

Knee Injury and Osteoarthritis Outcome Score in patients with isolated meniscus injury; Validity and reliability

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Background: The aim of this study is evaluation of the validity and reliability of the Persian version of Knee Injury and Osteoarthritis Outcome Score (KOOS) in patients with isolated meniscus injury. **Materials and Methods:** One hundred people with isolated meniscal injury (29 females and 71 males with a mean age \pm standard deviation [SD] = 32.37 \pm 9.97 years) and fifty normal people with no knee problems (34 females and 16 males with a mean age \pm SD = 28.42 \pm 8.84 years) participated in this study. In patients, the duration of meniscus injury ranged from 1 month to 4 years. For evaluation of discriminate validity, we compared scores of KOOS questionnaire between patients and healthy people, and for concurrent validity, in addition to filling KOOS questionnaire, patients completed Short Form (SF-36) questionnaire, test-retest reliability with intraclass correlation coefficient (ICC), and internal consistency with Cronbach's alpha was calculated. **Results:** Mean scores of patients (49.51 \pm 17.13) and healthy people (86.01 \pm 13.44) were different significantly ($P < 0.001$). The correlation between total score of SF-36 and KOOS was significant ($r = 0.77$, $P < 0.001$). ICC was 0.80 (ranged from 0.64–0.75) and Cronbach's alpha was 0.96 (ranged from 0.72 to 0.94). **Conclusion:** The Iranian version of KOOS is a reliable and valid tool for patients with isolated meniscus injury, so the clinicians and investigators may use this questionnaire in clinical settings and their researches.

Key words: Knee Injury and Osteoarthritis Outcome Score, knee outcome, meniscus injury, reliability, validity

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INTRODUCTION

In the age of 20–29, the most meniscal pathologies occur,^[1,2] and in America, the most intra-articular knee surgery is meniscal surgery.^[3,4] Today, the health systems are not only looking to manage the symptoms of the patient but also the change in the quality of patients' life after treatment is a main criterion for evaluating therapeutic services. One of the instrument for assessment of outcome and quality of life (QOL) is questionnaire. Questionnaires are available, economically advantageous, and cost benefits in term of time. One of the questionnaires of the knee is Knee Injury and Osteoarthritis Outcome Score (KOOS), which assess the long- and short-term signs and dysfunction in patient with knee disability and osteoarthritis. The reliability,

validity, and responsiveness of KOOS questionnaire were credible in many countries with different languages such as French,^[5] Portuguese,^[6] Italian,^[7] Swedish,^[8] Arabic,^[9] Greek,^[10] Spanish,^[11] Japanese,^[12] Dutch,^[13] Polish,^[14] Singapore-English,^[15] Chinese-English,^[15] and American versions.^[16] Iranian version of KOOS (IKOOS) was established by Salavati *et al.*^[17]

To use every tool in the clinic, we must first validate it. Since the meniscal injury is one of the most surgeries in the world, and this pathology occurs in active and economic young people; therefore, a valid and reliable tool for measuring outcomes of treatments and rehabilitative interventions after meniscal injuries is needed. Roos *et al.* and Salavati *et al.* studied validity and reliability of KOOS in patients after meniscus pathology, but in Roos study, only 21 patients were assessed, and in

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the Salavati *et al.* study, only 31 patients were assessed.^[16,17] Due to limitation in number of subjects in these studies, we cannot generalize their results to patients with isolated meniscal pathology. As there is not yet a specific tool to assess meniscus pathology, the aim of this study is to survey the reliability and validity of the IKOOS in Iranian patients with isolated meniscal injury.

MATERIALS AND METHODS

The Persian version of KOOS is translated and culturally adapted by Salavati *et al.*^[17] The 100 Iranian people with isolated meniscal injury and fifty healthy cases participated in our study. The results of all 150 cases were used for discriminate validity. The inclusion criteria were isolated meniscal pathology in magnetic resonance imaging or arthroscopy. They also should not have other musculoskeletal abnormalities of the knee or neurologic disorder. The exclusion criteria were inability to cooperate.

