ORIGINAL ARTICLE

Adaptation and validation of the Osteoarthritis Knee and Hip Quality of Life (OAKHQOL) questionnaire for use in patients with osteoarthritis in Spain

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Abstract This study aims to adapt and validate the Spanish version of the Osteoarthritis Knee and Hip Quality of Life (OAKHQOL) questionnaire. The OAKHQOL was adapted into Spanish using a forward–backward translation methodology. The Spanish version was then validated in a prospective, mixed-design study of 759 patients with hip or knee osteoarthritis (OA). Patients completed the OAKHQOL, Short Form 36 (SF-36), Western Ontario and McMaster Universities Osteoarthritis Index, and the EQ-5D. The internal consistency was evaluated using Cronbach's alpha. Convergent validity was assessed by examining correlations between the OAKHQOL and other patient-reported instruments;

known groups' validity was assessed by determining the capacity of the OAKHQOL to discriminate between patients with different levels of disease severity measured using the Lequesne Index. Test–retest reliability was evaluated by calculating the intraclass correlation coefficient (ICC) for all OAKHQOL domains in 409 stable patients with OA. Responsiveness was evaluated by calculating effect sizes among 129 patients undergoing hip or knee replacement. Cronbach's alpha for the five domains of the OAKHQOL ranged from 0.60 to 0.93 while ICCs ranged from 0.75 to 0.81 for all domains except the two social domains. Statistically significant differences (p<0.001) were observed between

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patients with different degrees of disease severity on all domains except "social support". The instrument showed convergent validity among hypothesized domains (p< 0.001). Results of the study supported that the Spanish version OAKHQOL questionnaire was a valid instrument to measure health-related quality of life in patients with OA of the lower limb.

Keywords Health-related quality of life · OAKHQOL · Osteoarthritis · Validation

Introduction

Osteoarthritis (OA) is a chronic disease whose prevalence increases with age [1, 2]. From 1995 to 2005, the number of patients suffering from OA has increased from 21 to nearly 27 millions in USA, probably owed to the aging population [3]. In Spain, musculoskeletal diseases are a source of pain and a significant cause of incapacity for work [4]. They reduce patients' quality of life, fostering the consumption of a large amount of resources such as medical visits or hospitalizations [5, 6]. OA also accrues high indirect costs as it often causes absences from work and extended disability.

Patient-reported outcomes (PROs) have been broadly defined as subjective assessment by patients of their health [7]. In the last 30 years, the PROs research has been consolidated, especially in the Health-Related Quality of Life (HRQoL) section [8]. HRQoL is an indicator of the impact of a disease on the population and offers a way to measure the effects of various therapies [9]. Numerous HRQoL questionnaires have emerged from this work. Some of these questionnaires are generic, others are disease specific.

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) has been the most widely used questionnaire to evaluate HRQoL among patients with hip or knee OA [10]. One drawback of the WOMAC is that it is limited to measuring pain, stiffness, and function. Yet OA can also affect mental health (anxiety and/or depression), sleep, sexuality, social functioning, and other aspects of life [11, 12]. In addition, social support and other variables have been shown to influence the results of this pathology [13, 14].

The Osteoarthritis Knee and Hip Quality of Life (OAKH-QOL) questionnaire was specifically designed to assess quality of life among patients with OA of the hip or knee. The original instrument was developed in French. It was shown to capture patients' perceptions of their disease, and possesses the necessary psychometric properties of validity and reliability for use in clinical trials and observational studies [15, 16].

The aim of our study was to perform a cross-cultural adaptation of the OAKHQOL questionnaire for use in Spain and to validate the Spanish version in terms of its psychometric properties of reliability, validity, and responsiveness.

Materials and methods

This prospective study was conducted among patients diagnosed with OA of the lower limbs. They were recruited between January 2007 and January 2008 in seven hospitals that are part of Spain's National Health System: four in the Basque Country, two in the Canary Islands, and one in Andalusia. The Institutional Review Boards of each hospital approved the study.

OAKHOOL questionnaire

The OAKHQOL questionnaire is made up of 43 items, 40 of which form five domains: physical activity, mental health, pain, social support, and social functioning. It also includes three independent items about relationships, sexual activity, and professional life. The Likert response scales in the items range from 0 (worst) to 10 (best). In each domain, the mean score of the items is calculated, yielding a score for each domain. The score is then standardized on a scale from 0 (worst quality of life) to 100 (best quality of life).

Adaptation of the OAKHQOL

We followed the method of forward translation and backtranslation by professionals [17, 18] and conducted a pilot study with patients.

The original French questionnaire was independently translated into Spanish by two translators (one rheumatologist and one professional translator) whose native language was Spanish and who had a high level of fluency in French. Both scored the difficulty of finding Spanish expressions that were conceptually equivalent to the original expressions. The two translations were compared and discussed in a meeting that included researcher team and the translators until a consensus was reached on a single adapted version (version 1.0).

