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Should aggregate scores of the Medical Outcomes Study 36-item Short Form Health Survey be used to assess quality of life in knee and hip osteoarthritis? A national survey in primary care

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Summary

Objective: To assess the relevance of using the aggregate physical component score (PCS) and mental component score (MCS) of the Medical Outcomes Study 36-item Short Form Health Survey (SF-36) for patients with knee and hip osteoarthritis (OA).

Methods: We conducted a cross-sectional national survey in a primary care setting in France. A total of 1474 general practitioners enrolled 4183 patients with hip or knee OA. Construct validity of PCS and MCS was assessed by convergent and divergent validity and factor analysis.

Results: Records of 4133 patients (98.8%) were analyzed (2540 knee, 1593 hip OA). PCS mean scores were 32.0 ± 8.4 and 31.8 ± 8.4 and MCS scores 47.1 ± 11.0 and 46.8 ± 11.1, for knee and hip OA, respectively. Acceptable convergent and divergent validity was observed, and correlation between PCS and MCS mean scores was low ($r = 0.14$). However, factor analysis performed on the eight subscale scores failed to support the use of PCS and MCS aggregate scores. It extracted two factors which were similar for both OA types and differed from the *a priori* stratification. Scores for two subscales usually attributed to MCS – emotional role and social functioning – were shared between factors, and scores for another subscale – general health perception – usually belonging to the PCS was in the mental component factor.

Conclusions: Our results suggest that aggregate scores from the PCS and MCS of the SF-36 as they are currently defined may not be optimal for used in hip and knee OA patients to assess health-related quality of life.

Key words: Knee, Hip, Osteoarthritis, HRQoL, Outcome measure, Survey.

Introduction

The patient point of view regarding health status has gained importance in decision-making procedures and has been considered a possible criterion standard to assess treatment efficacy[1]. Pain and physical disability, the two main symptoms of knee and hip osteoarthritis (OA) have a significant impact on health-related quality of life (HRQoL)[2]. Therefore, HRQoL has been widely accepted as one of the key outcome measures in hip and knee OA[3].

Several generic or specific instruments have been proposed to assess HRQoL in chronic illnesses. The Medical Outcomes Study (MOS) 36-item Short Form Health Survey (SF-36) has become one of the most widely used generic instruments to assess quality of life[4] and has been generalized progressively in the field of rheumatology and orthopedics[5,6]. Although the HRQoL field is continually expanding, with some debate about the relative merits of the use of generic or specific measures, most researchers recommend using one generic HRQoL tool, such as the SF-36, and one specific tool to assess outcomes in patients[7–10]. Disease-specific instruments are thought to be more sensitive to detect small but important clinical changes[7], while generic measures facilitate comparison between studies and can capture the full, even unanticipated, effects of interventions[7].

The SF-36 is composed of eight subscales that can be summarized in two aggregate scores: the physical component score (PCS), for physical functioning, physical role, bodily pain, and general health perception, and the mental component score (MCS), for mental health, vitality, emotional role, and social functioning[11]. However, the relevance of using the two aggregate scores representing the physical and mental components in knee and hip OA remains uncertain, because only one previous work, combining data from several randomized trials of both OA and rheumatoid arthritis, reported on their validity. Moreover, in this work, principal component analysis was not performed.

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Our objective was to evaluate the relevance of using the SF-36 PCS and MCS to assess HRQoL in knee and hip OA. For this purpose we assessed the construct validity of this questionnaire using convergent and divergent validity and principal component analysis followed by orthogonal rotation.

Methods

DESIGN

Data presented are from a cross-sectional survey of a national sample of general practitioners (GPs) in France assessing pain, disability and HRQoL of patients with hip and knee OA in primary care.

RECRUITMENT OF GPs

In June 2004, 2300 GPs were selected at random from a national database (MTV) according to a computerized allocation with geographic stratification and were invited to participate in the survey.

RECRUITMENT OF PATIENTS

Between September 2004 and February 2005, each GP was to enroll the first three patients consulting for knee or hip OA. Patients were included if (1) they were more than 45 years old (to avoid recruiting patients with peculiar forms of early OA that might have different repercussions on HRQoL), (2) the main motive for consulting was knee or hip OA, and (3) they had radiographic evidence of hip or knee OA. Patients were excluded if they (1) had both hip and knee OA; (2) had had surgery of the knee or hip; (3) had a disabling co-morbid disease that could interfere with HRQoL (the main co-morbid conditions were stroke, degenerative neurologic diseases, severe psychiatric disorders, chronic inflammatory arthritis, heart failure, severe respiratory disorders, systemic diseases, renal failure needing dialysis); (4) were unable to understand, speak, or write French; or (5) declined to participate.

