ORIGINAL ARTICLE

Translation and linguistic validation of the Persian version of the International consultation on Incontinence Questionnaire Vaginal Symptoms

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Background: There is no validated measurement tool to assess vaginal symptoms (VS), sexual matter (SS), and quality of life (QOL) among Persian-speaking women. This study aimed at translating and assessing the validity and reliability of the Persian version of the International Consultation on Incontinence Questionnaire for Vaginal Symptoms (PICIQ-VS). **Materials and Methods:** In this cross-sectional study, after obtaining permission from the International Consultation on Incontinence Questionnaire (ICIQ) Advisory Board, the English version of ICIQ-VS was translated into Persian per a standard translate and back translate process, and the validity and reliability were studied. Two hundred women with and without pelvic organ prolapse were asked to complete the PICIQ-VS (mean age: 52.1, range: 22–84 years). A panel of 10 experts evaluated the content and face validity of the questionnaire. Cronbach's alpha examined the internal consistency reliability of the measure. To evaluate the test–retest reliability, we redistributed the questionnaire among 30 patients 2 weeks after their initial visit using intra-class correlation coefficient (ICC). **Results:** Content and face validity of the questionnaire was confirmed after some light modification (content validity ratio ranged from 0.69 to 1.00, and content validity index ranged from 0.79 to 1.00). PICIQ-VS showed an acceptable internal consistency and stability reliability (VS: $\alpha = 0.64$, ICC = 0.84; SM: $\alpha = 0.69$, ICC = 0.88; and total scale: $\alpha = 0.72$, ICC = 0.91, respectively). Significant differences were observed between the asymptomatic and symptomatic groups for VS and the total score ($P < 0.05$). **Conclusion:** In the light of the results, interestingly, PICIQ-VS could be utilized as a valid and reliable tool to assess the VS among Persian-speaking women, both in research and clinical practice.

Key words: Pelvic organ prolapse, quality of life, sexual symptoms, translation, vaginal symptoms, validation

How to cite this article: Pourmomeny AA,Foolad F, Sedighmehr N, Zargham M, Sharifiaghdas F. Translation and linguistic validation of the Persian version of the International consultation on incontinence questionnaire vaginal symptoms. J Res Med Sci 2021;26:58.

INTRODUCTION

Pelvic organ prolapse (POP) is characterized by the descent of one or more pelvic structures (bladder, uterus, and vagina) from the normal anatomic location to or through the vaginal opening.[1] The POP is more common in old women.[2] Population studies estimated that 32%–98% of middle-aged and old women have some degree of prolapse,[3,4] showing high prevalence and burden of problem indicating the necessity of taking into account this issue.

POP is frequently associated with vaginal and sexual symptoms, which results in vagina appearance dissatisfaction, and reduced sexual activities.[5] Surgical or behavioral intervention depends on the degree of vaginal symptoms' (VS) bothersome, however, it is complicated, and time-consuming for a patient and her physician to get a clear history of genital and VS, besides

Access this article online

Quick Response Code:

Website: www.jmsjournal.net

DOI: 10.4103/jrms.JRMS_694_20

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Submitted: 09-Aug-2020; **Revised:** 03-Oct-2020; **Accepted:** 16-Mar-2021; **Published:** 30-Aug-2021

patients may be ashamed or be uncomfortable to share their sexual problems. Therefore, a customized questionnaire is essential for both patients and health-care professionals that can evaluate complaints of patients and reveal the severity of complaints. Few studies have examined the impact of POP on quality of life (QoL) with a generic QoL tool.[6]

In 2006, the International Continence Society (ICS) developed and validated a questionnaire called International Consultation on Incontinence Questionnaire VS (ICIQ-VS) as a module of the ICIQ project.[6] ICIQ-VS has been translated and used in different languages.[7-12] The ICIQ-VS is a self-administered report consisting of 14 items. It covers VS score, sexual matter (SS) score, and QoL score, which can be used in both clinical and research settings. ICIQ-VS demonstrated good psychometric properties in various languages and showed an acceptable level of linguistic properties, internal consistency and stability reliability, and content and construct validity.[7-12]

Access to a standard tool to explain the symptoms and their significance is essential for determining the progression of the condition and the impact of therapeutic intervention. There are other measures that were validated for assessing VS, sexual dysfunction, and QoL,[13-16] however, ICI recommended the use of the ICIQ-VS, particularly for evaluating patients with POP. Since the Persian version has not been translated and validated among Iranian population, therefore, this study aimed at translating and assessing the validity and reliability of the Persian version of the International Consultation on Incontinence Questionnaire for VS (PICIQ-VS).