To evaluate the equivalence version 1.0 to the original, it was independently back-translated from Spanish to French by two professional translators whose native language was French and who had a high level of fluency in Spanish. The two back translations were compared with the original French version and a consensus was reached on modifications that needed to be made to the Spanish version 1.0. The revised version of the Spanish OAKHQOL was tested on 17 patients with hip or knee OA in order to evaluate how well patients understood the items, as well as to determine the acceptability and feasibility of the questionnaire. Modifications were made based on the results of this pilot test, yielding a final version of the Spanish questionnaire.



Patients and validation process

The patients in the validation study were recruited from the waiting list to be operated on for a joint replacement in the seven participating hospitals from the orthopedic department. Patients with psychiatric diseases were excluded because these conditions could prevent them from completing all the questionnaires included. Patients were asked to fill out the OAKHQOL, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the Short Form 36 (SF-36), the Leguesne Index, the EuroOol (EO-5D), and questions about gender, age, affected joint, weight, and height. Of the total sample of 759 patients, a subsample of 409 patients contacted by mail, filled out the OAKHOOL a second time, 2 weeks after the first evaluation, together with a question on whether there had been any change in their clinical situations. A second subsample of 129 patients, contacted by mail, filled out the WOMAC and the OAKHQOL again 6 months after joint replacement. The sample size for the total sample as well as for the two subsamples exceeded the minimum sample size established by the literature for studies of reliability, validity, and responsiveness [19].

Other instruments

Patients completed the Lequesne Index in order to evaluate the severity of their disease. This index is made up of 15 questions grouped in three sections: pain or discomfort, maximum distance walked, and other difficulties. An overall score is created by adding the scores of each item. This index is categorized in six levels of severity: no severity, medium severity, moderate severity, serious, very serious, and extremely serious [20, 21].

Patients also completed two generic HRQoL instruments, SF-36, and the EQ-5D as well as one diseasespecific instrument, the WOMAC. The SF-36 includes 36 questions grouped in eight domains: physical function, physical role, bodily pain, general health, vitality, social function, emotional role, and mental health. Scores vary from 0 (worst health status) to 100 (best health status). The SF-36 generates two summary scores, the physical (PCS) and mental (MCS) summary components. We used a Spanish version of the SF-36 [22]. The EQ-5D is a selfadministered questionnaire that describes HRQoL in terms of five domains: mobility, personal care, daily activities, pain or discomfort, and anxiety or depression. The perception of an individual's own health status, measured by an analog visual scale (VAS), also forms part of the EQ-5D. It is evaluated separately and presented in the form of a thermometer whose ends are labeled with "worst imaginable health status" and "best imaginable health status" with scores from 0 to 100, respectively. Besides, this questionnaire presents social rates obtained from the use of the temporal equivalence method (TE rates) and from a visual analogical scale (VAS rates). The EQ-5D has been translated and validated in the Spanish population [23].

The WOMAC is a HRQoL questionnaire designed for patients with OA of the lower limbs. This multidimensional scale [10], is formed by 24 items grouped in three domains: pain (5 items), stiffness (2 items), and function (17 items). The data are standardized, generating scores for each dimension with a range from 0 (best health status) to 100 (worst). The WOMAC has been translated and validated in the Spanish population [24, 25].

Statistical analysis

The distribution of the scores in the Spanish version of the OAKHQOL was evaluated by mean, standard deviation, proportion of patients with one or more lost items, observed range, and the ceiling and floor effect [26]. We used the version 16.0 of the SPSS program to realized statistical analysis (SPSS Inc, Chicago, IL, USA).

Reliability

Reliability was analyzed in two ways: (1) internal consistency by means of Cronbach's alpha [27] and by the scaling success rates, (2) reproducibility by means of test–retest. Patients were explicitly asked whether they had experienced any change in their health status since completing the previous questionnaire. When no change was detected, we calculated the intraclass correlation coefficient (ICC) [28].

Validity

We evaluated the content validity. To accomplish this, we collaborated with a rheumatologist and three orthopedic surgeons who assessed the understanding and relevance of the items of the questionnaire [29].

The construct validity was evaluated through the known groups validation process using the Lequesne Index. Due to the low percentage of patients in the three lowest levels, we collapsed the six groups of severity into four: none/mild/moderate, severe, very severe, and extremely severe. The hypothesis here was that the groups with greater severity would have lower scores in the Spanish OAKHQOL questionnaire in the domains of physical activity, pain, and mental health. We also analyzed differences between groups according to gender, affected joint, and body mass index (BMI) in three groups (<25, 25–35, and >30). The nonparametric Mann–Whitney test was used to analyze difference by gender and joint, and analysis of variance with Scheffé test for multiple comparisons for Lequesne Index and BMI.



To analyze the criterion validity, we examined the convergent and divergent validity of the instrument. We hypothesized that the physical activity domain of the Spanish OAKHQOL would correlate better with the physical domains of the SF-36 and of the WOMAC (function), while the pain domain of the Spanish OAKHQOL would correlate better with pain and other physical domains of the SF-36. For the other domains, we expected lower correlations. The convergent and divergent validity was analyzed by means of the Pearson correlation coefficient.

