ISSN: 0975-833X

Available online at http://www.journalcra.com

International Journal of Current Research
Vol. 8, Issue, 03, pp.27549-27554, March, 2016

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

RESEARCH ARTICLE

TRANSLATION & LINGUISTIC VALIDATION OF KNEE AND OSTEOARTHRITIS OUTCOME SCORE (KOOS) QUESTIONNAIRE IN MARATHI LANGUAGE: CROSS SECTION SURVEY

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ARTICLE INFO

Article History:
Received 24th December, 2015
Received in revised form
20th January, 2016
Accepted 28th February, 2016
Published online 16th March, 2016

Key words:

Linguistic validation,
Disease specific self-report,
KOOS,
Marathi translation,
Quality of life.

ABSTRACT

Background: KOOS is a self -administered instrument which assesses patient's opinion about Knee associated problems. Original version of KOOS has been translated in various regional foreign languages. India, is multilingual country where each province has a unique language. Maharashtra is the second largest state in India and Marathi is the regional language of the communication. KOOS is a self-report disease specific measure needed to be translated with unique method in order to achieve a normative equivalence and linguistic validation.

Methods: After obtaining permission from KOOS web manager T1, T2, T12, B1 & B2 versions were formatted according to the guidelines laid down by AAOS for cross cultural adaptation of health status measure. T12 version was sent for the field testing. Total 32 subjects were included in this trial.

Results: Statistical analysis for reliability with test re-test method suggested perfect correlation (r =1) between day 1 & 2. A range of 0.83-0.54 co-relation co-efficient (r) demonstrated validity of KOOS and its subscales when compared against the 8 different domains of SF-36. All this correlations were statistically highly significant. Sport and recreation subscale had many missing responses since many items in this subscale were not appropriate for the Maharashtrian cultural set-up. Participants provided information about other functional activities which were specific to Indian cultural set up and difficult to execute due to knee associated impairments.

Conclusion: Marathi version of KOOS proved to be a reliable & valid measure.

Citation: Swati Meshram, Medha Deo and Kartik Doshi, 2016. "Translation & linguistic validation of knee and osteoarthritis outcome score (KOOS) questionnaire in Marathi language: Cross section survey", *International Journal of Current Research*, 8, (03), 27549-27554.

INTRODUCTION

The disease specific measures which are designed to assess and detect a clinical change (Patrick and Deyo, 1989) are proposed to be patient-centered and should have good reliability, validity, responsiveness, and low burden of administration to be clinically useful. (Terwee *et al*., 2007) Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire is a one such measure which was developed to assess short- and long-term patient-relevant outcomes following knee impairment. This is a self-report which assesses five outcomes: *Pain (P), Symptoms (S), Activities of Daily Living (A), Sport and Recreation Function (SP), and Knee-Related Quality Of Life (Q)*. KOOS has shown to be reliable and valid measure to evaluate the effectiveness of an intervention in knee osteoarthritis, (Roos *et al*., 1998; Lund *et al*., 2008; Roos and Dahlberg, 2005) total knee replacement (Lund *et al*., 2008; MacDonald *et al*., 2008; Lind *et al*., 2009), anterior cruciate ligament (Lind *et al*., 2009; Von Porat *et al*., 2004) and cartilage injury. (Bekkers *et al*., 2009) It has been translated in various regional languages. (www.koos.nu) In multi-linguistic country like India, KOOS has been translated in national language ie. Hindi (Pandharipande, 1992; Knee Injury and Osteoarthritis Outcome Score (KOOS), 1998) Maharashtra is second largest state in India with estimated population is over 117 million appx. (Knee Injury and Osteoarthritis Outcome Score (KOOS), 1998; www.censusindia.gov.in; http://r.search.yahoo.com) with 70 % of population communicate in Marathi language (Bhatt and Mahboob, 2008; Mallikarjun, 2004). Since KOOS is the self-administered instrument, its translation in Marathi language was thought to be necessary as majority of population attending physiotherapy clinics communicatesin Marathi.Responses to disability questionnaires are dependent on openness with strangers, political opinions, tendency to conform or assert oneself, since cultures differ on how willing they are to share their personal information. (Behling and Law, 2000) This is true especially if it is being employed to non-English population (Ferraz *et al*., 1997;

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Guillemin, 1993; Guyatt *et al*., 1993; Herdman *et al*., 1997). This emphasizes a need to translate a health status self-administered measure for the use in a new country. It is now recognized that a unique method should be used to achieve a linguistic validation to reach normative equivalence between the original source and target language of the measure or instrument. (Beaton *et al*., 2000)

