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ORIGINAL ARTICLE

Transcultural translation and validation of the FIGO Assessment Scoring System (FASS) to Portuguese language

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Abstract

Introduction and hypothesis Our aim was to validate the Brazilian Portuguese version of the International Federation of Gynecology and Obstetrics (FIGO) Assessment Scoring System (FASS) to identify and quantify signs and symptoms related to pelvic floor dysfunction.

Methods One hundred and seventy-nine women aged 18–82 (47.68 ± 14.42) years participated in this validation study. Collected data included a sociodemographic and clinical questionnaire, application of the FASS, and physical examination using the Pelvic Prgan Prolapse Quantification (POP-Q) system. The translation and cross-cultural adaptation were performed following the international methodology. The psychometric properties tested were criterion validity, construct validity, stability, and reliability. For this purpose, the comparison with POP-Q findings and between symptomatic and asymptomatic patients, test–retest and internal consistency (Cronbach's alpha) were used, respectively. The intraclass correlation coefficient (ICC) was calculated to assess the level of agreement between evaluations (inter- and intraobservers). $P < 0.05$ was considered statistically significant.

Results The calculated Cronbach's alpha coefficient was 0.76, indicating strong reliability for the validation sample. Symptomatic women had different scores on all FASS items as well as total score when compared with asymptomatic women ($p < 0.001$). Intraobserver coefficient ranged from 0.91 (urinary symptoms) to 0.98 (FASS total score), indicating excellent concordance level in all items. Interobserver coefficient ranged from 0.47 (intestinal symptoms) to 0.90 (FASS total score), indicating moderate to excellent correlation.

Conclusions The psychometric properties tested in the FASS Portuguese version proved to be a valid and reliable for evaluating signs and symptoms related to pelvic floor function in Brazilian women.

Keywords Validation studies · Pelvic organ prolapse · Psychometrics

Abbreviations

BMI	Body mass index
FASS	FIGO Assessment Scoring System
FIGO	International Federation of Gynecology and Obstetrics
ICC	Intraclass Correlation Coefficient
ICS	International Continence Society
IUGA	International Urogynecological Association
POP	Pelvic organ prolapse
POP-Q	Pelvic Organ Prolapse Quantification
QoL	Quality of Life
SPSS	Statistical Package for Social Sciences

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Introduction

Pelvic floor disorders are common conditions mainly affecting older women and include urinary and bowel symptoms and symptoms related to pelvic organ prolapse (POP). It is estimated that the prevalence of this condition reaches 25% of women in the USA [1]. Although not generally life threatening, it impacts the woman's well-being, predominantly by triggering bowel-related dysfunction, and bladder and/or sexual functions [2]. Some recognized risk factors for POP include number of pregnancies and deliveries, fetal macrosomia, previous pelvic surgery, high maternal body mass index (BMI), the aging process, hormone deficiency, diabetes mellitus, hypertension, chronic intestinal constipation, declining functional and structural characteristics of the pelvic floor musculature, muscular denervation, postural changes, and impaired perineal awareness. All these factors, isolated or in different associations, can lead to alterations in the pelvic organ support system [3–5].

The Pelvic Organ Prolapse Quantification (POP-Q) system is the internationally recognized objective examination method used to classify POP, as recommended by the International Continence Society (ICS) and International Urogynecological Association (IUGA) since 1996 [6]. However, its use presents difficulties in clinical practice because it was developed before a more complete understanding of the mechanism of physiological support of pelvic organs and symptoms of pelvic floor dysfunctions was available. In addition, the POP-Q uses an arbitrary classification of the stages of prolapses without considering the associated symptoms. Thus, the International Federation of Gynecology and Obstetrics (FIGO) developed a new scoring system for evaluating prolapse with its degree of bother by using the physical examination findings and associated urinary and bowel symptoms. A POP classification system should reflect the severity of the condition, taking into account both physical exam findings and symptoms related to pelvic floor dysfunction, with their degree of bother [7]. Instruments to identify and quantify both symptoms and signs on physical examination would be important for clinical practice and research. The FASS could act as a tool for comprehensive population studies to identify the prevalence of pelvic floor dysfunction in different populations and the degree to which these symptoms affect a patient's quality of life (QoL). However, cross-cultural research has specific methodological problems, most of which relate to translation quality and the comparability of results in different cultural and ethnic groups. It is not enough to translate an instrument literally. It is also important to adapt it in a culturally relevant and comprehensible form while maintaining the meaning and intent of the original terms [8]. The validation of this instrument in languages other than the original English is important for studies in populations speaking other languages. The standardization of results in different countries and ethnic groups would allow more reliable comparative studies among these populations.

