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Reliability and Clinically Important Improvement Thresholds for Osteoarthritis Pain and Function scales: A Multicenter study

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Abstract

Objective—To assess the reliability and clinically meaningful thresholds of intermittent and constant osteoarthritis pain (ICOAP) score, the Knee injury and Osteoarthritis Outcome Score Physical function Short-form (KOOS-PS), the Hip disability and Osteoarthritis Outcome Score Physical function Short-form (HOOS-PS), and the Quality of life subscales of HOOS/KOOS (HOOS-QOL/KOOS-QOL) in patients with knee or hip arthritis.

Methods—195 patients (141 knee, 54 hip) seen at two orthopedic outpatient clinics with a diagnosis of knee or hip osteoarthritis completed patient-reported questionnaires (ICOAP pain scale, KOOS-PS, HOOS-PS, KOOS-QOL, HOOS-QOL) at baseline and 2-week follow-up. Reliability was assessed using Intraclass correlation coefficients (ICC). We calculated minimally clinically important difference (MCID) and moderate improvement in the subgroup that reported change in their status of their affected joint.

Results—The reliability as assessed by ICCs was as follows: ICOAP pain scale, 0.63 (0.48, 0.74) in patients with knee arthritis, and 0.86 (0.73, 0.93) for hip arthritis; KOOS-PS, 0.66 (0.52, 0.77); HOOS-PS, 0.82 (0.66, 0.91); KOOS-QOL, 0.79 (0.69, 0.86); HOOS-QOL, 0.67 (0.42, 0.83). MCID and moderate improvement estimates in patients with knee arthritis were: ICOAP pain scale, 18.5 and 26.7; KOOS-PS, 2.2 and 15.0; and KOOS-QOL, 8.0 and 15.6. A smaller sample in hip arthritis patients precluded MCID and moderate improvement estimates.

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Conclusions—We found that ICOAP pain, and KOOS-PS/HOOS-PS scales were reasonably reliable in patients with hip osteoarthritis. Reliability of these scales was much lower in knee arthritis patients. Thresholds for clinically meaningful change in pain or function on these scales were estimated for patients with knee arthritis.

Keywords

Reliability; sensitivity to change; clinically important difference; Knee; Hip; arthritis; pain; function

Introduction

Recent efforts by two leading organizations, the Osteoarthritis Research Society International (OARSI) and Outcome Measures in Rheumatology Clinical Trials (OMERACT) (1, 2), have led to the development of new pain and function assessments for osteoarthritis (OA). These include the intermittent and constant osteoarthritis pain (ICOAP) score (3) and short forms of two validated function scales- the Hip disability and Osteoarthritis Outcome Score Physical function Short-form (HOOS-PS) and the Knee injury and Osteoarthritis Outcome Score Physical function Short-form (KOOS-PS) (4–6). These assessments are somewhat similar to Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (7) and are being used increasing in outcome studies in patients with OA.

Published studies have provided initial validation data for these instruments (4–6). In addition, reliability and sensitivity to change data have recently been published. ICOAP was reliable with an intraclass correlation coefficient (ICC) of 0.85 in patients with knee/hip arthritis (3) and ICC ranging 0.65–0.81 in patients who underwent knee/hip replacement surgery (8). In two studies of patients who underwent knee/hip replacement surgery, ICOAP was responsive to change with standardized response means (SRMs) ranging from 0.54–1.82 (8) and 1.02–2.29 (9), similar to other measures such as WOMAC (9), higher for hip than knee replacement. The SRMs for KOOS-PS and HOOS-PS ranged from 0.54–1.82 (8) in patients who underwent knee or hip replacement surgery. However, none of the prior studies estimated clinically important change thresholds for these instruments. In addition, validation in U.S. cohorts has not been performed.

The primary objective of this study was to examine the test-retest reliability of ICOAP pain, HOOS-PS and KOOS-PS questionnaires and the effect of age, race/ethnicity and gender on reliability in a multicenter U.S. study. We also assessed the thresholds for clinically important differences for these questionnaires in patients with knee or hip arthritis.

