

Cross-cultural adaptation and validation of the Persian version of the Intermittent and Constant Osteoarthritis Pain Measure for the knee

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ABSTRACT

Objective: The present study aimed to translate and evaluate the reliability and validity of the Persian version of the 11-item Intermittent and Constant Osteoarthritis Pain (ICOAP) measure in Iranian subjects with Knee Osteoarthritis (KOA).

Materials and Methods: The ICOAP questionnaire was translated according to the Manufacturers Alliance for Productivity and Innovation (MAPI) protocol. The procedure consisted of forward and backward translation, as well as the assessment of the psychometric properties of the Persian version of the questionnaire. A sample of 230 subjects with KOA was asked to complete the Persian versions of ICOAP and Knee injury and Osteoarthritis Outcome Score (KOOS). The ICOAP was readministered to forty subjects five days after the first visit. Test–retest reliability was assessed using Intraclass Correlation Coefficient (ICC), and internal consistency was assessed by Cronbach’s alpha and item-total correlation. The correlation between ICOAP and KOOS was determined using Spearman’s correlation coefficient.

Result: Subjects found the Persian-version of the ICOAP to be clear, simple, and unambiguous, confirming its face validity. Spearman correlations between ICOAP total and subscale scores with KOOS scores were between 0.5 and 0.7, confirming construct validity. Cronbach’s alpha, used to assess internal consistency, was 0.89, 0.93, and 0.92 for constant pain, intermittent pain, and total pain scores, respectively. The ICC was 0.90 for constant pain and 0.91 for the intermittent pain and total pain score.

Conclusion: The Persian version of the ICOAP is a reliable and valid outcome measure that can be used in Iranian subjects with KOA.

Key words: Intermittent and constant osteoarthritis pain measure, knee osteoarthritis, pain, pain questionnaire, Persian, reliability, validity

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INTRODUCTION

Osteoarthritis (OA) is a range of pathologic alterations in the synovial joints,^[1] most commonly affecting the knee.^[2] Painful OA is important because of the consequences such as physical disability and handicap, lost time at work and early retirement, reduced independence, and increased healthcare utilization.^[3,4] Thus, these subjects may seek specialized care to eliminate pain that is guaranteed by rehabilitation and nursing specialists.^[5] Pain is the most common reason for primary care visits by OA clients, is responsible for the majority of nonsteroidal

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antiinflammatory drug (NSAID) use, and is one of the most important causes of joint replacement surgery.^[6] Subjective client-oriented measurement of pain is critically valuable to improve and personalize nursing and rehabilitation services to KOA clients. Clinical outcomes are essential to determine the advantages and cost effectiveness of new diagnostic, surgical, and rehabilitative protocols. Clinicians and researchers are looking for instruments to measure pain in subjects with KOA that are patient-oriented, simple, and accessible,^[7] and that measure pain independent of its impact on physical function.^[8] As OA progresses, it has been found that people experience two distinct types of pain: A dull aching pain that is more regular and an irregular pain that often is more intense, unpredictable,^[9] and has a greater impact on quality of life (QOL) than background aching pain.^[10] Therefore, the Intermittent and Constant Osteoarthritis Pain (ICOAP) measure was developed in 2010 under the sponsorship of Outcome Measure in Rheumatology Clinical Trial/Osteoarthritis Research Society International (OMERACT/OARSI) initiative.^[11] ICOAP has been showed to be reliable, valid, and responsive to changes in OA pain following both pharmacological and surgical interventions.^[4,10,12] Two versions of ICOAP are available to evaluate pain in knee and hip OA.^[13] As a non-copyrighted questionnaire, ICOAP may be easily downloaded from the OARSI website and be completed via interview, phone, or self-report in less than 10 minutes.^[8] ICOAP has been used in numerous studies.^[8,9,14-16] It has been translated and cross-culturally adapted to German,^[17] Portuguese,^[18] Czech, Dutch, French (France), Italian, Norwegian, Spanish (Castilian), North and Central American Spanish, and Swedish.^[8,13] Cross-cultural adaptation to all of these languages had been studied and published in a multicenter research;^[8] ICOAP has been approved for multicenter international studies.^[8] The present study was designed to provide the Persian version of ICOAP and to compare its psychometric properties with the original and other versions.

