Validation of the Simplified Chinese version of the Core Outcome Measures Index (COMI)

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Abstract

Purpose To translate the Core Outcome Measures Index (COMI) into Simplified Chinese and then validate it for Mainland Chinese patients with low back pain (LBP).

Methods A total of 120 consecutive patients with LBP >3 months who visited our outpatient clinic from December 2011 to March 2012 were asked to complete a questionnaire booklet including the following: (1) the Roland Morris disability questionnaire (RMQ) (Fan et al. in Spine 37(10):875–880, 2012), (2) the Short Form Health Survey (SF-36) (Zhang et al. in Int J Med Sci 9(7):521–526, 2012), (3) the Oswestry Disability Index (ODI) (Liu et al. in Spine 34(11):1211–1216, 2009), (4) visual analogue scale (VAS) measure of pain, and (5) COMI. These patients were also asked to complete a second COMI questionnaire and a transition questionnaire (5-point Likert scale: better, a little better, no change, a little worse, worse) and to return the second COMI questionnaire via mail within 1 month.

Results The floor effects for the COMI items ranged from 5.8 to 12.5 %. High values (28.3, 27.5, and 25.8 %, respectively) were found for symptom-specific quality of life, social disability, and work disability. Regarding the ceiling effects, the social and work disabilities were relatively high at 17.5 and 24.2 %, respectively. For other items, the values ranged from 0 to 14.2 %. Neither floor nor ceiling effects were found for the COMI summary score. Excellent correlations were found between the COMI pain scores and VAS scores ($\text{Rho} = 0.89$) and between the COMI pain and the SF-36 bodily pain domain ($\text{Rho} = 0.84$). Other individual items and summary scores showed a very good correlation ($\text{Rho} = 0.54\text{--}0.72$) with the corresponding questionnaires except for “symptom-specific well-being” (0.31–0.45). One-way repeated measures ANOVA was used to determine the intraclass correlation coefficient (ICC). The ICC for the entire COMI score was 0.91 (95 % CI 0.85–0.94) and 0.81–0.86 for the two pain scores (back and leg). The “minimum detectable change” (MDC 95 %) for the COMI summary score was 1.91 points. No significant difference in the mean values was found for the repeated scores of individual items or the summary score.

Conclusion The Simplified Chinese version of COMI showed satisfactory reliability and good psychometric properties. This concise questionnaire is suitable for widespread use in Mainland China.

J. Qiao and F. Zhu contributed equally to this work.

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Introduction

Low back pain (LBP) is a major health problem in clinical practice [4]. According to the literature, almost everyone

experiences LBP in his or her lifetime [5]. In developing countries, the prevalence of LBP has steadily increased with industrialisation and urbanisation, which causes a heavy socioeconomic burden [6]. Several methods have been proposed to treat this disease, and the effectiveness of these methods is still challenged [7, 8]. A lack of reliable subjective measurement instruments could be one of the factors leading to doubts regarding the effectiveness of these treatments [9, 10]. Traditionally, physiological measures such as spine mobility and muscle strength, as well as imaging indices were used to evaluate LBP in clinical practice. However, these measures were found to be poorly associated with some outcomes such as symptom relief, functional ability and work status [11]. Currently, outcome assessment has shifted from imaging and objective indices of function towards patients' self-rated evaluation. It is generally accepted that self-rated evaluation questionnaires should include at least five domains: pain symptoms, LBP-specific function, well-being, work and social disability and patient satisfaction with care [12]. Many questionnaires with these domains have been developed and validated. However, most of these questionnaires are lengthy, making evaluation cumbersome and unfeasible in daily clinical practice. To address this problem, a short list of questions drawn from existing validated full-questionnaires titled the "Core Outcome Measures Index" (COMI) has been developed, which covers all of the domains needed [13]. Cross-cultural adaptations of the COMI have been completed for the German [14], Spanish [15], Italian [16] and French [17] languages, and the COMI has become the main tool for the Spine Tango registry of EuroSpine, the Spine Society of Europe [18]. The aim of this study was to translate the COMI into Simplified Chinese and then validate this version in Mainland China for patients with LBP.

