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Original Article

The Persian Syncope Functional Status Questionnaire: A Validity and Reliability Study

Shayan MirShafiee[1#], MD; Somayyeh Moradi[1#], MD; Ali Mehrakizadeh[1], MD; Reza Mazaheri[2], MD; Masih Tajdini[3], MD; Reza Mollazadeh[1], MD

[1]Department of Cardiology, School of Medicine, Imam Khomeini Hospital Complex, Tehran University of Medical Sciences, Tehran, Iran;
[2]Department of Sports and Exercise Medicine, Sports Cardiology Section, Tehran Heart Center, Tehran University of Medical Sciences, Tehran, Iran;
[3]Division of Cardiology, School of Medicine, Johns Hopkins University, Baltimore, Maryland, USA
#The authors contributed equally to this work.

Correspondence:
Reza Mollazadeh, MD;
Department of Cardiology, School of Medicine, Imam Khomeini Hospital Complex, Tohid Sq., Postal code:14197-33141, Tehran, Iran
Tel:+98 21 66939537
Email: mollazar@yahoo.com,
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Abstract

Background: Syncope is defined as a transient loss of consciousness, with vasovagal syncope (VVS) being the most common cause. Although VVS episodes are typically self-limiting, they can significantly impact patients' quality of life. The syncope functional status questionnaire (SFSQ) is an internationally standardized tool designed to assess two major health dimensions: the physical and psychosocial domains. This study aimed to translate and culturally adapt the SFSQ into Persian and assess its validity and reliability.

Methods: This study was conducted in Tehran, Iran, between October 2022 and January 2023. It consisted of three phases: first, the translation and cultural adaptation of the questionnaire into Persian; second, an assessment of the comprehensibility of the pre-final version through a pilot study involving 50 individuals; and third, an evaluation of the reliability and validity of the final translated version. We assessed test-retest reliability, content validity, and convergent validity by examining the correlations between the dimensions of the translated SFSQ and other relevant measures.

Results: Among 50 patients, 26 were women, and 24 were men. The mean age of the participants was 26.5±5.5 years. Test-retest reliability was good, with a Cronbach's alpha coefficient of 0.84. Both face validity and content validity index (CVI) were deemed acceptable, with a misunderstanding index of 18% (below the 20% significance threshold) and a CVI of 92% (above the 88% significance threshold for all questions).

Conclusion: The Persian version of the SFSQ was found to be a reliable and valid tool for data collection in patients with syncope. This instrument represents a significant step toward standardizing syncope-related research.

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Keywords ● Vasovagal syncope ● Questionnaires ● Quality of life ● Cross-cultural comparison

What's Known

- Vasovagal syncope is a common form of reflex syncope that significantly impacts quality of life.
- Several tools to assess its clinical and psychosocial effects have been developed and validated in various languages.

What's New

- This study established the first valid and reliable Persian version of the syncope functional status questionnaire (SFSQ).
- This instrument could aid in better understanding the needs of Persian-speaking patients with vasovagal syncope.

Introduction

Syncope is a clinical syndrome involving the cardiovascular and nervous systems. It is characterized by a sudden, transient, and complete loss of consciousness, followed by spontaneous and full recovery.[1, 2]

Among the various etiologies of syncope, the most prevalent is neurally mediated or reflex syncope—particularly vasovagal syncope (VVS). This contrasts with the less common but potentially life-threatening cardiac syncope. VVS is characterized

by a transient loss of consciousness resulting from a sudden drop in heart rate and blood pressure, typically triggered by prolonged standing, emotional stress, or pain. Although VVS is generally benign and self-limiting, its recurrent and unpredictable nature can significantly impact a patient's quality of life (QoL). The absence of symptoms between episodes often complicates diagnosis, posing challenges for both patients and physicians. Extensive research has been conducted to better understand the underlying mechanisms of VVS, including its pathophysiology, which involves reduced venous return and cardiac output, leading to activation of the vasovagal reflex. Despite its benign prognosis, the burden of recurrent episodes warrants further investigation into its physiological basis and clinical presentation.[3, 4]