MATERIALS AND METHODS

This methodological study was conducted by participation of 230 Iranians with KOA.

Translation process

Questionnaire translation was in accordance with the protocol recommended by the Manufacturers Alliance for Productivity and Innovation (MAPI), including forward translation into Persian, backward translation into English, face validation, and validation of the consolidated version. Translations and cross-cultural adaptations were conducted in parallel under the responsibility of the main investigator (ZSR).^[19]

For translation into Persian, the original version of questionnaire was given to two bilingual translators; the translators were blinded to the study protocol and to each other's translation. In a session, the translators and the research team discussed both Persian translations to finalize a merged Persian version. This version was given to a team of knee rehabilitation specialists for assessment of the content validity.

The preliminary Persian version then was translated back into English by two translators, different from previous two translators, who were unaware of the original English and were blinded to the study protocol. The backward translations were merged into one by another team of knee rehabilitation specialists. The team was also blind to the original version of the questionnaire. The main investigator explained the concept to the team throughout the session in cases. The finalized consolidated English translation was sent to the developer of the original questionnaire to assess its conceptual equivalency. For assessing the face validity, 40 subjects were requested to complete the questionnaire. There was no report of ambiguity in understanding the questions.

Participants

Between winter 2014 and spring 2015, a convenience sample of 230 Iranian subjects with symptomatic knee OA (KOA) were recruited from state and private hospitals, physical therapy clinics, and orthopedic and rheumatologic doctors' offices in Isfahan, Iran. After checking for inclusion and exclusion criteria, clinical signs and symptoms, and studying their X-ray findings, the eligible subjects were requested to sign an informed consent. Native Persian speakers were included if they were between 40 and 80 years old, with an intermediate or higher educational level. Illiterates were not included in the study. Eligible subjects were those with a diagnosis of unilateral or bilateral KOA according to the clinical and radiographic criteria established by the American College of Rheumatology (ACR),^[20] Kellgren-Lawrence grade one to four on radiographs,^[21] and pain intensity more than three on a 11-point Visual Analog Scale (VAS).^[22] In bilateral knee involvement, the grade of the worst knee was recorded as the K-L grade of joint involvement. Subjects were excluded if they had previous knee injury or surgery within the last year,^[10] prior arthroplasty of any joint of either lower extremity,^[10] fracture of either lower extremities within 6 months,^[22-24] presence of rheumatoid arthritis or any inflammatory arthritis, fibromyalgia, chronic low back pain,^[10] intra-articular steroid or HyLAN G-F20 injection within the previous 6 months,^[22-24] any type of pain management for KOA including medications, physical therapy, within 2 months prior to the study.

Instruments

A questionnaire was used to assess subjects' gender, age, body mass index (BMI), occupation, level of education, illness duration, and the number of involved knee joints.

For evaluating the definite effect of physical fitness on the pain perception in KOA subjects,^[10] the level of physical activity was also recorded using the Persian version of Tegner' Scale,^[25] which is approved as a valid and reliable grading instrument.^[26]

Subjects' pain was recorded using ICOAP. ICOAP consists of 11 items in two domains: A five-item scale assessing constant pain and a six-item scale assessing intermittent pain.^[8] For each pain type, a single item assesses pain intensity, effect on sleep, impact on QOL, extent to which the pain "frustrates or annoys," and the extent to which it "worries or upsets." For intermittent pain, two additional items including the frequency of pain and the degree to which the pain could be predicted, are also included.^[10] Items are scored on a Likert style from zero to four, where higher scores indicate worse pain. A score is separately produced for constant pain subscale (0–20) and intermittent pain subscale (0–24) and for total pain (0–44) according to the ICOAP user' guide, which is available on the OARSI website.^[27] Normalized scores for the two subscales and for the total pain are then calculated from zero (no pain) to 100 (extreme pain). Participants were asked to complete the questionnaire for the target joint (the worst/most troublesome knee) in the past week (i.e., past 7-day period).^[8,13]

The KOOS consists of 42 questions in five separate domains including symptoms (seven items), pain (nine items), function in daily life (or Activity of Daily Living (ADL): 17 items), function in sport and recreational activities (Sport/Rec: Five items), and quality of life (QOL: Four items). In the present study, only KOOS pain and symptoms subscales were administered for comparison and validating the ICOAP because ICOAP seeks pain characteristics in various daily situations; we hypothesized that ICOAP would have a stronger correlation with KOOS pain subscale than with the KOOS symptoms subscale. Pain subscale of KOOS provides information about frequency of knee pain and severity of knee pain in some activities such as twisting/pivoting on knee, straightening and bending knee fully, climbing upstairs, at night in bed, sitting or lying, standing and walking. KOOS symptoms asks about swelling, feel grinding/friction, clicking/cracking, locking at moving, ability to straighten and bend knee fully, severity of knee joint morning stiffness, and stiffness following sitting and lying.

