

Italian Version of the International Knee Documentation Committee Subjective Knee Form: Cross-Cultural Adaptation and Validation

Roberto Padua, M.D., Rosaria Bondi`, M.D., Enrico Ceccarelli, M.D., Lucia Bondi`, M.D., Emilio Romanini, M.D., Gustavo Zanoli, M.D., and Susanna Campi, M.D., for GLOBE

Purpose: Patient-oriented measures, represented by self-administered questionnaires, have become an important aspect of clinical outcome assessment. To be used with different language groups and in different countries, questionnaires must be translated and adapted to new cultural characteristics, and then validated by a widely accepted process to evaluate reliability and validity, fundamental characteristics for each measure. The aim of the study was to perform the cross-cultural adaptation and to assess the reliability and validity of the Italian version of the International Knee Documentation Committee (IKDC) Subjective Knee Form. **Type of Study:** A cross-cultural adaptation and cross-sectional study of a sample of patients undergoing anterior cruciate ligament (ACL) reconstruction with a subsample followed up prospectively for retest reliability. **Methods:** The IKDC Subjective Knee Form was culturally adapted for Italian-speaking people, following the simplified Guillemain criteria. Reliability and validity were assessed in a cross-sectional study of 50 consecutive patients undergoing ACL reconstruction. A subsample of 20 patients was followed up prospectively for retest reliability. **Results:** The results were compared with other validated patient-oriented measures. The principal IKDC scale showed a high correlation with other patient-oriented measures as hypothesized, and it also showed good values with regard to reproducibility, consistency, and validity, compared with the versions of IKDC published in other languages. **Conclusions:** These findings suggest that the evaluation capacities of the IKDC Italian version are equivalent to those of other language versions of the IKDC. **Level of Evidence:** Level II. **Key Words:** IKDC form—Anterior cruciate ligament—Questionnaire—Reliability—Validity—Cross-cultural adaptation.

Traditionally, orthopaedic outcome measurements have been focused on objective parameters such as radiographic analysis or clinical tests, such as the jerk and Lachman tests. In the last 10 years, the development of validated patient-oriented measures through question-

naires has added another dimension to clinical outcome evaluation. Health-related quality-of-life can be considered as one's perception of his or her health and it is a fundamental outcome measure for clinical research in orthopaedics. Health-related quality-of-life measures include general and specific measures of health-related quality of life.¹ These new measures, which focus on functional status and symptoms, are more relevant to patients' perception.^{2,3} Yet, to be truly useful and to assess patient perspective, questionnaires must be validated by an extensive process, which includes testing of reliability, sensitivity, and responsiveness.^{4,5} Those measures that pass these rigorous benchmarks function as well as or better than an observer scoring system.⁶ Both generic and specific measures have been recommended as components of outcome assessment.³

With the evolution of knee surgery, it was clear that

From the Orthopedics Department, San Giacomo Hospital (R.P., R.B., E.C.); GLOBE, Evidence Based Orthopedics Working Group of Italian Society of Orthopedics and Traumatology (R.P., E.R., G.Z.); the Orthopedics Department, Tor Vergata University (L.B.); the Orthopedics Department, La Sapienza University (E.R., S.C.); and the Orthopedics Department, University of Ferrara (G.Z.), Ferrara, Italy.

Address correspondence and reprint requests to Roberto Padua, M.D., Via P.S. Mancini 2 00196, Rome, Italy. E-mail: rpadua@mclink.it

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comparing outcomes of different surgical techniques or treatments was impossible with no standard evaluation system.⁷ There are various scoring systems to evaluate the disability caused by knee injuries and to evaluate the outcome of treatment⁸; for example, there are more than 54 different outcome measures used to assess the anterior cruciate ligament (ACL)-deficient knee.⁹ The differences among existing scales were an obstacle to the improvement of knee surgery.¹⁰ Then, a standard method of evaluation became more and more necessary. In 1987, a committee of international knee experts from the American Orthopaedic Society for Sport Medicine (AOSSM) and the European Society of Sports Traumatology, Knee Surgery and Arthroscopy (ESSKA) created the International Knee Documentation Committee (IKDC), to study a standardized international documentation system to assess knee outcome. Consequently the IKDC Subjective Knee Form was developed.¹¹ The questionnaire has been widely studied and applied and reported in the literature.¹²⁻¹⁵ In 1997, the revision process of the IKDC Subjective Knee Form began and in 1998 the final version was completed.^{1,10}

To use it with different language groups and in different cultural settings, the questionnaire must be translated into the new language and adapted to the new cultural characteristics, and then validated against the original version. The cross-cultural adaptation guidelines described by Guillemin et al. are widely accepted and used for the translation and adaptation of questionnaires.^{4,16} The purpose of this study was to perform the cross-cultural adaptation and to test the validity and reliability of the IKDC Subjective Knee Form.

