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Original Research Article

Validation of a patient-reported knee-specific outcome questionnaire specifically intended to assess pain, stiffness, and functional activities in Indians with osteoarthritis knees: an observational cross-sectional study

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ABSTRACT

Background: Patient-reported outcome measurement assessments that are frequently used for knee joint disorders have ceiling effect. This restriction is allegedly not there in New Hindi score. Purpose of this study is to validate New Hindi Score in patients with osteoarthritis knee.
Methods: Level II Prospective cohort study was conducted. In pilot study, 20 patients had their comprehension of New Hindi Score assessed. A prospective cohort study involving 200 individuals with osteoarthritis knee Kl grade 2 and 3 was conducted in AIIMS, Rishikesh, Uttarakhand. Patients' overall age 57.76±8.63 years, both mean and SD. There were 125 females & 75 males. Men's mean & SD were 59.52±9.39 while women's 56.70±8.00. All patients were requested to complete WOMAC, KOOS, OKS & New Hindi Score questionnaires. Validity, reliability, repeatability of New Hindi Score for knee function in KOA patients were evaluated. There's no floor ceiling effect. New Hindi Score's validity, responsiveness, and floor ceiling effect were assessed. Validity was measured using the Pearson correlation coefficient.
Results: In pilot study participants answered all question accurately. New Hindi Score shows moderate correlation with WOMAC & weak correlation with OKS and KOOS (Pearson coefficients of 0.45, 0.21, and 0.28, respectively) with 95% confidence interval, indicating strong construct validity in primary study. There was no floor or ceiling effect seen.
Conclusions: For KOA patients, New Hindi Score exhibits strong levels of validity, reliability, and reliability. As result, it can be effectively applied to research knee function in Indian population.

Keywords: WOMAC, New Hindi Score, OKS, KOOS

INTRODUCTION

A patient-centered analysis of outcomes is provided by patient-reported outcome measures (PROMs). The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the Oxford Knee Score (OKS), and the Knee Injury and Osteoarthritis Outcome Score (KOOS) are popular PROMs for knee arthritis. However, they have a ceiling effect, which means that they might not be able to distinguish between patients who achieve outcomes that are better than the upper bounds of the scores.[1,2] This study aims to develop and validate a functional knee joint evaluation instrument for patients who understand Hindi. This will make the New Hindi Score tool more applicable. The purpose of this study is to evaluate its validity, reliability, floor effect, and ceiling impact among KOA patients. Our hypothesis was that the questionnaire is a valid tool for functional assessment of the knee joint and

is free from the ceiling effect. It can also help establish a knee osteoarthritis (OA) rehabilitation protocol that would delay surgical procedures and potentially halt the progression of knee osteoarthritis. Finally, the questionnaire can identify risk factors for knee OA in the Indian population.

METHODS

This was a prospective observational study, conducted in All India Institute of Medical Sciences, Rishikesh, Uttarakhand, a tertiary care teaching institute of North India, from December 2021 to January 2022. Patients aged 45-75 were screened in the OPD of department of orthopedics with unilateral or bilateral osteoarthritis knee, with Grade 2 or 3 on the Kellgren Lawrence Scale and who fulfil inclusion criteria following EULAR diagnostic guidelines 2010. Men and women aged 45-75, All patients having knee pain interfering ADL, medial joint line tenderness, intra-articular crepitus, varus deformity, KL grade 2 or 3 were included in study while patients with post traumatic knee pain ,previous H/O of knee septic OA, dislocation of patella, any previous surgery of the knee, any inflammatory arthritis affecting the knee, with any spine deformity/LCS/or associated radiculopathy due to back-ache which may interfere with ADL, knee ligament injury, osteonecrosis were excluded. The patients were asked to fill up the New Hindi questionnaire, WOMAC, Oxford Knee Score and KOOS and after that SPSS version 21 was used for statistical analysis for result.

Pilot study

New Hindi Score was tested for comprehensibility, ease of reading, cultural suitability and acceptability in 20 patients. The patients assessed each question on a Likert scale of 1-5 (from highly unsuitable to highly suitable) The main study was carried out after this pilot testing. Data from the pilot study were not included in the main study.

