ORIGINAL ARTICLE



Reliability and validity of the cross-culturally adapted Turkish version of the Core Outcome Measures Index for low back pain

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Abstract

Purpose To produce a cross-culturally adapted and validated Turkish version of The Core Outcome Measure Index (COMI) Back questionnaire.

Methods Ninety-six Turkish-speaking patients with nonspecific low back pain (LBP) were recruited from orthopedic and physical therapy outpatient clinics in a public hospital. They completed a booklet of questionnaires containing Turkish version of COMI, adjectival pain scale, Roland Morris disability questionnaire, European 5 Dimension Questionnaire and brief version of World Health Organization Quality of Life Questionnaire. Within following 7–14 days,

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67 patients, reported no or minimal changes in their back pain status, completed the Turkish COMI again to assess reproducibility.

Results Data quality was good with very few missing answers. COMI summary index score displayed 3% floor effects and no ceiling effects. The correlations between the COMI summary index score and each of the full instrument whole scores were found to be excellent to very good ($\rho = -$ 0.81 to 0.74). Reliability expressed as intraclass correlation coefficient (ICC) was 0.95 (95% CI 0.91-0.97). Standard error of measurement (SEM_{agreement}) was acceptable at 0.41 and the minimum detectable change (MDC_{95%}) was 1.14. Conclusion Turkish version of the COMI has acceptable psychometric properties. It is a valid and reliable instrument and cross-culturally adapted, in accordance with established guidelines, for the use by Turkish-speaking patients. It can be recommended for use in evaluation of patients with chronic LBP in daily practice, in international multicenter studies and in spine registry systems.

Keywords Low back pain \cdot COMI \cdot Questionnaire \cdot Cross-cultural adaptation

Introduction

Patient-based outcome measures have been recommended for evaluation of patients with spinal disorders and outcome of treatments. Several measurement tools are available in different languages, encouraging multinational studies and the use of international spine registry systems. It may be challenging for clinicians to choose a comprehensive but easy applicable test among many questionnaires. It has been shown that time-consuming long questionnaires are reducing patient compliance [1]. The Core Outcome Measures Index (COMI) was defined by an international group of experts, is a brief self-administered multidimensional questionnaire intended to evaluate the affect of LBP on daily life. It has six core questions about pain (back and leg), function, symptom-specific well-being, quality of life, work and social disability [2]. It has been adapted and validated for German [3, 4], Spanish [5], French [6], Italian [7], Brazilian-Portuguese [8], Norwegian [9], Polish [10], Chinese [11] and Hungarian [12] languages. The COMI has been the principle instrument for the spine surgery registry of the Spine Society of Europe, Spine Tango.

The aims of this study were to carry out a cross-cultural adaptation of the COMI for use with Turkish-speaking patients and to analyze its psychometric properties in a group of patients presenting with chronic low back pain at orthopedic and physical therapy practices in a Public Hospital.

Materials and methods

The Core Outcome Measure Index

The COMI is a self-administered multidimensional questionnaire that consist of seven items intended to measure the intensity of patient's back and leg pain, difficulties in daily life functions, symptom-specific well being, general quality of life, and social and work disability. It examines the patient status in the last week, except the disability items, which are about the last 4 weeks. Back pain and leg pain are evaluated on 0-10 graphic rating scales and all other items on fivepoint adjectival scales. Higher score indicates worse status. The higher one of the pain scores is taken as the worst pain score and for the other items the five-point scale is converted to a 0–10 point scale giving 2.5 points to each incremental step. Disability score is calculated by taking the average of two disability items. Finally, the COMI summary index score is calculated by averaging the scores for the five core items (worst pain, function, symptom-specific well being, general quality of life and disability) [3, 4].

Translation and cross-cultural adaptation

The translation and cross-cultural adaptation of the original English version of the COMI into Turkish was carried out in accordance with previously published guidelines [13, 14]. Two native Turkish speakers independently translated the original version of COMI from English to Turkish. T1 was a spine surgeon, familiar with the concept; T2 was a professional English teacher was not familiar with the concept (native translator). Two translations were synthesized to form Turkish version (T12). Two native English-speaking professional translators then back translated T12 to English. Neither of the back-translators was familiar with the subject matter of the questionnaire; both were blind to the English original and each carried out their translation independently. Then an expert committee, consisting of translators (T1-T2), one of the back-translators, two clinicians (spine surgeon and physiotherapist) and one clinical research scientist, evaluated the translations, compared them with the original version and a pre-final version of the Turkish COMI was formed by consensus. The pre-final version was applied to a heterogeneous group of Turkish-speaking friends/colleagues and patients with chronic LBP (N = 20). Their comments about the questionnaire (ease of understanding, wording, ambiguities, etc.) were asked and considered by the study group. At the end, the final Turkish version of the COMI was produced which was used for further psychometric testing in the following study.

