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Original Research Article

Translation and Validation of Gujarati Version of WOMAC and Lequesne Questionnaire in Subjects with Knee Osteoarthritis

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ABSTRACT

Osteoarthritis (OA) of the knee is the most common joint disease in the elderly and is associated with significant physical disability for which there is no reliable and valid measure exists to determine functionality and activity of knee osteoarthritis in the Gujarati language. The WOMAC and LEQUESNE questionnaire are specifically designed for it but in English. The study aimed to translate the English version of WOMAC and LEQUESNE questionnaire into Gujarati language and validate a translated Gujarati version of it. The English version of WOMAC and LEQUESNE were translated into Gujarati language using the forward-translations and back-translation method according to WHO. After translation, the questionnaire was completed by 30 individuals (18 males and 12 females) aged 40-65 years (mean age: 51.53+9.80 years). The results on the reliability and validity of the Gujarati version of WOMAC and LEQUESNE were measured using Internal reliability index Cronbach's alpha, Intraclass Correlation Coefficient (ICC) and RASCH analysis. All the questions of WOMAC and LEQUESNE showed no statistically significant difference between the English version of WOMAC and LEQUESNE and the translated Gujarati version of WOMAC and LEQUESNE suggestive of valid tool for measuring the functionality and activity of knee OA in Gujarati population.

Key Words: Validity, Reliability, modified WOMAC, LEQUESNE questionnaire.

INTRODUCTION

Osteoarthritis of the knee is one of the most common type of arthritis and the major cause of chronic musculoskeletal pain and mobility disability in the elderly, resulting decreased functional activity. [1,2] There is no reliable and valid measure exists to determine functionality and activity of knee osteoarthritis in the Gujarati language. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and LEQUESNE are the most widely used condition-specific self-reported multidimensional instrument for the assessment of hip or knee osteoarthritis (OA), [3,4] but in English. Hence the objective of this study is to translate and to investigate the reliability and validity of modified WOMAC (mWOMAC) and LEQUESNE questionnaire Gujarati version in participants with knee OA.

MATERIALS AND METHODS

An observational study design was adopted. As there was no experimental human intervention to be undergone ethical

approval was not taken for the study. The participants were selected based on the inclusion and exclusion criteria designed for the study. These participants were registered for the study after obtaining the written informed consent form. The participants were provided with a participant information sheet. The samples included in our study were 30 individuals. The mean age of the participants was 51.53±9.80 (Table 2). The inclusion criteria were Both Male & Female patients aged between 40 years to 65 years with Chronic OA Knee (with symptoms for more than 3 months and less than 2 years) and Subjects who were not willing to take part in the study were excluded.

Process of translation of questionnaire:

For translation of modified WOMAC [5,6] and LEQUESNE from English language to Gujarati language cross culture adaptation guidelines were used. [7-9] This method included forward translation, expert panel, back-translation and testing of the questionnaire. **Step 1:** Forward translation- Two translators (one with the background of medical field and other with no background of medical field) who knew both English and Gujarati language were chosen to translate the questionnaire from English to Gujarati language. **Step 2:** Synthesis- Both the Gujarati versions were combined and two professionals who had knowledge of medical terminologies and were known to both the languages (English & Gujarati) developed a synthesised version. **Step 3:** Back-translation- The synthesised version of the questionnaire was back translated into English language by an independent translator, who knew both English and Gujarati language and had no information of the original questionnaire which was in English language. **Step 4:** Expert panel- A bilingual (in English and the Gujarati language) expert panel was convened which included the forward translator, health experts, as well as professionals with skill in questionnaire development and translation. The changes were done in the translated questionnaire based on the suggestions of the expert panel. **Step 5:** Testing of the questionnaire- A Pre Final Gujarati version of modified WOMAC and LEQUESNE were given to 30 participants who fulfilled the inclusion and exclusion criteria to find out the reliability and validity of the questionnaire. [10,11]

- **Reliability statistics**
- Three different tests have been conducted on Womac Index and Index of Severity *viz.*, Cronbach's Alpha, ANOVA with Cochran's Test and Intraclass Correlation Coefficient (ICC), in order to check for their reliability at baseline and on next day. The results are mentioned as below:

- **Reliability test results for WOMAC INDEX at baseline**

Cronbach's Alpha	
Cronbach's Alpha	N of Items
0.978	24

ANOVA with Cochran's Test						
		Sum of Squares	df	Mean Square	Cochran's Q	Sig
Between People		60.656	14	4.333		
Within People	Between Items	66.464	23	2.890	236.697	.000
	Residual	30.411	322	.094		
	Total	96.875	345	.281		
Total		157.531	359	.439		