Methods

Study Population

This study included patients recruited in two large medical centers (Veterans Affairs Medical Center, Minneapolis, Minnesota and MD Anderson Cancer Center, Houston, Texas). Cohorts consisted of consecutive patients with a diagnosis of knee or hip osteoarthritis (OA), who had radiographic evidence of hip or knee OA and were referred to orthopedic surgeons for consideration of joint replacement surgery. Patients were excluded if they had no knee/hip OA, prior knee or hip replacement, or concomitant inflammatory arthritis, or were unable to complete the questionnaire. These patients were recruited as a part of an international multicenter study of patients with knee or hip pain, details of the original study are described elsewhere (10). As a part of the original study, patients completed pain, function and quality of life assessments at the initial visit only. For this

study, each patient who completed the baseline survey at the two U.S. centers also received the same survey by mail at 2-weeks to test reliability and clinically important improvement thresholds. The study was approved by the Institutional review boards (IRBs) at the Minneapolis VA medical center and the MD Anderson Cancer Center.

Validation and Statistical analyses

All patients received a repeat survey at 2-weeks of the first survey with the same instruments as the first survey with two additional questions. The first additional question in the survey was whether they had undergone a joint replacement in the joint for which they were evaluated. The second additional question was "Since the last time you completed the survey 2 weeks ago, would you say your hip (or knee) arthritis is: A great deal better, somewhat better, about the same, somewhat worse or a great deal worse." Patients were asked to choose one of the response options. Patients were included in the analyses if they had not undergone joint replacement surgery, had answered the second question and returned their survey. Sensitivity analyses were performed in a subset that responded within 20 days of the first survey (extra 6-day window allowed for delay due to mailing time).

Each patient completed the following self-reported validated questionnaires: (1) Knee or hip function assessment -- either the Hip disability and Osteoarthritis Outcome Score Physical function Short-form (HOOS-PS) for hip or the Knee injury and Osteoarthritis Outcome Score Physical function Short-form (KOOS-PS) for knee for function (4–6), developed as short forms for assessments of physical function translated into multiple languages (11) (12); (2) pain assessment with intermittent and constant osteoarthritis pain (ICOAP) score (3)(9) translated into other languages (13) (14) (15); and (3) KOOS knee-related quality of life, KOOS-QOL and HOOS-QOL subscales of the original KOOS and HOOS questionnaires (16, 17). The score range for ICOAP pain, KOOS-PS and HOOS-PS is 0–100, 100 being the worst. The score range for KOOS-QOL and HOOS-QOL is 0–100, 100 being the best. ICOAP pain questionnaire has 11 questions, which are used to calculate the overall ICOAP pain; of these 5 questions related to constant pain and 6 questions to intermittent pain, which are used to calculate ICOAP intermittent pain and ICOAP constant pain scores, all three ICOAP pain scores ranged 0–100. ICOAP, KOOS-PS and HOOS-PS were administered as complete instruments; KOOS-QOL and HOOS-QOL are one of the 5 subscales of the original KOOS and HOOS questionnaires (17–19) that were administered as part of the original study (10), while other four subscales were not administered to reduce patient burden and due to relevance of the original study.

Those 110 patients who reported their hip (or knee) arthritis being "about the same" were included for the reliability/reproducibility analyses. We used intraclass correlation coefficients (ICC) to assess the correlation between baseline and follow-up assessments. 95% confidence intervals and p-values were presented. ICC was also calculated for patient subgroups by age, gender, race/ethnicity as follows: (1) age group: <65 vs. ≥65 year old; (2) gender; (3) race/ethnicity: Caucasian vs. non- Caucasian. We used one-way ANOVA to compute the ICC and determine the between subject variation and within subject variation as a measure of test–retest reliability.

Patients who chose that their knee (or hip) arthritis was great deal better or somewhat better constituted the datasets used for estimating minimal clinically important difference (MCID) for improvement (=somewhat better), as recommended (20–22), similar to previous studies (23, 24) and moderate improvement (=a great deal better), respectively. This was calculated as the mean of the difference between baseline and follow-up score for each patient reporting that their arthritis was better since last survey. We also calculated Minimal Detectable Change (MDC) using a statistical anchor to estimate of meaningful change, i.e.,.

