

Assessing the Responsiveness of the Persian Version of the Western Ontario Meniscal Evaluation Tool in Patients with Meniscus Injuries

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Article Type	ABSTRACT
Research Paper	Background and Objective: Responsiveness is one of the important properties of health-related questionnaires in demonstrating the changes in a patient's clinical conditions before and after therapy. The present study was carried out with the aim of assessing the responsiveness of the Western Ontario Meniscal Evaluation Tool (WOMET) and determining its minimal clinically important difference in patients undergoing physical therapy interventions after meniscus injuries. Methods: This cross-sectional methodological study was performed on 100 patients aged 18-70 years with meniscus injuries who underwent physical therapy interventions. Patients completed WOMET and Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaires in the first and tenth sessions. The minimum score obtained from the WOMET questionnaire was zero and the maximum was 1600, and the minimum score obtained from the KOOS questionnaire was zero and the maximum was 168. Internal and external responsiveness were the primary outcomes, and effect size tests, ROC curves, and correlation coefficients were used to examine them. The relationship between the WOMET and KOOS questionnaires were considered as secondary outcomes, which were evaluated by calculating the correlation coefficient. Findings: The results of internal responsiveness showed that the standardized response mean for the entire WOMET questionnaire was 0.11 (insignificant) and Cohen's d score for the entire WOMET questionnaire was -1.586 (large). The difference in the mean internal responsiveness between recovered (20%) and unrecovered (80%) patients reached a significant level ($p < 0.001$). This questionnaire had an acceptable external responsiveness; the area under the curve of the ROC curve was greater and equal to 0.7 and the optimal cut-off point was 20.031 ($p < 0.001$). The Pearson correlation coefficient between WOMET and KOOS questionnaires (except the emotions subscale) was moderate to large (0.5-0.8) with $p < 0.001$. Conclusion: The findings of the study showed that the Persian version of the WOMET questionnaire has a high level of responsiveness and is a suitable tool for evaluating the quality of life among patients suffering from meniscus injury. Keywords: Questionnaire, Psychological, Meniscus.

Received:

Feb 22nd 2023

Revised:

Apr 25th 2023

Accepted:

May 31st 2023

Cite this article: Jafari Rad Z, Amiri A, Javadian Y, Mansour Sohani S. Assessing the Responsiveness of the Persian Version of the Western Ontario Meniscal Evaluation Tool in Patients with Meniscus Injuries. *Journal of Babol University of Medical Sciences*. 2023; 25(1): 272-80.



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Publisher: Babol University of Medical Sciences

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Introduction

Meniscus injuries in knee may cause serious health problems and impose significant economic burden on patients and society due to their complications and effects on health-related quality of life (HRQOL) (1). One of the important methods in evaluating the quality of life in these patients is using the WOMET questionnaire. This questionnaire was designed by Kirkley et al. in 2007, which was the first self-assessment questionnaire to investigate health-related quality of life in patients with meniscus injury. This questionnaire has three important features: reliability, validity and responsiveness (2). Responsiveness is one of the most important features of the questionnaire, and as an essential psychometric measurement, shows the ability of a tool to demonstrate important clinical changes in a patient's health conditions over time (3). Internal and external responsiveness are the two main aspects that determine the flexibility of a tool over time (4, 5). Minimal Clinically Important Difference (MCID), as a responsiveness factor, is a treatment outcome directly related to the rate of changes in health status that are noticed by the patients (6).