Assessment of the psychometric properties of the Turkish version of the COMI

Questionnaire battery

The questionnaire booklet contained: questions about demographics and pain related variables, Turkish version of COMI and validated Turkish version of back specific questionnaires. These were (1) five-point verbal rating (adjectival) scale for back pain intensity in the last week, (2) the Turkish version [15] of the Roland Morris (RM) disability questionnaire [16], which evaluates back pain related disability on 24 daily activities, with possible responses of "yes" and "no" (scored 0-24 points), (3) the Turkish version [17] of the World Health Organization Quality of Life Questionnaire (brief version) WHO-QOL-BREF [18]. The WHOQOL-BREF consists of 26 items measuring four domains considered to contribute to overall quality of life: psychological, physical, social, and environmental well-being. Each domain is scored 4 (best status) to 20 (worst status), (4) European 5 Dimension Questionnaire (EQ-5D) and visual analogue scale (EQ-VAS) for general health state. The EQ is a standardized instrument for use as a measure of health outcome; it is applicable to a wide range of health conditions and treatments [19, 20] and has been validated in Turkish [21]. It comprises five single items-mobility, self-care, usual activities, pain/discomfort, and anxiety/depression-each rated with a three-point adjectival scale, and a 0-100 scale commonly referred to as a "visual analogue scale" (but numbered and presented as a vertical scale) for 'overall health state'. Summary index scores (ranging from -0.59 to 1) were computed using the unweighted method described by Prieto and Sacristan [22].

Patients

Ninety-six Turkish-speaking patients with LBP were recruited from orthopedic and physical therapy outpatient clinics (Table 1). Inclusion criteria were chronic LBP (pain more than 3 months) with or without radiation to the leg, age of 18 years or more, and ability to understand written Turkish. Exclusion criteria were: LBP due to specific causes (cancer, infection, inflammatory diseases or fracture) and previous back surgery. After giving informed consent, patients were asked to complete the questionnaire booklet.

 Table 1
 Patient characteristics

Total number	96
Sex (male/female)	37/59
Age mean \pm SD (range)	49 ± 11 (26–85)
Diagnostic category	
Non-specific LBP	23
Radiating pain, below knee	41
Radiating pain, not below knee	23
Radicular pain (± LBP)	9
LBP before this episode	
Yes	74
No	22
Duration of current episode (months)	
3–6	38
> 6 and < 18	34
> 18	24
Normal work	
Retired	19
Housewife	44
No paid work	2
Employee	3
Professional	28
Length of current sick leave	
Not applicable	65
Not on sick leave	26
< 7 weeks	3
7 weeks–3 months	1
> 3 and < 6 months	1
> 6 and < 18 months	-
> 18	-
Educational level	
Obligatory	69
Secondary	13
University	14
Type of work done for most of work-life	
Sedentary	13
Physical	65
Mixture of sedentary and physical	14
Missing	4

Booklet was checked for completion and a second appointment was scheduled between 7 and 14 days following the first one. On the second appointment patients were asked to complete a shorter booklet containing a transition question about any change in back status since the first questionnaire (seven-point Likert scale: very much worse, quite a bit worse, a bit worse, unchanged, a bit better, quite a bit better, very much better) [23] and The COMI. Of the 96 patients recruited, 89 (92%) returned for the second questionnaire. 67 of them reported no or only minimal changes in their back pain status. Hence, the data of 96 patients (see Table 1 for patient characteristics) were used for the analyses of floor/ ceiling effects and construct validity, and the data of 67 patients [41 women, 26 men; mean (SD) age 50 (11) years] were used for the assessment of the reproducibility. This study was approved by the Ethics Committee.

Statistical analysis

Scores for each instrument were calculated as per their authors' instructions. No missing answers were accepted for COMI or EQ-5D, because these have just one item per domain; for the WHOQoL and RM it was considered that a minimum of 80% answers should be required.

Floor and ceiling effects were determined by calculating the proportion of individuals obtaining scores equivalent to the worst and the best status, respectively, for each item and scale investigated. This indicates the proportion for whom, respectively; no meaningful deterioration or improvement in their condition could be detected since they are already at the extreme of the range. Floor/ceiling effects (70% are considered to be adverse [24] and 15–20%, ideal [25, 26]). Floor and ceiling effects were determined for all scales to provide some perspective for interpreting the corresponding values for the COMI.