(25) All analyses were performed using SAS, the Statistical Analysis System, version 9.3. Statistical significance was set at 0.05.

Results

Study Population

Clinical and demographic characteristics of the source and study populations are summarized in Table 1. Of the 107 patients in Minneapolis and 176 patients in Houston recruited for the original study that included the baseline survey (10), 83 patients from Minneapolis and 112 patients from Houston (total 195 patients) returned follow-up mailed surveys and constituted the analytic dataset (Table 1). Of these, 79 patients from Minneapolis and 71 patients from Houston returned their 2-week surveys within 20-days of the first survey and constituted the dataset for sensitivity analyses. Thus, this study included 195 patients- 141 had knee OA and 54 had hip OA. Four patients did not answer the patient global question, so were not eligible for reliability or sensitivity to change analyses.

The mean age of the patients was 61 years, 43% were female, 74% were Caucasians, 66% were married and the mean BMI was 33.9 kg/m^2. The mean (standard deviation) time to second survey completion and receipt was 17.6 days (±6.8).

Compared to responders, non-responders to the follow-up survey were younger (57 versus 61 years; p=0.0065), but had no significant differences in marital status, education level, ethnicity and employment status.

Clinically Important Change for Improvement

For patients reporting change in knee or hip arthritis transition question, we calculated estimates for MCID and moderate improvement. The distribution of patients in these categories is presented in Table 2. The baseline and follow-up scores in patients who improved somewhat, a great deal or were about the same are shown in Table 3. The MCID estimates for improvement in ICOAP pain, ICOAP constant pain and ICOAP intermittent pain were 18.5, 18.7 and 18.4 respectively; respective moderate improvement estimates were 26.7, 29.6 and 24.3. For KOOS-PS, MCID and moderate improvement were 2.2 and 15.0 (Table 4). MCID and moderate improvement estimates for KOOS-QOL were 8.0 and 15.6, respectively (Table 4). Sensitivity analyses with 150 patients showed minimal changes (Appendix 6–7).

Reproducibility/Reliability

110 patients (81, knee arthritis; 29 hip arthritis) reported that their arthritis was about the same as at the time of baseline survey. They constituted the analytic dataset for the assessment of reproducibility/reliability (Table 5). The ICC was 0.63 for ICOAP pain in knee and 0.86 in hip arthritis patients. Respective ICCs for ICOAP constant pain were 0.57 and 0.81 and for ICOAP intermittent pain were 0.64 and 0.83. ICC was 0.66 for KOOS-PS and 0.82 for HOOS-PS (Table 5). ICC for KOOS-QOL was 0.79 and for HOOS-QOL was 0.67.

Variation in reproducibility of ICOAP pain, HOOS/KOOS PS and QOL by age, gender and race/ethnicity is presented in Appendix 1. We noted variation in reproducibility in KOOS-PS by gender and race/ethnicity and by race/ethnicity in KOOS-QOL. In the hip cohort, variations in reproducibility for HOOS-PS and HOOS-QOL were noted by race/ethnicity (Appendix 1). Socio-demographic and clinical characteristics of sensitivity cohort is shown in Appendix 2. Sensitivity analyses with 150 patients showed minimal changes compared to the main analyses of the cohort of 195 patients (Appendix 3–5).

Discussion

In this two-center study of ethnically diverse U.S. cohorts, we found that three assessments of pain and function, i.e., ICOAP, KOOS-PS and HOOS-PS, were reproducible in patients with knee and hip arthritis. Reproducibility/reliability of ICOAP pain, HOOS-PS and KOOS-PS was good in hip OA (0.82–0.88) and moderate in patients with knee OA (0.52–0.66). Reliability varied somewhat with age, gender, and race/ethnicity, as expected. Our study also provided reliability statistics for KOOS-QOL and HOOS-QOL scales. We also present estimates for MCID and moderate improvement for these scales in patients with knee arthritis.

