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ORIGINAL ARTICLE

Cross-cultural adaptation and measurement property analysis of the Brazilian Portuguese version of the Three Incontinence Questionnaire

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Abstract

Introduction and hypothesis The differential diagnosis of urinary symptoms may allow health professionals to establish a therapeutic objective and to choose the appropriate treatment for the patient's complaint. The aim of this study was to cross-culturally adapt the Three Incontinence Questionnaire (3IQ) into Brazilian Portuguese (3IQ-Br) and to analyze test-retest reliability, construct, and criterion validity in women.

Methods The cross-cultural adaptation of the 3IQ-Br included forward-translation, back-translation, and consensus among an expert committee. Participants with and without urinary incontinence (UI) completed the 3IQ-Br, King's Health Questionnaire (KHQ), and Questionnaire for Female Urinary Incontinence Diagnosis (QUID-Br). Only women with UI answered 3IQ-Br after 7–10 days. Test-retest reliability and construct validity were analyzed using the Cohen linear kappa (k). The 3IQ-Br accuracy was analyzed using the area under the curve (AUC) of the receiver-operating characteristic (ROC) curve, considering the sensitivity and specificity to correctly classify women with and without UI.

Results The reliability of each question from the 3IQ-Br was considered substantial in the test-retest. The agreement among 3IQ-Br, QUID-Br, and KHQ was almost perfect for UI diagnosis ($k > 0.8$). The 3IQ-Br was considered to have good accuracy in distinguishing women with UI considering the KHQ (AUC 0.83, 95% confidence interval [CI] 0.78 to 0.87, $p < 0.001$), and fair to the QUID-Br (AUC 0.73, 95% CI 0.68 to 0.78; $p < 0.001$).

Conclusions The results of this study showed that this version of the 3IQ-Br has acceptable measurement properties for identifying and differentiating UI symptoms in Brazilian women.

Keywords Urinary Incontinence · Cross-Cultural Comparison · Reproducibility of Results · Reliability

Introduction

Approximately 346 million people worldwide present with some type of urinary incontinence (UI), and one in four women will be incontinent at some point in their lives [1]. According to the International Continence Society (ICS), UI is defined as a loss of urine [2], and the most prevalent types of UI are stress urinary incontinence (SUI), urge incontinence (UUI), and mixed urinary incontinence (MUI) [3].

Urinary symptoms are associated with a worse quality of life [4], as they are related to social, personal, and emotional disorders that affect important aspects such as sleep, mental health, and sexual function [5, 6]. In addition, UI is considered a predictor of mortality, since incontinent individuals, especially the elderly, have an increased mortality rate [7].

The ICS recommends the application of validated questionnaires to assess the presence, severity, and duration of urinary symptoms [3], with the aim of facilitating the diagnosis, prognosis, and follow-up of individuals. The differential diagnosis of urinary symptoms may allow health professionals to establish the therapeutic objective and to choose the appropriate treatment for the patient's complaint [8].

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Among the available questionnaires that may help health professionals to quickly diagnose the presence of UI, the Three Incontinence Questionnaire (3IQ) is self-administered and includes only three questions that can be answered in approximately 30 s. However, no previous study has aimed to validate the 3IQ in Brazilian Portuguese (3IQ-Br). Therefore, this tool is still not applicable to clinical and scientific practice. Moreover, the psychometric properties of 3IQ-Br have not been reported.

Therefore, the aim of the present study was to cross-culturally adapt the 3IQ to the Brazilian Portuguese and to analyze the 3IQ-Br measurement properties related to reliability, construct validation, and criterion validation, in line with two validated questionnaires (King's Health Questionnaire and QUID-Br).

Materials and methods

Study design

This observational study was conducted according to Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN), carried out at the Women's Health Research Laboratory between January 2019 and December 2020. This study was approved by the Ethics and Research Committee of the Federal University of São Carlos (UFSCar), São Carlos, São Paulo, Brazil (CAAE: 50,229,415.9.0000.5504). All participants were informed about the research and signed an informed consent form after consenting.

