



Original Article

Transculturalization and Validation of a Spanish Translation of the Specific Lower Limb Osteoarthritis and Quality of Life Questionnaire AMICAL: Arthrose des Membres Inférieurs et Qualité de vie AMIQUAL[☆]



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ABSTRACT

Introduction: Several generic questionnaires have been used to measure quality of life in patients with osteoarthritis (OA) since few instruments have been developed specifically for OA and none was developed for Spanish speaking patients. The purpose of the study was to validate and adapt to Spanish the French questionnaire AMICAL to measure quality of life in patients with hip and knee OA.

Methods: Transversal, analytical study. The validation process was performed in phases: translation from French to Spanish, translated version analysis by a multidisciplinary expert team, application of a pilot test to patients to evaluate grammatical and content equivalence, blind back translation, and analysis. The questionnaire was applied to hip and knee OA patients, together with the SF-36 questionnaire, as well as the WOMAC and the Lequesne indexes. The reproducibility was evaluated applying the questionnaire after 72 h. The clinimetric analysis was calculated with SPSS 16.0.

Results: One hundred patients with hip OA and 100 patients with knee OA, radiological stages II–III, were included to evaluate homogeneity. Sixty-five patients with hip OA and 65 patients with knee OA were included to evaluate consistency. The final sample included 100 hip and 100 patients knee OA patients to estimate homogeneities and 65 patients were evaluated to estimate consistency. Mean (SD) age of patients with hip and knee OA was 56.34 ± 13 and 60.1 ± 9.2, respectively. Sixty seven percent and 79.8% were female, respectively. Cronbach' alpha for AMICAL was 0.946 and 0.999, for hip OA and knee OA, respectively; and test-retest reliability using the intraclass correlation coefficients was 0.979 and 0.998, respectively. There was also a significant correlation with all the instruments ($P < .05$), except with the Lequesne index ($r = -0.383$).

Conclusions: The Spanish version of AMICAL questionnaire keeps the clinimetric properties, homogeneity, and consistency, and has a good correlation with other instruments. Consequently, it is reliable and self-applicable, and includes domains beyond the functional capacity that better evaluate the quality of life.

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Transculturización y validación al español del Cuestionario específico de artrosis de miembros inferiores y calidad de vida AMICAL: Arthrose des Membres Inférieurs et Qualité de vie AMIQUAL

RESUMEN

Introducción: El impacto en la calidad de vida (CV) que condiciona la osteoartrosis (OA) ha sido evaluado con cuestionarios genéricos debido a que hay escasos instrumentos desarrollados específicamente para

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esta entidad y ninguno ha sido validado al español. El objetivo del estudio fue validar y transculturizar al español el cuestionario francés AMIQUAL para medir CV en pacientes con OA de caderas y rodilla.

Métodos: Estudio transversal, analítico; el proceso de validación se llevó a cabo en las siguientes fases: traducción del francés al español, las versiones traducidas se analizaron con panel de expertos multidisciplinario, aplicación de prueba piloto en población con OA para valoración de equivalencia gramatical y de contenido, retrotraducción y análisis. Se validó en pacientes con OA de cadera y rodilla, junto con SF-36, así como índices de Womac y Lequesne. La reproducibilidad se evaluó aplicando el cuestionario a las 72 h. El análisis clinimétrico se calculó con SPSS 16.0.

Resultados: Se incluyó a 100 pacientes para cada tipo de OA (cadera y rodilla), grado radiológico II–III, para estimar homogeneidad, y 65 pacientes para cada tipo de OA, para evaluar consistencia; la edad promedio fue de $56,34 \pm 13$ y $60,1 \pm 9,2$ años, respectivamente; predominó el género femenino, el 67% y el 79,8%, respectivamente. El α de Cronbach fue de 0,946 y 0,999 para OA de cadera y de rodilla, respectivamente; los coeficientes de correlación intraclase fueron 0,979 y 0,998, respectivamente. Las correlaciones con todos los instrumentos fueron significativas ($p < 0,05$), excepto con el índice de Lequesne ($r = -0,383$).

Conclusiones: La versión en español del cuestionario AMICAL conserva las propiedades clinimétricas, la homogeneidad y la consistencia, y correlaciona con otros instrumentos, por lo que es confiable, autoaplicable e incluye dominios más allá de la capacidad funcional, que interpretan mejor la CV.