Responsiveness

To evaluate the responsiveness, we asked patients to complete the questionnaires WOMAC and OAKHQOL, 6 months after the procedure [30, 31]. The changes were evaluated by three methods: the paired t test, the effect size I or standardized effect size (SES), and the effect size II or standardized response mean (SRM) [32–34].

Results

Adaptation process. Face validity

Several difficulties with version 1.0 of the translated OAKH-QOL questionnaire emerged in the pilot study. Several patients described problems understanding some expressions or words, such as "dosing", "physical incapacity", or "secondary effects". There was also some confusion regarding the response options, with some participants interpreting "completely agree" as "completely disagree". Structural difficulties in items 11, 12, 22, and 23 were resolved by changing the original layout of the response "not applicable". The patients took a mean time of 15 min to complete the OAKHQOL.

Sample

A sample of 759 patients was recruited. Of these, 409 (53.9%) presented with knee OA and 350 (46.1%) with hip OA. The mean age was 69.81 years (SD 9.29) and 62.8% were women. The majority of patients (65.8%) were in the Lequesne Index greater severity group. Depending on the joint affected, we found statistically significant differences in relation to gender (p<0.001), with more women with knee OA; age (p<0.001), with patients with knee OA 3 years older; in the different Lequesne Index severity groups (p=0.003); and in BMI (p<0.001) being higher for patients with knee OA. Among patients with knee OA, 89.4% were in the two highest severity groups compared to 83.2% of the hip OA patients. With regard to the baseline measurement of HRQoL, there were no statistically significant differences between joints in any of the domains

of the OAKHQOL, and most of the domains of the WOMAC or SF-36. The exceptions were in function dimension of WOMAC (p=0.023), the PCS of SF-36 (p=0.024), and the VAS rates (p=0.007) and TE rates (p=0.011) of the EQ-5D, with the patients with hip OA showing worse scores (Table 1).

Of the 759 patients who completed the OAKHQOL and other questionnaires, 610 were sent a second mailing 2 weeks after and 409 (67.0%) responded to the OAKHQOL questionnaire a second time. Fifty-eight of these 610 patients were sent a third mailing with the OAKHQOL and WOMAC questionnaires, 6 months after the intervention and 49 patients responded. On the other side, the OAKHQOL and WOMAC questionnaire was sent as well to 149 of the patients who underwent joint replacement 6 months after their operation; 80 (53.7%) responded. So, we get a sample of 129 patients who responded these questionnaires 6 months after the intervention.

The distribution of the domains and reliability coefficients of the Spanish version of the OAKHQOL are shown in Table 2. The lowest scores were in the domains of physical activity (mean, 26.38; SD, 19.39) and pain (mean, 30.39; SD, 24.00); the highest in the domain of social support (mean, 73.29; SD, 22.54). The percentage of missing items did not exceed 9% in any of the domains. The observed theoretical ranges coincided for all the scores (from 0 to 100) and were distributed within the range of values covered. Table 2 shows a low floor effect that varies from 0.1% in the mental health domain to 8.7% in pain, and an equally low ceiling effect that ranged from 0.4% in the physical activity domain to 12.8% in the social support domain. All were within the range considered acceptable (<15%).

Reliability

The results of reliability are listed in Table 2. The question-naire had good internal consistency with Cronbach's alpha >0.78 in all domains with the exception of the social activities, which had a value of 0.60. The percentage of items in the OAKHQOL that correlated higher with their hypothetical domain than with the remainder of the domains was 100%. In relation to the test–retest, we found an ICC> 0.75 in all domains except for social support (ICC=0.39) and social activities (ICC=0.42).

Content validity

The rheumatologist and orthopedic surgeons who evaluated the understanding and relevance of the items of the questionnaire highlighted the simplicity of the terminology of the questionnaire, the clarity of the questions, and the fact that it included domains affected by osteoarthritis. They did not suggest adding or