The aim of this study was to validate the Portuguese version of the FASS through translation, cross-cultural adaptation, and analysis of its psychometric properties.

Materials and methods

Translation and cross-cultural adaptation

The technique used in this study to develop the translation and cross-cultural adaptation followed the method described by Guillemin [9]. First, six independent Brazilian translators fluent in English and without previous contact with the tool translated the English version to the Brazilian Portuguese language. Next, the six translated versions were analyzed by a committee comprised of the translators, a bilingual observer specializing in languages, and the first author, with the purpose of analyzing equivalences (semantics, idiomatic, cultural, and conceptual) and developing a consensual version. Third, two independent native-English-speaking translators, without previous FASS knowledge, carried out the back-translation. Subsequently, a committee of six English-speaking experts in different fields of knowledge (four health professionals, a bachelor's degree in language, a native translator, and the first author) evaluated the Portuguese-language consensus version to define the final version. Face validation of the consensual version was tested in ten women providing maximum information about the understanding of the five items (*see* "Appendix").

Questionnaire

FASS [7] includes: (1) physical examination findings (designated by the letter P); (2) presence of prolapse, urinary, and intestinal symptoms (designated by the letter S); (3) assessment of degree of bother (designated by the letter B). P ranged from 0 to 3 according to POP severity, and the score was determined during the Valsalva maneuver or cough: 0 when organ presentation

is above the hymen; 1 when the organ is at the height of the hymen; 2 when the organ is beyond the level of the hymen; 3 when there is complete eversion. S was calculated by adding all bulge, urinary, and bowel symptoms scores. B was scored from 0 to 4 depending on the severity of bother. If the woman reported that she had no bother (no discomfort), the score was 0; if uncomfortable (no change in social habit but hygiene changes), the score was 1; if uncomfortable (avoiding some social engagements), the score was 2; if very uncomfortable (avoiding most social engagements), the score was 3; if extremely uncomfortable (avoiding all social engagements), the score was 4. Total instrument score was calculated according to prolapse severity on physical examination (0–3); presence or absence of bulge (0–1), urinary (0–3). and intestinal (0–2) symptoms; and QoL impact (0–4) (Table 1).

Study design and participants

The study was approved by the Institutional Ethics Committee (CAAE 51039615.0.0000.5207), and all patients signed informed consent. Participants were recruited at two reference centers in urogynecology. Women with at least one symptom (intestinal, POP symptoms, or urinary findings) were considered symptomatic. The presence of dyspareunia was investigated in women who reported an active sexual life. Physical activity was defined as performing physical exercise at least three times a week for not less than 1 h each session. The use of pads was investigated if urinary symptoms were present. The study included women >18 years of age and able to perform the Valsalva maneuver. Pregnant women or those up to 6 months postpartum unable to tolerate the physical examination, those with a neurological condition, pelvic organ cancer, or auditory, verbal, or cognitive/mental deficiency were excluded. Collected data included a sociodemographic and clinical interview questionnaire, application of the Portuguese version of the FASS, and physical evaluation according to the POP-Q [6]. Examiners were previously trained to perform the FASS evaluation.

Table 1 Individual domain and total scores for the International Federation of Gynecology and Obstetrics Assessment Scoring System (FIGO-FASS)

Prolapse		Symptoms		Bother	
Severity	Score	Severity	Score	Severity	Score
0	0	0	0	0	0
1	1	1–2	1	1	1
2	2	3–5	2	2	2
3	3	6	3	3	3
				4	4

The physical examination, including the Valsalva maneuver, was performed with the volunteer placed in the supine position with the head elevated at 30°, the legs abducted at hip width, and knees flexed. A sample size of 75 women per group (symptomatic and asymptomatic) was calculated on the basis of a power >80% for detecting an effect size of ≥0.50, as described in the original article of the FASS [7]. The sample size for inter- and intraobserver reliability was reached with volunteers agreeing to return to the outpatient clinic.

Psychometric properties and statistical analysis

The psychometric properties tested were criterion validity, construct validity, stability, and reliability. Comparison of data obtained in symptomatic and asymptomatic patients was used to verify construct validity. The POP-Q was used as the gold standard to establish criterion validity. Test–retest and internal consistency were used to verify stability and reliability, respectively. The questionnaires were examined to identify errors filling for double typing. Data were inserted in the Excel program and analyzed by Statistical Package for Social Sciences (SPSS), version 22.0.