Questionnaire

The KOOS is a self-perceived measure with 42 questions. KOOS questionnaire contains five subscale: symptoms (seven questions), pain (nine questions), activity daily living (17 questions), sport and recreation function (five questions), and QOL (four questions). Each question scored from 0 to 4, 0 is the best and 4 is the worst score, and the total score was calculated as the summation of all questions. Then, the obtain score transformed to 0–100 scale, the 0 showing more impairment in the knee and 100 showing no problem of knee. The lower total score shows a greater amount of disability.^[16] Original KOOS questionnaire was translated and culturally adapted to Persian by Salavati *et al.* and revealed acceptable reliability and validity.^[17] Furthermore, the Persian version of KOOS showed good validity, reliability, and internal consistency in patients with anterior cruciate ligament (ACL) injury.^[18] This study approved by the Ethics Committee of Tehran University of Medical Sciences (ethic number: 9211452004-142973), the patients were informed and consented to participate.

Assessment of psychometric properties

Validity

Discriminate validity

The result of patients with isolated meniscal injury and healthy people was compared to determine the discriminate validity and discriminate of impairment in QOL in patients with meniscal injury by KOOS. For discriminate validity, we used the independent *t*-test.

Ceiling and floor effect

We choose ceiling and floor effect as if more than 15% of participants achieved the highest or lowest score.^[19] Ceiling and floor effect was checked by frequency table.

Concurrent criterion validity

For the concurrent criterion validity, the score was correlated with a gold standard.^[19] Due to the absence of a gold standard for meniscal problems in Persian language, we compared the score of KOOS with Short Form (SF-36) by Spearman correlation. SF-36 is encompassed from two summary components: physical health summary and mental health summary. We assessed the correlation between KOOS with physical health summary and related subscales but correlation of mental health summary and KOOS did not appraised. The Persian version of SF-36 translated and culturally adapted by Montazeri *et al.*^[20] To determine the concurrent criterion validity, the results of 100 patients were used.

Reliability

The comparative results of fifty patients randomly by closed packet selected from who have isolated meniscal pathology were used for reliability. To determine the test–retest reliability, the IKOOS questionnaire was tested twice in fifty patients with 7-day interval. During this period, the patients were not taking any intervention including any physiotherapy treatment and new injury. The reliability was determined by single measure of intraclass correlation coefficient ($ICC_{[2,1]}$); two times testing and one examiner. $ICC > 0.7$ was considered as acceptable level for reliability.^[19] Standard error of measurement (SEM) and smallest detectable change (SDC) calculated by $SEM = SD \times \sqrt{1 - ICC}$ and $SDC = 1.96 \times \sqrt{2 \times SEM}$.

Internal consistency

Internal consistency is typically a measure based on the correlations between different items on the same test or the same subscale. It measures whether several items that propose to measure the same general construct produce similar scores. We determine the internal consistency of the subscales and total score of the KOOS separately.^[19,21,22] To determine the internal consistency, Cronbach's alpha, and also Pearson correlation between score of subscales, and correlation between each question with total score of KOOS was used. Cronbach's alpha higher than 0.7 indicates good internal consistency.^[19]

RESULTS

The analysis was performed with SPSS software version 16.0 (IBM SPSS software). Quantitative data reported by mean and standard deviation (SD). Normality of data was checked by K-S test.

Study population

The 100 people with meniscal injury participated in this study (29 female and 71 male with mean age \pm SD = 32.37 \pm 9.97). The duration of meniscus injury

ranged from 1 month to 4 years (mean: 15.43 month, SD: ± 15.02). The other group was fifty normal people that did not have any knee problem (34 female and 16 male with mean age \pm SD = 28.42 ± 8.84) participated in this study. Descriptive statistics of KOOS questionnaire for patients and healthy people are reported in Table 1.

Validity

Salavati *et al.*'s illustrated that IKOOS has good construct validity. Translation and cultural adaptation procedures were done, and there were no problems in final IKOOS questionnaire.^[17]

Discriminate validity

The normal people earned the mean score of 86.01 (SD = ± 13.44), but the patient mean score was 49.51 (SD = ± 17.13). Compare the healthy people with patients had shown differences significantly ($P < 0.001$, mean difference = -36.50 , 95% confidence interval: -41.57 – -31.43).

