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Original Research

Validation of the Vietnamese Versions of the Pelvic Floor Distress Inventory-20 and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12

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Abstract

Background: Pelvic floor disorders substantially impair women's quality of life and sexual well-being. The Pelvic Floor Distress Inventory-20 (PFDI-20) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 (PISQ-12) are widely used patient-reported outcome measures (PROMs); however, formally validated Vietnamese versions are lacking in the literature. This study aimed to translate, culturally adapt, and validate the Vietnamese versions of the PFDI-20 and PISQ-12 in women with pelvic organ prolapse. **Methods:** This prospective longitudinal validation study included 118 Vietnamese women with Pelvic Organ Prolapse Quantification (POP-Q) stages II–IV who were scheduled for laparoscopic sacrohysteropexy or laparoscopic pectopexy between September 2023 and September 2025. Translation and cultural adaptation were performed in accordance with international recommendations. Content validity was assessed using item-level and scale-level content validity indices. Internal consistency was evaluated using Cronbach's alpha. Test–retest reliability was examined in 30 participants using intraclass correlation coefficients (ICCs). Construct validity was assessed using exploratory factor analysis (EFA) and hypothesis-testing construct validity based on correlations with POP-Q stage. Responsiveness to postoperative change was assessed by comparing preoperative and postoperative scores using the Wilcoxon signed-rank test and effect sizes. **Results:** The Vietnamese PFDI-20 and PISQ-12 showed good content validity, with item-level content validity indices ranging from 0.83 to 1.00. The scale-level Content Validity Index based on the average method (S-CVI/Ave) was 0.99 for both instruments, whereas the overall scale-level Content Validity Index based on universal agreement (S-CVI/UA) was 0.85 for the PFDI-20 and 0.92 for the PISQ-12. Cronbach's alpha was 0.834 for the PFDI-20 and 0.612 for the PISQ-12. The partner-related PISQ-12 subscale demonstrated low internal consistency ($\alpha = 0.278$), whereas the Urinary Distress Inventory-6 (UDI-6) subscale of the PFDI-20 had an $\alpha = 0.668$. Test–retest reliability was high for both instruments, with ICCs of 0.996 for the PFDI-20 and 0.975 for the PISQ-12. EFA yielded three-factor solutions for both questionnaires, although several items showed deviations from the prespecified domain structure or cross-loadings. The three factors explained 42.54% and 51.27% of the total variance, respectively. The total PFDI-20 score was not significantly associated with POP-Q stage (Spearman's $\rho = 0.09$, $p = 0.36$), whereas Colorectal–Anal Distress Inventory (CRADI-8) showed a weak positive association ($\rho = 0.20$, $p = 0.031$). The PISQ-12 score was not significantly associated with POP-Q stage (Spearman's $\rho = 0.02$, $p = 0.843$). Postoperative analyses demonstrated substantial treatment-related reductions in PFDI-20 scores, whereas PISQ-12 scores showed a moderate magnitude of change at 6 months. **Conclusions:** The Vietnamese PFDI-20 and PISQ-12 demonstrated good content validity and test–retest reliability, with limitations in internal consistency and structural validity. The partner-related PISQ-12 subscale should not be scored independently. Postoperative changes indicated sensitivity to treatment-related change, although anchor-based responsiveness could not be established. These findings primarily support the use of the PFDI-20 and PISQ-12 in Vietnamese-speaking women with stage II–IV pelvic organ prolapse undergoing reconstructive surgery.

Keywords: pelvic floor disorders; pelvic organ prolapse; PFDI-20; PISQ-12; Vietnamese validation

1. Introduction

Pelvic floor disorders encompass pelvic organ prolapse, urinary and bowel symptoms, sexual dysfunction, and pelvic pain, all of which can substantially impair quality of life. Because anatomical findings do not always correlate closely with patient-experienced symptoms, patient-reported outcome measures (PROMs) are important for quantifying symptom burden and treatment-related changes [1,2,3].

The Pelvic Floor Distress Inventory-20 (PFDI-20) is a 20-item short-form instrument that assesses distress related to prolapse, colorectal-anal symptoms, and urinary symptoms using the Pelvic Organ Prolapse Distress Inventory-6 (POPDI-6), Colorectal-Anal Distress Inventory-8 (CRADI-8), and Urinary Distress Inventory-6 (UDI-6) subscales [4]. The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 (PISQ-12) is a condition-specific, 12-item instrument for sexual function in sexually active

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women with pelvic organ prolapse and/or urinary incontinence [5]. Both instruments have undergone translation and psychometric evaluation across multiple languages and clinical settings [6,7,8,9,10,11,12,13,14,15,16].

Cross-cultural validation is necessary because linguistic meaning, symptom interpretation, concepts related to sexual health, and response patterns may differ across populations. International recommendations emphasize structured translation, cultural adaptation, content evaluation, reliability testing, and evaluation of validity and change over time when adapting PROMs [3,17,18,19,20,21].

A recent validation study of the Luganda versions of the PFDI-20 and PFIQ-7 demonstrated population-specific differences in the psychometric performance of translated pelvic floor instruments [7]. This finding supports the need for empirical evaluation of each translated instrument rather than assuming that the psychometric properties of the source-language version will transfer unchanged across populations.

In Vietnam, standardized, validated instruments for assessing pelvic floor symptoms and sexual function remain limited. A Vietnamese version of the Female Sexual Function Index (FSFI) has been validated [22], and Vietnamese translations of pelvic floor questionnaires have been used in clinical studies [23]; however, formal psychometric validation of the Vietnamese versions of the PFDI-20 and PISQ-12 has not been established.

Accordingly, this study aimed to translate and culturally adapt the PFDI-20 and PISQ-12 into Vietnamese and evaluate their content validity, internal consistency, test-retest reliability, structural validity, hypothesis-testing construct validity, measurement error, and change over time in women with stage II–IV pelvic organ prolapse undergoing laparoscopic reconstructive surgery.

