBP patients and 117 healthy controls participated. All respondents filled the following scales; the CDC HRQOL-4, Rolland Morris Questionnaire (RMQ), and the Hospital Anxiety and Depression Scale (HAD).

Results: Cronbach's alpha of CDC HRQOL-4-items in CLBP patients was 0.69. Of 57.1% CLBP patients and 13.7% healthy controls defined their health status as fair or poor. The number of physically and mentally unhealthy days, and activity limitation days was found to be higher in the CLBP patients than the healthy controls ($p < 0.05$). The CLBP patients with fair or poor health reported more physically unhealthy days, mentally unhealthy days, and activity limitation days than the CLBP patients with excellent, very good, or good health ($p < 0.05$). Correlation coefficients between physically unhealthy days ($r = 0.30$) and activity limitation days ($r = 0.22$), and RMQ scores were significant, but low in magnitude. Moderate correlations between mentally unhealthy days and HAD scores ($r = 0.41$ for anxiety; $r = 0.39$ for depression) were found.

Conclusion: The results of this study indicate that the Turkish version of the CDC HRQOL-4 is a short, reliable and valid tool to assess HRQOL in CLBP patients.

KEY WORDS: Low back pain, Health related quality of life, Reliability, Validity.

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INTRODUCTION

Low back pain (LBP) is a major medical, social, and economic problem worldwide.¹ Chronic pain is related to high levels of anxiety, depression, social and occupational dysfunction.^{2,3} Pain is also widely accepted as one of the most important determinants of quality of life because of its widespread adverse health effects, including diminishing mental health and well-being; and impairing the individual's ability to perform daily activities.⁴

Health-related quality of life (HRQOL) is thought to characterize the interaction between the circumstance or experiences associated with illness and patients' personal values and expectations.⁵ An important disadvantage of most indicators of HRQOL used in public health surveillance is their length.⁶ The Centers for Disease Control and Prevention (CDC)

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has developed a brief set of HRQOL items.⁷ The CDC HRQOL-4 which has been shown by international studies to be both valid and reliable, was chosen because of its shortness and apparent usefulness in the clinical population. CDC HRQOL-4 scale has been shown to perform well in clinical populations of individuals with rheumatic disease, asthma, stroke, diabetes, depression⁸ and musculoskeletal pain.⁹ The concepts assessed by the CDC HRQOL-4 scale are believed to be universal, however, and are therefore capable of being adapted for use in other cultures and languages. Spanish, Norwegian, Swedish, and Dutch versions of the CDC HRQOL-4 were developed.¹⁰ The scale has also been translated into Turkish.¹¹ But the Turkish version has not been previously validated.

The purpose of this study was to investigate the internal consistency, reliability, and construct validity of the Turkish version of CDC HRQOL-4 in patients with CLBP.

METODOLOGY

Participants and data collection: One hundred and eighty-nine CLBP patients and 117 healthy subjects participated in this study (Table-I). The study was carried out in two State Hospitals and two private physical therapy outpatient clinics between March and July 2006. All patients aged 25 to 65 years who had LBP for more than 12 weeks with or without clinical signs of radiculopathy were included in the study. Those who had a CLBP caused by a systemic organic or neurological disease, cancer, or psychiatric disease; were pregnant; or had acute severe pain needing immediate treatment or surgery were excluded. All gave their informed consent for participating. The characteristics of participants are presented in Table-I. The study was developed in accordance with the principles and standards of the Declaration of Helsinki, and with the Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects.

Instruments: Data were collected during face-to-face interviews. All subjects completed questionnaires for assessing disability (by the Turkish version of the Roland-Morris Questionnaire)¹⁰, anxiety and depression (by the Turkish version of the Hospital Anxiety and Depression Scale)¹¹, HRQOL (by the Turkish version of the CDC HRQOL-4 scale). CDC HRQOL-4 scale includes a core set of four questions:

1. Would you say that in general your health is excellent, very good, good, fair, or poor? (Self-rated health)

2. Now, thinking about your *physical* health, which includes physical illness and injury, for how many days during the past 30 days was your physical health *not* good? (Physically unhealthy days)
3. Now, thinking about your *mental* health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health *not* good? (Mentally unhealthy days)
4. During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation? (Activity limitation days).⁷ The adaptation of HRQOL-4 into Turkish followed the guidelines published in the literature.¹² These included: the translation, the synthesis, the back translation, and the initial testing phases. A team of three physiotherapists, and a teacher of English, translated the scale into Turkish. Cultural and vocabulary adaptations were agreed upon by consensus. Also, the final version was revised by a former CDC HRQOL team member (Dr. Hatice Zahran), who is bilingual.

