Validity and reliability of a Persian version of the 12-Item Pruritus Severity Scale in hemodialysis patients with uremic pruritus

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Received: 27 February 2020
Accepted: 26 May 2020

Background: The 12-Item Pruritus Severity Scale (12-PSS) is a multidimensional tool that evaluates pruritus intensity and duration along with an assessment of psychometric properties such as the patient´s mood, daily activities, and sleep pattern. Given its chronicity, uremic pruritus has a substantial impact on quality of life, so it is worth having a valid Persian questionnaire for assessing the various aspects of pruritus. This study was designed to evaluate the validity and reliability of the translated 12-PSS in hemodialysis patients with chronic uremic pruritus.

Methods: Participants in this cross-sectional study were hemodialysis patients with uremic pruritus who were referred to the dialysis departments of three hospitals in Tehran, Iran. Following forward-backward translation of the 12-PSS to and from Persian, we assessed its content validity index (CVI) and reliability. Finally, we asked patients to respond to questions using both the Visual Analog Scale (VAS) and the 12-PSS.

Results: Overall, 195 eligible patients participated in this study. The average age was 55.08 ± 12.34 years. The internal consistency (Cronbach's alpha) of the 12-PSS was found to be 0.88, indicating strong consistency. The mean VAS and 12-PSS scores were 6.40 ± 2.63 and 11.52 ± 3.91, respectively, and the correlation between VAS and the total raw points of the pruritus intensity domain of the 12-PSS (questions 9 and 10) was strong (P-value < 0.05, r = 0. 90).

Conclusions: This study showed that the translated form of the 12-PSS questionnaire has acceptable validity and reliability and has a strong correlation with the VAS in assessing pruritus intensity.

Keywords: Visual Analog Scale (VAS), pruritus, hemodialysis

Iran J Dermatol 2021; 24: 73-79

DOI: 10.22034/ijd.2021.221589.1036

INTRODUCTION

Uremic pruritus (UP), with a prevalence of 20-50%, is one of the major, potentially disabling complaints of patients undergoing hemodialysis [1]. In Iran, 41.9% of patients on maintenance hemodialysis suffer from UP [2]. Mathur *et al.* demonstrated a statistically significant connection between the severity of UP and health-related quality of life, particularly in terms of emotional state, social relations, and sleep quality. Based on this study, severe UP not only affects the quality of life but

also correlates with poor outcomes in the survival of patients undergoing chronic hemodialysis [3].

Obtaining an objective measurement of pruritus is a major challenge given that it is a subjective symptom. Hence, for evaluating the severity of pruritus and the efficacy of antipruritic treatments, the development of a strong and valid pruritus measurement scale is becoming increasingly important in dermatological research [4].

Several scales are available for the objective assessment of pruritus intensity, including mono-dimensional scales, such as the visual analog scale (VAS), or multidimensional scales, such as the 12-Item Pruritus Severity Scale (12-PSS) [5].

The VAS is a simple instrument for evaluating pruritus intensity; it is easy to use, time-efficient, and does not require the patient to be well-educated [6]. However, there are some disadvantages [7]; finding the exact point on the linear scale that shows the severity of pruritus may be difficult for patients. Also, some patients are not able to express the intensity in a numerical form and the VAS does not encompass all negative aspects of pruritus such as duration and frequency, the extent of body involvement, sleep impairment, patient's mood, and daily activities, meaning that it may not be an efficient tool to comprehensively evaluate the condition and response to treatment [8].

Given the points mentioned, recent consensus recommended the use of at least two different measurements such as a mono-dimensional scale like the VAS alongside another tool (e.g., multidimensional scales) in research studies or clinical trials for assessing multiple aspects of pruritus [9].

The 12-PSS is a pruritus questionnaire tool that was developed by Reich *et al.* in the English language in 2017 for evaluating subjects with dermatological disease [10]. This questionnaire consists of five domains, included pruritus frequency and duration (question 1), impairment of mood and daily activity due to pruritus (questions 2-5), scratching intensity because of pruritus severity (questions 6, 7, 8, and 12), pruritus intensity (questions 9 and 10), and body extent affected by pruritus (question 11). The total range of the 12-PSS questionnaire points includes 3 (for the best situation) to 22 (for the worst situation). These questions are easy to understand and almost all questions are of the closed-answer, yes/no type, meaning that its completion takes a short time [4].

