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ORIGINAL ARTICLE

Validation and cross-cultural adaptation of the Brazilian Portuguese version of the questionnaire for the assessment of pelvic floor disorders and their risk factors during pregnancy and postpartum

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Abstract

Introduction and hypothesis Pelvic floor dysfunction may be treated and prevented during pregnancy and postpartum, as it decreases women's quality of life. The aim of the present study was to translate and validate the Brazilian Portuguese questionnaire for the assessment of pelvic floor disorders and their risk factors during pregnancy and postpartum.

Methods This is a cross-sectional study. Two translators fluent in German translated the German version of the questionnaire into English. The back translation was performed by two other translators. The final version was tested on Brazilian pregnant/puerperal women. The participants answered the questionnaire twice, with an interval of 7–10 days between sessions. They also completed the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). To evaluate the test–retest reliability, we used the intraclass correlation coefficient (ICC), Cronbach's alpha coefficient, to test the internal consistency, and Pearson's linear correlation to assess construct validity.

Results Sixty-six women were included (77% pregnant; 23% puerperal women), with a mean age of 26.5 ± 5.8 years and a body mass index of 26.4 ± 5.7 kg/cm^2. There were no missing ceiling or floor effects. The construct validity presented a moderate correlation with the role physical domain of the SF-36 ($r = -0.48$), the ICC test–retest showed good reliability of 0.72, and the internal consistency was 0.71.

Conclusions These results provide evidence that the questionnaire for the assessment of pelvic floor disorders and their risk factors during pregnancy and postpartum is a valid and reliable instrument when utilized in Brazilian pregnant and postpartum women.

Keywords Urinary incontinence · Health education · Physical therapy specialty · Women's health

Introduction

During pregnancy, anatomical changes in the pelvis position [1] due to postural adaptations and uterine expansion [2, 3], endocrine changes [2], and mechanical overload [4] due to an increase in body mass can all lead to the development of pelvic floor dysfunction (PFD), including urinary incontinence (UI), fecal incontinence, pelvic organ prolapse (POP), and sexual dysfunction [1, 2, 5]. PFD can persist in the puerperal period [6] and negatively affect the quality of life of pregnant and postpartum women [7].

Risk factors for the development of PFD in pregnant and postpartum women include maternal age >35 years [7], instrumental vaginal delivery [8], multiparity, obesity [6], neurogenic and structural damage, as well as connective tissue and neurovascular structures of the pelvic floor muscles [4], especially the levator ani muscle [9], and perineal lacerations that occur during childbirth [8]. Pregnancy and vaginal delivery are considered the main risk factors for UI [6]. Vaginal delivery can lead to structural changes and pelvic floor muscle denervation [6].

The prevalence of UI during pregnancy varies between 25 and 75% [2], and 65% of women with UI report that

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their first episode of urinary loss occurs during pregnancy or postpartum [10]. The prevalence of POP is 10% during the gestational and postpartum phase [11], and the prevalence of sexual dysfunction in puerperal women can vary between 26 and 47% [12]. In addition, pregnancy and delivery are risk factors associated with fecal incontinence, which presents a prevalence range of 0.7% to 22% after delivery, with symptoms persisting for 3 to 4 years after delivery [13, 14]. Considering that pregnancy, childbirth, and the immediate postpartum period can predispose one to PFD, validation and reliable assessment tools for the evaluation of these dysfunctions are necessary [15], as they can be used to support physical therapy assessments and the prescription of physical therapy treatments that are suitable for pregnant or puerperal women [16].

Metz et al. [15] developed and validated a questionnaire for the assessment of pelvic floor disorders and their respective risk factors during pregnancy and postpartum in Germany. The questionnaire was developed based on the Australian Pelvic Floor Questionnaire [17], which is a validated instrument for assessing pelvic floor function and has the following domains: urinary function, intestinal function, prolapse, and sexuality. For the version aimed at pregnant and puerperal women, items were included to assess PFD risk factors and data related to previous deliveries [15]. Recently, the questionnaire was validated in Italian [18] and Turkish populations [19].

At present, none of the questionnaires addressed pelvic floor dysfunction specifically in pregnant and puerperal women in Brazilian Portuguese. Therefore, this study was aimed at performing a cross-cultural adaptation and validation of the Brazilian Portuguese version of the questionnaire for the assessment of pelvic floor disorders and their respective risk factors during pregnancy and postpartum.

