

# Androgen Deficiency in Aging Males: Translation and Validation Study of the Iranian Version

## Abstract

**Background:** Considering the importance of psychometric evaluation of the male sex hormone deficiency questionnaire by Iranian nurses, this study aimed to determine the translation and validation of the Iranian version of the Androgen Deficiency in Aging Males (ADAM) questionnaire. **Materials and Methods:** This study was cross-sectional. After obtaining permission from the instrument maker, translating it into Farsi, retranslated it into English, and determining validity and reliability. The study population was 200 Iranian men who admitted to hospitals affiliated with Iran University of medical science and were older than 50 years and selected by convenience sampling method. They were evaluated and monitored based on the Iranian version of the ADAM questionnaire. Sensitivity and specificity were assessed and analyzed by Rock Chart analysis. Descriptive and analytical statistical tests were used at a significant level of 0.05. **Results:** Findings showed that the Iranian version of the ADAM questionnaire had good face validity. Results showed that Cronbach's alpha in this questionnaire was 0.93, which indicates high reliability, and all the valid questionnaires were reported for the Scale-Content Validity Index (SCVI) calculation. Hence, the questionnaire has good content validity. The Iranian version of the ADAM questionnaire has a sensitivity of 93.85% and a specificity of 77.14% at the cut-off point of 2.2, indicating high sensitivity and specificity. **Conclusions:** The Iranian version of the ADAM questionnaire is valid and reliable and has high sensitivity and specificity. Nurses can also use it as an adjunctive scale to screen andropause men over 50 years of age.

**Keywords:** Aging, androgens, Iran, nurses, translations, validation study

## Introduction

Today there are over 580 million older adults globally, which is anticipated to reach one billion in 2020. According to the Iranian Census of Population and Housing, by 2050, our nation's elderly population is anticipated to reach 26 million, or about 23 percent. Men will make up a significant portion of this population. So, in the coming years, issues related to the elderly will be a top priority for health and wellness programs.<sup>[1]</sup> Nowadays, hormone biology in elderly men is one of the new topics of interest to scientists. Many studies have been done to investigate the specific aspects of elderly health in men.<sup>[2]</sup> The term Golden age in the lives of men is between 40 and 59 years of age, during which transition from the Middle Age to old age occurs<sup>[3]</sup> Andropause syndrome was first introduced in the 1930s. This means decreasing sex hormones in men due to old age, which has

symptoms of physical, psychological, and sexual nature.<sup>[4]</sup> Researchers believed that men with andropause symptoms had similar signs towards women, which was slower in men than women. This syndrome was not considered necessary in the past, but it is now progressing in developing countries.<sup>[5]</sup> The testosterone hormone depletion process is such that it declines by 1% per year after the age of 30, and its peak in men over 80 Years of Age. Experts believed that the prevalence of men's andropause could be at any age, but it is about 20% at age 50 and about 50% at age 60.<sup>[6]</sup>

Clinical signs of androgen deficiency were present in 85 patients of older man (49.7%). It has also shown that androgen deficiency's clinical signs cannot accurately predict sex hormone levels in older men. Still, the diagnosis of hypogonadism in the elderly should be considered.<sup>[7]</sup> Several questionnaires, including the Androgen

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### Access this article online

**Website:** www.ijnmrjournal.net

**DOI:** 10.4103/ijnmr.IJNMR\_209\_20

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**How to cite this article:** Ashghali-Farahani M, Khachian A, Vakilian P, Mahmoudi M. Androgen deficiency in aging males: Translation and validation study of the Iranian version. Iran J Nurs Midwifery Res 2021;26:144-9.

