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Cross-cultural validation of Hindi version Knee Injury and Osteoarthritis Outcome Score (KOOS) in osteoarthritis knee

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Abstract

Purpose To assess the reliability, validity and responsiveness of the Hindi version of the Knee Injury and Osteoarthritis Outcome Score (H-KOOS) in osteoarthritic knee.

Methods Two hundred and fourteen patients of osteoarthritis knee (OA) between 40 and 80 years of age were evaluated with H-KOOS, Short form health survey (SF12v2) and the WHOQOL-BREF questionnaire. The H-KOOS was re-evaluated after 48 h in 125 patients to assess the test–retest reliability. For responsiveness, 40 patients were treated with the intra-articular hyaluronic acid injection, and the effect was assessed after 6 weeks.

Results Most of the domains in H-KOOS did not show a ceiling effect. The floor values were observed in 3.75% of patients in sports/recreation function and 2.75% of patients in Quality of life (QoL). The test–retest reliability was excellent with the Intraclass-Correlation-Coefficient (ICC) ranging from 0.89 to 0.94. Internal consistency as assessed using Cronbach's alpha coefficient was acceptable for pain, activities of daily living (ADL) and sport/recreation function (range 0.86–0.93); however, symptoms and QoL had weak internal consistency. There were moderate to strong correlations ($r = 0.35$ to 0.6) between domains measuring similar constructs in H-KOOS, SF12v2 and WHOQOL-BREF indicating good convergent construct validity. The responsiveness as measured by the effect size (ES) and standardized response mean (SRM) was large for pain (ES 0.9, SRM 0.8), moderate for Sport/Rec (ES 0.66, SRM 0.2) and small for ADL, QoL and Symptoms subscales.

Conclusion The Hindi version KOOS is a valid, reliable and responsive measure to evaluate osteoarthritis knee with minimal ceiling and floor effects.

Level of evidence Prospective cohort study, level II.

Keywords KOOS · Knee injury · Knee osteoarthritis · Measurement properties · Patient-reported outcome measures · Psychometrics

Introduction

Recently, patient-reported outcome measures have been considered as one of the appropriate assessment methods to evaluate the hip and knee function in arthritic conditions, both before and after treatment [8]. Before the widespread clinical and research use of such outcome scale in a community, it should be rigorously tested for validity, reliability and responsiveness [1, 8].

The Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire is such a patient-reported outcome measure for knee assessment in osteoarthritis and traumatic conditions [9, 18]. The details of the KOOS were published for the first time in 1998, and since then, the psychometric properties of KOOS have been evaluated in many studies

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throughout the world [3, 5, 9, 10, 13–16, 20, 24]. The KOOS has been assessed and compared to other knee injury/arthritis outcome instruments in several reviews [5, 16]. It was developed as an extension toWestern Ontario and McMaster Universities Osteoarthritis Index (WOMAC), to appropriately evaluate the knee function in the younger active individuals [4, 6, 18, 19]. Because of its comprehensiveness, the KOOS questionnaire helps the physician to understand the patient's symptoms and difficulties in a better way and thus, guides the treatment [3, 5, 6, 9, 10, 13–16, 19, 20, 24].

Garratt et al. reviewed the studies on knee-related patient-oriented outcome measures and reported that the KOOS was the most appropriate assessment tool to evaluate the health problems associated with knee, both for clinical and research purposes [9]. The reliability, validity and responsiveness of KOOS were shown to be better than many other scores. The presence of two different subscales of the physical function such as ADL and sport/recreation function in the KOOS questionnaire enhances its validity for patients having a wide range of expectations on their physical activity [3, 5, 9, 10, 13–16, 20, 24]. Various translations of KOOS in different languages are available, and only a few of them (German, Singapore English, Chinese, French, Dutch, Japanese, Portuguese and Persian) have been validated [4–6, 10, 12–16, 19, 20, 24].

Language barrier poses a significant difficulty in clinometric. Merely translating a previously validated instrument is insufficient. The translated tool needs to be revalidated before it can be utilized in clinical or research settings [22]. KOOS is available in Hindi language but it has not yet been validated for use [2]. This study would validate the Hindi version of KOOS (H-KOOS) for functional assessment of knee joint for Hindi speaking patients; thereby it would increase the applicability of this knee function outcome measure in a wider population. The aim of this study is to evaluate the psychometric properties of H-KOOS in OA knee patients. Our hypothesis is that Hindi KOOS is a valid, reliable and responsive tool to evaluate the functional outcome of knee joint and it is free from ceiling and floor effects.

