

Original Article

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Validação do “international consultation on incontinence questionnaire urinary incontinence quality of life module”

Validación de la “consulta internacional sobre incontinencia cuestionario de incontinencia urinaria módulo de calidad de vida”

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ABSTRACT

Objective: To Validate the International Consultation on Incontinence Questionnaire Quality of Life for the Portuguese population. Urinary incontinence is a highly prevalent condition with a negative impact on people’s quality of life. The International Consultation on Incontinence Questionnaire Quality of Life was adapted in order to have a standardized structure that allows the assessment of the impact of urinary incontinence on quality of life.

Method: An observational cross-sectional study was carried out with two hundred and twenty participants recruited at the *Centro Hospitalar de Vila Nova de Gaia/Espinho* and at the *Centro Hospitalar Universitário de São João* during the period from September 2019 to January 2020. The psychometric properties of the questionnaire were assessed. For internal consistency, the standardized Cronbach’s alpha coefficient was calculated. In order to obtain construct validity, an exploratory factor analysis was performed using varimax rotation to extract the main components.

Results: The Portuguese version of the questionnaire has 21 items distributed by the three factors found, maintaining the items proposed in the original version. The result of

standardized Cronbach's alpha coefficient, $\alpha=0.906$ overall, confirms the internal consistency of the Portuguese version of the instrument. Pearson's correlation analysis was performed between each item and the item assessing the impact on quality of life in the form of a scale, verifying a positive correlation in all items.

Conclusions: The Portuguese version of the questionnaire proved to be reliable and valid in the study carried out for clinical and research use.

Keywords: Urinary incontinence. Surveys and questionnaires. Validation study. Quality of life.

RESUMO

Objetivo: Validar o *International Consultation on Incontinence Questionnaire Quality of Life* para a população portuguesa. A incontinência urinária é uma condição com elevada prevalência e com impacto negativo na qualidade de vida das pessoas. O *International Consultation on Incontinence Questionnaire Quality of Life* foi adaptado de forma a ter uma estrutura estandarizada e que permite avaliar o impacto da incontinência urinária na qualidade de vida.

Método: Foi realizado um estudo observacional do tipo transversal com duzentos e vinte participantes recrutados no Centro Hospitalar de Vila Nova de Gaia/Espinho e no Centro Hospitalar Universitário de São João durante o período de setembro de 2019 a janeiro de 2020. Foram avaliadas as propriedades psicométricas do questionário. Para a consistência interna foi calculado o coeficiente alfa de Cronbach padronizado. Para obter a validade do constructo foi realizada uma análise exploratória fatorial por rotação varimax para extração dos principais componentes.

Resultados: A versão portuguesa do questionário tem 21 itens distribuídos pelos três fatores encontrados mantendo, no entanto, os itens propostos na versão original. O resultado de coeficiente alfa de Cronbach padronizado, $\alpha=0,906$ global, confirma a consistência interna da versão portuguesa do instrumento. Foi realizada a análise da correlação de Pearson entre cada item e o item de avaliação do impacto na qualidade de vida em forma de escala verificando-se uma correlação positiva em todos os itens.

Conclusões: A versão portuguesa do questionário, mostrou-se confiável e válida no estudo realizado para utilização na clínica e na investigação.

Palavras-chave: Incontinência urinária. Inquéritos e questionários. Estudo de validação. Qualidade de vida.

RESUMEN

Objetivo: Validar la Consulta Internacional sobre Incontinencia Cuestionario de Calidad de Vida para la población portuguesa. La incontinencia urinaria es una condición altamente prevalente con un impacto negativo en la calidad de vida de las personas. Se adaptó el *International Consultation on Incontinence Questionnaire Quality of Life* para tener una estructura estandarizada que permita evaluar el impacto de la incontinencia urinaria en la calidad de vida.