Ceiling and floor effect

We did not observe ceiling or flooring effect in patients for total score. Just there was floor effect among patients in sport/recreation subscale. The ceiling/floor effect in all subscales and total score of KOOS are reported in Table 2 for all participants.

Concurrent criterion validity

Spearman correlation between the total score of KOOS and physical component and also total score of SF-36 questionnaires was significant ($P < 0.01$). Just the correlation between subscales of symptoms in KOOS and general health in SF-36 was not significant [Table 3].

Reliability

Paired *t*-tests showed no significant difference between test and retest total scores ($P = 0.28$, mean difference = -1.65 , 95%CI: -4.71 – -1.40). There was an excellent correlation between test–retest scores ($r = 0.80$, $P < 0.001$). Single measure ICC for total score was 0.80 ($P < 0.001$, 95%CI: 0.67–0.88)

and average measure ICC for total score obtained 0.89 ($P < 0.001$, 95%CI: 0.80–0.94). ICC for each subscale, SEM, and SDC of all subscales and total score are observable in Table 4.

Internal consistency

Cronbach's alpha for the total and symptoms, pain, activity daily living, recreation, and QOL subscales, among patients, were 0.96 and 0.74, 0.86, 0.94, 0.89, and 0.72, respectively, it's showed high internal consistency for total score and individual subscales of the KOOS. Correlation between each question and total score of KOOS questionnaire was significant (r : -0.44 – -0.78 , $P < 0.001$), but only second question of QOL subscale did not have significant correlation with total score ($r = -0.09$, $P = 0.35$). Correlation between subscales and total score is visible in Table 5.

DISCUSSION

Whereas reliability and validity of IKOOS in general knee injuries was studied, but there was no investigation of the reliability and validity of this Iranian questionnaire in knee meniscal injury, so we need to investigate the knee questionnaire's properties in specific knee injuries such as meniscal injury. The present study showed the IKOOS had good validity and reliability in meniscus injury.

All participants filled out IKOOS without any difficulty. There were no missing data in IKOOS. This reflects the ease of use of this questionnaire.

The total score of IKOOS in meniscal injury was significantly lower than the total score of healthy, so the scores of patients were worse than healthy people. Therefore, discriminative validity of IKOOS in meniscus injury was strongly supported. These findings indicate that IKOOS can differentiate between healthy and meniscus injured people. This difference between the scores of healthy and patients demonstrated that IKOOS can discriminate people with meniscal pathology from people with healthy knee.

Table 1: Descriptive statistics for Knee injury and Osteoarthritis Outcome Score questionnaire

Health status	Patients (n=100)						Healthy (n=50)					
	Mean \pm SD	Median	Minimum	Maximum	95% CI		Mean \pm SD	Median	Minimum	Maximum	95% CI	
					Lower bound	Upper bound					Lower bound	Upper bound
Symptoms	56.39 \pm 20.67	57.14	7.14	100.00	52.29	60.49	87.00 \pm 10.89	89.29	60.71	100.00	83.91	90.09
Pain	52.08 \pm 19.41	52.78	11.11	97.22	48.23	55.94	86.39 \pm 14.84	91.67	33.33	100.00	82.17	90.61
ADL	58.40 \pm 19.70	58.82	5.88	98.53	54.49	62.31	89.85 \pm 13.04	94.12	29.41	100.00	86.15	93.56
Sport/recreation	21.50 \pm 21.72	15	0.00	100.00	17.19	25.81	78.30 \pm 23.55	90	0.00	100.00	71.61	84.99
QOL	28.94 \pm 19.68	25	0.00	93.75	25.03	32.84	76.75 \pm 19.19	81.25	25.00	100.00	71.30	82.20
Total score of KOOS	49.51 \pm 17.13	48.81	14.88	87.50	46.11	52.91	86.01 \pm 13.44	90.48	33.93	99.40	82.19	89.83

KOOS = Knee Injury and Osteoarthritis Outcome Score; QOL = Quality of life; ADL = Activity daily living; CI = Confidence interval; SD = Standard deviation