Materials and methods

Patient recruitment

In a prospective, observational study between February 2013 and June 2014, the reliability, validity and responsiveness of the Hindi version KOOS were tested against Hindi version of WHOQOL-BREF questionnaire and Hindi version of Health Survey SF12v2 (H-SF12v2) [21, 23]. The hip function and its impact on the quality of life were evaluated using H-KOOS, WHOQOL-BREF Hindi questionnaire and H-SF12v2 questionnaire. The ethics committee approval of the institute (IEC ref No: NK/827/MS/3312-13, PGIMER Chandigarh, India) was obtained, and the patients were enrolled in the study after obtaining their consent.

Knee function assessment scale

There are 5 subscales and 42 items in the KOOS questionnaire. The subscales are pain, other symptoms, ADL, sport and recreation function, and knee-related quality of life (QoL). The score range from 0 (poor outcome) to 100 (no problems) and evaluated separately for each subscale [18].

The SF-12 Health Survey includes 12 questions derived from the SF-36 Health Survey (Version 2). This quality of life survey includes questionnaires related to physical functioning, role limitations due to physical health problems, bodily pain, general health perception, vitality (energy/fatigue), social functioning, role limitations due to emotional problems and general mental health. The score for each subscale was rated as 0 (worst health) to 100 (best health) independently [21].

There are four domains in the WHOQOL-BREF questionnaire. The physical (D1), psychological (D2), social (D3) and environment (D4) domains contain 26 questions on different aspects of quality of life. These scores are rated in a positive direction that means higher the score better is the quality of life [23].

Patient evaluation

A total of 214 patients were recruited. There were 59 males and 155 females. The average age of the participants was 56 ± 8 years (range 40–75 years). The demographic details, disease profile, treatment details and outcome as evaluated using the three scales were entered into a Microsoft excel sheet. There were 174 patients who were treated with physical therapy and analgesics, 40 patients were treated with intraarticular injection of hyaluronic acid (Fig. 1). The KOOS questionnaire was re-administered to 125 patients, 48-h after the first assessment to evaluate the instrument's test–retest reliability. The psychometric properties of the H-KOOS were evaluated using COnsensus-based Standards for the selection of health status Measurement Instruments (COSMIN) check list. As per COSMIN recommendation, minimum of 5 participants per item (minimum sample size of 210 for 42 items of H-KOOS) are needed for validation. Accordingly, the sample size of the present study was adequate [5, 25].

Statistical analysis

The data were analysed using the Statistical Product Service solutions version 17.0 for windows (SSPS Inc. Chicago,