Hence, a valid Marathi version was required to reflect a better expression of difficulties encountered by patients suffering from knee osteoarthritis. This study aims to translate and check the psychometric properties (Beaton *et al*., 2000) of the translated version of the KOOS as per the guidelines laid down by AAOS. (Beaton *et al*., 2000)

MATERIALS AND METHODS

Study design: cross section survey design- a validation study. Permission was obtained from Institutional local ethic committee. This study was carried out in 2 phases. Phase I consisted of translation of the English version of KOOS into the Marathi version. Second phase consisted of the field testing of the translated version to check test-retest reliability and validity. Phase I of this study was carried out as per the guidelines laid down by AAOS. (Beaton *et al*., 2002) To undertake the translation a written permission was obtained from KOOS web manager. According to AAOS guidelines, translation process involves six stages. T1 and T2 were the provisional Marathi translated versions of KOOS. Translator 1(T1) was the English teacher in a convent school. Translator 2 was a physiotherapist nonresidential Indian. Discrepancies in both of this version were dealt with extensive judgmental analysis and an agreement was reached on T12 version. After this phase of translation process, the T12 version was presented for further discussion and sent for pilot testing on patients to 5 physiotherapy clinics. This T12 version was well accepted in the Marathi speaking community except when there were few occasion when pure words used in the Marathi language were not understood by the village population. Hence, description had to be supplied along with that particular word. For e.g. for squatting the word ukidwe (उकीढवे) was suggested in T12 translation. This word required a description on the part of physiotherapist. Hence a supplementary short explanation was provided in final translation (T12) which means sitting on the feet on the floor (sp1- उकीडवे बसताना (दोन्ही पाउन्लावर जमिनीवर बसताना). This kind of discrepancies were sorted out with the suggestions by expert panel. B1 and B2 versions were the backward translation of the T12 version. One translator was a social worker and another translator was an accountant. A good consistency was reached when B1 and B2 versions were matched against original English version of KOOS. This back translations was carried out by the experts who were not involved in T1 and T2 translations or any of previous translation procedures. Thereafter, the revised final T12 version was sent for the field testing. *Appendix additional file*

Field testing constituted phase II part of this study

Data collection was carried out for over the period of four months. Participants were recruited from outpatient department of multispecialty hospital and polyclinics and private clinical setup of Navi Mumbai suburban area, Maharashtra. Eligible subjects who the fulfilled the inclusion criteria were register for the study.

Table 1. Demographic features of the participants

	Gender		Statistic
Age	M (n=11)	Mean	52.09
		Std. Deviation	5.76
	F (n=21)	Mean	46.80
		Std. Deviation	7.48

Subjects who were diagnosed for osteoarthritis of knee and who have not undergone any physical therapy treatment previously and who gave informed consent were considered eligible. Participants who were not ready to remain refrained from any form of the physical therapy treatment for 24 hours after their first consultation with the clinician were excluded. This was essential as this part of study was aiming to evaluate the test-retest reliability of T12 version of KOOS. Final T12 version of KOOS and SF- 36 v2 (Ware *et al*., 2000) was given to the participants by an assistant who was not involved with any prior procedure. Filled forms were collected by the same assistant. Next day participants were given another blank copy of Marathi KOOS T12 versions. All of this three forms were then dispensed to primary investigator for further analysis. Throughout the entire procedure, assistant was not allowed to discuss or to establish any kind of communications regarding the forms or results of it either with the participant or with the clinician.

RESULTS

Scores were calculated for 1st and the 2nd day KOOS (T12) subscale and 1st day SF-36 domains as follows: Physical functioning (PF), Role limitations due to physical health (PH), Role limitations due to emotional health (RE), Vitality (VT), Mental health (MH), social functioning (SF), Bodily pain (BP) and General health (GH). (Ware *et al*., 2000) SPSS version 19 for Windows was used for data analysis. (Ware *et al*., 1992)

SF--36 data

In SF-36 scale, higher scores represent better health status. Participants were limited in their ability to spend time and/ or experienced difficulty in accomplishing a given work as suggested by *PF* (25.0, 95% CI = 0.0-50.0) score. This could be attributed to the *BP* (33.75, 95%CI= 22.5-55.5) scores to significant extent and *PF* scores to moderate extent (50.0, 95% CI= 39.9 - 75.0). (Table 2)

Marathi KOOS

In Marathi KOOS, the score is a percentage score from 0 to 100, with higher scores represent better health status. All the KOOS subscales scores were similar (59.0-50.0, 95% CI = 50.0- 71.5, 50.0-56.25 resp) except sport and recreation subscale which scored significantly different from prior score ranges (33.5, 95% CI = 24.9 - 37.5). The relevance of this finding is explained in discussion below*.