For scoring each item, a five-point Likert scale ranging from zero (no problems) to four (extreme problems) is used.

KOOS-pain score is presented in percent (0–100 scale), with zero indicating extreme problems and 100 indicating no problems, calculated for each subscale separately.^[7] KOOS has been culturally adapted into Persian for subjects with knee injuries.^[7]

Measurement of psychometric properties

The Persian version of the questionnaire was self-administrated by 230 subjects with KOA.

Reliability

The ICOAP was readministered to 40 of the 230 subjects five days after the first visit to evaluate the instrument's test–retest reliability. The subjects were requested to complete the questionnaire for the same joint as previously reported for the prior week. Test–retest reliability of the ICOAP was analyzed using Intra-class Correlation Coefficient (ICC) to estimate the amount of variation over time. An ICC of ≥ 0.70 was considered acceptable.^[7,28] Internal consistency, an additional measure of reliability, was measured using Cronbach's alpha and item-total correlations. A Cronbach's alpha of ≥ 0.70 was considered satisfactory.^[18,28] Item-total correlation for each item in the subscales and total scores of 0.30 or higher was considered acceptable.^[7,18,28] In comparing first and second administration results, item by item comparisons were performed using the Mann–Whitney U test; *P* values of ≥ 0.05 were considered acceptable. We also reported minimal detectable change (MDC) as an additional parameter.^[29]

Validity

Construct validity can only be assessed by hypothesized patterns of associations with other validated instruments.^[7,18] In the present study, KOOS pain and symptoms subscales were administered as the validated instrument.

Construct validity was analyzed using Spearman's rank correlation with a correlation coefficient of 0.4 to 0.7 considered acceptable.^[10] The reference level of significance was set at 0.05. Statistical analyses were conducted using the Statistical Package for the social sciences (PASW statistics 18 (2009), SPSS Inc., Chicago, USA).

The Ethics Committee at the Isfahan University approved the entire study procedure (Approval code: 393823). All eligible subjects signed an informed consent prior to the study.

RESULTS

Demographic characteristics of the study sample are presented in Table 1. A total of 230 subjects (190 females and 40 males) were included in the study, out of which

Table 1: Demographic characteristics of the study sample

Parameter	Mean (SD)/count (%)
Age (years)	56.6 (10.6)
Height (m)	1.6 (0.1)
Weight (Kg)	75.8 (11.7)
Body mass index (Kg/m ²)	29.2 (4.4)
Illness duration (years)	3.6 (3.0)
Pain Intensity (visual analog scale: %)	67.5 (15.8)
Gender (%)	
Men	40 (17.4)
Women	190 (82.6)
Education (%)	
Elementary	145 (63)
High school	54 (23.5)
College or higher	31 (13.5)
Do you have any problem in your activity of daily living because of your knee pain? (%)	
Yes	108 (47)
No	122 (53)
Do you feel stiffness in your knee joint? (%)	
Yes	207 (90)
No	33 (10)
Because of your knee joint problem, do you have difficulty using stairs? (%)	
Yes	191 (83)
No	39 (17)
Tegner's score (%)	
0	7 (3)
1	47 (20.4)
2	65 (28.3)
3	78 (33.9)
4	28 (12.2)
5	5 (2.2)
Kellgren-Lawrence scale for the target knee (%)	
1	74 (32.2)
2	100 (43.5)
3	50 (21.7)
4	6 (2.6)
Affected knee (%)	
Right	29 (12.6)
Left	35 (15.2)
Both sides	166 (72.2)
Symmetry (%)	
Unilateral	63 (27.4)
Bilateral symmetrical	140 (60.9)
Bilateral asymmetrical	27 (11.7)

SD: Standard deviation

40 subjects were reassessed in the reliability study. There were no missing data for any individual item of the ICOAP,

KOOS pain, and KOOS symptoms subscales. MDC was 4.31 for constant pain and 4.42 for both the intermittent pain and total pain score.