Among healthy individuals, approximately 35% will experience at least one syncope episode in their lifetime. These episodes can significantly impact an individual's QoL, and several studies have established a clear relationship between syncope and a decline in overall QoL.[5-7] The relationship between syncope and diminished QoL and mental health is direct. This evidence highlighted the significant burden of syncope and underscored the necessity for further research in this area.[6-8]

Many studies assessing the QoL in patients with cardiovascular diseases utilize the Short Form 36 (SF-36) questionnaire.[3, 4, 7] The SF-36 is an internationally recognized tool designed to measure physical, mental, and emotional health across eight distinct domains.[9]

Among the specific questionnaires focusing on syncope, the syncope functional status questionnaire (SFSQ) evaluates both the physical and psychological dimensions of the condition and its consequences. This specialized tool consists of 11 yes/no questions that assess the quality of daily life, along with three eight-point Likert-scale questions measuring fear and worry. The impairment score was calculated by dividing the number of areas in which syncope interferes with the patient's life (ranging from 0-11) by the total number of areas applicable to a patient's life, multiplied by 100. This score ranges from 0 to 100, with higher scores representing greater interference. The three Likert-scale questions are linearly converted to a 0-100 scale and averaged to calculate the fear–worry score, also scaled from 0 to 100, where higher scores indicate more fear and worry. A syncope dysfunction score (SDS) is then calculated as the mean of the impairment score and the fear–worry score.[10, 11]

The SFSQ has been extensively used in various studies to evaluate QoL in patients with syncope, and its reliability and validity are well established in both English-speaking and non-English-speaking populations.[12-14] Using a disease-specific tool enables more precise assessment of treatment outcomes and disease severity. Therefore, developing a culturally adapted Persian version of the SFSQ is crucial for improving the understanding and management of syncope in Persian-speaking patients.[14-16]

While the SFSQ has been validated in other languages, the methodologies used for translation and the psychometric outcomes of those adaptations were often not detailed. The development of a Persian version of the SFSQ, with established validity and reliability, is essential for standardizing national studies and aligning them with international research in the field of syncope. Therefore, the objective of this study was to evaluate the reliability and validity of the Persian version of the SFSQ in patients presenting with syncope.

Materials and Methods

Translation and Cross-cultural Adaptation

This study was conducted following approval from the Local Ethics Committee of Tehran University of Medical Sciences (Tehran, Iran) (code: IR.TUMS.IKHC.REC.1399.262). Written informed consent was obtained from all participants. The research involved a systematic process, including forward and backward translation of the original questionnaire, multiple expert reviews, and pilot testing with cognitive debriefing. These procedures were employed to ensure semantic, conceptual, and cultural equivalence between the original English version and the Persian adaptation (figure 1). The Persian version of the questionnaire and its English back-translation are provided in Supplementary files 1 and 2, respectively.

Step 1: Forward Translation

The original English questionnaire was independently translated into Persian by two translators. They were instructed to use straightforward language that conveyed the original meaning, rather than adhering to a literal, word-for-word translation. One translator was a physician familiar with the concepts addressed in the questionnaire, while the other was a professional translator without a medical background, ensuring an unbiased perspective.