Statistical Methods: The results were analyzed using the Statistical Package for Social Science (SPSS) version 11.5 software system for Windows. To evaluate socio-demographic variables, descriptive statistical methods were used. Descriptive Statistics, including mean \pm standard deviation (S.D.) and frequencies (count and percentage) were calculated. Self-rated health was dichotomized into two groups (i.e., fair or poor versus excellent, very good, or good). The statistical differences between the means of variables in two groups were compared with the Mann Whitney U test. The Chi square test was used to examine the differences in self perceived health between CLBP patients and healthy controls. Spearman's correlation coefficients were used to express the relationship between CDC HRQOL-4, RMQ and HAD scores, because of the non-normal distribution of the data. Interpretation of correlation coefficients was as follows: $r \leq 0.49$, weak relationship; $0.50 \leq r \leq 0.74$, moderate relationship; and $r^3 \leq 0.75$, strong relationship.¹³ Reliability was assessed in the form of internal consistency reliability by calculating Chronbach's alpha of three of CDC HRQOL-4 items (i.e., the 2nd, 3rd, and 4th.). The statistical significance was set at 5% level ($p \leq 0.05$).

RESULTS

Reliability of the HRQOL-4 scale was assessed in the form of internal consistency. Chronbach's alpha

of three of the four CDC HRQOL-4 items (i.e., physically unhealthy days, mentally unhealthy days and activity limitation days) was 0.69 among CLBP patients.

Self-rated health was strongly associated with the HRQOL-4 "days" items. Compared to the CLBP patients with excellent, very good, or good health, the CLBP patients with fair or poor health reported an average of 20.7 (versus 16.1) physically unhealthy days, 16.5 (versus 10.3) mentally unhealthy days, and 14.1 (versus 9.3) activity limitation days ($p < 0.05$) (Table-II).

As expected, the frequency with which CLBP patients reported fair or poor health (57.1%) was significantly *higher* than it was in the healthy controls (13.7%) ($p < 0.05$), while the frequency with which CLBP patients reported excellent /very good or good health (42.8%) was significantly *lower* than it was in the healthy controls (86.3%) ($p < 0.05$).

The CLBP patients reported substantially more physical unhealthy days, mentally unhealthy days, and activity limitation days than the healthy controls ($p < 0.05$). Also, ceiling and floor effects were observed. For example, 37.6% of the CLBP patients reported 30 physical unhealthy days (floor effect). In contrast, 35% of the healthy controls reported zero physical unhealthy days (ceiling effect) (Table-III).

The mean HAD-anxiety score (9.11 ± 4.15) and the mean HAD-depression score (8.12 ± 4.64) for the CLBP patients were higher than either the mean HAD-anxiety score (6.54 ± 3.92) or the mean HAD-depression score (5.24 ± 3.75) for the healthy controls ($p < 0.05$).

Correlation coefficients between physically unhealthy days and RMQ-disability scores ($r = 0.30$, $p < 0.05$) were significant, but were low in magnitude. The same results were seen between activity limitation days and RMQ scores (a disability scores) ($r = 0.22$, $p < 0.05$). On the other hand, moderate correlations were found between mentally unhealthy days and HAD-anxiety scores ($r = 0.41$, $p < 0.05$) and between mentally unhealthy days and HAD-depression scores ($r = 0.39$, $p < 0.05$). Correlation coefficients between activity limitation days and HAD-depression scores ($r = 0.18$, $p < 0.05$) was low. However, correlation between activity limitation days and

Table-I: Socio-demographics characteristics of study participants

Variables	CLBP patients (n=189) mean±SD	Healthy population (n=117) mean±SD
Age (year)	43.54±10.70	33.28±7.9
Height (cm)	163.75±9.27	167.33±8.56
Weight (kg)	72.86±13.04	66.36±13.36
Education in year	7.84±4.89	13.74±3.40
	n (%)	n (%)
Gender		
female	140 (74.1)	74 (63.2)
male	49 (25.9)	43 (36.8)
Marital status		
single	12 (6.4)	38 (32.5)
married	158 (83.6)	77 (65.8)
widowed/divorced	17 (9.0)	2 (1.7)
Work status		
housewife/ homemaker	98 (52.1)	7 (6.0)
retired	21 (11.2)	5 (4.3)
full-time	66 (35.2)	101 (86.4)
unemployed	3 (1.6)	74 (3.4)

CLBP: Chronic low back pain.

HAD-anxiety scores was low and not statistically significant ($r = 0.13$, $p > 0.05$) (Table-IV).

DISCUSSION

We found Chronbach's alpha of three of the four CDC HRQOL-4 items was 0.69 in CLBP patients. The widely-accepted cut-off is that alpha should be 0.70 or higher for a set of items to be considered a scale, but some use cut-offs as lenient as 0.60.¹⁴ Therefore, we can conclude that the Turkish version of CDC HRQOL-4 had acceptable internal consistency reliability among CLBP patients. The findings from this study are consistent with the findings of Toet et al. study. Toet et al. showed good internal consistency reliability and an excellent construct validity of three of the CDC HRQOL-4 items when comparing samples of a Dutch population with or without a chronic condition.⁶ The findings from this study are

Table-II: Comparison of between self-rated health and three of the CDC HRQOL-4 items among the CLBP patients.

