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Cross-cultural adaptation and validation of the Urinary Incontinence Scale After Radical Prostatectomy for the Brazilian context

Adaptação transcultural e validação da Urinary Incontinence Scale After Radical Prostatectomy para o contexto brasileiro

Adaptación transcultural y validación de la Escala de Incontinencia Urinaria Tras Prostatectomía Radical para el contexto brasileño

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ABSTRACT

Objective: To translate, adapt, and validate the Urinary Incontinence Scale After Radical Prostatectomy for Brazil.

Method: Methodological study: cross-cultural adaptation (translation, synthesis, back translation, expert committee (n=25), pre-testing (n=40) and presentation to original authors) and evaluation of measurement properties (n=80). Data were collected between January 2018 and February 2019 in an oncology unit. The calculated measurement properties: structural validity, hypothesis testing, criterion validity and reliability.

Results: The Brazilian version was called *Escala de Incontinência Urinária Pós-Prostatectomia Radical*. One item was excluded due to low factor loading (0.322). A significant correlation was identified between the total score of the scale and instruments applied ($p<0.001$). Incontinent men had higher scores on the total scale in relation to continents ($p<0.001$). Cronbach's alpha was 0.94 and composite reliability was 0.97.

Conclusion: The Brazilian version was considered valid and reliable for the assessment of urinary incontinence in prostatectomized patients.

Keywords: Urinary incontinence. Prostatectomy. Validation Study. Reproducibility of results. Surveys and questionnaires.

RESUMO

Objetivo: Traduzir, adaptar e validar a *Urinary Incontinence Scale After Radical Prostatectomy* para o Brasil.

Método: Estudo tipo metodológico: adaptação transcultural (tradução, síntese, retrotradução, comitê de especialistas (n=25), pré-teste (n=40) e apresentação para os autores originais) e avaliação das propriedades de medida (n=80). Os dados foram coletados entre janeiro de 2018 e fevereiro de 2019 em unidade oncológica. As propriedades de medida calculadas: validade estrutural, teste de hipótese, validade de critério e confiabilidade.

Resultados: A versão brasileira denominou-se Escala de Incontinência Urinária Pós-Prostatectomia Radical. Um item foi excluído devido carga fatorial baixa (0,322). Identificou-se correlação significativa entre escore total da escala e instrumentos aplicados ($p<0,001$). Homens incontinentes apresentaram maior escore no total da escala em relação aos continentes ($p<0,001$). Alfa de Cronbach foi 0,94 e confiabilidade composta 0,97.

Conclusão: A versão brasileira foi considerada válida e confiável para avaliação da incontinência urinária em prostatectomizados.

Palavras-chave: Incontinência urinária. Prostatectomia. Estudo de validação. Reprodutibilidade dos testes. Inquéritos e questionários.

RESUMEN

Objetivo: Traducir, adaptar y validar la Escala de Incontinencia Urinaria Post-Prostatectomía Radical para el Brasil.

Método: Estudio de tipo metodológico: adaptación transcultural (traducción, síntesis, retro traducción, comité de expertos (n=25), pre-test (n=40) y presentación a los autores originales) y evaluación de las propiedades de medición (n=80). Los datos se recogieron entre enero de 2018 y febrero de 2019 en una unidad de oncología. Las propiedades de medición calculado: validez estructural, prueba de hipótesis, validez de criterio y la fiabilidad.

Resultados: La versión brasileña se denominó *Escala de Incontinencia Urinaria Pós-Prostatectomía Radical.* Un ítem fue excluido debido a una carga factorial baja (0.322). Se identificó una correlación significativa entre la puntuación total de la escala y los instrumentos aplicados ($p<0,001$). Los hombres en incontinente tuvieron puntuaciones más altas en la escala total en relación a los continentes ($p<0,001$). El alfa de Cronbach fue de 0,94 y la fiabilidad compuesta 0,97.

Conclusión: La versión brasileña se consideró válida y fiable para la evaluación de la incontinencia urinaria en prostatectomizados.

Palabras clave: Incontinencia urinaria. Prostatectomía. Estudio de Validación. Reproducibilidad de los resultados. Encuestas y cuestionarios.

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INTRODUCTION

Prostate cancer (PC) is the second most common cancer among men in Brazil and worldwide[1]. Radical prostatectomy (RP) is considered the gold standard treatment for localized PC[2]. Although this surgery can reduce mortality, it has a significant impact on quality of life (QoL) as it can trigger undesirable effects such as urinary incontinence (UI)[2].