Intraclass Correlation Coefficient							
	Intraclass Correlation	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.375	.228	.611	15.429	14	345	.000
Average Measures	.935	.877	.974	15.429	14	345	.000
One-way random effects model							

- **Reliability test results for WOMAC INDEX on next day**

Cronbach's Alpha	
Cronbach's Alpha	N of Items
0.979	24

ANOVA with Cochran's Test						
		Sum of Squares	df	Mean Square	Cochran's Q	Sig
Between People		60.917	14	4.351		
Within People	Between Items	70.975	23	3.086	243.747	.000
	Residual	29.483	322	.092		
	Total	100.458	345	.291		
Total		161.375	359	.450		

Intraclass Correlation Coefficient							
	Intraclass Correlation	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.367	.222	.603	14.943	14	345	.000
Average Measures	.933	.873	.973	14.943	14	345	.000
One-way random effects model							

- **Reliability test results for index of Severity at baseline**

Cronbach's Alpha	
Cronbach's Alpha	N of Items
.901	11

ANOVA with Cochran's Test						
		Sum of Squares	df	Mean Square	Cochran's Q	Sig
Between People		15.782	14	1.127		
Within People	Between Items	54.315	10	5.432	116.390	.000
	Residual	15.685	140	.112		
	Total	70.000	150	.467		
Total		85.782	164	.523		

Intraclass Correlation Coefficient							
	Intraclass Correlation	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.114	.021	.318	2.416	14	150	.004
Average Measures	.586	.191	.837	2.416	14	150	.004
One-way random effects model where people effects are random.							

- **Reliability test results for index of Severity on next day**

Cronbach's Alpha	
Cronbach's Alpha	N of Items
.898	11

ANOVA with Cochran's Test						
		Sum of Squares	df	Mean Square	Cochran's Q	Sig
Between People		15.112	14	1.079		
Within People	Between Items	54.567	10	5.457	117.005	.000
	Residual	15.388	140	.110		
	Total	69.955	150	.466		
Total		85.067	164	.519		

Intra-class Correlation Coefficient							
	Intraclass Correlation	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.107	.016	.307	2.315	14	150	.007
Average Measures	.568	.156	.830	2.315	14	150	.007
One-way random effects model							

- **Validity Statistics**
- **Validity test results for WOMAC INDEX : Rasch analysis**

FIT OF ITEMS OF THE WOMAC INDEX TO THE RASCH MODEL					
		Base Line Value		Next Day	
Sr. No.	Item No.	INFIT MNSQ	OUTFIT MNSQ	INFIT MNSQ	OUTFIT MNSQ
1	23	1.36	0.90	1.24	0.83
2	22	1.20	0.61	1.09	0.53
3	7	1.33	1.42	1.47	1.68
4	5	1.23	0.71	1.17	0.69
5	11	1.23	0.71	1.20	0.64
6	12	0.88	0.75	0.78	0.71
7	24	0.73	0.85	0.66	0.81
8	6	0.83	0.81	0.80	0.74
9	16	0.93	1.23	0.86	1.17
10	1	0.90	0.77	0.84	0.72
11	13	0.98	0.93	0.91	0.87
12	3	0.62	0.82	0.59	0.78
13	2	0.73	1.72	0.64	1.68
14	4	0.69	1.14	0.61	1.01
15	8	0.93	1.21	0.88	1.19
16	9	1.17	0.62	1.11	0.57
17	10	1.03	0.79	1.08	0.91
18	14	1.28	0.81	1.21	0.93
19	15	0.73	1.02	0.71	1.08
20	17	0.84	1.86	0.77	1.76
21	18	0.68	1.70	0.69	0.74
22	20	1.23	1.71	1.28	1.79
23	19	1.39	0.66	1.23	0.61
24	21	0.60	0.96	0.78	1.01