Participants

The recruitment was conducted by social media, websites, leaflets, newspapers, and radio. Participants with and without UI aged ≥ 18 years old were included in the study. The presence of UI was identified by an affirmative answer to one of the following questions from the King's Health Questionnaire: "How much does stress incontinence affect you, e.g., urinary leakage with physical activity, e.g., coughing, running?" and/or "How much does urge incontinence affect you, e.g., by a strong and difficult to control desire to pass urine?" [9].

The non-inclusion criteria were pregnant women; postpartum women (up to 6 months after delivery); women with lower urinary tract infection at the time of evaluation, interstitial cystitis, urogenital cancer, and neurological diseases; and women who underwent treatment for pelvic floor muscle dysfunction in the last 3 months.

Procedures

Participants with and without UI were evaluated initially by filling in a questionnaire elaborated by the researchers of the present study that aimed to evaluate the characteristics related to personal, gynecological, and obstetric data. Subsequently, participants completed the Three Incontinence Questionnaire Diagnosis (3IQ-Br), King's Health Questionnaire (KHQ) [9], and the Questionnaire for Female Urinary Incontinence Diagnosis (QUID-Br) [10]. Participants with UI answered the 3IQ-Br again 7 to 10 days after the first evaluation to analyze the questionnaire test-retest reliability.

Instruments

Three Incontinence Questionnaire (3IQ)

The 3IQ is a questionnaire that includes three questions that aim to differentiate between SUI and UUI [8, 11]. The first question identifies whether the subject had UI episodes in the last 3 months and should be answered dichotomously, with "yes" or "no" as options. In the case of a negative answer, the questionnaire is considered completed. If women answer affirmatively to the first question, then questions 2 and 3 must be answered. The subject is instructed to select the answer option that is similar to his/her urinary loss and is allowed to choose more than one alternative. The third question aims to classify the types of UI. Therefore, the subject should choose only one alternative that refers to the frequent urinary symptom, and then the type of UI will be classified considering the individual's answer [8].

King's Health Questionnaire (KHQ)

The KHQ, which has already been validated in Brazilian Portuguese [9], assesses the quality of life of women with UI symptoms [12]. It consists of 21 questions grouped into eight domains (general perception of health, impact of UI, daily activity limitations, physical activity limitations, social limitations, personal relationships, emotions, and sleep/disposition). In addition, two more independent scales that assess the severity of UI and intensity of urinary symptoms. Numerical values are given to each of the answers and are summed by domains. The overall quality of life score will then be generated using mathematical formulas ranging from 0 to 100. In this case, the higher the value to judge, the worse the quality of life [13]. The internal consistency of the Brazilian Portuguese KHQ ranged from 0.49 to 0.92 [9].

QUID-Br

The Questionnaire for Urinary Incontinence Diagnosis (QUID) was developed in US American English, with the

goal of distinguishing SUI and UUI symptoms [14]. It consists of six answer options related to the frequency at which urine loss episodes occur, ranging from "never" (0) to "all the time" (5). The sum of the values of each question gives separate results to the diagnosis of the SUI and UUI (subscales) and ranges from 0 to 15 points each. The cut-off value that identifies women with SUI is ≥ 4, and UUI is classified with a cut-off ≥ 6 [15]. This questionnaire has already been validated in Brazilian Portuguese (QUID-Br) [10], with results indicating that it has acceptable measurement properties to assess UI symptoms in Brazilian women.

Procedures

Cross-cultural adaptation of the Three Incontinence Questionnaire (3IQ) to Brazilian Portuguese (3IQ-Br)

