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ORIGINAL ARTICLE

Cross-cultural adaptation and validation of the Brazilian Portuguese version of the Female Sexual Distress Scale-Revised questionnaire for women with vaginal laxity

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Abstract

Introduction and hypothesis Vaginal laxity (VL) can impair women´s quality of life and there are not many tools aimed at quantitatively addressing this complaint. Sexual distress can be present within this group of patients. The aim of our study is to carry out the cross-cultural adaptation/translation and validation of the Female Sexual Distress Scale-Revised (FSDS-R) for Brazilian Portuguese women with VL.

Methods Women age ≥ 18 years, with VL (n=82), and without VL (n=53) were included. Continuous variables were described in the form of mean/standard deviation or median/range, and Student's t test was used. The Chi-squared test was used for dichotomous variables. Cronbach's alpha coefficient was used for internal consistency and Spearman's correlation was used to assess construct validity (FSDS-R, Female Sexual Function Index [FSFI], and Incontinence Questionnaire Vaginal Symptoms [ICIQ-VS]). A significance level of 5% was established using a two-tailed test.

Results Women with VL presented more anal/vaginal sexual intercourse than women without VL (p=0.030). All three instruments (FSDS-R, FSFI, and ICIQ-VS) presented discriminant validity between women with and without VL (p<0.001). A high internal consistency (Cronbach´s alpha =0.887) was found in women with VL and without VL (0.917). Regarding construct validity (n=82), there was a strong positive correlation between FSDS-R score and ICIQ-VS scales, except for a weaker correlation between the ICIQ-VS vaginal symptoms subscale (r: +0.2788; p=0.013). A moderate negative correlation was found between FSDS-R and all FSFI domains (p<0.001), except for pain (p<0.062).

Conclusions The Brazilian version of the FSDS-R showed adequate internal consistency and discriminant validity, and a correlation was found with other instruments such as FSFI and ICIQ-VS.

Keywords Vaginal laxity · Sexual dysfunction · Surveys and questionnaires · Validation study

Introduction

Vaginal laxity (VL) is defined as a complaint of excess vaginal flaccidity and is described as a vaginal symptom of sexual function specific to pelvic floor dysfunction by the latest International Urogynecological Association (IUGA)/International Continence Society (ICS) terminology [1, 2]. Women with VL may be representative of an early stage of development of pelvic organ prolapse [3]; however, a consensus on this matter has not yet been reached. According to another study, VL differs from pelvic organ prolapse, the former being related to symptoms concentrated in the vagina and the latter involving the descent of one or more pelvic organs [4]. The decreased vaginal sensation during intercourse may be related to anatomical damage to the perineal body, vaginal canal or introitus, underlying nerve and connective tissue damage during pregnancy and childbirth, or potentially a combination of these factors [5].

The diagnosis of VL is based on the patients' self-report [6]. A comprehensive medical history, physical examination,

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and psychosexual evaluation are the initial steps for the proper identification of patients with VL. The Vaginal Laxity Questionnaire is an instrument used in clinical research to assist in the identification and severity of VL [7]. However, this instrument does not fully understand the extent of the impact on the quality of life of women with VL.

The Female Sexual Distress Scale-Revised – FSDS-R assesses sexual distress with a composite score ≥ 11 [8]. Sexual distress is characterized by a set of feelings and emotions that individuals have about their sexuality. It differs from sexual dysfunction related to symptoms of sexual function, such as arousal, orgasm, and pain, separate from emotions [8]. Assessing sexual distress in women complaining of VL can help to understand its pathophysiology. Sexual distress in women with VL has already been investigated in previous studies in the English language [7, 9]; however, this questionnaire has not yet been translated into or validated in Brazilian Portuguese, making it difficult to investigate the Brazilian population. Therefore, the aim of this study is to carry out the cross-cultural adaptation, translation, and validation of the Female Sexual Distress Scale-Revised (FSDS-R) in Brazilian Portuguese for women with VL.

Materials and methods

This is a cross-sectional study conducted from November 2021 to January 2022 at Women's Hospital - Prof. Dr. José Aristodemo Pinotti, CAISM, at the University of Campinas – Brazil. The study was approved by the Institutional Review Board under the number CAAE: 53164221.3.0000.5404 and followed the Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures [10].