Table 1 Baseline clinical, demographic, and HRQoL characteristics of the sample

Table 1 Baseline clinical, demographic, and HRQoL characteristics of the sample		Total sample $n=759 \ (\%)^*$	Knee OA n=409 (%)*	Hip OA n=350 (%)*	$\chi^2 p$ value
	Number (% women)	477 (62.8)	302 (63.3)	175 (36.7)	< 0.001
	Age groups				
	≤59	109 (14.4)	31 (7.6)	78 (22.3)	< 0.001
	60–69	226 (29.8)	127 (31.1)	99 (28.3)	
	70–79	343 (45.2)	205 (50.1)	138 (39.4)	
	≥80	81 (10.7)	46 (11.2)	35 (10.0)	
	LEQUESNE index				
	None/mild/moderate severity Severe	24 (4.2) 53 (9.3)	8 (2.6) 24 (7.9)	16 (6) 29 (10.8)	0.003
	Very severe	118 (20.7)	51 (16.8)	67 (25.0)	
	Extremely severe	376 (65.8)	220 (72.6)	156 (58.2)	
	•	Mean (SD)	Mean (SD)	Mean (SD)	t test p Value
	Age	69.81 (9.29)	71.26 (7.71)	68.13 (10.61)	< 0.001
	BMI ^a	29.36 (4.37)	30.04 (4.27)	28.57 (4.35)	< 0.001
	SF-36 ^b				
	Physical function	23.15 (20.35)	23.55 (19.97)	22.68 (20.80)	0.558
	Role physical	29.77 (25.10)	30.64 (24.50)	28.75 (25.79)	0.310
	Bodily pain	27.79 (21.38)	29.07 (21.55)	26.28 (21.11)	0.075
	General health	44.10 (20.25)	44.47 (19.88)	43.68 (20.70)	0.603
	Vitality 42.90 (23.60) 41.60 (22.60) 4 Social function 53.73 (29.94) 54.66 (29.31) 5	44.46 (24.70)	0.099		
The percentages for the age	Social function	53.73 (29.94)	54.66 (29.31)	52.62 (30.68)	0.356
groups and Lequesne index, are	Role emotional	65.37 (31.55)	64.58 (31.63)	66.30 (31.48)	0.470
percentages of the column; the	Mental health	55.23 (21.91)	55.60 (21.10)	54.79 (22.87)	0.642
percentages for the gender are percentages of the row	PCS^{c}	26.37 (7.75)	27.03 (7.82)	25.57 (7.61)	0.024
^a BMI Body mass index	MCS^d	43.78 (13.13)	43.48 (12.69)	44.14 (13.66)	0.545
^b SF-36 Short-Form 36	WOMAC ^e				
^c PCS Physical component	Pain	52.25 (19.36)	52.82 (19.61)	51.59 (19.07)	0.389
summary	Stiffness	51.02 (24.33)	51.30 (24.34)	50.69 (24.36)	0.731
^d MCS Mental component	Function	57.26 (20.02)	55.72 (20.16)	59.07 (19.73)	0.023
summary	OAKHQOL ^f				
^e WOMAC Western Ontario and	Physical activity	26.38 (19.39)	27.57 (19.33)	24.96 (19.40)	0.069
McMaster Universities Osteoar- thritis Index	Pain	30.39 (24.00)	30.93 (24.22)	29.76 (23.75)	0.513
fOAKHQOL Osteoarthritis Knee	Mental health	50.06 (23.48)	49.16 (22.71)	51.14 (24.36)	0.259
Hip Quality of Life	Social support	73.29 (22.54)	72.89 (23.25)	73.77 (21.70)	0.605
gVAS rates social rates obtained	Social activities	56.29 (26.05)	55.04 (20.16)	59.07 (19.73)	0.167
from the visual analogical scale	EQ-5D				
hTE rates social rates obtained	VAS rates ^g	0.430 (0.208)	0.449 (0.203)	0.408 (0.213)	0.007
from the method of the temporal	TE rates ^h	0.368 (0.329)	0.397 (0.319)	0.335 (0.339)	0.011
equivalence iV4S visual analogical scale	VAS ⁱ	45.68 (19.64)	46.25 (19.28)	45.07 (20.03)	0.457

deleting any item. However, they pointed out that the question related to sexual activity could be uncomfortable for some patients.

Known groups validity

ⁱVAS visual analogical scale

Regarding Lequesne index, in the Spanish OAKHQOL, scores in the physical activity, pain, and mental health domains declined (indicating poorer HRQoL) as the severity increased (Table 3). This confirmed our initial hypothesis, since we found statistically significant differences (p<0.001) among the severity groups, verifying that the groups with greater disease severity had worse scores. For the remainder of the analyzed variables, we found statistically significant differences among BMI groups in the physical activity (p=0.003) and mental health (p=0.003) 0.040) domains. We also found statistically significant differences (p<0.001) by gender in all domains except the



Table 2 Distribution and reliability coefficients for the five domains of the Spanish OAKHQOL

OAKHQOL ^a	Number of items	Mean	SD^b	Missing items (%) ^c	Observed range	Theoretical range ^d	Floor effect (%) ^e	Ceiling effect (%) ^e	% Scaling success ^f	Cronbach Alpha	ICC ^g (n)
Physical activity (n=737)	16	26.38	19.39	34 (4.4)	0–100	0–100	4.2	0.4	100	0.93	0.81 (361)
Pain $(n=726)$	4	30.39	24.00	45 (5.8)	0 - 100	0-100	8.7	1.5	100	0.83	0.75 (358)
Mental health $(n=720)$	13	50.06	23.48	51 (6.6)	0–100	0-100	0.1	1.1	100	0.91	0.80 (349)
Social support $(n=717)$	4	73.29	22.54	54 (7)	0–100	0–100	1.5	12.8	100	0.78	0.39 (353)
Social activities $(n=705)$	3	56.29	26.05	66 (8.6)	0–100	0–100	3.3	7	100	0.60	0.42 (343)

^a OAKHQOL Osteoarthritis Knee Hip Quality of Life

two social domains. No differences were observed according to the affected joint in any of the domains.