2. Materials and Methods

2.1 Study Design and Participants

This prospective longitudinal validation study was conducted at the Department of Obstetrics and Gynecology of Hue Central Hospital, between September 2023 and September 2025. Patients were eligible for inclusion if they had Pelvic Organ Prolapse Quantification (POP-Q) stage II–IV and were scheduled to undergo laparoscopic sacrohysteropexy or laparoscopic pectopexy. The exclusion criteria were age <18 years, inability to understand Vietnamese and/or complete a patient-reported outcome questionnaire, and visual impairment.

The sample size was determined based on COSMIN-oriented recommendations for factor analysis. An adequate sample size was defined as at least five times the number of items and at least 100 participants, or at least six times the number of items when the sample size was below 100 [18,24]. A total of 124 women were assessed for eligibility, of whom 6 were excluded or declined participation, leaving 118 Vietnamese women who provided informed consent and were enrolled in the study. For pilot testing, a convenience sample of 10 Vietnamese women with pelvic organ prolapse who presented to the Department of Obstetrics and Gynecology was recruited. These participants were recruited independently of the main validation cohort and were not included in the subsequent validation study of 118 participants. For test-retest reliability, 30 participants completed a repeat assessment, consistent with the prespecified sample size for the reliability sub-study [25]. Participants completed the baseline questionnaires prior to surgery. A subgroup of 30 participants completed a repeat assessment after a 2-week interval before surgery. Postoperative assessments were planned at 1 and 6 months (Fig. 1).

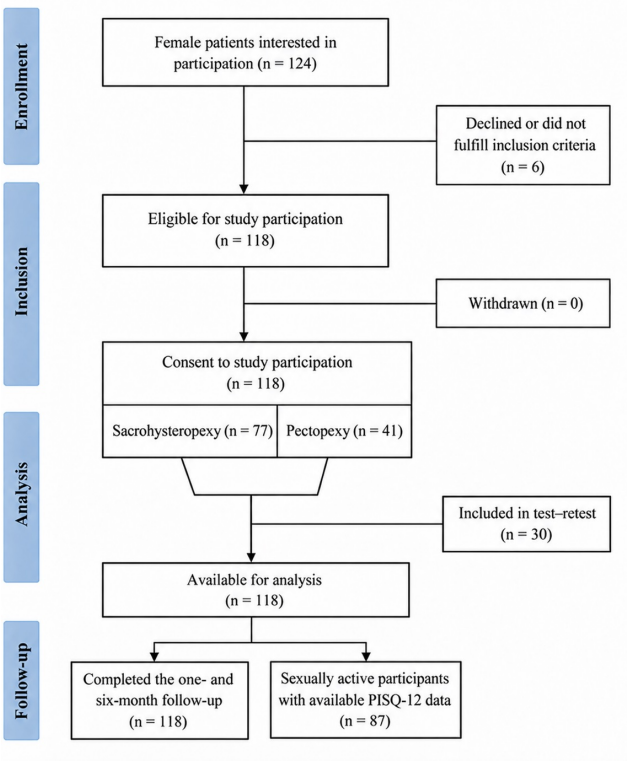


Fig. 1. Flowchart of patient recruitment and participation. PISQ-12, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12.

2.2 Translation and Cultural Adaptation

The translation and cultural adaptation of the PISQ-12 and PFDI-20 into Vietnamese were carried out in accordance with established guidelines for the translation and cross-cultural adaptation of PROMs, based on the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines [17,18].

Two independent bilingual translators performed forward translations from English to Vietnamese, one with expertise in urogynecology and one without a medical back-

ground, to ensure both clinical accuracy and natural language use. The research team reconciled the translations into a single version ("Vietnamese version 1"), which was then back-translated into English by two independent native English speakers who were fluent in Vietnamese and blinded to the original instruments. The research committee, comprising experts in obstetrics and gynecology, urogynecology, linguistics, and epidemiology, reviewed all versions to ensure semantic, conceptual, and cultural equivalence. The translation review committee and the content validity rating panel were independent, with no overlap in membership.

Subsequently, the revised Vietnamese version was evaluated by six specialists (three obstetrician-gynecologists, two urogynecologists, and one epidemiologist) using a 4-point Likert scale to assess semantic equivalence, clarity, cultural relevance, and clinical relevance. The same verbal anchors were used for all four attributes: 1 = not appropriate, 2 = partially appropriate, 3 = fairly appropriate, and 4 = highly appropriate. Item-level Content Validity Index (I-CVI), scale-level Content Validity Index based on the average method (S-CVI/Ave), and scale-level Content Validity Index based on universal agreement (S-CVI/UA) were calculated. Because the CVI framework was originally developed to assess item relevance, its application to translation attributes such as equivalence and clarity was treated as an adaptation.

Following expert review, the prefinal Vietnamese versions of the PISQ-12 and PFDI-20 were pilot-tested in 10 Vietnamese women with pelvic organ prolapse. These 10 pilot participants were independent of the 118 participants in the main validation study. Participants independently completed the prefinal questionnaires and rated the comprehensibility of each item using a 4-point scale (1 = very difficult to understand, 2 = difficult to understand, 3 = easy to understand, and 4 = very easy to understand). This self-rated item comprehensibility assessment was used to evaluate face validity. Participants also provided feedback on the response options and cultural acceptability. No cognitive interviewing or probing techniques were performed. Feedback from the pilot participants was reviewed by the research team to determine whether any further modifications to the instruments were necessary before the main validation study.

2.3 Measurement Instruments

The PFDI-20 includes three subscales: the POPDI-6, CRADI-8, and UDI-6. Each item is rated on a 5-point Likert scale (0–4), with higher scores indicating greater symptom distress. The total score ranges from 0 to 300 after conversion, with each subscale scored 0 to 100 [4].

The PISQ-12 measures three domains: behavioral-emotive (items 1–4), physical (items 5–9), and partner-related (items 10–12). It is a self-administered questionnaire, with responses rated on a 5-point Likert scale ranging from 0 (always) to 4 (never). Items 1–4 are reverse-scored, and the maximum score is 48 [5].

