

Assessing the impact of urinary incontinence on quality of life: systematic review of instruments in Portuguese.

Avaliação do impacto da incontinência urinária na qualidade de vida: revisão sistemática de instrumentos em português.

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Abstract

Introduction: Urinary incontinence (UI) can have a large impact on quality of life (QOL), which can harm social, economic, psychological and sexual aspects. Instruments are used to assess such damages. As it comes to subjective information, questionnaires are suitable tools to measure these variables. **OBJECTIVE:** To identify the instruments used to assess the impact of urinary incontinence on quality of life and evaluate them regarding the psychometric properties. **METHOD:** A search for articles that used specific questionnaires to assess the impact of urinary incontinence on QOL was conducted using the following descriptors: urinary incontinence, questionnaire, quality of life, in English, Portuguese and Spanish in the following databases: PubMed, SciELO and Scopus, then the validation of questionnaires in Portuguese (Brazil) to classify them as to the process of cross-cultural adaptation and psychometric properties. **RESULTS:** Seven questionnaires were found: International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF), International Consultation on Incontinence Questionnaire - Overactive Bladder (ICIQ-OAB), Overactive Bladder Questionnaires (OAB-q), OAB-q generated the short form (OAB-q SF), Urinary Incontinence - Specific Quality of Life Instrument (I-QOL), King's Health Questionnaire (KHQ) and Qualiveen. Only KHQ, ICIQ-SF and ICIQ-OAB followed all the steps of cultural adaptation. ICIQ-OAB and I-QOL showed higher number of assessed and certified psychometric properties. None of the studies showed results on responsiveness, "floor or ceiling" effects and interpretability. **CONCLUSION:** The data collected in this review showed that the instrumentation of UI is being made incomplete and is not respecting the prerequisite of the completion of steps in the process of creation and testing, possibly compromising an effective assessment of quality of life.

Keywords: urinary incontinence, quality of life, questionnaires, validation studies.

Resumo

Introdução: A incontinência urinária (IU) pode causar grande impacto na qualidade de vida (QV), acarretando prejuízos sociais, econômicos, psicológicos e sexuais. Instrumentos são utilizados para avaliar tais prejuízos. Como se trata de informações subjetivas os questionários são ferramentas adequadas para a mensuração destas variáveis. **OBJETIVO:** identificar os instrumentos utilizados na dimensão avaliação do impacto da incontinência urinária na qualidade de vida e, avaliá-los quanto às propriedades psicométricas. **MÉTODO:** Realizou-se uma busca por artigos que utilizaram questionários específicos de avaliação do impacto da IU na QV através dos descritores: urinary incontinence, questionnaire, quality of life, nos idiomas inglês, português e espanhol, nas bases de dados *PubMed*, *SciELO* e *Scopus*. Em seguida, buscou-se as validações dos questionários no idioma português (Brasil) para então avaliá-los quanto ao processo de adaptação transcultural e propriedades psicométricas. **RESULTADOS:** Foram encontrados 7 questionários: International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF), ICIQ-OAB, Overactive Bladder Questionnaires (OAB-q), OAB-q generated the short form (OAB-q SF), Urinary Incontinence - Specific Quality of Life Instrument (I-QOL), King's Health Questionnaire (KHQ) e Qualiveen. Apenas o KHQ, o ICIQ-SF e o ICIQ-OAB seguiram todas as etapas da adaptação transcultural. O ICIQ-OAB e o I-QOL apresentaram maior número de propriedades psicométricas avaliadas e atestadas. Nenhum dos estudos apresentou informações sobre responsividade, efeito chão ou teto e interpretabilidade. **CONCLUSÃO:** Os dados levantados nessa revisão mostraram que a instrumentação da IU está sendo feita de forma incompleta e não está respeitando o pré-requisito de cumprimento das etapas no processo de criação e testagem dos mesmos, possivelmente comprometendo uma avaliação eficaz da qualidade de vida.

Palavras-Chave: incontinência urinária, qualidade de vida, questionários, estudos de validação.