Método: Se realizó un estudio transversal observacional con doscientos veinte participantes reclutados en el *Centro Hospitalar de Vila Nova de Gaia/Espinho* y en el *Centro Hospitalar Universitário de São João* durante el período de septiembre de 2019 a enero de 2020. Las propiedades psicométricas del cuestionario. Para la consistencia interna se calculó el coeficiente alfa de Cronbach estandarizado. Para obtener la validez de constructo se realizó un análisis factorial exploratorio mediante rotación varimax para extraer los componentes principales.

Resultados: La versión portuguesa del cuestionario tiene 21 ítems distribuidos por los tres factores encontrados, manteniendo los ítems propuestos en la versión original. El resultado

del coeficiente alfa de Cronbach estandarizado, $\alpha=0,906$ global, confirma la consistencia interna de la versión portuguesa del instrumento. Se realizó el análisis de correlación de Pearson entre cada ítem y el ítem que evalúa el impacto en la calidad de vida en forma de escala, verificándose una correlación positiva en todos los ítems.

Conclusiones: La versión portuguesa del cuestionario demostró ser confiable y válida en el estudio realizado para uso clínico y de investigación.

Palabras clave: Incontinencia urinaria. Encuestas y cuestionarios. Estudio de validación. Calidad de vida.

INTRODUCTION

Urinary incontinence (UI) is a highly prevalent condition with a negative impact on people's quality of life^(1,2). The International Continence Society (ICS) defines UI as a complaint of involuntary loss of urine⁽³⁾. UI can be considered a common condition, associated with the aging process, being two to three times more prevalent in women than in men^(4,5).

Despite not being a life-threatening condition, it has a great impact on quality of life. Urinary incontinence has a significant impact at the psychosocial level with significant indirect costs⁽⁶⁾. These costs are associated with a high emotional burden and social isolation, and direct costs related to spending on medical devices to contain urine and carrying out treatments⁽⁷⁾.

Instruments have been used for assessment of the specific quality of life related to urinary incontinence. The International Consultation on Incontinence Questionnaire Quality of Life (ICIQ-LUTSQoL) was adapted to have a standardized structure allowing the assessment of the impact of urinary incontinence on quality of life. It is a twenty-two question questionnaire, psychometrically robust and self-administered, for use in clinical practice and in research. The ICIQ-LUTSQoL is the correspondent of the "King's Health Questionnaire" (KHQ) adapted according to the structure of the International Consultation on Incontinence Questionnaire (ICIQ) by the ICIQ Study group, providing a detailed assessment of the impact of UI on quality of life⁽⁸⁾. In urinary incontinence, the perception of its impact on quality of life and the measurement of its severity would be inadequately assessed using generic questionnaires. In view of this need, a specific questionnaire was constructed and validated in English to assess the impact of urinary incontinence on women's quality of life, the KHQ⁽⁹⁾. The ICIQ-LUTSQoL is a questionnaire that includes twenty-two simple questions, divided into eight domains that allow assessing the impact on quality of life in its different dimensions, given the presence of urinary incontinence. In each of the questions, is also assessed the grade of impact of each of these domains. The score is summed in each of the domains, ranging

from 0 to 100, where the higher the score, the worse the quality of life related to that domain⁽¹⁰⁾. The validation of this instrument in the Portuguese population, in a hospital setting, will allow assessing its suitability and reliability.

The use of this questionnaire as an instrument validated for the Portuguese population allows for a more systematic assessment of the impact of urinary incontinence on quality of life. This assessment will guide the interventions of health professionals in monitoring people with urinary incontinence.

The objective of the study is to validate the ICIQ-LUTSQol for the Portuguese population. The recommendations of *Guillemin et al.* were complied which indicates five stages for the instrument validation, based on the study hypothesis: The ICIQ-LUTSQol translated and validated for the Portuguese population is an instrument that allows assessing the quality of life in people with urinary incontinence.