Sexual activity was defined as having sexual intercourse with a partner at the time of baseline assessment and was ascertained by direct questioning by the researcher before administration of the PISQ-12. PISQ-12 analyses were restricted to sexually active participants with available PISQ-12 data; non-sexually active participants were excluded from these analyses. Sexual activity status was unavailable for 2 participants, who were therefore excluded from the PISQ-12 analyses.

2.4 Measurement Properties

The questionnaire was validated according to the following measurement properties:

2.4.1 Assessment of Content Validity

Content validity was evaluated using the I-CVI, S-CVI/Ave, and S-CVI/UA [19,20,21]. Six experts independently rated each item on a 4-point scale, with ratings of 3 or 4 considered agreement. An I-CVI $\geq$0.78, S-CVI/Ave $\geq$0.90, and S-CVI/UA $\geq$0.80 were considered acceptable [20,21]. The chance-corrected modified kappa (k*) and probability of chance agreement (Pc) were calculated for each item according to Polit, Beck, and Owen [21].

2.4.2 Reliability Analysis

Internal consistency was assessed for each theoretically defined subscale and, secondarily, for the total composite scores using Cronbach's alpha. An alpha of $\geq$0.70 was prespecified as the conventional threshold for adequate group-level internal consistency. The total-score alpha for a multidimensional instrument was interpreted as a reliability estimate for the overall score rather than as evidence of unidimensionality [26,27].

Test-retest reliability was assessed in a convenience sample of 30 participants from the main validation cohort. Participants completed each questionnaire twice approximately 2 weeks apart before surgery [25]. Intraclass correlation coefficients (ICCs) were calculated using a two-way mixed-effects model with absolute agreement and average measures. ICC values <0.50, 0.50–0.75, 0.75–0.90, and >0.90 were interpreted as indicating poor, moderate, good, and excellent reliability, respectively. Standard error of measurement (SEM) was calculated as standard deviation (SD) $\times$ sqrt(1-ICC), and smallest detectable change (SDC) as 1.96 $\times$ sqrt(2) $\times$ SEM [28,29].

2.4.3 Construct Validity

Structural validity was explored using exploratory factor analysis (EFA) with principal axis factoring and promax rotation for both instruments. Sampling adequacy was evaluated using the Kaiser-Meyer-Olkin statistic and Bartlett's test of sphericity. Three factors were retained to examine correspondence with the theoretical domain structure. Fac-

tor loadings ≥0.30 were considered salient, whereas cross-loadings and items loading on unexpected factors were reported explicitly.

2.4.4 Assessment of Hypothesis-Testing Construct Validity

Associations between questionnaire scores and POP-Q stage were evaluated as hypothesis-testing construct validity rather than criterion validity because POP-Q is an anatomical staging system and not a gold-standard measure of symptom distress or sexual function. We hypothesized *a priori* that the associations would be weak (absolute Spearman rho approximately 0.10–0.30), as symptom severity and anatomical prolapse stage are known to be only partly concordant. Directionally, a higher POP-Q stage was expected to be associated with higher PFDI-20 distress scores and lower PISQ-12 scores. Spearman rank correlations were used because POP-Q stage is ordinal. Stage-stratified differences across POP-Q stages II–IV were additionally assessed using the Kruskal–Wallis test.

2.4.5 Assessment of Postoperative Changes Over Time

Postoperative changes were evaluated by comparing baseline scores with postoperative scores using paired tests selected according to score distributions. Wilcoxon signed-rank tests were used for the reported non-normally distributed data, and the effect size (r) was calculated as Z/sqrt(N). For the PFDI-20, baseline scores were compared with scores at 1 and 6 months after surgery. Changes in PISQ-12 scores were evaluated at 6 months; a 1-month sexual function assessment was not performed because resumption of sexual activity was not routinely expected at this early postoperative time point. *A priori*, a moderate or greater magnitude of postoperative change was considered meaningful, corresponding to an effect size r ≥0.30 [30].

In the absence of an external patient-global-change anchor, these analyses were interpreted as estimates of the magnitude of postoperative change rather than as definitive evidence of anchor-based responsiveness.

Effect sizes were interpreted descriptively to characterize the magnitude of change. Statistical significance alone was not considered proof of responsiveness. Because no patient global rating of improvement was collected, an anchor-based minimal important change (MIC) could not be estimated, and the relationship between the SDC and MIC remains unknown.

2.5 Statistical Analysis

All statistical analyses were performed using SPSS version 25 (IBM Corp., Armonk, NY, USA) and Microsoft Excel 2019 (Microsoft Corporation, Redmond, WA, USA). The normality of continuous variables was assessed using the Shapiro–Wilk test. For analyses of measurement properties, participants with missing data for a specific questionnaire or variable were excluded from the corresponding analysis, and analysis-specific denominators were reported where applicable. No imputation was performed. There were no withdrawals during follow-up; all 118 participants completed the scheduled 1- and 6-month PFDI-20 assessments. For the PISQ-12, 87 sexually active participants with available paired data completed the 6-month assessment. Statistical significance was set at $p < 0.05$.

3. Results

3.1 Baseline Characteristics

A total of 118 women were included in the study. The mean age was 62.5 ± 8.5 years (range, 37–83 years), and the mean body mass index (BMI) was 21.9 ± 2.2 kg/m^2. The median parity was 4 (interquartile range [IQR], 3–5). Most participants had primary or secondary education (62.7%). Regarding pelvic organ prolapse, most patients were classified as stage III (57.6%) or stage IV (36.4%). Laparoscopic sacrohysteropexy was performed in 65.3% of the cases, whereas laparoscopic pectopexy accounted for 34.7%. Among the 118 participants, 87 (73.7%) were sexually active, 29 (24.6%) were not sexually active, and sexual activity status was missing for 2 participants (1.7%). Comorbidities were present in 28% of the participants, with hypertension being the most common (18.6%), followed by diabetes mellitus (4.2%). Other comorbid conditions were infrequent (Table 1).