ETHICAL APPROVAL

French bioethics legislation does not require consent from the Hospital Ethics Committee for this type of survey. The survey was conducted in compliance with the protocol Good Clinical Practices and Declaration of Helsinki principles. In accordance with the French national law, GPs and patients gave their written agreement to participate after being informed of the survey protocol.

MAIN OUTCOME MEASURE

The French version of the SF-36 was used to assess HRQoL[4,12]. This self-administered questionnaire covers eight areas: physical function, physical role, bodily pain, general health, vitality, social function, emotional role, and mental health. For each area, the score ranges from 0 (worst health status) to 100 (best health status). Scores of these eight subscales can be summarized in two aggregate scores[11]: the PCS, for physical functioning, physical role, bodily pain, and general health perception and the MCS, for mental health, vitality, emotional role, and social functioning. We did not use norm-based scoring of SF-36 profiles because data on the general population are not available in France and perceived HRQoL in the French population may differ from populations for which data are available (i.e., United States, Canada, Norway, and Sweden).

PHYSICIAN QUESTIONNAIRE

The physician self-administered questionnaire concerned demographics (age and sex) and professional data (years and environment [rural/urban] of practice).

PATIENT QUESTIONNAIRE

GPs recorded the following data about patients: demographic data (age, sex), main motive for consultation (treatment renewal, OA flare-up, OA diagnosis), clinical data (weight, height, body mass index, disease duration, OA location [hip/knee], number of days with pain during the previous month, number of days with disability during the previous month), treatments for OA, and the Lequesne index score of severity of OA[13].

The patient self-administered questionnaire concerned pain level (on an 11-point numeric scale, ranging from 0, no pain; to 10, maximal pain), patients' perceived disability (on a 6-point Likert scale, from no disability to unbearable), functional status (function subscale of the Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC] for hip OA[14,15] and modified WOMAC function subscale score for knee OA[16, 17], from 0, no disability; to 100, worst disability), and HRQoL (SF-36). This questionnaire was completed by the patient alone after the consultation at the doctor's clinic and supervised by the physician to avoid missing data.

STATISTICAL ANALYSIS

Data analysis involved use of SAS 8.2 software (SAS Institute Inc, Cary, NC, USA). Construct validity of the SF-36 PCS and MCS was investigated in four ways. Convergent and divergent analysis was assessed by correlating the questionnaire scores with scores on variables supposedly assessing similar (convergent validity) or different (divergent validity) dimensions or concepts. We assumed that the SF-36 PCS would have convergent validity with the WOMAC, Lequesne, patients' perceived disability, and pain level scores, the SF-36 MCS would have divergent validity with these measures, and that both the SF-36 PCS and MCS would have divergent validity with age, body mass index, and OA duration. Because a normal distribution could not be demonstrated for all parameters studied, the nonparametric Spearman rank coefficient (r) was used to assess the correlation between two quantitative variables. Spearman's coefficients were interpreted as excellent (>0.91), good ($0.90-0.71$), moderate ($0.70-0.51$), fair ($0.50-0.31$), or little or none (<0.31)[18]. Internal consistency was assessed with the Cronbach's α coefficient. Principal component analysis was used to extract factors, from the eight subscale scores of the SF-36. Then, independent factors were obtained by use of the varimax rotation method.

Results

PHYSICIANS' CHARACTERISTICS

A total of 1471 GPs (64% of GPs invited to participate) enrolled at least one patient. Physicians' mean age was

49 years old and most were male (85%), working in a rural environment (59%). The mean number of patients included by GPs was 2.81 ± 0.52. Geographic distribution of GPs followed that of the general population.

PATIENTS' DEMOGRAPHIC AND CLINICAL DATA

Patients' demographic characteristics and clinical data according to OA location are shown in Table I. Scores of the SF-36 subscales according to OA location are in Table II. For comparison, scores of SF-36 subscales in the general Swedish population are given (Sweden was chosen because it is the nearest European country where data from the general population are available).

Most patients (57%) visited their GP for treatment renewal, 40% for OA flare, and 3% for diagnosis of OA. According to GPs, hand OA was present in 17% of the sample, spine OA in 57%, and foot OA in 8%. Complaints induced by these other OA locations were not recorded.