Convergent and divergent validity

As we hypothesized, the OAKHQOL physical activity domain was moderately correlated with the physical domains of the SF-36 (physical function, r=0.58; physical role, r=0.61; pain, r=0.64; general health, r=0.41; and PCS, r=0.59) and the WOMAC (function, r=-0.80; Table 4). In the same way, the OAKHOOL pain domain was highly correlated with pain (r=0.61) and other physical domains of the SF-36 and with the pain domain of the WOMAC (r=-0.69). The OAKHQOL mental health domain showed higher correlation with the mental domains of the SF-36 (vitality, r=0.53; social function, r=0.59; emotional role, r=0.59; mental health, r=0.61; and MCS, r=0.65). However, both the social support (r=-0.06) and social activities (r=0.18) domains of the OAKHQOL were poorly correlated with social function domain of the SF-36. In addition, the three OAKHQOL domains of physical activity, pain, and mental health were modestly correlated (r>0.5) with the two social rates (VAS rates and TE rates) of the EQ-5D.

Responsiveness

A total of 129 patients completed the OAKHQOL questionnaire before joint replacement and 6 months afterward: 77 (59.7%) patients had knee OA, the mean age was 69.82 years (SD=8.74), and 76 (58.9%) were

women. As can be seen in Table 5, OAKHQOL scores improved following surgery. The differences were statistically significant (p<0.001) in all domains except the social activities domain (p=0.211). The two domains most responsive were pain (SES=1.37, SRM=1.02) and physical activity (SES=1.20, SRM=0.98). Negative values were presented for the social support and social activities domains.

Discussion

The intention when developing OAKHQOL was to introduce elements of QoL that patients with hip and knee OA report as affecting their daily lives. Existing instruments for use in OA like the WOMAC, but provide no information about the overall perceived impact of the disease; patient-reported outcome instruments fail in that respect because they measure only functional status or are not specific to lower limb OA, like the SF-36.

So, the OAKHQOL besides measures the typical domains of the specific questionnaires as physical activity and pain, it analyzes other domains equally important and influential in the HRQoL of patients with OA: mental health, social activities, and social support. These domains are very important to understand patients' family and the social atmosphere, and to know social support networks with patient has. Likewise, the OAKHQOL obtains more global vision of the patients HRQoL than the WOMAC.

In this study, we found that our version of the OAKHQOL had good content, good acceptability, ease of



^b Standard deviation

^c Number and percentage of patients with some missing items in the domain

^d The theoretical range in the OAKHQOL questionnaire is 0 (worst HRQoL) to 100 (best HRQoL), except for items 12, 22, and 23, where scale ranges from 0 (best health state) to 10 (worse health state)

e Percentage of patients with the worst (floor effect) and the best (ceiling effect) HRQoL

f Scaling success rates are the percentages of the items that correlate higher with their domains than with the other domains of the questionnaire

g ICC intraclass correlation coefficient

Table 3 Known groups validity in the Spanish OAKHQOL domains

		OAK	OAKHQOL scales														
		Physi	Physical activity			Pain			Mental health	th		Social support	upport		Social activities	vities	
		N	Mean	SD	p^{a}	Mean	SD	p^{a}	Mean	SD	p^{a}	Mean	SD	p^{a}	Mean	SD	p^{a}
BMI^b	<25 (a) 25–30 (b)	107	29.34 c 28.45 c	21.28	0.003	32.07 31.71	25.07 24.57	0.242	50.34 52.40 c	25.06	0.040	70.29	25.57 22.35	0.252	57.00 56.81	26.90 26.18	0.928
	>30 (c)	295	23.65 ab	17.81		28.71	23.00		47.51 b	22.82		74.55	21.34		56.08	25.53	
Gender	Female Male	463 274	23.89 30.59	17.97 20.95	<0.001	27.46 35.38	22.72 25.30	<0.001	46.35 56.33	22.27 24.17	<0.001	74.46	22.24 22.96	0.069	55.19 58.17	26.51 25.16	0.144
Joint	Hip Knee	337	24.96 27.57	19.40	0.069	29.76 30.93		0.513	51.14 49.16	24.36 22.71	0.259	73.77	21.70 23.25	0.605	57.76 55.04	25.26 26.67	0.167
Severity (Leginesne)	None/mild/ moderate (a)	24	51.02 cd	21.32	<0.001	64.27 cd	22.05	<0.001	67.95 d	21.12	<0.001	65.63	24.33	0.202	26.67	29.53	<0.001
(aucanhar)	Severe (b)	53	47.68 cd	19.66		51.70 cd	26.50		65.46 d	23.25		72.29	24.98		65.03 d	28.75	
	Very severe (c)	117	34.03 abd	14.19		38.80 abd	21.20		56.22 d	21.31		72.99	20.72		63.78 d	22.80	
	Extremely severe (d)	371	18.62 abc	13.68		22.40 abc	18.23		43.66 abc	21.30		74.75	20.89		52.61 bc	25.59	

Bolded letters indicate statistically significant differences among the marked groups. For example, (ab) in group c means that group c is significantly different from groups a and b ^a The p-value was calculated for the OAKHQOL domains scores between the different severity groups by means of ANOVA with Scheffé test ^b BMI Body Mass Index