As this questionnaire has not been translated to the Persian language for UP, and given the lack of any reliable published translated pruritus assessment tools that assess the various facets of the condition [8], we aimed to develop and validate a Persian version of the 12-PSS questionnaire. This is expected to help clinicians in decision-making about the efficacy of a treatment regimen for pruritus, besides allowing an evaluation of other aspects of the condition like the number of scratching episodes, mood, daily activities, and sleep among patients who speak in the Persian language.

PARTICIPANTS AND METHODS

This cross-sectional study was conducted to evaluate the validity and reliability of the Persian version of the 12-PSS for evaluating UP in patients undergoing hemodialysis. Participants were hemodialysis patients with UP that referred to the dialysis departments of Imam Khomeini Hospital, affiliated with Tehran University of Medical Sciences (TUMS), Labbafinezhad Hospital, affiliated with Shahid Beheshti University of Medical Sciences (SBUMS), and Ghiassi Hospital, affiliated with Iran University of Medical Sciences (IUMS), in Tehran, Iran, from July 20, 2018, through January 30, 2019. Given that the 12 questions of the 12-PSS do not need any training to answer, the participants were asked to answer both the 12-PSS and VAS at the same time.

Participants and study design

All hemodialysis patients with UP aged 18 years and older with at least a history of hemodialysis for more than three months were enrolled in this study. Eligibility criteria included the ability to understand and speak in Persian. Both the 12-PSS and VAS were completed by the patients at the same time.

Translation validity

The validity and reliability of the confirmed Persian questionnaire were investigated according to Beaton's intercultural adaptation principles [11].

The forward-backward translation method was used to translate the original form of the questionnaire (Figure 1) to Persian (Figure 2) [12].

For this purpose, two healthcare providers with proficiency in the English language translated the English questionnaire to Persian, and a third person, a clinical pharmacist, checked and homogenized the Persian form. Then, the Persian form was back-translated to English by the English language experts again. Ultimately, the two English versions of the questionnaire (original and translated) were compared with each other and any differences were detected and corrected in the final Persian version.

Content and face validity

The final Persian version form was sent to three clinical pharmacists and three nephrologists to evaluate face validity and assess the content validity index (CVI). Relevance between the questions and concept of the questionnaire was evaluated; experts gave a score in a range between 0 to 4 to each item according to clarity, ambiguity, relevance, and simplicity [13]. A CVI equal or more than 0.78 was considered to indicate good content validity [14].

Internal consistency

We assessed Cronbach's alpha coefficient to evaluate the homogeneity in the items of the questionnaire, and a value of more than 0.7 was considered to indicate acceptable internal consistency [15].

Statistical methods

The sample size with r = 0.58, 100% power,

	Question	Possible answers	Scoring
(1)	How often did you feel pruritus within the last 3 days?	(i) All time	3 points
		(ii) All morning/afternoon/evening/night long itch episodes	2 points
		(iii) Occasionally, short itch episodes	1 point
(2)	Did pruritus hinder your ability to do simply things, like watching TV, hearing music, etc.?	(i) Yes	1 point
		(ii) No	0 points
(3)	Did you feel irritated or nervous because of your itching?	(i) Yes	1 point
		(ii) No	0 points
(4)	Did your pruritus cause you depressed?	(i) Yes	1 point
		(ii) No	0 points
(5)	Did your pruritus impede your work or learning abilities?	(i) Yes	1 point
		(ii) No	0 points
(6)	Did you scratch your skin because of itching?	(i) Yes	1 point
		(ii) No	0 points
(7)	Did scratching bring you relief?	(i) Yes	0 points
		(ii) No	1 point
(8)	Were you able to refrain from scratching?	(i) Yes	0 points
		(ii) No	1 point
(9)	Did you wake up during last night because of pruritus?	(i) No	0 points
		(ii) Yes, 1-2 times	1 point
		(iii) Yes, 3-4 times	2 points
		(iv) Yes, 5 and more times	3 points
(10)	Could you assess the severity of your pruritus within last 3 days?	(i) Very mild	1 point
		(ii) Mild	2 points
		(iii) Moderate	3 points
		(iv) Severe	4 points
		(v) Very severe	5 points
(11)	Could you indicate pruritus location?	(i) Single locations of pruritus	1 point
		(ii) Large body areas	2 points
		(iii) Generalized pruritus	3 points
(12)	Are excoriations or other scratch lesions present?	(i) Yes	1 point
		(ii) No	0 points