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INTRODUCTION

Urinary incontinence (UI) is defined by the International Continence Society (ICS) as the complaint of any involuntary leakage of urine, which causes social or hygienic problems.^(1,2) Gomes⁽³⁾ complements this definition by stating that UI can impact the quality of life (QOL) of women for causing varied losses, including economical. The prevalence of UI varies between 25 and 45 %, rising the concerns of health professionals about preventive and rehabilitative aspects.⁽⁴⁾

Studies^(4,5) have found that although UI is widely studied and is clearly a public health problem among women, it should be explored with tools of easy management and high applicability,^(6,7) since there are discrepancies of information when comparing data from research using different instruments.⁽⁸⁻¹⁰⁾

To fill the gap in the selection of these instruments and to improve safety, accuracy and application of these instruments, researchers and professionals should consider the construction process and the cultural adaptation to the target language and assessment of psychometric properties.⁽¹¹⁾ Such processes ensure that the instrument is clear, simple, objective and accurate in order to master the subject, relate issues, avoid unreliable information and generate no doubt considering that the respondent does not always have knowledge about the subject.⁽¹²⁾

Considering the above and few discussions on the topic, this study aims to identify, through a systematic structure, the instruments used to assess the relationship between UI and QOL published in reference literature. It seeks to evaluate and compare them regarding the stage of validation, reliability and adaptation to the Brazilian context.

METHOD

This systematic review was carried out according to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA recommendations) for the process of recovery, selection, evaluation, synthesis and writing up of results.

Search strategy

Surveys were conducted from September to December 2012 on the following databases: PubMed, Scopus and SciELO. In all databases, the search strategy was performed using the following keywords: urinary incontinence AND questionnaire AND quality of life. The research used filters with the 2008-2012 period and selected articles written in English, Portuguese (Brazil) and Spanish.

The selection was performed by two independent researchers, respecting the following inclusion criteria: studies related to women, with the questionnaire nomenclature in the abstract and available in full. Studies that evaluated men or children, fecal incontinence and unavailable abstracts even after contact with authors were excluded. According to these criteria, evaluation for eligibility excluded generic questionnaires, i.e., not specific to UI. First, the titles of the selected studies were analyzed. Subsequently, the abstracts of the remaining studies were evaluated and, finally, the importance of articles in full was considered, as in figure 1.

Of these, a survey of questionnaires used was conducted, and those who underwent validation processes in Portuguese were selected, in view of the concern about the process of creating and testing instruments as for the psychometric properties and the steps to be followed in the adaptation to the Brazilian context.

Methodological evaluation

To assess the validity stage, reliability and adaptation to the Brazilian context, criteria established by Terwee et al⁽¹³⁾ shown in Table 1 were used. The criteria were classified as positive (the psychometric property was proven), negative (the psychometric property was not proven), inconclusive (insufficient data for the psychometric property to be assessed) and absent (no information).

The translation method and cross-cultural adaptation were classified according to the Guidelines for Cross-Cultural Adaptation of Questionnaires.⁽¹⁴⁾ The steps described in Table 2 were classified as positive when the

Table 1. Concepts of evaluative criteria of the quality of questionnaires according to Terwee et al⁽¹³⁾

Criteria	Concept
Content validity	How much the concepts of interest are largely represented by the items of the questionnaire
Internal consistency	Measure of extent to which the items of a questionnaire of a scale are correlated (homogeneous), thus measuring the same concept.
Criteria Validity	Degree to which a score on the instrument in particular relates to the gold standard.
Construct validity	Measure in which the score of an instrument relates to other measures consistent with hypotheses theoretically derived about the concepts that are being measured.
Reproducibility	Degree to which repeated measurements in stable individuals provide similar responses.
Responsiveness	Capacity of a questionnaire to detect clinically important changes over time, even if these changes are small.
"Floor" and "ceiling" effects	More than 15% of respondents achieved the lowest or highest possible score, respectively.
Interpretability	Degree to which one can assign qualitative meaning to quantitative scores.

procedure was according to the quality criteria adopted; inconclusive when the method was carried out in a questionable way; negative, when the procedure was per-

formed correctly, but with insufficient number of translators and / or back-translators, or absent when there was no enough information to qualify the step.