- **Validity test results for INDEX OF SEVERITY: Rasch analysis**

FIT OF ITEMS OF THE INDEX OF SEVERITY TO THE RASCH MODEL					
		Base Line Value		Next Day	
Sr. No.	Item No.	INFIT MNSQ	OUTFIT MNSQ	INFIT MNSQ	OUTFIT MNSQ
1	3	1.39	1.20	1.44	1.33
2	5	1.01	0.93	1.09	1.03
3	6	0.75	1.16	0.87	1.28
4	1	1.23	1.31	1.17	1.69
5	4	1.23	1.71	1.20	1.64
6	8	0.77	0.75	0.78	0.71
7	9	0.74	0.61	0.74	0.61
8	10	0.79	0.66	0.80	0.69
9	7	0.93	1.23	0.86	1.04
10	11	0.89	0.63	0.84	0.59
11	2	0.57	0.50	0.43	0.48

- **Paired T Test for variation in WOMAC index scale response between therapist**

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair between	therapist_1	33.40	15	2.558	.660
	therapist_2	33.00	15	2.070	.535

Paired Samples Test									
		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair between	therapist_1 and therapist_2	0.400	1.183	0.306	-0.255	1.055	1.309	14	0.212

- **Paired T Test for variation in womax index scale response due to time gap**

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	first_day	33.27	15	2.404	.621
	second_day	33.07	15	2.520	.651

Paired Samples Test									
		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	first_day - second_day	.200	.561	.145	-.110	.510	1.382	14	.189

Paired Samples Test									
		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	therapist_2 - therapist_1	-0.133	0.915	0.236	-0.640	0.374	-0.564	14	0.582

- **Paired T Test for variation in index of severity scale response between therapist**

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	therapist_2	8.73	15	1.710	.441
	therapist_1	8.87	15	1.995	.515

- **Paired T Test for variation in index of severity scale response due to time gap**

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	first_day	8.80	15	2.077	.536
	second_day	8.60	15	1.682	.434

Paired Samples Test									
		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	first_day - second_day	0.200	0.775	0.200	-0.229	0.629	1.000	14	0.334

RESULTS

- **Reliability of both scales**
- Internal consistency was obtained through Cronbach's alpha. It was obtained good for both WOMAC (0.978 & 0.979 at first and second day respectively) and Lequesne Index (0.901 and 0.898 for first and second day respectively). Another measure to test reliability of the scales was Intraclass Correlation Coefficient (ICC), it was adequate for both scales WOMAC (0.935 and 0.933 at first and second day respectively) and Lequesne (0.586 and 0.568 at firsts and second day respectively)

- **Validity of both scales**
- It was assessed through RASCH analysis which is based on item response theory. Fit of WOMAC and Lequesne Index showed adequate fit of items to a single construct. In WOMAC items 7, 17 and 20 show an outfit of (1.68), (1.86;1.76) and (1.71;1.79) respectively. It shows abnormal response of participants to these items. Item 22 shows less fit 0.53, thereby suggesting some redundancy in scale. For Lequesne item 1 and 4were problematic with an outfit of 1.69 and 1.71 respectively and item 2 shows less fit. Other than these items most of the items show adequate fit to RASCH model.
- **T-Test**
- **Paired T-Test**
- It was conducted to check variation (if any) in WOMAC INDEX scale and Lequesne questionnaire response between first and second day and between two different therapists. In both scales the p value obtained was >0.05 suggesting no difference in scale measurements.

DISCUSSION

There is much emphasis today on using standardized and validated research instruments as these enable comparison of results both within and across countries. A patient reported outcome (PRO) is an umbrella term that covers a whole range of potential types of measurement; it is used specifically to refer to measures that quantify a patient's state of health in terms of outcomes reported by himself/ herself. The common feature of PROMs is their grounding in the patient's perspective. PROMs are increasingly seen as complementary to biomedical measures and they are being incorporated more frequently into clinical trials and clinical practice. When they are used, there is the underlying assumption that the use of a validated instrument ensures that it increases the certainty with which the instrument accurately reflects what it is supposed to measure. [12] Thus, in a country like India, instruments like the WOMAC have significant ethical implications for several reasons. Linguistically translated versions are not the same as those that have undergone cross-cultural adaptation; the latter being needed when the scale is used in another country, language and setting. [13] In India, there are 22 officially recognized languages. Data in multi-centric studies are ultimately pooled and, thus, cross-cultural adaptation is necessary for each one of these languages if the pooled data are to be really relevant. [14] Our results showed that Gujarati version of WOMAC and Lequesne questionnaire are used to be reliable and valuable tool for measuring the functionality and activity of knee osteoarthritis patients.

CONCLUSION

This study concluded that the translated Gujarati version of WOMAC and Lequesne Questionnaire are considered to be a valid tool for measuring functionality and activity of patient with knee osteoarthritis in Gujarati population.

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