Post-radical prostatectomy urinary incontinence (PRPUI) may be associated with urinary sphincter dysfunction, caused not only by direct injury to adjacent muscle tissue and ligaments, but also by functional deficit caused by changes in innervation. Another possible cause refers to changes in the detrusor muscle, especially detrusor overactivity[3]. It is estimated that up to one year after surgery, 40% of men experience some degree of UI[2–3] and, therefore, a condition that requires assessment and specific treatment[2].

The International Continence Society (ICS) recommends that when evaluating an incontinent person, it is important to specify the circumstances, frequency and severity of urinary leakage[2]. In this context, the literature presents different instruments[4–6], however, when considering RP as a triggering factor for UI, it was identified only the Urinary Incontinence Scale After Radical Prostatectomy (UISRP)[7].

Thus, the use of measurement instruments developed in other cultures consists as an important strategy when there are no national instruments available and capable of measuring what is desired. However, in order to be applied in clinical practice and in research, it is necessary that the instrument be submitted to the methodological process of translation, cross-cultural adaptation and validation in the culture in which it will be used. Such stages allow satisfactory measurement properties, which will enable comparisons of a construct with other populations in several contexts[8].

The UISRP was developed and validated in China in 2010, it is self-applicable and consists of eight items. It presented good psychometric results in its original version and is available in the published version in English[7]. Due to the specificity and objectivity of the instrument for assessing UI in the target population, the cross-cultural adaptation and validation of the UISRP for the Brazilian context becomes relevant.

Thus, in order to provide a measurement instrument aimed at measuring the severity of PRPUI and the relevance of the instrument for use in measuring outcome in future intervention research, this study is proposed, which aims to translate, adapt and validate the Urinary Incontinence Scale After Radical Prostatectomy for Brazil.

METHOD

This is a methodological study developed in two steps: cross-cultural adaptation followed by the evaluation of the measurement properties of the scale. The cross-cultural adaptation process consisted of six stages[9]: 1) initial translation; 2) translation synthesis; 3) back-translation; 4) evaluation by an expert committee ; 5) pre-testing; and 6) presentation of the final version of the adapted instrument to the original authors. The study was conducted from January 2018 to February 2019. Clinical data were collected at a high complexity oncology care unit (UNACON) in the interior of Minas Gerais, Brazil.

The methodological guidelines were based on the checklist Consensus-based Standards for the selection of the health Measurement Instruments (COSMIN)[10]. To guide the information presentation, the guidelines for quality improvement studies (Standards for Quality Improvement Reporting Excellence- SQUIRE 2.0)[11] were also considered.

In the first and second stages of the cross-cultural adaptation process, the translation of the UISRP was performed by two Brazilian translators, fluent in English: the first, a health professional, who was aware of the objective of the translation (T1); and the second, who was not from the health area and was not informed about the objective of the study (T2). The two versions generated by the translators (T1 and T2) were gathered and synthesized into a single final instrument (T12) in order to verify differences between the translations (T1 and T2). The version (T12) was analyzed by one of the researchers, named in this study as "observer[9]". This is a university professor, with a doctorate and expertise in the method and thematic of the instrument, in addition to mastering the English language, following strict care to maintain the meaning of the original scale[7].

In the third stage, referring to back-translation, from the T12 version, the scale was independently re-translated to the original language by two American translators (R1 and R2), living in Brazil and fluent in Portuguese and familiar with the Brazilian culture. The translators had no experience in the health field and were not informed about the objective of the study. This stage aimed to identify discrepancies in the translation process.

In the fourth stage, it was performed the analysis of semantic, idiomatic, cultural and conceptual equivalences[9] by an expert committee. Such equivalences were evaluated through four options on a Likert scale (1 to 4 points): 1- non-equivalent item/ "requires complete retranslation"; 2- item needs major revision to be equivalent/ "requires partial translation with many changes"; 3- equivalent item,

but it needs minor adjustments/"requires partial retranslation with minor adjustments"; and 4- absolutely equivalent item/"does not require retranslation". If they pointed to partial or complete retranslation for a given equivalence, the experts should describe suggestions for improvement[8].

The expert committee was composed by 25 professionals, 20 of whom experts in UI and five professionals in the field of applied linguistics. The number of participants was defined according to the methodological framework[12], which suggests between six and 20 specialists.

As a selection criterion, all experts had knowledge in English language. In addition, it was considered previous participation in expert committees for studies on cross-cultural adaptation of instruments[9]. For the selection of experts in the field of linguistics, work in translation studies was prioritized. For UI experts, care experience or research experience in the area of UI, with scientific publication or preparation of thesis (specialization, master or doctorate) on UI, according to criteria adapted from Fhering[13]. Recruitment was made by convenience, through the indication of researchers who developed studies with the same methodological scope and by the WhatsApp application group of nurses working in the UI area from different regions of Brazil, in which the study authors participate. An e-mail was sent to each expert with the invitation letter, the access link to the e-Surv web platform and the free and informed consent form (FICF).