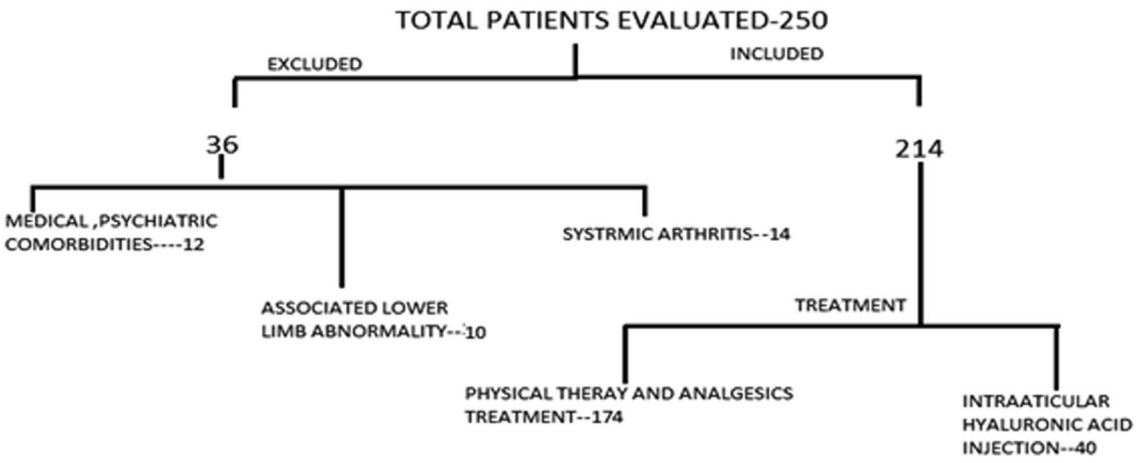

Fig. 1 Showing the flow chart of patient enrolment of the study

IL). The statistical tests were two-tailed and conducted at a 5% level of significance. The test–retest reliability was analysed using the Intraclass Correlation Coefficient (ICC). The ICC of ≥ 0.70 was considered as satisfactory for test–retest reliability, whereas ICC of ≥ 0.8 was considered as excellent reliability [7]. The internal consistency, an additional measure of reliability, was measured using Cronbach's alpha coefficient. Cronbach's alpha coefficient of ≥ 0.70 was considered acceptable. The dimensionality actually indicates the item-scale correlation. It was considered acceptable if the Spearman correlation coefficient was ≥ 0.40 [7].

The content validity was assessed by asking the patients about the importance of all subscales of H-KOOS. The participants rated their response as extremely important, very important, moderately important, somewhat important, or not important at all. To assess the construct validity of an outcome measure, the researchers need to have a priori hypothesis on the associations with other validated instruments. There should be moderate to strong correlations between domains measuring similar concepts (convergent construct validity) and weak correlations between domains measuring dissimilar concepts (divergent construct validity). The correlation was considered as strong, moderate, and weak based on the coefficient value of > 0.50, 0.35–0.50, and < 0.35, respectively [22]. The floor and ceiling effects were analysed in the descriptive statistics. The floor and ceiling values were acceptable if $< 15\%$ of the patients scored either the lowest score or the highest possible score [18]. Responsiveness was evaluated in the hyaluronic acid joint injection group by comparing the pre- and post-injection results. The standardized response mean (SRM) and effect size (ES) were calculated to look for responsiveness. SRM is the mean score change between baseline and 6 weeks post-injection, divided by the SD of the mean score change. The ES is the mean score change between baseline and 6 weeks post-injection, divided by the SD of the pre-surgery value. The ES was interpreted as large (≥ 0.80), moderate (≥ 0.50) or small (≥ 0.20) as described by Husted et al. [11].

Results

The test–retest reliability of H-KOOS was excellent as the ICCs were 0.94 for pain, 0.93 for symptoms, 0.91 for ADL, 0.89 for Sport/Rec function and 0.92 for QoL. The internal consistency or correlation between items of the H-KOOS domains was satisfactory except for symptoms and QoL. The Cronbach's alphas coefficient for pain was 0.86, symptoms 0.43, ADL 0.93, sport/Rec 0.88 and QoL 0.58. The dimensionality was acceptable, with item-to-domain Spearman's rank correlations coefficient of > 0.40 for all H-KOOS items except two items in the symptoms subscale (Table 1).

Regarding content validity, 94% of patients reported that the pain, symptoms, ADL and QoL were extremely important or very important. However, the response for sports and recreation function was very important in only 30% patients.

The construct validity of H-KOOS correlated well with the assumption. The H-KOOS pain correlated strongly with SF-12v2 BP (0.529, $p < 0.001$) and WHOQOL-BREF D1 ($r = 0.500$, $p < 0.001$) subscales (Table 2). Similarly, all priori hypotheses for convergent construct validity were supported by moderate to strong correlation coefficient ($r = 0.355$ to 0.6) between domains measuring similar paradigms in H-KOOS, SF12v2 and WHOQOL-BREF (Table 2). Contrary to it, the subscales of H-KOOS correlated weakly ($r < 0.3$) with the mental health subscale of SF12v2 and social/environmental subscales of the WHOQOL-BREF questionnaire. These findings indicate satisfied divergent or discriminant validity of H-KOOS (Table 3).