Construct validity addresses the extent to which a questionnaire's scores relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the concepts that are being measured [27]. One type of construct validity, convergent validity, requires that different measures of the same or similar construct agree to an acceptable extent [25]. The relationship was evaluated using Spearman Rank correlation coefficients, corrected for ties. Spearman's Rho coefficients were interpreted as follows: $\rho \ge 0.81 - 1.0 =$ excellent, 0.61–0.80 = very good, 0.41-0.60 = good, 0.21-0.40 = fair, and 0-0.20 = poor.Good-to-excellent coefficients were expected for the relationship between each item of the COMI and their corresponding full-length questionnaires (listed in Table 3) and between the COMI summary index score and RMQ, WHOQOL-physical and EQ-5D summary index scores. As a measure of divergent validity, correlations < 0.4 were expected for the COMI summary index score and the social, environmental, and psychological items of the WHOQOL.

Reproducibility indicates the extent to which the same results are obtained on repeated administration of the given instrument when no change is expected. For the COMI fivepoint ordinal scales, reproducibility (stability) of measures was assessed by examining the proportion of participants recording test-retest differences for each item within a reference value of ± 1 point (where at least 90% was considered acceptable) [28]. For scales/items yielding approximately normally distributed values (pain scales, COMI whole score, function, symptom-specific well-being and quality of life), the differences in means for the repeated trials were examined using one-way repeated measures ANOVA, with determination of the intraclass correlation coefficients (ICCs) and their 95% confidence intervals. ICCs greater than 0.7 in groups of at least 50 patients are generally considered to indicate acceptable reliability [27]. Standard errors of measurement SEM_{agreement} were used to indicate the absolute measurement error ("agreement" [27]) and to calculate the minimum detectable change (MDC_{95%}) for the instruments, i.e., the degree of change required in an individual's score to establish it (with a given level of confidence) as being a real change, over and above measurement error. At the 95% confidence level, this is defined as $1.96 \times \sqrt{2} \times \text{SEM}$ which is equivalent to $2.77 \times SEM$.

Results

Cross-cultural adaptation of the COMI

The Turkish version of the COMI is presented in "ESM Appendix". Few difficulties arose during translation. In Turkish "back pain" means "sırt ağrısı", pain in the thoracic part of spine; for this reason we used "bel ağrısı" term, means lower back pain, as Turkish translation of back pain. The authors also discussed Turkish translation of "satisfied and dissatisfied" words in symptom-specific well-being question. Although "hoşnut-hoşnutsuz" and memnun-memnuniyetsiz" words both correspond forward and back translation of "satisfied–dissatisfied" words in Turkish, for each couple negative meaning words are not in common use in Turkish. We decided to use "memnun-memnuniyetsiz" words; and during the pilot study these were clear for the patients.

Missing data

There were missing answers for 4% of the type of work done for most of work–life (demographic data) question. There were no missing answers for the COMI and EQ-5D items. For the RMQ, only 5 (5%) patients had ≤ 2 missing questions; thus all of the RMQ were valid for calculation. For the WHOQOL, missing domain answers were ranging from 2% of the patients for WHOQOL-physical up to 12% for WHOQOL-social; nevertheless ratio of answers for each domain was enough for a valid calculation.

Floor and ceiling effects

The floor effects (worst status) and ceiling effects (best status) for each of the questionnaire items/scales are shown in Table 2. Acceptable floor effects were found for the COMI items pain, function, quality of life and social disability, (9–14%), but higher values were found for work disability and symptom-specific well-being (16–53%). A low ceiling effect (0–1%) was found for most of the individual COMI items; however, ceiling effects were 23% for leg pain, 29% for social disability, and 31% for work disability. There was a low floor effect for the COMI summary index score (3%). The EQ-5D items showed generally acceptable floor effects (0–12%) except for pain (27%), but ceiling effects were high

 Table 2
 Floor and ceiling effects for all the instruments in the first evaluation

Instrument	Floor effects (worst status) (%)	Ceiling effects (best status) (%)		
COMI LBP	6.3	0		
COMI LP	8.3	22.9		
COMI worst pain (leg or back)	9.4	0		
COMI function	13.5	1		
COMI symptom-specific well- being	53.1	0		
COMI quality of life	13.5	0		
COMI social disability	13.5	29.2		
COMI work disability	15.6	31.3		
COMI summary index score	3.1	0		
Roland Morris score	3.1	0		
EQ-5D mobility	0	17.7		
EQ-5D self-care	2.1	50.0		
EQ-5D usual activities	9.4	17.7		
EQ-5D pain	27.1	1		
EQ-5D anxiety/depression	11.5	33.3		
EQ-5D summary index score	0	1		
EQ-5D VAS general health	0	0		
WHOQoL physical	0	1		
WHOQoL psychological	0	0		
WHOQoL social	1	0		
WHOQoL environmental	1	0		
WHOQoL whole score	0	0		