In the pre-testing (fifth stage), as the methodological framework adopted suggests the participation of 30 to 40 individuals[9], 40 men with PRPUI were invited. The participants were asked about the comprehensibility and ease of choice of items. It was decided to apply the instrument orally in order to facilitate the identification of words or terms incomprehensible by the interviewer. When the patient requested to repeat the item again or expressed not having understood a word, the difficulty was recorded. Items that 15% of the participants had difficulty in understanding were reformulated[14]. In the sixth stage, reports on the cross-cultural adaptation process of the scale were sent to the authors of the original version.

Finally, the analysis of the measurement properties was performed[9]. The definition of the number of participants was based on the COSMIN[10] recommendation which suggests seven observations for each item of the instrument to be validated. Thus, considering the number of UISRP items equal to eight, the minimum estimated sample size was 56 men with PRPUI. Both for the pre-testing stage and for the evaluation of the measurement properties participated men aged between 18 and 80 years, submitted to RP between two months and two years, in postoperative follow-up at the institution under study, with hearing and orally capacity to answer the questions of the instrument. Those who were using an indwelling urinary catheter (IUC) and/or reported preoperative UI were excluded. It is noteworthy that the pre-testing participants were different from the participants in the measurement properties assessment stage.

Data collection referring to the measurement properties analysis stage was performed in the institution's nursing room on the return days scheduled with the urologists. Due to the low schooling level and the possible reading difficulty of some participants, the form of application of the instruments was the same performed in the pre-testing, from the oral reading of the items by the researcher. The interviews lasted an average of 30 minutes.

The instrument under study called Urinary Incontinence Scale After Radical Prostatectomy has eight statements evaluated by a five-point Likert scale, in which zero corresponds to "never" and four to "always". The total score ranges between zero and 32, with higher scores indicating greater severity of UI. Content validity presented indexes between 0.90 and 1.00, which suggests that more than 90% of the consulted experts obtained agreement among themselves for each item of the instrument. The reliability analysis of the original version showed good internal consistency (Cronbach's alpha equal to 0.90) in a sample of 102 patients undergoing RP. Construct validity was tested using exploratory factor analysis (EFA) which ranged from 0.48 to 0.90 between items and provided support for viewing the UISRP as a one-dimensional measure. The criterion validity of the scale was confirmed by the correlation between UISRP and "University of California, Los Angeles Prostate Cancer Index" (UCLA-PCI) ($r = 0.74$, $p < 0.001$) and between UISRP and one-hour pad test ($r = 0.58$, $p < 0.001$)[7].

For the analysis of the measurement properties of the scale, in addition to the Brazilian Portuguese version of the UISRP, two other instruments Brazilian version of the King's Health Questionnaire – KHQ[6] and the Brazilian version of the International Consultation on Incontinence Questionnaire – Short Form – ICIQ-SF[5] were used. These instruments were chosen because they are related to the severity and impact of UI on QoL.

The KHQ[6] has the objective of assess the impact of UI on QoL from 21 questions divided into nine domains: general health perception (GHP); incontinence impact (II); role limitations (RL); physical limitations (PL); social limitations (SL); personal relationships (PR); emotions (E); sleep/energy (S/E) and severity measures (SM). The scores for each domain range from 0 to 100, and the higher the score, the worse the QoL related to that domain. It was adapted and validated

for the Brazilian culture in a sample of patients with UI. The Cronbach's alpha coefficient of the scale was 0.87. The test-retest reliability was analyzed by the Intraclass Correlation Coefficient (ICC), ranging from 0.53 (domain "general health perception") to 0.81 (domain "severity measures")[6].

The ICIQ-SF Brazilian version[5] is composed by three questions that assess the frequency, severity and impact of UI on QoL. The total score is obtained by adding the scores of the questions, and the values range from zero to 21, classified as: no impact (0 points); light impact (from 1 to 3 points); moderate impact (from 4 to 6 points); severe impact (from 7 to 9 points) and very severe impact (10 or more points). It was adapted and validated in a sample of 123 patients with UI and obtained a reliability index (Cronbach's alpha) of 0.88[5]. In addition to the aforementioned instruments, a sociodemographic and clinical questionnaire was also used to the participant's characterization.

Data were organized in a spreadsheet using Excel® version 2007 and exported to the statistical software Statistical Package for Social Science® (SPSS) version 21.0, and Factor version 10.10.03 developed by *Rovira i Virgili* University. The results obtained for the explanatory variables (sociodemographic and clinical characterization) were analyzed using descriptive statistics with measures of central tendency (mean or median) and variability (standard deviation or 25th and 75th percentiles – p25 and p75) for continuous variables, and relative frequency for categorical variables.