Figure 1. Original version of the 12-Item Pruritus Severity Scale (12-PSS) questionnaire

نام و نام خانوادگی:	**گروه:**
تاریخ پر نمودن فرم:	**تشخیص بیماری:**
سوالات جهت ارزیابی خارش در 3 روز اخیر	
1. در طی 3 روز گذشته , در چه وقت ها یی از شبانه روز دچار خارش شده اید؟	☐ در تمام طول شبانه روز ☐ فقط صبح ها/ فقط ظهر ها/ فقط بعد از ظهر ها/ فقط شبها ☐ گهگاه خارش دارم. مدت زمان کوتاه در طول روز است
2. آیا خارش مانع از انجام کارهای ساده روزانه مثل تماشای تلویزیون، گوش دادن به موسیقی، ... شده است؟	بله / خیر
3. آیا به خاطر خارش آشفته و مضطرب شدید ؟	بله / خیر
4. آیا خارش شما را غمگین کرد؟	بله / خیر
5. آیا خارش باعث اختلال در یادگیری یا فعالیت های شغلی شد؟	بله / خیر
6. آیا شدت خارش باعث خراشیده شدن پوست شما گردید؟	بله / خیر
7. آیا با خاراندن خود خارش شما برطرف شد؟	بله / خیر
8. آیا قادربه خوداری از خاراندن پوستتان بودید؟	بله / خیر
9. آیا به خاطر خارش دیشب از خواب بیدار شدید ؟	خیر / بله. یک الی دو بار بله سه بار الی چهار / بله. پنج بار یا بیشتر
10. آیا میتوانید به شدت خارشتان در 3 روز گذشته نمره دهید ؟	1.یک (خیلی کم) ☐ 2. دو (کم) ☐ 3.سه (متوسط) ☐ 4.چهار(زیاد) ☐ 5. پنج (خیلی زیاد) ☐
11. آیا محل خارش را می توانید تعیین کنید؟	1.فقط در یک منطقه از بدن ☐ 2.منطقه وسیعی از بدن ☐ 3.تمام بدن ☐
12. آیا آثاری از کنده شدن پوست ناشی از خارش بر روی پوست شما دیده می شود؟	1.بله ☐ 2.نخیر ☐

Figure 2. Translated (Persian) version of the 12-Item Pruritus Severity Scale (12-PSS) questionnaire

5% significance, and a 20% drop out rate, was calculated as 195 patients [4].

Mean ± standard deviation (SD) was used to show continuous data and categorical ones were expressed by frequency (percentage) and/or median (interquartile range). The Kolmogorov–Smirnov test was performed on numerical variables for evaluating normality. Comparison of parametric and non-parametric variables was carried out by independent t-test and Mann-Whitney U test, respectively. The correlation of VAS and 12-PSS was analyzed by the Pearson correlation test.

The receiver operating characteristic (ROC) curve was used to determine the discrimination threshold for 12-PSS compared with VAS as a state variable. The VAS scores were categorized into three groups including mild (score: 1-3), moderate (score: 4-6), and severe/very severe (score: 7-10) [6]. The area under the curve reflected the accuracy of the test, which was categorized as follows: 0.5-0.6 (fail), 0.6-0.7 (poor), 0.7-0.8 (fair), 0.8-0.9 (good), and 0.8-0.9 (excellent) [16].

All statistical analyses were performed in SPSS software (version 21.0, SPSS Inc., Chicago, IL, USA). In this study, P-values < 0.05 were considered significant.

Ethical considerations

This study had the approval of the Ethics Committee of TUMS (IR.TUMS.TIPS.REC.1397.040). Signed written consent was obtained from all participants.

RESULTS

Patient characteristics

A total of 195 participants including 115 males (59%) and 80 females (41%) were assessed. The mean age was 55.08 ± 12.34 years, ranging from 30 to 70 years. The mean dialysis duration was 6.99 ± 4.06 years.

The internal consistency (Cronbach's alpha) of the Persian 12-PSS was found to be 0.88. The CVI was analyzed for each question (Table 1).

The average scores of the VAS, the 12-PSS, and the pruritus intensity domain of the 12-PSS (questions 9 and 10) of the patients were 6.40 ± 2.63, 11.52 ± 3.91, and 4.96 ± 1.15, respectively.