Study population

Total 200 patients were enrolled in the study. The mean age of patients was 58.79±10.69 years. There were 125 (62.50%) females and 75 (37.50%) males. Both knees were scored and mean score was taken as the final value. Patients aged 45-75 both men and women were screened in the OPD of Department of Orthopedics with unilateral or bilateral osteoarthritis knee, with Grade 2 or 3 on the Kellgren Lawrence Scale and who fulfill inclusion criteria following EULAR diagnostic guidelines 2010. Informed and written consent was taken from all the patients included in the study. Sample size was calculated on the basic of pilot study on 20 patients. The patients were asked to fill up the New Hindi questionnaire, WOMAC, Oxford Knee Score and KOOS. Scores other than Hindi score were in English language, assistance of a health care personnel was provided in case the patient was not fluent in English. After that statistical analysis was done to get the result. The New Hindi Questionnaire was tested methodology for validity, reliability and responsiveness according to the Consensus-based Standard for the selection of health status Measurement instruments (COSMIN) checklist.[3]

Validity

The validity of a score is a measure of how closely an instrument can measure the parameter that it is intended to measure.[4] Construct validity was tested for the New Hindi Score. It tests the correlation of the score with other scoring systems. Correlation coefficient >0.7 was taken as good, 0.3-0.7 as moderate and <0.3 relates as poor.[5,6]

Reliability

Test–retest reliability or reproducibility is the extent to which the score remains unchanged on repeated measurements.

Floor and ceiling effects

It is the ability of the score to discriminate between readings in its extreme ranges, and is present if more than 15% of participants achieve the lowest or highest possible score.[7]

Statistical analysis

Normal distribution were age and body mass index (BMI), while the other variables did not. Descriptive statistics for normally distributed data, the mean and standard deviation were used. When comparing means between two sets of normally distributed data, the t-test was used and for continuous variable Chi-square test was used, p values of 0.05 or less were regarded as significant. SPSS version 21 was used to do the statistical calculations.

RESULTS

Pilot study

In the pilot study, it was seen that all the questions were answered by most of the participants. The results of the pilot study are summarized in (Table 1). The pilot study showed good cross-cultural adaption of New Hindi Score.

Final study

Data of 200 patients were analyzed (Figure 1). Demographic data of these patients are given in (Table 2). The second questionnaire was completed, on average, 20.8±7.4 days (range 14-32 days) after the first questionnaire, for calculation of test-retest reliability. The mean of two scores was taken as the final score for this study. The distribution of scores in relation to gender is summarized in (Table 3).

Table 1: Translated English version of new Hindi questionnaire (actual questionnaire is available in supplementary) with pilot study and final study values.

New Hindi questionnaire translated version		Pilot Study		Final Study	
In the last two months	**Likert score (Mean±SD)**	**New Hindi score (Mean±SD)**	**%**	**New hindi score (Mean±SD)**	%
What difficulties are you having because of knee pain?	2.65±1.26	0.11±0.04	100	0.10±0.04	100
When do you feel pain in your knees?	2.61±0.09	0.13±0.03	100	0.11±0.04	100
Are you facing inconvenience in doing your daily life activity?	2.45±1.19	0.12±0.43	100	0.11±0.52	100
Do you have sleep disturbance due to knee pain?	2.65±1.22	0.04±0.05	100	0.04±0.03	100
Due to knee pain you have pain in other joints also?	2.4±.94	0.04±0.42	100	0.05±0.04	100
How do you treat pain in your knees?	2.75±1.20	0.07±0.05	100	0.06±0.05	100
Does knee pain affect your social life (like meeting friends/going to functions/prayer meetings)?	3.2±1.05	0.03±0.03	100	0.04±0.04	100
Total	18.7±2.65	0.55±0.17	100	0.5±0.2	100