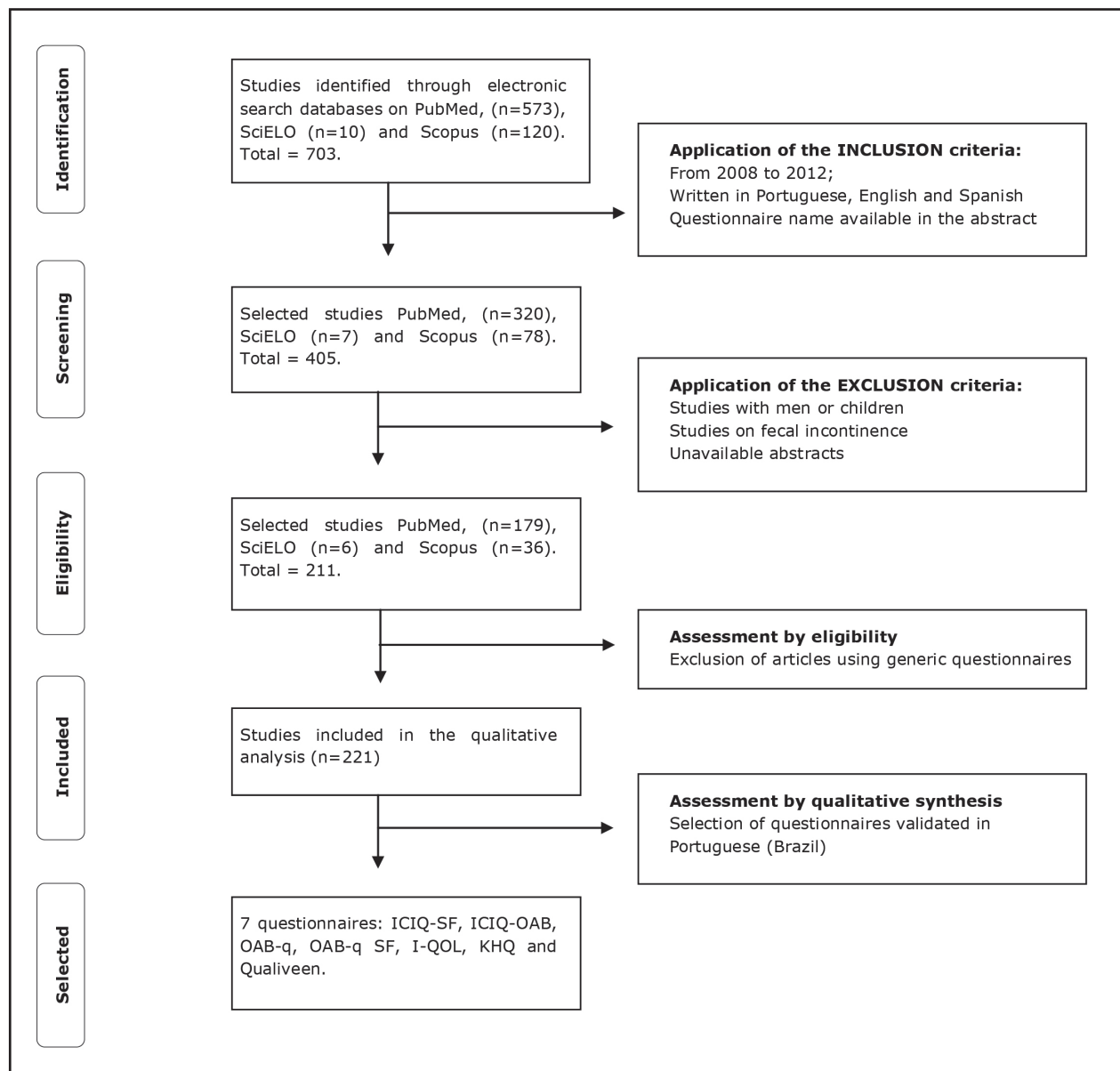


Figure 1. Flow diagram with the search criteria in three electronic databases according to PRISMA (The Preferred Reporting Items for Systematic Reviews and Meta-Analyses).

Subtitle: ICIQ-SF = International Consultation on Incontinence Questionnaire - Short Form; ICIQ-OAB = International Consultation on Incontinence Questionnaire - Overactive Bladder; OAB-q = Overactive Bladder Questionnaires; OAB-q SF = OAB-q generated the short form; I-QOL = Urinary Incontinence - Specific Quality of Life Instrument; KHQ = King's Health Questionnaire.

Table 2. Guidelines for procedures of cross-cultural adaptation of questionnaires according to Beaton et al¹⁴.

Step	Description
Translation	Performed by two or more independent translators of same native language to target language.
Synthesis of translations	Production of a consensual translation through the synthesis of translations.
Back-translations	Translation of the consensus translation into the original language by two or more translators who have no knowledge on the questionnaire.
Analysis of the committee	Elaboration of the pre-final translation by a committee of experts through the analysis of all translations.
Pretest	Application of pre-final translation in a sample of the target population.

