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ORIGINAL ARTICLE

The Portuguese validation of the International Consultation on Incontinence Questionnaire—Vaginal Symptoms (ICIQ-VS) for Brazilian women with pelvic organ prolapse

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Abstract The aim of this study is to validate the International Consultation on Incontinence Questionnaire—Vaginal Symptoms (ICIQ-VS) in Portuguese. Two hundred four women (108 symptomatic, 94 asymptomatic, and two with no data) with mean age of 55.4 years received a Portuguese version of the ICIQ-VS. Clinical data and pelvic organ prolapse quantification index (POP-Q) were obtained. Retest was performed 3 weeks later. Responsiveness was assessed after 20 weeks of postsurgical follow-up. Overall, most patients presented POP-Q > 2. ICIQ-VS demonstrated good psychometric properties (validity, reliability and responsiveness). The test–retest reliability was moderate to excellent for all questions. The construct validation distinguished differences in ICIQ-VS scores between symptomatic (ICIQ-VS5a > 0) and asymptomatic (ICIQ-VS5a = 0) women. ICIQ-VS was highly responsive to surgical treatment and discriminated between levels of change in the vaginal symptoms score, sexual matters score, quality-of-life score, and POP-Q. The Portuguese version of ICIQ-VS was successfully validated.

Keywords ICIQ-VS · Pelvic organ prolapse · Quality of life · Sexual symptoms · Vaginal symptoms · Validation

Introduction

Pelvic floor dysfunction (PFD) is a common condition affecting at least one third of adult women and is strongly associated with parity and spontaneous delivery [1]. Apart from this, PFD is also associated with other factors such as ageing, pregnancy, hormonal status, and forceps-assisted delivery, among others. The most prevalent symptoms relating to this condition are urinary and anal incontinence [2].

Self-completed questionnaires have been used to objectively standardize the subjective assessment of bother, severity, and impact on quality of life (QoL) of many pelvic floor symptoms such as urinary and fecal incontinence, and symptoms of pelvic organ prolapse (POP) as well. Some questionnaires for assessing the severity of POP and its impact on QoL do exist [3], but they have had

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limited use due to their large size. The Prolapse Quality of Life Questionnaire (P-QoL) [4] and the International Consultation on Incontinence Questionnaire—Vaginal Symptoms (ICIQ-VS) [5] have been recently developed and are ready to be used in their original English version.

Because there is a lack of fully validated POP questionnaires in Portuguese, our aim in this study was to translate into Portuguese, cross-culturally adapt, and validate the ICIQ-VS for assessing the severity of POP symptoms, sexual matters, and their impact on the quality of life among Brazilian women.

Materials and methods

Study population, data collection, and analysis

Women were enrolled in this cross-sectional observational study between January 2006 and September 2007. Patients were recruited at four pelvic floor and voiding dysfunction reference centers in the State of São Paulo. Patients were included in the study whether or not they were complaining of pelvic floor symptoms and regardless of whether POP was present in the gynecological examination. The exclusion criteria were that the women could not be younger than 18years, pregnant or puerperal, and could not present mental incapacity that would preclude completion of the questionnaires.

According to recommendations from statistical analysis, the sample size for this study needed to be at least 190 individuals.

At the first interview, sociodemographic and clinical data were collected, and the Portuguese version of ICIQ-VS was applied so that it could be tested. About 3weeks later, the patients returned to their referral centers to complete the ICIQ-VS for the retest. The patients were seen by a urogynecologist who performed a gynecological examination in the supine position using the Pelvic Organ Prolapse Quantification system (POP-Q), as approved by the International Continence Society (ICS). This is a reliable and specific method that measures in centimeters the support for various aspects of the vaginal canal [6]. To describe the signs and symptoms associated with lower urinary tract dysfunction, the International Continence Society definitions were used [7]. The women were asked to self-complete the questionnaire. If a particular woman could not read or write, a relative or accompanying person helped her to complete the questionnaire, when available. If not, support personnel (nurses) who were unfamiliar with the concepts of urogynecology and QoL provided nondirective assistance to such patients.