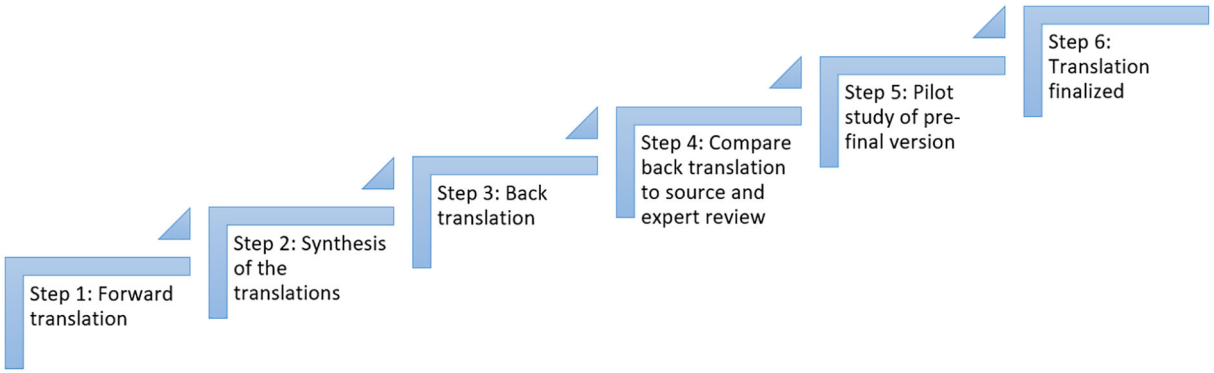

Figure 1: The diagram depicts the step-by-step process of translation methodology.

Step 2: Synthesis of the Translations

The two translated versions were compared, and any discrepancies were discussed in detail. This collaborative process resulted in a single, unified Persian translation of the questionnaire.

Step 3: Back Translation

The synthesized Persian version was independently translated back into English by two native Persian speakers fluent in English, both of whom had lived in English-speaking countries for a long time. They were blinded to the original English questionnaire and had no prior knowledge of the concepts being assessed to ensure an unbiased back-translation.

Step 4: Compare Back Translation to Source and Expert Review

A committee comprising an epidemiologist, a cardiologist, a cardiac electrophysiology specialist, an interventional cardiology specialist, a psychiatrist, a sports medicine specialist, and two translators compared the back translation with the original English source. They assessed the coherence and fidelity of the back translation, identifying and discussing any discrepancies until a consensus was reached on necessary modifications. This process yielded the pre-final version of the Persian questionnaire.

Step 5: Pilot Study of the Pre-Final Version

Fifty patients with syncope participated in a pilot study to assess their comprehension of the questionnaire. Each participant completed the SFSQ independently. Subsequently, the interviewer reviewed each item and response with the participant to initiate a discussion. At the conclusion of the interview, patients were asked to identify any difficult-to-understand words or phrases and to share their overall impressions.

To assess content validity, a separate panel of eight experts individually reviewed each item using the content validity index (CVI). The final version of the Persian questionnaire was approved by this expert committee.

Face validity was assessed by calculating a misunderstanding index for each item. Participants first shared their interpretation of each question's meaning. The percentage of individuals whose interpretations contradicted the question's intended purpose was calculated and recorded as the misunderstanding index. Based on previous studies, a rate of less than 20% was considered acceptable.[10, 17] Any item with an index exceeding 20% would have required wording modifications.

Data Collection Procedure

Study participants were patients diagnosed with VVS following a comprehensive evaluation by a cardiac electrophysiologist, which included history-taking, physical examination, and a 12-lead electrocardiogram. If the diagnosis remained uncertain, additional evaluation was performed at the physician's discretion. Eligible individuals were aged 18 to 60 with a confirmed VVS history. Participants were required to have experienced at least two syncope episodes in the preceding year and to be literate in Persian.[12, 13]

Exclusion Criteria

Participants were excluded from the study based on the following criteria: A history of structural heart disease (including coronary artery disease, valvular disorders, cardiomyopathy, or heart failure), abnormal baseline electrocardiogram results, the presence of arrhythmias, or the use of any cardiac devices, any diagnosed psychiatric disorder or epilepsy, or the experience of any syncope episodes during the test-retest interval.

To sample size for assessing the questionnaire's readability was determined using STATA software (version 17, StataCorp LLC, College Station, TX, USA). Based on an expected proportion (P1) of 0.80, a 95% confidence interval, a specified width of 0.20, and two replicates, the required sample size was calculated to be 50 participants.

This ensures adequate precision for evaluating the readability of the Persian version of the questionnaire.