**Submitted:** 31-Aug-2020. **Revised:** 22-Sep-2020.

**Accepted:** 28-Dec-2020. **Published:** 05-Mar-2021.

Deficiency in Aging Males (ADAM), Aging Males Syndrome (AMS), and Morisky Medication Adherence Scale (MMAS), were designed to assess hypogonadism in older men.<sup>[8]</sup> The ADAM questionnaire is one of the most suitable clinical scales for screening men with testosterone deficiency.<sup>[9]</sup> Many studies examined the sensitivity and specificity of the ADAM questionnaire. One of them reported 88% sensitivity and 60% specificity for the ADAM questionnaire, which is an acceptable limit for the validity of a questionnaire.<sup>[9]</sup> In another study with a sample size of 230, a very low sensitivity (36.6%) was noted for this instrument.<sup>[10]</sup> Another study reported a sensitivity of 88% and specificity of 44% for the ADAM questionnaire's psychometric properties.<sup>[11]</sup> In comparison, a study demonstrated a very low specificity (26%) for this scale.<sup>[12]</sup> This diversity in results indicates the need for translation and greater validity and reliability of the instrument in other countries special Iran. Researchers in this field conducted extensive research in this field demonstrated that many psychometric studies have investigated Adam's questionnaire in older men in many countries other than Iran.

Given the contradictory results regarding its sensitivity and specificity in many countries of the world, the necessity of a psychometric scale in nursing in Iran is becoming increasingly evident. On the other hand, given that Iran has a smaller group of the elderly population at present. But, in the coming years, we will see an increasing number of the elderly population, and this questionnaire can play an essential role in their screening. Also, nurses can use reliable and validated version of the Adam questionnaire to screen men who inpatient in the hospital and over the age of 50. This study aimed to determine the translation and validation of the ADAM questionnaire in Iran.

## Materials and Methods

This study was cross-sectional and performed in hospitals affiliated with the Iran University of Medical Science in the period 2019-2020. The ADAM Questionnaire was the first designed by John Morley in 2000, which intended to examine the symptoms of testosterone deficiency in older men with ten questions. If participants answered yes to Question 1, or question 7, or another three questions, maybe deficient in testosterone hormone or andropause syndrome.<sup>[9]</sup> The Adam questionnaire was first translated into Persian according to WHO protocol by two researchers and then re-translated by two experts in English. The transcript's final form was sent back to the questionnaire designer to reflect their views on the English translation form. From the translator's perspective, the Farsi-English translation format questionnaire was much more accessible and more understandable. For face validity, ten patients completed the questionnaire who met the inclusion criteria to evaluate its validity. After face validity, content validity done in both quantitative and qualitative forms.

In quantitative validity, the questionnaire was given to ten experts to comment on each item's necessity, and the result was judged according to Lauche's formula. According to this formula, the Content Validity Ratio (CVR) minimum numerical value for ten assessors is 0.62. Accordingly, items with a score below 0.62 were removed. Next, Scale-Content Validity Index (SCVI) was calculated for each item, so ten experts were asked to rate each item's relevance on a 4-point scale (1: unrelated 2: somewhat relevant 3: acceptable relevance 4: Completely relevant). According to this index, scores above 0.90 were completely relevant, scores ranging from 0.79 to 0.89 were acceptable relevance, scores ranging from 0.69 to 0.79 were somewhat relevant, and scores below 0.60 were unrelated and eliminated.

Next, the researchers assessed the content's qualitative validity based on the four criteria of "grammar compliance," "use of appropriate words," "putting items in their proper place," and "appropriate scoring." Well-known group method used to validity. In this stage, sensitivity, specificity, and Rock analysis curves plotted. After the validity, the reliability of the questionnaire began. At this stage, the test-retest method and Interclass correlation coefficient were used. In this stage, 17 samples completed the scale, and, after 7 to 10 days later, the scales were completed by the same again. Spearman correlation coefficient and Interclass correlation coefficient were done, and finally, Cronbach's alpha coefficient was used for data analysis. Finally, the Mann-Whitney U test used to compare the mean of the questionnaire in men with normal testosterone and low testosterone.

The study population was men older than 50 years admitted to hospitals affiliated with the Iran University of Medical Science for various reasons. Participants were selected by convenience sampling method. In these hospital's nephrology and urology departments, all men who met the inclusion criteria were selected. After obtaining informed consent, they were selected to participate in the study. Inclusion criteria included: "over 50 years", "no hormonal problems (hypogonadism) and all types of cancers," "no use of hormonal drugs for sexual enhancement," "no mental illness (psychosis, depression, mania, schizophrenia). Exclusion criteria included: "History of any type of cancer," "Unclear testosterone levels," and "Patients who treated with testosterone supplementation. After obtaining a consent form from individuals who met the inclusion criteria, the laboratory technician obtained a fast peripheral venous blood sample at 7 am for fasting bio testosterone levels. Then the amount was measured in nmol/dl. Normal levels of testosterone in men ranged from 2.20 to 8.30 nmol/dl. That means that people with a testosterone level of less than 2.20 mmol/dl were suspected of having testosterone deficiency. To determine the number of samples, and researchers calculate the sample size with 204 individuals after  $d = 09$   $\alpha$ , Sensitivity prevalence = 0.88,