METHODS

With the authorization for adaptation and validation by the ICIQ study group, an observational, cross-sectional study was conducted with two hundred and twenty participants, of both genders, who sought the Urology and Gynecology outpatient service of the *Centro Hospitalar de S. João*, the urology service and the Urology and Gynecology inpatient service of the *Centro Hospitalar Vila Nova de Gaia/Espinho*, reference institutions in northern Portugal. Data collection took place from September 2019 to January 2020. The number of sample elements must be at least five times the number of items in the scale, so the sample of 220 participants was constituted⁽¹¹⁾, obtained the approval of the ethics committees of the *Centro Hospitalar de S. João* with No. 139/19 and of the *Centro Hospitalar Vila Nova de Gaia/Espinho* with No. 99/2019-2. Patients under eighteen years old were excluded. Patients of both genders with urinary problems were included.

In the approach to the participants, the study was explained and their consent to participate was requested in compliance with the Helsinki principles⁽¹²⁾. Filling out the ICIQ-LUTSQol was requested at the end of the nursing consultation or at the beginning of hospitalization, either in Urology or in Gynecology.

As already mentioned, this questionnaire is self-administered and assesses the impact of urinary incontinence on quality of life comprising different domains.

In the first part of the study, the recommendations of *Guillemin et al.* were followed to establish the cultural equivalence of the original English version of the ICIQ-LUTSQol, which foresees five stages⁽¹³⁾: initial translation, translation synthesis, back-translation, committee

review and pre-testing of the final version. The procedure was started after authorization by the ICIQ study group, according to the following stages:

1. Initially, two translations were performed by Portuguese translators, fluent in English language, knowledgeable of the study objectives during February and March 2019, who worked independently.
2. The two translations were edited in order to achieve adjustment in a single version.
3. The back-translation into English was then performed by two English people fluent in Portuguese language and unaware of the study objectives between April and May 2019.
4. After adjustment of the back-translation with the original in English, the translation was considered grammatically and semantically equivalent to the original version and suitable for submission to a group of three experts, in the health area, Portuguese and fluent in English language, during the June 2019.
5. After this verification, the Portuguese version of the ICIQ-LUTSQoL was pre-tested in ten patients from the gynecology outpatient clinic at *Centro Hospitalar de S. João* in August 2019.

Statistical analysis

A descriptive analysis was performed using the frequencies of categorical variables and measures of position and dispersion of continuous variables.

As a measure of reliability, the instrument's internal consistency was assessed. For internal consistency, the standardized Cronbach's alpha coefficient was calculated. The significance level adopted was 5% for a 95% CI.

For assessment of the construct validity, an exploratory factor analysis of the instrument was performed using varimax rotation and the analysis of Pearson's correlation between each item and the item assessing the impact on quality of life. It was used the Statistical Package for the Social Sciences (SPSS) software version 27.0 for Windows.

RESULTS

Two hundred and twenty users were interviewed, with different urological complaints, being 193 (87.7%) female and 27 (12.3%) male (Table 1).

Table 1 - Distribution of participants by gender. Porto, Portugal, 2020

	Frequency	Percentage
Male	27	12.3
Female	193	87.7
Total	220	100.0

Source: Study database analyzed by SPSS 27.0

Participants had a mean age of 58.37 with a standard deviation of 13.486 and a minimum age of 24 years and a maximum of 94 years. It was verified that 73 (33.2%) are over 65 years old, 126 (57.3%) are between 40 and 65 years old and 21 (9.5%) are aged between 24 and 40 years old (Table 2).

Table 2 - Distribution of participants by age groups. Porto, Portugal, 2020

	Frequency	Percentage
24-40	21	9.5
40-65	126	57.3
>65	73	33.2
Total	220	100.0

Source: Study database analyzed by SPSS 27.0

Regarding the impact that the urinary problem has on quality of life, on a scale from 0 to 10 where 0 is nothing and 10 corresponds a lot, we found out that 134 (60.9%) of the participants were positioned between 8 and 10 on this scale, 51 (23.2%) were positioned between 4 and 7 on this scale and 35 (15.9%) were positioned between 0 and 3, allowing us to state that the impact of the urinary problem interferes with more half of the study participants.

