Knee Surg Sports Traumatol Arthrosc (2014) 22:104–108
DOI 10.1007/s00167-012-2290-1

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Reliability, validity and responsiveness of the Spanish version of the Knee Injury and Osteoarthritis Outcome Score (KOOS) in patients with chondral lesion of the knee

Javier Vaquero · Umile Giuseppe Longo · Francisco Forriol · Nicola Martinelli · Ricardo Vethencourt · Vincenzo Denaro

Received: 20 March 2012 / Accepted: 29 October 2012 / Published online: 10 November 2012

Abstract
Purpose The purpose of this study was to perform a cross-cultural adaptation of the Knee Injury and Osteoarthritis Outcome Score (KOOS) into Spanish and to evaluate the psychometric properties of this version in patients with chondral lesion of the knee, as expressed by its validity, reliability and responsiveness.
Methods The translation followed an established forward–backward translation procedure with independent translations and counter-translation, according to the recommendations for the cross-cultural adaptation of HRQL measures. Twenty Spanish-speaking patients who underwent arthroscopic surgery for knee cartilage defects with a microfracture technique were enroled in the study. Diagnosis was made based on clinical criteria and radiological confirmation through magnetic resonance imaging. Patients showing signs of instability, axial malalignment or generalised knee osteoarthritis were excluded from the study.
Results Cronbach's alpha value for the study of the questionnaire was >0.7 in all the KOOS domains except for Symptoms domain. The test–retest reliability was confirmed with an ICC value greater than 0.8 in all the KOOS domains. A significant agreement between the KOOS domains and the scales of the SF-36 with related content, particularly in the areas of physical function and pain, was observed.
Conclusion Spanish KOOS questionnaire is valid, reliable and responsive for use in Spanish patients with symptomatic chondral lesion of the knee receiving surgical intervention.
Level of evidence IV.

Keywords Knee · Evaluation · KOOS · Spanish

J. Vaquero · R. Vethencourt
Department of Orthopaedic and Trauma Surgery, Hospital Universitario Gregorio Marañón, Madrid, Spain

U. G. Longo · N. Martinelli · V. Denaro
Department of Orthopaedic and Trauma Surgery, Campus Bio-Medico University, Via Alvaro del Portillo, 200, 00128 Trigoria, Rome, Italy

F. Forriol (✉)
School of Medicine, University CEU, Campus Monteprincipe, 28668 Boadilla del Monte, Madrid, Spain
e-mail: fforriol@mac.com

Introduction

The Knee Injury and Osteoarthritis Outcome Score (KOOS) was developed as an extension of the WOMAC and designed to assess short-term and long-term symptoms and function in subjects with a variety of knee injuries that could possibly result in osteoarthritis [18]. Bekkers et al. [3] evaluated the validity and reliability of the KOOS in measuring the clinical condition of patients after treatment for focal cartilage lesions.

Because of the increase in large multicenter international studies and the requirement for globally meaningful epidemiologic and/or therapeutic study results, there is a need for cross-cultural adaptation and validation of health status measures. The cross-cultural adaptation of the KOOS may require not only translation but also adjustment of cultural words, idioms and colloquialism. This process may involve substantial transformation of some items to fully capture the essence of the original concepts. Validated versions of KOOS have been currently published for use in English, Swedish [18], French [16], Japanese [15], Portuguese [7], Persian [20], Dutch [4], Singapore English and Chinese [23]. To date, a validated Spanish version of KOOS is not available.

The purpose of this study was therefore to perform a cross-cultural adaptation of KOOS into Spanish and to evaluate validity, reliability and responsiveness of this version in patients with chondral lesion of the knee that underwent surgical treatment.

Materials and methods

The translation followed an established forward–backward translation procedure with independent translations and counter-translation, according to the recommendations for the cross-cultural adaptation of HRQL measures [8]. Forward translation into Spanish of the KOOS was independently performed by two informed translators, orthopaedic surgeons, mother tongue Spanish and fluent in English. The first version was obtained after a consensus meeting of the two translators. This provisional Spanish version was translated back into English by two mother tongue Spanish subjects fluent in English, with medical background but unfamiliar to the outcome measure. This back translation was reviewed against the source by a second consensus meeting of all translators in order to check for discrepancies or any problems. The final Spanish version was obtained after testing it on ten patients with knee osteoarthritis to ascertain that there were no problems with acceptance and comprehension of the questionnaire content. None of the patients reported problems to complete questionnaires because of language problem or redundancy.