CONSTRUCT VALIDITY OF THE SF-36

Table III shows the results for convergent and divergent validity of the PCS and MCS of the SF-36 for all patients and for hip and knee OA groups. Similar and acceptable convergent and divergent validity was observed, and correlation between the two scores was low, as expected ($r = 0.14$ for the whole population). PCS scores were fairly correlated with disability (Lequesne score, WOMAC score, and patient's opinion) and pain level, whereas MCS scores were poorly correlated with these outcome measures. The score from one subscale of the SF-36, general health perception, was correlated equally with PCS and MCS scores (Table IV). Cronbach α coefficients were 0.81, 0.80, and 0.82 for all patients, and knee and hip OA groups, respectively, for PCS, and 0.86, 0.85, and 0.87 for all patients, and knee and hip OA groups, respectively, for PCS.

For all patients and for both OA groups, factor analysis of the eight subscales (Table V) extracted two factors that were similar and accounted for 70% (all patients), 69% (knee OA), and 71% (hip OA) of the total variance. These factors differed from the *a priori* stratification (results most often presented when using the SF-36, that is, the two factors PCS and MCS, PCS being the mean of physical functioning, physical role, bodily pain, and general health perception scores and MCS the mean of mental health, vitality, emotional role, and social functioning scores). In fact, two subscales supposedly belonging to MCS (emotional role and social functioning) were shared between both factors and could not be clearly attributed to either, whereas general health perception, supposedly belonging to PCS, was clearly in the mental component factor. The loading of each subscale score and items after varimax rotation are shown in Table V.

Discussion

MAIN RESULTS

Our results suggest that aggregate scores from the PCS and MCS of the SF-36 as they are currently defined may not be used in hip and knee OA to assess HRQoL. The use of two aggregate scores, corresponding to physical components related to physical functioning, physical role, and bodily pain, and mental components related to mental health, general health perception, and vitality could be an alternative. This must be confirmed in further studies.

Table I
Demographic and clinical characteristics of patients with knee or hip OA

	Whole sample, $N = 4133$	Knee OA, $N = 2540$	Hip OA, $N = 1581$
Age (mean ± SD), years	67 ± 10	67 ± 10	67 ± 10
Age > 65 years (yes)	2510 (61%)	1539 (61%)	971 (61%)
Sex (M)	1703 (42%)	994 (40%)	709 (45%)
OA duration (mean ± SD), years	5.7 ± 4.9	5.9 ± 5.0	5.4 ± 4.8
Body mass index (kg/m^2)	27.7 ± 4.6	28.2 ± 4.8	27.0 ± 4.0
Main reason for consulting GPs			
Treatment renewal	2362 (57%)	1430 (56%)	932 (59%)
OA flare-up	1650 (40%)	1034 (41%)	616 (38%)
OA diagnosis	121 (3%)	68 (3%)	43 (3%)
Medications			
Analgesics (yes)	3317 (84%)	2014 (84%)	1303 (85%)
NSAIDs (yes)	3120 (79%)	1876 (78%)	1244 (81%)
SYSADOA (yes)	1725 (44%)	1086 (45%)	639 (42%)
Pain level (mean ± SD)	5.2 ± 2.0	5.2 ± 2.1	5.3 ± 2.3
Number of days with pain during the last month (mean ± SD)	17.4 ± 9.1	17.2 ± 8.9	17.7 ± 9.2
Number of days with disability during the last month (mean ± SD)	18.2 ± 9.3	18.1 ± 9.2	18.5 ± 9.4
Self-rated disability			
None	31 (1%)	18 (1%)	13 (1%)
Weak	469 (12%)	266 (11%)	203 (13%)
Moderate	1567 (39%)	957 (39%)	610 (39%)
Severe	1365 (34%)	869 (35%)	496 (32%)
Extremely severe	556 (14%)	347 (14%)	209 (14%)
Unbearable	49 (1%)	28 (1%)	21 (1%)
Lequesne index score (0–24)	11.9 ± 4.3	12.0 ± 4.2	11.8 ± 4.3
WOMAC score (0–100)	45.6 ± 18.8	45.7 ± 19.3	45.2 ± 17.3

Values are number of patients (percentages), unless indicated; NSAIDs = nonsteroidal anti-inflammatory drugs; SYSADOA = slow-acting drug for OA.