Table 2. Summary statistics table presenting, median, 95% CI, of Marathi KOOS and SF 36 subscale scores

	Median	95% CI
ADL	58.25	47.24 - 65.00
PAIN	53	44.49 - 64.00
Quality of life	50	50.000 - 56.250
Sport & recreation	33.5	24.988 - 37.506
SYMPTOMS	59	50.000 - 71.508
B.P	33.75	22.500 - 55.000
G.H	57.5	45.000 - 65.000
M.H	72	63.981 - 76.000
R.E	66.66	33.330 - 100.000
R.PH	25	0.000 - 50.000
P.F	50	39.988 - 75.000
S.F	50	37.500 - 50.060
V.T	47.5	24.988 - 60.000

Table 3. Correlation coefficient showing relationship between KOOS subscales and SF36 domains

Subscales		PF	PH	BP	GH	VT	SF	RE	MH
Pain	r	.789	.718	.775	.726	.779	.749	.817	.802
	Sig. (2-tailed)	.000	.000	.000	.000	.000	.000	.000	.000
Symptoms	r	.718	.656	.703	.737	.850	.796	.837	.807
	Sig. (2-tailed)	.000	.000	.000	.000	.000	.000	.000	.000
ADL	r	.754	.725	.723	.677	.703	.694	.750	.726
	Sig. (2-tailed)	.000	.000	.000	.000	.000	.000	.000	.000
Sport &	r	.695	.683	.615	.575	.658	.645	.693	.769
recreation	Sig. (2-tailed)	.000	.000	.001	.003	.000	.001	.000	.000
Quality of	r	.545	.567	.561	.540	.550	.563	.623	.708
life	Sig. (2-tailed)	.001	.001	.001	.001	.001	.001	.000	.000

PF= physical functioning, PH= role limitation due to physical health, BP= bodily pain, GH= general health perception, VT= vitality, SF= Social functioning, RE= role limitation due to emotional problems, MH= general mental health. ADL=activities of daily living.

SF-36 vs. Marathi KOOS

Subjects scored higher in *RE* (66.66, 95%CI=33.3-100) and *MH* (*72.0*, 63.9 - 76.0) *domain* trending towards internationally standardized normal *Mental component summary (MSC)* (50.0, 95% CI= 49.7–50.3) in SF-36. (Ware *et al*., 1992) Whereas domains in the *physical component* (25-57.5, 95%CI=0.0-50.0, 45.0-65.0) (Table 2) showed a greater deviation from normal standardized scores (65.6-86.0, 95% CI=65.0–66.1, 85.4–86.7). [27] Ranges of scores obtained in *physical components of SF-36* simulates to those obtained across KOOS subscales (59.0-50.0, 95% CI = 50.0- 71.5, 50.0-56.25 resp.). Differences in scores of 2 seemingly similar domains of *(Pain)* KOOS (53, 95% CI=44.4-64.0) and *(bodily pain BP)* of SF-36 (33.7, 95%CI=22.5- 55.0) suggests that this scales were testing different aspects of pain.

The reliability

To test the stability and reliability, correlation coefficient (spearmen's rho) was computed using test re-test method for all the 5 subscale scores of the Marathi version of KOOS for 32 participants. 10 out of 10 correlations were statistically significant and were equal to correlation coefficient; r=1.00, p < 0.000, two-tailed. Day 1 and day 2 administration of Marathi KOOS produced consistent scores. Hence, this Marathi version of KOOS can be considered to have an excellent reliability. Cronbach's alpha for the 7 symptom, 9 pain, 17 ADL, and 4 QOL items were 0.88, 0.94, 0.91, and 0.69 resp. Cronbach's alpha for sport and recreation couldn't be calculated due to missing responses.

The validity

SF -36 subscales scores were compared against the 5 sub scales of KOOS to determine construct validity of Marathi version. The co-relation co-efficient was computed and shown in Table 3.

Correlation analysis showed a significantly positive and good relation between the two scales' similar sub-fields i.e.*PF and ADL (activities of daily living)*: r =0.75; moderate relation for *GH*, *PF of SF-36*, and *QOL* (quality of life) subscale of KOOS; r=0.54; ($p < 0.001$). The results also suggests that 8 out of 8 correlations were statistically significant. (Table 3) However, Data which seem to be in poor agreement can also produce quite high correlations. The test of significance may show that the two methods are related, but it would be amazing if two methods designed to measure the same quantity were not related. The test of significance is irrelevant to the question of agreement. (Bland and Altman, 1986) To test such scenario, Bland and Altman recommended the use of plots, with bias and precision statistics, to determine agreement between 2 methods of measurement. The plot consists of the average of the paired values from each method on the x-axis and the difference of each pair of readings on the y-axis. It is anticipated that the 95% limits consist of 95% of the differences between the two measurement methods. Bland and Altman proposed that researchers should apply two methods on a group of participants, then plot the different scores against the mean for each participant. (Hopkins, 2004) Bland Altman was plotted using MedCalc software version 14.8.1, for the SF-36 subscales and Marathi KOOS with normally distributed data ie.