The WOMET questionnaire has 16 questions in three areas: 1) sports, recreation, work, lifestyle with 4 questions, 2) physical symptoms with 9 questions, and 3) emotions with 3 questions (2). The studies conducted in different countries show different levels of validity, reliability and responsiveness according to its translation into the native languages of those countries. The study of Sihvonen et al. on 485 patients undergoing knee meniscus surgery showed high reliability, reproducibility and responsiveness (7). The study of Tong et al. on 121 patients undergoing meniscus surgery showed that this questionnaire has high reproducibility and reliability as well as responsiveness (8). Celik et al. presented the result of their study as the Turkish version of WOMET, which had high validity and reliability. But its responsiveness was not evaluated in their study (9). The results of a study by Ebrahimi et al. showed that this questionnaire has high validity and reliability to evaluate the quality of life, but in this study, the responsiveness of the questionnaire was not evaluated (10). A study by Van der Wal et al. on 86 patients with meniscus injuries showed high reproducibility and responsiveness (11). The study of Sgroi et al. on 192 patients with meniscus tears showed that the WOMET questionnaire had high reliability and validity, but in this study, like some other studies, the responsiveness of questionnaire was not investigated (12).

According to the results of the studies, the English (2), Persian (10), Finnish (7), Chinese (8), Turkish (9), Indian (11) and German (12) versions were acceptable and reproducible. The responsiveness of the English (2), Finnish (7), Chinese (8) and Indian (11) versions of this questionnaire was investigated.

Among the three important features of the WOMET questionnaire, only the validity and reliability of its Persian version have been investigated. However, its responsiveness in Persian version has not been evaluated so far. Considering that the responsiveness of the WOMET questionnaire is one of its most important features in evaluating the quality of life among patients with meniscus injury, the present study was conducted to evaluate the responsiveness of the WOMET questionnaire in Iranian patients with meniscus injuries as the primary outcome and the relationship between this questionnaire and the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire as the secondary outcome.

Methods

After being approved by the ethics committee of Iran University of Medical Sciences with the ethics code IR.IUMS.REC.1397.299, this cross-sectional methodological study was conducted on 100 Persian-speaking patients with meniscus injuries aged 18-70 years who were able to read and write and could complete the questionnaire. Patients with cruciate and lateral knee ligament injury, osteoarthritis and

inability to complete the questionnaire, malignancy, infection, neuromuscular skeletal disorder, knee joint replacement and any other knee surgery and unwillingness to participate were excluded from the study. An informed consent form was received from all patients.

Patients with meniscus injuries were referred to the physiotherapy clinic of Iran University of Medical Sciences by a knee specialist after examination and meeting the inclusion criteria. Then, patients completed the Persian version of KOOS and WOMET questionnaires on the first day of physiotherapy treatment and also 4 weeks later (session 10). They also completed the 7-point Global Rating of Change (GRC) scale in session 10.

Assessment of outcomes: WOMET questionnaire includes 16 questions that represent three areas of sports, recreation, work, lifestyle (4 questions), physical symptoms (9 questions) and emotional symptoms (3 questions). Each question has a score from 0 to 100, so the total score is between 0 (best) and 1600 (worst). The score of the questionnaire can be calculated as a total score, total score for each area or as a normal percentage by subtracting the total score from 1600, dividing by 1600, and multiplying the percentage. If the score of the questionnaire is expressed as a percentage, the closer a person's score is to zero, the worse the person's condition is (2, 13).

The KOOS questionnaire contains 42 questions with five domains of pain, symptoms, daily activities, sports, recreation and health-related quality of life. Each item is scored from 0 to 4. The minimum score of the questionnaire is zero and the maximum score is 168 (14).

Regarding responsiveness, GRC is a reference standard and a valid tool that shows the following seven levels of changes: so much worse= 1, much worse= 2, slightly worse= 3, unchanged= 4, slightly better= 5, so much better= 6, much better= 7. Based on this scale, patients were divided into two groups of improved subjects at the levels of "so much better" and "much better", and unimproved subjects at the levels of "slightly better", "unchanged", "slightly worse", "much worse" and "so much worse" (15-17).