Materials and methods

Translation and cross-cultural adaptation

The translation and cross-cultural adaptation of the original English version of the COMI into Simplified Chinese were performed by following the guidelines for the process of cross-cultural adaptation of self-report measures [19].

Translation and synthesis

Two native Simplified Chinese speakers (T-1, T-2) carried out independent translations of the COMI from English to Simplified Chinese. T-1 was an orthopaedist familiar with the concepts and the clinical content of the questionnaires. T-2 was a professional translator who had expertise in language translation but lacked a medical background. The

two translations were compared with each other and with the original English version. After discussing the discrepancies of the two translations, a consensus was finally reached, and the two versions were synthesised to form one common Simplified Chinese version, T-12.

Back translation

Back translation was undertaken independently by another bilingual professional translator and an orthopaedist. Both back translators were blind to the original English version.

Expert committee

The expert committee was formed by the 2 forward translators and 2 back translators themselves. The Simplified Chinese version and the back-translated English version were compared with the original English version to detect misinterpretations and nuances, which may have been missed. Consensus was eventually found between the members of the committee regarding all parts of the questionnaire (instructions, items, and response options). All stages of the translation process and discrepancies, problems, or difficulties were recorded in written form.

Test of the pre-final version

Twenty patients with LBP participated in this part of the study and finished the pre-final version of the Simplified Chinese COMI questionnaire. They were asked about their responses and general comments (wording, ambiguities, ease of understanding, etc.). The findings from this phase of the adaptation process (face validity) were taken into account by the work group when the final Simplified Chinese version was produced.

Questionnaire battery

After informed consent was obtained, patients completed a booklet of questionnaires. In addition to questions on demographics, LBP history and the Simplified Chinese version of the COMI, this booklet contained validated translations of full-length questionnaires exploring most of the domains covered by the COMI including the following: (1) the Simplified Chinese version of the Roland Morris disability (questionnaire RMQ) [1], (2) the Simplified Chinese version of the Short Form Health Survey (SF-36) [2], (3) the Oswestry Disability Index (ODI) [3], and (4) the visual analogue scale (VAS) measure of pain.

Patients

A total of 120 consecutive patients with LBP >3 months who visited our outpatient clinic from December 2011 to

March 2012 were asked to complete the questionnaires. The questionnaire was part of their normal care procedure. In our hospital, all patients with LBP are asked to complete a booklet of questionnaires including SF-36 [2], ODI [3], RMQ [1] and VAS. For these 120 patients, a COMI was also completed. These patients were also asked to complete a second COMI questionnaire and a transition questionnaire evaluating any perceived change in back status since the first booklet (5-point Likert scale: better, a little better, no change, a little worse, worse). The data of all 120 patients were used for the analyses of floor/ceiling effects and construct validity. Of the 120 patients, 96 (80 %) returned a second questionnaire, 90 of which were mailed back within 1 month after the first questionnaire had been completed. Of these 90 patients, 75 reported no change in their back pain status. The data of these 75 patients [42 women, 33 men;

mean (SD) age 50 (12) years] were used for the assessment of questionnaire reproducibility (Table 1).

The study was approved by the hospital ethical committees.

Statistical analysis

No missing answers were allowed for the COMI and VAS because each of these has just one item per domain. For the RMQ, SF-36 and ODI, a minimum of 80 % of answered questions were required for each domain/questionnaire [1–3].

Floor and ceiling effects were calculated by the number of individuals obtaining scores equivalent to the worst and the best status, respectively, for each item and for the global COMI score. Floor/ceiling effects of 70 % are considered to be adverse and effects of 15 % are ideal [20].