Study population

Women aged ≥ 18 years, with VL and women without VL assessed by a single, dichotomous question (do you consider yourself to have vaginal laxity) and by the Vaginal Laxity Questionnaire (VLQ) [7] were included in the present study. We considered the answers (very loose, moderately loose, slightly loose) for VL and (neither loose nor tight) for women without VL. Women with VL were recruited through advertisements on the Hospital's official website and referred to the study through the urogynecology outpatient clinic. Participants without VL were recruited in their first appointment at the Family Planning outpatient clinic. These participants were referred for counseling for or to receive contraceptive methods, without any complaints of prior genital or sexual dysfunction. We excluded women with reading and language comprehension difficulties, who had undergone surgeries for pelvic floor disorders, who had undergone previous treatment for VL, and who had used vaginal estrogen in the past 6 months. The women who agreed to participate in the study signed the consent form.

Regarding the sample size, as we know from the literature that there is heterogeneity for calculating the minimum sample size from instrument validation studies, these data show a variation ranging from 100 to 300 cases [11]. As the complaint of VL is rarely discussed among women and health professionals, we expect to analyze at least 100 participants.

The female sexual distress scale – revised – FSDS-R

The FSDS-R is a self-administered questionnaire validated by Derogatis et al., consisting of 13 questions in English that can be answered as 0-never, 1-rarely, 2-occasionally, 3-frequently, and 4-always [8]. The FSDS-R total score ranges from 0 to 52 and provides sexual distress measurement (the higher the score, the higher the sexual distress).

Translation and cross-cultural adaptation

Our study followed the six stages of translation and the cross-cultural adaptation process proposed by Beaton et al. [10]. Permission for the translation and validation of the FSDS-R was granted by Derogatis Measurement Assessments, LLC, and by the company Mapi Research Trust. After receiving authorization, we started stage I - translation.

The initial translation of the original questionnaire was performed by two native speakers of the Brazilian Portuguese language who were fluent in advanced English. The first translator had experience in sexual dysfunction and was aware of the topic assessed by the questionnaire. Their translation (T1) was responsible for the clinical relevance. In contrast, the second translator had no knowledge of the issues related to the questionnaire's topic and their translation (T2) was responsible for the language relevance. A synthesis of the two initial translations produced a common version called T-12. The synthesis process of the two translations was carefully analyzed and documented.

Subsequently, the translation of the T-12 version from Brazilian Portuguese into English was performed by two translators (back translation 1 and back translation 2) who were not aware of the original version of the questionnaire.

An expert committee composed of the authors, two health professionals specializing in gynecology and urogynecology who work at the Women's Hospital - CAISM, and translators, were responsible for consolidating all translated versions and developing the pre-final version to test the questionnaire. The pre-final version was applied to 30 volunteers complaining of VL. The volunteers were asked about the difficulty in understanding the questionnaire items. The expert committee was also responsible for evaluating questionnaire questions that might be not understood and needed clarification.

Finally, the approved version of the FSDS-R (Brazilian Portuguese version) was added to a form containing sociodemographic and clinical questions, in addition to two other questionnaires validated for Brazilian Portuguese. We chose to apply the form to all participants, including the thirty volunteers who participated in the cross-cultural adaptation test phase. The study objectives were explained to all women who agreed to participate. A researcher was responsible for collecting the signature of the consent form from each participant, delivering the data collection form, answering all possible questions, and providing guidance on each question in the questionnaires when needed, thus, ensuring due privacy for each participant during the data collection process.

Analyzed variables

Sociodemographic and clinical data were as follows: age, marital status, ethnicity, years of education, body mass index, menopausal status, number of pregnancies, births, and abortions, types of delivery, type of affective and/or sexual relationship, and complaints of VL.