Twenty Spanish-speaking patients who underwent arthroscopic surgery for knee cartilage defects with a microfracture technique were enroled in the study. The institutional review board approved the study, and each patient gave written informed consent to participate in this study. The sample was recruited in an orthopaedics outpatient clinic when they were diagnosed with focal chondral defects of the knee by an orthopaedic surgeon. Diagnosis was made based on clinical criteria and radiological confirmation through magnetic resonance imaging. Patients showing signs of instability, axial malalignment, anterior cruciate ligament and meniscal injury, or generalised knee osteoarthritis were excluded from the study. Furthermore, subjects were excluded if they were younger than 18 years, unable to understand Spanish written language, and if they had inflammatory arthritis. Physical therapy treatments or intra-articular drug injections (corticosteroids or hyaluronic acid) within the previous 3 months were also considered as exclusion criteria. The inclusion criteria were quite narrow, in order to enrol patients naive to outcome measures and to previous treatment, which could influence the results. This produced a small number of patients for evaluation of the Spanish version of the KOOS.

During the preadmission visit, patients were asked to fill out the Spanish version of the KOOS and SF-36. The time required to complete the KOOS, and any difficulties with this were recorded for each patient. After 2 weeks, the KOOS was re-administered to the patients in an outpatient setting. Two weeks were considered an acceptable time to assume that the clinical situation would not change during this period, and that patients would not remember their answers to the first administration [21].

Defects were divided into osteochondral defects (11 knees) and degenerative chondral defects (9 knees). Each patient underwent arthroscopic microfracture technique for an isolated chondral defect of the knee. One year after surgery patients were evaluated, KOOS and SF-36 were re-administered during a follow-up visit.

The KOOS comprises 42 items in 5 separately scored subscales assessing pain and function of the knee in patient with injury or osteoarthritis [17–19]. The subscales are divided in Pain (nine items); Symptoms (seven items); Function in daily living (ADL) (17 items); Sport and Recreation Function (Sport/Rec) (five items); Quality of Life (QOL) (four items). Each item is rated on a 0- to 4-Likert scale, and each of the five subscales is calculated as the sum of the items included. Scores are then transformed to a 0–100 scale. The measure generates five separate scores where the higher the score, the best the health state.

The SF-36 consists of 36 questions on the general health status of patients. This questionnaire provides eight separate subscales: Physical Functioning (PF), Role-Physical (RP), Bodily Pain (PAIN), General Health (GH), Vitality (EV), Social Functioning (SF), Role Emotional (RM), Mental Health (MH), which are then aggregated into two main scores: the physical composite score (PCS) and the mental composite score (MCS). SF-36 has been validated for use in Spain [1].

Statistical analysis

Data were entered into a Microsoft Excel spreadsheet (Microsoft Corporation, Redmond WA) and analysed using SPSS 13.0 (SPSS Inc., Chicago, IL, USA). All tests were two-tailed and conducted at a 5 % level of significance. The data are reported as the mean ± standard deviation. Normal distribution of the scores was tested using the Kolmogorov–Smirnov test.

Internal consistency is a measure based on the correlations between different items on the same test or the same subscale on a larger test. Internal consistency was assessed using Cronbach's alpha [8]. Values equal or above 0.7 indicate acceptable reliability [9, 22].

The intraclass correlation coefficient (ICC) (Two-way Random Effect Model Absolute Agreement Definition)

was used to assess instrument test–retest reliability with the 95 % confidence interval (95 % CI). An ICC of more than 0.80 is usually considered an indicator of good reliability [5, 12].

Evidence for construct validity must be accumulated by a priori hypothesised patterns of associations with other validated instruments, which purport to measure relatively similar constructs (for positive correlations) [6, 11]. Spearman's rank correlation coefficient was used to assess the association between KOOS and different SF-36 subscales, preoperatively. It was hypothesised a priori that strong correlations will be detect between the KOOS Symptoms with SF-36 physical functioning; KOOS Pain with SF-36 bodily pain. Moreover, it was hypothesised a priori that the KOOS and SF-36 subscales for general perception of health and mental health were weakly correlated.