Materials and methods

This cross-sectional study was performed by consensus based on the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) guidelines [16], approved by the Ethics Committee of the Federal University of São Carlos (CAAE: 51787815.5.0000.5504), conducted in Brazil at the Women's Health Research Laboratory, at the Physical Therapy Department, Federal University of São Carlos.

Participants were invited to participate through social media and invitation brochures, and they were recruited from a Brazilian public health clinic and from a private gynecology and obstetrics clinic. Women were included if they were over 18 years old, if they were at any gestational period, if they had children aged 6 months or less, and if they could read and speak Brazilian Portuguese. The exclusion criteria were women who had cognitive impairments. All the women who consented to participate in the study read and signed an informed consent form.

The Questionnaire for the assessment of pelvic floor disorders and their respective risk factors during pregnancy and postpartum contains four domains related to pelvic floor function: urinary function, bowel, prolapse, and sexuality [15]. It also contains two extra domains: risk factors, with questions on associated diseases, family history, lifestyle, physical activity, previous treatments, as well as childbirth history, with questions related to the number and type of previous deliveries, emotional assessment, and aspects related to pain.

The calculation of the final score is described in the Fig. 1 below for each domain, with a minimum score of 0 and a maximum of 10, of the questionnaire for the assessment of pelvic floor disorders and their risk factors during pregnancy and postpartum. The greater the score (closer to 40), the worse the condition; the lower the score (closer to zero), the better the condition regarding health status in relation to PFD during the gestational or puerperium phases.

However, because this questionnaire is a recent addition to the field and only German and Italian versions exist, its usefulness has not yet been thoroughly analyzed in clinical practice, and further research is necessary to evaluate its feasibility and accessibility.

First, authorization was requested for the translation and validation of the Brazilian Portuguese version of the questionnaire for the assessment of pelvic floor disorders and respective risk factors during pregnancy and postpartum. Two translators fluent in German translated the questionnaire and presented two versions in Brazilian Portuguese. Two other translators who were fluent in German performed the back-translation of the instruments. Both versions were discussed and analyzed in five meetings by a committee of experts, composed of seven people (three physiotherapists, a

Urinary function: score 1 to 16 = result / 48 = result x 10
Bowel function: score 1 to 11 = result / 31 = result x 10
Prolapse: score 1 to 5 = result / 15 = result x 10
Sexuality: score 1 to 9 = result / 24 = result x 10
Urinary function + bowel function + prolapse + sexuality = final score

Fig. 1 Calculation of the score for each domain, with a minimum score of 0 and a maximumof 10, of the Questionnaire for the assessment of pelvic floor disorders and their risk factorsduring pregnancy and postpartum

physician, and three lay people regarding PFD), from which the final version was defined and used for the pre-test [20].

The pre-test was performed from January to April 2018. Thirty women were included in this stage of the cross-cultural adaptation and validation of the questionnaire, of which 17 were pregnant and 13 were puerperal (13 were primiparous and 17 multiparous). Participants had a mean age of 28.1 (± 5.6) years and a mean body mass index of 24.6 (± 6.0) kg/cm^2.

The questionnaires were administered to participants, who were always accompanied by a member of the research team. Participants were instructed to notify the researcher if they had any queries regarding the questionnaire and the researcher wrote down their queries or suggestions. The participants' queries were presented at a meeting with a panel of experts, and the questionnaire was modified, as shown in the Fig. 2 below.

Data collection

At the first assessment, a medical history was obtained to collect sociodemographic and obstetric information. Subsequently, the participants answered the Brazilian–Portuguese version of the Questionnaire for the assessment of pelvic floor disorders and respective risk factors during pregnancy and postpartum (see Supplementary Material) and completed the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) questionnaire [21].

The SF-36 is an instrument validated in Brazilian Portuguese [21] that assesses quality of life. It is widely used and can be used in different populations. It is a questionnaire with multiple aspects, consisting of 36 items and eight domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. The final score of the instrument ranges from 0 to 100, where zero corresponds to the worst general health and 100 to the best general health. Participants completed the Brazilian Portuguese version of the Questionnaire for the assessment of pelvic floor disorders and respective risk factors during pregnancy and postpartum in a second evaluation, 7–10 days after the initial evaluation. All questionnaires were answered in person by the women themselves in the presence of a member of the research team.