Translation process

The preliminary version of the Persian ICOAP questionnaire was well-accepted in the face validity phase. All the questions and response options were considered satisfactorily comprehensible by the subjects.

Reliability

As shown in Table 2, Cronbach's alpha coefficients (≥ 0.89), corrected item-total correlations (0.59–0.84), and ICCs (≥ 0.90) were acceptable. Based on the results of paired comparisons [Table 3], after five days the participants' responses did not change significantly; the only exceptions were in item 1 (constant pain intensity) which increased significantly ($P = 0.01$) and item 6 (intermittent pain intensity) which decreased significantly ($P = 0.03$). In addition, the intermittent pain subscale score reduced significantly after five days ($P = 0.02$).

Construct validity

Negative correlations existed between ICOAP and KOOS. Correlations between the scores of ICOAP and KOOS subscales are presented in Table 4. Statistically significant correlations were found for ICOAP constant pain with KOOS pain (-0.7) and with KOOS Symptoms (-0.6). The correlation between ICOAP intermittent pain and total pain scores with KOOS pain and symptoms was relatively lower, but acceptable (correlation coefficient ≥ -0.5). Stronger correlation was recorded between ICOAP constant pain, intermittent pain and total pain scores, and KOOS pain score than those with the KOOS symptom score.

DISCUSSION

The results of the present study indicated that the Persian version of ICOAP is a reliable and valid measure of KOA pain. In line with the results of the previous studies on cross-cultural adaptation of ICOAP into various languages,^[8,17,18] Persian translation of ICOAP was easy to understand for native Persian speaking subjects. Easily understandable phrasing of ICOAP questions and response options facilitated simple convenient forward translation into Persian. The primary Persian translation was comprehensible and simple to complete. Like other versions,^[8] the majority of the participants found the questionnaire easy to understand and complete and reported the questions to be good descriptions which fit with their feelings. Similar to the original version of the questionnaire,^[8] few subjects (less than five people) were confused about the concepts of the constant and intermittent

Table 2: The results for the reliability study

	First Administration	Second Administration	Intra-class correlation coefficient ¹	Cronbach's alpha ²	Item-total correlation ³
	Mean (SD)	Mean (SD)			
Constant pain	49.0 (24.5)	46.0 (24.1)	0.90*	0.89*	0.66-0.78*
Intermittent pain	48.0 (24.0)	42.9 (25.4)	0.91*	0.93*	0.68-0.84*
Total pain score	48.4 (22.3)	44.3 (22.8)	0.91*	0.92*	0.59-0.78*

¹Acceptable Intra-class correlation coefficients ≥ 0.70 , ²Acceptable Cronbach's alpha coefficients ≥ 0.7 , ³Acceptable item-total correlations ≥ 0.3 , *Acceptable reliability coefficients. SD: Standard deviation

Table 3: Item by item comparison between the first and second filled ICOAP questionnaires

Number	The ICOAP Item	P value
	Wording	
1	In the PAST WEEK, how severe was your constant knee pain?	0.01*
2	In the PAST WEEK, how much has your constant knee pain affected your sleep?	0.60
3	In the PAST WEEK, how much has your constant knee pain affected your overall quality of life?	1.00
4	In the PAST WEEK, how much hurt and frustration have you felt due to your constant knee pain?	0.11
5	In the Past Week, how much sadness or anxiety have you had due to your constant knee pain?	0.26
6	In the PAST WEEK, how severe was your knee pain that comes and goes?	0.03*
7	In the PAST WEEK, how often has your knee pain that comes and goes, repeated?	0.38
8	In the PAST WEEK, how much has your knee pain that comes and goes affected your sleep?	0.049*
9	In the PAST WEEK, how much has your knee pain that comes and goes affected your overall quality of life?	0.62
10	In the PAST WEEK, how much hurt and frustration have you felt due to your knee pain that comes and goes?	0.28
11	In the PAST WEEK, how much sadness and anxiety have you had due to your knee pain that comes and goes?	0.81
Constant pain score	-	0.51
Intermittent pain score	-	0.02*
Total ICOAP score	-	0.12

*Pair comparison is significant at the 0.05 level (2-tailed). ICOAP: Intermittent and constant osteoarthritis pain

pain and the problem was addressed by providing a short explanation regarding the nature of each pain type.