To evaluate the level of agreement between evaluations, the intraclass correlation coefficient (ICC) was calculated; values <0.20 were considered poor, between 0.21 and 0.40 weak, between 0.41 and 0.60 moderate, between 0.61 and 0.80 good, and between 0.81 and 1.00 excellent [10]. For interobserver evaluation, the FASS and POP-Q were applied by two examiners independently, so there was no interference in results. Intraobserver evaluation was performed with a 2-week interval between the first and the second evaluation to allow analysis of test–retest reliability. FASS validity was verified by the correlation between FASS physical examination scores and POP-Q results using Spearman's correlation coefficient (rho; construct validity). The coefficient of 1.0 indicates a perfect correlation (the two scoring systems measure an identical construct), and a coefficient of ≥0.7 is considered acceptable. The Mann–Whitney *U* test was used to compare FASS scores between symptomatic and asymptomatic women. Cronbach's alpha was performed to verify internal consistency, and values >0.7 were considered satisfactory. A level of 5% ($p < 0.05$) was considered statistically significant.

Results

A total of 179 women aged 18–82 (47.68 ± 14.42) years participated of this study. Of these, 101 (56.4%) reported at least

Table 2 Comparison of clinical and sociodemographic variables among women with and without signs and symptoms of pelvic floor dysfunction

Variables	Pelvic floor dysfunctions signs or symptoms		Mann–Wihtney U/X^2	P value
	Asymptomatic ($n = 78$)	Symptomatic ($n = 101$)		
Age [median (Q1–Q3)]	42.0 (31.0–50.0)	52.0 (42.0–64.0)	2159.50	**0.001***
BMI [median (Q1–Q3)]	24.5 (23.4–29.1)	28.5 (25.0–31.1)	2921.50	**0.003**
Parity [median (Q1–Q3)]	2.0 (1.0–4.0)	4.0 (2.0–6.0)	2548.00	**0.001**
Vaginal deliveries [median (Q1–Q3)]	0.0 (0.0–3.0)	2.0 (1.0–5.0)	2590.50	**0.001**
Physical activity *f* (%)				
No	62 (79.5)	86 (85.1)	0.985	0.321
Yes	16 (20.5)	15 (14.9)		
Menstrual status *f* (%)				
Premenopausal	56 (71.8)	48 (47.5)	10.649	**0.001**
Postmenopausal	22 (28.2)	53 (52.5)		
Hypertension *f* (%)				
No	65 (83.3)	63 (62.4)	9.487	**0.002**
Yes	13 (16.7)	38 (37.6)		
Diabetes *f* (%)				
No	74 (94.9)	90 (89.1)	1.904	0.168
Yes	4 (5.1)	11 (10.9)		
Education level *f* (%)				
Illiterate	1 (1.3)	16 (15.8)		
Incomplete elementary school	23 (29.5)	39 (38.6)		
Complete elementary school	15 (19.2)	10 (9.9)		
Incomplete high school	4 (5.1)	4 (4.0)	6.738	**0.009**
Complete high school	26 (33.3)	21 (20.8)		
Incomplete undergraduation	5 (6.4)	7 (6.9)		
Complete undergraduation	4 (5.1)	4 (4.0)		
Race *f* (%)				
Black	7 (9.0)	13 (12.8)		
White	19 (24.3)	30 (29.7)	1.566	0.211
Mulatto	49 (62.8)	54 (53.5)		
Other	3 (3.9)	4 (4.0)		
Family monthly income** *f* (%)				
Up to 1 MS	28 (35.9)	48 (47.5)		
1–2 MS	31 (39.7)	36 (35.6)	1.936	0.164
2–3 MS	13 (16.7)	11 (10.9)		
3–4 MS	4 (5.1)	3 (3.0)		
4–5 MS	2 (2.6)	3 (3.0)		
Employed *f* (%)			0.890	0.346
No	44 (56.4)	64 (63.4)		
Yes	34 (43.6)	37 (36.6)		
Marital status *f* (%)				
With partner	61 (78.2)	65 (64.4)	4.050	**0.044**
Without partner	17 (21.8)	36 (35.6)		
Sexual activity *f* (%)				
No	17 (21.8)	50 (49.5)	14.430	**0.001**
Yes	61 (78.2)	51 (50.5)		
Smoking *f* (%)				
No	76 (97.4)	94 (93.1)	1.757	0.185
Yes	2 (2.6)	7 (6.9)		

Bolded data statistically significant

Q1–Q3 interquartile interval, *MS* minimum salary (corresponds to approximately US$250.00/month)

Table 3 Individual domain and total scores for the International Federation of Gynecology and Obstetrics Assessment Scoring System (FIGO-FASS) in symptomatic and asymptomatic women