prev = 0.25 and d = 0.09. Four samples were excluded and finally selected 200 samples. For data analysis, version 8 of medcalc software has been performed. In descriptive statistics for quantitative variables, mean and standard deviation and to analyzed qualitative variables in inferential statistics, Mann-Whitney, Spearman test, and rock curve analysis were used to determine the cutting point.

### Ethical considerations

The study obtained the Ethics Code under No IR.IUMS.REC 1398.653 from Iran University of Medical Sciences. Also, the following ethical consideration was taken in the process of study. These considerations are signing an informed consent form by each participant before participating in the study, explaining the study's purpose to the study participants before participating in the study, and ensuring participants about confidentiality and privacy.

### Results

The results of the demographic variables analysis are presented in Table 1. The reliability of The Iranian version of the ADAM questionnaire showed that Cronbach's alpha in this questionnaire was 0.93, which indicates high reliability for this questionnaire. The mean and standard deviation of each item with the significant Spearman correlation coefficient, relative variability index are presented in Table 2. Questions with the Interclass correlational coefficient in the single test were higher than 0.80 had excellent reliability. Examination of items showed that only questions 8 and 10 had a poor Interclass Correlational Coefficient (ICC <0.60), while other questions had an appropriate and acceptable relative variability index (ICC >0.60). In terms of content validity, findings also showed that in calculating CVR, there should be agreement among ten experts over 0.63, which calculated according to CVR formula. In the present study, only items 3, 6, and 9 had an agreement of 0.60, which was maintained by experts in the field. According to the experts in this study, it was better to include all items in the questionnaire. There was also a consensus among experts, and their views were homogeneous. All the VALID questionnaires were reported for the SCVI calculation, so the questionnaire has good content validity.

In this study, 200 samples were evaluated for the bio-testosterone level and completed Adam's questionnaire. After examining the peripheral blood sample. Results showed that among the participants in this study, 130 (65%) had low levels of bio-testosterone, and 70 (35%) also had normal testosterone levels. On the other hand, Table 3 shows the Iranian version of the ADAM questionnaire's sensitivity and specificity analysis. The most appropriate cut-off point for the testosterone level was 2.20 with a 95% confidence interval. It should be noted that if testosterone was lower than the cut-off point, it was considered as a positive test. This study showed a sensitivity of 93.85% and specificity of 77.14% at a point less than 2.20. These