Table 1 Dimensionality of KOOS items

KOOS domains and items	Spearman's rank correlation coefficient
Pain	
P1. How often do you experience knee pain	−0.52
P2. Twisting/pivoting on your knee	−0.68
P3. Straightening knee fully	−0.76
P4. Bending knee fully	−0.72
P5. Walking on flat surface	−0.67
P6. Going up or down stairs	−0.68
P7. At night while in bed	−0.60
P8. Sitting or lying	−0.73
P9. Standing upright	−0.70
Symptoms	
S1. Do you have swelling in your knee	−0.60
S2. Do you feel grinding/friction, hear clicking/cracking or any other type of noise when your knee moves	−0.62
S3. Does your knee jam or lock when moving	−0.49
S4. Can you straighten your knee fully	**−0.18**
S5. Can you bend your knee fully	**−0.09**
S6. How severe is your knee joint stiffness after first wakening in the morning	−0.62
S7. How severe is your knee stiffness after sitting, lying or resting later in the day	−0.59
ADL	
A1. Descending stairs	−0.68
A2. Ascending stairs	−0.71
A3. Rising from sitting	−0.73
A4. Standing	−0.74
A5. Bending to floor/pick up an object	−0.73
A6. Walking on flat surface	−0.70
A7. Getting in/out of car	−0.74
A8. Going shopping	−0.70
A9. Putting on socks/stockings	−0.66
A10. Rising from bed	−0.77
A11. Taking off socks/stockings	−0.69
A12. Lying in bed	−0.71
A13. Getting in/out of bath	−0.69
A14. Sitting	−0.60
A15. Getting on/off toilet	−0.65
A16. Heavy domestic duties	−0.62
A17. Light domestic duties Sport/Rec	−0.73
Symptoms	
Sp1. Squatting	−0.82
Sp2. Running	−0.84
Sp3. Jumping	−0.84
Sp4. Twisting/pivoting on your injured knee	−0.72
Sp5. Kneeling	−0.79
QoL	
Q1. How often are you aware of your knee problem	−0.53
Q2. Have you modified your life style to avoid potentially damaging activities to your knee	−0.61
Q3. How much are you troubled with lack of confidence in your knee	−0.70
Q4. In general, how much difficulty do you have with your knee	−0.7

Correlations were negative as higher item scores reflect lower QoL, while higher domain scores reflect higher QoL. Item-scale correlations less than 0.40 are in bold figures

Table 2 Convergent construct validity among similar domains of the assessment scale

Koos subscale	SF12v2 BP (r)	WHOQOL-BREF D_1 (r)
Pain	0.529	0.500
KOOS subscale	SF12v2 PF(r)	WHOQOL-BREF D_1(r)
ADL	0.488	0.600
KOOS subscale	SF12v2 BP(r)	
Sport/Rec	0.548	
KOOS subscale	SF12v2 BP(r)	SF12v2 PF(r)
QoL	0.433	0.355

r = correlation-coefficient

Table 3 Divergent construct validity between domains measuring dissimilar constructs

A. All KOOS domains with SF-12v2 MH, WHOQOL-BREF D3, D_4			
KOOS Subscale	SF-12v2 MH(r)	WHOQOL-BREF D_3(r)	WHOQOL-BREF D_4(r)
Pain	0.332	0.185	0.167
Symptoms	0.232	0.047	0.015
ADL	0.354	0.223	0.251
Sport/Rec	0.300	0.213	0.286
QoL	0.294	0162	0.158
B. KOOS pain, symptoms, and sport and recreation function with SF-12 social functioning.			
Pain	0.247		
Symptoms	0.118		
Sport/Rec	0.309		

Table 4 The mean values of KOOS subscale with floor/ceiling percentages

KOOS subscale	Mean	Standard deviation	Range	Percent at floor/ceiling
Pain	48.02	18.083	3–97	0/0
Symptoms	44.48	16.426	4–96	0/0
ADL	44.88	19.449	0–88	0.46/0
Sport/rec	23.40	18.642	0–80	3.75/0
QoL	26.86	16.431	0–100	2.5/0.46

Most of the domains in H-KOOS did not show a ceiling effect. The floor values were observed in 3.75% of patients in sport/recreation function and 2.75% of patients in QoL assessment (Table 4, Fig. 2). These values were within the acceptable range (< 15% patients, Fig. 2).

The responsiveness, as evaluated after 6 weeks of intraarticular hyaluronic acid showed large responsiveness (ES 0.9, SRM 0.8) for pain and moderate responsiveness (ES 0.66, SRM 0.62) for the sport/recreation domain. The symptoms, ADL and QOL, showed small responsiveness (≥ 0.2) (Tables 5, 6, Fig. 3).

