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## RELIABILITY AND VALIDITY OF PERSIAN VERSION OF FRAX QUESTIONNAIRE IN IRANIAN ELDERLY

**ABSTRACT: Objective:** This study was conducted to evaluate the reliability and validity of the Persian version of FRAX questionnaire and examine the risk of fracture in the next ten years in Iranian elderly.

**Methodology:** 200 elderly aged 60 and over living in the city of Isfahan, Iran completed FRAX Questionnaire. To check the reliability after 2 weeks, 32 participants were asked to complete the questionnaire for the second time. To evaluate construct validity, the relationship between questionnaire scores with BMI and between the questionnaire's result and BMD were examined. Also, the internal consistency and the ICC were calculated.

**Results:** The face and content validity were confirmed separately according to the experts and the elderly. Intra-class correlation coefficient was determined. Regarding the correlation between the two indices (i.e. BMD and BMI) with the FRAX Questionnaire, the results showed the significant correlation between these variables (correlation coefficient equal to 0.658 and  $P > 0.001$ ). To determine the risk of fracture in the next ten years, as the result showed, BMI and FRAX Questionnaire can be used instead of BMD. Then, the internal reliability of the questionnaire was

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determined, for which obtained Cronbach's alpha was equal to 0.321, showing that the internal consistency in the 12-questions questionnaire is lower than the acceptable level of 0.70.

**Conclusion:** Persian version of FRAX Questionnaire has good psychometric properties to evaluate the risk of osteoporosis-related fractures in the next ten years in Iranian elderly.

**Key words:** Osteoporosis, FRAX, Elderly, Validity, Reliability

## ***INTRODUCTION***

Osteoporosis is a silent disease with no symptoms, which is considered an important factor treating public health in the world, because it can increase the risk of fractures and its complications and has a great impact on the person's quality of life from physical and social – economic perspectives.<sup>1</sup> Bone fractures and subsequent complications are the clinical consequence of osteoporosis. Osteoporosis is a generalized bone disease, so almost all fractures in the elderly are partly due to the loss of bone density. Fractures can either be completely cured or can lead to chronic pain, physical disability or even death.<sup>2,3</sup>

For this reason, it is essential to have a simple, low cost and reliable assessment tool to predict the fracture risks in the next ten years. In Iran, in spite of the significant growth of the elderly population in the future and socio-economic conditions, the prevalence of osteoporosis and osteomalacia seems to be high in the society, especially in the elderly population. Thus, such a tool is required at least to predict the condition of the elderly and prepare a treatment plan for them, because this tool can help to identify people with osteoporosis earlier and to treat them before they enter into the stage of osteoporosis and are put at risk of fracture. Thus, the complications of fractures can be greatly decreased, and the high financial burden caused by them will be lifted off the shoulders of the families and the health care system. Currently, bone mineral densitometry (BMD) is the only reliable method for the diagnosis of osteoporosis and the risk of bone fracture. Although this test has a high sensitivity for the diagnosis, it may not possible to perform it everywhere, and even in modern societies where it is available, the bone mineral densitometry is not economical. So, the best way is that it is performed only for patients at risk of bone mineral density testing, and other people are identified with a more accessible and less costly method, i.e. FRAX Questionnaire.<sup>3,4</sup> The use of FRAX Questionnaire allows us to easily estimate the risk of fracture for the next 10 years, only by asking 12 simple questions and also eliminates the high cost of unnecessary bone mineral densitometry tests that impose the heavy burden of costs on public institutions, insurers and patients themselves.<sup>5</sup> FRAX questionnaire has so far been translated and localized into 18 languages of

the world, but it has so far not translated into Persian, and there is no similar tool or questionnaire in Persian.