To obtain construct validity, an exploratory factor analysis was performed using varimax rotation to extract the main components, except for the questions on the impact of incontinence associated to each question and the overall perception of the impact of incontinence, as they are single-item measures. Four factors were identified, letting two isolated questions, presenting a value close to one, questions 9a and 10a, with a Cronbach's alpha of 0.4 making it impossible its use, so it was decided to include in the daily activities that corresponds to factor 1, thus leaving a three-factor extraction. Table 3 shows the final structure of the ICIQ-LUTSQol Portuguese version. The results were grouped according to the order of items presentation in order to facilitate reading.

Table 3 - Factor analysis of the Portuguese version of the ICIQ-LUTSQol.Porto, Portugal, 2020

Items	Factor 1	Factor 2	Factor 3
3a-To what extent does your problem affect your household tasks?	0.774		
4a-Does your urinary problem affect your job, or your normal daily activities outside the home	0.807		
5a-Does your urinary problem affect your physical activities	0.784		
6a-Does your urinary problem affect your ability to travel	0.799		
7a-Does your urinary problem limit your social life	0.642		
8a-Does your urinary problem limit your ability to see/visit people		0.547	
9a-Does your urinary problem affect your relationship with your partner		0.927	
10a-Does your urinary problem affect your sex life		0.936	
11a-Does your urinary problem affect your family life		0.563	
12a-Does your urinary problem make you feel depressed		0.792	
13a-Does your urinary problem make you feel anxious or nervous		0.812	
14a -Does your urinary problem make you feel bad about yourself		0.807	
15a-Does your urinary problem affect your sleep		0.627	
16a- Do you feel worn out or tired		0.747	
21a-Do you feel embarrassed because of your urinary problem		0.599	
17a-Wear pads to keep dry			0.583
18a-Are you careful about how much fluid you drink			0.509
19a-Do you change your underclothes when they get wet			0.712
20a- Worry about the possibility of smelling bad			0.680

Source: Study database analyzed by SPSS 27.0

Thus, the Portuguese version of the ICIQ-LUTSQol has 21 items distributed by the three factors found. Factor 1 was assigned by “Daily activities”, consisting of five items, Factor 2 which was assigned by “Emotions and social relationships” encompassing ten items and Factor 3 which was assigned by “Urinary symptoms” which encompassed four items. The Portuguese version clustered the items into three factors, maintaining, however, the proposed items in the original version.

As a measure of reliability, the instrument’s internal consistency was assessed using the standardized Cronbach’s alpha coefficient. The overall result of $\alpha=0.906$ allows us to state that the instrument has almost perfect internal consistency⁽¹⁴⁾. Table 4 shows the standardized Cronbach’s alpha overall score value and of each factor identified in the Portuguese version of the ICIQ-LUTSQol with values ranging between 0.602 for the domain corresponding to urinary symptoms and 0.885 for the domain corresponding to emotions and social relationships, suggesting an almost perfect internal consistency and high reliability. These results confirm the internal consistency of the Portuguese version of the ICIQ-LUTSQol. In

general, the instrument's Portuguese version has a positive correlation between its items, really assessing the impact of urinary incontinence on the participants' quality of life.

Table 4 - Psychometric properties of the Portuguese version of the ICIQ-LUTSQol (n=220). Porto, Portugal, 2020

Domain	Standardized Cronbach's α	ICC (95 %CI)
Daily activities	0.877	0.876 (0.848-0.900)
Emotions and social relationships	0.885	0.875 (0.849-0.899)
Urinary symptoms	0.602	0.596 (0.501-0.676)
Overall Score	0.906	

Source: Study database analyzed by SPSS 27.0

ICC: intraclass correlation coefficient; CI: confidence interval

Pearson's correlation analysis was performed between each item and the item assessing the impact on quality of life in the form of a scale verifying a positive correlation in all of the items. In items 3a to 16a, 20a and 21a, the correlation was above 0.8, with a significance level of $p < 0.001$, considered high. In items 17a, 18a and 19a, the correlation was between 0.5 and 0.6, with a significance level of $p < 0.001$, considered moderate.