For the evaluation of the scale by the expert committee, the content validation index (CVI) was considered, calculated by the sum of answers three (equivalent item, but requires minor adjustments) and four (absolutely equivalent item) of the participants and dividing the result by the total number of responses, whose value must be greater than 0.90[8].

In the analysis of measurement properties, the EFA was performed using the Factor program to assess the structural validity of the scale, using a polychoric correlation matrix with the Robust Diagonally Weighted Least Squares (RDWLS) extraction method. It is noteworthy that the choice of EFA in detriment to confirmatory is based on the fact that despite the original author having presented a one-dimensional structure, the analyses performed were based on main components[7]. Thus, it is currently known that there are more robust EFA strategies, such as, for example the method adopted in the present study[15].

Prior to the EFA, the sampling adequacy was determined by the Kaiser-Meyer-Olkin (KMO) test, whose required score must be greater than or equal to 0.60. A hypothesis test was also performed using Bartlett's test of sphericity, which verifies if the covariance matrix is an identity matrix and checks if there are no correlations. Ideally, the test should be significative and the null hypothesis should be refuted[15].

The decision on the number of factors to be retained was performed using the technique of parallel analysis with random permutation of the observed data and the rotation used was the Robust Promin. From the correlation matrix, the commonalities and the factor loading were estimated. Only items with factor loadings equal to or above 0.4 remained on the scale[16].

The adequacy of the model was evaluated using the chi-square test (χ^2) and the adjustment indexes Root Mean Square Error of Approximation (RMSEA), Comparative Fit Index (CFI) and Tucker-Lewis Index (TLI). The χ^2 test verifies the probability of the model adjusting the data and the analysis is based on the ratio between the test statistic and the degree of freedom (χ^2/g.l), with the maximum value for an adequate fit equal to three[15]. RMSEA values should be less than 0.08, and CFI and TLI values must be above 0.90 or, preferably, 0.95[17].

For the hypothesis test of the UISRP (translated and adapted version), the total score of the same was compared with the score of each domain of the KHQ and with the total score of the ICIQ-SF. Spearman's correlation coefficient was adopted, which considers: correlation coefficients < 0,4 (weak magnitude correlation), > 0,4 to < 0.7 (moderate magnitude) and > 0,7 (strong magnitude)[18]. Thus, the following hypotheses were tested: 1- the higher the score on the UISRP scale (greater severity of UI), the higher the score in the KHQ domains (worse QoL); 2- the higher the score on the UISRP scale (greater severity of UI), the higher the ICIQ-SF score (greater impact on QoL).

For criterion validity, the complaint of any involuntary leakage of urine[2] was considered the gold standard criterion. A comparison was then performed, using the Mann-Whitney test, between the scores obtained by the UISRP (translated and adapted version) and the complaint of leak or not of urine. The complaint was evaluated by one of the items that make up the ICIQ-SF (How often do you leak urine?), with the answer "never" classifying the individual as continent and answers "always" as incontinent, regardless of frequency.

Item reliability was analyzed using Cronbach's alpha coefficients and composite reliability, considering values greater than 0.7 as acceptable reliability[19].

Finally, the most appropriate prediction cut-off point was defined to discriminate between continent and incontinent individuals. Thus, it was conducted the construction of the receiver operating characteristics curve (ROC Curve – Receiver Operating Characteristics). It was highlighted the cut-off point whose values had the highest sum of sensitivity and

specificity indicated in the literature as preferred[20]. In all analyses, a significance level of 5% was considered.

This research was authorized by the original authors of the scale via e-mail and approved by the research ethics committee of the proposing institution under opinion No. 2.335.585/2017 and CAAE No. 73961317.4.3001.5130. All participants who agreed to participate in the research signed the FICF in compliance with Resolution 466/12 of the National Health Council.

RESULTS

Regarding the characterization of the expert committee, 72.0% (n=18) were female, 100% (n=25) declared that they understood English with ability in text reading and 56% (n=14) had already participated in an expert committee for the validation of measurement instruments. Regarding the specialists in the field of applied linguistics, 100% (n=5) worked in translation studies. As for the UI experts, 100% (n=20) were nurses and 20% (n=4) also had training in physical therapy. Also, among the UI experts, 60% (n=12) had a publication in the UI area, 40% (n=8) developed a course thesis involving the theme, and 25% (n=5) in courses of specialization, 10% (n=2) in specialization and master's degree and 5% (n=1) in specialization, master's degree, and doctorate. From the specialists in the field of linguistics, 16% (n=4) were still studying for a doctorate or had already completed doctorate.