Based on the aforementioned criteria, 50 eligible patients were selected from those referred to the Cardiovascular Clinic of Imam Khomeini Hospital Complex (IKHC) between October 2022 and January 2023. To assess test-retest reliability, these 50 participants were asked to complete the questionnaire for a second time after a one-week interval.

Statistical Analysis

All analyses were conducted using SPSS software (version 26, SPSS Inc., Chicago, Illinois, USA). Quantitative and categorical variables were reported as mean±SD and frequency (percentage), respectively.

Test-retest reliability was assessed using the intra-class correlation coefficient (ICC) with a one-way random effects model for each item. Internal consistency for each aspect of the questionnaire was evaluated using Cronbach's alpha, with a value greater than 0.7 considered acceptable.

The CVI for each item was determined based on ratings from the panel of experts. Experts rated each item on a three-point scale of relevance (1=useful and necessary, 2=not useful but necessary, and 3=unnecessary). Based on previous studies, the level of agreement must exceed the probability of chance occurrence. For a committee of eight members, the required agreement ratio was set at 0.75. Consequently, a CVI above this threshold was deemed acceptable for our evaluation.[14]

Convergent validity was assessed by analyzing the relationship between the dimensions of the SFSQ and the corresponding domains of the SF-36 questionnaire, whose validity and reliability were established. The Pearson correlation coefficient was used for this analysis. The SF-36 is a 36-item questionnaire designed to assess QoL in the general population and among individuals with various medical conditions (figure 2).

Results

Demographic Information

The study included 50 patients, of whom 26 (52%) were women, and 24 (48%) were men. The mean age of the participants was 26.5±5.5 years.

Test-Retest Reliability Results

Test-retest reliability was calculated for each item. The mean kappa for all 11 yes/no questions, assessed over an 8-day interval, demonstrated good reliability. The kappa values for questions 12, 13, and 14 were 0.976, 0.975, and 0.927, respectively. As shown in table 1, all items exhibited strong to excellent reliability. The overall Cronbach's alpha coefficient for the 14-item questionnaire was 0.84, indicating good internal consistency.

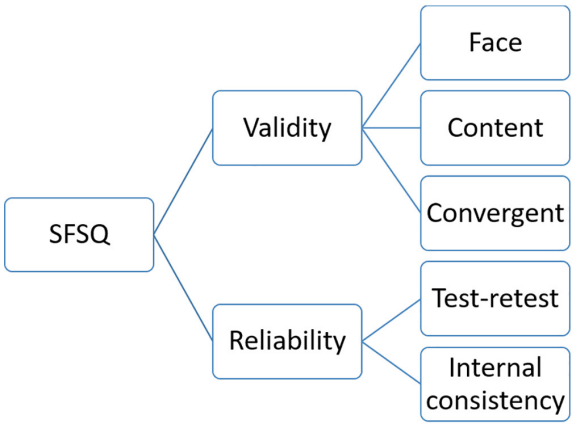

Figure 2: The method of reliability and validity assessment is illustrated.

Table 1: Reliability results for each item using Cronbach's alpha and Cohen's kappa statistic

Item number	Item	Kappa
1	Interfering with my life or routine	1
2	Preventing or causing me to avoid driving a vehicle	1
3	Reducing the amount of walking I do each day	1
4	Interfering with my use of public transportation (buses, trains, etc.)	1
5	Interfering with my performing errands (grocery shopping, housekeeping)	1
6	Interfering with my physical activities (entertainment, sports)	1
7	Affecting my ability to work at my job	1
8	Affecting my relations with my spouse /boyfriend /girlfriend	1
9	Affecting my relationship with my family	1
10	Affecting my relationships with my friends	1
11	Affecting my sexual functioning	1
12	How much do you worry about your episodes?	0.976
13	How much do you fear a typical episode coming on?	0.975
14	How does worry about an episode affect your daily life?	0.927

P<0.05 was considered statistically significant.