Two questionnaires validated for the Portuguese language were also applied: the Female Sexual Function Index (FSFI) and the International Consultation on Incontinence Questionnaire Vaginal Symptoms (ICIQ-VS). The FSFI is a brief and multidimensional questionnaire that assesses sexual function in women. This instrument was developed and validated by Rosen et al. and consisted of 19 items. It investigates sexual response over the last 4 weeks and performance in six domains: sexual desire, arousal, lubrication, orgasm, satisfaction, and pain[12]. Validation in Portuguese occurred in 2008 by Thiel et al. [13]. Last, the ICIQ-VS is a 14-question questionnaire that assesses the presence and intensity of vaginal symptoms, associated sexual issues, as well as their relationship with quality of life in research and clinical practice. Tamanini et al. validated the ICIQ-VS in Portuguese in 2008 [14].

Statistical analysis

Data collected from the interviewed women were organized in a spreadsheet and exported for analysis into Intercooled Stata 13.0 (Stata, College Station, TX, USA). The normality of sampling was assessed by the Shapiro–Francia test. Continuous variables were described in the form of mean/standard deviation or median/range, and for calculating discriminant validity, Student's *t* test and Chi-squared test were used for continuous and dichotomous variables respectively. Cronbach's coefficient alpha, item–test correlation, item–rest correlation were used to measure the internal consistency (homogeneity of items belonging to the same scale). Spearman's correlation was calculated by comparing the FSDS-R and FSFI and ICIQ-VS scores for construct validity. Floor and ceiling effects were considered if more than 15% of participants had the lowest and highest scores on the questionnaires respectively. A significance level of 5% was established using a two-tailed test. No imputation method was used owing to missing data.

Results

After careful analysis of the FSDS-R instrument, both the initial translated versions and the back-translated versions were, in general, similar. In the initial translation, only the first, the tenth, and the twelfth questions presented moderate, mild, and mild divergences respectively. In question one, for the term "distressed," we opted for the translation of "*angustiada* - distressed" instead of "*desconfortável* - uncomfortable", as the term "*desconfortável* - uncomfortable" is broader and could be interpreted differently within the Brazilian context. In questions ten and twelve, the translated terms were synonymous and would not cause problems of interpretation or understanding. Likewise, the back-translation process showed mild differences related only to synonymous terms.

Sociodemographic and clinical characteristics

Table 1 shows the distribution of both groups according to sociodemographic and clinical characteristics. The mean age was similar in the two groups. Education longer than 8 years was frequent in both groups, with women without VL more likely to present a higher level of education (98.12% vs 78.04%). Women with VL were more likely to be multiparous and to have a higher number of pregnancies when compared with the non-VL group. On the other hand, women in the non-VL group were more likely to undergo cesarean and to perform vaginal intercourse than women with VL.

Discriminant validity

Table 2 describes the discriminant validity according to the FSDS-R, FSFI, and ICIQ-VS scores and their domains between the groups. Sexual distress measured by the FSDS-R presented significantly higher scores in women with VL than in the non-VL group (26.88±14.39 vs 11.09±11.92). Although the floor effect was seen in FSDS-R (17.04%), no ceiling effect was observed (4.44%) in this questionnaire. Regarding the FSFI questionnaire, women without VL presented higher scores in all FSFI domains, except for desire and pain. Higher scores were seen in women with VL in all ICIQ-VS subscales ($p<0.001$).

Table 1 Sociodemographic and clinical characteristics of the interviewed women (*n*=135)