MATERIALS AND METHODS

International Consultation on Incontinence Questionnaire-Vaginal Symptoms translation process

After authorization approval from the ICIQ (www.iciq.net), the translation and the validation of the questionnaire were prepared according to the guidelines provided [Figure 1]. A bilingual native speaker translated the ICIQ-VS into Persian, then two urogynecologists reviewed the Persian version, and another bilingual native speaker translated it back into English. The ICIQ-VS development research team evaluated the English version, and the final version of the questionnaire was prepared after considering recommendations and some alterations.

The PICIQ-VS is a self-administered report consisting of 14 items and divided into 3 separate scores: VS score, sexual symptom (SS) score, and QoL score, which can be used in both clinical and research settings. Some items have two sections, a and b, for symptom and bother severity, respectively.

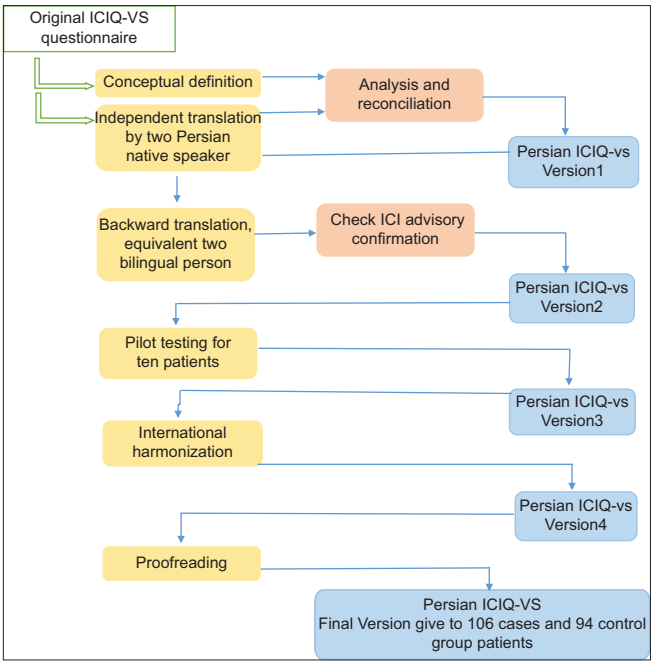

Figure 1: Translation and validation process of ICIQVS

Persian version of the International Consultation on Incontinence Questionnaire-Vaginal Symptoms scoring

To assess the VS score, the answers provided for the part "a" of the first eight questions are taking into account, which results in the scores ranging over 0–53. For estimating the sexual matter score, the answers provided for the part "a" of questions 11, 12, and 13 were taken into account. This results in the scores ranging over 0–53. The ninth question is about the complaint of postoperative vaginal stenosis. To calculate the QoL score, the answer given to question 14 is taking into account, which leads to the score ranging over 0–10 [Table 1]. Higher severity of complaints would lead to higher scores in the VS, sexual matter, and QoL.

Participants

This cross-sectional study was conducted during May 2018 and December 2018. A total of 210 women were referred to the urology clinic of Isfahan University of Medical Sciences; all of them were entered in this study using census method of data collection. The participants were Iranian Persian-speaking women aged between 18 and 80 years. Ninety-four women with vaginal prolapse (more than Grade 1 according to POP-Q) were categorized as "symptomatic group," and 106 women without POP were categorized as "asymptomatic group."