Table II
Mean ± SD health-related quality of life scores assessed by the SF-36 subscales in knee and hip OA

	Whole sample, $N = 4133$	Knee OA, $N = 2540$	Hip OA, $N = 1581$	Swedish general population, $N = 8930$*
Physical functioning	39.6 ± 24.5	40.0 ± 24.5	39.0 ± 24.6	87.9 ± 19.6
Physical role	31.8 ± 37.1	32.9 ± 37.5	30.1 ± 36.5	83.2 ± 31.8
Bodily pain	39.6 ± 15.7	39.6 ± 15.6	39.7 ± 15.8	74.8 ± 26.1
General health perception	48.7 ± 18.4	48.7 ± 18.3	48.6 ± 18.6	75.8 ± 22.2
Mental health	60.9 ± 18.8	61.1 ± 18.8	60.6 ± 18.9	80.9 ± 18.9
Emotional role	55.2 ± 43.0	55.8 ± 43.1	54.3 ± 42.9	85.7 ± 29.2
Vitality	51.4 ± 18.2	51.7 ± 18.2	51.4 ± 18.2	68.8 ± 22.8
Social functioning	60.5 ± 23.0	61.2 ± 22.7	59.4 ± 23.6	88.6 ± 20.3
PCS	31.9 ± 8.4	32.0 ± 8.4	31.8 ± 8.4	
MCS	47.0 ± 11.0	47.1 ± 10.9	46.8 ± 11.1	

*Data available at http://www.sf-36.org/nbscalc/index.shtml.

Although the PCS and MCS have acceptable convergent and divergent validity for both locations of OA, their factorial structure was not totally confirmed in this study. Less than optimal (Cronbach's α coefficients values < 0.90) but acceptable (Cronbach's α coefficients values > 0.70) internal consistency was observed > 0.70)[19]. Factor analysis extracted two factors that were distinct from the *a priori* stratification, and scores of two subscales supposedly belonging to the mental component (emotional role and social functioning) had dual-factor content and one supposedly belonging to the physical component (general health perception) was clearly in the mental component factor. The two subscales with dual-factor content also had only moderate (less than 0.7) loading in each factor, and both scores could probably be presented independently.

The factorial complexity of the SF-36 has already been pointed out by the analysis of three British surveys of adults living at home to obtain population norms for the SF-36 in the United Kingdom[20]. General health perception and vitality scores correlated equally with PCS and MCS in previous studies of French and North American populations[12, 21] and had a dual-factor content in a sample of patients with OA and rheumatoid arthritis[5]. Our results correlating each SF-36 subscale score with PCS and MCS scores confirmed those reported by Kosinski *et al.*[5], except that general health perception and vitality had a higher correlation with the MCS score in our sample than in Kosinki's study ($r = 0.57$ vs 0.47, and $r = 0.74$ vs 0.60, for general health perception and vitality, respectively). These small differences may be due to different cultural backgrounds or differences in patients recruited (strictly hip or knee OA patients in primary care in our study, and OA or rheumatoid arthritis patients recruited for randomized clinical trials in Kosinsky's study). Finally, in systemic sclerosis, factor analysis extracted three factors, the physical factor restricted to physical functioning and the mental factor to mental health and vitality[22].

Therefore, the relevance of use of the SF-36 PCS and MCS as they are currently defined, at least for study of HRQoL in knee and hip OA, is debatable. Obviously, the main advantage in summarizing HRQoL by two predefined aggregate scores is homogeneity of assessment and the ability to compare different clinical situations and settings. However, studies reporting different factorial structures of the SF-36 in different situations[5,12,20–22] raise the question of whether disease-specific SF-36 aggregate scores should be used and imply the risk of presenting scores that possibly mix apples with oranges if deciding to do so. The use of disease-specific aggregate scores does not defeat the purpose of a generic instrument. The eight SF-36 subscales are very useful to compare the HRQoL between clinical situations and between patients and the general population. The question is more about using generic summary scores because we are not sure what we are measuring and whether we are measuring the same things in different clinical situations. Therefore, use of generic summary scores to compare clinical situations should be interpreted with extreme caution.

We did not observe significant differences in SF-36 subscale scores between knee and hip OA patients, and principal component analysis followed by orthogonal rotation extracted similar factors for both locations of the disease. These results suggest that patients consulting their GPs

Table III
Convergent and divergent validity of the PCS and MCS of the SF-36 in knee and hip OA (Spearman's rank correlation coefficient)

	Whole sample, $N = 4133$		Knee OA, $N = 2540$		Hip OA, $N = 1581$	
	PCS	MCS	PCS	MCS	PCS	MCS
Lequesne index score	0.64	0.30	0.64	0.25	0.64	0.38
WOMAC score	0.65	0.39	0.62	0.37	0.68	0.42
Patient's opinion of disability	0.52	0.34	0.51	0.32	0.53	0.37
Pain level	0.58	0.36	0.57	0.33	0.59	0.42
Age	0.20	0.01	0.21	0.02	0.19	0.01
OA duration	0.22	0.02	0.22	0.02	0.22	0.03
Body mass index	0.14	0.04	0.15	0.04	0.11	0.04
PCS	1.00	0.14	1.00	0.12	1.00	0.16
MCS	0.14	1.00	0.12	1.00	0.16	1.00