**Table 1: Demographic characteristics of study participants**

| Characteristics                   |                   | n (%)            |
|-----------------------------------|-------------------|------------------|
| Age                               | 50-55             | 40 (20)          |
|                                   | 56-60             | 42 (21)          |
|                                   | 61-65             | 47 (23.50)       |
|                                   | 66-70             | 55 (27.50)       |
|                                   | >70               | 16 (8)           |
| Marital status                    | Single            | 9 (4.50)         |
|                                   | Married           | 148 (92)         |
|                                   | Divorced          | 0 (0)            |
|                                   | Widow (Wife died) | 7 (3.50)         |
|                                   | Sexual partner    | 0 (0)            |
| Educational level                 | High school       | 60 (30)          |
|                                   | Diploma           | 66 (33)          |
|                                   | Associate         | 12 (6)           |
|                                   | Bachelor          | 50 (25)          |
|                                   | Master            | 12 (6)           |
| History                           | Yes               | 20 (10)          |
|                                   | No                | 180 (90)         |
| Smoking                           | Yes               | 59 (29.50)       |
|                                   | No                | 141 (70.50)      |
| Alcohol                           | Yes               | 18 (9)           |
|                                   | No                | 182 (91)         |
| Drug                              | Yes               | 0 (0)            |
|                                   | No                | 200 (100)        |
| Sport                             | Yes               | 82 (41)          |
|                                   | No                | 118 (59)         |
| Hospitalization                   | Yes               | 108 (54)         |
|                                   | No                | 92 (46)          |
| Type sport                        | Walking           | 170 (85)         |
|                                   | Body building     | 11 (5.50)        |
|                                   | Swimming          | 4 (2)            |
|                                   | etc.              | 15 (7.50)        |
| Chronic                           | COPD*             | 34 (17)          |
|                                   | Diabetes          | 1 (0.50)         |
|                                   | Asthma            | 0 (0)            |
|                                   | Heart attack      | 2 (1)            |
|                                   | Stork             | 2 (1)            |
|                                   | Parkinson         | 6 (3)            |
|                                   | Hypothyroidism    | 1 (0.50)         |
|                                   | Depression        | 2 (1)            |
|                                   | HTN**             | 0 (0)            |
|                                   | HIV***            | 30 (15)          |
|                                   | kidney            | 2 (1)            |
|                                   | Etc.              | 60 (30)          |
|                                   | No disease        | 60 (30)          |
| BMI****                           | <19               | 17 (8.50)        |
|                                   | 19-25             | 94 (47)          |
|                                   | >25               | 89 (44.50)       |
|                                   |                   | <b>Mean (SD)</b> |
| Total Duration of hospitalization |                   | 30.38 (14.48)    |
| N. Child                          |                   | 2.9 (2.07)       |
| Testosterone                      |                   | 2.53 (2.01)      |

\*COPD=Chronic obstructive pulmonary disease;

\*\*HTN=Hypertension; \*\*\*HIV=Human Immunodeficiency Viruses; \*\*\*\*BMI=Body Mass Index

**Table 2: Reliability measures of ADAM\* questionnaire**

| Variable | Mean (SD)   |             | p     | Spearman<br>Correlation coefficient | Interclass Correlation (ICC) |                | p     | Cronbach<br>alpha (ICC) |
|----------|-------------|-------------|-------|-------------------------------------|------------------------------|----------------|-------|-------------------------|
|          | First test  | Second test |       |                                     | Average measure              | Single measure |       |                         |
| Q1**     | 0.88 (0.33) | 0.88 (0.33) | 0.999 | 1                                   | 1                            | 1              | -     | 1                       |
| Q2       | 0.52 (0.51) | 0.64 (0.49) | 0.157 | 0.78                                | 0.87                         | 0.78           | 0.001 | 0.87                    |
| Q3       | 0.41 (0.50) | 0.58 (0.50) | 0.083 | 0.70                                | 0.82                         | 0.7            | 0.001 | 0.82                    |
| Q4       | 0.52 (0.51) | 0.7 (0.46)  | 0.083 | 0.68                                | 0.81                         | 0.68           | 0.001 | 0.81                    |
| Q5       | 0.64 (0.49) | 0.64 (0.49) | 0.999 | 1                                   | 1                            | 1              | -     | 1                       |
| Q6       | 0.23 (0.43) | 0.23 (0.43) | 0.999 | 0.67                                | 0.80                         | 0.67           | 0.001 | 0.80                    |
| Q7       | 0.82 (0.39) | 0.82 (0.39) | 0.999 | 1                                   | 1                            | 1              | -     | 1                       |
| Q8       | 0.47 (0.51) | 0.52 (0.51) | 0.655 | 0.41                                | 0.58                         | 0.41           | 0.043 | 0.58                    |
| Q9       | 0.41 (0.50) | 0.41 (0.50) | 0.999 | 1                                   | 1                            | 1              | -     | 1                       |
| Q10      | 0.47 (0.51) | 0.58 (0.50) | 0.317 | 0.54                                | 0.70                         | 0.54           | 0.009 | 0.70                    |
| Total    | 5.41 (2.45) | 6.05 (2.16) | 0.032 | 0.88                                | 0.93                         | 0.88           | 0.001 | 0.93                    |