Data extraction and assessment were carried out by two independent evaluators, who gathered and discussed the data, and if there were divergent opinions, a third evaluator was requested.

RESULTS

Data Extraction

The electronic search yielded a total of 703 references. Of these, 298 articles were excluded by titles, 135 by abstracts because they were not relevant to the purpose of the study, and 49 for not using specific questionnaires to assess the impact of urinary incontinence on QOL. Finally, 221 studies were evaluated, obtaining a final number of 7 questionnaires validated and widely used in the Brazilian context regarding the impact of urinary incontinence on QOL: International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF), International Consultation on Incontinence Questionnaire - Overactive Bladder (ICIQ-OAB), Overactive Bladder Questionnaires (OAB-q), OAB-q generated the short form (OAB-q SF), Urinary Incontinence - Specific Quality of Life Instrument (I-QOL), King's Health Questionnaire (KHQ) and Qualiveen. These are described below:

KHQ

The KHQ was developed and validated by Kelleher et al⁽¹⁵⁾ in 1997 in the UK. It assesses symptoms of UI and its relative impact. It is self-administered and used in both sexes, and consists of 30 questions divided into nine domains: health perception, incontinence impact, limitations in performing tasks, physical limitations, social limitations, personal relationships, emotions, sleep and energy and severity measurements. There is also a scale of symptoms composed of the following items: urinary frequency, nocturia, urgency, bladder hyperreflexia, urinary incontinence, nocturnal enuresis, incontinence in sexual intercourse, urinary tract infections and bladder pain. Finally, there is an open space for women to report any other problems related to UI.⁽⁸⁾

ICIQ-SF

The ICIQ-SF was developed and validated by Avery et al⁽¹⁶⁾ in 2004. It is a short and simple questionnaire that can be self-administered. It provides a rapid assessment of the impact of UI on QOL and classifies urinary losses experienced by subjects of both sexes. It consists of four questions that assess frequency, severity and impact of UI, as well as a set of eight self-diagnosis items related to the causes or urinary incontinence situations experienced by respondents.⁽¹⁷⁾

ICIQ-OAB

It was developed by ICS from Class International Consultation on Incontinence Questionnaire (ICIQ). It is

a short and appropriate questionnaire to specifically assess overactive bladder in men and women. It consists of six questions that provide a measure that indicates the impact of urinary frequency, urgency, nocturia and incontinence on QOL.⁽¹⁸⁾

I-QOL

The Urinary Incontinence - Specific Quality of Life Instrument (I-QOL) is a tool used to specifically assess QOL of people with urgent and mixed urinary incontinence. It was developed in the USA by Patrick et al⁽¹⁹⁾ in 1999, and can be self-administered. It contains 22 items, each with a Likert-type five-point scale, generating total score and three subscales (evasion and limiting behaviors, psychosocial and social embarrassment). The scores of items are summed and the result of this sum is transformed into a scale from 0 to 100 for greater interpretability, where higher scores representing better quality of life.⁽⁵⁾

OAB - q

The Overactive Bladder Questionnaires (OAB-q) was developed and validated in English in the USA by Coyne et al^(20,21) in 2002 and can be self-administered. It consists of 33 questions divided into symptoms and impact on QOL, with sub-scales of coping, concern, sleep and social interaction. The responses are in the Likert format of 6 items. The score ranges from 0 to 100, and the scales are inversely proportional, i.e., the higher the score the lower the impact of UI symptoms on QOL.

OAB-q SF

The OAB-q generated the short form, the OAB-q SF. This was developed and validated in 2004 by Coyne et al⁽²²⁾ and contains six questions on symptoms and 13 on the impact of urinary incontinence on QOL. It is self-administered, with the same answer and scoring format as the OAB-q.

Qualiveen

The Qualiveen was developed in France by Costa et al⁽²³⁾ in 2001. It is a self-administered questionnaire specific to individuals with spinal cord injury, multiple sclerosis and myelomeningocele. It is divided into two sections: impact of urinary problems on QOL and overall quality of life. The first section is divided into four areas: inconvenience, restrictions, fears, and impact on daily life, with a total of 30 questions. The responses are in the ordinal Likert-5 format with scores from 0 (no impact) to 4 (greatest negative impact). The average for each domain was obtained, which will also be processed by average to achieve the final score of the section, also with values from 0 to 4 (greatest negative impact). The second section (overall quality of life), consisting of nine questions also in the Likert format, ranges from very

bad to very good, with values between -2 and 2, respectively. The final score is generated by the average of nine questions, varying from -2 to 2.⁽²⁴⁾

Methodological evaluation

Table 3 presents a summary of the validation process in the Brazilian context. The validation of criteria, considered when there is a relationship between the scores of the questionnaire with the “gold standard”, showed that the KHQ had to be compared with generic question-

naire Short-Form Health Survey (SF-36), because there were no specific questionnaires to assess UI until then. As for the others, ICIQ-SF and I-QOL used KHQ and Qualiveen and ICIQ-OAB were compared with ICIQ-SF. The OAB-q and OAB-q SF did not evaluate this criterion.

