

Validation of the "International Consultation on Incontinence Questionnaire - Short Form" (ICIQ-SF) for Portuguese

José Tadeu Nunes Tamanini, Miriam Dambros, Carlos Arturo Levi D'Ancona, Paulo César Rodrigues Palma and Nelson Rodrigues Netto Jr

Disciplina de Urologia da Faculdade de Ciências Médicas. Universidade Estadual de Campinas. Campinas, SP, Brasil

Keywords

Urinary incontinence.
Questionnaires. Validation.
Translation. Quality of life.

Abstract

Objective

To translate into and validate for Portuguese the "International Consultation on Incontinence Questionnaire - Short Form" (ICIQ-SF), a condition-specific quality-of-life questionnaire for patients with urinary incontinence.

Methods

Two Brazilians independently translated the original ICIQ-SF into Portuguese. These two translations were harmonized, and then checked by independent back-translation by two native English speakers. The harmonized translation was pre-tested in a pilot study on 20 patients. The final version of the ICIQ-SF in Portuguese was applied to 123 consecutive patients aged 16 or over (29 males and 94 females) with a complaint of urinary incontinence, who had sought the Department of Urogynecology and Urology of the School of Medical Sciences of Unicamp. The Portuguese version of the King's Health Questionnaire (KHQ) was also applied to the same group. The psychometric properties of the questionnaire, such as reliability and construct validity were assessed.

Results

The median age was 53 years (range: 16 to 86). The mean retest interval for the ICIQ-SF was 14.37 days (range: 6 to 41). No changes from the original format of the ICIQ-SF were observed at the end of the process of translation and cultural adaptation. The internal consistency was high (0.88), as measured by the Cronbach alpha coefficient. The test-retest value was considered moderate to strong, as measured by the weighted Kappa index (range: 0.72 to 0.75) and Pearson correlation coefficient (0.89). The correlation between the ICIQ-SF and KHQ was considered to be moderate to good for most items (range: 0.44 to 0.77). The evaluation of the construct and concurrent validity was also satisfactory and statistically significant.

Conclusions

The "International Consultation on Incontinence Questionnaire" (ICIQ-SF) was successfully translated into Portuguese and validated for application to Brazilian female and male patients complaining of urinary incontinence, with satisfactory reliability and construct validity.

INTRODUCTION

The use of generic or specific questionnaires as instruments for evaluating the quality of life has intensified in scientific research over recent years.

This is due to the fact that there is growing interest in subjective clinical evaluation methods among health researchers. Patients' opinions on their state of health are thus given value. Over the last decade, various questionnaires in the field of urinary dysfunctions

Correspondence to:

José Tadeu Nunes Tamanini
Rua Floriano Peixoto, 443
17201-100 Jaú, SP, Brasil
E-mail: tadeutamanini@jau.flash.tv.br

Received on 16/7/2003. Reviewed on 23/3/2004. Approved on 22/4/2004.

have been constructed. These instruments, generally compiled in the English language, evaluate the impact of such dysfunctions on patients' quality of life. Because of their length, such questionnaires become inefficient and consequently difficult to apply in clinical practice, or even in scientific research.

For the use of questionnaires in other languages and cultures to be appropriate, they need to be submitted to the international translation and cultural adaptation rules for the target language.⁹

Urinary incontinence is not a disease, but rather a symptom and sign of vesical dysfunction and/or urethral sphincter mechanism dysfunction.¹² The standardization committee of the International Continence Society (ICS) considers urinary incontinence to be "a complaint of any involuntary loss of urine".¹ This committee recommended in 1997 that quality-of-life measurements should be included in all clinical research on urinary incontinence, as a complementary addition to the traditional clinical parameters.⁴ There is a consensus in the international literature that urinary incontinence may adversely affect quality of life, with significant implications in many spheres, such as the psychological, social, physical, economic, personal relational and sexual domains.⁶ It is presented not only as a threat to self-esteem, but also as a factor in social isolation and depression. Another consensus among quality-of-life researchers in the field of urinary dysfunctions is that patients themselves are the best judges in evaluating quality of life.¹⁴