\*Androgen Deficiency in Aging Males; \*\*Q=Question

**Table 3: Sensitivity, specificity, PPV\*, NPV\*\*, PLR\*\*\*, NLR\*\*\*\*, and AUC\*\*\*\*\* for ADAM scale on ROC\*\*\*\*\* analysis**

| Index                    | Estimate | 95% Confidence interval |       |
|--------------------------|----------|-------------------------|-------|
|                          |          | Lower                   | Upper |
| Sensitivity              | 93.85    | 88.20                   | 97.30 |
| Specificity              | 77.14    | 65.60                   | 86.30 |
| PPV                      | 4.11     | 2.70                    | 6.30  |
| NPV                      | 0.08     | 0.04                    | 0.20  |
| LR+                      | 88.40    | 81.90                   | 93.20 |
| LR-                      | 87.10    | 76.10                   | 94.30 |
| Area under the roc curve | 0.85     | 0.79                    | 0.90  |

\*Positive Predictive Value, \*\*Negative Predictive Value, \*\*\*Positive Likelihood Ratio, \*\*\*\*Negative Likelihood Ratio, \*\*\*\*\*Area under the roc curve, \*\*\*\*\*Receiver Operating Characteristic

findings mean that if men older than 50 years had lower testosterone levels in their laboratory samples, Adam's questionnaire would identify 93.85% of this andropause, and 77.14% of them were healthy.

In this study, the Rock Curve was used for diagnostic validity. Figure 1 shows the power of the instrument to distinguish high and low testosterone levels in men, and the results showed that the area under the curve of the testosterone cut-off point was the basis of Adam's questionnaire was 0.85 with a value of (0.90- 0.79) 95% confidence interval. This finding indicates the high diagnostic power of The Iranian version of the ADAM questionnaire.

Finally, in Table 4, the Mann-Whitney U test was used to determine the mean of the questionnaire dimensions in men with different testosterone levels. The results showed that questionnaire dimensions (sex, energy, and mood) in men who had testosterone lower than 2.20 was significantly higher than men who had testosterone higher than 2.20 nmol/dl. This finding means that Most participants in this study have lower testosterone levels and have more problems in terms of mood, energy, and sexual dimension

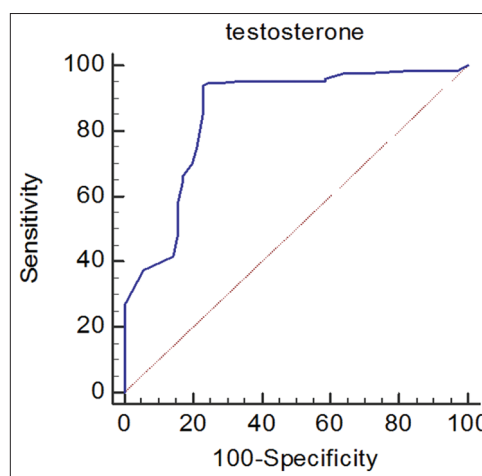


Figure 1: Testosterone hormone cutoff curve based on Adam's questionnaire

as compared to men who are older than 50 with normal testosterone levels.

## Discussion

The results of this study showed that testosterone levels decreased with age. A survey reported that the lowest testosterone levels in people over 70 and normal testosterone levels in people age 40.<sup>[13]</sup> This finding was similar to another study who reported the highest testosterone levels at age 30 to 40 and the lowest at age 60 to 70, which is similar to the studies published.<sup>[11]</sup> The difference in the finding of the studies, because the range of age in participants was slightly different. In this study, men who inpatient and older than 50 years were selected as participants and were examined; however, in many studies, men younger than 50 were also included in the participants' list.<sup>[13]</sup> However, all studies have shown a decrease in testosterone levels with age in men.

The present study results showed that The Iranian version of the ADAM questionnaire had good validity and reliability, and it is a suitable questionnaire for screening older men hospitalized by nurses. This result

**Table 4: Comparison of mean and standard deviation of testosterone dimensions of questionnaire**

| Testosterone | Mean (SD)       |                 |                 |
|--------------|-----------------|-----------------|-----------------|
|              | Mood. D*        | Energy. D**     | Sexual. D***    |
| ≤2.20        | 1.24 (1.11)     | 2.79 (1.16)     | 1.89 (0.84)     |
| >2.20        | 0.62 (0.75)     | 0.75 (0.70)     | 0.2 (0.60)      |
| Mann-Whitney | 2297.50         | 839             | 919.50          |
| <i>p</i>     | <i>p</i> <0.001 | <i>p</i> <0.001 | <i>p</i> <0.001 |