Table 4 shows the results of the evaluation criteria of the psychometric properties of instruments. Table 5 shows the analysis of cross-cultural adaptations of questionnaires according to the Guidelines for Cross-Cultural Adaptation of Questionnaires.

Table 3. Summary of the validation process in the Brazilian context of questionnaires and languages that they have been tested.

Questionnaire	Study	Sample	Validation	Reliability		Other languages
				α Cronbach	ICC Test-retest	
KHQ	Fonseca et al ⁸	134 women with UI	Correlation with SF-36 (moderate)	0.87	0.53 to 0.81.	German ⁽³¹⁾ , Spanish ⁽³²⁾ , Turkish ⁽³³⁾ , Thai ⁽³⁴⁾
ICIQ-SF	Tamanini et al ¹⁷	94 women and 29 men with UI complaint	Correlation with KHQ (moderate)	0.88	0.80	Spanish ⁽³⁵⁾ , Greek ⁽³⁶⁾ , Thai ⁽³⁷⁾ , Japanese ⁽³⁸⁾ and other languages 16 languages ⁽³⁹⁾
I-QOL	Souza et al ⁵	70 women with UI	Correlation with KHQ (significant)	0.93	0.88	Iranian ⁽⁴⁰⁾ and in 15 languages ⁽⁴¹⁾
OAB-q	Acquadro et al ⁴²	5 individuals with overactive bladder	Linguistic validity only	Not reported	Not reported	French, Belgian, Dutch, Finnish, German, Hungarian, Spanish and UK English and in 14 languages ⁽⁴²⁾
OAB-q SF	Acquadro et al ⁴²	5 individuals with overactive bladder	Linguistic validity only	Not reported	Not reported	In 14 languages ⁽⁴²⁾
Qualiveen	D’Ancona et al ²⁴	40 men and 11 women with spinal cord injury and urinary disorders	Correlation with ICIQ-SF (significant)	0.75 to 0.90	0.62 to 0.86	German ⁽⁴³⁾ , English ⁽⁴⁴⁾ and Spanish ⁽⁴⁵⁾
ICIQ-OAB	Pereira et al ¹⁸	104 women and 38 men with urinary complaints	Correlation with ICIQ-SF (significant)	0.70	0.91 to 0.95	16 languages ⁽³⁹⁾

Subtitle: KHQ = King’s Health Questionnaire; ICIQ-SF = International Consultation on Incontinence Questionnaire - Short Form; I-QOL = Urinary Incontinence - Specific Quality of Life Instrument; OAB-q = Overactive Bladder Questionnaires; OAB-q SF = OAB-q generated the short form; ICIQ-OAB = International Consultation on Incontinence Questionnaire - Overactive Bladder.

Table 4. Results of the evaluation criteria of questionnaires that measure the impact of urinary incontinence on quality of life.

Questionnaires	Content validity	Internal consistency	Criteria Validity	Construct validity	Reproducibility		Respon-siveness	“Floor” and “ceiling” effects	Interpret-ability
					Agreement	Reliability			
KHQ	+	+	-	-	+	+	0	0	0
ICIQ-SF	+	+	-	-	+	+	0	0	0
I-QOL	+	+	-	+	+	+	0	0	0
OABq	+	?	0	+	0	0	0	0	0
OAB-q SF	+	?	0	+	0	0	0	0	0
Qualiveen	+	+	?	?	0	+	0	0	0
ICIQ-OAB	+	+	+	+	0	+	0	0	0

Rating: (+) positive score, (-) negative score; (?) inconclusive score; (0) absent. KHQ = King’s Health Questionnaire; ICIQ-SF = International Consultation on Incontinence Questionnaire - Short Form; I-QOL = Urinary Incontinence - Specific Quality of Life Instrument; OAB-q = Overactive Bladder Questionnaires; OAB-q SF = OAB-q generated the short form; ICIQ-OAB = International Consultation on Incontinence Questionnaire - Overactive Bladder.