## **METHODOLOGY**

FRAX or Fracture Risk Assessment Tool is a questionnaire that has been approved by the WHO to determine the risk of bone fracture in the next ten years. This questionnaire has been translated into many languages of the world and its validity and reliability was confirmed.<sup>6</sup> This questionnaire, which was designed for persons aged 40 years and older, consists of 12 questions with yes or no answers, which the score obtained from the answers is entered in the relevant standard tables, and thus helps to determine the risk of osteoporosis-related fractures in the next ten years.<sup>4,5</sup>

After permission from FRAX author, the questionnaire was translated with the aim of providing intercultural adaptation and includes the following processes, for which IQOLA protocol.<sup>6,7</sup> In the next step, the content validity was examined using Lawshe's technique and CVI in each of the domains of relevance, clarity, simplicity and necessity. The correlation coefficient ICC was calculated to evaluate the reproducibility of the scores derived from the Persian version of FRAX questionnaire; it was measured twice within two weeks among 32 elderly people.<sup>8</sup> Construct validity of the Persian version of FRAX Questionnaire in this study is examined with the aim of determining the degree of correlation between the scores obtained from the questionnaire with BMI and the scores obtained from the questionnaire with BMD, in order to determine the risk of osteoporosis-related fractures in the next ten years in the elderly. In this questionnaire, concerning the correlation between the two indices, the Kolmogorov Smirnov test was first used to test the normality of the two indices, and since their distribution was not normal, thus, the Spearman's correlation coefficient test was used to examine the correlation between these two variables.

## **RESULTS**

The mean and standard deviation of age, height, weight and BMI of participants were presented in table 1.

Table 1. Mean and Standard Deviation of descriptive variables among participations

Mean± SD	Variable
66.76±5.131	Average Age
156.6±6.791	Height
68.82±11.40	Weight
28.10±4.620	BMI

The face validity of the questionnaire confirmed based on expert opinion. In the next step, the content validity of the individual questions was examined using Lawshe's technique and CVI in each of the domains of relevance, clarity, simplicity and necessity. Therefore, four-value variables of Likert-type were considered, and therefore, the validity was accepted provided that the average score of CVI is greater than 2.8 (i.e. 0.7 of the total score). The results showed that the validity of all questions can be accepted.

In the end, total validity of the questionnaire was examined using Lawshe's technique and CVI in each of domains. For these domains, three-value of Likert-type were considered. As a result, the validity can be accepted if the average score of CVI is greater than 2.1 (i.e. 0.7 of the total score). The results showed that average desirability is significantly greater than 2.1, and as a result, its face validity is desirable ( $P < 0.05$ ). The correlation coefficient ICC was calculated to evaluate the absolute and relative reproducibility of scores obtained from the Persian version of FRAX questionnaire, which was measured twice within two weeks. Repeatability tests were performed on 32 patients. To evaluate the reproducibility of the tests,  $0.7 \geq \text{ICC}$  was regarded as acceptable level of reproducibility. The results showed that correlation coefficients are higher than the acceptable level for multi-question scales (i.e. 70-percent), and thus, a high relative reproducibility is derived for the Persian version of FRAX questionnaire. Thus, the ICC was in an acceptable and unsatisfactory range. The construct validity of the Persian version of FRAX Questionnaire is examined with the degree of correlation between the scores obtained from the questionnaire with BMI and the scores obtained from the questionnaire with BMD, in order to determine the risk of osteoporosis-related fractures in the next ten years in the elderly. According to the results of the Spearman's correlation coefficient test, there is a significant correlation between the two variables, i.e., BMD and BMI (correlation coefficient equal to 0.658 and  $P > 0.001$ ). Then, the internal consistency of the questionnaire was measured by determining the Cronbach's alpha coefficient and intra-class correlation for internal reliability. Regarding the internal reliability of the questions, the results of Cronbach's alpha coefficient and ICC, which were obtained to evaluate the reliability of the 12-questions questionnaire, are summarized in the table 2.

Table 2. ICC for FRAX Questionnaire

Coefficient of internal consistency			
Internal consistency	95% confidence interval		
	Lower limit	Upper limit	
0.321	0.169	0.454	Mean

Also, the results indicate that the internal reliability of the questionnaire is not significant. Given that the ICC (internal reliability) was not favorable, as the first step to start cultural adaptation process, it was necessary to determine the questions that have more need to change. So, we had to first determine the question that, if removed, causes the greatest increase in the Cronbach's alpha coefficient (It should be noted that only 5 to 12 questions were examined for removal).