\*Mood Dimention, \*\*Energy Dimention, \*\*\*Sexual Dimention

was consistent with one of the studies. In this study, the questionnaire's validity and reliability were reported very desirably, which means Adam's questionnaire to be a valid and reliable questionnaire for assessing testosterone levels.<sup>[9]</sup> On the other hand, a study estimated Cronbach's alpha for the ADAM questionnaire to be 0.71, indicating excellent reliability for this questionnaire,<sup>[13]</sup> and another study states, Adam's internal consistency and test-retest methods were tested. Their findings found high reliability for this questionnaire.<sup>[14]</sup> As mentioned in various studies, this questionnaire's reliability and validity have been evaluated in different countries, and almost all of Adam's questionnaire studies had excellent reliability and validity. The researcher did not find any research to the contrary. These results showed that the ADAM questionnaire was very well in content and structure. It also showed high reliability and validity in Iran and It is a suitable questionnaire for nurses to screen older men for sex hormone deficiency.

Also, in the present study, the findings showed that the ADAM questionnaire's Iranian version has high sensitivity and specificity. This finding means that this questionnaire can be used as an auxiliary scale in the diagnosis of andropause syndrome in inpatient men over 50 years of age by nurses. Similarly, a study reported high sensitivity and acceptable specificity for this questionnaire. In this study, the participants' biological testosterone hormone was also examined. However, high sensitivity but low specificity reported in most other studies.<sup>[9]</sup> In a study, they reported high sensitivity but moderate specificity in their results.<sup>[11]</sup> Similarly, Another study reported very high sensitivity and very low specificity.<sup>[13]</sup> The difference in the present study results with other studies may be due to differences in the selection of participants in the studies because the participants in this study were men who inpatient in different wards in the hospital and were older than 50 years. While most studies selected healthy people in the community as participants and the majority were younger than 50 years, the differences in this study's results with other studies in this area can be explained.

Finally, the study's findings showed that people with lower testosterone levels had a depressed mood, less energy for daily activities, and less desire and sexuality than men with normal testosterone levels. A study examined the

characteristics of men with low levels of testosterone. And in their research, they found that men who had low testosterone levels had physical, psychological, and sexual symptoms. In these individuals, the physical ability was significantly reduced, depressed, and had the insufficient sexual ability.<sup>[14]</sup> Another study also found that men with low testosterone levels had a variable lifestyle and health level, with anger, apathy, and decreased libido is the most important signs and symptoms of these individuals.<sup>[15]</sup> But another Study founded different symptoms. They showed that men with low testosterone had low motivation and energy and did the least amount of energy for their physical activity and leisure time.<sup>[2]</sup> The findings of the studies reviewed were all in the same direction. They showed that lowering testosterone in all dimensions can have adverse effects on the mood, energy, and sexual ability of men older than 50 years. The results of this study call for more attention to men over the age of 50 who are at a time of declining mood, energy, and sexual ability.

However, this study's first limitation was the selecting men older than 50 years who inpatient in different parts of the hospital and had reasons other than hormonal diseases and affecting sex hormones. It suggested that all men older than 50 years without any specific disease in the community be selected in future studies. The sensitivity and specificity of this questionnaire will be asses in these persons. The second limitation of this study was the low number of men over the age of 70 in this study; in the future study, it suggested that most men over the age of 70 choose to be a research sample.

## Conclusion

The Iranian version of the ADAM questionnaire has high sensitivity and specificity that nurses can use as a screening scale to diagnose sex hormone deficiency in hospitalized men older than 50. This study addresses the need to pay attention to men over the age of 50 and screen them for mood and hormonal abilities. Nurses have played an important and effective role in the care and treatment of elderly patients for many years. This study has developed the roles of nurses and participated in screening elderly patients.

## Acknowledgements

The authors would like to thank all the participants who were part of the study. The authors also acknowledge the institute's ethical committee and patients of nephrology and urology departments.

## Financial support and sponsorship

Nil.

## Conflicts of interest

Nothing to declare.

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