The correlation between subscales of KOOS and the subscales of SF-36 was significant except between symptoms and general health subscale. This significance and good correlation support KOOS construct validity, so these two instruments evaluate similar construct. Significant correlation between the two questionnaires showed

that IKOOS can assess the QOL among patients with meniscal injury and is a good tool for evaluation of QOL. Correlation between symptoms' subscale of IKOOS and general health subscale of SF-36 was not significant in this study. In the other version of KOOS, correlation between these two subscales was weak significant or not significant, also.^[6-8,13-16] As this general health subscale of SF-36 is a general item that has general questions to assess the QOL, but symptoms' subscale of IKOOS is a specific item that includes specific questions about knee joint, it was expected that the relationship between these two subscales was not significant.

Total score of IKOOS did not have ceiling and floor effect among all participants [Table 2]. However, we observed floor effect in sport/recreation subscale between patients and healthy people. Furthermore, there was ceiling effect in healthy participants for symptoms and ADL subscales. We expected that this ceiling effect among healthy people

Table 2: Ceiling/floor effect of Knee Injury and Osteoarthritis Outcome Score questionnaire among patients (n=100) and healthy participants (n=50)

	Patients (n=100)		Healthy (n=50)	
	Ceiling (%)	Floor (%)	Ceiling (%)	Floor (%)
Symptoms	1	0	18	0
Pain	0	0	12	0
ADL	0	0	16	0
Sport/recreation	1	22	18	2
QOL	0	6	12	0
Total score of KOOS	0	0	0	0

KOOS = Knee Injury and Osteoarthritis Outcome Score; QOL = Quality of life; ADL = Activity daily living

Table 3: Spearman correlation between Knee Injury and Osteoarthritis Outcome Score subscales and physical component of Short Form-36 (n=100)

	P					
	Symptoms	Pain	ADL	Sport/recreation	QOL	Total score of KOOS
General health	0.18 (0.067)	0.32 (0.001)	0.36 (<0.001)	0.37 (<0.001)	0.41 (<0.001)	0.36 (<0.001)
Physical functioning	0.49 (<0.001)	0.62 (<0.001)	0.68 (<0.001)	0.57 (<0.001)	0.35 (<0.001)	0.70 (<0.001)
Role physical	0.46 (<0.001)	0.53 (<0.001)	0.57 (<0.001)	0.44 (<0.001)	0.46 (<0.001)	0.60 (<0.001)
Bodily pain	0.57 (<0.001)	0.69 (<0.001)	0.78 (<0.001)	0.51 (<0.001)	0.47 (<0.001)	0.77 (<0.001)
Physical health summary	0.58 (<0.001)	0.74 (<0.001)	0.81 (<0.001)	0.65 (<0.001)	0.54 (<0.001)	0.83 (<0.001)
Total score of SF-36	0.54 (<0.001)	0.68 (<0.001)	0.75 (<0.001)	0.64 (<0.001)	0.56 (<0.001)	0.77 (<0.001)

Correlation is significant at the 0.01 level (two-tailed). Underline number is not significant. KOOS = Knee Injury and Osteoarthritis Outcome Score; QOL = Quality of life; ADL = Activity daily living; SF-36 = Short Form-36

Table 4: Mean, median, standard deviation, intraclass correlation coefficient, standard error measurement and standard error measurement for Knee Injury and Osteoarthritis Outcome Score Questionnaire (re-test, n=50)

	Mean	SD	Median	Min	Max	CI 95%		Average ICC (95%CI)	Single ICC (95%CI)	SEM*	SDC
						Lower bound	Upper bound				
						Symptoms	60.71				
Pain	57.17	18.32	55.56	16.67	94.44	51.96	62.37	0.78 (0.62-0.88)	0.64 (0.45-0.78)	9.10	25.22
ADL	61.44	17.80	61.03	20.59	92.65	56.38	66.50	0.86 (0.75-0.92)	0.75 (0.59-0.85)	7.37	20.43
Sport/recreation	26.80	20.55	25	0.00	85.00	20.96	32.64	0.82 (0.69-0.90)	0.70 (0.52-0.82)	9.21	25.53
QOL	35	25.63	37.50	0.00	87.50	27.72	42.28	0.80 (0.65-0.89)	0.66 (0.48-0.79)	8.80	24.39
Total score of KOOS	53.76	16.61	51.79	18.45	89.29	49.04	58.48	0.89 (0.80-0.94)	0.80 (0.67-0.88)	5.68	15.74