The main finding from our study was that ICOAP, KOOS-PS and HOOS-PS had moderate to good test-retest reproducibility. In a recent single center study in Europe that assessed test-retest reliability at 2-weeks in OA patients that later underwent joint arthroplasty, ICCs for ICOAP, HOOS-PS and KOOS-PS scales ranged 0.80–0.84 in hip and 0.65–0.85 in knee patients, similar to WOMAC (8). Our ICCs were within this previously reported range, thus our multicenter study confirms this earlier finding in a more ethnically diverse population. The study cohorts were assembled similarly in the two studies. However we had a racial/ethnically diverse population compared to the previous study, which might partially explain a ICCs towards the lower end of the range in our knee cohort. Another potential reason for lower ICC in knee cohort may be due to a week-to-week variation in knee pain that is not captured in the global question asking about the worsening of arthritis. The ICCs may also differ due to differences in prevalence of disease, which has been shown to impact ICC (26) or due to random variation, given a small sample size for hip cohort. The studies differed in that we only analyzed patients who reported no change in the status of their knee/hip arthritis between two visits (56.4% of the cohort) versus analyses of all patients in the previous study (since transition question was not asked) for reliability assessment, a more conservative approach. In our study, reliability for KOOS-QOL and HOOS-QOL were 0.79 and 0.67, respectively, lower than the ICC of 0.89 reported for the Persian version of KOOS-QOL (27). This may be due to minor content differences due to translation, difference in study populations.

We noted minimal variation in reproducibility for pain and minimal to moderate variation in reproducibility for QOL assessments by various patient characteristics including age, gender and race/ethnicity. Most 95% confidence intervals were overlapping, signifying that these differences were not statistically significant in this small sample, indicating the lack of difference or the lack of power to detect a small difference. These findings highlight the impact of patient characteristics on patient-reported outcomes. This is not unexpected and has been reported previously with Short-form 36 with reliability ranging 0.65 to 0.94 across patient groups (28). However, reliability variation has not been studied in previous validation studies of most other instruments. Thus, our adds to the existing body of knowledge. One must also not over-interpret these findings that need to be reproduced. These findings also suggest that future studies reporting on validity of instruments should consider performing the statistics by gender, race and age, which could all provide useful guidance to the users of the instruments. This also raises a question, whether various validation characteristics of instruments, such as MCID and validity statistics that are usually reported for overall populations and not for individual subgroups, are more accurate and applicable to some patient subgroups than others. This is likely the case, since the overall average incorporates a range among respondents. This is a broad research agenda, not limited to these instruments, that needs more attention

Our study provides estimates of clinically important improvement by estimating MCID and moderate improvement for these instruments in patients with knee OA, thus adding to the

current knowledge; the hip OA sample was not large enough to perform analyses. ICOAP (8) (9), HOOS-PS and KOOS-PS (8) have been shown be sensitive to change in previously published studies in patients who underwent knee or hip arthroplasty, surgeries demonstrated to be associated with significant improvements in pain and function after knee/hip joint replacement, similar to WOMAC. Thus, these measures have desirable psychometric properties.

Estimation of clinically meaningful changes are critical for validated instruments, since these provide guidance for calculating sample sizes for studies aimed at examining patient-relevant outcomes and comparing different interventions in patients with knee/hip OA or those undergoing arthroplasty, such as comparing arthroplasty implants or treatment pathways. Moderate improvement represents really important change for the patients. For knee cohort, moderate improvement was estimated at 27 units for ICOAP pain scale, 30 units for ICOAP constant pain and 24 units for ICOAP intermittent pain. To our knowledge, this is the first study to provide MCID and moderate improvement estimates for these validated scales. We also provided estimates for MCID for KOOS-PS and KOOS-QOL. These thresholds represent meaningful changes that can be appreciated by patients as above and beyond the daily variation. Future studies should estimate MCID and moderate improvement for hip OA patients, since due to only a few patients providing this information we were unable to estimate these.