First, the authors of the present study contacted the researchers who published the original paper on the 3IQ, seeking their consent for validation and use of the instrument in Brazilian Portuguese [16]. The cross-cultural adaptation process consisted of five phases [17]: (1) translation of the 3IQ questionnaire from English to Brazilian Portuguese, performed by two translators (a layman [T1] and a construct specialist [T2]) fluent in both languages, with Brazilian Portuguese being the first language; (2) the two Brazilian Portuguese versions were compared and synthesized, resulting in one single version of the questionnaire that was prepared by a committee of translators composed of five specialist researchers (with at least 5 years of experience in the area; they held three meetings) and lay people [17]; (3) back-translation of the synthesis in Brazilian Portuguese into English by two translators (one who was born in the USA [RT1] and one Brazilian researcher who has lived in an English-speaking country for 7 years [RT2]); (4) the second committee meeting was held to create the pre-final version (synthesis of the two retroversion); (5) assessment of the pre-test, which included 30 women (target audience) who answered the pre-final version of the questionnaire. At this phase, the acceptability and comprehensibility of the questionnaire were assessed by the women through a semi-structured questionnaire with questions related to the impression of each item and its answers, relevance of item, clarity of instructions, and instrument layout. The final version did not change. Figure 1 shows the cross-cultural adaptation of 3IQ-Br.

Measurement properties A summary of the criteria for the measurement properties of the 3IQ-Br Brazilian is presented in Box 1.

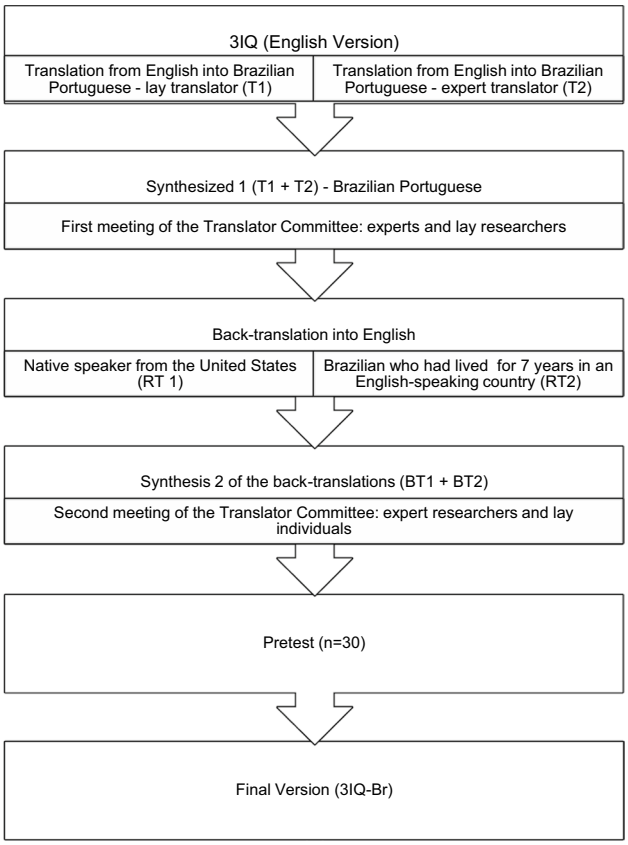

Fig. 1 Research phases of the cross-cultural adaptation of the 3IQ-Br

Box 1. Measurement's properties of 3IQ-Br

Measurement properties	Instruments
Reliability test-retest	Reliability was assessed according the results of the first and second assessment (with 7–10-day interval)
Construct validity	Agreement between 3IQ-Br answers with two questions from KHQ that assess SUI and UUI, respectively ("Do you have urinary loss that occurs during physical effort such as coughing, sneezing, running, etc.?" and "Do you have a very strong urge to urinate, with urinary loss before reaching the bathroom? [12, 17]"). For MUI it was considered when the answer was yes to both questions and IU when any one of the answers was yes Hypothesis: Moderate agreement between the type of UI identified by 3IQ-Br (In the past 3 months, have you lost urine, most of the time?) and the answers to the questions from KHQ that identify SUI and UUI, respectively

Measurement properties	Instruments
Construct validity	Agreement between 3IQ answers with QUID-Br [10], considering women with UUI (QUID ≥ 6 for UUI domain), SUI (QUID ≥ 4 for SUI domain) and MUI (points in both domains) Hypothesis: Moderate agreement between the type of UI identified by 3IQ-Br and the QUID-Br domains of UUI and SUI

Statistical analysis

Statistical analyses were performed using the SPSS software package (version 23.0, SPSS Inc., Chicago, IL, USA). Initially, a descriptive analysis was performed to characterize the study's participants, with the descriptive data presented as mean, standard deviation, or frequency and percentages (%). To analyze the differences between the characteristics of the sample, the Mann-Whitney test was applied to compare the age and body mass index of women with and without UI. Subsequently, the chi-squared test was used to assess the differences between the categorical variables. The significance level was set at 5%.

