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Brief Report

Development of the Italian version of the knee injury and osteoarthritis outcome score for patients with knee injuries: cross-cultural adaptation, dimensionality, reliability, and validity

M. Monticone †*, S. Ferrante †‡, S. Salvaderi †, B. Rocca †, V. Totti §, C. Foti ||, G.S. Roi §

† *Physical Medicine and Rehabilitation Unit, Salvatore Maugeri Foundation, Institute of Care and Research (IRCCS), Scientific Institute of Lissone, Milan, Italy*
‡ *Neuroengineering and Medical Robotics Laboratory, Bioengineering Department, Politecnico di Milano, Italy*
§ *Education & Research Department, Isokinetic Medical Group, Bologna, Italy*
|| *Chair of Physical and Rehabilitation Medicine, Tor Vergata University of Rome, Rome, Italy*

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SUMMARY

Objective: Translating, culturally adapting and validating an Italian version of the Knee injury and Osteoarthritis Outcome Score (KOOS-I) to allow its use with Italian-speaking patients with knee complaints.

Design: The KOOS-I was developed by means of forward–backward translation, a final review by an expert committee, and a test of the pre-final version to establish its correspondence with the original English version. The psychometric testing included analysis of dimensionality using item-scale correlation after correction for overlap, reliability by means of internal consistency (Cronbach's alpha) and test–retest reliability (Intraclass Correlation Coefficients), and construct validity using an *a priori* hypothesised Pearson correlations with a Numerical Rating Scale (NRS) and the Short-Form 36 Health Survey (SF-36).

Results: The questionnaire was administered to 224 subjects with knee injuries and proved to be acceptable. Hypothesised item-to-domain correlations were observed for all of the items. The questionnaire showed good internal consistency (0.782–0.977), and a high level of test–retest reliability (0.850–0.949). Construct validity was supported by the confirmation of the *a priori* hypothesised correlations.

Conclusions: The KOOS outcome measure was successfully translated into Italian, and proved to have good psychometric properties that replicated the results of existing versions. Its use is recommended for clinical and research purposes in patients with knee injuries.

Introduction

Knee complaints include frequently combined damage to bones, cartilage, ligaments and menisci, and often lead to the development of osteoarthritis (OA)[1]. Given the epidemiological and clinical burden related to knee complaints[2], it is important that comprehensive outcome measures are used to help clinicians to quantify knee-related disability and the quality of life, improving interventional measures[3]. A number of disease-specific measures are available for assessing functional outcomes related to knee dysfunction[4], including the Knee injury and Osteoarthritis Outcome Score (KOOS), a 42-item questionnaire designed to assess patients' opinions about their knees and the associated problems[5]. It was simultaneously developed in 1995 by EM Roos at the Orthopaedic Departments of Lund University (Swedish version) and the University of Vermont (American-English version)[5]. The psychometric properties of the original versions have been tested in a wide variety of clinical conditions, and have been found to have satisfactory levels of reliability, validity and responsiveness[3,5].

The KOOS has so far been cross-culturally adapted and validated in Singapore-English and Chinese[6], French[7], Persian[8], Dutch[9] and Portuguese[10]; non-validated translations are available in several other languages[3].

No validation trial of an Italian translation of the KOOS has ever been conducted and so, as this limited the ability of Italian clinicians and researchers to share validated outcome data, the aim of this study was to describe the translation, cultural adaptation and validation of an Italian version of this measure in subjects with knee complaints. The KOOS was successfully translated and showed good psychometric properties that replicated the results

* Address correspondence and reprint requests to: M. Monticone, Via Monsignor Bernasconi 16, 20035 Lissone MI, Italy. Tel: 39-039-4657277; Fax: 39-039-4657279.
E-mail address: marco.monticone@fsm.it (M. Monticone).

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of existing versions. Its use is recommended for clinical and research purposes.

Methods

The study was approved by the Institutional Review Board of our hospital. The patients gave their written consent to take part. We obtained permission to adapt the original version from Prof. EM Roos.

Patients

Outpatients referred to our rehabilitation hospital and two affiliated centres were enrolled between June 2010 and May 2011.

The inclusion criteria were patients with knee complaints (anterior cruciate ligament, meniscus, or combined injuries) diagnosed by an orthopaedic surgeon, an age of at least 18 years, and the ability to read and speak Italian fluently. The exclusion criteria were central or peripheral neurological signs, systemic illness or psychiatric deficits, recent myocardial infarction, cerebrovascular events, or chronic lung or renal diseases.

Process of translation and cross-cultural adaptation

The working group consisted of three medical doctors, two physiotherapists, a psychologist, and a psychometrician.