King's Health Questionnaire (KHQ)¹¹ is an instrument for evaluating the impact of lower urinary tract symptoms on women's quality of life. It was recently submitted to the process of translation and cultural adaptation to Portuguese and is now available for use in clinical research in Brazil.¹⁵

The "International Consultation on Incontinence Questionnaire - Short Form" (ICIQ-SF) is a simple and brief questionnaire that can be self-administered, and which was originally developed and validated in the English language by Avery et al.³ It was chosen for translation and adaptation to Brazilian culture because it provides a rapid evaluation of the impact of urinary incontinence on quality of life, and classifies urinary losses experienced by patients of both sexes.

The objective of the present study was therefore the translation of the ICIQ-SF into Portuguese, with cultural adaptation and validation for use in clinical research in Brazil.

METHODS

A cross-sectional observational study was made on 123 consecutive patients of both genders who sought the urogynecology and urodynamics outpatient services of the School of Medical Sciences of Unicamp between September and December 2002. Patients were considered to be incontinent and were included in this study if they declared that they had been experiencing at least one episode of urinary loss per week over the preceding three months. Patients were excluded if they were pregnant or breast-feeding women, or if they were under 16 years old. The patients included signed a statement of free and informed consent, and the study was approved by the Medical Ethics Committee of Unicamp, under the number 349/2001.

At the first interview with the patients, sociodemographic data were collected such as age, color (white, black or brown), schooling (none completed, elementary completed, high school completed, tertiary level), marital status (single, married, separated, widowed), professional occupation (student, at home, employed, unemployed, retired), family income (1, 2-4, >4 monthly minimum wages). Clinical variables were also collected such as how long they had had the complaint of urinary incontinence (<1 year or \geq 1 year), type of complaint (urge incontinence, stress incontinence or mixed incontinence), pad usage (yes or no) and number of pads (1-2, 3-4 or >4 units/day).

The patients were asked to fill out the Portuguese-language versions of the ICIQ-SF and KHQ. The latter is made up of 21 questions, divided between eight domains, and a separate scale for measurement of the severity of urinary symptoms. It is scored by domain, and there is no general score. Scores can range from 0 to 100 and the higher the score obtained is, the worse the quality of life related to that domain is.

The ICIQ-SF is a questionnaire that can be self-administered. It evaluates the impact of urinary incontinence on quality of life and classifies the urinary losses of the patients analyzed. It is made up of four questions that evaluate the frequency, severity and impact of urinary incontinence, plus a set of eight self-diagnosis items related to the causes or situations of urinary incontinence experienced by the patients.

At the second interview, which was arranged within an average of 15 days after the first interview, the ICIQ-SF was again applied. During this interval, no patient was submitted any clinical or surgical treatment for urinary incontinence.

The sample size was determined by means of the

assumption of a minimum correlation of 0.30 between the KHQ domains and the general ICIQ-SF score; and setting an α (error type I) of 5% and a β (error type II) of 0.10. Thus, a minimal sample size of 113 patients was obtained.

Translation and cultural adaptation

The recommendations from Guillemin et al⁹ were rigorously followed for establishing cultural equivalence with the original version of the ICIQ-SF in English. Two translations were made by Brazilians who were fluent in the English language and aware of the research objectives. After harmonization, the resultant translation (V1) was back-translated into English by two people who were natives of England, fluent in Portuguese, but unaware of the research objectives. After harmonization of the back-translation (V2) with the original in English, the translation into Portuguese (V1) was considered to be grammatically and semantically equivalent to the original version in English, and ready for submission to a committee of five bilingual judges who all worked in the field of healthcare. After their suggestions had been taken into account, the Portuguese version of the ICIQ-SF (V1) was pretested on a total of 20 patients with urinary incontinence.

After final adjustments to the text of the questionnaire, in accordance with the results from the first pretest (10 patients), in which the majority of the patients did not understand question no. 4, there was a need to make a second pretest (10 patients) to improve the cultural adaptation of this question.