3.2 Content and Face Validity

3.2.1 Content Validity

Across the four expert-rated attributes, the PFDI-20 had S-CVI/Ave values of 0.99–1.00 and S-CVI/UA values of 0.95–1.00. The PISQ-12 had S-CVI/Ave values of 0.98–1.00 and S-CVI/UA values of 0.92–1.00. Item-level I-CVI values ranged from 0.83 to 1.00 (Table 2). The overall S-CVI/Ave was 0.99 for both the PFDI-20 and PISQ-12, while the overall S-CVI/UA was 0.85 and 0.92, respectively. These values met the prespecified index-specific thresholds. Chance-corrected modified k* values ranged from 0.816 to 1.00 across the four evaluated attributes, with item-level Pc and k values presented in **Supplementary Table 1**.

3.2.2 Face Validity

Face validity was assessed through self-rated item comprehensibility in 10 women who completed the prefinal questionnaires and provided feedback on item comprehensibility, response options, and cultural relevance. All 32 items were rated as easy or very easy to understand (scores 3–4) by all participants, with no ratings of 1 or 2 given. The mean comprehensibility score was 3.17 ± 0.38 across all items, with item-level means ranging from 3.0–3.4. No specific difficulties or concerns were identified, and no further modifications to the instruments were deemed necessary. The detailed item-level findings are presented in **Supplementary Table 2**.

Table 1. Baseline characteristics of participants included in the factor analysis of PFDI-20 (n = 118) and PISQ-12 (n = 87).

Characteristic	Value
Age, years (mean ± SD)	62.5 ± 8.5 (range 37–83)
BMI, kg/m^2 (mean ± SD)	21.9 ± 2.2
Parity (median, IQR)	4 (3–5)
Education level, n (%)	
Primary/secondary school	74 (62.7)
High school	38 (32.2)
College/university	6 (5.1)
POP-Q stage, n (%)	
Stage II	7 (5.9)
Stage III	68 (57.6)
Stage IV	43 (36.4)
Type of surgery, n (%)	
Laparoscopic sacrohysteropexy	77 (65.3)
Laparoscopic pectopexy	41 (34.7)
Sexual activity status, n (%)	
Sexually active	87 (73.7%)
Not sexually active	29 (24.6%)
Missing	2 (1.7%)
Comorbidities, n (%)	33 (28)
Hypertension	22 (18.6)
Diabetes mellitus	5 (4.2)
Atrial fibrillation with mitral regurgitation	1 (0.8)
Lower extremity varicose veins	1 (0.8)
History of thyroid tumor surgery	2 (1.7)
Chronic otitis media	1 (0.8)
History of cerebral infarction	1 (0.8)

PFDI-20, Pelvic Floor Distress Inventory-20; PISQ-12, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12; SD, standard deviation; IQR, interquartile range; POP-Q, Pelvic Organ Prolapse Quantification; BMI, body mass index.

3.3 Reliability

For the multidimensional PFDI-20, the subscale alpha coefficients were 0.744 for POPDI-6, 0.754 for CRADI-8, and 0.668 for UDI-6, while the total composite alpha was 0.834. Thus, two subscales met the prespecified ≥0.70 group-level threshold, whereas the UDI-6 was below this threshold. For the PISQ-12 (n = 87), the total alpha was 0.612, indicating questionable internal consistency. The behavioral-emotive, physical, and partner-related subscales showed good (alpha = 0.884), low (alpha = 0.608), and unacceptable (alpha = 0.278) internal consistency, respectively. Therefore, the partner-related subscale should not be used as an independent subscale score in this population without further evaluation.

Test-retest reliability was excellent for both total scores: ICC = 0.996 (95% confidence interval [CI]: 0.991–0.998) for the PFDI-20 and ICC = 0.975 (95% CI: 0.947–0.988) for the PISQ-12. In the 30-patient test–retest subsample, the baseline converted PFDI-20 total score had a mean ± SD of 83.200 ± 38.307, compared with 84.822 ± 43.864 in the full validation cohort (n = 118). Using the baseline SD of the converted PFDI-20 total score in the 30-patient test–retest subsample (SD = 38.307), the SEM and SDC were 2.423 and 6.715, respectively. For the PISQ-12, the SEM and SDC were 0.814 and 2.256, respectively (Table 3A). These baseline scores are presented in Table 3B.

3.4 Structural Validity

For the PFDI-20, principal axis factoring with promax rotation was conducted with three factors specified *a priori*. Sampling adequacy was acceptable (Kaiser–Meyer–Olkin (KMO) measure = 0.708; Bartlett chi-square = 1010, $p < 0.001$). Most items had factor loadings at or above 0.30, but Q4, Q19, and Q20 loaded on factors different from their theoretical subscales, while Q13 had a loading slightly below the 0.30 threshold (0.288). The three factors explained 42.54% of the total variance. These findings provide partial, rather than unequivocal, support for the original three-domain structure.

For PISQ-12, principal axis factoring with promax rotation was performed, with three factors specified *a priori*. Sampling adequacy was modest (KMO = 0.647), and Bartlett's test was significant (chi-square = 453, $p < 0.001$). The three factors explained 51.27% of the total variance (25.93%, 15.08%, and 10.25%). Several items grouped differently from the original domains, including Q12, indicating that the Vietnamese factor pattern was only partly concordant with the theoretical structure (Table 4).

3.5 Construct Validity

Correlations with the POP-Q stage were weak (Table 5A). The total PFDI-20 score was not significantly associated with POP-Q stage (Spearman's ρ = 0.09, $p = 0.36$). CRADI-8 showed a weak positive association (ρ = 0.20, $p = 0.031$), whereas POPDI-6 and UDI-6 showed very weak, nonsignificant associations. The total PISQ-12 score was not significantly associated with POP-Q stage (Spearman's ρ = 0.02, $p = 0.843$). In stage-stratified analyses, no significant differences were observed across POP-Q stages II–IV for the PFDI-20 total score or any of its domains (Kruskal–Wallis $p = 0.740$, 0.567, 0.803, and 0.564, respectively). Similarly, PISQ-12 scores did not differ significantly across the POP-Q stages (Kruskal–Wallis $p = 0.687$). Interdomain correlations among the PFDI-20 subscales are presented in Table 5B, and are reported descriptively, without interpretation as evidence of internal consistency or convergent validity.