Clinical examination

A female urologist confirmed the clinical examination of each patient. The type and severity of POP were determined in the pelvic examination, according to the International Urogynecological Association (IUGA-ICS) terminology and POP-Q classification.[14] The POP stages described to four

Table 1: Sociodemographic characteristics of the studied groups

Variables	Case group	Control group
Level of literacy [*n*(%)]		
Illiterate	6 (6.4)	15 (14.2)
Primary education	59 (62.8)	35 (33)
High school	20 (21.3)	35 (33)
University degree	9 (9.6)	21 (19.8)
Job [*n* (%)]		
Housewife	86 (91.5)	85 (80.2)
Employed/retired	8 (85)	21 (19.8)
Menopause [*n*(%)]		
Yes	68 (72.3)	49 (46.2)
No	26 (27.7)	57 (53.8)
Sexual activity [*n*(%)]		
Yes	10 (10.6)	59 (55.7)
No	84 (89.4)	47 (44.3)

stages (0–IV) as follow: Stage 0 (no prolapse), Stage I (more than 1 cm above the level of the hymen), Stage II (1 cm or less proximal to or distal to the plane of the hymen, Stage III (more than 1 cm below the plane of the hymen), and Stage IV (complete eversion of the total length of the lower genital tract).[9] Based on the POP-Q examination values, Stages 0–IV were assigned to each vaginal compartment (anterior, posterior, uterus-cervix, or the apex of the vagina) and describe the position of the most distal point of protruded organ.

Content/face validity

Both qualitative and quantitative methods were used in the process of content validity of PICIQ-VS. In the qualitative method, the experts were requested to put their comment on the questionnaire. After assessing in terms of grammar, use of correct words, location of items, and a scoring, alterations were made based on their feedback. The content validity ratio (CVR)[17] and content validity index (CVI)[18] were used for the quantitative evaluation. A form involving questions in two general sections was managed for each expert. In the first section, to assess the CVR, the questions were asked about the necessity of each item based on a three-point scale ("unnecessary," "useful but not necessary," and "necessary"). They were considering the number of experts, and according to the Lawshe's table, the item considered as necessary if a CVR ≥0.62 was obtained. In the next section, to assess the CVI, the questions were asked about the relevancy, clarity, and simplicity of each item based on a four-point Likert scale. A CVI score >0.75 was considered reasonable.[19] An open question also was asked to extract the opinions of the experts on each item. Besides, the levels of difficulty, irrelevancy, and ambiguity of each item were assessed qualitatively for face validity. Then, proper alterations were made.

Besides, a researcher supervised the 30 subjects while filling out the questionnaire. In cases where the subjects were confused, she interviewed them and recorded all the ambiguous items and explanation phrases in a standard form. Considering the integrated feedback, the questionnaire was re-assessed by the panel to resolve any ambiguity and confusion in the translated version items.

Internal consistency and stability reliability

Internal consistency of PICIQ-VS was assessed by calculating Cronbach's alpha coefficient.[20] Alpha coefficients higher than 0.70 were considered satisfactory. Test–retest reliability was evaluated by completing the questionnaire twice by 30 randomly selected women within a 2-week interval when they returned for receiving their treatment plan. The intraclass correlation coefficient (ICC) of PICIQ-VS was running to evaluate the stability over time. ICCs ≤0.4 were considered poor to fair, 0.41–0.60 moderate, 0.61–0.80 good, and >0.80 excellent.[7,21,22]

Ethical considerations

The signed written informed consent forms were obtained from all participants. Literate patients read and filled the questionnaire independently, and illiterate patients were assisted by their relatives to fill the questionnaire. The Institutional Review Board of Isfahan University of Medical Sciences approved the protocol of this study (ethics code: IR.MUI.REC.1395.3.796).