Face Validity Evaluation

The face validity of the Persian version was assessed using the misunderstanding index following the pilot study. The results indicated that the misunderstanding index for all items was below the 20% threshold. The average time taken to explain and complete the questionnaire, including the detailed interview and debriefing, was 27 min.

Content Validity Assessment

The CVI was calculated for each item. In this study, all CVI values exceeded the essential threshold of 0.78, as detailed in table 2.

Convergent Validity Analysis

Mean and standard deviation are shown in table 3.

To evaluate the validity of the SFSQ dimensions, Pearson's correlation coefficients were calculated between the SFSQ dimensions and the relevant subscales of the SF-36 questionnaire. The analysis revealed strong correlations between the instruments. The correlation coefficients for the SFSQ dimensions with the SF-36 total score and its subscales are presented in table 4.

Discussion

This study confirmed that the Persian version of the SFSQ is a reliable and valid instrument for assessing the QoL in patients with syncope. The development of a culturally adapted version was essential to ensure accurate measurement in Persian-speaking populations, as language and cultural context significantly influence patients' interpretation of QoL items.

The SFSQ captures both the physical limitations and psychological burden associated with syncope, serving as a comprehensive tool for evaluating patients' QoL. While its psychometric properties are well-established in English-speaking populations, they have not yet been validated in Persian.[11, 12]

Our findings were consistent with previous studies on the original English and Dutch versions of the SFSQ, which also demonstrated strong reliability and validity.[10, 18] This alignment suggested that the Persian SFSQ could be confidently used in both local and international research, supporting the broader goal of standardizing syncope-related QoL assessment across different populations. Importantly, the validation process adhered to established

Table 2: Content validity index for the 14 items of the Persian version of the syncope functional status questionnaire

Questions	CVI
Q1 (routine life)	1.00
Q2 (driving a vehicle)	0.88
Q3 (walking)	1.00
Q4 (public transportation)	1.00
Q5 (performing errands)	0.88
Q6 (physical activities)	1.00
Q7 (job)	1.00
Q8 (spousal relationship)	1.00
Q9 (family relationship)	1.00
Q10 (friends' relationship)	1.00
Q11 (sexual functioning)	1.00
Q12 (worry about episodes)	1.00
Q13 (fear of episodes)	1.00
Q14 (episode affected daily life)	1.00

CVI: Content validity index; Q: Question; P<0.05 was considered statistically significant.

Table 3: Descriptive statistics for each dimension of the Persian syncope functional status questionnaire

Quantitative Variables	Mean±SD
Total SF-36	67.98±20.17
Physical functioning	89.1±19.65
Role limitations physical	62±44.1
Role limitations emotional	67.33±43.37
Energy	45.7±16.31
Emotional wellbeing	46.16±16.48
Social functioning	68.75±36.35
General health	61.80±31.18
Mean impairment score	34.24±32.59
Fear-worry	28.57±25.28
Syncope dysfunction score	31.40±26.2

SD: Standard deviation

Table 4: Correlations between the Persian syncope functional status questionnaire and the SF-36 dimensions

SF-36 Questionnaire	SFSQ dimension score		
	Impairment	Fear-worry	Syncope dysfunction
Total SF-36	-0.730**	-0.750**	-0.816**
Physical functioning	-0.608**	-0.655**	-0.694**
Role limitations physical subscale	-0.658**	-0.688**	-0.741**
Role limitations emotional	-0.607**	-0.608**	-0.671**
Energy	-0.459**	-0.360*	-0.459**
Emotional wellbeing	-0.235	-0.172	0.229
Social functioning	-0.631**	-0.605**	-0.685**
General health	-0.682**	-0.744**	-0.783**

SFSQ: Syncope functional status questionnaire; *Correlation was significant at the 0.05 level (2-tailed); **Correlation was significant at the 0.01 level (2-tailed); Others were non-significant; P<0.05 was considered statistically significant.

guidelines for translation and cultural adaptation, ensuring conceptual rather than merely linguistic equivalence.