Reliability (test-retest)

The reliability measures of the scores for patients who have not changed are the same under several conditions [18]. The reliability of the 3IQ-Br was calculated from the results obtained from the first and second assessments, with a break of 7–10 days between them. Reliability was classified according to Cohen linear kappa (k) and classified as absence of agreement (< 0.00) and poor (0–0.19), fair (0.20–0.39), moderate (0.40–0.59), substantial (0.60–0.79), and almost perfect (0.80–1.00) [19] agreement.

Construct Validity

To analyze the construct validity, we considered the agreement between 3IQ-Br and QUID-Br and KHQ, respectively, based on k test. Values were classified as an absence of agreement (< 0) and poor (0–0.19), fair (0.20–0.39), moderate (0.40–0.59), substantial (0.60–0,79), and almost perfect (0.80–1.00) agreement [19]. For both analyses, we considered the capacity to identify UI and distinguish between the types of UI.

According to the QUID-Br score, women were classified as having UUI (QUID ≥ 6 for UUI domain), SUI (QUID ≥ 4 for SUI domain), and MUI (points in both domains). We expected moderate agreement between the type of UI identified by 3IQ-Br and the QUID-Br domains of UUI and SUI.

Regarding the KHQ, the hypothesis was that statistical analysis would show a moderate agreement between the type of UI identified by 3IQ-Br (in the past 3 months, have you lost urine, most of the time?) and the answers to the following two questions from KHQ: "Do you have urinary loss that occurs during physical effort such as coughing, sneezing, running?" and "Do you have a very strong urge to urinate, with urinary loss before reaching the toilette?" [9].

Criterion validation

Criterion validity was analyzed according to the area under the curve (AUC) of the receiver-operating characteristic (ROC) curve, considering the sensitivity and specificity values to correctly classify women with and without UI. Two statistical analyses were performed using the MedCalc program with QUID-Br and KHQ as anchors.

The ROC curve synthesizes information in the form of a graph representing the "true-positive rate" (sensitivity) vs. the "false-positive rate" (specificity) [20]. The cut-off point of an instrument can be identified by selecting a score that combines the highest specificity and sensitivity value [21]. In the present study, the analysis of the AUC values determined the 3IQ-Br accuracy to correctly classify women with and without UI. The instrument accuracy was classified as excellent discriminatory ability (AUC = between 0.90 and 1.0), good discrimination ability (AUC = 0.80 and 0.90), moderate discrimination capacity (AUC = 0.70 to 0.80), poor ability to discriminate (AUC = between 0.60 and 0.70), and ability to discriminate worse than random (AUC ≤ 0.50) [22].

Results

During the pre-test phase, when the questionnaire was administered to 30 participants, no interpretation problems were identified. Three hundred seventy women were included (186 without UI and 184 with UI). Among the incontinent participants, 154 answered the questionnaires twice (retest). The characteristics of the continent and incontinent participants are presented in Table 1. There were significant differences between groups in age, body mass index, educational level, annual family income, presence of pelvic organ prolapses, prevalence of other diseases, history of gynecological surgeries, use of hormonal replacement therapy, post-menopausal status, obstetric history, and history of vaginal deliveries ($p < 0.05$).

Table 2 shows the results for the reliability (test-retest) for each question of the 3IQ-Br, which was classified with substantial agreement for all the questions. The statistical analysis of construct validity is presented in Table 3. There was an almost perfect agreement between the 3IQ-Br and KHQ (κ 0.82, 95% CI 0.76 to 0.88, $p < 0.001$) and a moderate agreement between 3IQ-Br and QUID-Br (κ 0.54, 95% CI 0.46 to 0.63, $p < 0.001$), considering the

identification (presence or absence) of UI. The analysis that calculated the distinction between the types of UI showed moderate agreement for UUI and SUI in both the KHQ and QUID-Br questionnaires.