FASS domain	Pelvic floor dysfunctions signs or symptoms		*P* value
	Symptomatic (FASS score > 0) Average ± SD Median (Q1–Q3)	Asymptomatic (FASS score = 0) Average ± SD Median (Q1–Q3)	
Physical examination (P)	1.16 ± 0.98 1.00 (0.00–2.00)	0.29 ± 0.62 0.00 (0.00–0.00)	<0.001
POP symptoms	0.51 ± 0.50 1.00 (0.00–1.00)	0.01 ± 0.11 0.00 (0.00–0.00)	<0.001
Voiding symptoms	1.50 ± 0.81 2.00 (1.00–2.00)	0.01 ± 0.11 0.00 (0.00–0.00)	<0.001
Bowel symptoms	0.52 ± 0.59 0.00 (0.00–1.00)	0.00 ± 0.00 0.00 (0.00–1.00)	<0.001
Total symptoms (S)	2.47 ± 1.22 2.00 (1.00–3.00)	0.03 ± 0.22 0.00 (0.00–0.00)	<0.001
Bother score (B)	1.08 ± 1.07 1.00 (0.00–2.00)	0.02 ± 0.11 0.00 (0.00–0.00)	<0.001
Total score	3.06 ± 1.61 3.00 (2.00–4.00)	0.06 ± 0.57 0.00 (0.00–0.00)	<0.001

Mann–Whitney *U*test

SD standard deviation, *Q1–Q3* interquartile interval

one signal or symptom related to pelvic floor dysfunction; 78 (43.6%) were included as being asymptomatic. Of women with urinary symptoms (42.5%), 42.1% used pads; 72 (40.2%) and 50 (27.9%) reported, respectively, some intestinal and bulge symptoms. Asymptomatic women were younger, thinner, and had fewer pregnancies and number of vaginal deliveries than symptomatic volunteers. A third of all participants (34.5%) had incomplete primary education, and more than half of color (57.5%), had no job (60.3%), and did not smoke (95.0%). Only 31 (17.3%) practiced regular physical activity. Systemic arterial hypertension (SAH) and diabetes were present in 51 (28.5%) and 15 (8.4%), respectively. Most participants had an active sexual life (62.6%). Of these, 33 reported dyspareunia (29.5%). Sociodemographic and clinical variables are described in Table 2.

The Cronbach's alpha coefficient was 0.76. The scores of each FASS domain (P, S, B) and total FASS score in symptomatic and asymptomatic women are described in Table 3. The construct validity was confirmed by the significant difference between scores obtained in all FASS domains and total score when compared with asymptomatic women ($p < 0.001$).

Instrument stability was tested by calculating the intraobserver agreement. The intraobserver concordance was studied in 26 women and ranged from 0.91 (urinary symptoms) to 0.98 (FASS total score), showing excellent concordance level in all

Table 4 Intraobserver reliability ($n = 26$)

	Mean difference	95% CI limits of agreement (lower–upper)	ICC
Stage (POP-Q)	0.038	0.94–0.99	0.97
Physical examination (P)	0.077	0.91–0.98	0.96
POP symptoms	0.038	0.91–0.98	0.96
Voiding symptoms	−0.038	0.81–0.96	0.91
Bowel symptoms	−0.038	0.83–0.97	0.92
Total symptoms (S)	−0.038	0.90–0.98	0.95
Bother score (B)	−0.038	0.93–0.99	0.97
Total score	−0.346	0.96–0.99	0.98

POP-Q Pelvic Organ Prolapse Quantification system, *POP* pelvic organ prolapse, *ICC* intraclass correlation coefficient, *CI* confidence interval

Table 5 Interobserver reliability ($n = 21$)

	Mean of difference	95% CI limits of agreement (lower–upper)	ICC
Stage (POP-Q)	−0.381	0.55–0.92	0.81
Physical examination (P)	−0.190	0.69–0.95	0.87
POP symptoms	−0.047	0.85–0.97	0.94
Voiding symptoms	−0.238	0.06–0.84	0.62
Bowel symptoms	−0.238	−0.30–0.78	0.47
Total symptoms (S)	−0.524	−0.12–0.81	0.54
Bother score (B)	0.286	0.18–0.88	0.68
Total score	−0.428	0.75–0.96	0.90

POP-Q Pelvic Organ Quantification system, *ICC* intraclass correlation coefficient, *CI* confidence interval

domains evaluated (Table 4). The interobserver concordance was studied in 21 volunteers and ranged from 0.47 (bowel symptoms) to 0.90 (FASS total score), indicating moderate to excellent agreement (Table 5).

The concordance of prolapse stage using POP-Q and FASS (criterion validity) is shown in Table 6. There was a positive correlation between POP evaluation using FASS and POP-Q staging.