In the first round of the expert committee, seven items and the instructions for completing the scale had a CVI of less than 0.90, thus requiring orthographic and linguistic changes. Thus, after the second round and with the return of 17 participants, the CVI was greater than 0.90 for all items on the scale, ranging from 0.94 to 1.00, as shown in Table 1.

As for the pre-testing, the mean age of the 40 participants was 66.8 years (±4.8), most (80.0%) were unemployed or retired, with a mean of 4.28 (±3.89) years of study. The three changes made after the pre-testing were: (1) replacement of the expression "urinary incontinence" by "urine leakage" in the instructions for completing the scale; (2) substitution of the verb "run" for "walk"; (3) inclusion of meanings for all instrument answer options. The original version and the final version after the cross-cultural adaptation process are shown in Chart 1.

In the stage related to the analysis of measurement properties, the sample consisted of 80 participants, who had a mean age of 66 (±8.8) years, 23.8% of residents of rural areas. More than half (80%) were retired or unemployed, 58.8% were white and 77.5% had a partner. The mean number of years of complete education was four (±3.3) years. As for the time after surgery, 14 (17.5%) participants had between two and three months after surgery, 13 (16.3%) from three to six months, 33 (41.3%) from six months to one year and 20 (25.0%) between one and two years. Therefore, the mean time after surgery was 286.2 (±191.4) days, which corresponds to approximately nine and a half months. Regarding data on UI, 40% of men reported using diapers or pads, with an average of two devices per day. Only 21.3% performed pelvic floor muscle training to control UI.

The Bartlett's test of sphericity (χ^2 (28) =869.2; $p < 0.001$) and KMO (0.773) suggested interpretability of the correlation matrix of the items, which justified the performance of the EFA. The parallel analysis showed that the scale fits a one-dimensional structure, since a factor is responsible for the explained variance of the data (empirical) equal to 77.3%, being, therefore, the only one superior to the explained variance of the random data (simulated).

Factor loadings were higher than 0.40 in all items, except for item two (I always get up at night two or more times to urinate) which had a factor loading of 0.322 (Table 2). Thus, it was opted for the exclusion of item two and all subsequent validity and reliability analyses were performed considering the seven-item scale.

The factorial structure of the one-dimensional theoretical model of the instrument showed adequate fit indexes (χ^2 = 13.019, gl = 20; χ^2/g.l.= 0,65; RMSEA = <0,001; CFI = 1,00; TLI = 1,00).

The researchers used the scores of each domain of the KHQ scale and the total score of the ICIQ-SF scale to perform the hypothesis test, and the results showed that the greater the severity of UI, the greater the impact on QoL (Table 3). There was a significant correlation between EIUPR scores and KHQ domains, except for "perception of health and personal relationships". In cases where the correlation was significant, the strength of the correlation ranged between moderate and strong magnitude, except for the domain "sleep/energy". A significant correlation was also found between the EIUPR and the ICIQ-SF, indicating a positive correlation of strong magnitude.

Regarding criterion validity, there was a statistically significant difference in the EIUPR total score between individuals who reported leaking urine (incontinent) (median: 0 grams; p25:0; p75: 1.0) and those who denied any urinary leakage (continents) (median: 11 grams; p25: 5.0; p75: 24.0) (p<0.001).

As for the reliability of the model, the global Cronbach's alpha (0.94) and the composite reliability showed satisfactory values (0.97). The correlation coefficients of each item on the scale, as well as Cronbach's alpha if the item is excluded, are

Table 1 – Description of Urinary Incontinence Scale After Radical Prostatectomy (UISRP) items after the first and second rounds performed by the Expert Committee with the content validity index. (n=25). Divinópolis, Minas Gerais, Brazil, 2018