To test construct validity, Spearman Rank correlation coefficients were used to measure the correlations between COMI and other Simplified Chinese questionnaires (ODI, RDQ, the SF-36 and VAS). Correlation values of ≥ 0.40 were considered satisfactory ($r \geq 0.81$ –1.0 as excellent, 0.61–0.80 very good, 0.41–0.60 good, 0.21–0.40 fair, and 0–0.20 poor) [16]. Good to excellent coefficients were expected for the relationship between each item of the COMI and their corresponding full-length questionnaires. Good to very good coefficients were expected between the COMI summary scores and other questionnaires (RMQ, ODI and SF-36). One-way repeated measures ANOVA was used to determine the intraclass correlation coefficient (ICC; model ICC_{agreement} 2,1). Values of reliability higher than 0.70 in at least 50 patients were considered acceptable [20]. Standard errors of measurement (SEM) agreement were employed to indicate the absolute measurement error and to calculate the minimum detectable change (MDC95 %) for the instruments [20]. The 95 % confidence level is defined as $1.96 \times \sqrt{2} \times \text{SEM}$, equivalent to $2.77 \times \text{SEM}$.

Results

Missing data

From 1 to 10 % of the demographic and pain history items were missed (Table 1). There were no data missed for the individual COMI items or COMI summary score, RMQ, or VAS. For SF-36, 6 patients had left too many items unanswered to ensure a valid calculation. For the ODI, 15 patients did not answer questions concerning their sex life.

Floor and ceiling effects

The floor effects for the COMI items including pain, function and quality of life ranged from 5.8 to 12.5 %.

Table 1 Patient characteristics

Total number	120
Sex (male/female)	48/72
Age, mean $\pm$ SD (range)	51.6 $\pm$ 12.6 (20–85)
LBP before this episode	
Yes	64 (53.3 %)
No	56 (46.7 %)
Duration of current episode	
3–6 months	47 (39.2 %)
>6 and <8 months	35 (29.2 %)
>18 months	38 (31.6 %)
Normal work	
Retired	45 (37.5 %)
Employed	58 (48.3 %)
Unemployed	17 (14.2 %)
Length of current sick leave	
Not applicable	51 (42.5 %)
Not on sick leave	39 (32.5 %)
<7 weeks	12 (10.0 %)
7 weeks–3 months	8 (6.7 %)
>3 and <6 months	4 (3.3 %)
>6 and <18 months	3 (2.5 %)
>18 months	3 (2.5 %)
Educational level	
No formal education	18 (15 %)
Obligatory	34 (28.3 %)
Secondary education	37 (30.8 %)
University education	20 (16.7 %)
Higher degree	11 (9.2 %)
Type of work	
Sedentary	45 (37.5 %)
Physical	37 (30.8 %)
Mixture of sedentary and physical	31 (25.8 %)
Missing	7 (5.7 %)

High values (28.3, 27.5, and 25.8 %) were found for symptom-specific quality of life and social and work disability, respectively. Regarding the ceiling effects, social and work disabilities were relatively high at 17.5 and 24.2 %, respectively. For other items, the values ranged from 0 to 14.2 %. Neither floor nor ceiling effects were found for the COMI summary score (Table 2).

Construct validity

Excellent correlations were found between the COMI pain scores and VAS scores ($Rho = 0.89$) and between the COMI pain and the SF-36 Bodily pain domain ($Rho = 0.84$). Very good correlations (Rho between -0.60 and 0.72) were found between the scores for the COMI function item and the full-length function/disability questionnaires (RMQ: 0.62, ODI: 0.73, SF-36 physical function: -0.60). The correlation between the scores for the COMI symptom-specific well-being and RMQ was only 0.31, and the correlation between this item and ODI was 0.45. The scores for the COMI general QoL item showed very good correlations with the scores of the SF-36 and the general health (-0.72). A very good correlation was also noted between the COMI social disability and SF-36 social functioning (-0.67). The correlation between the COMI work disability and SF-36 role physical was good (-0.54). Good to very good correlations were found between the COMI summary scores and the RMQ, SF-36 and ODI (-0.59 – 0.64), respectively (Table 3).