General health (SF-*GH*) and for *symptoms, pain, and ADL* KOOS subscales. This two scales was having good adaptability in the *physical functions (PH), general health (GH)* perception. Fig.1 (a-c)

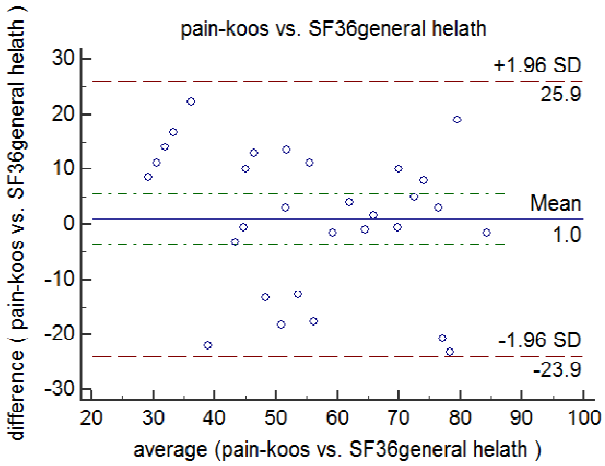

Fig.1 (a) Bland Altman plot showing agreement between pain-KOOS vs. SF36- general health (GH)

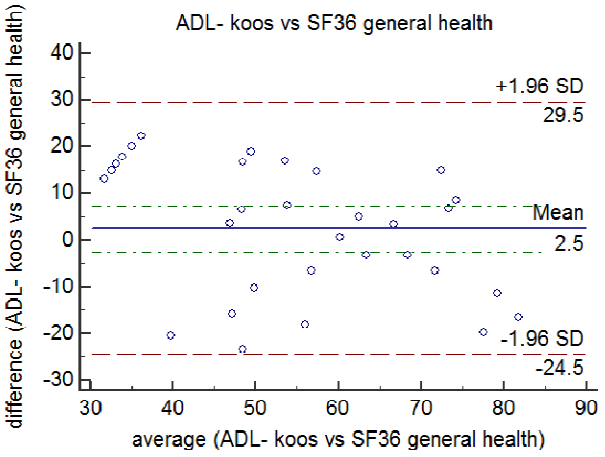

Fig.1 (b) Bland Altman plot showing agreement between ADL-KOOS vs. SF36- *general health (GH)*

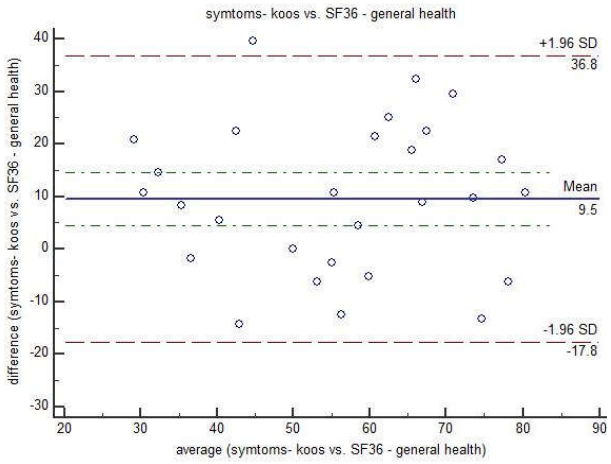

Fig.1(c) Bland Altman plot showing agreement between symptoms -KOOS vs. SF36- *general health (GH)*