	1st round	CVI*	2nd round	CVI*
Title	*Escala de Incontinência Urinária Pós-Prostatectomia Radical (EIUPR)*	0.92	*Escala de Incontinência Urinária Pós-Prostatectomia Radical (EIUPR)*	-
Instruction	*Por favor,* ***consulte*** *o nível de gravidade e* ***depois*** *circule o número correspondente a cada item* ***considerando*** *sua experiência com* ***IU*** *nas últimas 4 semanas.*	0.60	*Por favor,* ***considere*** *o nível de gravidade e* ***então*** *circule o número correspondente a cada item* ***baseado*** *em sua experiência com a* ***incontinência urinária*** *nas últimas 4 semanas.*	0.94
1	*Eu não consigo* ***esperar*** *mais de 2 horas* ***para*** *urinar.*	0.84	*Eu não consigo* ***ficar*** *mais de 2 horas* ***sem*** *urinar.*	0.94
2	*Eu sempre* ***acordo*** à noite duas ou mais vezes para urinar.	0.80	*Eu sempre* ***me levanto*** à noite duas ou mais vezes para urinar.	0.94
3	*Antes de* ***ir*** *ao banheiro, eu tenho* ***vazamento de urina****.*	0.48	*Antes de* ***chegar*** *ao banheiro,* ***eu tenho perda de urina****.*	1.00
4	*Eu sempre uso fraldas devido a problemas urinários.*	0.92	*Eu sempre uso fraldas devido a problemas urinários.*	-
5	*Quando* ***me levanto pra me sentar na cama ou sair dela, eu urino.***	0.32	*Quando* ***eu sento ou levanto da cama, eu tenho perda de urina.***	1.00
6	*Quando* ***ocorrem ações imediatas, tais como tosse, levantamento de objetos pesados, gargalhadas altas, etc, eu urino****.*	0.44	*Quando* ***faço esforço*** *como* ***tossir****,* ***levantar*** *objetos pesados,* ***dar*** *gargalhadas, etc.,* ***eu tenho perda de urina.***	0.94
7	*Após ficar um longo período de pé, a urina geralmente sai.*	0.60	*Após ficar um longo período* ***em*** *pé,* ***tenho perda de urina.***	1.00
8	*Quando me exercito (por exemplo, corro),* ***urina sai.***	0.68	*Quando me exercito (por exemplo, corro),* ***tenho perda de urina.***	1.00
Answer options	*Nunca/ Sempre/ Gravidade*	1.00	*Nunca/ Sempre/ Gravidade*	-

Source: Research data, 2018
Note: *CVI- Content Validity Index

shown in Table 4. It is observed that the alpha value ranged between 0.92 and 0.95. Regarding the correlation strength of the items, there was a strong correlation between the total scale and items four, six and seven, and moderate correlation with the other items. The exclusion of one of the seven items did not change the alpha values, which remained between 0.92 and 0.95, compared to the total Cronbach's alpha (0.94). The result obtained points out to a satisfactory value for the internal consistency of the EIUPR.

Original version	Adapted final version
Title: Urinary incontinence Scale after Radical Prostatectomy (UISRP)	***Título:*** *Escala de Incontinência Urinária Pós-Prostatectomia Radical (EIUPR)*
Directions: Please consult the severity level and then circle the number following each statement based on your experience of UI in the past 4 weeks.	***Instruções:*** *Por favor, considere o nível de gravidade e então circule o número correspondente a cada item baseado em sua experiência com a perda de urina nas últimas 4 semanas.*
Answer options- Severity: 0- Never / 1 / 2 / 3 / 4- Always	***Opções de resposta-*** *Gravidade: 0- Nunca / 1- Quase nunca / 2- Às vezes / 3- Quase sempre / 4- Sempre*
1 – I cannot wait for more than 2 hours to urinate.	1- *Eu não consigo ficar mais de 2 horas sem urinar.*
2 – I always wake up at night to urinate two or more times.	2- *Eu sempre me levanto à noite duas ou mais vezes para urinar.*
3 – Before going to the restroom, I have urine leakage.	3- *Antes de chegar ao banheiro, eu tenho perda de urina.*
4- I always wear diapers because of urinary problems.	4- *Eu sempre uso fraldas devido a problemas urinários.*
5 – When sitting up or getting out from the bed, I will urinate.	5- *Quando eu sento ou levanto da cama, eu tenho perda de urina.*
6 – When immediate actions, such as coughing, lifting heavy objects, laughing out loud, etc..occur, I urinate.	6- *Quando faço esforço como tossir, levantar objetos pesados, dar gargalhadas, etc., eu tenho perda de urina.*
7- After a long time standing, the urination often comes out.	7- *Após ficar um longo período em pé, tenho perda de urina.*
8 – When exercising (e.g. jogging), urine comes out.	8- *Quando me exercito (por exemplo, caminho), tenho perda de urina.*

Chart 1 – Translation and cross-cultural adaptation stage of the Urinary Incontinence Scale after Radical Prostatectomy (UISRP). Divinópolis, Minas Gerais, Brazil, 2018
Source: Research data, 2018

Regarding the ROC curve, Figure 1 shows that the EIUPR had a good predictive power, that is, the area under the curve was 0.930 (confidence interval – 95% CI: 0.874; 0.986). The cut-off point was established at four, as it presented the highest sum between sensitivity (79.2%) and specificity (100%). This indicates that 100% of continent men have scores below four on the EIUPR, and among incontinent men, 79.2% have scores above four.