In addition to the SFSQ, another syncope-specific QoL instrument, the impact of syncope on quality of life (ISQL), has been developed and validated, offering a useful point of comparison. Rose and others showed that ISQL scores correlated strongly with the SFSQ as well as with syncope frequency.[19] Unlike the SFSQ, the ISQL used Likert-scale responses rather than dichotomous yes/no items, a feature that might improve its sensitivity to subtle clinical changes. This difference suggested that incorporating more graduated response options in future revisions of the Persian SFSQ could enhance its responsiveness.

Recent research has further emphasized the significant impact of syncope on patient well-being. Miranda and colleagues reported that individuals with neurally mediated reflex syncope experienced persistently reduced QoL compared to healthy controls, even after diagnosis.[20] These findings underscored the necessity of reliable, disease-specific tools, such as the Persian SFSQ, to identify long-term functional and psychological impairments that might otherwise remain unrecognized in routine clinical practice.

Beyond assessment, the clinical literature highlighted the role of psychological and interventional therapies in improving QoL. A recent randomized pilot trial found that weekly psychotherapy significantly reduced recurrence of VVS and improved SF-36 scores compared to controls.[21] Similarly, studies of patients undergoing cardioneuroablation reported marked post-procedural improvements in QoL, demonstrating the utility of validated tools for capturing these patient-reported outcomes.[22] These collective findings supported the value of a robust, culturally adapted Persian instrument for monitoring therapeutic efficacy.

While the questionnaire demonstrated strong psychometric properties, several issues warrant consideration. First, the reliance on self-reported data introduces potential for response bias, particularly in culturally sensitive domains, such as psychological distress and sexual functioning.[8] Second, although convergent validity was established through correlations with the SF-36, future studies should compare the Persian SFSQ with other condition-specific tools, such as the ISQL.[19, 23] Third, longitudinal research is required to examine the instrument's responsiveness to clinical change over time, including in response to interventions such as psychotherapy or cardioneuroablation.[21, 22] Finally, specific limitations of the present study should be noted. The single-center design in a capital city might limit the generalizability of the findings to patients in smaller towns or rural regions. The sample size, while adequate for this validation, was relatively small; larger, multicenter studies are required to strengthen the robustness of these findings. Moreover, although participants were all Persian-speaking, cultural diversity within this population might influence health perceptions and self-reporting, thereby affecting the tool's applicability across different subgroups. These factors, together with the inherent limitations of self-reported data—such as recall and social desirability bias—should be considered when interpreting the results.

Despite these limitations, the Persian SFSQ provided an important framework for both clinical practice and research. Given the high prevalence of VVS in Iran's large population, this tool could facilitate the evaluation of pharmacological and non-pharmacological interventions and help standardize QoL research across Persian-speaking communities. Extending similar translation and validation efforts to other languages could further contribute to the international harmonization of syncope research.

Conclusion

This study indicated that the Persian version of the SFSQ is a valid and reliable instrument for data collection in syncope research. Its use can help standardize studies, enhance the comparability of research and clinical trials, and facilitate data integration across the field. Furthermore, it could provide physicians treating patients with VVS with a crucial tool to understand the impact of syncope on their QoL, thereby informing strategies for its improvement.

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Authors' Contribution

R.M.Z. and S.H.M: Contributed to the study design, interpretation of data, and critical review of the manuscript. A.M: Was involved in the conception of the study, data analysis, and interpretation. S.M. R.M. and M.T: Contributed to data acquisition, interpretation, and drafting of the manuscript. All authors participated in

drafting the work and critically reviewing it for important intellectual content. All authors approved the final version of the manuscript for publication and agreed to be accountable for all aspects of the work, ensuring that any questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Declaration of AI

During the preparation of this manuscript, the authors used Grammarly for language editing, grammar improvement, summarization, and idea clarification. After its use, the authors thoroughly reviewed, verified, and revised all AI-assisted content to ensure accuracy and originality. The authors take full responsibility for the integrity and final content of the published article.

Conflict of Interest: None declared.

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