Our study findings must be interpreted considering study limitations. Patients in this study were recruited from orthopedic offices where they were assessed for potential evaluation for joint replacement surgery and these estimates may be different for populations with milder arthritis or other causes of knee pain and in younger patients. Our study was not powered to examine differences in reliability by patient characteristics (age, gender and race) and therefore we may have missed small differences. Despite reasonable study sample size, we had a small sample for estimating clinically important differences, especially for moderate improvement estimations (standard errors were large) and for assessing reliability in the hip cohort. Although similar sample sizes have been used to derive reliability and validation statistics (29–31), our confidence in these estimates is not high. A small sample also did not allow us to examine MCID and moderate improvement thresholds by categories of baseline scores. More studies are needed to confirm our estimates in larger groups of patients. Study strengths include that this was a multicenter study, recruited a significant number of minority patients and women and assessed instruments that are relevant to patients with OA.

In summary, we found that in the hip cohort ICAOP pain, HOOS-PS, and HOOS-QOL had moderate-high reliability. Reliability was moderate for ICOAP pain and KOOS-PS and high for KOOS-QOL in the knee cohort. Our study provided estimates for clinically meaningful changes for improvement for these assessments, which can be used to calculate sample sizes for future randomized and cohort studies and allow comparison of different treatment modalities/implants. Future studies should assess whether our estimates for clinically meaningful changes in patients with knee or hip arthritis are stable across other populations.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Clinical and Demographic features of the all source population and overall study cohort that responded to both baseline and follow-up survey

	All (n=195) n (%) of Mean (SD)	**Houston (n=112) n (%) of Mean (SD)**	**Minneapolis (n=83) n (%) of Mean (SD)**
Age in Years	60.8 (±11.4)	60.1 (±8.9)	61.8 (±14)
BMI (kg/m^2)	33.9 (±7.2)	34.9 (±7.7)	32.6 (±6.4)
Duration of symptoms in months	111.1 (±129.9)	92.4 (±114.2)	138.4 (±146.3)
Gender			
Female	83 (42.6%)	77 (92.8%)	6 (7.2%)
Male	112 (57.4%)	35 (31.3%)	77 (68.8%)
Marital Status			
Married	129 (66.2%)	78 (60.5%)	51 (39.5%)
Not Married	66 (33.8%)	34 (51.5%)	32 (48.5%)
Education			
Above college	67 (34.4%)	44 (65.7%)	23 (34.3%)
Some college	100 (51.3%)	54 (54%)	46 (46%)
High school or below	27 (13.8%)	14 (51.9%)	13 (48.1%)
Ethnicity			
Black	37 (19%)	34 (91.9%)	3 (8.1%)
Hispanic	6 (3.1%)	5 (83.3%)	1 (16.7%)
Non-Hispanic white	144 (73.8%)	68 (47.2%)	76 (52.8%)
Other	8 (4.1%)	5 (62.5%)	3 (37.5%)
Employment Status			
Employed	85 (43.6%)	60 (70.6%)	25 (29.4%)
Other	109 (55.9%)	52 (47.7%)	57 (52.3%)
Lives alone			
No	140 (71.8%)	84 (60%)	56 (40%)
Yes	54 (27.7%)	28 (51.9%)	26 (48.1%)
ICOAP Pain	53.9 (±22.3)	54.8 (±22.5)	52.6 (±22.2)
ICOAP constant pain	51.1 (±25.6)	51.7 (±25.6)	50.1 (±25.6)
ICOAP intermittent pain	56.3 (±22.8)	57.4 (±23)	54.7 (±22.6)

	All (n=195) n (%) of Mean (SD)	Houston (n=112) n (%) of Mean (SD)	Minneapolis (n=83) n (%) of Mean (SD)
HOOS-PS/KOOS-PS	55 (±20)	55.7 (±18.9)	54 (±21.4)
HOOS-QOL/ KOOS-QOL	26.9 (±20.9)	24 (±20.3)	30.7 (±21.1)

Table 2

Patients by response to the patient global question at follow-up survey

Since the last time you completed the survey 2 weeks ago, would you say your hip (or knee) arthritis is:	**Combined (n=191[a]) N (%)**	**Houston (n=112) N (%)**	**Minneapolis (n=79[a]) N (%)**
A great deal better	14 (7%)	8 (7%)	6 (8%)
Somewhat better	32 (17%)	21 (19%)	11 (14%)
About the same	110 (58%)	58 (52%)	52 (66%)
Somewhat worse	27 (14%)	22 (20%)	5 (6%)
Great deal worse	8 (4%)	3 (3%)	5 (6%)