Content/face validity

The only alteration of the translation, in relation to the original text, occurred in question no. 4: "*We would like to know how much urine you think leaks. How much urine do you usually leak (whether you wear protection or not)?*" Its initial translation was: "Gostaríamos de saber quanta urina você pensa que perde. Quanta urina você normalmente perde (se você usa proteção ou não)?" From the translation and back-translation made, the Portuguese version was considered to be grammatically and semantically correct. However, during the pretest phase, we observed comprehension difficulty among the majority of the patients, mainly because this question was made up of two sentences with the same meaning in our culture. The sentence in parentheses did not help in explaining the overall meaning of the question for the majority of the patients. Question 4 was modified as follows: "Gostaríamos de saber a quantidade de urina que você pensa que perde. (assinale uma

resposta)". With this sentence, in the second pretest, we obtained a comprehension rate of 90%. Consequently, it was considered that the Portuguese translation of the ICIQ-SF had been finalized for application among the sample of 123 patients.

Construct and concurrent validity

The construct validity was evaluated by comparison of the Portuguese translation of the KHQ (already validated) with the Portuguese translation of the ICIQ-SF. The concurrent validity was evaluated by determining the capacity of the ICIQ-SF to distinguish between different subgroups of patients with different clinical complaints, such as urge, stress and mixed incontinence, all of which had been diagnosed by means of anamnesis.

We evaluated the hypothesis that worsened quality of life would be related to some sociodemographic parameters such as gender, schooling, marital status and family income. We also evaluated whether worsened quality of life would be related to the severity of some clinical parameters such as how long the patient had had the complaint, the type of complaint and pad usage.

Reliability

The reliability was analyzed by means of the internal consistency and test-retest.

Statistical analysis

Descriptive analysis was performed by means of the frequencies of the category variables and measurements of the position and dispersion of the continuous variables.

As a measurement of the reliability, the internal consistency of the instruments and the test-retest were evaluated. For the internal consistency, the standardized Cronbach alpha coefficient was applied. For the test-retest analysis of questions 3 and 4, the weighted Kappa coefficient was utilized. For the test-retest evaluation of question 5, the Pearson correlation coefficient was applied. For the test-retest analysis of the ICIQ-SF final score (the sum of the scores for questions 3, 4 and 5), the Intraclass correlation coefficient was utilized (ICC).

For comparison of the proportions, the chi-squared test or Fisher exact test was utilized, when necessary. In comparisons of continuous or rankable variables between pairs of independent groups, the Mann-Whitney test was utilized. When there were three or

Table 1 - Reliability study: internal consistency and test-retest of the ICIQ-SF and KHQ.

| Instrument | Standard Cronbach alpha coefficient | Test-retest weighted Kappa ¹ Pearson correlation coefficient ² / Intraclass correlation coefficient ³ | 95% CI p-value |
|-----------------------|--|---|-------------------|
| ICIQ-SF - Question 3 | 0.88 | 0.75 ¹ | 0.67 - 0.83 |
| ICIQ-SF - Question 4 | | 0.72 ¹ | 0.62 - 0.81 |
| ICIQ-SF - Question 5 | | 0.89 ² | p-value<0.0001 |
| ICIQ-SF - Question 6* | - | 0.69 a 0.91 ¹ | - |
| Final ICIQ-SF score | - | 0.80 ³ | 0.73 - 0.85 |
| KHQ | 0.93 | - | - |

*Multiple choice

more groups, the Kruskal-Wallis test was utilized. The significance level adopted was 5%.

The software utilized was SAS (Statistical Analysis System) for Windows, version 8.2 (SAS Institute Inc, 1999-2001, Cary, NC, USA). The statistical analysis was based on guidance in Agresti et al² and Fleiss.⁸

RESULTS

Interviews were held with 123 patients with a complaint of urinary incontinence, of whom 94 were female patients. The mean age was 53±15 years (range: 16 to 86 years). Around 96 patients (78.1%) were white. The average interval until the ICIQ-SF retest was 14.37±5.16 days (range: 6 to 41 days). Most of the patients were either illiterate (22 or 17.9%) or had only completed elementary school (58 or 47.1%). Most of the patients were married (84 or 68.3%) and active workers (51 or 41.5%) with a family income of greater than or equal to four monthly minimum wages (59 or 48%). Around 103 patients (83.7%) had presented urinary incontinence for more than one year. Urge incontinence was the most frequent complaint, reported by 52 patients (42.3%). Eighty patients (65%) were using pads and, of these, 47 patients (58.7%) were using at least three pads per day.