In this study, the Pearson correlation coefficient between the VAS and total raw points of the pruritus intensity domain of the 12-PSS was strong, with a direct and meaningful relationship between the two scores (r = 0.90, P-value < 0.05).

The cut-off points for classifying the Persian version of the 12-PSS into the three groups of mild, moderate, and severe/very severe were determined using the VAS. The area under the curve for defining cut-off points for mild, moderate, severe/very severe pruritus was 0.96 ± 0.01 (CI 95%: 0.94-0.98), 0.92 ± 0.18 (CI 95%: 0.89-0.96), and 0.91 ± 0.02 (CI 95%: 0.87-0.95), respectively (Table 2 and Figure 3).

DISCUSSION

Because of the negative effects of pruritus on mood, sleep pattern, and daily activities, developing a multifaceted scale for assessing the antipruritic treatment response in terms of the different aspects of pruritus is essential. In this study, the Persian 12-PSS was compared with the VAS, and the validity and reliability tests were performed for

Table 1. Evaluation of content validity index (CVI) for questions of the Persian translation of the 12-Item Pruritus Severity Scale (12-PSS).

Question	Relevance%	Simplicity%	Clarity%	Ambiguity%
1	100%	100%	100%	100%
2	100%	100%	100%	100%
3	100%	100%	100%	100%
4	83.33%	83.33%	83.33%	83.33%
5	100%	100%	100%	83.33%
6	100%	100%	100%	100%
7	100%	100%	100%	100%
8	100%	100%	100%	100%
9	100%	100%	100%	100%
10	100%	100%	100%	100%
11	100%	100%	100%	100%
12	100%	100%	100%	100%

Table 2. Sensitivity and specificity for defining descriptive cut-off points by Roc test analysis for the 12-Item Pruritus Severity Scale (12-PSS) in comparison with the Visual Analog Scale (VAS)

Roc test for 12-PSS in comparison with VAS (mild, moderate to very severe)		
Positives if greater than	**Sensitivity%**	**Specificity%**
6.5	97.5	82.1
7.5	93.9	83.1
8.5	84.7	90.1
12-PSS in comparison with VAS (mild-moderate, severe, and very severe)		
11.5	85.9	79.9
12.5	78.8	88.6