Variables	Vaginal laxity group (*n*=82)		Nonvaginal laxity Group (*n*=53)		*p* Value
	Mean ± SD/*p* (%)	Median (min–max)	Mean ± SD/*n* (%)	Median (min–max)	
Age (years)	41.19±9.45	41 (22–60)	40.20±8.64	41 (21–61)	0.533*
Marital status					0.988**
Single	19 (23.18)		12 (22.64)		
Married	50 (60.97)		33 (62.27)		
Divorced	13 (15.85)		8 (15.09)		
Ethnicity					0.135**
White	42 (51.22)		36 (67.93)		
Black	10 (12.20)		3 (5.66)		
Other	30 (36.58)		14 (26.41)		
Years of education					**0.001****
< 8 years	18 (21.96)		1 (1.88)		
> 8 years	64 (78.04)		52 (98.12)		
BMI					0.151**
< 25 kg/m^2	30 (36.58)		26 (49.05)		
> 25 kg/m^2	52 (63.42)		27 (50.95)		
Gravidity	2 (0–8)		2 (1–3)		**0.001***
Type of birth					**0.001****
Vaginal	47 (59.49)		14 (26.41)		
Cesarean	20 (25.32)		35 (66.05)		
Both	12 (15.19)		4 (7.54)		
Parity					**0.011*****
Primiparous	19 (24.05)		24 (45.28)		
Multiparous	60 (75.95)		29 (54.72)		
Instrumental delivery					0.090**
No	63 (79.74)		48 (90.56)		
Yes	16 (20.26)		5 (9.44)		
Menopause status					0.948**
Premenopause	69 (87.34)		46 (86.79)		
Postmenopause	10 (12.66)		7 (13.21)		
Sex orientation					0.408**
Hetero-affective	77 (98.71)		53 (100.00)		
Homo-affective	1 (1.29)		0		
Type of sexual intercourse					**0.030****
Vaginal	55 (70.51)		46 (86.79)		
Vaginal and anal	23 (29.49)		7 (13.21)		

SD standard deviation, *BMI* Body Mass Index

*Student's *t* test

**Chi-squared test

Bold *p* values considered statistically significant

Internal consistency

Internal consistency with item correlation and Cronbach's alpha for FSDS-R, FSFI, and ICIQ-VS questionnaires are found in Table 3. The FSDS-R has demonstrated a high ICC of 0.88 and 0.91 respectively, for women with and without VL. The remaining questionnaires also presented a higher Cronbach's alpha ranging from 0.88 to 0.89 in the VL group and from 0.91 to 0.92 in the non-VL group in the FSFI scores and domains; and from 0.88 to 0.89 in the VL group and 0.92 in the non-VL group in the ICIQ-VS subscales.

Construct validity

The construct validity among the FSDS-R, FSFI, and ICIQ-VS questionnaires is described in Table 4. Construct validity

Table 2 Discriminant validity between women with and those without vaginal laxity according to the Female Sexual Distress Scale-Revised (FSDS-R), Female Sexual Function Index (FSFI), and Incontinence Questionnaire Vaginal Symptoms (ICIQ-VS) questionnaires

Questionnaires	Vaginal laxity group (n=82)			Nonvaginal laxity group (n=53)			p Value
	Mean ± SD/n (%)	(95% CI)	(min–max)	Mean ± SD/n (%)	(95% CI)	(min–max)	
FSDS-R	26.88±14.39	(23.63–30.13)	(1–52)	11.09±11.92	(7.80–14.38)	(0–50)	**0.001***
Floor effect (17.04)	6 (7.32)			17 (32.08)			**0.001****
Ceiling effect (4.44)	5 (6.10)			1 (1.89)			0.246**
FSFI							
Desire	3.14±1.18	(2.87–3.40)	(1.2–6.0)	3.44±0.97	(3.17–3.71)	(1.2–6.0)	0.131*
Arousal	3.41±1.23	(3.13–3.69)	(1.2–5.7)	4.24±1.17	(3.92–4.56)	1.2–6.0	**0.001***
Lubrication	4.16±1.35	(3.85–4.46)	1.2–6.0	4.79±1.25	(4.44–5.14)	1.2–6.0	**0.008***
Orgasm	3.66±1.42	(3.33–3.98)	1.2–6.0	4.58±1.20	(4.25–4.92)	1.2–6.0	**0.001***
Satisfaction	4.03±1.41	(3.71–4.35)	1.2–6.0	4.86±1.22	(4.53–5.20)	1.2–6.0	**0.001***
Pain	4.43±1.55	(4.08–4.78)	(1.6–6.0)	4.82±1.39	(4.43–5.20)	(1.2–6.0)	0.147*
Total	22.85±6.28	(21.43–24.27)	(6.0–34.5)	26.76±5.76	(25.17–28.35)	(7.6–33.6)	**0.001***
ICIQ-VS							
Vaginal symptoms	16.29±7.77	(14.54–18.04)	(2–39)	6.09±5.53	(4.56–7.61)	(0–28)	**0.001***
Q4. Vagina is too loose or lax	2.29±0.79	(2.11–2.47)	(1–3)	0	0	0	**0.001***
Sexual matters	26.06±19.88	(21.58–30.54)	(0–58)	4.54±8.82	(2.11–6.97)	(0–37)	**0.001***
Quality of life	6.05±3.42	(5.27–6.82)	(0–10)	1.33±2.47	(0.65–2.02)	(0–10)	**0.001***