Because ICOAP has been developed as a measure of the OA pain experience, stronger correlations between ICOAP scores with the KOOS pain versus KOOS symptoms scores

were expected and confirmed. Before development of the ICOAP, constant and intermittent pain concepts were not measured separately in OA subjects. According to our unpublished clinical data, we believe that the pain reported by subjects suffering from KOA is more likely related to the constant pain they experienced more regularly than irregular intermittent pain. However, because of the frustration resulting from higher frequency and longer duration of the constant pain, subjects suffering from advanced severe OA may report the intensity of constant pain when they are requested to score their pain on VAS. This fact may explain stronger correlation between constant pain score with KOOS pain and symptom subscales that those of intermittent and total pain scores.

This finding is in agreement with the German version^[17] and the original version of ICOAP;^[10] construct validity of the ICOAP reported by Hawker, *et al.*^[10] was indicated by significant associations with Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale, KOOS symptoms subscale, and self-reported quality of life (Spearman's correlation coefficients of 0.81, 0.60, and 0.63, respectively) and the KOOS pain subscale (correlation coefficient between -0.64 and -0.91).^[17]

In the Portuguese version of ICOAP, the results of the construct validity were similar to our results, the only difference was that KOOS pain presented higher negative correlation with ICOAP total pain than with constant and intermittent subscales,^[18] (correlation coefficient = -0.68 , -0.8 , -0.81 for KOOS pain and -0.61 , -0.73 , -0.73 KOOS symptom with ICOAP constant, intermittent, and total pain score, respectively).^[18]

High Cronbach's alpha and item-total correlation coefficients provide strong evidence supporting the internal consistency of ICOAP subscales and total pain scores, which are similar to the original^[10] and the Portuguese versions.^[18]

High ICC for the constant pain scale, intermittent pain scale and total pain scores indicate that the Persian version of ICOAP is reproducible. Based on the paired comparisons, the selected options for each item did not change considerably when the questionnaire was administered

Table 4: Spearman correlation coefficient between ICOAP scores and KOOS subscales

	Constant pain Spearman correlation coefficient	Intermittent pain Spearman correlation coefficient	Total pain Spearman correlation coefficient
KOOS symptoms	-0.6**	-0.5**	-0.5**
KOOS pain	-0.7**	-0.6**	-0.6**

**Correlation is significant at the 0.01 level (1-tailed). ICOAP: Intermittent and constant osteoarthritis pain, KOOS: Knee injury and osteoarthritis outcome score

again after five days. The only exceptions were items one and six, which both seek subjects' idea about the intensity of the pain (constant and intermittent pain, respectively) and intermittent pain score. We believe that this finding is related to the typical questions in the questionnaire which brings the subjects attention toward their actual suffering from pain. That means that the questions cause the participants to look for any change in the pain they experienced, especially the intermittent one, which was not previously considered. On the other hand, perception of pain intensity may be affected by subjects' psychological and emotional state and physical fatigue or environmental conditions such as climate and weather; these conditions are not controllable and may not affect the subjects' QOL. Another item that changed significantly in pair comparison was item eight (sleep disturbance due to intermittent pain). Along with significant alteration of intermittent pain score, this finding may also be a result of unsteady nature of intermittent KOA pain and the way subjects interpret this concept personally.

The original version of ICOAP has also been validated for administration by phone call and interview. The main limitation of this study is that all the participants were literate because the questionnaire was supposed to be administered as a self-report. In addition, the responsiveness of ICOAP was not explored in the present study. It is suggested to assess the responsiveness of Persian version of ICOAP in the future studies, which will make it a valid instrument for evaluating the effectiveness of surgical and rehabilitative interventions. The authors also recommend further validation of the Persian version of the ICOAP in subjects with hip osteoarthritis.

CONCLUSION

The Persian version of ICOAP knee-specific questionnaire offers psychometric properties that make it a valid and reliable instrument for subjects with symptomatic KOA. This measure may be used by nurses, medical, and rehabilitation specialists to communicate more effectively with KOA subjects.

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Conflicts of interest

There are no conflicts of interest.

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