It was possible to identify adequate accuracy (AUC) for the identification of the types of UI with the 3IQ-Br and KHQ (AUC 0.83, 95% CI 0.78 to 0.87, $p < 0.001$) and between 3IQ-Br and QUID-Br (AUC-Br 0.73, 95% CI 0.68 to 0.78, $p < 0.001$). Table 4 and Fig. 2 show the ROC AUC analyses.

Discussion

The aim of this study was to carry out the cross-cultural adaptation of 3IQ-Br and to verify its measurement properties, such as internal consistency, construct validity,

Table 1 Characterization of the participants

Variables	Without UI = 186	With UI = 184	*P*
Age (years), mean (SD)	30.67 (11.25)	50.86 (19.32)	< 0.001#
IMC (years) mean (SD)	24.22 (6.54)	25.75 (8.65)	0.001#
Marital status, *n* (%)			
Married	58 (31.2)	76 (41.3)	0.03*
Unmarried	128 (68.8)	107 (58.2)	
Educational level, *P* (%)			< 0.001*
Primary education	1 (0.5)	47 (25.5)	
Secondary education	70 (37.6)	52 (28.3)	
Tertiary education	115 (61.8)	84 (45.7)	
Annual family income, *n* (%)*			
< R$650,00	0	3 (1.6)	< 0.001*
R$1500–R$2500	57 (30.6)	59 (32.1)	
R$4500–R$9000	88 (47.3)	55 (29.9)	
> 20,000	28 (15.1)	5 (2.7)	
Pelvic floor distress, *n* (%)			
Pelvic organ prolapse	14 (7.5)	44 (23.9)	< 0.001
Fecal incontinence	44 (23.7)	43 (23.4)	0.60
Intestinal constipation	83 (44.6)	65 (35.3)	0.12
Other diseases, *n* (%)			
Diabetes mellitus	3 (1.6)	23 (12.5)	< 0.001*
Systemic arterial hypertension	12 (6.5)	54 (29.3)	< 0.001*
Heart disease	2 (1.1)	16 (8.7)	0.001*
Gynecological surgeries, *n* (%)	24 (12.9)	58 (31.5)	< 0.001*
Hormone replacement therapy, *n* (%)			
Yes	10 (5.4)	11 (6.0)	0.76
No	176 (94.6)	169 (91.8)	
Missing	-	4 (2.2)	
Post-menopausal status, *n* (%)	15 (8.1)	106 (57.6)	< 0.001*
Obstetric history, *n* (%)			< 0.001*
Nulliparous	133 (71.5)	53 (28.8)	
Pregnancies 1	28 (15.1)	23 (12.5)	
2 or more	25 (13.4)	102 (55.4)	
Vaginal deliveries			0.006*
1	8 (4.3)	19 (10.3)	
2 or more	4 (2.2)	53 (29.0)	
Cesarean sections			0.46
1	22 (11.8)	31 (16.8)	
2 or more	18 (9.7)	34 18.5)	

*Chi-squared test: $p < 0.05$

#Mann-Whitney test: $p < 0.05$

Table 2 Realiability (test-retest) ($n = 154$)

Realiability (test-retest)	Kappa	95% CI
When you coughed, sneezed, lifted a heavy object (pushed), and/or exercised (physical activity)	0.76	0.65–0.88
When you had the urge or the feeling that you needed to empty your bladder, but you couldn't get to the toilet fast enough?	0.65	0.52–0.78
Without physical activity and without a sense of urgency?	0.60	0.43–0.77
When you coughed, sneezed, lifted a heavy object (pushed) and/or exercised (physical activity)	0.72	0.61–0.83
When you had the urge or the feeling that you needed to empty your bladder, but you couldn't get to the toilet fast enough?	0.76	0.65–0.87
Without physical activity and without a sense of urgency?	0.70	0.43–0.98
About the same frequency with coughing, sneezing, lifting a heavy object (pushing), and/or doing (without physical activity) and with an urgent need to urinate	0.47	0.26–0.67
Answer to the third question of the 3IQ	0.67	0.55–0.79
Type of incontinence	0.66	0.54–0.78

Table 3 Construct validity ($n = 370$)