Initial question	Final question
Você consegue avaliar o quão cheia está sua bexiga? *(Can you assess how much your bladder is full?)*	Você consegue avaliar o quanto sua bexiga está cheia? *(Can you assess how full your bladder is?)*
Você consegue avaliar o quão cheio está seu intestino? *(Can you assess how much your bowels are full?)*	Você consegue avaliar o quanto seu intestino está cheio? *(Can you assess how full your bowels are?)*
Prolapso *(Prolapse)*	Prolapso (órgão pélvico caído) *(Prolapse [fallen pelvic organ])*
Você sente que sua vagina é muito apertada ou tensa? *(Do you feel that your vagina is too tight or tense?)*	Você acha que sua vagina é muito apertada ou tensa? *(Do you think your vagina is too tight or tense?)*

Fig. 2 Initial questions considered unclear during the pre-test, modified by the Committee ofExperts

Statistical analysis

Statistical analyses were performed using SPSS. Continuous variables were summarized by means, and standard deviation (SD) data were compared using *t* tests. For nominal and ordinal variables, percentages and frequencies were calculated, and groups were compared using the Chi-squared test. The level of significance was 5%.

Internal consistency was considered adequate when Cronbach's alpha was > 0.70 [22]. Reliability was calculated using the intraclass correlation coefficient (ICC) and 95% confidence interval (CI) and was classified as weak (ICC < 0.4), moderate (0.40 < ICC > 0.7), or strong (ICC > 0.7) [23]. The construct validity of the questionnaire was measured using Pearson's linear correlation analysis according to the correlation between the questionnaire for the assessment of pelvic floor disorders and respective risk factors during pregnancy and postpartum scores and the SF-36 scores. Correlation coefficients (r) below 0.3 indicated a weak correlation, whereas score correlations between 0.3 and 0.6 were considered moderate, and scores above 0.6 indicated a good correlation [24].

Regarding the SF-36, the hypothesis was that the statistical analysis would show a moderate agreement between the questionnaire for the assessment of pelvic floor disorders and respective risk factors during pregnancy and postpartum total score and the following SF-36 domains: role physical, vitality, and social functioning.

Sample size calculation was performed according to the study by Terwee et al. [24], which considered a sample size adequate when it ranged from 50 to 99 participants.

Results

Eighty-six women participated in this study. One participant who completed the first and second assessments incorrectly was excluded from the final statistical tests. Twenty women answered the questionnaire only once, and 66 women answered the questionnaire twice, as planned. The participants' characteristics are shown in Table 1.

The internal consistency analysis for each domain of the Questionnaire for the assessment of pelvic floor disorders and respective risk factors during pregnancy and postpartum, as well as the reliability results (test–retest)

Table 1 Characteristics of participants and score for each item and the total score of the questionnaire for the assessment of pelvic floor disorders and their risk factors during pregnancy and postpartum

Variables	Pregnant women ($n=45$)	Postpartum ($n=13$)	Total ($n=58$)	p
Age[a]	27.94 ± 4.72	28.50 ± 7.05	26.5 ± 5.8	0.34*
Body mass index[a]	26.20 ± 6.03	27.84 ± 4.72	26.4 ± 5.7	0.49*
Years of study				0.79**
Until 8	0	0	0	
Between 9 and 11	23 (51.1)	7 (53.8)	30 (51.7)	
More than 11	22 (48.9)	6 (46.2)	28 (48.3)	
Marital status				<0.001**
Single	9 (20.0)	3 (23.1)	12 (20.7)	
Married	35 (77.8)	10 (76.9)	45 (77.6)	
Divorced/widower	1 (2.2)	0	1 (1.7)	
Pregnancies				<0.001**
1	16 (35.6)	3 (23.1)	19 (32.8)	
2	10 (22.2)	6 (46.2)	16 (27.6)	
3 or more	8 (17.8)	9 (69.2)	8 (13.8)	
Missing data	11 (24.4)	4 (30.8)	15 (25.9)	
Previous childbirth				<0.001**
1	2 (4.4)	2 (15.4)	4 (6.9)	
2	2 (4.4)	–	2 (3.4)	
3 or more	(2.2)	–	1 (1.7)	
Missing data	40 (88.9)	11 (84.6)	51 (87.9)	
Vaginal				<0.001**
1	2 (4.4)	–	2 (3.4)	
2	2 (4.4)	–	2 (3.4)	
3 or more	2 (4.4)	–	2 (3.4)	
Missing data	39 (86.7)	13 (100.0)	52 (89.7)	
Cesarean				<0.001**
1	6 (13.3)	2 (15.4)	8 (13.8)	
2	3 (6.7)	1 (7.7)	4 (6.9)	
3 or more	1 (2.2)	3 (23.1)	1 (1.7)	
Missing data	35 (77.8)	10 (76.9)	45 (77.6)	