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Introduction

The most prevalent rheumatic disease is osteoarthritis (OA),^{1,2} affecting at least 13.9% of adults from age 25 years and 33.6% of those over 65.³ OA of the knee is present in 16% of subjects from the age of 45⁴ and 12.1% of those aged 65 years⁵; hip OA is reported in 4.4% of the population older than 55.² In Mexico, the prevalence of OA is 10.5%, predominating in women.⁶ Its main manifestations are pain and stiffness, followed by limitation of motion, decreased strength and joint instability^{7,8} thus affecting functional capacity and causing a significant impact on quality of life (QOL) related to the state of health. QOL is considered a comprehensive indicator of the biopsychosocial role and is useful in the assessment of the patient situation and for making decisions about their management; however, there is no QOL tool in Spanish to evaluate these patients. Specific questionnaires of functional capacity, such as the WOMAC or Lequesne index, are limited to measure the specific impact on the QOL, because they are only partial assessments of this complex perception.^{1,8} On the other hand, it is known that the Spanish language is spoken by at least 500 million people in the world; therefore, it is the second most spoken European language and because of the migratory movement this frequency is increasing, so in countries like the United States it ranks fourth as the most spoken and is the second in Canada. In Brazil and EU countries such as Germany, France or Britain, there are millions of Spanish speakers. However, there are few validated instruments in Spanish to measure QoL in OA and those available are generic (e.g. SF-36), which determine loss of fidelity and specificity of information and monitoring after therapeutics,^{9–11} thus leading to the need for validated instruments specific to Spanish speakers. The AMIQUAL questionnaire is specific to assess QoL in patients with OA of the lower extremities; it was developed in France in 2005 and consists of 43 items, now in version 2.3, it is grouped into 5 domains: physical activity (19 items), mental health (14 items), social support (4 items), social functioning (3 items) and pain (3 items), plus 3 items related to family, sexuality and employment. Each item is answered on a simple scale of 1–10, with lower scores reflecting better QOL, the sense of the score is invested in questions 30–32, 39, 40, 42 and 43, so their interpretation can be quantified backwards; filling time takes approximately 11–15 min.^{12,13} It has been validated and transculturized in different languages, demonstrating significant correlation coefficients (intraclass correlation coefficient [ICC] 0.70–0.85) with instruments such as SF-36 (r 0.43–0.75) and satisfactory discrimination, however, has not yet been validated in Spanish,^{14–17} so the objective of this study was to validate and AMICAL and transculturize the questionnaire as well as determine its correlation with other instruments. The authors

of the original instrument in French, AMIQUAL, Francis Guillermin and Anne-Christine Rat, have provided authorization for the Spanish transculturization and validation of the questionnaire, and their respective use by the authors of this article.

Materials and Methods

A cross-sectional analytical study was conducted, in which the target population included adults with knee osteoarthritis and radiographic osteoarthritis of any degree, who accepted to participate under informed consent, of any gender and that excluded patients with cognitive impairment or previous neurological disorder that prevented the filling of questionnaires. Sampling of consecutive cases was non-probabilistic; the sample size was obtained by Epidat 3.1 software, by calculating the expected concordance, consistency and correlation, considering the sample size of its transculturation in other countries, the incidence of patients with osteoarthritis of the lower limbs of a rehabilitation unit and taking the specific QOL as the main variable. The study was submitted to the corresponding Local Committee for Research in Health according to the World Medical Association Declaration of Helsinki¹⁸ and the General Health Law, under informed consent.

Transculturation

The AMIQUAL 2.3 version questionnaire was translated by a bilingual professional with French as mother tongue, without medical knowledge, and a bilingual Spanish mother tongue health professional. Both versions were subjected to analysis by a multidisciplinary panel of 5 experts with at least 5 years of experience in the field of OA, which included: a nurse, a general practitioner or family doctor, a rehabilitation physician, a metrologist, a professional translator and a patient type. This analysis was blinded, independent and evaluated the grammar and content equivalence; it was confronted with the results of a pilot study of patients without OA, homogeneous in age and gender, and the final version was obtained by unanimous consent attaining a kappa of at least 0.80. The final version was submitted for reverse-translation by a teacher in bilingual French, with French as a mother tongue and a diagnosis of knee OA, and a bilingual professional Spanish mother tongue health professional, with final approval by unanimous agreement of linguistic equivalence made by the panel and the final name given to the instrument as Osteoarthritis of lower limbs and Quality of Life (AMICAL) (see Banexo Appendix 1).

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