Spearman's coefficient was read as follows: strong correlation for values >0.50; moderate correlation for values between 0.35 and 0.50; weak correlation for values <0.35 [10].

Responsiveness to arthroscopic microfracture was evaluated using Student's *t*-test comparing the pretreatment and posttreatment scores. The standardised effect size (ES) and standardised response mean (SRM) were also evaluated.

The effect size is the difference between the mean baseline scores and posttreatment scores on the measure, divided by the standard deviation of baseline scores. The SRM is equal to the mean change in score divided by the standard deviation of the change scores.

The effect size was calculated as described by Husted et al. [10] values >0.20, >0.50 and >0.80 were considered small, moderate and large, respectively.

Results

The forward and back-translations of the KOOS presented no major difficulties or problems with the language.

The mean age of the subjects was 41.3 ± 14.0 (range 24 to 70 years) with 14 males and 6 females. There were no missing data for any KOOS item. Cronbach's alpha value for the study of the questionnaire was greater than 0.7 in all the KOOS domains except for Symptoms domain (Table 1). The test–retest reliability was confirmed with an ICC value greater than 0.8 in all the KOOS domains (Table 2). Means scores for first and second KOOS administration were similar for all domains (n.s.; Table 2).

Table 3 shows the correlations between the KOOS and SF-36 subscales. A significant agreement between the KOOS domains and the scales of the SF-36 with related content, particularly in the areas of physical function and pain, was observed. The highest correlations were found between KOOS Pain and SF-36 PAIN ($\rho = 0.79$), KOOS ADL and SF-36 PAIN ($\rho = 0.84$), KOOS Pain and SF-36 PF ($\rho = 0.76$).

The mean KOOS scores improved in all the domains after treatment with the microfracture technique ($p < 0.01$, Table 4). The responsiveness was high with a large effect size (Table 4).

Table 1 Internal consistency of the KOOS domains

KOOS domains	Cronbach's alpha coefficient
Pain	0.88
Symptoms	0.66
ADL	0.96
Sport/Rec	0.91
QOL	0.88

Table 2 Mean KOOS score and test–retest reliability of Spanish KOOS subscales assessed preoperatively

KOOS domains	Mean KOOS score (SD)		ICC (95 % CI)
	First assessment	Second assessment	
Pain	54.5 (18.5)	55.0 (21.9)	0.94 (0.85–0.97)
Symptoms	54.2 (17.7)	53.2 (17.6)	0.94 (0.87–0.97)
ADL	54.7 (22.3)	55.1 (23.4)	0.99 (0.97–0.99)
Sport/Rec	31.2 (25.7)	31.7 (25.1)	0.98 (0.96–0.99)
QOL	30.6 (21.8)	30.3 (22.5)	0.99 (0.98–0.99)

Two assessments were calculated for all the patients, separated with an interval of 2 weeks

SD standard deviation, *ICC* intraclass correlation coefficient, *CI* confidence interval

Table 3 Construct validity results: correlation between KOOS and SF36 (Spearman's ρ)

SF-36 subscales	KOOS domains				
	Pain	Symptoms	ADL	Sport/ Rec	QOL
PFSF-36	**0.76****	**0.70****	**0.81****	**0.54***	**0.74****
RPSF-36	**0.52***	**0.51***	**0.65****	**0.55***	0.49*
RMSF-36	0.37	0.20	**0.53***	0.28	0.39
SFSF-36	−0.31	−0.17	−0.48*	−0.11	−0.42
MHSF-36	**0.52***	0.25	0.58**	0.25	**0.62****
EVSF-36	−0.22	−0.25	−0.06	0.002	−0.13
PAINSF-36	**0.79****	**0.72****	**0.84****	**0.66****	**0.75****
GHSF-36	0.22	0.40	0.05	0.1	0.09

Strong correlation value are shown in bold typeface

** Correlation is significant at the 0.01 level (2-tailed)

* Correlation is significant at the 0.05 level (2-tailed)