Table 4 Pearson's correlations
matrix of the Spanish OAKH-
QOL domains with the SF-36,
WOMAC and EQ-5D

^aOAKHQOL Osteoarthritis Knee Hip Quality of Life ^bSF-36 Short-Form 36 ^cPCS Physical Component Summary ^dMCS Mental Component Summary eWOMAC Western Ontario and McMaster Universities Osteoarthritis Index fVAS rates social rates obtained from the visual analogical scale gTE rates social rates obtained from the method of the temporal equivalence hVAS visual analogical scale *p=0.05, correlation significant level **p=0.01, correlation significant level

	OAKHQOL ^a				
	Physical activity	Pain	Mental health	Social support	Social activities
SF-36 ^b					
Physical function	0.58**	0.42**	0.34**	-0.04	0.12**
Role physical	0.61**	0.44**	0.40**	-0.10**	0.17**
Bodily pain	0.64**	0.61**	0.47**	-0.14**	0.10**
General health	0.41**	0.39**	0.53**	-0.01	0.20**
Vitality	0.42**	0.43**	0.53**	-0.01	0.17**
Social function	0.52**	0.39**	0.59**	-0.06	0.18**
Role emotional	0.38**	0.36**	0.59**	-0.01	0.22**
Mental health	0.36**	0.31**	0.61**	-0.04	0.16**
PCS ^c	0.59**	0.46**	0.25**	-0.12**	0.09*
MCS^d	0.36**	0.29**	0.65**	0.01	0.22**
WOMAC ^e					
Pain	-0.63**	-0.69**	-0.46**	0.15**	-0.09*
Stiffness	-0.48**	-0.46**	-0.34**	0.10*	-0.07
Function	-0.80**	-0.66**	-0.50**	0.16**	-0.12**
EQ-5D					
VAS rates ^f	0.64**	0.56**	0.50**	-0.10*	0.12**
TE rates ^g	0.62**	0.54**	0.48**	-0.10**	0.11**
VAS ^h	0.36**	0.34**	0.34**	-0.11**	0.10*

administration, moderate-to-high internal consistency, and excellent reproducibility for the physical domains (physical activity and pain) and the mental health domain in a large sample of patients with knee or hip OA. The Spanish OAKHQOL discriminated well among groups of severity, measured by Lequesne index, in the domains mentioned. It has also high responsiveness in these domains.

The questionnaire showed a low floor and ceiling effect as well as a low percentage of missing items. The reliability of the questionnaire was reflected in the good internal consistency we observed with Chronbach's alpha >0.78 in all domains except social activities. This suggests that all the scales can be used to compare groups, and some of them, such as physical activity and mental health, may even be useful at the individual level. The social domains are clearly differentiated from the others, as were the results obtained in the French original validation [15].

With respect to the known group's validity, two matters should be highlighted. One is the capacity of the questionnaire to differentiate between groups of severity, except for the social domains. This could be due to the fact that the social domains are not related to the severity. The variables such as BMI, gender, and affected joint in our study have a similar effect for the known group's validity, with respect to

Table 5 Responsiveness parameters of the Spanish OAKHQOL domains

OAKHQOL ^a	N	Pre intervention mean (SD)	6 months mean (SD)	Difference mean (SD) ^b	P value ^c	SES^d	SRM ^e
Physical activity	122	26.56 (17.49)	47.63 (26.35)	21.08 (21.59)	< 0.001	1.20	0.98
Pain	120	31.47 (23.43)	63.51 (30.33)	32.03 (31.52)	< 0.001	1.37	1.02
Mental health	120	50.95 (22.57)	64.86 (23.98)	13.88 (22.14)	< 0.001	0.61	0.63
Social support	118	75.16 (19.39)	68.16 (26.35)	-7.00 (25.80)	< 0.001	-0.36	-0.27
Social activities	118	59.36 (26.15)	55.85 (30.14)	-3.52 (37.54)	0.211	-0.13	-0.09

^a OAKHQOL Osteoarthritis Knee Hip Quality of Life

e Standardized Response Mean (SRM), the mean score change divided by the standard deviation of that score change



^b Difference=6 months-pre-intervention

^c P value, comparison of means pre intervention–6 months (paired t test)

d Standardized effect size (SES), the difference between the mean baseline scores and follow-up scores on the measure, divided by the standard deviation of the baseline scores

the original French study. The small differences between our results and those of the original OAKHQOL study by Rat et al. could be due to differences in the sample. The original French study included three different groups of severity (patients managed medically, patients in the waiting list for joint replacement, and patients who had undergone joint replacement) while our study included only patients waiting for joint replacement [15].

In relation to convergent validity, the OAKHQOL was generally well correlated with the pertinent domains of the WOMAC and the SF-36. The exception was in the social domains, where the correlation was weak. A similar trend was observed in the original French validation study. Our results are in line with those obtained by Rat et al. [16], in which good or moderate correlations of the OAKHQOL were found with the SF-36 in all of the domains except the two social domains. This is possibly due to the fact that the social domains of the OAKHQOL do not measure the same aspects of HRQoL as the corresponding domain of the SF-36.