The difference between the average scores obtained before and after the intervention was used to calculate response rates for each questionnaire. Internal responsiveness was evaluated using effect size (standardized response mean and Cohen's d) as well as T-test (18). Correlation coefficient and ROC curve were used to evaluate external responsiveness. In correlation analysis, Small Detectable Change (SDC) was used instead of GRC, because patients may misreport results. SDC for WOMET questionnaire is 26.13. Patients with WOMET scores greater than 26.13 were considered improved and those with WOMET scores less than 26.13 were considered unimproved (10). Pearson's correlation coefficient was used to calculate the correlation coefficient between WOMET questionnaire and SDC. The values of correlation coefficients range from low or no change (<0.25), fair (0.25-0.5), moderate to good (0.5-0.75), good to excellent (0.75) (18). The area under the ROC curve (AUC) can be interpreted as the probability of an improved patient who is correctly identified from two groups of improved and unimproved patients, which ranges from 0 to 1 (4, 19-21). AUC greater than 0.70 indicates acceptable external response (4, 22, 23). The MCID, depicted near the top left corner of the graph, serves as the best cutoff point on the ROC curve and shows the greatest specificity and sensitivity. This feature is defined as the number of scores required to show a clinically significant change that is able to differentiate between improved and unimproved patients (20, 24, 25).

In this study, T-test, Cohen's d and standardized response mean were used to calculate the internal responsiveness. Standardized effect sizes less than 0.20 are insignificant, 0.20-0.50 and 0.50-0.80 are considered "smallest" and "moderate" values, and sizes above 0.80 can be considered "large" effect sizes (26, 27). $P < 0.05$ was considered significant.

Results

The mean age of the patients was 45.55 ± 14.42 years, of which 39 were women and 61 were men, who had symptoms of meniscus injury for a mean period of 6.20 ± 4.51 months (Table 1). Descriptive statistics for WOMET subscales and total WOMET scores are shown in Table 2. Out of 100 patients, 20 patients were classified as improved patients and 80 patients as unimproved patients according to the SDC scale. The subscales of WOMET and total WOMET have a very acceptable response with AUC of 0.7 and indicate MCID of 20.031 (specificity= 1 and sensitivity= 1) for the Persian version of WOMET (Table 3).

Table 1. Demographic characteristics of the participants (100 people)

Demographic information	Mean $\pm$ SD
Gender	
Man (number)	61
Female (number)	39
Age (years)	45.55 ± 14.42
Height (meters)	169.6 ± 9.135
Weight (kg)	79.16 ± 14.03
BMI	27.64 ± 5.311
Duration of illness (months)	6.20 ± 4.51

Table 2. Mean scores before and after treatment and changes for the WOMET questionnaire and its subscales in patients with meniscal injury

Questionnaire and subscale	Before treatment Mean $\pm$ SD	After treatment Mean $\pm$ SD	Change Mean $\pm$ SD
WOMET questionnaire			
All patients (100 people)	44.70 ± 22.28	46.81 ± 22.72	2.10 ± 24.04
Improved (20)	24.49 ± 16.27	60.00 ± 13.02	35.50 ± 14.14
Unimproved (80)	49.76 ± 20.71	43.51 ± 23.47	-6.24 ± 17.98
Physical symptoms subscale of WOMET questionnaire			
All patients (100 people)	50.97 ± 24.45	54.38 ± 24.09	3.41 ± 26.25
Improved (20)	27.66 ± 18.02	68.85 ± 13.86	41.18 ± 18.95
Unimproved (80)	56.79 ± 22.35	50.76 ± 24.80	-6.03 ± 18.05
Subscale of sports, recreation, work, lifestyle of WOMET questionnaire			
All patients (100 people)	37.48 ± 25.00	39.64 ± 25.21	2.16 ± 24.08
Improved (20)	18.08 ± 15.94	51.75 ± 21.52	33.66 ± 17.33
Unimproved (80)	42.32 ± 24.56	36.61 ± 25.27	-5.70 ± 18.45
Emotions subscale of WOMET questionnaire			
All patients (100 people)	35.56 ± 24.92	33.66 ± 35.25	-1.90 ± 34.91
Improved (20)	23.53 ± 21.95	44.48 ± 19.71	20.95 ± 18.58
Unimproved (80)	24.84 ± 2.77	30.96 ± 37.77	-7.61 ± 35.76

Pearson's correlation coefficient was 0.698 for the total score of WOMET questionnaire, 0.723 for physical symptoms, 0.657 for sports, recreation, work, lifestyle and 0.329 for emotions subscale. This correlation was moderate to good except for the emotions subscale which was nonsignificant. The ROC curve for the WOMET questionnaire showed a high responsiveness due to the good AUC.