3.6 Change Over Time After Surgery

The magnitude of postoperative change in the Vietnamese version of the PFDI-20 was evaluated in 118 patients who completed both preoperative and postoperative assessments at 1 and 6 months after surgery. Significant postoperative improvements were observed across all PFDI-20 domains and in the total PISQ-12 scale (Table 6).

Table 2. Content validity indices (I-CVI and S-CVI) for the Vietnamese PFDI-20 and PISQ-12.

Instrument/domain	Item range	I-CVI (n = 6 experts)	S-CVI/Ave	S-CVI/UA	Interpretation
PFDI-20					
Semantic	All items	-	0.99	0.95	Excellent
Clarity	All items	-	1.00	1.00	Excellent
Cultural	All items	-	0.99	0.95	Excellent
Clinical	All items	-	0.99	0.95	Excellent
POPDI-6 domain	Q1–Q6	0.83–1.00	-	-	Excellent
CRADI-8 domain	Q7–Q14	1.00	-	-	Excellent
UDI domain	Q15–Q20	1.00	-	-	Excellent
Overall scale	Q1–Q20		0.99	0.85	Acceptable
PISQ-12					
Semantic	All items	-	1.00	1.00	Excellent
Clarity	All items	-	1.00	1.00	Excellent
Cultural	All items	-	1.00	1.00	Excellent
Clinical	All items	-	0.99	0.92	Excellent
Behavioral–Emotive domain	Q1–Q4	0.83–1.00	-	-	Excellent
Physical domain	Q5–Q9	1.00	-	-	Excellent
Partner-related domain	Q10–Q12	1.00	-	-	Excellent
Overall scale	Q1–Q12		0.99	0.92	Excellent

I-CVI ≥0.78 was considered acceptable at the item level; S-CVI/Ave ≥0.90 and S-CVI/UA ≥0.90 were interpreted as excellent, whereas S-CVI/UA of 0.80–0.89 was interpreted as acceptable. I-CVI, item-level content validity index; S-CVI/Ave, scale-level content validity index based on the average method; S-CVI/UA, scale-level content validity index based on universal agreement; PFDI-20, Pelvic Floor Distress Inventory-20; PISQ-12, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12; POPDI-6, Pelvic Organ Prolapse Distress Inventory-6; CRADI-8, Colorectal-Anal Distress Inventory-8; UDI-6, Urinary Distress Inventory-6.

Table 3A. Internal consistency, test–retest reliability, and measurement error.

Measurement instrument	n	Cronbach's alpha	Interpretation	Test-retest (n = 30)	Measurement error		
				ICC (95% CI)	SD	SEM	SDC
PFDI-20	118	0.834	Composite reliability; multidimensional	0.996 (0.991–0.998)	38.307	2.423	6.715
POPDI-6		0.744	Acceptable				
CRADI-8		0.754	Acceptable				
UDI-6		0.668	Questionable				
PISQ-12	87	0.612	Questionable	0.975 (0.947–0.988)	5.148	0.814	2.256
BE-4		0.884	Good				
P-5		0.608	Questionable				
PR-3		0.278	Unacceptable; do not score independently				

Median (IQR) scores at 1 month decreased markedly for the POPDI-6 ($Z = –9.3$, $p < 0.001$), CRADI-8 ($Z = –6.3$, $p < 0.001$), and UDI-6 subscales ($Z = –9.1$, $p < 0.001$), as well as for the total PFDI-20 score ($Z = –9.4$, $p < 0.001$). Median (IQR) scores at 6 months decreased for the POPDI-6 ($Z = –9.4$, $p < 0.001$), CRADI-8 ($Z = –6.5$, $p < 0.001$), and UDI-6 subscales ($Z = –9.2$, $p < 0.001$), as well as for the total PFDI-20 score ($Z = –9.4$, $p < 0.001$).

Effect size analysis demonstrated large magnitudes of postoperative change across all domains. At 1 month, correlation effect sizes (r_1) were 0.86 for POPDI-6, 0.59 for CRADI-8, 0.84 for UDI-6, and 0.87 for the total PFDI-20 score. At 6 months, correlation effect sizes (r_2) were 0.86 for POPDI-6, 0.60 for CRADI-8, 0.85 for UDI-6, and 0.87 for the total PFDI-20 score. These findings indicate substantial treatment-related changes after pelvic floor reconstructive surgery.

At 6 months postoperatively, PISQ-12 scores showed a statistically significant improvement compared with the baseline ($Z = –3.4$, $p < 0.001$), with a moderate effect size ($r = 0.36$), indicating a moderate magnitude of postoperative change. PISQ-12 was not evaluated at 1 month as postoperative sexual activity was not routinely expected to have resumed.

Table 3B. Baseline converted PFDI-20 total score.

Population	n	Mean ± SD
Full validation cohort	118	84.822 ± 43.864
Test–retest subgroup	30	83.200 ± 38.307

n, number of participants included in the internal consistency analysis. PFDI-20 total scores were converted to a 0–300 scale. Cronbach's alpha was calculated in the full validation cohort (n = 118), whereas ICC and measurement-error indices (SD, SEM, and SDC) were calculated in the 30-participant test–retest subgroup. The baseline mean ± SD of the converted PFDI-20 total score was 84.822 ± 43.864 in the full validation cohort and 83.20 ± 38.307 in the test–retest subgroup. The SD of the converted PFDI-20 total score in the test–retest subgroup was used to calculate SEM and SDC. For the PISQ-12, the 30 participants included in the test–retest analysis were drawn from the 87 sexually active participants. ICC, intraclass correlation coefficient; SD, standard deviation; SEM, standard error of measurement; SDC, smallest detectable change; PFDI-20, Pelvic Floor Distress Inventory-20; PISQ-12, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12; UDI-6, Urinary Distress Inventory; BE-4, Behavioral-Emotive; P-5, Physical; PR-3, Partner-Related.