Statistical analysis

Data were presented using mean (standard deviation [SD]) and median (minimum–maximum) for the numeric normal and nonnormal variables, respectively, and frequency (percent) for categorical variables. Normality of the numeric variables was checked by Kolmogorov–Smirnov test and skewness (within ± 1.5) and kurtosis (within ± 2) measures of distribution. The between-group comparisons of baseline measures and demographic variables were done by independent *t*-test, Mann–Whitney *U*-test, and/or Chi-square test where appropriate. Spearman correlation test was conducted to assess the correlation between POP grade and the scales. In all analyses, $P<0.05$ was considered significant. The data were analyzed using the SPSS version 16.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

A total of 200 women – 94 women with POP (symptomatic) and 106 without POP (asymptomatic) – participated in this study. The mean age in the symptomatic group (56.4 [SD: 11.5] years) was higher than that of the asymptomatic group (48.6 [SD: 13.9] years) ($P < 0.001$). Significant differences in clinical and demographic variables such as education level, menopause, sexual activity, delivery type, age, postdelivery time, and delivery number were found between the two groups (all $P < 0.05$) [Table 2].

Content/face validity assessment

The minimum of CVR was estimated to be 0.69 (all

Table 2: Correlations between each question and total score and Cronbach alpha value of each question if item deleted

Questions	Corrected Item-Total Correlation (*r*)	Cronbach's Alpha if Item Deleted
Abdominal pain (q1a)	0.424	0.694
Vaginal pain (q2a)	0.557	0.686
Vaginal sensation (q3a)	0.108	0.719
Vaginal loosening (q4a)	0.168	0.716
Vaginal pop (q5a)	0.375	0.696
Visible pop (q6a)	0.391	0.693
Vaginal dryness (q7a)	-0.074	0.749
Digitations defecation (q8a)	0.273	0.707
Vaginal tightness (q9a)	0.127	0.719
Worry and sex (q11a)	0.489	0.692
Nonsexual relation (q12a)	0.655	0.680
Bothersome (q13a)	0.618	0.653
Quality of life (q14a)	0.638	0.648

items >0.62), and a minimum of CVI was obtained to be 0.79 (all items >0.75). Although none of the items in the PICIQ-VS was vague when qualitative face validity was determined, 25 records were left blank (2.4%) as missing data for VS, SM, and QoL sections of the questionnaire.

Internal consistency and stability reliability

The internal consistency of the questionnaire, as assessed by Cronbach's alpha coefficient, was 0.64 and 0.69 for VS and SS scores and 0.72 for the total scale, respectively. In addition, the ICC of the VS score and SS score and total score was 0.84 (95% confidence interval [CI]: 0.79–0.89), 0.88 (95% CI: 0.81–0.95), and 0.91 (95% CI: 0.87–0.95), respectively.

DISCUSSION

Standard questionnaires are physicians' common approach for an explanation of patients' sufferings. Remarkably, this study showed that PICIQ-VS is a reliable and valid questionnaire for evaluating VS, sexual matters, and QoL of patients. PICIQ-VS had a low rate of missing data, an acceptable level of internal consistency/stability reliability, reasonable construct validity in VS and total score, and acceptable level of correlation with the POP-Q classification in patients with POP. This is in line with the results of other studies.[7-13,23] Besides, the PICIQ-VS matches the assessment of VS with QoL scoring measurements. Therefore, it is a useful self-administrated questionnaire for women presented with vaginal and genital symptoms and POP, which could be used for researchers and clinicians.

The face validity of PICIQ-VS seems acceptable so that the items were clear enough to be understood by average Persian-speaking participants. The PICIQ-VS showed an adequate level of content/face validity and low level of missing data. Despite cultural differences between European and Asian Muslim countries regarding expressing concerns about genital tract, this descriptive questionnaire provides proper and correct questions.[8,9,19] The face validity and content validity of the translated questionnaire were 9% and CV1 >80%, respectively, which indicate its validity among Persian.