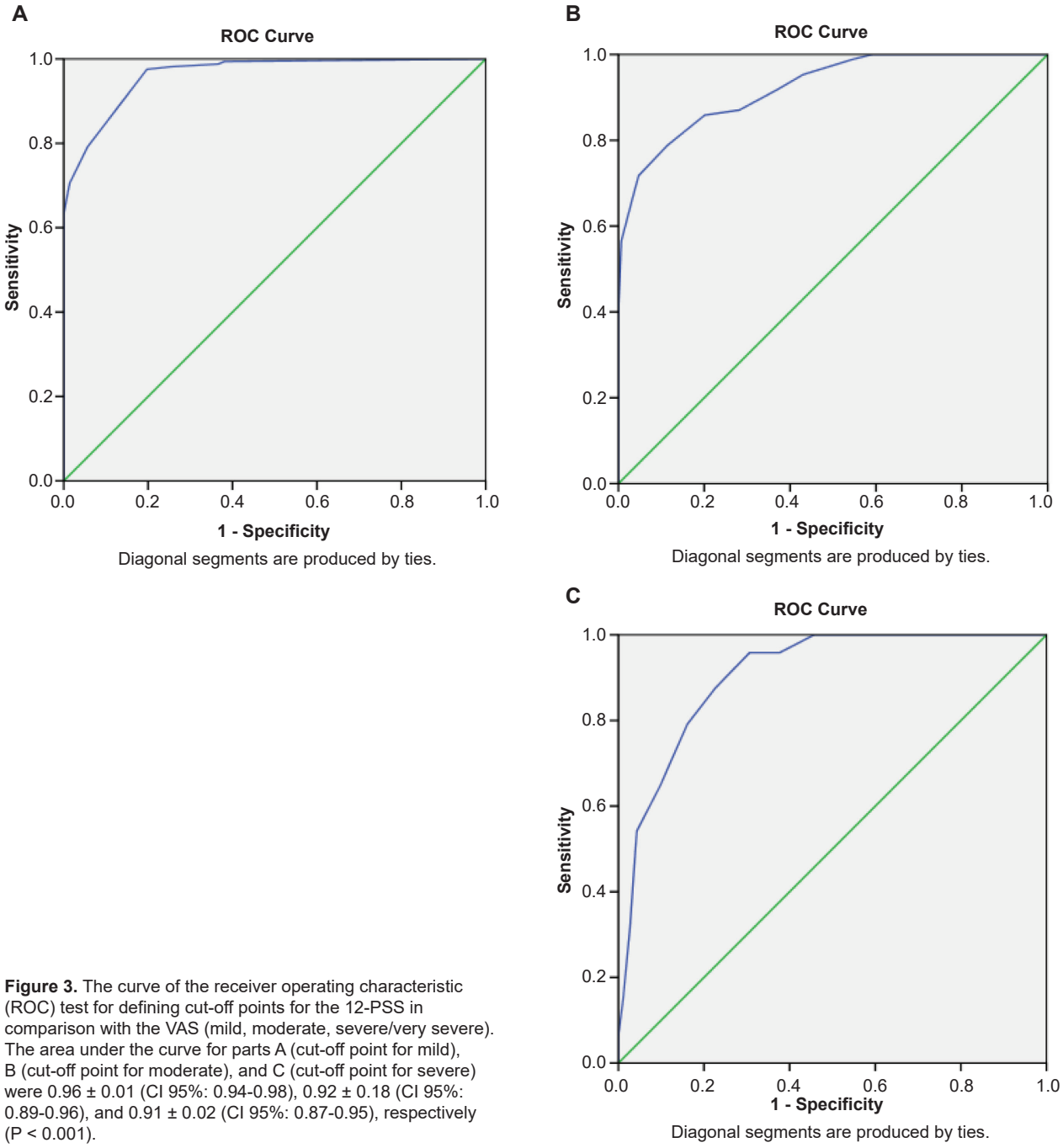

Figure 3. The curve of the receiver operating characteristic (ROC) test for defining cut-off points for the 12-PSS in comparison with the VAS (mild, moderate, severe/very severe). The area under the curve for parts A (cut-off point for mild), B (cut-off point for moderate), and C (cut-off point for severe) were 0.96 ± 0.01 (CI 95%: 0.94-0.98), 0.92 ± 0.18 (CI 95%: 0.89-0.96), and 0.91 ± 0.02 (CI 95%: 0.87-0.95), respectively (P < 0.001).

the translated questionnaire. We concluded that the Persian 12-PSS is valid and reliable for assessing the various facets of pruritus in hemodialysis patients with UP.

The 12-PSS may be a useful tool in both clinical trials and routine daily practice to qualify patients. According to Table 1, the CVI of all questions was more than 0.78, which means that all questions have sufficient content validity. Furthermore, for questions with a CVI of less than 100%, the recommendations of a panel of experts were applied to reach the maximum content validity possible.

We found the 12-PSS and VAS to have a significant correlation with each other in assessing the intensity of pruritus, which is in agreement with the findings of Adam Reich *et al.* (r = 0.58;

$P < 0.05$) [4].

In our study, the internal consistency for the Persian 12-PSS was 0.88 ($P < 0.05$), and the correlation between VAS and the translated pruritus intensity domain in the 12-PSS was 0.90 ($P < 0.05$), indicating that there was strong relevance.

Due to the strong correlation between 12-PSS and VAS, the 12-PSS could be arranged into three categories (mild, moderate, severe/very severe) in accordance with the VAS. The area under the graph of each ROC was more than 0.90, which showed the excellent accuracy of the test to separate the cut-off of each classification [16]. The cut-off points for classifying the 12-PSS into three descriptive terms were: less than 6 as mild, 6-12 as moderate, and 13-22 as severe/very severe (Table 2). According to Figure 3 (A, B, and C), these cut-off points have appropriate sensitivity and specificity. Such a descriptive classification system for the 12-PSS has not been proposed in any other study, so comparing these results was not possible.

CONCLUSION

Our results showed that the Persian form of the 12-PSS questionnaire is a reliable and valid instrument for the evaluation of the severity of pruritus in hemodialysis patients with UP, sharing a strong correlation with the VAS.

Acknowledgment

This study was financially supported by an educational grant from the Tehran University of Medical Sciences (TUMS). The authors wish to express their sincere gratitude to all the study participants and clinical staff who made this research possible.

Conflict of interest: None declared.

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