Discussion

The most important findings of the present study were that the Hindi version of the KOOS was a reliable, responsive and valid measure of patient-relevant outcomes in osteoarthritis knee. The H-KOOS correlated very well with the WHOQOL- BREF scale and the subscales of SF-12v2 on its ability to measure the physical health (convergent construct validity) accurately. However, a low correlation (divergent construct validity) was observed when H-KOOS were correlated to the WHOQOL-BREF and SF-12v2 in the subscales that evaluate mental health.

The content or face validity evaluates the importance of the domains/items on patient's health condition. A low content validity towards sport/recreation function domain of H-KOOS indicated that there was less demand of sports and recreation activity among patients of advanced OA. Contrary to it, Roos et al. observed a greater demand of sports and recreation activities in their patients who were expecting a greater functional activity after total knee arthroplasty [19].

Reliability denotes the degree to which an outcome measure produces the same results on frequent applications in a population with steady health. If the outcome measure is less reliable, there will be more variability in the observation [22]. In such a scenario, the instrument cannot detect small but important clinical changes. In the current study, test and retest reliability in a random sample of 125 patients were excellent for all subscales which were consistent with Portuguese, Italian and French versions KOOS with the ICC > 0.70 for all subscales [10, 13, 15]. Singapore English and Chinese version had ICC > 0.70 for four of five domains in both versions [24]. Similarly, the Persian version KOOS had acceptable reliability in all subscales except sport/recreation [20]. The test–retest reliability assessments in most of the studies were performed between 2 and 4 weeks [6, 10, 13, 14]. However, with treatment, there is a possibility of improvement within this period, and the patient may demonstrate improvement in knee and health condition. Therefore the assessment at such a gap may reveal responsiveness rather than reliability [2]. The patients in this study were evaluated after 2 days which is the minimum duration for test–retest reliability assessment, and there was no expected gross improvement in the health condition of the patient in such a short time. The KOOS questionnaire assessed the test–retest reliability more accurately, particularly in an advanced stage of osteoarthritis where medical treatment has minimal effect on the outcome.

Internal consistency, another measure of reliability, is the extent to which items in a scale or subscale are