METHODS

As previously described,^{4,17} the authors submitted to the validation process the IKDC Subjective Knee Form through translation, cultural adaptation, and testing phases. The hypothesis of the study was that the IKDC Subjective Knee Form scores would correlate significantly with the physical health scores on the SF-36.

Translation and Cultural Adaptation

In projecting the study phase, in particular in searching literature, we found a Web site with an IKDC Subjective Knee Form Italian translated version not validated (www.esska.org). To validate the questionnaire, 3 new translations from English to Italian

were obtained by 2 independent professional mother-tongue translators and 1 physician. In a collegial meeting, the translation was discussed and a new single version was chosen. This new version was not substantially different from the pre-existing unvalidated version from ESSKA. As recommended by Guillemin et al.,⁴ a translation of this version back into English was then made and checked for inconsistencies with the original English text. This is a process of validity, checking to make sure that the translated version reflects the same item content as the original version. Once the new Italian version was assessed, we decided to test the existing IKDC Subjective Knee Form because no meaningful differences were detected from the other. After assuring comparability of the draft IKDC Subjective Knee Form, Italian version, we tested the questionnaire on patients.

Patients

The study was conducted on 50 patients (41 male and 9 female; mean age, 24 years; range, 18 to 42 years) undergoing ACL reconstruction. All patients were assessed and the diagnosis confirmed by orthopaedic clinical examination and imaging studies (radiographic analysis and magnetic resonance imaging).

The Italian version of the IKDC Subjective Knee Form was administered to the patients concurrently with the SF-36 official Italian version.^{18,19} The questionnaires were administered by medical students in waiting rooms before patients met the physician, in accordance with published guidelines.^{18,20} The time required for completing the IKDC Subjective Knee Form and for any difficulties was recorded for each patient. The questionnaires were scored as recommended by their developers.

Outcomes Tools

The IKDC Subjective Knee Form consists of 18 items that inquire about symptoms, function, and sports activity related to orthopaedic disorders of the knee, such as meniscal and ligament injuries, patellofemoral disease, and articular cartilage lesions.¹⁰

This questionnaire is a part of a complete Documentation Form promoted by the IKDC evaluation system that includes personal information (e.g., demographic and educational data, comorbidity index), a general health-status questionnaire (SF-36), and an objective form on clinical and radiographic data (www.esska.org). An ordinal method is used to score the response to each item and the questionnaire provides a single main score.

Higher IKDC Subjective Knee Form scores indicate a lower level of symptoms and a higher level of function, and lower scores indicate a higher level of symptoms and a lower level of function. Thus, no symptoms and no limitations with activities of daily living or sports activities are represented by a score of 100.

The SF-36 consists of 36 questions on the general health status of patients. This questionnaire provides 8 separate scale scores (Physical Functioning, Role Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional, and Mental Health), which are then aggregated into 2 main scores: Physical Composite Score (PCS) and Mental Composite Score (MCS). Very low scores for the PCS indicate severe physical disorder, distressing bodily pain, frequent tiredness, and unfavorable evaluation of health status. Very low scores for the MCS indicate frequent psychologic distress and severe social and role disability due to emotional problems.^{18,19} Its wide diffusion in the scientific literature, with valid translations in many languages, allows use of this scale as a standard.

Testing

Reproducibility was tested by administering the IKDC Subjective Knee Form twice to 20 randomly selected patients. The authors used a 5-day interval, assuming that during this period the clinical situation had not changed. To minimize the risk of short-term clinical change, no treatment was provided to these patients over the 5-day interval. The content validity (item relevance and adequacy for intended use) was tested by health experts involved in the study. The distribution of scores and the ceiling and floor effects were calculated by examining the item responses. The construct validity was tested by comparing the IKDC Subjective Knee Form with the SF-36.

Statistical Analysis

Statistical analysis was performed by using the STAT-SOFT (Tulsa, OK) and SPSS 8.0 (Chicago, IL) packages. Kolmogorov-Smirnov and Lilliefors probability tests were used to assess distribution. The interval measurements (SF-36, IKDC Subjective Knee Form scores) were normally distributed and, therefore, correlation was performed by parametric test (Pearson's correlation) and the comparison between subgroups population (test-retest groups *v* whole population) by the Student *t* test to assess age, sex, and patient-oriented measures. Instrument test-retest reli-

ability was assessed with the interclass correlation coefficient (ICC). Cronbach's alpha was used to assess internal consistency.

RESULTS

The questionnaire was favorably accepted by patients: no one found difficulties in filling it in, requiring less than 10 minutes on average. Translation of the questionnaire was not particularly difficult, and the back translation proved to correspond to the original version very well. The patients considered most of the IKDC Subjective Knee Form items clear and relevant to the condition of their knee.