Test–retest reproducibility

The intraclass correlation coefficients (ICCs) were 0.91 for the COMI summary score and 0.81–0.86 for the two pain

Table 3 Correlations between COMI individual items and full-length reference questionnaires

Core index items	Reference scales	Rho
Pain	VAS	0.89
	SF-36 Bodily pain	0.84
Function	RMQ	0.62
	ODI	0.72
	SF-36 Physical functioning	-0.60
Symptom-specific well-being	RMQ	0.31
	ODI	0.45
Quality of life	SF-36 General health	-0.72
Social disability	SF-36 Social functioning	-0.67
Work disability	SF-36 Role physical	-0.54
Summary score	RMQ	0.64
	ODI	0.69
	SF-36	-0.59

scores (back and leg). The “minimum detectable change” (MDC 95 %) for the COMI summary score was 1.91 points. No significant difference in the mean values was found for the repeated scores of individual items or the summary score (Table 4).

Discussion

As self-rated instruments have become the primary assessment tool for LBP, several questionnaires specifically designed for LBP have been developed. Most of these questionnaires have been validated and subsequently translated and culturally adapted into different languages. Regarding Simplified Chinese, the language used in Mainland China, the Simplified Chinese version of ODI, RMQ and SF-36 have been established and validated [1, 3, 21]. However, no common consensus has been reached as to which one is the best choice, and different physicians choose different self-rated instruments. When conducting a multi-centre study, the diversity of the questionnaires used may cause problems with the comparability of the results from different centres. Because the COMI has become the main tool for the spine registry of the Spine Society of Europe (EuroSpine) Spine Tango [22], it is convenient for us to cooperate with European colleagues in terms of conducting multi-centre studies and sharing data using COMI. Moreover, COMI has advantages over other questionnaires. The impressive traits of the COMI include conciseness and easy comprehension. Some of the questionnaires we are currently using are lengthy and hard to understand. In Mainland China, the educational backgrounds of patients differ considerably, and the rate of illiteracy is relatively high. Thus, using these lengthy

Table 2 Floor and ceiling effects

	Floor effects (worst status) (%) (N)	Ceiling effects (worst status) (%) (N)
COMI low back pain	10 (12)	0 (0)
COMI leg pain	5.8 (7)	14.2 (17)
COMI worst pain (back or leg)	12.5 (15)	0 (0)
COMI function	7.5 (9)	1.6 (2)
COMI symptom-specific well-being	28.3 (34)	0 (0)
COMI quality of life	5.8 (7)	3.3 (4)
COMI social disability	27.5 (33)	17.5 (21)
COMI work disability	25.8 (31)	24.2 (29)
COMI summary score	0 (0)	0 (0)

Table 4 Test–retest reliability results for each of the domain index-items and the full reference scales

Instrument	No items	Range	M1	M2	<i>P</i>	ICC	95 %CI _{ICC}	SEM _{agreement}	SEM %	MDC95 %
COMI whole score	5	0–10	5.4 (1.7)	5.5 (1.7)	0.67	0.91	0.85–0.94	0.69	6.9	1.91
COMI back pain	1	0–10	5.1 (2.1)	5.1 (2.1)	0.24	0.86	0.78–0.92	0.76	7.6	2.11
COMI leg pain	1	0–10	3.9 (2.6)	4.0 (2.7)	0.62	0.85	0.77–0.91	1.06	10.6	2.94
COMI worst pain	1	0–10	5.9 (2.1)	5.6 (2.0)	0.07	0.81	0.70–0.88	0.91	9.1	2.52

M1, *M2* Mean value at first and second assessment, *P* significance of difference between mean values on the two occasions, *ICC* intraclass correlation coefficient (ICC2,1), *CI_{ICC}* 95 % confidence intervals for the ICC, *SEM* standard error of measurement, *SEM %* SEM as percentage of maximum score, *MDC 95 %* minimum detectable change score

questionnaires is not suitable. In addition, COMI measures the function and QoL by general conditions, while other questionnaires tend to assess individual daily activities. The lifestyles are highly variable between different regions, and an activity frequently performed in one region may be seldom performed in another region. For example, one of the items of the Quebec Back Pain Disability Scale is “throw a ball” [23]. In Mainland China, the elderly seldom play ball games but do often perform an exercise called Taiji. This difference may cause some bias for the LBP evaluation even after cultural adaptation. Based on these differences, we thought measuring the function and QoL by general conditions was more reasonable than by individual activities.