Floor effect (>15 %)

SD standard deviation

*Student *t* test, **Chi-squared test

Table 3 Internal consistency with item-rest correlation and Cronbach's alpha for the Female Sexual Distress Scale – Revised (FSDS-R), Female Sexual Function Index (FSFI), and International Consultation on Incontinence Questionnaire Vaginal Symptoms (ICIQ-VS)

Questionnaire	Vaginal laxity group (n=82)			Nonvaginal laxity group (n=53)		
	Item-test correlation	Item-rest correlation	Cronbach's alpha	Item-test correlation	Item-rest correlation	Cronbach's alpha
FSDS-R	0.7101	0.6462	0.8879	0.7738	0.7235	0.9170
FSFI						
Desire	0.5126	0.4212	0.8970	0.5298	0.4436	0.9268
Arousal	0.7341	0.6745	0.8861	0.7454	0.6900	0.9179
Lubrication	0.6997	0.6342	0.8880	0.8202	0.7789	0.9149
Orgasm	0.8255	0.7836	0.8815	0.8142	0.7717	0.9152
Satisfaction	0.7092	0.6453	0.8874	0.7275	0.6690	0.9187
Pain	0.5248	0.4348	0.8964	0.7694	0.7183	0.9172
Total	0.5388	−0.3036	0.8855	0.5937	−0.1435	0.9150
ICIQ-VS						
Vaginal symptoms	0.6254	0.5483	0.8921	0.6751	0.6082	0.9219
Q4. Vagina is too loose or lax	0.5564	0.4702	0.8956			
Sexual matters	0.6905	0.6234	0.8889	0.6343		0.9237
Quality of life	0.5932	0.5116	0.8938	0.6671		0.9220

was performed to assess the relationship between the FSDS-R score and those from the other questionnaires. There was a strong positive correlation between FSDS-R score and ICIQ-VS scales, except for a weaker correlation between the ICIQ-VS vaginal symptoms subscale (r: +0.2788; p=0.013). A moderate negative correlation was found between FSDS-R and all FSFI domains (p<0.001), except for the pain domain (p<0.062).

Table 4 Construct validity among the Female Sexual Distress Scale – Revised (FSDS-R), Female Sexual Function Index (FSFI), and International Consultation on Incontinence Questionnaire Vaginal Symptoms (ICIQ-VS) questionnaires in participants with vaginal laxity (*n*=82)

Questionnaires	FSDS-R	
	r	*p* value
FSFI		
Desire	−0.4036	0.001
Arousal	−0.4571	0.001
Lubrication	−0.4016	0.001
Orgasm	−0.5565	0.001
Satisfaction	−0.4906	0.001
Pain	−0.2117	0.062
Total	−0.5510	0.001
ICIQ-VS		
Vaginal symptoms	0.2788	0.013
Q4. Vagina is too loose or lax	0.3881	0.001
Sexual matters	0.6415	0.001
Quality of life	0.4726	0.001

r Spearman correlation coefficient; Dancey & Reidy interpretation

Discussion

This study presents the cross-cultural adaptation and validation of the FSDS-R instrument for the Brazilian Portuguese language for women with VL. Overall, we found slight divergences throughout the cross-cultural adaptation process, and we may suggest that the final Brazilian version of the FSDS-R can be considered similar to the original English version. Considering the questionnaire scores, sexual distress, sexual dysfunction, and vaginal symptoms were higher in women with VL. Our findings showed an acceptable and satisfactory internal consistency for all questionnaires (FSDS-R, FSFI, and ICIQ-VS). Regarding construct validity, a correlation was found between FSDS-R score and ICIQ-VS vaginal symptom subscales. Similarly, a moderate negative correlation was found between FSDS-R and all FSFI domains, except for the pain domain.