[a] 4 patients from Minneapolis site did not respond to the this transition question at the follow=up survey; p=0.05, comparing Houston to Minneapolis site

Table 3

Mean scores on instrument subscales at baseline and follow-up in patients with knee symptoms[a]

		Patient global on follow-up		
	Baseline	**Great deal better**	**Somewhat better**	**About the same**
KNEE	**N=141**	**N=12**	**N=26**	**N=81**
ICOAP Pain	53.3 (±23.0)	17.4 (±12.2)	41.3 (±14.1)	47.4 (±22.0)
ICOAP constant pain	50.7 (±26.0)	13.8 (±13.3)	38.5 (±19.7)	43.0 (±24.3)
ICOAP intermittent pain	55.5 (±23.3)	20.5 (±14.9)	43.6 (±15.5)	51.1 (±22.1)
HOOS-PS/KOOS-PS	54.5 (±19.4)	31.4 (±12.2)	52.1 (±17.4)	51.0 (±18.5)
HOOS-QOL/KOOS-QOL	27.4 (±21.1)	59.4 (±19.9)	34.8 (±16.5)	29.5 (±20.2)

N=141

[a] Only 1 and 5 patients reported feeling great deal better or somewhat better among those with hip symptoms, thereby not allowing us to perform meaningful analyses for patients with hip symptoms

[b] N=20 and N=69 for the respective categories for HOOS-QOL/KOOS-QOL scores; 11 patients reported worse status on patient global question

Table 4

Minimal Clinically Important Difference (MCID) and Moderate Improvement thresholds in patients with knee symptoms

	Improvement in score Mean (SD)	Relative (%) improvement in score	MDC90
ICOAP Pain (scale 0–100)			
Moderate Improvement (=“great deal better”) (N=12)	−26.7 (±14.8)	−60.5%	49.6
MCID Improvement (=“somewhat better”) (N=26)	−18.5 (±22.0)	−31.0%	46.6
ICOAP Constant Pain			
Moderate Improvement (=“great deal better”) (N=12)	−29.6 (±14.8)	−68.3%	53.8
MCID Improvement (=“somewhat better”) (N=26)	−18.7 (±24.4)	−32.7%	49.6
ICOAP Intermittent Pain			
Moderate Improvement (=“great deal better”) (N=12)	−24.3 (±17.9)	−54.3%	48.7
MCID Improvement (=“somewhat better”) (N=26)	−18.4 (±25.4)	−29.7%	50.8
KOOS-PS (scale 0–100)			
Moderate Improvement (=“great deal better”) (N=12)	−15.0 (±16.4)	−32.3%	35.5
MCID Improvement (=“somewhat better”) (N=26)	−2.2 (±17.5)	−4.0%	28.3
KOOS-QOL (scale 0–100)			
Moderate Improvement (=“great deal better”) (N=12)	15.6 (±18.8)	35.7%	39.0
MCID Improvement (=“somewhat better”) (N=25)	8.0 (±16.1)	25.7%	29.0

Relative (%) improvement in score was calculated as = **100*** (followup score mean−baseline score mean)/baseline score mean

Table 5

Reproducibility assessed with intraclass correlation coefficients in knee and hip patients

	Intra-class coefficient (95% confidence interval)	
	Knee (n=81)	**Hip (n=29)**
ICOAP pain	0.63 (0.48, 0.74)	0.86 (0.73, 0.93)
ICOAP constant pain	0.57 (0.40, 0.70)	0.81 (0.64, 0.90)
ICOAP intermittent pain	0.64 (0.49, 0.75)	0.83 (0.68, 0.91)
KOOS-PS	0.66 (0.52, 0.77)	N/A
HOOS-PS	N/A	0.82 (0.66, 0.91)
KOOS-QOL	0.79 (0.69, 0.86)	N/A
HOOS-QOL	N/A	0.67 (0.42, 0.83)