Translation

We conducted the translation and cultural adaptation processes by strictly following those of French and Italian versions. Seeing that EQ-5D, DPQ or WHOQoL, which were used for the construct validity for Italian or French versions, were not translated and culturally adapted to Simplified Chinese, we used the RMQ, ODI, SF-36 and VAS questionnaires for construct validity. We believe that this modification would not impose adverse influences on our study because the questionnaires we used have been proven reliable and responsive.

Floor and ceiling effects

Similar to other versions, high rates of floor or ceiling effects were observed for two items (symptom-specific QoL and disability). For symptom-specific QoL, the floor effect reached 28.3 %, which was highest among all of the items. The floor effects also reached 27.5 and 25.8 % for social disability and work disability, respectively. The ceiling effects were also high for these two items at 17.5 % for social disability and 24.2 % for work disability. However, none of these effects reached an adverse level (>70 %) [20] and the summary score did not show any floor or ceiling effect. Some scholars claim that floor and ceiling effects could be decreased by increasing the number

of response options [24]. However, a previous study demonstrated that humans could not discriminate much beyond seven levels, and responsiveness was similar between scales with 7-point response categories and those with 4-point response categories [25]. Based on these facts, we believed that the number of response options for items of COMI (5 options per item) was adequate and that it is not a factor that threatens the accuracy of the questionnaire.

Missing data

No data were missed for the individual COMI items or COMI summary score, RMQ, or VAS. However, for SF-36, 6 patients had too many items unanswered to ensure a valid calculation, and these unanswered questionnaires were excluded from the analysis. We believed that the long scale length and poor understandability of some items made some patients unable to complete the SF-36 questionnaires. Similar to other studies, the section of the ODI (sexual life) had the lowest response rate, which reflects the very private nature of sexual activities of patients in Mainland China [3].

Construct validity

As was mentioned, we used RMQ, ODI, SF-36 and VAS questionnaires for construct validity instead of EQ-5D, DPQ or WHOQoL. Each of the individual items and the summary score of the COMI were examined in relation with these validated Simplified Chinese questionnaires. A good correlation with the corresponding questionnaires was observed for the majority of the individual items and summary scores of the COMI. The highest correlation was found between pain and VAS. The form of rating pain items on the COMI was almost the same as that of the VAS, as both were rated by a line with a 10-point scale. Thus, it is not surprising to observe such a strong correlation between the two items. Similar to the versions in other languages, the symptom-specific item of the QoL showed a low correlation with corresponding questionnaires. We agreed with Genevay and Mannion’s viewpoints that this item was unique and was not captured by other questionnaires on LBP [17, 24]. In clinical

practice, we found that only the SRS-22 questionnaire, which was specifically designed for evaluating the QoL of scoliosis patients, had similar items to the symptom-specific QoL [26].

Test–retest reliability

The test–retest reliability was strong for the pain and summary scores. The intraclass correlation coefficients were 0.84 to 0.86 for pain and 0.89 for the summary scores, which were similar to those of other versions. It could be concluded that the reproducibility of the Simplified Chinese COMI compared well with those of COMI versions in other languages and to the full-length questionnaires. The minimal detectable change (MDC 95 %) was 1.91 for the COMI summary scores, which was similar to the French version (1.98) but slightly larger than the Italian (1.51) and German versions (1.74). Previous studies have demonstrated that the minimal clinically important difference (MCID) for the COMI is 2–3 points, which exceeded our study by 1.91 points. Therefore, the Simplified Chinese version of COMI is suitable for the evaluation of LBP.

In conclusion, the Simplified Chinese version of COMI showed strong psychometric properties and satisfactory reliability. This concise questionnaire is suitable for widespread use in Mainland China.

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Conflict of interest None.

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