Table 4 Mean KOOS score and responsiveness of Spanish KOOS subscales

KOOS domains	Mean KOOS score (SD)		*p* value	ES	SRM
	Pretreatment	Posttreatment			
Pain	54.5 (18.5)	82.7 (13.8)	<0.01	1.5	1.9
Symptoms	54.2 (17.7)	74.8 (13.1)	<0.01	1.1	1.1
ADL	54.7 (22.3)	88.5 (11.8)	<0.01	1.5	1.9
Sport/Rec	31.2 (25.7)	73.0 (13.2)	<0.01	1.6	1.9
QOL	30.6 (21.8)	58.6 (17.6)	<0.01	1.2	1.6

SD standard deviation, *ES* effect size, *SRM* standardised response mean

Discussion

In this study, the cross-cultural adaptation of the KOOS to the Spanish language has been presented. It showed acceptable psychometric properties in patients with chondral lesion of the knee.

The psychometric properties of the Spanish KOOS were generally similar to the original KOOS. After adaptation, the Spanish version of KOOS seems to be a feasible instrument as illustrated by the absence of missing data that reflects the good acceptance of the Spanish KOOS.

No floor or ceiling effects were observed. In accordance with the original English version of the KOOS, reliability was satisfactory [18]. Internal consistency was comparable to that observed in the original version [18].

In this validation study, Cronbach's alphas were above 0.70 for almost all subscales in the patient groups. This indicates a good internal consistency, which is in line with the study of Roos et al. [17, 18]. However, for the subscale Symptoms, we found a Cronbach's of 0.66, indicating a moderate internal consistency. Previous validation studies reported also a lower Cronbach's alpha (<0.70) for this subscale in patients with OA of the knee [23].

High ICC for the five subscales scores revealed that the stability of the Spanish KOOS over time was good. The same pattern of results was obtained in other studies with different samples and pathologies [16, 19].

The hypothesis for cross-sectional and longitudinal construct validity of the Spanish KOOS was confirmed. The construct validity of the KOOS questionnaire was determined by comparing the KOOS subscales with the subscales of the SF-36 and the VAS for pain. Similarly to previous studies, the validity of the Spanish KOOS showed a strong correlation between its scores and those of the SF-36 subscales (physical functioning and bodily pain) and VAS for pain, which aim to measure similar constructs [4, 7, 15, 16, 18, 20, 21]. Furthermore, the divergent validity was observed by its low-to-moderate correlation with the mental component domains of the SF-36.

The results of the responsiveness assessment showed that the Spanish version of KOOS was able to detect change over time. Large effect size was found after microfractures. There is high evidence that this surgical treatment reduces pain and improves physical function in knee of patients with chondral defects, and this study proves that this clinical change can be measured by this questionnaire [2].

Disease-specific disability scales have become complementary to traditional outcome measures, such as physical or radiographic assessments [13]. The widespread use of these assessment instruments in international clinical trails and in clinical practice requires either the elaboration of new scores or the adaptation and validation of questionnaires already accepted in the scientific community [14].

The need for multiple-language versions of existing validated questionnaires plays an important role in standardising the outcome assessment and increasing the statistical power of clinical studies. To date, the KOOS was not validated in Spanish language. Thus, the use of the Spanish version of KOOS should be recommended in a research setting for comparison of outcome in groups of Spanish patients.

The present study has some limitations. The small sample size used is not representative of the entire population of Spanish patients. Further validation studies are required in different patient populations and in different knee pathologies in order to confirm psychometric properties of the Spanish version of the KOOS.

Conclusion

In conclusion, the Spanish KOOS version proved to have equivalent evaluation capacities to the English version, which makes it a valid instrumentation as an outcome measure for use in patients with symptomatic chondral lesion of the knee receiving surgical intervention.