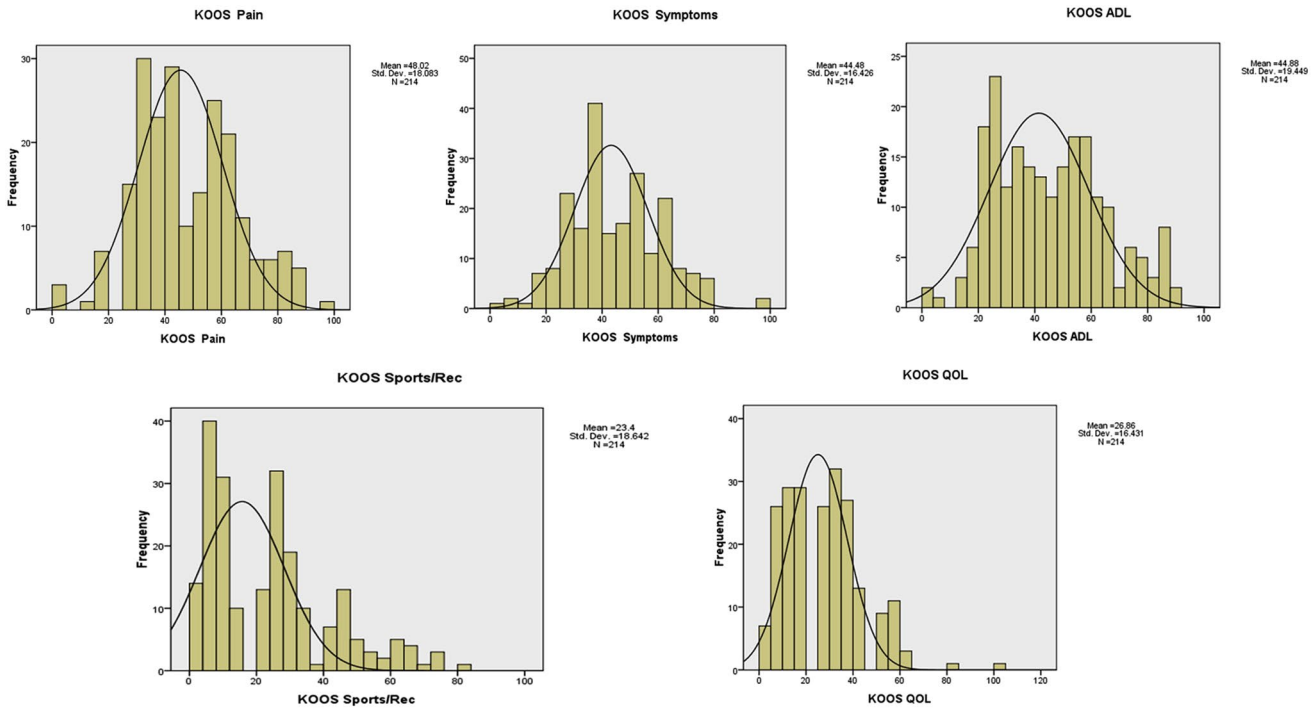

Fig. 2 Figure showing Floor and ceiling effects of KOOS domains

Table 5 Responsiveness in different domains of KOOS scale after IA Hyaluronic acid injection

KOOS subscale	Standardized effect size (effect size I)	Standardized response Mean (effect size II)
Pain	**0.90**	**0.80**
Symptoms	0.30	0.43
ADL	0.38	0.40
Sport/Rec	*0.62*	*0.66*
QoL	0.28	0.34

The effect sizes were calculated as described by Husted et al.; effect size values were interpreted as large (≥0.80), moderate (≥0.50) or small (≥0.20). The questionnaire was completed twice, before and after 6 weeks of IA hyaluronic acid injection. Large responsiveness in bold; moderate responsiveness in italic

Table 6 Change in KOOS-subscale after 6 weeks of intraarticular hyaluronate injection (responsiveness)

		Mean	*N*	Std. Deviation	Std. Error Mean
Pair 1	KOOS Pain	40.65	40	14.811	2.342
	KOOS pain2	54.04	40	18.567	2.936
Pair 2	KOOS symptoms	46.79	40	16.312	2.579
	KOOS symptoms 2	51.79	40	13.841	2.188
Pair 3	KOOS ADL	40.74	40	19.136	3.026
	KOOS ADL2	47.94	40	19.368	3.062
Pair 4	KOOS sport/Rec	20.25	40	13.911	2.200
	KOOS sport/Rec2	28.87	40	17.522	2.770
Pair 5	KOOS QOL	26.62	40	16.526	2.613
	KOOS QOL2	31.29	40	13.284	2.100

correlated, thus measuring the same construct. The internal consistency reliability was satisfactory in this study in all subscales except symptoms and QoL. This result was similar to that of the Persian version of KOOS [20]. The internal consistency in the Chinese version of KOOS was satisfactory for all subscales except symptoms and pain [24]. The internal consistency was acceptable in the Portuguese, Italian, French, Swedish and Singapore English versions of the KOOS [10, 13, 15, 17, 24].

The dimensionality of H-KOOS was satisfactory, with item-to-domain Spearman's rank correlations coefficient of more than 0.40 for all KOOS items except for symptom items 4 and 5. This observation was in consistence with other validated versions calculating dimensionality of the KOOS [6, 10, 13–15, 20, 24]. Italian version showed similar dimensionality, with item-to-domain Spearman's rank correlations coefficient of > 0.40 for all KOOS items [13]. The Persian version had an acceptable correlation in all

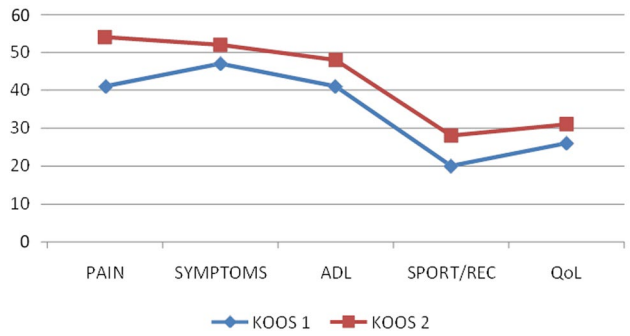

Fig. 3 Improvement in KOOS subscales after 6 weeks of IA hyaluronate injection (KOOS 1= subscale scores before intraarticular hyaluronic acid injection, KOOS 2= subscale scores after intraarticular hyaluronic acid injection)

