DOI: 10.34172/mejdd.2020.194

Validity and Reliability of Persian Version of 12-Item Pruritus Severity Score Questionnaire in Patients with Chronic Liver Disease and Pruritus

Ayda Esmaeili [1,8], Parya Baharvand [2], Leyla Sahebi [3], Aysan Esmaeili [4], Mohssen Nassiri Toosi [5,6], Soha Namazi [7,*]

1. PharmD, Clinical Pharmacist, Assistant professor, Clinical Pharmacy Department, School of Pharmacy, Urmia University of Medical Sciences (UMSU), Urmia, Iran
2. PharmD, Clinical Pharmacist, Clinical Pharmacy Department, School of Pharmacy, Tehran University of Medical Sciences (TUMS), Tehran, Iran
3. Institute of Family Health, Maternal-Fetal and Neonatal Research Center, Tehran University of Medical Science, Tehran, Iran
4. MD, Internist, Internal Medicine Department, School of Medicine, Urmia University of Medical Sciences (UMSU), Urmia, Iran
5. MD, Internist, Associate Professor of Gastroenterology and Hepatology, Internal Medicine Department , School of Medicine, Tehran University of Medical Sciences (TUMS), Tehran, Iran
6. Liver Transplantation Research Center, Tehran University of Medical Sciences, Tehran, Iran
7. PharmD, Clinical Pharmacist, Professor, Clinical Pharmacy Department, school of Pharmacy, Tehran University of Medical Sciences (TUMS), Tehran, Iran
8. Research center for experimental and applied pharmaceutical science, Urmia University of Medical Sciences (UMSU), Urmia, Iran

* **Corresponding Author:**
Soha Namazi, PharmD
Keshavarz Blv., Imam Khomieni Hospital Complex, Valiasar Hospital, Pharmaceutical Care Department.
Postal Code: 1419733141

Telefax: + 98 21 61192353
Email: namazisoha@yahoo.com

Received: 26 Dec. 2019
Accepted: 19 Jul. 2020

ABSTRACT

BACKGROUND

Currently, there is no published questionnaire translated in the Persian language for pruritus evaluation in patients with chronic liver disease. Therefore, it would be well worth having a valid and reliable Persian questionnaire for assessing pruritus with its different aspects. This study was designed to evaluate the validity and reliability of the translated version of the 12-Item Pruritus Severity Score (12-PSS)

METHODS

The patients with pruritus due to chronic liver disease, who referred to the liver clinic affiliated to Tehran University of Medical Sciences, were enrolled in this cross-sectional study. Following the forward-backward translation of 12-PSS into Persian, the content validity index (CVI) and its reliability were assessed. The patients were asked to respond to the visual analog scale (VAS) along with 12-PSS on their visits to evaluate the correlation between them.

RESULTS

160 eligible patients were entered in the present study. The mean age was 46.03 (±13.05) years. The Cronbach's alpha for all domains of 12-PSS was 0.81-0.92 (average 0.89), which showed a strong consistency. The mean VAS and 12-PSS were 5.47±2.55 and 11.71 ± 5.25, respectively, and the correlation of VAS and 12-PSS was strong ($p < 0.05$, $r = 0.89$).

CONCLUSION

The Persian version of 12-PSS is a valid questionnaire for assessing pruritus and follow up response to treatment for patients with chronic liver disease.

KEYWORDS:
12-Item Pruritus Severity Scale, Visual analog scale, Pruritus, Reliability, Validity, Liver disease

Please cite this paper as:
Esmaeili A, Baharvand P, Sahebi L, Esmaeili A, Nassiri Toosi M, Namazi S. Validity and Reliability of Persian Version of 12-Item Pruritus Severity Score Questionnaire in Patients with Chronic Liver Disease and Pruritus. *Middle East J Dig Dis* 2020;**12**:278-283. doi: 10.34172/mejdd.2020.194.