4. Discussion

In this study, we evaluated the psychometric properties of the Vietnamese versions of the PFDI-20 and PISQ-12 in women undergoing pelvic reconstructive surgery. Overall, our findings indicate that both instruments demonstrate supportive but not uniformly satisfactory psychometric properties, including acceptable validity, excellent test–retest reliability, limitations in internal consistency and structural validity, and substantial postoperative changes in this population. These findings support their use primarily for group-level research among similar surgical populations rather than broad application to all women with pelvic floor disorders.

The Vietnamese versions of the PFDI-20 and PISQ-12 demonstrated high content validity. I-CVI values ranged from 0.83 to 1.00. The overall S-CVI/Ave was 0.99 for both instruments, whereas the overall S-CVI/UA was 0.85 for the PFDI-20 and 0.92 for the PISQ-12. At the attribute level, S-CVI/UA values ranged from 0.95 to 1.00 for the PFDI-20 and from 0.92 to 1.00 for the PISQ-12. These findings indicate strong expert agreement regarding semantic equivalence, clarity, cultural relevance, and clinical relevance, while also showing that the overall S-CVI/UA was lower for the PFDI-20 than for the PISQ-12. The overall S-CVI/UA of 0.85 for the PFDI-20 indicates acceptable rather than excellent overall content validity, whereas the value of 0.92 for the PISQ-12 meets the prespecified criterion for excellent content validity.

These findings are comparable to those reported in previous validation studies. Mashayekh-Amiri et al. [12] reported a CVI of 0.94 for the PFDI-20 following translation and cultural adaptation, supporting excellent content validity. Additionally, previous studies of the Turkish PISQ-12 demonstrated a CVI of 1.00, supporting the content validity of the PISQ-12 in another cultural context [13].

Following the assessment of content validity, reliability was examined as an essential psychometric property. The Vietnamese version of the PISQ-12 showed questionable internal consistency, with a Cronbach's alpha of 0.61 for the total score. This finding is comparable to that of the Dutch validation, in which Cronbach's alpha values ranged from 0.57 to 0.69 [31], and to other validation studies reporting alpha values between 0.71 and 0.79 [14,15,31]. Similar to previous studies, the lower internal consistency in our study appeared to be driven primarily by the partner-related subscale, which demonstrated unacceptable internal consistency ($\alpha = 0.28$), a pattern consistently observed across different cultural adaptations of the PISQ-12 [31]. Therefore, the partner-related subscale should not be used independently for subscale scoring in this population. Despite this limitation, the test–retest reliability of the PISQ-12 was excellent, with an ICC of 0.98. This finding is consistent with prior validations reporting ICCs between 0.75 and 0.92, supporting the reproducibility of the instrument [11,31].

For the PFDI-20, the Cronbach's alpha coefficient for the full questionnaire was 0.83, while the coefficients for the extracted subscales ranged from 0.67 to 0.75, indicating generally acceptable internal consistency, although the UDI-6 showed questionable internal consistency ($\alpha = 0.67$). These findings were consistent with values reported for the Iranian [12], Brazilian [16], Norwegian [6], and Finnish [11] versions. Test–retest reliability of the PFDI-20 was excellent, with ICC values exceeding 0.90. These results were consistent with those reported for the Iranian version [12] and were greater than the values reported for the Swedish [8] and Finnish [11] versions. Overall, these findings support good reproducibility of both instruments, while the internal consistency results indicate limitations in specific domains, particularly the UDI-6 and the partner-related PISQ-12 subscale.

Construct validity was subsequently assessed to evaluate the underlying measurement structure of the instruments. The Vietnamese version of the PISQ-12 demonstrated a three-factor solution in EFA, with the items loading on these factors partially reflecting the behavioral–emotive, physical, and partner-related domains originally described for the PISQ-12 [5]. Items loading on Factor 1 predominantly concerned emotional and sexual desire and satisfaction, whereas Factor 2 encompassed partner- and prolapse-related concerns, and Factor 3 primarily captured pain and fear avoidance during sexual activity. Notably, the Viet-

Table 4. Results of EFA of the Vietnamese PFDI-20 and PISQ-12.

PFDI-20 item	F1	F2	F3	PISQ-12 item	F1	F2	F3
PFDI20_Q1		0.476		PISQ12_Q1	0.732		
PFDI20_Q2		0.725		PISQ12_Q2	0.907		
PFDI20_Q3		0.542		PISQ12_Q3	0.826		
PFDI20_Q4	0.612			PISQ12_Q4	0.820		
PFDI20_Q5		0.615		PISQ12_Q5		0.555	
PFDI20_Q6		0.446		PISQ12_Q6			0.662
PFDI20_Q7	0.786			PISQ12_Q7			0.734
PFDI20_Q8	0.811			PISQ12_Q8		0.698	
PFDI20_Q9	0.557			PISQ12_Q9		0.379	
PFDI20_Q10	0.392			PISQ12_Q10		0.628	
PFDI20_Q11	0.301		0.303	PISQ12_Q11		0.606	
PFDI20_Q12	0.517			PISQ12_Q12	0.561		
PFDI20_Q13							
PFDI20_Q14	0.480						
PFDI20_Q15		0.399	0.330				
PFDI20_Q16			0.753				
PFDI20_Q17			0.671				
PFDI20_Q18			0.671				
PFDI20_Q19		0.447					
PFDI20_Q20		0.516					
% variance explained	22.81%	11.38%	8.34%	% variance explained	25.93%	15.08%	10.25%
Total variance explained (%)		42.54%		Total variance explained (%)		51.27%	

Extraction method: Principal axis factoring; Rotation method: Promax with Kaiser normalization; Factor loadings ≥0.30 were considered significant and are reported; F1–F3 denote latent factors identified by EFA. EFA, exploratory factor analysis; PFDI-20, Pelvic Floor Distress Inventory-20; PISQ-12, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12.

Table 5A. Hypothesis-testing construct validity of the Vietnamese PFDI-20 and PISQ-12. Associations and stage-stratified comparisons according to POP-Q stage.