DISCUSSION

In the present study, translation of KOOS in Marathi language was undertaken along with the linguistic validation. Reliability and validity of the Marathi version of KOOS is established as shown by moderate to high construct validity and excellent test–retest reliability. Participants responded to almost all the items in the scale except the sport and recreation subscale. In this subgroup, higher missing responses were present since certain items were not applicable to general population in Indian scenario. Rest of the subgroups showed good 100% response rate. As mentioned previously SF-36 was used to validate the Marathi KOOS scale. SF-36 has been proven to be as responsive and sensitive as the Lysholm and International Knee Documentation Committee scores with treatment (surgical and nonsurgical) over time. (Shapiro *et al*., 1996) However, validity, sensitivity and an association between Lysholm knee scoring scale itself (Risberg and Ekeland, 1994) and other different knee scoring scales and functional tests in measuring different aspects of ACL and knee injury has been argued. (Neeb *et al*., 1997) On the other hand, patient-relevant questionnaires, such as the KOOS, adds information and proposed to be used, as the primary outcome measure in clinical trials of knee injury and knee OA etc. (Roos *et al*., 1998) The KOOS consistently has proven to be a valid instrument in different languages. Similar to our study results, KOOS was compared to the International Knee Documentation Committee (IKDC) form to determine which instrument better reflected the symptoms and disabilities of the cartilage repair patient (Hambly, 2008) Comparisons of Marathi KOOS with the SF-36 were made to determine convergent and divergent construct validity. Generally, we expected higher correlations to the SF-36 subscales with a high ability to measures physical health (convergent validity) and lower correlations to SF-36 scales with a high ability to measure mental health (divergent validity). Results of current study showed high correlations of *symptoms, pain and ADL* KOOS subscales on comparing with physical components summary (PCS) (0.67-0.79) as well as with Mental Component Summary (MCS) of SF-36 (0.72-0.83) (Table 3). Whereas moderate correlation with sport and recreation (SP) and quality of life (QOL) with PSC (0.54-0.56) and high correlation with MSC (0.62-0.70) were obtained. Three subscales (PF, RP, BP) correlate most highly with the physical component and contribute most to the scoring of the Physical Component Summary (PCS) measure. (Ware, 1995) Whereas MH, RE and SF scales correlates highly with Mental Component Summary (MCS) measure of SF-36. (Ware JE. SF-36, 2004) Mean correlations of the five KOOS subscales of 0.50 and 0.36, respectively, were obtained in the Swedish (paper V) (Roos, 1998) and the American (paper IV) (Roos *et al*., 1998) validation with SF-36 Physical Function (PCS) and 0.20 and 0.19 resp. when compared to the SF-36 Mental (MCS) Health were suggesting divergent validity. As apparent, results of our study are different where a high correlation is achieved with physical and mental component summery scores of SF- 36. The reasons for this finding could include differences in diagnoses and diverse cultures. This finding warrants further research.

Hence, disease specific Marathi version of KOOS is proven to be a valid method since it has excellent to moderate correlation

with SF-36 generic measure. The agreement was shown to reach between the first three subscale of Marathi KOOS and general health of SF-36. Items in Sport and recreation subscale of KOOS was shown to be less relevant to the Indian population *There were 7 missing responses to the sport and recreation subscale. 7 participant did not respond to even a single items and many participant felt that certain items were irrelevant to their daily routine. This points out its relevance in Indian population and suggests the failure to achieve a normative equivalence. This also raises a need to undertake the cross cultural adaptation of this sub- scale by including certain items which would be more cultural specific. This plausibility was anticipated by the members of validation committee prior to finalization of T12 version. A consensus was reached to evaluate a pattern of limitation in undertaking certain common daily activities which were not posed by original English version KOOS scale. Hence, participants were given a choice to state *any other specific physical activity* (अन्य किंवा दुसऱ्या प्रकारच्या क्रिया वा स्तिथी) in T12 Marathi KOOS scale. Interesting responses were obtained to this item. There emerged a pattern of limited activities which can be grouped into 2 major categories of movement. One that involves sitting cross legged on the floor and second which involves sitting on floor in kneeling position. First activity is common mode of position adopted by the Indian population to undertake several activities like while worshipping or practicing meditation or most commonly practicing yoga such as padamasana. Second is namaz or paying homage position while worshiping. Overall this is a most common yoga posture assumed known as vajrasana. This finding proposes a need to undertake a cross cultural adaptation of the original KOOS in the Indian population.

Conclusion

Based on the clinimetric properties which were evaluated in the present study, we conclude that the KOOS questionnaire is a reliable and valid instrument for assessment of patient-relevant outcomes in subjects with advanced osteoarthritis. A further assessment in other subgroups of the patient such as surgical and sport related injuries is warranted.

Future scope and Suggestions

The subscale Sport and Recreation function was having many missing response since many items were not relevant to all patients. All the participants were given instructions to mention any other activities in this domain. Many participants additionally mentioned cross leg sitting and namaz position as the relevant tasks carried out on the routine basis. This subscale might improve on validity if those functions are assessed which suits Indian scenario and which are culture specific. However, examining the cross cultural adaptation was beyond the scope of present study and hence future recommendation are made to undertake another study with larger sample with substantial representation of the population.

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