Table 5. Analysis of cross-cultural adaptations of questionnaires that measure the impact of urinary incontinence on quality of life in Portuguese, according to the Guidelines of the Cross-Cultural Adaptation Process.

Questionnaires	Translation	Synthesis of translations	Back-translations	Analysis of the committee	Pretest
KHQ	+	+	+	+	+
ICIQ-SF	+	+	+	+	+
I-QOL	+	+	+	0	+
OABq	+	+	-	+	+
OAB-q SF	+	+	-	+	+
Qualiveen	0	0	0	+	+
ICIQ-OAB	+	+	+	+	+

Rating: (+) positive score, (-) negative score; (0) absent. KHQ = King's Health Questionnaire; ICIQ-SF = International Consultation on Incontinence Questionnaire - Short Form; I-QOL = Urinary Incontinence - Specific Quality of Life Instrument; OAB-q = Overactive Bladder Questionnaires; OAB-q SF = OAB-q generated the short form; ICIQ-OAB = International Consultation on Incontinence Questionnaire - Overactive Bladder.

DISCUSSION

The cross-cultural adaptations to Portuguese (Brazil) of KHQ, ICIQ-SF and ICIQ-OAB questionnaires followed the standards described by Beaton et al.⁽¹⁴⁾ The Qualiveen did not inform the number of translators who performed the translation and back translation steps, while I-QOL did not report the analysis of the consensus translation by a committee of experts. OABq and OAB-q SF were back-translated by one translator, obtaining negative score in this step. This fact is exploited by Lopes et al,⁽²⁵⁾ which argues that the Guidelines may present processes difficult to perform, depending on the population tested, complex steps, long duration and high cost, justifying the use of a translator.

ICIQ-OAB and I-QOL proved to be the tools with the highest number psychometric properties assessed and certified, which ensures higher reliability and usability, although ICIQ-SF and OAB-q are the instruments with the greatest number of validated languages. The internationalization condition is justified for being more succinct and objective.

Surprisingly, none of the studies showed information on responsiveness, "floor or ceiling" effects and interpretability. If these tests are not performed, the instrument cannot detect the variability needed to measure the phenomenon.^(26,27)

The internal reliability, which considers the accuracy of the measurement, showed that all instruments have reached a high degree of accuracy. The same occurred in the external reliability that has been verified by test / retest, in which KHQ and Qualiveen showed weak intraclass correlation indices in domains general health perception and impact, respectively. The only instruments that did not meet such steps were the OAB-q and its short form (OAB-q SF).

In the electronic search, KHQ obtained the highest number of citations, which can be justified considering that the ICS classifies it as "highly recommended" or "A" level for use in clinical research.⁽²⁾ Although this tool is identified as gold standard, it failed to demonstrate con-

struct and criterion validity. This fact can demonstrate certain fragility of the instrument, which suggests caution in its use and reinforces the need for testing both criteria in future studies with different populations.

Another argument regarding the popularity of KHQ, followed by I-QOL and ICIQ-SF compared with others is that these are more comprehensive and can evaluate the various types of UI. On the other hand, OAB-q, OAB-q SF and ICIQ-OAB are specific for patients with HV and Qualiveen is used in patients with neurological disorders. Questionnaires that measure QOL of patients with UI, besides contributing to measure the effectiveness in clinical trials, are also useful in the diagnosis and differentiation of types of UI, as they record women's complaint with reliability.^(28,29) The importance of the research instrument specificity is shown in the study by Wagner et al,⁽³⁰⁾ who created a specific questionnaire (I-QOL) to be used in patients with UI, being more sensitive to the impact on quality of life when compared to other generic questionnaire (SF -36).

It is concluded that the data collected in this review showed that the instrumentation of UI is being made incomplete and is not respecting the prerequisite of the completion of steps in the process of creation and testing,⁽³⁶⁾ possibly compromising an effective assessment of quality of life.

Although the instruments used in health traditionally do not make use of psychometry, it is suggested that instruments compared in this study, as well as those produced in the future, consider the importance of theoretical review, the definition of dimensions and the creation of the respective items seeking isomorphism.⁽²⁶⁾

CONCLUSION

The data collected in this review showed that the instrumentation of the impact of UI on QOL is being made incomplete and is not respecting the prerequisite of the completion of steps in the process of creation and testing, possibly compromising an effective assessment of quality of life.

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