References

1. Alonso J, Prieto L, Antó JM (1995) The Spanish version of the SF-36 Health Survey (the SF-36 health questionnaire): an instrument for measuring clinical results. Med Clin (Barc) 104:771–776
2. Bedi A, Feeley BT, Williams RJ III (2010) Management of articular cartilage defects of the knee. J Bone Joint Surg Am 92:994–1009
3. Bekkers JE, de Windt TS, Raijmakers NJ, Dhert WJ, Saris DB (2009) Validation of the Knee Injury and Osteoarthritis Outcome Score (KOOS) for the treatment of focal cartilage lesions. Osteoarthr Cartil 17:1434–1439
4. de Groot IB, Favejee MM, Reijman M, Verhaar JA, Terwee CB (2008) The Dutch version of the Knee Injury and Osteoarthritis Outcome Score: a validation study. Health Qual Life Outcomes 6:16

5. Fleiss JL, Shrout PE (1977) The effects of measurement errors on some multivariate procedures. Am J Public Health 67:1188–1191
6. Froberg DG, Kane RL (1989) Methodology for measuring health-state preferences—II: scaling methods. J Clin Epidemiol 42:459–471
7. Gonçalves RS, Cabri J, Pinheiro JP, Ferreira PL (2009) Cross-cultural adaptation and validation of the Portuguese version of the Knee injury and Osteoarthritis Outcome Score (KOOS). Osteoarthr Cartil 17:1156–1162
8. Guillemin F, Bombardier C, Beaton D (1993) Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. J Clin Epidemiol 46:1417–1432
9. Hamon A, Mesbah M (1999) Internal statistical validation of a quality of life questionnaire. Rev Epidemiol Sante Publique 47:571–583
10. Husted JA, Cook RJ, Farewell VT, Gladman DD (2000) Methods for assessing responsiveness: a critical review and recommendations. J Clin Epidemiol 53:459–468
11. Irrgang JJ, Anderson AF (2002) Development and validation of health-related quality of life measures for the knee. Clin Orthop Relat Res 402:95–109
12. Landis JR, Koch GG (1977) The measurement of observer agreement for categorical data. Biometrics 33:159–174
13. Longo UG, Saris D, Poolman RW, Berton A, Denaro V (2012) Instruments to assess patients with rotator cuff pathology: a systematic review of measurement properties. Knee Surg Sports Traumatol Arthrosc 20:1957–1966
14. Martinelli N, Longo UG, Marinozzi A, Franceschetti E, Costa V, Denaro V (2011) Cross-cultural adaptation and validation with reliability, validity, and responsiveness of the Italian version of the Oxford Hip Score in patients with hip osteoarthritis. Qual Life Res 20:923–929
15. Nakamura N, Takeuchi R, Sawaguchi T, Ishikawa H, Saito T, Goldhahn S (2011) Cross-cultural adaptation and validation of the Japanese Knee Injury and Osteoarthritis Outcome Score (KOOS). J Orthop Sci 16:516–523
16. Ornetti P, Parratte S, Gossec L, Tavernier C, Argenson JN, Roos EM, Guillemin F, Maillefert JF (2008) Cross-cultural adaptation and validation of the French version of the Knee injury and Osteoarthritis Outcome Score (KOOS) in knee osteoarthritis patients. Osteoarthr Cartil 16:423–428
17. Roos EM, Lohmander LS (2003) The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. Health Qual Life Outcomes 1:64
18. Roos EM, Roos HP, Ekdahl C, Lohmander LS (1998) Knee injury and Osteoarthritis Outcome Score (KOOS)—validation of a Swedish version. Scand J Med Sci Sports 8:439–448
19. Roos EM, Toksvig-Larsen S (2003) Knee injury and Osteoarthritis Outcome Score (KOOS)—validation and comparison to the WOMAC in total knee replacement. Health Qual Life Outcomes 1:17
20. Salavati M, Mazaheri M, Negahban H, Sohani SM, Ebrahimian MR, Ebrahimi I, Kazemnejad A (2008) Validation of a Persian-version of Knee injury and Osteoarthritis Outcome Score (KOOS) in Iranians with knee injuries. Osteoarthr Cartil 16:1178–1182
21. Streiner DL, Norman GR (2004) Health measurement scales. A practical guide to their development and use. Oxford University Press, Oxford, pp 5–27
22. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, Bouter LM, de Vet HC (2007) Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol 60:34–42
23. Xie F, Li SC, Roos EM, Fong KY, Lo NN, Yeo SJ, Yang KY, Yeo W, Chong HC, Thumboo J (2006) Cross-cultural adaptation and validation of Singapore English and Chinese versions of the Knee injury and Osteoarthritis Outcome Score (KOOS) in Asians with knee osteoarthritis in Singapore. Osteoarthr Cartil 14:1098–1103