Table 2 – Results of the exploratory factor analysis of the *Escala de Incontinência Urinária Pós-Prostatectomia Radical* (EIUPR) with their respective commonalities and factor loadings (n=80). Divinopolis, Minas Gerais, Brazil, 2018

Item	Commonality	Factor loading
1- Eu não consigo ficar mais de 2 horas sem urinar.	0.794	0.791
2- Eu sempre me levanto à noite duas ou mais vezes para urinar.	0.676	0.322
3- Antes de chegar ao banheiro, eu tenho perda de urina.	0.940	0.923
4- Eu sempre uso fraldas devido a problemas urinários.	1.000	0.953
5- Quando eu sento ou levanto da cama, eu tenho perda de urina.	1.000	0.979
6- Quando faço esforço como tossir, levantar objetos pesados, dar gargalhadas, eu tenho perda de urina.	0.940	0.732
7- Após ficar um longo período em pé, tenho perda de urina.	0.987	0.985
8- Quando me exercito (por exemplo, caminho), tenho perda de urina.	1.000	0.999

Source: Research data, 2018

Table 3 – Correlation between the EIUPR total score with the ICIQ-SF and the KHQ domains (n=80). Divinópolis, Minas Gerais, Brazil, 2018

EIUPR§	Coefficient*	p-value
General Health Perception Domain‡	0.047	0.677
Incontinence Impact Domain‡	0.693	<0.001†
Role Limitations Domain‡	0.619	<0.001†
Physical Limitations Domain‡	0.654	<0.001†
Personal Relationships Domain‡	0.078	0.466
Emotions Domain‡	0.667	<0.001†
Social Limitations Domain‡	0.600	<0.001†
Sleep/Energy Domain‡	0.359	0.001†
Severity Measures Domain‡	0.822	<0.001†
ICIQ-SF Total Scoreǁ	0.814	<0.001†

Source: Research data, 2018
Note: * Spearman correlation; †p≤0.05; ‡KHQ – King's Health Questionnaire; §EIUPR – *Escala de Incontinência Urinária Pós-Prostatectomia Radical*; ǁICIQ-SF – International Consultation on Incontinence Questionnaire – Short Form.

Table 4 – Presentation of the values of item-total correlation coefficients of the EIUPR and Cronbach's alpha values, if the item is excluded (n=80). Divinópolis, Minas Gerais, Brazil, 2018

EIUPR* (7 items)	Item-total correlation coefficient	Cronbach's Alpha (if excluded item)
1- Eu não consigo ficar mais de 2 horas sem urinar.	0.68	0.94
2- Antes de chegar ao banheiro, eu tenho perda de urina.	0.84	0.93
3- Eu sempre uso fraldas devido a problemas urinários.	0.83	0.93
4- Quando eu sento ou levanto da cama, eu tenho perda de urina.	0.91	0.92
5- Quando faço esforço como tossir, levantar objetos pesados, dar gargalhadas, eu tenho perda de urina.	0.61	0.95
6- Após ficar um longo período em pé, tenho perda de urina.	0.87	0.93
7- Quando me exercito (por exemplo: caminho), tenho perda de urina.	0.91	0.92
EIUPR Global Score*	-	0.94

Source: Research data, 2018
Nota: *EIUPR – *Escala de incontinência urinária pós-prostatectomia radical*

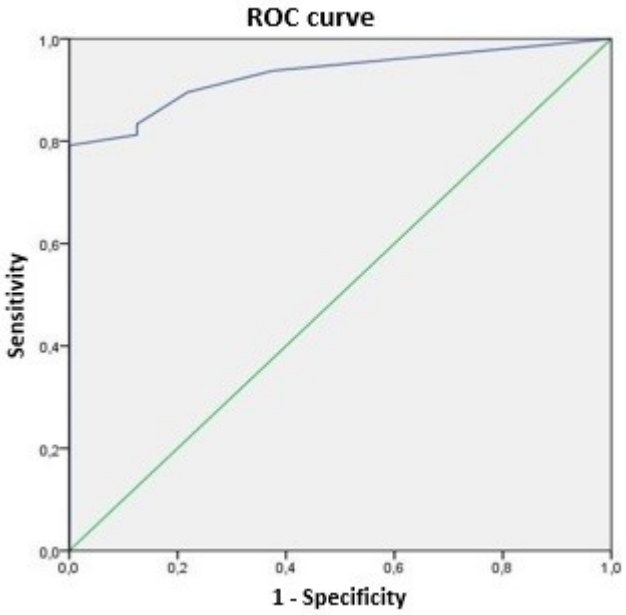

Figure 1 – Graph of ROC curve of EIUPR total scores for UI prediction
Source: Research data, 2018
Note: ROC Curve (Receiver Operating Characteristics)

DISCUSSION

The EIUPR met the equivalence criteria between the original instrument and the culturally adapted instrument, proving to be reliable, understandable, and relevant to Brazilian culture in the context of the PRPUI. It is suggested that the main characteristics of the UISRP are simplicity, clarity and the relationship with the main clinical manifestations associated with UI. The statements encompass the two main types of UI present in men undergoing RP, urgency and effort[2–3], which clarifies their specificity for this target audience.