The impact of urinary incontinence on quality of life was generally worse among the women than among the men (p=0.03). It was also worse for the patients with low levels of schooling [illiterate patients and those with only elementary schooling (p=0.0005)].

The study of the associations between the scores for the questionnaires analyzed and the variable categories was unable to detect any significant differences in relation to color and marital status, as was

already expected. However, the study was able to detect significant differences in the correlations of the variable categories of schooling, gender, family income (p<0.0001), type of complaint (p=0.0176) and pad usage (p<0.0001), with the ICIQ-SF general score.

Significant differences in these variables were also found in relation to most of the KHQ domains.

The studies of reliability and validity are presented in Tables 1 and 2, respectively.

The complete Portuguese version of the ICIQ-SF is shown in Figure.

DISCUSSION

The lack of quality-of-life assessment instruments translated and validated for Portuguese in the fields of urology and gynecology has, until now, restricted research in these fields in Brazil. Within this area, the KHQ in Portuguese has been proven to be robust, through analysis of its measurement properties.¹⁵ Its construct, however was devised for evaluating urinary dysfunctions in general. The decision to translate and culturally adapt the ICIQ-SF was made because it is an instrument that specifically assesses the impact of urinary incontinence symptoms on patients' lives.

One of the limitations of the study might be in relation to the schooling of the sample population. Although the questionnaire can be self-administered, it had to be read out for 17% of the sample, by the interviewer. This procedure is commonly utilized so that patients with little or no schooling can be included in studies.⁵

The reliability, measured by the internal consist-

Table 2 - Construct validity: linear association between the ICIQ-SF score and the KHQ domains (Pearson correlation coefficient).

| | GHP | II | RL | PL | KHQ domains | | | | |
|---------------------|---------|---------|---------|---------|-------------|---------|---------|---------|---------|
| | | | | | SL | PR | E | S/E | SM |
| Final ICIQ-SF score | 0.54 | 0.76 | 0.71 | 0.68 | 0.63 | 0.44 | 0.69 | 0.50 | 0.74 |
| p-value | <0.0001 | <0.0001 | <0.0001 | <0.0001 | <0.0001 | <0.0001 | <0.0001 | <0.0001 | <0.0001 |

GHP: General health perception; II: Impact of incontinence; RL: Role limitations; PL: Physical limitations; SL: Social limitations; PR: Personal relationships; E: Emotions; S/E: Sleep/Energy; SM: Severity measurements.

ency of the items and evaluated via the standardized Cronbach alpha coefficient, was calculated from the scores of questions 3, 4 and 5. This coefficient is utilized for verifying the homogeneity of the items of the instrument, or in other words, its accuracy. As a general rule, the accuracy should not be less than 0.80 if the scale is fully utilized, although values of over 0.60 are already indicative of consistency.¹⁰ The Cronbach alpha was considered to be satisfactory, with a value of 0.88. The test-retest, another method for assessing the reliability, was analyzed separately for each question. The weighted Kappa test was utilized for questions 3, 4 and 6, varying from 0.69 to 0.91; the Pearson correlation coefficient for question 5, giving 0.89; and the Intraclass correlation coefficient for the final ICIQ-SF score, giving 0.80.

The construct validity was analyzed by measuring the correlations between the final ICIQ-SF score and the KHQ domains. It was observed that there was generally a moderate association between the two instruments. This would not be expected to be otherwise, because they do not evaluate the same concept but, rather, related concepts. The KHQ is a questionnaire with a greater number of items, and evaluates urinary symptoms in general and the impact they have on different aspects of patients' lives. Even so, we observed significant correlations between the final ICIQ-SF score and all the KHQ domains ($p < 0.0001$). Only in the Personal Relations domain was the correlation less than 0.50. As was expected, the greatest correlation was found with the domain Impact of Incontinence, for which the correlation index was 0.77. Since question 5 of the ICIQ-SF and the Impact of Incontinence question of the KHQ have the same theoretical concept, we would have expected a strong correlation between them. We observed a satisfactory correlation of 0.79 (p -value < 0.0001). One explanation for this phenomenon would be the fact that the questions have different scales and scoring for the responses, as well as one using the term "urinary incontinence" and the other "bladder problems".