	3IQ	Kappa	95% CI
KHQ	UI	0.82	0.76–0.88
	SUI	0.38	0.28–0.48
	UUI	0.56	0.47–0.66
	MUI	0.24	0.11–0.38
	Type	0.58	0.52–0.65
QUID	UI (score)	0.54	0.46–0.63
	SUI	0.39	0.28–0.51
	UUI	0.49	0.38–0.61
	MUI	0.23	0.07–0.4
	Type	0.47	0.39–0.55
	King (type)	0.58	0.50–0.65

reliability, and criterion validity, in accordance with international recommendations [17, 23], in women with UI. The 3IQ-Br demonstrated good acceptance and understanding since the pretest. To our knowledge, it is the first patient-reported outcome measure (PROM) questionnaire available in Brazilian Portuguese for UI diagnosis and differentiation. PROMs capture the perception of health-related aspects and outcomes that are important to patients through questionnaires, allowing health professionals to promote the most appropriate treatment, and they are effective methods to address a key question in evaluative research, understanding what is really important to patients. In this way, its use, in some cases, shifts from secondary results to main results because of its potential relevance for routine care [24].

A previous study conducted in the USA concluded that the 3IQ is a simple assessment tool that can be quickly applied and considered reproducible, with good accuracy in the differential diagnosis of SUI, UUI, and MUI [8]. In addition, the authors reported fair to moderate sensitivity and specificity of the questionnaire to correctly distinguish women with SUI (0.86, 95% confidence interval [CI] 0.79 to 0.90; 0.60, 95% CI 0.51 to 0.68) and UUI (0.75, CI 0.68 to 0.81; 0.77, 95% CI 0.69 to 0.84) [8].

The results of the present study indicate that 3IQ-Br is suitable for use in the differential diagnosis among the most frequent types of UI (UUI and SUI) in Brazilian women. The application of validated questionnaires is indicated by the ICS to assess the presence, severity, and duration of any urinary symptom [8]. From the application of questionnaires, it is possible to convert subjective information into objective and measurable data. In addition, the use of questionnaires includes advantages such as self-completion of the instrument by the patient or the health professional in research and/or clinical practice.

The present study was based on recommendations from the literature and followed research protocols to perform the cross-cultural adaptation process and measurement properties of the evaluation instrument [19, 25]. The sample size to evaluate construct validity followed the recommendations of the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN), i.e., 5–7 times larger than the number of items [26].

The test-retest reliability presented substantial results, and our results are consistent with those of a previously published study that sought to evaluate the reliability of the

Table 4 Accuracy, standard error, Youden index J, and sensitivity and specificity values for the 3IQ-Br in relation to KHQ and QUID-Br

	n	AUC (CI 95%)	SE	J	Sensitivity	Specificity	*p* (0.05)
KHQ	260	0.83 (0.78—0.87)	0.03	0.65	74.19	90.91	< 0.0001
QUID-Br	303	0.73 (0.68—0.78)	0.03	0.52	76.47	76.19	< 0.0001