*t test

**Chi-squared test

[a]Mean ± standard deviation

and confidence intervals, are shown in Table 2. The urinary function domain and questionnaire for the assessment of pelvic floor disorders and respective risk factors during pregnancy and postpartum total score presented adequate internal consistency (>0.70) and strong reliability (ICC > 0.70). Bowel function, prolapse, and sexuality showed moderate reliability (0.40 < ICC > 0.7) and poor internal consistency.

Table 2 Results for internal consistency using Cronbach's alpha and test–retest reliability

Domains	Score (mean and standard deviation)	Cronbach's alpha (p)	Intraclass correlation coefficient (95% CI)
Urinary function	1.6 ± 1.0	0.85 (< 0.001)	0.86 (0.77—0.91)
Bowel	2.4 ± 1.4	0.59 (< 0.001)	0.53 (0.32–0.69)
Prolapse	0.5 ± 1.2	0.53 (< 0.001)	0.54 (0.33–0.70)
Sexuality	1.4 ± 1.2	0.69 (< 0.001)	0.67 (0.51–0.79)
Total score	5.8 ± 3.1	0.71 (< 0.001)	0.72 (0.57–0.83)

CI confidence interval

Table 3 presents the scores for the SF-36 questionnaire and the construct validity of the questionnaire for the assessment of pelvic floor disorders and the respective risk factors during pregnancy and the postpartum instrument. A significant moderate correlation was found between the questionnaire and SF-36 domains, especially the physical role, vitality, and social functioning domains.

No missing data or ceiling effects were identified in this study. None of the participants reached the highest or lowest possible score in any of the domains of the questionnaire.

Discussion

The process of translation and cross-cultural adaptation of the questionnaire for the assessment of pelvic floor disorders and respective risk factors during pregnancy and postpartum followed the COSMIN guidelines [16] according to suggestions regarding the use of guidelines for the cross-cultural adaptation of patient-reported outcome measurements [20]. The study reached statistical results considered appropriate and utilized adequate sample sizes for all proposed measurement properties, similar to an Italian study that validated the Italian version of the questionnaire and included 50 participants [18]; in contrast, the validation of the Turkish version included 80 women [19].

There are validated instruments in Brazilian Portuguese that assess pelvic muscle disorders and their impacts, such as the Pelvic Floor Impact Questionnaire (PFIQ-7), the Pelvic Floor Distress Inventory (PFDI-20) [25], and the Pelvic Floor Bother Questionnaire (PFBQ) [26]. These instruments can be applied to women in general, whereas the different versions of the questionnaire for the assessment of pelvic floor disorders and respective risk factors during pregnancy and postpartum are specific questionnaires to be applied in pregnant and postpartum women, which is its differential. In addition to assessing women postpartum and during pregnancy, the questionnaire also includes some questions regarding obstetric history and risk factors for PFD [15]. A reliable instrument that assesses PFD in pregnant women is essential because changes in the pelvic floor muscles during pregnancy are considered risk factors for the development of PFD in midlife [5, 7]. Therefore, questionnaires can be used to identify and characterize PFD and can be applied to observe modifications in patients' status in urogynecology.

A Cronbach alpha of 0.71 was found for the total score and for the urinary function domain during the internal consistency analysis. This result for internal consistency is similar to the values reported in the original study [15] and to the internal consistency reported by Palmieri et al.[18], who translated the questionnaire for the assessment of pelvic floor disorders and respective risk factors during pregnancy and postpartum to the Italian version. Internal consistency is a relevant piece of information as it assesses the degree to which each item of the instrument correlates with the other items and the final score; therefore, it shows an aspect related to reliability [16, 24].