INTRODUCTION

Pruritus is known as a complication and symptom of many diseases such as atopic dermatitis, uremic condition, and liver disease.[1]

Pruritus is a perceptive symptom, so for evaluating the severity of pruritus

and evaluating the effect of antipruritic medical treatment, there is a need to develop new tools. Patients have various descriptions of pruritus intensity and how strong its negative impact on their life is. Various questionnaires have been designed to assess pruritus intensity, such as the Visual Analog Scale (VAS), which was used for different types of diseases such as cholestatic pruritus.[2]

Notwithstanding the fact that VAS is an easy and user-friendly instrument for determining the intensity of pruritus as a perceptive sense, which only takes a few seconds to perform and does not require that the patient be literate.[3] However, there are some disadvantages, for example,[4] finding the point on the liner that indicates the severity of pruritus may be difficult for some patients. Some patients are not able to express themselves verbally when they are asked about the intensity of pruritus in the grading form. Also, VAS does not include all the aspects and items to explain the impact that pruritus has on them, such as duration, frequency, and extent of body that is affected by pruritus, frequency of waking up when asleep, and the effect on patients' mood, daily activity, and housework. So it may not be an efficient tool to evaluate and follow up patients' responses to treatment, as was concluded by Bergasa and colleagues in cholestatic patients.[2]

12-Item Pruritus Severity Score (12-PSS) is a questionnaire that was developed and evaluated in subjects with dermatological diseases by Reich and colleagues in the English language in 2017. 12-PSS has included other aspects of pruritus in addition to the intensity of pruritus in objective consequence, as follows; frequency and duration of pruritus (question number 1), mood and daily activity disturbance due to pruritus (question numbers 2-5), scratching intensity (question numbers 6-8 and 12), the severity of pruritus (question numbers 9, 10), and extent expanse of pruritus (question number 11), which are categorized in five domains. The score of 12-PSS can range from 3 (equivalent to the best situation) up to 22 (equivalent to the worst situation).[5] The answers to almost all questions are either yes or no, so it only takes a short time to complete.

As this questionnaire has not been translated into the Persian language and there is no published translated questionnaire in Persian that contains multiple domains of health-related quality of life, and as it would help clinicians in the evaluation responses to antipruritic medications and itching intensity in Persian-speaking patients, the present study was designed to evaluate the validity of the Persian version of the 12-PSS questionnaire. Also, the correlation between VAS and 12-PSS was also evaluated.

MATERIALS AND METHODS

This cross-sectional study was conducted to evaluate the validity and reliability of the Persian version of 12-PSS for evaluating pruritus in patients with chronic liver disease. Patients who referred to liver disease clinics affiliated to Tehran University of Medical Sciences (TUMS), from July 15, 2018, to January 31, 2019, were enrolled in this study. The 12-PSS has 12 questions, which does not require any special training in order to answer them. Participants were asked to answer 12-PSS and VAS at the same time. This study had the approval of the Ethics Committee of TUMS (no.IR.TUMS.TIPS.REC.1397.043).

Subjects

Patients aged 18 years or older with pruritus induced by liver diseases such as primary biliary cholangitis (PBC), primary sclerosing cholangitis (PSC), autoimmune hepatitis (AIH), viral hepatitis, and drug-induced liver injury were enrolled in this study. Patients should understand and be able to speak Farsi (Persian language). All patients signed the written informed consent. Both 12-PSS and VAS were completed by the patients at the same time.

Translate validity

The translation process of the questionnaire was performed according to Beaton's intercultural adaptation principles.[6]

The forward-backward translation method was used to translate the original questionnaire (appendix 1) into Persian language,[6] as follows; two translators who were both health care providers and fluent in English translated the English form into the target language, and then a third person, a clinical pharmacist, checked and homogenized the Persian form. The final Persian form was back-translated to English by English language experts; thereafter, this English version was compared with the original one by a person who was fluent in English language and also an expert in the field of health science.

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 gastroenterologists to evaluate face validity and assess the content validity index (CVI). Relevance between questions and the concept of the questionnaire was evaluated with CVI; the six mentioned experts gave points 0-4 to each item according to clarity, ambiguity, relevance, and simplicity.[7] CVI equal to or more than 0.78 was considered as a good content validity.[8]

$$CVI = \frac{count\ of\ experts\ who\ gave\ point\ 3\ or\ 4\ for\ question}{all\ experts\ who\ answered}$$

Construct validity

The construct validity is evaluated by comparing the scores of 12-PSS with VAS to see how high the correlation between the two independent variables is. The Pearson test was used to calculate the validity coefficient, which was considered excellent at 0.81 to 1.