Italicized rows indicate scores from scales with more than one item Floor/ceiling effects > 70% are considered to be adverse and < 15%, ideal

(18–50%) for all domains other than pain (1%). There were no floor effects for the EQ-5D whole score or EQ–VAS general health status, and there were no ceiling effects for the EQ–VAS general health status. A minimal ceiling effect was found for the EQ-5D whole score (1%). There were minimal floor (0–3%) and ceiling (0–1%) effects for the Roland Morris disability score and the domains/whole score of the WHOQOL-BREF.

Construct validity

The correlation coefficients for the relationship between the scores for each item of the COMI and its corresponding full-length questionnaire are shown in Table 3. A very good correlation ($\rho = 0.80$) was found between COMI worst pain score and the adjectival pain scale scores. Also very good correlations ($\rho = 0.72$ and -0.78) were found between the scores for the COMI function item and the full-length function/disability questionnaires (RMQ and WHOQOL-BREF physical). COMI symptom-specific well-being scores showed a very good correlation with the WHOQOL-BREF physical health scores ($\rho = -0.65$) and a good correlation with the WHOQOL-BREF whole scores ($\rho = -0.43$). The scores for the COMI general quality of life showed very good to good correlations ($\rho = -0.65$ and -0.50) with the scores for the global quality of life scales (EQ-5D summary index and WHOQOL-BREF whole score). Very good correlations ($\rho = 0.70$ and - 0.69) were found between COMI disability scores and RMQ and WHOQOL-BREF physical scores. The correlations between the summary index score of the COMI and each of the full instrument whole scores (RMQ, WHOQOL-BREF physical and EQ-5D summary index) were found to be excellent to very good ($\rho = -0.81$ to 0.74). All the hypotheses concerning the convergent validity of the COMI items were confirmed. Regarding the divergent validity, COMI summary index scores showed fair correlations ($\rho = -0.35$ and -0.24) with WHOQOL-BREF social and environmental scores as hypothesized except correlation with WHOQOL-BREF psychological was greater than expected ($\rho = -0.43$).

Reproducibility

The mean duration between the first and the second questionnaire was 10.3 (SD 2) days. Differences in response to each domain on the COMI were \pm 1 category in 98% patients for the domain "function" and "symptom-specific well-being", 100% for "general quality of life", "social disability" and "work disability", hence all satisfying the stability criterion of \geq 90% suggested by Nevill et al. [28]. Table 4 shows the mean (SD) scores on the two test occasions, and the ICC, SEM and MDC_{95%} for each of the scales. The ICCs for all domains were favorable (0.87–0.97). The ICC for COMI summary index score was 0.95. The SEM for the COMI summary index score was 0.41 and the MDC_{95%}, 1.14 points. Expressed as a percentage of the maximum score range for

Core index items	Reference scales	
Convergent validity		
Pain symptoms	Adjectival pain scale	0.80
Back function	Roland and Morris	0.72
	WHOQOL-BREF physical health	-0.78
Symptom-specific well-being	WHOQOL-BREF physical health	- 0.65
	WHOQOL-BREF whole score	- 0.43
Quality of life	EQ-5D summary index	- 0.65
	WHOQOL-BREF whole score	- 0.50
Disability	Roland and Morris	0.70
	WHOQOL-BREF physical health	- 0.69
COMI summary score	Roland and Morris	0.74
	WHOQOL-BREF physical health	- 0.81
	EQ-5D summary index	- 0.77
Divergent validity		
COMI summary score	WHOQOL-BREF social	- 0.35
	WHOQOL-BREF environmental	- 0.24*
	WHOQOL-BREF psychological	- 0.43

Spearman rank correlation coefficients (ρ) are represented

All correlations are significant at p < 0.01 level (two-tailed), (*p < 0.05)

Values in bold indicate those where the pre-defined hypothesis for the extent of the correlation could not be confirmed