The following sociodemographic characteristics were analyzed: age, skin color (white, black/brown, yellow, and other), and education (illiterate, primary school completed, high school completed, and university-level completed). Women who had not had any schooling or could not read any sentence were considered illiterate.

The following clinical characteristics were analyzed: POP-Q stage, body mass index, parity, and type of delivery.

Questionnaire

The ICIQ-VS is a module from the ICIQ modular questionnaires (ICIQ Study Group) for assessing a range of pelvic floor dysfunction symptoms such as bowel and vaginal, along with sexual matters [8]. It is composed of 14 questions divided into three independent scores. The vaginal symptom score (VSS) has a possible minimum of 0 and maximum of 53. The sexual matter score (SMS) has a possible minimum of 0 and maximum of 58. The quality-of-life score (QoLS) has a possible minimum of 0 and maximum of 10. In general, vaginal symptom and sexual matter items use four- or five-point response frames, and the problem subquestions use an 11-point scale. The higher the scores are, the worse the severity of the symptoms is [5].

Translation and cultural adaptation

The standardized method for the validation procedure was rigorously followed in accordance with international criteria [9].

Three Portuguese versions of the ICIQ-VS were made by three independent native Portuguese speakers who were fluent in English and blinded to the aim of this study. After harmonization, this first Portuguese version was back-translated into English by another three independent native English speakers who were fluent in Portuguese. The back translation was reviewed by the ICIQ Research Group to ensure that the original content was retained. After a meeting with an expert panel that included professional translators, physicians, and health-related professionals, a common consensual Portuguese version of the questionnaire was produced. Next, this version was pretested on ten patients, and after revisions and new adjustments, the final Portuguese version was produced, ready for use in the present study. To help women with poor eyesight, the questionnaire was printed in large letters (minimum of 16 points).

Psychometric testing

The women were divided into two groups according to their urogenital prolapse symptoms. Their condition was characterized by means of question 5a (Are you aware of a lump or bulge coming down in your vagina?), as symptomatic (ICIQ-VS 5a > 0) or asymptomatic (ICIQ-VS 5a = 0).

Validity analysis

Content validity was assessed by measuring the levels of missing data and by performing cross-cultural adaptation into Portuguese.

Construct validity was assessed by comparing symptom scores between symptomatic and asymptomatic women (Mann–Whitney *U* test).

Criterion validity was assessed by comparing symptom scores with objective vaginal examination [POP-Q stage; analysis of variance (ANOVA) and Tukey tests] in the symptomatic group.

Reliability analysis

Internal consistency, referring to the degree of correlation between the items, was assessed by using Cronbach's alpha coefficient.

Stability over time was assessed by means of a 3-week test–retest analysis. During this period of time, no women included in the study were treated for their pelvic floor dysfunction symptoms. The reliability was measured using the intraclass correlation coefficient (ICC) coefficient and weighted Kappa index whenever necessary.

Sensitivity to change

The assessment of internal responsiveness involves statistical estimation of the size of the effect, i.e., an estimate of the magnitude of the change in health status. Standardized effect size (SES or ESI) and standardized response mean (SRM or ESII) provide a standardized measurement of changes in scores given by an instrument [10]. Score changes from before to after surgery presented by different groups were assessed using the Wilcoxon matched-pairs signed rank test and the symmetry test (question 10). VSS, SMS, and QoLS before and after surgery were compared with regard to POP stage using the Mann–Whitney *U* test and Kruskal–Wallis test when necessary.

The data analysis was performed using SAS (Statistical Analysis System), version 9.1.3, Service Pack 3 (SAS Institute Inc, 2002–2003, Cary, NC, USA). The level of significance was taken to be 5%.

The study was approved by and followed ethics committee guidelines, and all the women agreed to participate in the study by signing a written informed consent statement.

The full Portuguese version of ICIQ-VS is available from the authors and the ICIQ office (www.iciq.net) upon request.