The evaluation of the scale by the expert committee made it possible to improve it from the point of view of research and care professionals in the UI area, which provided greater rigor in terms of content, in addition to professionals of the linguistics area who contributed to the organization of the best language for the Brazilian context. It is noteworthy that the constitution of the committee is essential for the evaluation of an instrument and must be composed by experts of the explored construct and experts in the area of languages and translation[9].

In the pre-testing, in the filling instructions, the term "urinary incontinence" was not well understood by participants with advanced age and low schooling level. It is noteworthy that this is a profile already identified in another study that evaluated the effectiveness of a teaching program for the discharge of prostatectomized patients[21] and, therefore, technical terms should be avoided as they cause confusion and limit participation. The greater difficulty in reading and understanding basic information also impacts decision-making, since many patients do not ask for clarification on unfamiliar terms, which compromises the effectiveness of communication[14].

Although the one-dimensional structure shown here is in accordance with the study of the original version[7], the EFA results suggested the exclusion of item two "I always get up at night two or more times to urinate". It is known that nocturia is a urinary symptom strongly related to the presence of urgency UI[2]. However, considering that PRPUI is mainly characterized by stress UI (70%)[22], and low relevance of this item may justify the result found.

The hypothesis test showed that, overall, there was a significant positive correlation of strong magnitude between the total score of the EIUPR and the domains evaluated by the KHQ, as well as the general score of the ICIQ-SF. Together, such results confirm the previously raised hypotheses that the worst QoL is related to the greater severity of UI. These data are also corroborated by the international literature that demonstrates that UI significantly affects the QoL of patients after RP[2–3].

As for the criterion validity results, which indicated a statistically significant difference in the total score of the EIUPR between continent and incontinent men, it is known that the severity of UI is directly associated with the amount of urinary leakage regardless of the type: urgency, stress or both[2]. Thus, the result obtained is what was expected and reflects an adequate capacity of the instrument to ensure that the target measure is properly related to variables from which it should differ[8].

The internal consistency of the EIUPR measured by the standardized Cronbach's alpha coefficient and by the composite reliability was satisfactory and adequate according to the literature[18]. In general, the EIUPR has a positive correlation between its items and can really measure the severity of the PRPUI. It is noteworthy that the EIUPR Cronbach's alpha was similar to that reported by the original authors of the scale in the English version (0.90)[7].

Regarding the most appropriate cutoff point to discriminate continent from incontinent individuals, it can be noticed that the ROC curve has the power to discriminate ill patients and healthy patients and the better the test, the more the area under the ROC curve approaches value one[20]. Thus, EIUPR was sensitive, specific, with good predictive power and good diagnostic accuracy.

CONCLUSION

The results showed that the EIUPR meets the equivalence criteria between the original and the adapted instrument, being reliable, understandable, and relevant to the Brazilian culture. The measurement properties were considered satisfactory, which characterizes the scale as valid. Due to its simplicity, brevity and specificity, the instrument becomes practical and useful for use in clinical research and in future epidemiological trials.

As a limitation of this study, the application of the scale in men with low schooling level is evident, whose average years of study was four. Thus, it was decided to read the items of the scale for all participants aiming at standardizing its application, although originally the UISRP was developed for self-completion. This alternative allows the inclusion of patients with low or no education, being a resource of common use, mainly in studies that use scales.

Another limitation refers to the participants' profile in terms of postoperative time, with a predominance of men with surgery time of more than six months. It is known that PRPUI is mainly characterized by stress and urgency UI, however, urinary urgency is more present in the initial phase of the postoperative period, and after one year of surgery few men have urgency UI. On the other hand, the inclusion of participants with up to two years of postoperative period was important because it considers men who have already passed the period of spontaneous improvement of the event, which can occur up to one year after the surgery.

Finally, it is observed that the language of the UISRP scale is a limitation in the process of cross-cultural adaptation of the instrument, as it was validated in China, however, the published version of the scale made available by the original authors was only the English version. The researchers of the original version did not make the instrument available in the Chinese version.

To date, the Brazilian version called EIUPR is the only scale available in the literature capable of evaluating UI with specificity for individuals undergoing RP in Brazil.

The application of this scale can help in the evaluation of the PRPUI and, consequently, provide data that will make it possible to determine the severity and thus support the performance of health professionals in the face of treatment and rehabilitation options. In addition, the scale can be a useful tool in the development of strategies aimed at providing more qualified men's health care.

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