Item responses were well distributed for the IKDC Subjective Knee Form (mean, 59.38; SD, 22.88; median, 55.74; range, 19-97). No patients had maximum or minimum scores for IKDC Subjective Knee Form.

Test-retest reliability showed good results. The ICC was 0.90 ($P < .001$). The internal consistency reached a Cronbach's alpha of 0.91. No significant differences were found between the 2 patient groups (the whole population and the 30 patients used for the test-retest) concerning sex and age. Table 1 summarizes data and statistical analysis of correlation between IKDC Subjective Knee Form and SF-36 scores (using the 8 domains and 2 composite scores).

DISCUSSION

Outcome questionnaires have been developed to measure patients' perspective with regard to symptoms and function. Outcome research related to the knee is based on the measure of health-related quality of life considering disability due to impairment of the knee.¹ Most of the questionnaires in the literature are in English and are tailored to the Anglo-Saxon culture. Many are already de facto standards for the world scientific community,^{18,20} yet the appropriate use of these tools depends on adapting them to different languages and cultures while maintaining cultural equivalence. For example, a culturally equivalent mobility question might refer to automobiles in some cultures and buses, trams, or even carts in others. Yet it might not be valid to substitute a question about driving a car with one about walking, as these are in different functional domains. Thus, to avoid the potential harmful distribution of new questionnaires not comparable with those existing in the literature, a rigorous adaptation process is needed.^{5,21} Mere translation is not enough.

The presence of culturally equivalent outcome mea-

TABLE 1. *IKDC Subjective Knee Form and SF-36 Scores and Statistical Analysis*

	Mean Scores (SD)	Correlation With IKDC Subjective Knee Form
IKDC Subjective Knee Form	59.38 (22.88)	—
SF-36 (PF)	85.39 (14.25)	$R = 0.67$ $P < .02$
SF-36 (RP)	56.58 (41.38)	$R = 0.56$ $P < .02$
SF-36 (BP)	66.52 (24.46)	$R = 0.75$ $P < .02$
SF-36 (GH)	80.95 (12.84)	$R = 0.26$ NS
SF-36 (VT)	71.71 (14.06)	$R = 0.36$ $P < .05$
SF-36 (SF)	80.79 (19.12)	$R = 0.58$ $P < .02$
SF-36 (RE)	77.21 (39.60)	$R = 0.44$ $P < .05$
SF-36 (MH)	76.53 (15.11)	$R = -0.65$ $P < .02$
SF-36 (PCS)	47.63 (8.03)	$R = -0.60$ $P < .02$
SF-36 (MCS)	51.79 (10.17)	$R = -0.40$ $P < .02$

Abbreviations: PF, Physical Functioning; RP, Role Physical; BP, Bodily Pain; GH, General Health; VT, Vitality; SF, Social Functioning; RE, Role Emotional; MH, Mental Health; PCS, Physical Composite Score; MCS, Mental Composite Score; SD, standard deviation; R = Spearman correlation and its statistical significance P ; NS, not significant.

sure allows multicenter studies to be carried out reliably in different countries. In addition, the use of culturally equivalent, standardized questionnaires simplifies the problems of meta-analysis for clinical research, allowing comparison of studies and minimizing reporting bias.^{2,5,20,22}

The validation process of the Italian IKDC Subjective Knee Form performed in this study shows that it preserves characteristics of reliability and validity similar to the published English original version.¹⁰ The strong correlation between IKDC Subjective Knee Form and SF-36 scores supports this validity and the test-retest assessment shows values similar to the original validation paper.¹⁰ Moreover, the lack of floor and ceiling effects reassures the authors of the validity of this version of the IKDC Subjective Knee Form. These effects exist when a questionnaire score repetitively the maximum or minimum score; this fact represents a measuring limitation of the questionnaire because it may not be set properly to what is being measured. The ICC value of 0.90 and the Cronbach's

alpha of 0.91 (range of value, 0-1) analyze the construct validity confirming that the meaning of the questionnaire items are in agreement in measuring the same area. Spearman correlation ranges from 0 to 1 (0 = no correlation and 1 = maximum correlation).

Some limitations have to be considered: first, the absence of a standard Italian-language disability measure for knee disease such that we were not able to test the criterion validation; second, the statistical power was not tested, but similar papers included equivalent samples; and moreover the study includes patients affected only by ACL lesions undergoing ACL reconstruction.

Even with the aforementioned limitations, we can conclude that the IKDC Subjective Knee Form, Italian version, has evaluation capacities equivalent to the English version. The basic features of any measuring tool, such as reproducibility, consistency, and validity, satisfied the statistical criteria.

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