Results

Two hundred and four women were enrolled in this cross-sectional observational multicenter study. There were 108 symptomatic women, 94 asymptomatic women, and two women with missing data. Overall, there were 175 white women (86%) and 21 who were illiterate (10.3%). For the symptomatic group, the mean age was 55.4years (range, 26 to 84), the mean BMI was 28.6kg/m^2 (range, 16.8 to 45.4), mean parity was 4 (range, 0 to 10), mean number of spontaneous vaginal deliveries was 2.6 (range, 0 to 10), and mean number of caesarean sections was 0.6 (range, 0 to 4). On the other hand, for the asymptomatic group, the mean age was 52.5years (range, 25 to 80), mean BMI was 28.2kg/m^2 (range, 20 to 40.3), mean parity was 3 (range, 0 to 14), mean number of spontaneous vaginal deliveries was 2.2 (range, 0 to 11) and mean number of caesarean sections was 0.7 (range, 0 to 5).

Significant differences in clinical variables such as parity (p = 0.0003; Mann–Whitney *U* test), forceps-assisted delivery (p = 0.0005; Mann–Whitney *U* test) and POP stage ($p < 0.0001$; chi-square test) were found between the symptomatic and asymptomatic women.

Psychometric testing

The frequency of missing items ranged from 0 to 5, and the majority of items were easily understood. There were no missing items regarding vaginal symptoms (n = 204) or sexual matters (n = 117, for sexually active women only).

Table 1 Construct validity: descriptive analysis and comparisons of ICIQ-VS scores between symptomatic and asymptomatic women (Mann–Whitney *U* test)

Instrument	Group	Score	Number of patients	Mean	SD	Median	Range	*p* Value
ICIQ-VS	Symptomatic women	VSS	108	28.3	10.3	29	0–53	<0.0001
		SMS[a]	63	31.6	20	31	0–58	0.0015
		QoL	106	7.9	2.9	9	0–10	<0.0001
	Asymptomatic women	VSS	94	9.7	7.1	10	0–28	
		SMS[a]	54	20	20.8	14.5	0–58	
		QoL	94	4.4	4.3	3	0–10	

[a] Sexually active women only

Question 10 had the highest frequency of missing items (five patients).

For cultural adaptation, minor changes had to be made to some questions, without altering the original meaning.

Some terms in English were translated in two ways in the same question. Firstly, the term was translated as the grammatically correct form in Portuguese, while maintaining the original meaning. Secondly, a synonym more frequently used by the general population was put in brackets afterwards, thus accomplishing cultural adaptation. As an example, we can cite the term "empty your bowels," which translates as "evacuar." However, in colloquial Brazilian Portuguese, this term is better represented by the expression "fazer cocô," which was placed in brackets afterwards, as shown in question 8a.

Validity

Construct validity The ICIQ-VS distinguished differences between symptomatic (ICIQ-VS5a > 0) and asymptomatic (ICIQ-VS5a = 0) patient groups, as assessed by VSS ($p < 0.0001$), SMS ($p = 0.0015$), and QoLS ($p < 0.0001$; Mann–Whitney *U* test; Table 1).

Criterion validity The severity of VSS and QoLS was strongly correlated with the POP-Q stage. The ANOVA and Tukey tests confirmed that the VSS and QoLS (which are designed to assess the effect of prolapse symptoms on quality of life) correlated with the objective vaginal examination findings. Conversely, SMS (for sexually active women only) did not show any difference in relation to POP grades ($p = 0.1538$; ANOVA and Tukey tests; Table 2).