The standardized response mean for the total score of WOMET questionnaire was 0.11, for the subscale of physical symptoms was 0.13, for the subscale of sports, recreation, work, lifestyle was 0.09, and for the subscale of emotions was 0.02, all of which are insignificant values. However, Cohen's d value for the WOMET questionnaire and the subscale of sports, recreation, work, lifestyle and physical symptoms is high (-1.586 for the WOMET questionnaire, -1.331 for the subscale of sports, recreation, work, lifestyle and -1.666 for the physical symptoms subscale, respectively) but is moderate for the subscale of emotions (-0.705).

Paired t-test showed a significant difference before and after treatment; it was 0.875 for the total score of WOMET ($p=0.197$), 1.299 for physical symptoms ($p=0.197$), 0.899 for sports, recreation, work, lifestyle ($p=0.371$) and -0.544 for emotions ($p=0.588$).

The independent t-test showed a significant difference between the improved and unimproved groups; -9.651 for the total score of WOMET ($p<0.001$), -10.358 for physical symptoms ($p<0.001$), -8.634 for sports, recreation, work, lifestyle ($p<0.001$), and -0.544 for emotions ($p<0.001$), and $p<0.05$ was significant.

Pearson correlation between WOMET questionnaire and KOOS subscales is shown in Table 4. In general, there was moderate to high correlation ($p<0.5$) between WOMET and KOOS questionnaires (except for the emotions subscale). Figure 1 shows the ROC curve of the WOMET questionnaire.

Table 3. The results of the area under the curve, optimal cut-off point, sensitivity, and 1-specificity of the WOMET questionnaire and its subscales in patients with meniscus injury

Questionnaire	Area under the curve (CI 95%)	Optimal cut-off point	Sensitivity (CI 95%)	1-Specificity (CI 95%)
Physical symptoms subscale of WOMET questionnaire	0.984	22.944	0.95	0.05
Subscale of sports, recreation, work, lifestyle of WOMET questionnaire	0.952	15.625	0.9	0.11
Emotions subscale of WOMET questionnaire	0.848	4.5	0.75	0.25
WOMET questionnaire	1.000	20.031	1	0

Table 4. Pearson correlation between WOMET and KOOS questionnaires in patients with meniscus injury

WOMET KOOS	Emotions subscale	Sport, recreation, work, lifestyle subscale	Physical symptoms subscale	WOMET
Other symptoms subscale	0.315 $p<0.001$	0.621 $p<0.001$	0.667 $p<0.001$	0.651 $p<0.001$
Pain subscale	0.447 $p<0.001$	0.803 $p<0.001$	0.770 $p<0.001$	0.795 $p<0.001$
Daily activities subscale	0.448 $p<0.001$	0.801 $p<0.001$	0.773 $p<0.001$	0.797 $p<0.001$
Sports, recreation subscale	0.450 $p<0.001$	0.750 $p<0.001$	0.720 $p<0.001$	0.752 $p<0.001$
Quality of life subscale	0.373 $p<0.001$	0.554 $p<0.001$	0.492 $p<0.001$	0.542 $p<0.001$