Table 3Correlations betweenCOMI subscales and full-lengthquestionnaires

Table 4 Test-retest reliability results for COMI domains

	•								
	No items	Range	M1	M2	ICC	95% CI	SEM _{agg}	SEM (%)	MDC _{95%}
COMI whole score	5	0–10	6.1 (2.1)	5.8 (1.9)	0.95	0.91-0.97	0.41	4.1	1.14
COMI back pain	1	0-10	5.9 (2.1)	5.8 (1.9)	0.90	0.83-0.93	0.64	6.4	1.77
COMI leg pain	1	0-10	5.0 (3.4)	4.7 (3.2)	0.97	0.94-0.98	0.55	5.5	1.52
COMI worst pain	1	0-10	6.4 (2.2)	6.1 (2.0)	0.90	0.84-0.94	0.62	6.2	1.72
COMI function	1	0-10	5.7 (2.4)	5.5 (2.3)	0.87	0.79-0.92	0.86	8.6	2.38
COMI symptom-spe- cific well- being	1	0–10	8.0 (2.6)	7.6 (2.5)	0.89	0.81–0.93	0.83	8.3	2.30
COMI quality of life	1	0–10	6.5 (1.8)	6.3 (1.8)	0.89	0.82-0.93	0.59	5.9	1.63

the given scale, the SEMs were similar for all instruments, being approximately 4–9%.

Discussion

The aim of present study was to produce a Turkish version of the COMI Back that would be valid and reliable for use in Turkish-speaking patients with low back problems. Turkish cross-cultural adaptation of COMI was carried out in accordance with established guidelines [13, 14]. Only a few difficulties were encountered during translation process, some terms (back pain and satisfied–dissatisfied) were discussed more for a better Turkish corresponding. Overall, this study shows that the Turkish version of COMI has acceptable psychometric properties.

Floor and ceiling effects

Scores for the COMI symptom-specific well-being and work disability domains exceeded the ideal range of 15% [25, 26] for the floor effect (worst status) but lower than the critical adverse level of 70% [24]. Similar findings have been reported in the French [6], Italian [7], Norwegian [9], Polish [10] and Hungarian [12] versions. Social disability domain showed an ideal floor effect distinctively from the referred versions. For the ceiling effect (best status) COMI LP, social and work disability scores exceed the ideal range of 15% but lower than the adverse level of 70%, similar to those in Italian [7] and Brazilian-Portuguese [8] versions. COMI summary index score, formed from combination of domain scores, did not show any floor or ceiling effects. Theoretically, high floor and ceiling effects have potential to affect the responsiveness of the questionnaires; and the number of response categories and population characteristics has significant impact on results [24]. Turkish COMI has acceptable floor and ceiling effects similar to other versions in different languages.

Construct validity

Each of the individual core items and the summary score was examined in relation to multi-item reference questionnaires validated in the Turkish language. Overall, Turkish version demonstrated very good correlation with the reference scales. Regarding the convergent validity, our entire pre-defined hypothesis was confirmed (Table 3). The COMI summary index score showed very good correlations with RM and EQ-5D scores and excellent correlation with WHO-QOL-BREF physical health score, which were higher than corresponding values published for French [6] and Italian [7] versions. Although the symptom-specific well-being item was found to have the lowest correlation (r = -0.43) with the corresponding full-length scale, it was higher than fair correlation values of the Italian [7] (r = -0.35) and Hungarian [12] (r = -0.26) studies and similar to good correlation value of French [6] (r = -0.43) study. Regarding the divergent validity, all hypotheses were confirmed except the COMI summary index score showed a good correlation (r = -0.43) with WHOQOL-BREF psychological score, it was again similar to Italian version (r = -0.40).

Reproducibility

The test–retest reliability results of the Turkish COMI was very good (Table 4). The ICC for the summary index score was 0.95, which was similar to those previously reported for other language versions [3, 5–12]. The minimum detectable change (MDC_{95%}) for the summary index score was 1.14. This means that for a change of 1.14 or more, there is 95% likelihood that it is a result of the real change in patients' condition instead of the measurement error. This value was lower than the reported values of the German (1.74) [3], French (1.98) [6], Italian (1.51) [7], Brazilian-Portuguese (1.66) [8], Norwegian (2.21) [9], Polish (1.79) [10], Chinese (1.91) [11] and Hungarian (1.63) [12] versions. Previous studies indicated that the minimal clinically important difference (MCID) for the COMI summary index score is 2–3 points [3, 29]. If a similar range was assumed for the Turkish

version, then these clinically relevant values are significantly greater than the minimum detectable change of 1.14, confirming Turkish version as a suitable clinical tool.

Conclusion

Turkish version of the COMI has acceptable psychometric properties. It is a valid and reliable instrument and crossculturally adapted, in accordance with established guidelines, for the use by Turkish-speaking patients. It can be recommended for use in evaluation of patients with chronic LBP in daily practice, in international multicenter studies and in spine registry systems (e.g., Spine Tango Registry). Refined systematic documentation might improve the quality of follow-up and eventually the treatment strategies in patients with chronic LBP.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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