Table 3 ICIQ-VS test–retest reliability (intraclass correlation coefficient with 95% confidence interval, CI)

Question	ICC	95% CI
ICIQ-VS1	0.66	0.56, 0.75
QV1	0.65	0.55, 0.74
ICIQ-VS2	0.69	0.59, 0.77
QV2	0.70	0.57, 0.76
ICIQ-VS3	0.69	0.59, 0.77
QV3	0.62	0.50, 0.71
ICIQ-VS4	0.71	0.61, 0.78
QV4	0.76	0.68, 0.82
ICIQ-VS5	0.87	0.82, 0.90
QV5	0.75	0.66, 0.81
ICIQ-VS6	0.85	0.80, 0.89
QV6	0.75	0.66, 0.81
ICIQ-VS7	0.73	0.64, 0.80
QV7	0.68	0.57, 0.76
ICIQ-VS8	0.76	0.69, 0.82
QV8	0.64	0.53, 0.73
ICIQ-VS9	0.59	0.47, 0.69
QV9	0.54	0.40, 0.65
ICIQ-VS11	0.72	0.60, 0.81
QV11	0.76	0.65, 0.84
ICIQ-VS12	0.71	0.58, 0.80
QV12	0.73	0.61, 0.82
ICIQ-VS13	0.74	0.62, 0.82
VSS	0.85	0.80, 0.89
SMS	0.78	0.70, 0.84
QoLS	0.70	0.60, 0.77

Reliability

Internal consistency Cronbach's alpha coefficient for items assessing the instrument used presented good values

Table 2 Criterion validity: descriptive analysis and comparisons of ICIQ-VS scores and POP stage (POP-Q) among symptomatic women (Mann–Whitney *U* test; ANOVA and Tukey test)

POP-Q stage	ICIQ-VS score	Number of patients	Mean	SD	Median	Range
0	VSS*	7	20.3	10.2	21	3–32
	SMS**	4	17.5	13	18.5	2–31
	QoLS***	7	4	3.4	4	0–8
1	VSS	13	23.6	7.4	23	12–35
	SMS	10	22.9	17.7	17	8–58
	QoLS	13	6.2	3.9	8	0–10
2	VSS	42	26.9	10.2	26	0–52
	SMS	27	30.9	21.9	24	0–58
	QoLS	42	8.2	2.6	10	0–10
3+4	VSS	46	32.1	9.7	33.5	12–53
	SMS	22	38.9	17.3	42	0–58
	QoLS	44	8.8	1.9	10	0–10

*p=0.0020 (ANOVA and Tukey tests) comparing all POP stages: differences between 0 and 3+4, and between 1 and 3+4
**p=0.1538 (ANOVA and Tukey tests) comparing all POP stages: 1, 2, and 3+4 (sexually active women only)
***p=0.0004 (ANOVA and Tukey tests) comparing all POP stages: differences between 0 and 2, and between 0 and 3+4

Table 4 Sensitivity to change in ICIQ-VS using effect size I or standardized effect size (SES) and effect size II or standardized response mean (SEM; n=44 patients)

ICIQ-VS score	Number of patients	Pre	Post	ESI or SES	Pre	Post	ESII or SRM
VSS	44	26.5	9.6	2.76	26.5	10.1	2.62
SMS	21	40.2	14.6	2.75	40.2	15	2.68
QoLS	44	7.3	2.3	3.17	7.3	3.5	2.09

of 0.79 (VSS) and 0.88 (SMS), thus showing inter-rater reliability.

Stability The test–retest reliability assessed by the ICC was moderate (0.59) for question 9 and also moderate in relation to the impact on QoL (0.54). For the remaining items, the ICC was substantial and ranged from 0.54 to 0.82 (Table 3). The test–retest reliability for question 10 showed excellent correlation and stability, as assessed by the weighted Kappa index = 0.85 (0.77; 0.93; 95% CI). The mean VSS for the first and second completions was 18.1 (range, 0–52) and 18.2 (0–51), respectively. The mean SMS was 25.6 (0–58) and 26.1 (0–58). The mean QoLS was 6.1 (0–1–0) and 6.2 (0–10). The mean time between the test and retest was 19days (range from 1 to 44; median = 19days).

Sensitivity to change

This was investigated in a sample of 44 women (median age, 59.7; range, 36–78years) out of 204 urogynecological clinic attendees undergoing surgical treatment for POP. The surgical intervention included vaginal hysterectomy (VH), anterior vaginal repair (AR), posterior vaginal repair (PR), posterior vaginal slingplasty using polypropylene mesh (PVS), and various combinations of these procedures: AR (3 cases), AR + PR (2), AR + PR + PVS (1), PR (3), and VH + AR + PR + PVS (35).