Internal Consistency (reliability)

Internal consistency was evaluated to show homogeneity in items of the questionnaire. Cronbach's alpha coefficient was used to assess internal consistency. Cronbach's alpha of ≥ 0.70 was considered to indicate satisfactory internal consistency. Very good internal consistency was suggested by a Cronbach's alpha coefficient > 0.80.[9]

Statistical analysis:

The sample size with r: 0.58, 100% power, 5% significance, and considering a 20% drop out was calculated as 135 patients.[5]

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

Receiver operating characteristic or ROC curve was used to determine the discrimination threshold for 12-PSS compared to VAS as a state variable. VAS was categorized into four groups, including mild (1-3), moderate (4-6), severe (7-8), and very severe (9-10).[3] The area under the curve shows the accuracy of test and 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).[10]

All statistical analysis of the study was performed by SPSS software (version 21.0, SPSS Inc. Chicago, IL, USA). In this study, the p value <0.05 was considered significant.

RESULTS

Patients' characteristics

A total of 160 participants (55% male, 45% female) were included in this study. The age range was from 21-71 years, with an average of 46.03 ± 13.05. Patients had pruritus (> 4weeks) induced by liver disease as follows: 62.5% PSC, 40% cirrhosis, 17.5% PBC, 12.5% AIH, 7.5% Hepatitis B, and 7.5% Hepatitis C (some patients had co-occurring diseases).

The Cronbach's alpha for all domains of the Persian 12-PSS was 0.81-0.92, with an average of 0.89, which showed very good reliability. CVI was analyzed for each question and is shown in table 1.

The average VAS and 12-PSS of patients were 5.47 ± 2.55 and 11.71 ± 5.25, respectively.

VAS and 12-PSS were shown to have a strong correlation (r = 0.89, p < 0.001). The correlation between VAS and the Persian version of 12-PSS was obtained as excellent (r = 0.89, p < 0.001). Furthermore, the correlation between the total raw point of questions 9 and 10, which are related to the intensity domain with VAS was assessed, and the Pearson value was 0.78 (p < 0.001), and this correlation is defined as excellent.

Cut off points for classifying the Persian version of 12-PSS in the four groups: mild, moderate, severe, and very severe were determined by using VAS. The area under the curve for each category was more than 0.95 with p < 0.001, and for defining cut points for mild, moderate, severe to very severe were 0.98 ± 0.01, 0.95 ± 0.17, and 0.97 ± 0.02, respectively (Figure1).

DISCUSSION

The severity of pruritus has a negative impact on

Table 1: **Evaluation of content validity index (CVI) for questions of 12-PSS**

Question	Relevance	Simplicity	Clarity	Ambiguity
1	100%	100%	100%	100%
2	100%	100%	100%	100%
3	100%	100%	83.33%	83.33%
4	83.33%	83.33%	83.33%	83.33%
5	100%	100%	100%	83.33%
6	100%	100%	100%v	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%

patients' quality of life, for which physicians may be obliged to choose invasive procedures for patients with cholestasis, such as early liver transplantation due to disturbing pruritus. According to a systematic review in 2016, pruritus leads to limitations in physical and social activities and daily energy requirements.[11]

As pruritus disturbs sleep patterns, mood, and daily activity, developing new tools that could evaluate the different domains of pruritus to come to an appropriate conclusion is required. There are some tools that evaluate pruritus, such as VAS, and 5-D itch scale.[12] But according to the conclusions in Bergasa and colleagues' study in which VAS efficiency was evaluated in eight cholestatic patients, VAS was not deemed a proper questionnaire to follow up and define goal responses to present potential treatment in pruritus.[2] Kamath and others developed a new tool in 2018 for evaluating pruritus in cholestatic pediatric patients with different aspects of health-related quality of life who were affected by pruritus in various ways such as sleep disturbance and mood changes concurrently.[13] Overall, the need to develop novel tools for assessing pruritus and complications induced by it would be a valuable asset.

12-PSS was a new questionnaire, which did not have a Persian version. In this study, 12-PSS was compared with VAS, and the validity and reliability tests for a Persian version were also evaluated. According to the results, the Persian version of 12-PSS was a valid and reliable instrument to evaluate the severity and four other items related to pruritus in patients with chronic cholestatic liver disease.

According to table 1, CVI was determined for each question, and the results of all questions were more than 0.78, which means that all questions have sufficient content of validity for questions with CVI less than 100%. Experts' recommendations were applied and corrected where possible.