Table 3. Results of Cronbach's alpha coefficient, in case of the removal of question

Cronbach's alpha	Item
0.335	Question 5
0.357	Question 6
0.298	Question 7
-0.24	Question 8
0.058	Question 9
0.467	Question 10
0.338	Question 11
0.328	Question 12

Table 3 showed that the removal of question-10 (Secondary osteoporosis) causes the greatest increase in the reliability of the questionnaire. This means that the removal of question-10 was caused the internal consistency of the questionnaire's questions to increase from 0.321 to 0.467, but the internal solidarity was not at acceptable level. Thus, according to the table above, the question-10 was removed from the questionnaire, and the reliability of the 11-questions questionnaire was examined. Question 6 (Parent fractured hip) was the next question whose removal could cause the greatest change in increasing the reliability of the questionnaire. After removal of the question 6, internal correlation reached 0.515, which still was not an acceptable reliability. Similarly, the 10-question questionnaire was then studied, and after removal of question-11, the internal solidarity reached 0.548, and so, this number rose to 0.592, after removal of question 5. In the end, the internal reliability of the 8-question questionnaire reached 0.666 after removal of question-12, which was a good value for the internal reliability of the questionnaire. Thus, after examining the Cronbach's alpha coefficient and intra-class correlation coefficient, the results indicated that the

7-questions questionnaire has a significant reliability. In other words, the 12-questions questionnaire in Iran may not have a significant reliability, so some questions need to be changed.

## **DISCUSSION**

The results showed that, in general, the translation of phrases and sentences of FRAX Questionnaire into Persian was easy in the translation process, and we did not encounter with an item whose Persian equivalent is unclear for the elderly. In examining the validity of the content, all questions of the questionnaire was sufficient in terms of relevance, clarity, simplicity and necessity; and the entire questionnaire was evaluated at acceptable level in terms of desirability. Thus, the face validity of the questionnaire was also confirmed. Repeatability of the Persian version of the questionnaire scores was evaluated at a high level. Studies showed that the degree of correlation between the relationship of the scores obtained from the questionnaire with BMI and the relationship of the scores obtained from the questionnaire with BMD, in order to determine the risk of osteoporosis-related fractures in the next ten-years in the elderly in the 12-questions questionnaire, has good correlation with each other. This means that the risk of fracture in the next ten years can be identified using the body mass index (instead of bone mineral densitometry) and the number of risk of factors derived from the questionnaire.

As explained previously, some questions such as question 5,6,10,11 and 12 related to secondary osteoporosis, *parents' of hip fracture*, *consuming alcohol*, *past history of bone fracture*, may need to be modified in Persian version of FRAX. For example, Consuming alcohol is illegal and banned in Iran because it is not in accordance with the Islamic Sharia, and since the consumption of alcoholic beverages is legally treated in Iran and there is punishment for that, the answers to this question cannot be assured. Since the questionnaire was designed in the UK where health is at a very high level and geriatrics has covered the elderly for many years, so the elderly are aware of all of their underlying diseases because of periodic examinations and clinical tests. Unfortunately, since the culture of prevention rather than treatment is still underdeveloped in Iran, the elderly may not be aware of the diseases that may lead to secondary osteoporosis; and/or in spite of the understanding of the underlying disease, they may not be aware of the relationship between the underlying disease and osteoporosis, due to low levels of knowledge or literacy. Thus, the participants might answer incorrectly to the question. Finally, Persian version of FRAX Questionnaire has good psychometric properties to evaluate the risk of osteoporosis-related fractures in the next ten years in Iranian Persian-speaking elderly, providing that the cultural adaptation is in accordance with Iranian culture. In this case, this questionnaire can be used to reduce costs and speed up the diagnosis of osteoporosis and prevention of fractures caused by it in the next ten years.

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