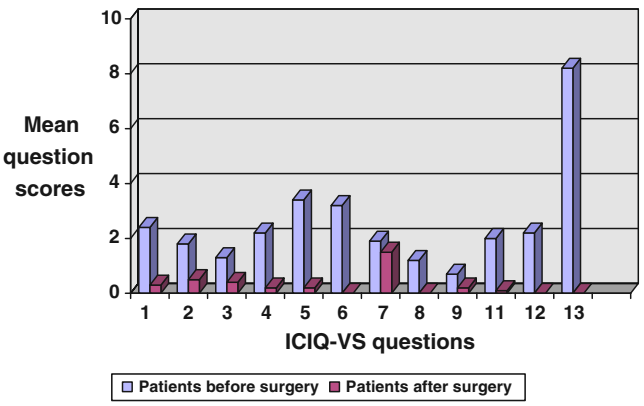

Fig 1 Sensitivity to change—internal responsiveness analysis on ICIQ-VS: comparison of the mean levels of question scores for symptomatic clinical group before and after surgery (n=44 patients) (Wilcoxon matched-pairs signed rank test)

The percent change in the presence of symptoms between baseline and the last follow-up (20weeks) was calculated.

The effect size I or SES for VSS, SMS, and QoLS was 2.76, 2.75, and 3.17, respectively. The effect size II or standardized response mean (SRM) for VSS, SMS, and QoLS was 2.62, 2.68, and 2.09, respectively. Both methods demonstrated large effect sizes (Table 4). Question 10 did not show any significant difference (symmetry test; p = 0.8013). There was a significant difference in the mean levels of question scores for the symptomatic group from before to after surgery, as assessed by the Wilcoxon matched-pairs signed rank test (Fig. 1). Table 5 shows the analysis of external responsiveness in which pre- and post-treatment scores were compared with vaginal examination findings, with regard to POP-Q stage (Mann–Whitney U test and Kruskal–Wallis test).

Discussion

With more than 200 million native speakers, Portuguese is the sixth most widely spoken first language in the world. In spite of this, there is a lack of fully validated POP questionnaires in Portuguese. Furthermore, to allow its

Table 5 External responsiveness analysis on ICIQ-VS: comparison of VSS and QoLS before and after surgery in relation to POP stages (n= 44 patients)

	POP stage	Score	Number of patients	Mean	Range	p Value
Before treatment	3	VSS	37	32.1	12–49	0.8851
		QoLS	37	8.5	0–10	0.6821
	4	VSS	7	32.7	16–53	
		QoLS	7	9.3	8–10	
After treatment	0	VSS	22	3.1	0–8	0.0147[a]
		QoLS	22	0.7	0–8	0.0077[b]
	1	VSS	14	4.9	0–13	
		QoLS	14	0.9	0–8	
	2+3	VSS	8	14.4	0–34	
		QoLS	8	4.1	0–10	

[a] Difference between 2+3 and 0 (Mann–Whitney U test)
[b] Differences between 2+3 and 0, and between 2+3 and 1 (Kruskal–Wallis test)

utilization in different countries, translation and validation of the English original version is needed.

In 1996, Bump et al. proposed a standardized method for POP grading that was validated and adopted by the ICS. However, patients' subjective perceptions of disease and related symptoms have not been formally assessed. It is known that POP has an impact on QoL that is similar to or more severe than what objective measurements are able to demonstrate [11].

The management of women with POP should rely on symptom severity and their impact on QoL rather than the POP staging alone. The role of POP/QoL questionnaires has been widely demonstrated to be useful in clinical practice and treatment follow-up [12].

We have presented the results from the process of validating the ICIQ-VS in Portuguese from its English version. This instrument is designed to assess vaginal symptoms, sexual matters, and the impact of POP on QoL among women with this condition. Overall, the findings support the clinical validity, reliability, and sensitivity to change of the ICIQ-VS by demonstrating good to excellent psychometric properties.