Variable	Spearman's ρ	*p*-value	Stage II, Median (IQR)	Stage III, Median (IQR)	Stage IV, Median (IQR)	Kruskal–Wallis *p*
PFDI-20 total	0.09	0.36	100.00 (35)	90.63 (72)	93.75 (79)	0.740
POPDI-6	0.05	0.63	50.00 (8)	45.83 (46)	45.83 (29)	0.567
CRADI-8	0.20	0.031	0.00 (9)	4.69 (16)	6.25 (13)	0.803
UDI-6	0.02	0.86	41.67 (13)	31.25 (28)	29.17 (33)	0.564
PISQ-12 total	0.02	0.843	32.50 (3)	34.00 (6)	33.00 (7)	0.687

Denominators: PFDI-20, n = 118 (Stage II n = 7; Stage III n = 68; Stage IV n = 43); PISQ-12, n = 87 (Stage II n = 6; Stage III n = 56; Stage IV n = 25).

Panel A: Spearman's rank correlation coefficients (ρ) and two-sided *p*-values are shown for associations with POP-Q stage. Stage-stratified differences were assessed using the Kruskal–Wallis test. Values are medians (IQR).

namese version differed from the original version with respect to item 12, "Compared with the orgasms you have had in the past, how intense are the orgasms you have had in the past 6 months?", which loaded on Factor 1 (behavioral–emotive and physical). This result is consistent with that of the Chinese version. The present findings suggest that orgasm intensity among Western women may be influenced primarily by sexual partners, whereas in Eastern populations, it may be more closely associated with emotional and behavioral factors [14].

For the PFDI-20, items Q4, Q19, and Q20 exhibited cross-loadings across domains in this study. Specifically, Q4 ("Do you ever have to push on the vagina or around the rectum to have or complete a bowel movement?") loaded more strongly on the colorectal domain rather than on the prolapse domain, whereas Q19 ("Do you usually experience difficulty emptying your bladder?") and Q20 ("Do you usually experience pain or discomfort in the lower abdomen or genital region?") loaded on the prolapse domain rather than the urinary domain. These findings are inconsistent with the factor structure of the original version developed by Barber et al. [4].

These findings may indicate potential cultural influences on symptom interpretation among Vietnamese

Table 5B. Interdomain correlations among the PFDI-20 subscales.

	POPDI-6	CRADI-8	UDI-6
POPDI-6	1.000	0.412*	0.661*
CRADI-8	0.412*	1.000	0.407*
UDI-6	0.661*	0.407*	1.000

Panel B: Spearman's rank correlation coefficients among PFDI-20 subscales. *p < 0.001 (two-sided; n = 118). UDI-6, Urinary Distress Inventory-6; IQR, interquartile range; PFDI-20, Pelvic Floor Distress Inventory-20; PISQ-12, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12; POP-Q, Pelvic Organ Prolapse Quantification; POPDI-6, Pelvic Organ Prolapse Distress Inventory-6; CRADI-8, Colorectal-Anal Distress Inventory-8.

women, with bowel symptoms more frequently perceived as rectal disorders and bladder symptoms or pelvic pain more often attributed to pelvic organ descent rather than urinary dysfunction. Although some cross-cultural validation studies, such as the Iranian version [12], have used confirmatory factor analysis (CFA) and confirmed the original three-domain model, none have reported notable item-level cross-loadings. Therefore, further studies with larger samples employing both exploratory and confirmatory factor analyses are warranted to verify the factor structure and explore potential cultural differences in symptom interpretation.

Overall, the exploratory factor analyses of both the PFDI-20 and PISQ-12 provided partial support for their theoretical three-factor structures, which were largely consistent with those of the original English versions. However, the observed item reassignment and cross-loadings indicate that structural validity was not fully established. Further research with larger samples should incorporate CFA to verify the stability of these models across diverse populations.

Regarding hypothesis-testing construct validity, PFDI-20 scores were not significantly associated with prolapse severity as assessed by the POP-Q system, reflecting the distinction between subjective symptom reporting and anatomical prolapse severity. However, the CRADI-8 subscale showed a weak but statistically significant association with POP-Q stage, whereas the PISQ-12 score was not significantly associated with POP-Q stage. In particular, the total PFDI-20 score showed no significant association with POP-Q stage (Spearman's ρ = 0.09, p = 0.36). These findings are consistent with those of previous studies [32,33], in which POP-Q staging has often been reported to correlate poorly with overall symptom severity. Unlike some studies that used symptom-based questionnaires as reference standards [9], the present study evaluated hypothesis-testing construct validity by examining associations with the POP-Q system to reflect the anatomical severity of pelvic organ prolapse.

In the present study, substantial postoperative changes in PFDI-20 scores were observed at both 1 and 6 months postoperatively, accompanied by moderate to large nonparametric effect sizes (r = 0.59–0.87). These findings provide evidence of sensitivity to postoperative change in this surgical population; however, they do not establish anchor-based clinically important change.

These results are consistent with those of the original validation and longitudinal study of postoperative change by Barber et al. [34], which reported moderate to large standardized response means for the PFDI-20 subscales at 3 and 12 months after intervention. Similarly, the Norwegian validation study reported high sensitivity to change of the PFDI-20 following treatment, supporting its ability to capture symptom changes in clinical settings [6]. The concordant direction of improvement across these studies supports the robustness of the PFDI-20 in detecting treatment-related symptom changes across different populations and cultural contexts.

Our findings showed a moderate magnitude of postoperative change in PISQ-12 scores at 6 months, with a statistically significant improvement in total scores with a moderate effect size (r = 0.36). Although the PISQ-12 has been widely used to assess sexual function before and after pelvic floor surgery, most published studies have focused on postoperative sexual outcomes rather than formal psychometric evaluation of change over time [35,36].

In addition, previous validation studies of translated versions of the PISQ-12 have primarily addressed reliability and construct validity, although the Dutch validation study explicitly evaluated change over time but could not demonstrate significant change due to the small number of patients available at the 6-month follow-up [31].

