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Tamanini T[1], Almeida F G[2], Girotti M E[2], Riccetto C L Z[3], Palma P[3], Rios L A S[4]
1. *State Prevention and Treatment Centr of Urinary Dysfunctions of Jaú,* ***2.*** *Department of Urology - Federal University of São Paulo,* ***3.*** *Department of Urology - Faculty of Medicine of Campinas - UNICAMP,* ***4.*** *Sector of Urology - Hospital do Servidor Público de São Paulo*

THE PORTUGUESE VALIDATION OF THE "INTERNATIONAL CONSULTATION ON INCONTINENCE QUESTIONNAIRE – VAGINAL SYMPTOMS" (ICIQ-VS) FOR WOMEN WITH PELVIC ORGAN PROLAPSE

Hypothesis / aims of study

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.

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 quality of life among women.

Study design, materials and methods

Women were enrolled in this cross-sectional observational study between January 2006 and September 2007 and were recruited at four pelvic floor and voiding dysfunction reference centres. 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 gynaecological examination.

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 three weeks later, the patients returned for the retest. The patients underwent gynaecological examination using the Pelvic Organ Prolapse Quantification system (POP-Q). To describe the signs and symptoms associated with lower urinary tract dysfunction, the International Continence Society definitions were used. The following sociodemographic characteristics were analysed: age, race and education. The following clinical characteristics were analysed: POP-Q stage, body mass index (BMI), parity and type of delivery.

Questionnaire

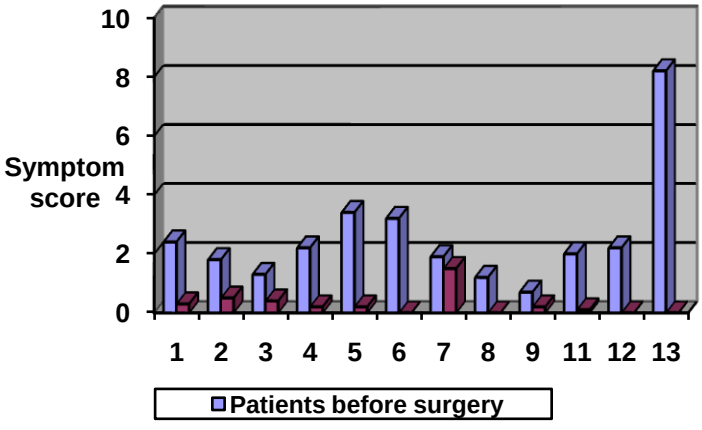
The ICIQ-VS is a module from the ICIQ modular questionnaires (1) for assessing a range of pelvic floor dysfunction symptoms such as bowel and vaginal, along with sexual matters. It is composed of 14 questions divided into three independent scores. The vaginal symptom score (VSS) has a possible minimum 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. The standardized method for the validation procedure was rigorously followed, in accordance with international criteria.

Psychometric testing

The women were divided into two groups according 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 and reliability analysis as well as sensitivity to change were performed. 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.

Figure. 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)



Results

Two hundred and four women were enrolled in this study. There were 108 symptomatic women, 94 asymptomatic women and two women with missing data.

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). *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 correlated with the objective vaginal examination findings ($p=0.0020$ and 0.0004 respectively). SMS (for sexually active women only) did not show any difference in relation to POP grades ($p=0.1538$).

Internal Consistency: Cronbach's alpha coefficient for items assessing the instrument used presented good values, of 0.79 (VSS) and 0.88 (SMS), thus showing inter-rater reliability. *Stability:* the test-retest reliability assessed by the intraclass correlation coefficient (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. The test-retest reliability for Question 10 showed excellent correlation and stability, as assessed by the weighted Kappa index = 0.85.
Sensitivity to change: this was investigated in a sample of 44 women out of 204 urogynaecological clinic attendees undergoing surgical treatment for POP. The percent change in the presence of symptoms between baseline and the last follow-up (20 weeks) was calculated (Figure). The effect size I or standardized effect size (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.

Interpretation of results
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.
We have presented the results from the process of validating the ICIQ-VS in Portuguese, from its English version. Overall, the findings support the clinical validity, reliability and sensitivity to change of the ICIQ-VS, by demonstrating good to excellent psychometric properties and sensitivity to change.

Concluding message
The Portuguese version of ICIQ-VS has demonstrated psychometric properties that establish its potential as a useful condition-specific quality-of-life instrument among women with pelvic organ prolapse, with or without vaginal and sexual symptoms.

References
1. BJOG (2006) 113(6); 700-12.

Specify source of funding or grant	**none**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Committee from Hospital do Servidor Público Estadual de São Paulo - Brazil**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**