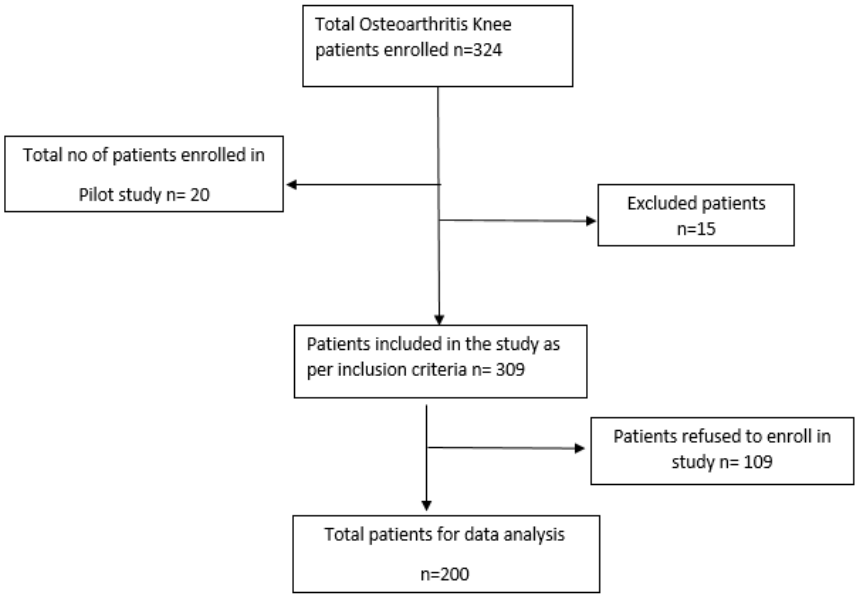

Figure 1: Flow chart of patients in the study.

Table 2: Demographic details of the patients in the study.

Parameters	Mean±SD	Range
Age (years)		
Females	50.50±0.68	45-59
Males	66.5±6.63	59-75
Total age	58.79±10.69	45-75
BMI (kg/m^2)	25.36±5.69	45-75
Variables	**N**	**%**
Gender		
Female	125	62.50
Male	75	37.50
Education		
Female	44	40
Male	23	21
Kellgren-Lawrence scale		
Grade II	39	19.5
Grade III	161	80.5

Table 3: Distribution of age and PROMs with respect to gender and correlation of new Hindi Score with other PROMs.

Variables	Male (mean±SD)	Female (mean±SD)	Total (mean±SD)	Correlation coefficient (r)	P value
New Hindi score	48.14±22.78	53.49±19.61	44.04±22.19	-	-
WOMAC	42.75±21.90	47.82±23.21	39.24±20.57	0.418	<0.05
KOOS	27.8±14.28	25.35±8.41	45.46±21.46	0.284	<0.05
OKS	25.86±13.24	32.2±17.08	26.27±12.64	0.418	<0.05

The new Hindi score questionnaire has been translated to English but the actual questionnaires are available in supplementary, and shared the link to the Hindi questionnaire.

Validity

The average new Hindi score was 44.04±22.19. Construct validity was good, with New Hindi Score showing moderate correlation with WOMAC and weak with OKS and KOOS (Table 3).

DISCUSSION

Good validity and reliability were seen for New Hindi score, with the absence of ceiling or floor effect. This study showed good internal consistency, consistent with the available literature.[1,3] A good test-retest reliability was seen.[5-10] No floor or ceiling effect was found. Baumann et al Clement et al found a high ceiling effect in the pain and stiffness components of WOMAC and WOMAC is a commonly used score for knee and has validated versions in about 80 languages.[8,11] Gandek et al found high internal consistency and test-retest reliability for the WOMAC score.[12] The pain score of WOMAC may not be an accurate measure of pain as it closely corresponds with physical activity (or pain due to physical activity). Pain during function may be influenced by other associated problems such as back pain, hip pain, or contralateral knee pain rather than being specific to the joint in question.[13]

Limitations

This study's significant weakness is that it was not possible to measure new Hindi score to ascertain periodic variations.

CONCLUSION

New Hindi score shows high validity, reliability and reproducibility for Osteoarthritis knee patients. It is devoid of floor or ceiling effect. Thus, it can be an important tool for studying knee function in the Indian population.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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