Table IV
Correlation of the PCS and MCS of the SF-36 with its subscale scores in knee and hip OA (Spearman's rank correlation coefficient)

	Whole sample, $N = 4133$		Knee OA, $N = 2540$		Hip OA, $N = 1581$	
	PCS	MCS	PCS	MCS	PCS	MCS
Physical functioning	0.84	0.30	0.84	0.27	0.85	0.32
Physical role	0.70	0.42	0.71	0.41	0.69	0.43
Bodily pain	0.72	0.43	0.71	0.41	0.73	0.45
General health perception	0.58	0.57	0.58	0.56	0.58	0.58
Mental health	0.26	0.87	0.25	0.86	0.27	0.89
Emotional role	0.22	0.83	0.21	0.83	0.24	0.83
Social functioning	0.55	0.70	0.54	0.70	0.57	0.71
Vitality	0.47	0.74	0.46	0.73	0.48	0.76

for knee and hip OA have a similar level and type of HRQoL change and that similar aggregate scores could be used for patients with both types of the disease.

LIMITATIONS

We used exploratory and not confirmatory analysis to assess the factor structure of the eight subscales of the SF-36. Confirmatory analysis is considered more appropriate if the aim of a study is to confirm the existing second-order two-factor structure of the eight subscales of the SF-36[23]. However, exploratory analysis is considered appropriate if the aim of the study is to examine the factor structure of the SF-36 in a population or language in which the SF-36 has not yet been evaluated[23]. Because the factorial structure of the SF-36 in hip and knee OA with use of principal component analysis followed by rotation is unknown and only preliminary psychometric evaluation of the SF-36 in the French population has been published[12], we considered that exploratory analysis was relevant.

Although we tried to ensure a national representation of GPs, our sample differed slightly from the general population of French GPs (national register) by involving more men (85.0% vs 71.3% in the national register) who were older (49 years vs 47 years in the national register) and more likely worked in a rural environment (no reliable data available because of different definitions of rural/urban). This result has already been observed in previous national surveys of acute and subacute low back pain conducted in a primary and secondary care setting[24,25]. One explanation could be that older men working in a rural environment are more likely to participate in this type of survey. The response rate achieved was low but higher than that previously reported for this kind of survey in this setting in France[24]. Therefore, we cannot exclude the fact that our patient sample differs slightly from the knee and hip OA population consulting GPs in France. These limitations might bias the generalizability of our results. However, to our knowledge, the factorial structure of an HRQoL instrument has never been tested before in such a large sample of patients with OA.

Another possible limitation is that we used a definition of OA based on GPs opinion and X-rays with probably a poor interrater reliability of X-rays among GPs. Finally, even though hip or knee OA had to be the main complaint to be recruited for the survey, hand OA was present in 17% of the sample, spine OA in 57%, and foot OA in 8%, and we did not record complaints induced by these other OA locations that could have interfered with HRQoL.

In conclusion, the relevance of using the SF-36 PCS and MCS to assess HRQoL in knee and hip OA is debatable. Our results suggest that hip and knee OA-specific aggregate

Table V
Factor analysis and Varimax rotated factor matrix of the SF-36 with its eight subscales

SF-36 with the eight subscales of the questionnaire									
Factor	Eigenvalue			% Variance			Cumulative %		
	Whole sample	Knee OA	Hip OA	Whole sample	Knee OA	Hip OA	Whole sample	Knee OA	Hip OA
Factor 1	4.77	4.70	4.87	0.60	0.59	0.61	0.60	0.59	0.61
Factor 2	0.85	0.85	0.85	0.11	0.11	0.11	0.71	0.70	0.72

SF-36: The highest loaded subscale score is italicized, except for subscale scores that are equally correlated in both factors

Subscales	Factor 1			Factor 2		
	Whole sample	Knee OA	Hip OA	Whole sample	Knee OA	Hip OA
Physical functioning	0.30	0.30	0.30	*0.75*	*0.74*	*0.76*
Physical role	0.21	0.21	0.21	*0.82*	*0.82*	*0.81*
Bodily pain	0.33	0.33	0.35	*0.77*	*0.76*	*0.79*
General health perception	*0.74*	*0.74*	*0.75*	0.34	0.34	0.34
Mental health	*0.90*	*0.90*	*0.90*	0.19	0.18	0.20
Emotional role	0.55	0.54	0.57	0.43	0.43	0.44
Social functioning	0.63	0.62	0.64	0.57	0.57	0.58
Vitality	*0.84*	*0.84*	*0.85*	0.32	0.32	0.32

scores of the MOS SF-36 might reflect more accurately the HRQoL of patients. This has to be confirmed in further studies.

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