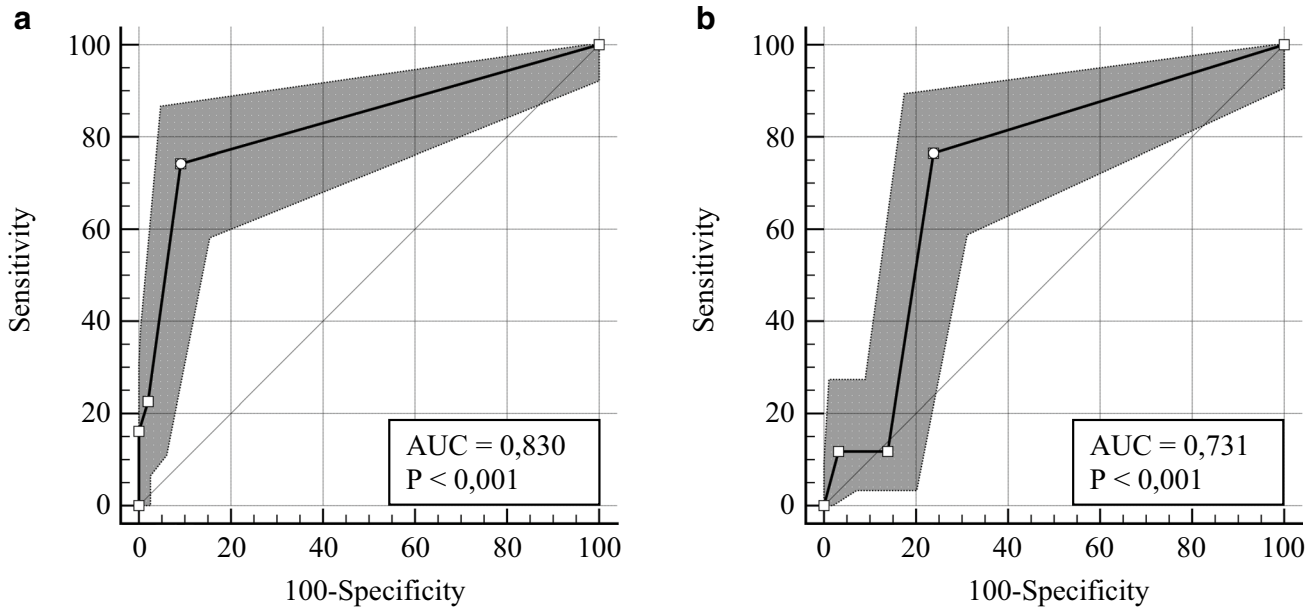

Fig. 2 Sensitivity and specificity values (ROC Curve) for analyzing the criterion value of 3IQ-Br. Differentiation between types of incontinence in relation to: KHQ (A) and QUID-Br (B)

original version of the 3iQ, which presented good reliability, with statistics ranging from 0.65 0.69 [8].

By analyzing the correlation between the 3IQ-Br and other instruments, we observed a moderate to strong correlation between the 3IQ-Br and the questions related to the characterization of UI, being UUI or SUI, which suggests the possibility of using the instrument in the differential diagnosis of UI. However, the correlation was poor and moderate in the cases of SUI and MUI, respectively, in the analysis between 3IQ-Br and QUID-Br, which can be explained by the distinct nature of the two instruments.

The KHQ in this study is restricted to the differentiation between UUI and SUI because only the questions related to this have been used, while the QUID-Br encompasses the valuation of characteristics also of severity of UI, that is, QUID-Br is based on a numerical score with a pre-established cutoff point to diagnose women for the presence of UI [10]. 3IQ-Br only classifies the presence of the symptom according to an affirmative answer to the questions' options [8]. In this respect, it is worth noting that 3IQ plays an important role in the differential diagnosis of UI, and it is possible to start an appropriate follow-up and treatment program for patients.

Considering the data of the ROC curve, representing sensitivity vs. specificity, the accuracy of the 3IQ-Br was considered adequate for the identification of UI types according to the comparison with the KHQ and QUID-Br instruments, indicating that the 3IQ-Br presented good ability to differentiate both UUI and SUI, which corroborates the results presented in the original version of the 3IQ [8].

Future studies should analyze the responsiveness of 3IQ-Br, since this measurement property refers to the ability of the instrument to detect clinical changes during a follow-up period [27]. Future studies should also analyze the properties of questionnaire measurements during the evaluation of other populations, such as pregnant women and puerperium, at different levels of health care (primary and/or secondary).

In conclusion, the results of this study showed that the 3IQ-Br version has acceptable measurement properties for identifying and differentiating UI symptoms in SUI and UUI in Brazilian women, in line with KHQ and QUID-Br. The 3IQ-Br can be easily and quickly used in the daily practice of healthcare professionals in Brazil and in scientific research. As a positive impact, it can equip scientific research methodologies with practicality, reliability, and reproducibility.

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Author contributions MER Alem: project development, data collection and analysis, manuscript writing.
JB Silva: data collection, support for writing the manuscript.
ACS Beleza: drafting and revising the article critically.
TC Chaves: data analysis.
P Driusso: project development, drafting and revising the article critically, and final approval of the version to be published.

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Declarations

Conflicts of interest None.

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