The Portuguese version of ICIQ-VS was easy to understand and answer, even in a population of low educational level. To accomplish the research goals in this specific demographic study group and to ensure reliable data collection, a nurse or a relative provided some help toward completing the questionnaire. This method has been used in validation studies in Brazil [13] and in other developing countries [14–16] where the illiteracy rate is higher than in developed countries.

One of the limitations of this study is that the questionnaire used the Portuguese language spoken in the State of São Paulo at four tertiary referral centers. The questionnaire should also be tested in different Brazilian regions/states, as the way the Portuguese language is spoken in the State of São Paulo differs somewhat from the way it is spoken in other regions/states, which also differ from each other. Cultural differences are frequently present between different regions of the same country.

The construct validation distinguished differences in ICIQ-VS scores between the symptomatic (ICIQ-VS5a>0) and the asymptomatic (ICIQ-VS5a=0) women (Table 1). The criterion validaton showed strong and positive correlation between the severity of VSS and QoLS, and the vaginal examination findings, as assessed by the POP-Q stage. VSS and QoLS could distinguish patients with grade 0 (no prolapse) from those with POP grading 3 + 4 (p= 0.0020 and p=0.0004, respectively; Table 2). According to the VSS and QoLS, patients with more severe stages of POP scored higher than did women with minimal POP grade or no POP. This finding would indicate that ICIQ-VS truly measures the impairment of QoL due to POP.

Conversely, SMS (assessed only for sexually active women) did not show any difference between POP grades (p=0.1538; Table 2).

There was no correlation between impairment of sexual symptoms and worsening of POP grade. Furthermore, despite the presence of some degree of POP, its severity seemed not to interfere in these women's sex lives. According to some authors [17], increasing POP grade predicted interference with sexual activity but did not affect the description of satisfaction with the sexual relationship or the frequency of intercourse. Moreover, some studies have found mild to moderate correlation between the impairment of sexual activity and worsening prolapse in all three compartments [18].

In our population study, women who underwent forceps-assisted extraction delivery had higher VSS than was found in other types of delivery. This result is in line with a recent study [19] that found a high association between forceps-assisted delivery and perineal tears in primiparae. A strong association between forceps-assisted extraction delivery and pelvic floor dysfunction symptoms, including POP, has been extensively demonstrated [20].

The reliability of the ICIQ-VS was excellent in terms of its internal consistency, which was considered very good for VSS and excellent for SMS. This means that the items used for calculating the internal consistency for both scores (VSS and SMS) presented good and positive correlations between each other. The ICIQ-VS showed moderate to excellent stability in all ICIQ-VS questions, including VSS, SMS, and QoLS, as assessed by test–retest analysis (Table 3).

The ICIQ-VS was highly responsive to surgical treatment. It was able to discriminate between levels of change in VSS, SMS, and QoLS (Table 4 and Fig. 1) and POP-Q stage (Table 5), which are frequent clinical outcomes for POP treatments. Reduction of the POP stage was associated with significant score improvement in most of the ICIQ-VS questions, thus indicating that this level of clinical changes translated into significant QoL benefits and reductions in bothersome symptoms.

The Portuguese version of ICIQ-VS will enable cross-cultural comparisons to be made and will encourage research into the prevalence and QoL impact of POP in Brazilian populations, as well as routine clinical assessment of women before and after treatment.

In conclusion, the Portuguese version of ICIQ-VS has demonstrated psychometric properties that establish its potential as a useful condition-specific quality-of-life instrument among Brazilian women with pelvic organ prolapse, with or without vaginal and sexual symptoms. It has been successfully validated in Portuguese, and because it is brief and easy to answer, it is now available for research and clinical practice in Brazil. There is need for studies to evaluate the relative impact of surgical and

nonsurgical management of POP on QoL among Brazilian women with this condition. The Portuguese version of ICIQ-VS should prove useful in this regard.

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Conflicts of interest None.

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