DISCUSSION

After the factor analysis of the Portuguese version of the instrument, we can state that the original structure of the instrument consisting of seven factors was not replicated. In this study, the Portuguese version of the ICIQ-LUTSQol kept all the items included in the original version, but the factor analysis of main component resulted in a structure consisting of three factors instead of the original seven-factor structure. This result may probably be explained by the assumptions described that suggest that the interpretation of results related to symptoms and aspects of quality of life in different populations can be influenced by cultural factors⁽¹⁵⁾. This three-factor structure is similar to that found in the validation of the Portuguese version of the KHQ, which has a similar structure to the ICIQ-LUTSQol⁽¹⁶⁾.

The psychometric analysis comprises the assessment of the quality of a measurement instrument based on reliability and validity tests⁽¹⁷⁾. The main criteria to determine the quality of a quantitative measure is reliability. This refers to the consistency with which the instrument measures the attribute. Reliability, in general, was very satisfactory and the item analysis for each factor showed that they were all significantly associated with the global questionnaire to which they belong, contributing to its internal consistency.

The limitations that this study presents are about the population sampling, consisted predominantly by the female gender. The selection of participants in the study consisted of users with complaints of urine leaks who attended urology consultations or were hospitalized in urology or gynecology, thus being a convenience sample. The sample was thus consisted of a sole objective of validating the instrument for the Portuguese culture, and some of the participants answered the questionnaire immediately before carrying out urodynamic studies. The authors of the KHQ selected participants based on their complaints and also aimed to assess the psychometric properties of the new instrument, in which the assessment of quality of life according to the diagnosis of the urodynamic study was a secondary objective⁽⁹⁾. The validation study of KHQ for the Portuguese language involved one hundred and three women diagnosed with SUI recruited from the Gynecology and Obstetrics Department of a Hospital Unit⁽¹⁶⁾.

The calculation of Cronbach's alpha coefficient allows to estimate the extent to which each item on the scale equivalently measures the same concept, that is, it assesses the fidelity of an instrument through internal consistency⁽¹⁸⁾. The calculated internal consistency of the instrument was satisfactory, obtaining an overall score of 0.906, which exceeds the minimum value used as a reference of 0.80 for the use of questionnaires in the investigation⁽¹⁹⁾. This result is consistent with the result found in other studies that conducted the validation of this instrument, confirming the internal consistency of the instrument and its robustness as an instrument that allows assessing the quality of life associated with urinary incontinence^(20,21,22,23). Regarding the internal consistency of the domains separately, values between 0.602 (urinary symptoms) and 0.885 (Emotions and social relationships) were obtained. Despite Cronbach's α , in the domain Urinary symptoms, has a lower value than the other domains, there is no significant change in the standardized overall Cronbach's α value, if this domain is removed, presenting a value of 0.902. The Portuguese version of the ICIQ-LUTSQol presented a correlation between the items and the questions about the assessment in the form of a scale, showing that it allows the assessment of the quality of life in the studied sample, with Pearson's correlation values high between each item and its corresponding rating scale.

The correlation indices obtained in each domain were considered moderate to strong, ranging from 0.596 (urinary symptoms) to 0.876 (daily activities).

CONCLUSION

The Portuguese version of the ICIQ-LUTSQol proved to be reliable and valid in this study, which involved participants of both genders who had urinary leaks, allowing to use it in clinical activity and in research studies. The use of a scale to assess the quality of life in urinary incontinence allows, in clinical practice, to perceive the impact of urinary incontinence on patients' lives, identifying the affected domains. In the research, the use of validated questionnaires to assess quality of life in urinary incontinence allows identifying the impact that urinary incontinence may have on different populations, contributing to greater knowledge about this problem.

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