The concurrent validity was assessed by means of the correlation between some sociodemographic and clinical variables and the final ICIQ-SF score.

With regard to the length of time of the complaint, the difference was borderline ($p=0.07$) between those that had been using pads for a

period of less than one year, versus greater than or equal to one year. Mixed urinary incontinence was considered to be the complaint that most negatively interfered with quality of life in this population sample ($p < 0.0001$). This is corroborated by the results from an epidemiological study on urinary incontinence performed in Sweden by Simenova et al.¹³ Patients who were using pads also had worse impact on their quality of life than those who did not use such protection ($p < 0.0001$). This result is similar to what was found in the validation of the KHQ for Portuguese.¹⁵ One possible explanation for this finding could be the fact that women with urinary incontinence may adapt their lifestyle so as to avoid situations of physical effort. On the other hand, women who have a predominance of urge incontinence are incapable of exercising control over their urinary function and are subjected to sudden involuntary losses.

The internal consistency of the ICIQ-SF was satis-

| ICIQ-SF | |
|---|--|
| Nome do Paciente: _____ Data de Hoje: ____/____/____ | |
| Muitas pessoas perdem urina alguma vez. Estamos tentando descobrir quantas pessoas perdem urina e o quanto isso as aborrece. Ficaríamos agradecidos se você pudesse nos responder às seguintes perguntas, pensando em como você tem passado, em média nas ÚLTIMAS QUATRO SEMANAS. | |
| 1. Data de Nascimento: ____/____/____ (Dia / Mês / Ano) | |
| 2. Sexo: Feminino <input type="checkbox"/> Masculino <input type="checkbox"/> | |
| 3. Com que frequência você perde urina? (assinale uma resposta) | |
| | Nunca <input type="checkbox"/> 0 |
| | Uma vez por semana ou menos <input type="checkbox"/> 1 |
| | Duas ou três vezes por semana <input type="checkbox"/> 2 |
| | Uma vez ao dia <input type="checkbox"/> 3 |
| | Diversas vezes ao dia <input type="checkbox"/> 4 |
| | O tempo todo <input type="checkbox"/> 5 |
| 4. Gostáramos de saber a quantidade de urina que você pensa que perde (assinale uma resposta) | |
| | Nenhuma <input type="checkbox"/> 0 |
| | Uma pequena quantidade <input type="checkbox"/> 2 |
| | Uma moderada quantidade <input type="checkbox"/> 4 |
| | Uma grande quantidade <input type="checkbox"/> 6 |
| 5. Em geral quanto que perder urina interfere em sua vida diária? Por favor, circule um número entre 0 (não interfere) e 10 (interfere muito) | |
| 0 1 2 3 4 5 6 7 8 9 10 | Interfere muito |
| Não interfere | |
| ICIQ Escore: soma dos resultados 3 + 4 + 5 = _____ | |
| 6. Quando você perde urina? (Por favor assinale todas as alternativas que se aplicam a você) | |
| | Nunca <input type="checkbox"/> |
| | Perco antes de chegar ao banheiro <input type="checkbox"/> |
| | Perco quando tusso ou espirro <input type="checkbox"/> |
| | Perco quando estou dormindo <input type="checkbox"/> |
| | Perco quando estou fazendo atividades físicas <input type="checkbox"/> |
| | Perco quando terminei de urinar e estou me vestindo <input type="checkbox"/> |
| | Perco sem razão óbvia <input type="checkbox"/> |
| | Perco o tempo todo <input type="checkbox"/> |
| "Obrigado por você ter respondido às questões" | |

Figure - Portuguese version of the ICIQ-SF.

factory, with a general index of 0.88 obtained. This shows that the three questions utilized for calculating the internal consistency had a good degree of correlation between each other, and also presented a positive correlation between their items. The internal consistency of the KHQ was 0.93, which was considered to be very satisfactory.