Among patients who underwent joint replacement, we observed an improvement in OAKHOOL scores in the physical activity, pain and mental health domains 6 months after the intervention. In spite of the observed changes the two social domains are different. This was to be expected since the intervention more directly affects physical and mental function than social activities or social support. The decrease in the scores on the social support domain could be related to the four items that constitute it. Of these, two are related to specific support for the osteoarthritis while two are items about support in general. The post-surgery decrease in the OAKHQOL social support domain was largely due to changes in these general items. This could be due to patients' perception of a decrease in global support following surgery, while the support that the patient has due to the disease remains unchanged. Besides, the advanced age could be influencing the lack of change of the social activities domain. At old age, individuals present a high change resistance; they are routinary, can put in changes within a short time but on a long term tend to become accustomed to old habits. These data agree with those obtained by Rat et al. [16], who found an SRM < 0.2 for the social domains. The social activities and social support domains are quite relevant for understanding a patient's family and social atmosphere, as well as the support networks he or she has. Likewise, social support can be considered a baseline predictor variable because of has showed to be related with better results in health [35].

The difference in the results of this social domains with respect to French study could be explained because of in our culture both domains are more closely related. In general, social activities in Spain are carried out inside our family's and friends' social support network. On the other

side, possibly in France, people have support networks out of family network; there is a deep differentiation between these two social domains. In this way, old people over there are much more independent than in Spain, being more inclined to carry out social activities out of their social support circle.

Our study has several strengths. These include the careful adaptation process following international recommendations [36], the large sample size, the inclusion of patients with hip or knee OA recruited from various hospitals around Spain, the use of several appropriate PRO instruments to assess the validity of the Spanish OAKHQOL, and testing of the instrument's responsiveness after an intervention of recognized clinical efficacy. Due to the growing number of quality-of-life questionnaires developed in other languages and other cultures, we have made every effort to guarantee that the Spanish OAKHOOL was the equivalent of the original French version. For this reason, our findings suggest good comprehension and, therefore, we did not need to modify any item. The only minor modification we made was in layout of the response options for items 11, 12, 22, and 23.

Several limitations of the study must be noted. To date, the OAKHQOL questionnaire has been tested only in France and Spain, thus its conceptual relevance and psychometric properties in other countries and cultures is unknown. Another limitation was the time interval for retesting. In this study, the interval of 2 weeks was somewhat longer than the time interval recommended (no longer than 1 week). It may be supposed that the agreement results decrease when the time interval is increased for retesting.

In conclusion, our results confirmed the psychometric properties of the translated Spanish version of the OAKH-QOL questionnaire. By comparing it with the original, we obtained similar results regarding validity, reliability, and responsiveness. These findings indicates that the Spanish OAKHQOL questionnaire is a valid tool for use in cross-sectional as well as longitudinal studies that evaluate HRQoL in patients with OA of the lower limbs. The Spanish OAKHQOL can also be used to evaluate predictors of the HRQoL after joint replacement surgery, and could facilitate decision making.

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Disclosures None



Appendix

Por favor, lea detenidamente las frases, una por una, pensando en su calidad de vida DURANTE LAS ÚLTIMAS 4 SEMANAS.

Marque la casilla que mejor corresponda a su experiencia diaria con la artrosis:

No.	'Nir	gur	10 (a	a)					N	luch	nísin	no (a)
Q1. Tengo dificultad para andar	0	1	□ 2	3	4	□ 5	□ 6	□ 7	8	9	10	
Q2. Tengo dificultad para agacharme o levantarme	0	1	2	3	4	□ 5	6	□ 7	8	9	10	
Q3. Tengo dificultad para llevar cosas pesadas	0	1	□ 2	3	4	□ 5	□ 6	□ 7	8	9	□ 10	
Q4. Tengo dificultad para bajar escaleras	0	1	□ 2	3	□ 4	□ 5	□ 6	□ 7	8	9	□ 10	
Q5. Tengo dificultad para subir escaleras	0	1	□ 2	3	□ 4	□ 5	□ 6	□ 7	8	9	□ 10	
Q6. Tengo dificultad para bañarme	0	1	□ 2	3	4	□ 5	□ 6	□ 7	8	9	10	
Q7. Tengo dificultad para vestirme (calcetines, zapatos, medias,)	0	1	2	3	4	□ 5	6	□ 7	8	9	10	
Q8. Tengo dificultad para cortarme las uñas de los pies	0	1	2	3	4	□ 5	6	□ 7	8	9	□ 10	
Q9. Tengo dificultad para moverme después de permanecer mucho tiempo en la misma postura	0	_ 1	□ 2	3	4	□ 5	□ 6	 7	8	9	10	
Q10. Tengo dificultad para entrar o salir del coche	0	1	□ 2	3	4	□ 5	□ 6	□ 7	8	9	□ 10	
Q11. Tengo dificultad para utilizara los transportes públicos (autobús, tren, metro,)	0	1	2	3	4	□ 5	6	7	8	9	10	□ No los utilizo
Q12. La artrosis afecta a mi vida laboral	0	1	2	3	4	□ 5	6	7	8	9	10	□ No trabajo
Q13. Tengo que dosificar mi actividad	0	□ 1	□ 2	3	□ 4	□ 5	□ 6	□ 7	8	9	□ 10	
Q14. Tardo más tiempo en hacer las cosas	0	1	□ 2	3	4	□ 5	□ 6	□ 7	8	9	10	
Q15. Estoy desanimado/a por el dolor	0	□ 1	□ 2	3	4	□ 5	□ 6	□ 7	8	9	10	
Q16. Temo tener que depender de los demás	0	1	□ 2	3	4	□ 5	□ 6	□ 7	8	9	□ 10	
Q17. Me asusta la idea de sufrir una discapacidad física	0	1	2	3	4	□ 5	6	7	8	9	10	
Q18. Me molesta que me miren	0	□ 1	□ 2	3	□ 4	□ 5	□ 6	□ 7	8	9	10	