CDC HRQOL-4 items	Excellent- very good- good(n=81)mean±SD	Fair- Poor(n=108)mean±SD	P*
Physically unhealthy days	16.14±10.48	20.65±9.93	0.004
Mentally unhealthy days	10.27±9.97	16.49±11.46	0.000
Activity limitation days	9.33±10.55	14.10±12.10	0.006

*Mann Whitney U test was used.

CDC HRQOL-4: CDC Core Healthy Days Measures.

Table-III: Comparison of the CDC HRQOL-4 item scores and scaling limits between the CLBP patients and the healthy controls.

Items	CLBP patients (n=189)			Healthy population (n=117)			P*
	mean±SD	Percent at 0 (ceiling)	Percent at 30 days (floor)	mean±SD	Percent at 0 days (ceiling)	Percent at 30 days (floor)	
Physically unhealthy days	18.71±10.39	4.8	37.6	3.48±4.46	35	0	0.000
Mentally unhealthy days	13.83±11.26	17.5	23.8	5.56±7.11	29.9	2.6	0.000
Activity limitation days	12.12±11.74	28	21.7	2.53±5.41	62.4	1.7	0.000

*Mann-Whitney U test was used.

also in accordance with other previously published reliability studies of the CDC HRQOL-4 in a geriatric population¹⁵ and in adults with chronic disease (e.g., asthma and congestive heart failure).¹⁶ Musculoskeletal problems including LBP cause disability and deterioration of quality of life (QoL).^{17,18} We hypothesized those CLBP patients had poorer health status compared with the healthy subjects and that the CDC HRQOL-4 scale would be able to distinguish between the health status of CLBP patients and healthy subjects.

The results of this current study showed that compared to those subjects without CLBP, subjects with CLBP reported poorer general health, more physically unhealthy days, mentally unhealthy days, and activity limitation days. The findings from the previous studies^{6,19} were similar to the findings from this study, in that persons with any chronic condition reported significantly more physically unhealthy days, mentally unhealthy days, and activity limitation days than those without any chronic conditions. We also found that LBP has a significant impact on specific aspects of HRQOL. In this current study, construct validity of CDC HRQOL-4 scale was assessed by determining the correlation between HRQOL-4 scale items and RMQ and between HRQOL-4 scale items and HAD in CLBP patients. We found low level coefficients for the association between disability, according to the RMQ with physically and mentally unhealthy days, and activity limitation days.

Furthermore, our data support the findings of Yazici et al.²⁰ that depression and anxiety were correlated to a modest extent with QoL in patients with chronic pain. Validation research has revealed that the US- version of the CDC HRQOL-4 scale demonstrated good construct validity in a statewide sample.²¹ Several validity studies have been undertaken with the CDC HRQOL-4 scale with patients. Andresen et al.²² reported good construct validity for the CDC HRQOL-4 scale "day" items using the SF-36. The results of the study by Andresen et al.

showed that the CDC HRQOL-4 poor physical health days item and the SF-36 physical summary scale were correlated at $r = -0.45$, and the CDC HRQOL-4 poor mental health days item and the SF-36 mental summary scale were correlated at $r = -0.68$ in spinal cord-injury patients. The physical health days item, however, also correlated with the SF-36 mental health summary ($r = -0.60$). Dominic et al.²³ reported that subjects with osteoarthritis and rheumatoid arthritis had poorer scores than those subjects without arthritis on all CDC HRQOL-4 items. Another previous study, in a direct comparison with several rheumatic condition-specific health status and psychological measures, the CDC HRQOL-4 measures validly distinguished groups of patients with fibromyalgia and osteoarthritis.²⁴

Several studies in older adults who had pain,⁹ in adolescents,²⁵ and in adults aged 18 years and older showed that subjects with fair or poor health status reported more physically and/or mentally unhealthy days or activity limitation days than did persons whose health status was good, very good, or excellent. Consistent with previous study findings, LBP patients with fair or poor health reported more physically and/or mentally unhealthy days or activity limitation days than did LBP patients with good, very good, or excellent health.

In conclusion, the findings from this study indicate that the Turkish version of the CDC HRQOL-4 is a reliable and valid instrument to assess QoL in patients with chronic LBP. It is short

Table-IV: Correlations among Health-Related Quality of Life (HRQOL) "days" items, RMQ-disability, HAD-anxiety, and HAD- depression in the CLBP patients.

Tool	Physical unhealthy days r	Mental unhealthy days r	Activity limitation days r
Roland Morris	0.30**	0.24**	0.22**
HAD- Anxiety	0.11	0.41**	0.13
HAD-Depression	0.17*	0.39**	0.18*

* $p < 0.05$, ** $p < 0.01$

and can be a valuable instrument to replace longer health status measures for public health surveillance in Turkey.

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Turkish version of CDC HRQOL-4 scale & chronic low back pain

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Authors' contributions:

UBA completed the study design, manuscript writing, and statistical analysis. UC did study management, editing of the manuscript and review and final approval of manuscript. NY and EB did data collection and analysis of the data.