In our sample, women with VL had a higher frequency of vaginal delivery and multiparity than participants without VL. These findings corroborate those of other previously published studies that also found evidence for a connection between vaginal delivery/parity and symptoms of VL [5, 15, 16].

As we notice the growing development of instruments to assess sexual function, it is possible to transform subjective measures into objective data [17]. However, most of the questionnaires assessing sexual function were developed in the English language [18]. Thus, because Brazil is a country with continental extension and a known prevalence of sexual dysfunction of 67.7% [19], we believe that the translation of the FSDS-R will contribute immensely to the assessment of sexual distress in women, not only with symptoms of VL but also with other sexual dysfunctions. In our findings, sexual distress, as well as sexual dysfunction and vaginal symptoms, was higher in women complaining of VL. Sexual distress has also been assessed in women with VL in previous studies, but these studies had lower mean scores than our findings. The study by Millheiser et al. had a mean total FSDS-R score of 13.6 ± 8.7 in a group of 24 women in the pre-treatment period [7]. Likewise, Krychman et al., in a randomized clinical trial, observed a total score of 19.4 ± 12.0 in a group of 122 patients in the active group [9]. The mean total score found in our population was 26.88 ± 14.39. We reinforce the need to assess sexual distress in patients complaining of vaginal laxity.

As observed in the original article [8], high inter-item correlations were also observed in our study. We found few studies that performed validation, translation, and/or cross-cultural adaptation of the FSDS-R for their respective populations. The study by Berenguer et al. translated the FSDS-R into the Portuguese language of Portugal and showed an internal consistency similar to our findings [20]. The construct validity and the correlations between FSDS-R and FSFI were also similar in the two studies, only differing in the pain domain (FSFI) in our study (r -0.2117; *p*=062) [20]. The Turkish version was published in 2016 with a population of 248 women with complaints of sexual interest/arousal disorder and other female sexual dysfunctions and participants without complaints of sexual dysfunction [21]. The authors performed a similar data analysis, differing only in the test-retest, factor structure, and cut-off point analysis, which we did not perform. In addition, a correlation analysis of the FSDS-R and the FSFI questionnaires was performed, as in the present study; however, the results differed slightly between studies [21]. The Persian version of the FSDS-R was constructed by a group of Iranian researchers in 2014 and applied to 652 healthy participants [22]. In this study, only the internal consistency could be compared with our study, proving to be similar to our findings [22]. Finally, the Polish version of the FSDS-R was applied to a population of 75 women with hypoactive sexual desire disorder, 31 women with other dysfunctions, and 104 participants without sexual dysfunction complaints. Internal consistency was similar to ours with a coefficient $\alpha > 0.70$ [23].

The strength of our study can be related to recruited participants—women complaining of VL, a symptom that has been rarely investigated. Moreover, we were able to perform the analyses that comprise the process of translation, validation, and cross-cultural adaptation for a country with a population of 214.1 million and compare it with other translations, and also with other studies that have already

used the FSDS-R in the same target population as our study. However, we have some limitations: we were not able to perform test-retest analysis in our population owing to COVID-19 pandemic restrictions. We believe that this analysis would add value to our study. Likewise, our sample size was affected by the restrictions of the COVID-19 pandemic in that we only applied the questionnaires to patients who already had appointments scheduled at the outpatient clinic, and it was not possible to invite other patients to participate in the study. Also, we also did not carry out further qualitative measurement analyses of the Brazilian version of the FSDS-R.

Conclusions

The FSDS-R is a valuable instrument for assessing sexual distress in women with VL. Its Brazilian version showed satisfactory internal consistency and construct validity, and a correlation was found when compared with FSFI and ICIQ-VS.

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Author contributions G.M.V. Pereira: protocol/project development; data collection or management; data analysis; manuscript writing/editing; C.R.T. Juliato: protocol/project development; data collection or management; data analysis; manuscript writing/editing; D.A.Y. Gomes: data collection or management; data analysis; manuscript writing/editing; T.S. Beltramini: data collection or management; data analysis; M.V.C. Monteiro: data collection or management; data analysis; L.G.O. Brito: protocol/project development; data collection or management; data analysis; manuscript writing/editing.

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Declarations

Conflicts of interest None.

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