In analyzing the general results obtained, we observed that the hypotheses put forward previously were confirmed, since the worst quality of life measured by the ICIQ-SF was related to the greatest severity of clinical and sociodemographic parameters surveyed.

We would propose in the future to study the re-

sponsiveness of the ICIQ-SF. This questionnaire forms part of an international project called the "ICIQ Modular Questionnaire", which involves the construction and validation of short and specific questionnaires for hyperactive bladders, fecal incontinence and nocturia, among others.⁷

CONCLUSIONS

The ICIQ-SF was successfully translated and validated for Portuguese, according to the result of the final analysis of its measurement properties. Because of its simplicity and brevity, it becomes a practical instrument that is available for utilization in clinical research and epidemiological trials in Brazil.

REFERENCES

- Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, van Kerrebroeck P et al. The standardisation of terminology of lower urinary tract function: report from the standardization sub-committee of the international continence society. *Neurourol Urodynamics* 2002;21:167-78.
- Agresti A, Finlay B. Statistical methods for the social sciences. San Francisco: Dellen Publishing Company; 1986.
- Avery K, Donovan J, Abrams P. Validation of a new questionnaire for incontinence: the International Consultation on Incontinence Questionnaire (ICIQ). Abstract nº 86 of the International Continence Society 31st annual meeting. Seoul, Korea. *Neurourol Urodynamics* 2001;20:510-1.
- Blaivas JG, Appell RA, Fantl JA. Standards of efficacy for evaluation of treatment outcomes in urinary incontinence: recommendations of the Urodynamic society. *Neurourol Urodynamics* 1997;16:145-7.
- Ciconelli RM, Ferraz MB, Santos W, Meinão I, Quaresma MR. Tradução para a língua portuguesa e validação do questionário genérico de avaliação de qualidade de vida SF-36 (Brasil SF-36). *Rev Bras Reumatol* 1999;39:143-50.
- Chiverton PA, Wells TJ, Brink CA, Mayer R. Psychological factors associated with urinary incontinence. *Clin Nurse Specialist* 1996;10:229-33.
- Donovan J, Badia X, Corcos J, Gotoh M, Kelleher C, Naughton M, Shaw C. Symptom and quality of life assessment. In: Cardozo L, Khoury S, Wein A, editors. Proceedings of the Second International Consultation on Incontinence; 2001 Jul 1-3. 2nd ed. Plymouth: Health Publication Ltd; 2002. p. 267-316.
- Fleiss JL. Statistical methods for rates and proportions. 2nd ed. New York: John Wiley & Sons Inc; 1981.
- Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. *J Clin Epidemiol* 1993;46:1417-32.
- Kelleher CJ, Cardozo LD, Khullar V, Salvatore S. A new questionnaire to assess the quality of life of urinary incontinent women. *Br J Obstet Gynaecol* 1997;104:1374-9.
- Pereira JCR. Análise de dados qualitativos: estratégias metodológicas para as ciências da saúde, humanas e sociais. 3^a ed. São Paulo: Edusp; 2001.
- Raz S, Little NA, Juma S. Female urology. In: Walsh PC, Retik AB, Stamey TA, Vaughan Jr ED, editors. Campbell's urology. 6th ed. Philadelphia: W.B. Saunders Co.; 1992. p. 2782-828.
- Simeonova Z, Milsom I, Kullendorff AM, Molander U, Bengtsson C. The prevalence of urinary incontinence and its influence on the quality of life in women from an urban Swedish population. *Acta Obstet Gynecol Scand* 1999;78:546-51.
- Swithinbank LV, Abrams P. The impact of urinary incontinence on the quality of life of women. *World J Urol* 1999;17:225-9.
- Tamanini JTN, D'Ancona CAL, Botega N, Rodrigues Netto N. Tradução, confiabilidade e validade do "King's Health Questionnaire" para a língua portuguesa em mulheres com incontinência urinária. *Rev Saude Pública* 2003;37:203-11.