12-PSS was designed by Reich and colleagues, and they showed that the relevance between questions was high with Cronbach's alpha 0.81. Also, they reported the correlation between VAS and 12-PSS as strong (r: 0.58; $p < 0.05$).[5]

In the current study, the internal consistency was 0.89 ($p < 0.05$), and the correlation between VAS and translated 12-PSS was 0.89 ($p < 0.05$), which indicated there was strong relevance that is in line with Reich's results.[5]

12-PSS is a multidimensional questionnaire, similar to 5-D itch scale, which was designed by Elman and coworkers.[12] There is no published study to compare with these two questionnaires. Questions in 5-D itch scale were multiple-choice in five items and used adverbs to differentiate them, so patients may become slightly confused when trying to choose exact answers; however, in 12-PSS, almost all questions are binary, and answer options are more direct in yes/no form so it is more user-friendly.

Due to the strong correlation between VAS and 12-PSS, it is wise to arrange 12-PSS in four categories (mild, moderate, severe, and very severe). The area under the graph of each ROC was more than 0.90, which meant the accuracy of the test in separating classifications was excellent.[10] As mentioned in the results, the cut points for classifying 12-PSS translated into four descriptive terms, which are as follows: less than 9 as mild (sensitivity 87.6%, specificity 100%), 9-13 as moderate (sensitivity 86.8%, specificity 86%), 14-16 as severe and 17-22 as very severe (sensitivity 89.5%, specificity 89%). Defining descriptive terms for 12-PSS has not been published in any study to date, so we cannot compare these results with others.

A limitation of the present research was the education level of the patients, which was not used to evaluate the effects on the validity and reliability of the questionnaire; however, the literacy of patients were not mentioned in the original study of this instrument [5] and some other studies that evaluated the validity and reliability of translated P-QOL (Perceived- Quality of Life) and caregiver burden questionnaires into the Persian language.[14,15]

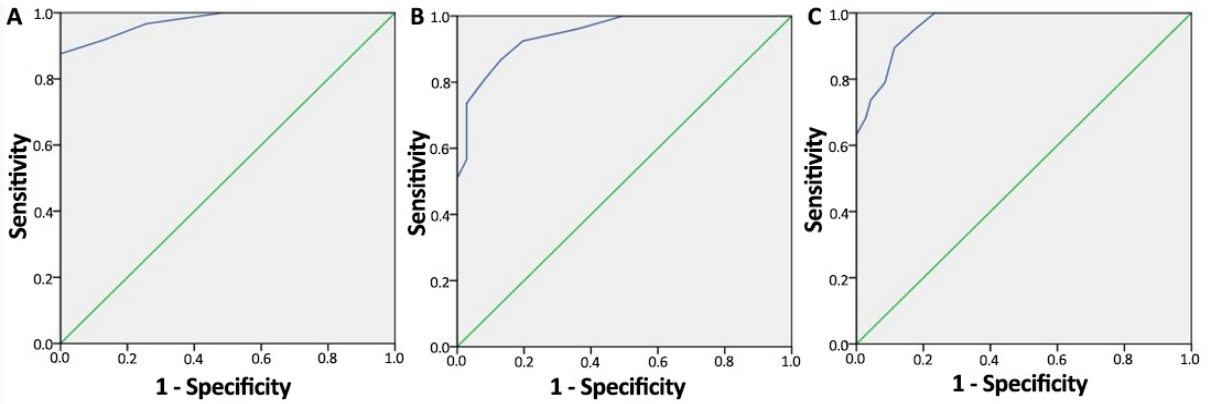

Fig.1: The curve of receiver operating characteristic test for defining cut point for 12-PSS in comparison with VAS (mild, moderate, severe, and very severe). The area under the curve for figure A (defining cut point mild), B (defining cut point moderate), and C (defining cut point severe), with 95% confidence interval were 0.98 ± 0.01, 0.95 ± 0.02, and 0.97 ± 0.02, respectively with *p*-value < 0.001. Abbreviations: Visual analog scale (VAS), 12-item pruritus severity score (12-PSS).