The first and second applications of the questionnaire obtained results considered strong for the domain urinary function and for the total score, similar to previous studies [16, 21]. For the domains intestinal function, prolapse, and sexuality, the results were considered moderate, which shows that the questionnaire for the assessment of PFD and respective risk factors during pregnancy and postpartum can be considered a reproducible questionnaire for research purposes and clinical practice when assessing PFD in Brazilian pregnant and postpartum women.

The construct validity of an instrument should be tested to assess its quality as a whole; therefore, the use of an instrument considered the gold standard is recommended [16]. In the present study, the questionnaire scores considered here correlated with the scores of the SF-36 questionnaire, which is widely used in research to assess quality of life [21, 27]. In the present study, moderate construct validity was found when the general questionnaire was analyzed in relation to the role physical domain of the SF-36, which encompasses aspects of physical function, physical performance, and pain [27].

Currently, emphasis on the measurement of patient-reported health outcomes (often by using instruments

Table 3 Results for construct validity of the questionnaire to assess pelvic floor disorders and their risk factors during pregnancy and postpartum (QMAP) and results for each domain of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) quality-of-life questionnaire

Domain	Final SF-36 score, mean and standard deviation	Construct validity, overall score (QMAP)	*p* value
Physical functioning	74.3 ± 23.3	−0.24	0.52
Role physical	54.9 ± 43.9	−0.48	0.03
Bodily pain	63.7 ± 23.4	−0.35	0.004
General health	70.1 ± 19.2	−0.15	0.24
Vitality	58.3 ± 20.8	−0.45	<0.001
Social functioning	79.9 ± 23.7	−0.36	0.003
Role emotional	57.1 ± 44.8	−0.018	0.88
Mental health	65 ± 19.5	−0.39	0.001

developed and validated for specific purposes) has become very common and important in clinical practice. The results collected by these instruments can add to the patient's perspective, health condition, and experience, enabling their involvement in decision-making regarding their care, which is one of the essential pillars of evidence-based practice. The use of validated instruments also helps health professionals to identify the concerns and needs that will addressed in individuals [28].

One limitation of the present study may be related to the sample size, as few postpartum women were included in the data analysis. However, previous studies that aimed to translate and validate a questionnaire for the assessment of pelvic floor disorders and their respective risk factors during pregnancy and postpartum in other languages included only a few participants in their validation process [18]. Moreover, sample size studies have rarely been justified in validation studies [28]. However, because this questionnaire is a recent addition to the field and only German, Turkish, and Italian versions exist, its usefulness has not yet been thoroughly analyzed in clinical practice, and further research is necessary to evaluate its feasibility and accessibility [29]. Future studies should also investigate the responsiveness of the Brazilian Portuguese questionnaire for the assessment of pelvic floor disorders and their respective risk factors during pregnancy and postpartum.

The results of this study indicate that the questionnaire for the assessment of pelvic floor disorders and their respective risk factors during pregnancy and postpartum is considered reproducible and valid for use in Brazilian pregnant and postpartum women. The Brazilian Portuguese version of the questionnaire will contribute to the clinical practice of health professionals and scientific research through the optimization of assessments related to PFD in Brazilian pregnant and postpartum women. This will allow objective measurements to be collected using the questionnaire scores and sub-items, thus facilitating clinical decision-making, follow-up, and reassessment. Further research encompassing structural validity and confirmatory analyses is required.

Supplementary information The online version contains supplementary material available at https://doi.org/10.1007/s00192-022-05101-z

Contributions R.C.M. da Silva Vieira: project development, data collection and analysis, manuscript writing, and final approval of the version to be published; J.B. da Silva: data collection, drafting and revising the article critically, and final approval of the version to be published; R. de Carvalho Cavalli: drafting and revising the article critically, and final approval of the version to be published; P. Driusso: project development, data analysis, drafting and revising the article critically, and final approval of the version to be published.

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Declarations

Ethical approval This study was approved by the Ethics and Research Committee of the Federal University of São Carlos.

Conflicts of interest None.

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