*SD that used for calculation of SEM is related to 100 patients. SD = Standard deviation; CI = Confidence interval; ICC = Intraclass correlation coefficient; SEM = Standard error measurement; SDC = Small detectable change; KOOS = Knee Injury and Osteoarthritis Outcome Score; QOL = Quality of life; ADL = Activity daily living

Table 5: Spearman correlation between subscales and total score of Knee injury and Osteoarthritis Outcome Score (n=100)

	P				
	Symptoms	Pain	ADL	Sport/recreation	QOL
Pain	0.77** (<0.001)				
ADL	0.70** (<0.001)	0.88** (<0.001)			
Sport/recreation	0.41** (<0.001)	0.48** (<0.001)	0.61** (<0.001)		
QOL	0.30** (0.002)	0.35** (<0.001)	0.47** (<0.001)	0.60** (<0.001)	
Total score of KOOS	0.80** (<0.001)	0.91** (<0.001)	0.96** (<0.001)	0.69** (<0.001)	0.54** (<0.001)

**Correlation is significant at the 0.01 level (two-tailed). KOOS = Knee injury and Osteoarthritis Outcome Score; QOL = Quality of life; ADL = Activity daily living

was observed because they are normal persons with no problem of knee, so the best score of the questionnaire could be earned by this group of participants. Floor effect of sport/recreation subscale also was observed in other version in a range of 1.6%–66.9%. This finding suggests that sport/recreation subscale can be greatly affected by many knee injuries. On the other hand, severe disability of patients in our study may be the cause of this finding.^[5-10,13-15,17]

Good average ICC for IKOOS in meniscus pathology is similar to other languages of KOOS that indicate in general knee injury, especially knee osteoarthritis. Furthermore, single ICC for a total score of IKOOS was >0.7, but single ICC for symptom, pain, and QOL subscales was <0.7. The reported ICC of KOOS in knee injuries ranges from 0.45 to 0.95, but some of these studies do not clear that what kind of ICC (single or average) is used.^[5-17] High ICC for a total score of KOOS in this study indicates IKOOS is a suitable tool for assessment of QOL in patients with meniscus injury.

The original version of KOOS and its translated versions also showed Cronbach's alpha >0.7.^[5-9,12,14-16] This high Cronbach's alpha indicates that IKOOS is homogeneous and internally consistent. Only the symptom subscale in Iranian,^[17] Dutch,^[13] Spanish,^[11] and Greek^[10] version was lower than 0.7. Nonhomogeneity of patients, who have participated in these studies, could be the cause of low Cronbach's alpha.

To compare the present study with the study of Salavati *et al.* that assessed the reliability and validity of Persian KOOS in ACL injury showed high internal consistency and acceptable ICC in two studies. In the IKOOS in ACL injury, the correlation of all subscales of KOOS and SF-36 was significant, whereas in the IKOOS in meniscal injury, correlation of symptoms subset and the general health subset was not significant.^[18]

One limitation of this study was the absence of a gold standard questionnaire in Iranian language for meniscus injury evaluation, to compare with KOOS questionnaire for validity. On the other hand, KOOS questionnaire is relatively a time-consuming instrument and also, all questions of it are not exactly related to meniscal pathology; thus, the need for a dedicated tool to assess QOL in patients with meniscus injury is felt. Future study can investigate the responsiveness of IKOOS.

CONCLUSION

According to the findings of the present study, the Persian KOOS questionnaire is a reliable and valid instrument for the assessment of QOL and impairment in people with isolated meniscus pathology. Thus, the orthopedists,

therapists, and investigators may use KOOS in their clinical settings and their researches for patients who have meniscal injury.

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Conflicts of interest

The authors have no conflicts of interest.

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