The results of this study indicate that there was a correlation between the stage of POP and VS and a total score indicating that PICIQ-VS showed some degrees of discriminant validity. Even in women with severe prolapse, surgical intervention depends on the prolapse's burden for the patient. On the other hand, the management of women with POP even in high stage depends on symptom severity and its influence on patient's QoL. Therefore, accurate determination of the severity of symptoms and its correlation with prolapse severity is crucial.[4,7,9]

The reliability of PICIQ-VS was acceptable; with a slight difference, the Danish, Turkish, Portuguese, and Asian language version of ICIQ-VS has an excellent test–retest reliability (ICC: 0.61–88).[7-10] One explanation would be, for example, the majority of Danish patients were candidates for surgical operation and had severe symptoms. In contrast, many of our patients and all of them in the asymptomatic group did not have vaginal pathology or were not candidates for surgical intervention. Furthermore, for patients older than 60 years, the receptionist or patient's caregiver must read the questionnaire for the patients because of the patient's low degrees of education, lack of concentration, visual impairment due to aging, and an embarrassment for explaining symptoms. During the interval, patients did not receive any treatment or change their lifestyle. Although a long interval between test and retest is recommended, all of our patients had to visit after 2 weeks and receive their treatment plan as a routine program of our clinic. Our result was consistent with the German version of ICIQ-VS; internal consistency of the questionnaire was moderate, and the correlation coefficient was more than 0.71 in the test–retest assessment, which is acceptable, and the correlation coefficient was more than 0.71 in the test–retest group, which is acceptable.[12] Sri Lanka is another in Asia that translated and validated this questionnaire. Ekanayake *et al*. validated the questionnaire in two different regions in the country to eliminate the bias resulted from different dialects used for communication. However, we conducted our study in a metropolitan city with a considerable number of migrants from other cities with different dialects. The internal consistency of that study was 0.78.[8] One limitation of both studies (Sri Lanka and Persian version) are that the validation was not conducted in a general manner but the hospital and/or urology base. Using an uro- and urogynecological clinical-based community would likely have included women who were urinary symptoms that may influence vaginal sensation.

However, economic and cultural constraints a limitation to include a community sample for vaginal examination or genital history.

A significant difference was observed between the medians of the VS score and total score between the symptomatic and asymptomatic groups. In the Turkish version for Grade ≤1 and ≥2 POP, a significant difference was found between the medians of the VS score, sexual matter score, and QoL score.[9] Furthermore, in the Portuguese validation study, patients with Grade 0 and ≥3 POP were able to be discriminated using VS scores and QoL scores.[10] In the Danish, Sinhala, and Tamil validation studies, a significant correlation was observed between POP-Q grades and all three parameters.[7,8]

One of the limitations of this study was the missing or incomplete data of patients with prolapse in the SM section. As another limitation, there were differences in sexual activity between both groups. Furthermore, many patients in the symptomatic group have limitations in their sexual activity; therefore, they did not respond to the SM question. More than 60% of these women were sexually inactive because of their husband's death or impotence. Another factor resulting in sexual inactivity was prolapse which leads to painful intercourse and low self-esteem because of the wide and ugly vagina, which is more prevalent in aged and menopause women. Removing this bias is very difficult. Besides, even though the symptomatic and asymptomatic groups did not have a significant age difference, in general, cases were older than controls, which will have less libido and consequently less sexual activity.

Another limitation of this study was lack of another questionnaire in Persian, which could be used for comparison with Persian ICIQ-VS. We could make a comparison for other ICIQs such as ICIQ-QOL or ICIQ-FS. The scoring system of PICIQ-VS was adjusted from the original format, and therefore, symptoms of patients could be measured and followed up. Other symptoms in prolapsed women are "voiding dysfunction" and "urinary incontinence," and ICS has developed other questionnaires including lower urinary tract symptom. Both female lower urinary tract questionnaire short and long forms had been translated and validated in Persian and can be used for estimation of other related symptoms.[22-24]

CONCLUSION

The PICIQ-SV is a reliable and valid tool for assessing VS associated with sexual matter, and its impact on QoL in our population. Due to the importance of early diagnosis and predicting sexual disturbances in those with urinary tract abnormalities and defects, determining the severity of POP disturbances can effectively help us to prevent the decline of sexual activities in those who suffer from urinary tract problems.

Acknowledgments

The authors are grateful to Urology and Nephrology Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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