Discussion

The FASS classification system was validated to a Portuguese language version through translation, cross-cultural adaptation, and analysis of psychometric properties following methodology described by Guilhemin [9]. Analysis of internal consistency using Cronbach's alpha correlation coefficient demonstrated a strong reliability in the validation sample. Furthermore, the instrument identified symptomatic women and the presence of different alterations when compared with asymptomatic women.

Table 6 Comparison between the International Federation of Gynecology and Obstetrics Assessment Scoring System (FASS) physical examination score and Pelvic Organ Prolapse Quantification (POP-Q) system examination (construct validity)

POP-Q stage	FASS physical examination (P)				Total
	0	1	2	3	
1	78	0	1	0	79
2	20	22	21	0	63
3	1	1	30	0	32
4	0	0	1	4	5
Total	99	23	53	4	179

Rho coefficient = 0.82 ($p < 0.01$)

Test–retest reliability is the extent to which an instrument produces stable scores over time. Instruments must have adequate test–retest reliability to ensure they are consistently measuring the construct of interest without excessive measurement error [11, 12]. The FASS score proved to be stable based on the scores obtained at baseline and after 15 days (intraobserver correlation). There was the inconvenience of obtaining a smaller sample size for the inter- and intraobserver study, because many volunteers did not return to the centers. Despite this, inter- and intraobserver correlation of both FASS and POP-Q were excellent, and this correlation was similar to results found in the original study [7].

FASS showed a correlation with POP-Q, demonstrating that both are similar in efficacy for prolapse identification. The FASS also permits quantification of symptoms related to pelvic floor function and degree of discomfort caused by the condition. This is the first study to attempt validating the FASS in a language other than English by following similar methodology to that of the original study. Translation and validation in other languages of a standardized instrument such as FASS would allow future prevalence studies of pelvic floor dysfunctions, comparing results in different populations and ethnic groups. Subsequent population studies will be relevant to confirm this association.

In conclusion, the instrument of evaluation of pelvic floor dysfunction proposed by FIGO, translated and validated to a Portuguese version, is a useful tool for use in clinical and prevalence studies due to its rapidity and simplicity in being completed and its independence of educational level of the population studied.

Compliance with ethical standards

Conflicts of interest AERA Mathias: None; MS Oliveira: None; CM Haruta: Speaker of the Astellas laboratories; FM Lima: None; KCL Petribú: Speaker of the Jansen and Servier; GA Cavalcanti: Speaker of the Astellas laboratories; SE Swift: None; A Digesu: None.

Appendix

EXAME FÍSICO DO PROLAPSO ÓRGÃO PÉLVICO	ACHADOS RELACIONADOS AOS SINTOMAS INTESTINAIS
0-APRESENTAÇÃO DO ÓRGÃO ACIMA DO HÍMEN	0-SEM SINTOMAS
1-ÓRGÃO NA ALTURA DO HÍMEN	1-INCONTINÊNCIA ANAL(GASES, FEZES LÍQUIDAS OU SÓLIDAS)
2-ÓRGÃO ABAIXO DO HÍMEN	1-DIFICULDADE DE ESVAZIAMENTO (ESVAZIAMENTO INCOMPLETO E/OU NECESSIDADE DE USAR OS DEDOS)
3-EVERSÃO COMPLETA	**ACHADOS RELACIONADOS Á PERCEPÇÃO DO DESCONFORTO DE UMA MANEIRA GERAL**
SINTOMAS ACHADOS RELACIONADOS AO PROLAPSO	0-SEM DESCONFORTO
	1-POUCO DESCONFORTÁVEL. SEM MUDANÇAS NOS HÁBITOS SOCIAIS.MAS MUDANÇAS NA HIGIENE
0- SEM SINTOMAS	2-DESCONFORTÁVEL. EVITA ALGUNS HÁBITOS SOCIAIS.
1-ABAULAMENTO QUE PODE SER VISTO OU SENTIDO. PRESSÃO OU SENSAÇÃO DE "ALGO DESCENDO"	3-MUITO DESCONFORTÁVEL. EVITA A MAIORIA DOS HÁBITOS SOCIAIS.
ACHADOS URINÁRIOS	4-EXTREMAMENTE DESCONFORTÁVEL. EVITA TODOS OS HÁBITOS SOCIAIS.
0-SEM SINTOMAS	
1-INCONTINÊNCIA URINÁRIA	
1-DIFICULDADE DE MICÇÃO(ESVAZIAMENTO INCOMPLETO. MICÇÃO EM DOIS TEMPOS E/OU ESFORÇO PARA URINAR	
1-URGÊNCIA.FREQUENCIA. NOCTURIA	

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