A prospective study of the Polish PISQ-12 evaluated reliability and changes in sexual function before and after pelvic organ prolapse reconstructive surgery, providing evidence of postoperative change [37]. Taken together, these findings provide preliminary evidence that the Vietnamese PISQ-12 is responsive to postoperative changes in sexual function following pelvic floor reconstructive surgery. Nevertheless, the absence of an external patient-global-change anchor precludes assessment of anchor-based responsiveness and determination of clinically important change.

Limitations

Several limitations warrant consideration. First, the study was conducted at a single center and included a surgical cohort composed predominantly of women with advanced pelvic organ prolapse (stage II–IV). This restricted clinical spectrum may limit the generalizability of the findings to women with milder prolapse or those managed with conservative treatment. Second, analyses of the PISQ-12

Table 6. Postoperative change in PFDI-20 and PISQ-12 scores.

Scale/subscale	Preoperative (median, IQR)	1 month (median, IQR)	6 months (median, IQR)	Z_1	p_1	r_1	Z_2	p_2	r_2
PFDI-20 total	93.23 (47.40–118.75)	7.00 (0.00–12.30)	4.00 (0.00–8.00)	–9.4	<0.001	0.87	–9.4	<0.001	0.87
POPDI-6	45.83 (25.00–62.50)	0.00 (0.00–4.00)	0.00 (0.00–4.00)	–9.3	<0.001	0.86	–9.4	<0.001	0.86
CRADI-8	3.00 (0.00–10.00)	0.00 (0.00–3.00)	0.00 (0.00–3.00)	–6.3	<0.001	0.59	–6.5	<0.001	0.60
UDI-6	29.00 (17.00–46.00)	2.00 (0.00–8.00)	0.00 (0.00–4.00)	–9.1	<0.001	0.84	–9.2	<0.001	0.85
PISQ-12 total	33.00 (31.00–37.00)	NA	35.00 (33.30–37.80)	NA	NA	NA	–3.4	<0.001	0.36

Values are presented as median (IQR). Wilcoxon signed-rank tests were used for paired comparisons. Z_1 and Z_2 denote the Wilcoxon signed-rank test statistics for comparisons between preoperative and 1-month scores and between preoperative and 6-month scores, respectively. r denotes effect size, calculated as $Z/\sqrt{N}$. PFDI-20 analyses included 118 paired participants at both 1 and 6 months; PISQ-12 analysis included 87 paired participants at 6 months. PISQ-12 was not assessed at 1 month because resumption of sexual activity was not routinely expected during the early postoperative period. *p* denotes the two-sided *p*-value. NA, not assessed; IQR, interquartile range; UDI-6, Urinary Distress Inventory-6; PFDI-20, Pelvic Floor Distress Inventory-20; PISQ-12, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12; POPDI-6, Pelvic Organ Prolapse Distress Inventory-6; CRADI-8, Colorectal-Anal Distress Inventory-8.

were limited to 87 sexually active participants with usable questionnaires, potentially introducing selection bias. Third, convergent validity was not assessed against an external validated comparator, such as the Vietnamese version of the Female Sexual Function Index (FSFI). Fourth, the study did not incorporate a patient global-change anchor, precluding the determination of a MIC. Fifth, the PISQ-12 showed questionable overall internal consistency, with unacceptable internal consistency in the partner-related subscale, while several PFDI-20 and PISQ-12 items exhibited suboptimal factor loadings or cross-loadings in the EFA. Finally, cognitive interviewing was not performed during the face-validity assessment, precluding systematic probing of participants' interpretations and limiting the identification of potential difficulties in understanding individual items. In addition, the use of a single relevance-type anchor across all four rated attributes may have limited the specificity with which each content-validity attribute was evaluated.

5. Conclusions

In women with predominantly advanced pelvic organ prolapse undergoing reconstructive surgery, the Vietnamese PFDI-20 demonstrated excellent test–retest reliability and generally favorable psychometric performance, although the UDI-6 internal consistency and several factor loadings were suboptimal. The Vietnamese PISQ-12 likewise showed excellent test–retest reliability but questionable overall internal consistency, with unacceptable internal consistency in the partner-related subscale, which should not be used as an independent subscale score. These versions support the use of the Vietnamese PFDI-20 and PISQ-12 primarily for group-level research in similar surgical populations. However, additional validation, external comparator testing, and anchor-based evaluation of clinically important change is required before these instruments can be used for individual-level clinical interpretation or generalization to all Vietnamese-speaking women with pelvic floor disorders.

Availability of Data and Materials

The datasets generated and analyzed in the current study are not publicly available because they contain sensitive clinical information and patient-reported outcome data. However, anonymized data may be made available from the corresponding author upon reasonable request and with permission from the Ethics Committee of Hue University of Medicine and Pharmacy.

Author Contributions

TNH and NTC designed the research study. TNH, QVT, and TXN performed the translation, cultural adaptation, and data collection. NTC and QVT provided clinical expertise and methodological advice during the validation process. TNH and TXN analyzed the data. TNH drafted the manuscript. NTC, QVT, and TXN critically revised the manuscript for important intellectual content. All authors contributed to the editorial revisions, read and approved the final manuscript, and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

This study was conducted in accordance with the Declaration of Helsinki. The research protocol was approved by the Ethics Committee of Hue University of Medicine and Pharmacy, Hue University, Vietnam (Ethics Approval No.: H2023/031; Approval Date: 30 March 2023). All participants were informed of the study objectives and procedures, and written informed consent was obtained from all participants prior to enrollment.

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Conflicts of Interest

The authors declare no conflicts of interest.

Declaration of AI and AI-Assisted Technologies in the Writing Process

During the preparation of this manuscript, the authors used ChatGPT (OpenAI; GPT-5.6 Luna) to support English language editing, grammar checking, and improvement of clarity. The authors reviewed and edited all AI-assisted outputs as needed and took full responsibility for the content, accuracy, and integrity of the final manuscript.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.31083/CEOG55280.

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