The process of translation and cross-cultural adaptation of the KOOS followed Beaton's guidelines[11] and involved *translating it into Italian* (two native Italian speakers compared their versions while keeping the language compatible with a reading age of 14 years), *back-translating it into English* (done by two bilingual mother-tongue English translators who were careful to reflect the same item content as the original), *a review* of the final version by a bilingual committee of clinicians and psychometric experts, and *the testing the pre-final version* (50 patients were asked what was meant by each item and the chosen response in order to verify whether the formulation of the items was clear).

KOOS-I is reproduced in the Appendix.

Outcome measures

The KOOS is a 42-item self-administered questionnaire with five subscales: Pain (P), Symptoms (S), Activities of Daily Living (ADL), Sport and Recreation (Sport/Rec) and Knee-related Quality of Life (QoL). A five-point Likert scale ranging from 0 (no problems) to 4 (extreme problems) is used to score each item, and the raw scores of each subscale are separately transformed into a 0–100 scale with 0 indicating the worst problems and 100 indicating no problems[3,5].

The Numerical Rating Scale (NRS) is a self-administered measure of the intensity of pain, ranging from 0 (no pain) to 10 (the worst imaginable pain)[12].

The Short-Form Health Survey is a 36-item generic self-administered questionnaire of health status[13]. It consists of eight subscales: Physical Functioning (PF), Physical Role (PR), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Emotional Role (ER) and Mental Health (MH). The subscales are scored from 0 to 100, with higher scores indicating better health status. We used the Italian version of the SF-36[14].

The patients were given the questionnaires soon after their enrolment into the study.

Psychometric scale properties and data analyses

Acceptability: The time taken to answer the questionnaire was recorded, the patients were asked about any difficulties that had been encountered, and all of the data were checked for missing or multiple responses.

Content analysis: Descriptive statistics were calculated in order to determine floor/ceiling effects, which were considered to be present when more than 15% of the patients received either the lowest or highest possible subscale scores[15].

Dimensionality: This was assessed using the correlation between an item and its subscale, which was estimated using a formula proposed by Howard and Forehand[16] as if the item was not in the whole subscale score (i.e., the correlation was corrected for overlap) in order to avoid inflating the item-scale correlation coefficient. Pearson correlation coefficients >0.40 were considered acceptable[8].

Reliability: Reliability was tested by means of internal consistency (which can be considered good if the value of Cronbach's alpha is between 0.70 and 0.95[15]) and day 1–7 test–retest stability for each subscale (intraclass coefficient correlation – ICC, with good and excellent reliability being respectively indicated by values of 0.70–0.85 and >0.85[15]).

Validity: Construct validity was assessed by comparing the KOOS-I with the NRS and the subscales of the SF-36. It was hypothesised *a priori* that: (1) the correlations between the KOOS P and SF-36 BP subscale would be high; (2) the negative correlations between the KOOS subscales and the NRS should be moderate to high; (3) the correlations between the KOOS ADL and Sport/Rec subscales and the SF-36 PF subscale would be high; and (4) the correlations between the KOOS subscales and the SF-36 subscales of Physical Health (PF, PR, BP) would be higher than those between the KOOS subscales and the SF-36 subscales of Mental Health (GH, VT, SF, ER, MH). Pearson correlations: $r < 0.30$ = low; $0.30 < r < 0.60$ = moderate; $r > 0.60$ = high. We defined the construct validity of the KOOS questionnaire as good if $\geq$75% of the hypotheses were confirmed[9,15].

The analyses were made using the Italian version of SPSS 19.0 software.

Results

Subjects

The study included 224 subjects (90 females [40.2%] and 134 males [59.8%]) with a mean age of 48.2 $\pm$ 21.2 years and a mean body mass index (BMI) of 25.7 $\pm$ 4.31; 124 (55.4%) were married; 100 (44.6%) were employees, 37 (16.5%) were students and 87 (38.9%) were pensioners; 68 (30.4%) had ACL injuries, 71 (31.7%) meniscal injuries, and 85 (37.9%) combined injuries. The median duration of pain was 6 months.

Translation and cross-cultural adaptation

The questionnaire was translated into Italian using a process of forward–backward translation involving four translators. It took 2 months to reach a culturally-adapted version; all of the items were easily translated except four items (P2, S2, Sport/Rec4, and QoL3), but difficulties were overcome by means of careful wording. A further review by experts and testing of the pre-final version (over a period of 2 months) confirmed the work done.

Psychometric scale properties

Acceptability: All of the questions were well accepted. The questionnaire was completed in 9.0 $\pm$ 2.7 min. Only two of the 10,248 items (0.01%) were missing. No multiple answers were found. There were no problems of comprehension.