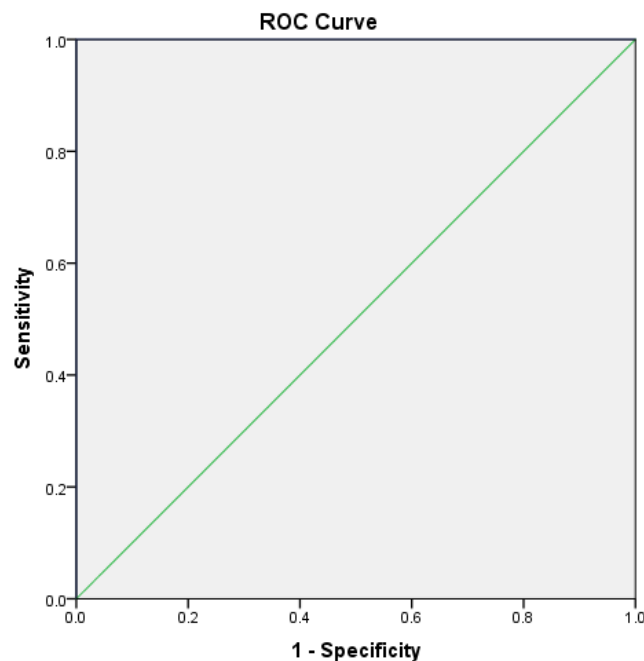


Figure 1. ROC curve of WOMET questionnaire in people with meniscus injury

Discussion

The results of the present study showed considerable values for the external responsiveness of the Persian version of the WOMET questionnaire. However, in the case of internal responsiveness, the results are different. The standardized response values were low, but Cohen's *d* values were medium to high. In general, no significant changes were observed in the scores of the WOMET questionnaire and its subscales before and after the treatment, but the changes were significant separately in each group before and after the treatment, which is normal. When we consider all people together, they neutralize each other's effects, so the result does not become significant. There was also a significant difference between the improved and unimproved groups. For the WOMET questionnaire, the optimal cut-off point was 20.031 with the best balance between Specificity and Sensitivity, 0 and 1, respectively. Therefore, the WOMET questionnaire has an acceptable differentiation ability in identifying the change in patients with injury or after meniscus surgery in the course of the disease and follow-up treatment.

The results of the correlation between the Persian version of the WOMET and KOOS questionnaires showed that the correlation between these two questionnaires is moderate to large (except for the emotions subscale). As a result, it can be said that the change in each of these two questionnaires has a moderate to large power in predicting the change in the other questionnaire (except for the emotions subscale).

Among other translated versions of the WOMET questionnaire, only the external responsiveness of the Indian version has been investigated by van der Wal et al., which was through correlation between the WOMET questionnaire and several other questionnaires, and generally showed good results (11). Kirkley et al. found the standardized response mean of the English version of the WOMET questionnaire as 0.65 (moderate), which was higher than the present study (2).

In the studies of Sihvonen et al. (7) and Tong et al. (8), the total effect value and the standardized response mean of the WOMET questionnaire were large. Since an external standard measure is used in examining external responsiveness, it is more valid than internal responsiveness (27). In many articles, the external

response capability of the questionnaires has been cited, so in the present research, considering the acceptable external responsiveness of the Persian version of the WOMET questionnaire, it can be said that this questionnaire is a tool with appropriate responsiveness.

The present research is the first study in which the external responsiveness of this questionnaire has been investigated through the ROC curve and correlation with the external criterion of SDC, which had satisfactory results. Also, this research is the first study in which the correlation between the Persian version of WOMET questionnaire and KOOS in patients with meniscus injury or after meniscus surgery has been investigated.

The results of the study showed that the Persian version of WOMET is sufficiently responsive according to suitable external responsiveness in patients with meniscal injury, although some contradictory results still existed for internal responsiveness. Since external responsiveness is more valid, it can be concluded that this questionnaire is responsive and can be used to evaluate the effects of physical therapy interventions in patients with meniscal tears and undergoing surgery.

Acknowledgment

We would like to thank the Vice-Chancellor for Research & Technology of Iran University of Medical Sciences for funding and also the respected colleagues of Tehran Orthopedic Clinic for their cooperation in conducting this research.

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