No/ Ningur	no (a)							Мι	ıchí	sim	o (a)
Q19. Estoy ansioso/a	1	2	3	□ 4	□ 5	6	□ 7	8	9	10		
Q20. Me siento deprimido/a	1	2	3	□ 4	□ 5	6	□ 7	8	9	10		
Q21. Me siento incómodo/a en mi vida familiar		2	3	□ 4	□ 5	6	□ 7	8	9	10		
Q22. Me siento incómodo/a en mi vida de pareja		2	3	4	5	6	7	8	9	10		□ lo tengo pareja
Q23. Tengo limitaciones durante las relaciones sexuales	0 1	2	3	4	5	6		8 sexu			o rel las	□ No he laciones s últimas emanas
	Nu	nca									Si	iempre
Q24. Me cuesta permanecer en la misma posto durante mucho tiempo (sentado/a, de pie, inmóvil)		0	□ 1	 2	3	□ 4	□ 5	□ 6	□ 7	8	9	□ 10
Q25. Necesito un bastón (o muletas) para caminar		0	1	□ 2	3	□ 4	□ 5	□ 6	□ 7	8	9	□ 10
Q26. Tengo dolor (frecuencia)		0	1	2	3	□ 4	□ 5	□ 6	□ 7	8	9	□ 10
	Ning	ıunc)							Ins	sope	ortable
Q27. Tengo dolor (intensidad)		0	1	2	3	□ 4	□ 5	6	□ 7	8	9	□ 10
Totalmente e	en de	esac	uei	ďo			Tot	talm	nent	e d e	e ac	cuerdo
Q28. Necesito ayuda (tareas domésticas, compras,)		0	1	□ 2	3	□ 4	□ 5	□ 6	□ 7	8	9	□ 10
Q29. Tengo la sensación de envejecer prematuramen	te	0	_ 1	□ 2	3	□ 4	□ 5	□ 6	□ 7	8	9	□ 10
Q30. Soy capaz de hacer proyectos a largo plazo								•				
add. Goy dapaz do nadol proyectos a largo plazo		0	□ 1	□ 2	3	□ 4	□ 5	□ 6	□ 7	8	9	□ 10
Q31. Salgo de casa cuando me apetece		0 0	1 0		3		5 5 5					
		0	1	2	3	4	5	6	7	8	9	10
Q31. Salgo de casa cuando me apetece	e a	0 0 0	1	2 2 2	3 3	4 □ 4	5 5 5	6 6	7	8 8	9 9	10 10



N	lunca								Sie	mpre
Q35. Me pregunto qué va a ser de mí	□ □ 0 1	□ □ I 2	3	□ 4	□ 5	□ 6	□ 7	8	9	□ 10
Q36. Estoy irritable, agresivo/a	0 1	□ □ I 2	3	□ 4	□ 5	□ 6	□ 7	8	9	□ 10
Q37. Tengo la impresión de agobiar a los que me rodean	0 1	□ □ I 2	3	4	□ 5	6	7	8	9	10
No/ Nin	iguno	(a)					N	/luc	hísi	imo (a)
Q38. Temo los efectos secundarios del tratamiento	0 1	□ □ I 2	3	□ 4	□ 5	□ 6	□ 7	8	9	□ 10
Q39. Puedo contar a los demás los problemas que me causa la artrosis siempre que quiero	0 1	□ □ I 2	3	4	□ 5	6	7	8	9	□ 10
Q40. Creo que los demás entienden las dificultades que me causa la artrosis	0 1	□ □ I 2	3	4	□ 5	6	7	8	9	10
Q41. Me da apuro pedir ayuda si la necesito	□ □ □ □ 0 1	□ □ I 2	3	□ 4	□ 5	□ 6	□ 7	8	9	□ 10
Q42. Me siento apoyado/a por mis allegados (pareja, familia)	0 1	□ □ I 2	3	4	□ 5	6	7	8	9	10
Q43. Me siento apoyado/a por mi entorno (amigos, vecinos, compañeros de trabajo,)	0 1	□ □ I 2	3	□ 4	□ 5	□ 6	□ 7	8	9	□ 10

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