subscales except seven symptom items and one QoL item [20]. The study by Xie et al. appraised the dimensionality of Singapore English and Singapore Chinese versions KOOS in elderly individuals of OA [24]. They reported a satisfactory correlation between the items and domains of sport/recreation and QoL (correlations ≥ 0.3) as it was for ADL items in the English version. But the correlations were suboptimal for pain items 1 and 2, symptoms items 2 and 6, and ADL items 14 and 15 [24]. An acceptable dimensionality has been reported after anterior cruciate ligament and meniscus injury in young patients [17, 18]. The Italian, Portuguese and French versions did not evaluate KOOS for dimensionality [10, 13, 15].

The floor and ceiling effects, as observed in this study, was acceptable. The sport/recreation function of H-KOOS demonstrated the floor effect probably because of the inclusion of advanced OA knee patients who were severely impaired to perform high functional demand activities. A similar observation was noted by the developers and all other adapted versions of KOOS except the Portuguese version [6, 10, 13–15, 18, 20, 24]. The Portuguese KOOS did not show floor or ceiling effects in any of the KOOS subscales [10].

The changes in the H-KOOS subscales after the medical intervention was appreciable in this study. The responsiveness as measured by ES and SRM in 40 subjects before and after IA hyaluronic acid injection was large for pain subscale, moderate for sport/recreation subscale and small for ADL, QoL and Symptoms subscales. The moderate to small responsiveness in most of the subscales in this study could be due to advanced OA knee where IA hyaluronic acid injection could not produce substantial impacts. Collins and associates reported that the ES is expected to be more with surgical intervention (total knee replacement, TKR) than the nonsurgical treatment [5]. The responsiveness, as reported in this study, is hence justified. Even then, IA hyaluronate resulted in a substantial decrease in knee pain, indicating a beneficial effect of this treatment in OA knee for symptomatic pain relief. The Portuguese version of KOOS showed large to moderate responsiveness after 4 weeks of physical therapy for all subscales [10]. The French version of KOOS showed large responsiveness for all the subscales after 3 months of TKR in patients with OA knee [15]. Swedish version demonstrated large responsiveness for all the subscales after 6 months of partial meniscectomy in patients with a knee injury [17]. The responsiveness has not been evaluated in many other languages (Singapore English and Chinese, Persian, Italian, Dutch versions) [13, 17, 20, 24].

Limitations

There are several limitations to this study. The subjects evaluated in this study may not fully represent the whole Indian population. Although Hindi is the national language of India, India has multiple languages. It should be noted that there may be cultural and language variations as well. As most of the study participants were in the advanced stage of the disease, this study possibly may not represent the complete disease profile of OA knee. Furthermore, knee injury and postoperative patients were not recruited in this study. Nevertheless, this study has validated the H-KOOS for the first time, and it can be widely applied among Hindi-spoken patients throughout the world to assess the treatment response or knee function in osteoarthritic conditions.

Conclusion

Hindi version of KOOS demonstrated strong measurement properties in terms of validity, reliability and responsiveness. It has low ceiling and floor effects. Thus Hindi version KOOS can be an important patient-reported outcome measure to evaluate knee function in Indian population. The psychometric properties of Hindi version KOOS need to be evaluated for other knee pathologies and treatment for its wider acceptance.

Author contributions This study was conducted in the Department of Orthopaedics, Postgraduate Institute of Medical Education and Research, Chandigarh, INDIA as a part of dissertation submitted by Dr. Ranjan Kumar Jha for his M.S. degree in Orthopedics under the guidance of Dr. RK Sen, Dr G Nirmal Raj and Dr SK Sharma. The initial concept was designed by RKS, GNR, SKT, TG and SKS. The data were collected by RKJ, GNR and RKS. The data were analyzed and statistical analysis was performed by SKS and TG. The final draft was prepared by SKT, TG, RKJ and RKS. All the authors have read the final manuscript and approved for publication.

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Compliance with ethical standards

Conflict of interest The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval The study was conducted in Postgraduate Institute of medical Education and Research, Chandigarh, India. The institutional ethics committee approved the study (IEC approval No: NK/827/MS/3312-13).

Informed consent Informed consent was obtained from all individual participants included in the study. Each author certifies that he or she has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

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