CONCLUSION

The Persian version of 12-PSS questionnaire is a proper, translated instrument for the evaluation of the severity of pruritus in patients with liver disease with an excellent correlation with VAS. Also 12-PSS gives an objective evaluation from different aspects such as mood, daily activity, and sleep patterns affected by pruritus, so it is a valid questionnaire which can be used for following up and evaluating treatment response in the Persian clinical studies.

ACKNOWLEDGMENT

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

ETHICAL APPROVAL

There is nothing to be declared.

CONFLICT OF INTEREST

The authors declare no conflict of interest related to this work.

REFERENCES

1. Ständer S, Raap U, Weisshaar E, Schmelz M, Mettang T, Handwerker H, et al. Pathogenesis of pruritus. *J Dtsch Dermatol Ges* 2011;**9**:456-63. doi: 10.1111/j.1610-0387.2011.07585.x.
2. Bergasa NV, Jones EA. Assessment of the Visual Analogue Score in the Evaluation of the Pruritus of Cholestasis. *J Clin Transl Hepatol* 2017;**5**:203-7. doi: 10.14218/JCTH.2017.00001. Epub 2017 Jul 7.
3. Reich A, Heisig M, Phan NQ, Taneda K, Takamori K, Takeuchi S, et al. Visual analogue scale: evaluation of the instrument for the assessment of pruritus. *Acta Derm Venereol* 2012;**92**:497-501. doi: 10.2340/00015555-1265.
4. Klimek L, Bergmann K-C, Biedermann T, Bousquet J, Hellings P, Jung K, et al. Visual analogue scales (VAS): Measuring instruments for the documentation of symptoms and therapy monitoring in cases of allergic rhinitis in everyday health care. *Allergo j Int* 2017;**26**:16-24. doi: 10.1007/s40629-016-0006-7. Epub 2017 Jan 19.
5. Reich A, Bożek A, Janiszewska K, Szepietowski JC. 12-Item Pruritus Severity Scale: Development and Validation of New Itch Severity Questionnaire. Biomed Res Int 2017;**2017**:3896423. doi: 10.1155/2017/3896423. Epub 2017 Oct 2.
6. Behling O, Law KS. Translating questionnaires and other research instruments: Problems and solutions. *Sage* 2000. doi: 10.4135/9781412986373.n1.
7. Zamanzadeh V, Ghahramanian A, Rassouli M, Abbaszadeh A, Alavi- H. Design and implementation content validity Study : development of an instrument for measuring patient-centered communication. *J Caring Sci* 2015;**4**:165–78.
8. Polit DF, Beck CT, Owen SV. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. *Res Nurs Health* 2007;**30**:459-67. doi: 10.1002/nur.20199.
9. Cronbach LJ, Shavelson RJ. My current thoughts on coefficient alpha and successor procedures. *Educ Psychol Meas* 2004;**64**:391-418. doi: 10.1177/0013164404266386.
10. Hosmer DW, Lemeshow S. Applied logistic regression. *Wiley New York* 2000. doi: 10.1002/0471722146.
11. Jin XY, Khan TM. Quality of life among patients suffering

from cholestatic liver disease-induced pruritus: A systematic review. *J Formos Med Assoc* 2016;**115**:689-702. doi: 10.1016/j.jfma.2016.05.006.

12. Elman S, Hynan L, Gabriel V, Mayo M. The 5-D itch scale: a new measure of pruritus. *Br J Dermatol* 2010;**162**:587-93. doi: 10.1111/j.1365-2133.2009.09586.x. Epub 2009 Dec 1.
13. Kamath BM, Abetz-Webb L, Kennedy C, Hepburn B, Gauthier M, Johnson N, et al. Development of a novel tool to assess the impact of itching in pediatric cholestasis. *Patient* 2018;**11**:69-82. doi: 10.1007/s40271-017-0266-4.
14. Morovatdar N, Hghighi L, Najmi Z, Hashemi A, Nojomi M. Response validity of Persian version of P-QOL questionnaire in patients with prolapse. *Eur J Obstet Gynecol Reprod Biol* 2015;**193**:88-91. doi: 10.1016/j.ejogrb.2015.07.013.
15. Abdollahpour I, Nedjat S, Noroozian M, Golestan B, Majdzadeh R. Development of a caregiver burden questionnaire for the patients with dementia in iran. *Int J Prev Med* 2010;**1**:233-41.

Appendix 1: Original version of 12-item Pruritus Severity Score (12-PSS) questionnaire.

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