Original Article

Validation of the Ureteral Stent Symptom Questionnaire for use in Brazil

Validação do instrumento *Ureteral Stent Symptom Questionnaire* para uso no Brasil

Renan Castaldeli Marques Santos[1]
Rita Simone Lopes Moreira[1]
Bartira de Aguiar Roza[1]

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Corresponding author
Renan Castaldeli Marques Santos
Napoleão de Barros street, 754,
04024-002 Vila Clementino,
São Paulo, SP, Brazil.
renancastaldeli@hotmail.com

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Abstract

Objective: To translate the Ureteral Stent Symptom Questionnaire, developed in English in the United Kingdom, into Brazilian Portuguese, to adapt and validate it to the Brazilian reality through analysis of demographic characteristics, instrument reliability, inter-item correlation, and exploration for sensitivity to change.
Methods: A methodological study performed according to instrument validation criteria recommended in the international literature, as follows: initial translation, synthesis of translation, committee of expert judges, back translation, and pretest of the final version.
Results: The Portuguese version had moderate to high internal consistency in all domains. The highest rates of inter-item correlation were in the domains of pain and urinary symptoms.
Conclusion: The results showed that the USSQ-Brazil version is a valid and reliable instrument to measure the impact of various symptoms related to the ureteral stent in Brazilian patients.

Resumo

Objetivo: Traduzir para a língua portuguesa do Brasil o instrumento intitulado *Ureteral Stent Symptom Questionnaire*, desenvolvido no idioma inglês no Reino Unido, adaptá-lo e validá-lo à realidade brasileira através da análise das características demográficas, confiabilidade de instrumento, correlação inter-itens e exploração quanto à sensibilidade à mudança.
Métodos: Trata-se de um estudo metodológico realizado segundo critérios de validação de instrumentos preconizado pela literatura internacional, sendo: tradução inicial, síntese da tradução, comitê de juízes especialistas, retradução (*backtranslation*) e pré-teste da versão final.
Resultados: A versão em português possui moderada à alta consistência interna em todos os domínios. A análise de correlação inter-itens revelou que os maiores coeficientes são observados entre os domínios dor e sintomas urinários.
Conclusão: Nossos resultados mostram que a versão do USSQ-Brasil é um instrumento válido e confiável para medir a repercussão dos vários sintomas relacionados ao *stent* ureteral em pacientes brasileiros.

[1]Escola Paulista de Enfermagem, Universidade Federal de São Paulo, São Paulo, SP, Brazil.
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Introduction

Urolithiasis mainly affects young individuals of working age, causing disturbances for the individual and his family, due to injuries that they experience. It represents a major public health problem, and is the third most frequent cause of urological admissions, causing a strong impact on the social security system, because of work days missed and recurrent hospitalizations.[1]

It is clear that the evolution of optical systems and the development of new endoscopic instruments began a new era in the treatment of patients with urolithiasis.[2]

The double J ureteral stent, developed in 1967, is considered a versatile and indispensable instrument in the adequate management of various urological disorders, such as obstructive pyelonephritis, acute renal colic, accidental perforation of the ureter during endoscopic procedure, calculus obstruction, urethral and oncological surgeries, extrinsic compression of the ureter, prevention of complications in patients undergoing extracorporeal lithotripsy, kidney transplant, and urinary tract infection.[3] Patients can experience side effects, along with benefits, related to the use of ureteral stents, and thus have their quality of life affected: sometimes subtly, sometimes catastrophically. The most common adverse reactions during treatment with the ureteral stent are: worsening of urinary symptoms, such as pollakiuria, dysuria, urinary urgency, hematuria, stent-associated pain, difficulty performing routine activities, and increased stress.[4]

Approximately 80% of patients using a ureteral stent report a negative impact on their quality of life, which makes the use of a specific instrument indispensable for measurement of the influence of certain diseases on their daily routine.[5]

It is pertinent to point out that measuring the concept of quality of life is a difficult task, since its definition is marked by subjectivity; it is surrounded by physical, psychological, social, cultural and spiritual components, which makes it multiconceptual, multidimensional, and dynamic.[6-8]

There are two classifications for quality of life in the health area. One is a generic classification, which states that "Quality of life is an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns." Another classification divides it into four areas: physical health, mental health, social and economic health, and general health. This classification also includes the risks related to these areas, and covers health practices and policies, and their influence.[6,9,10]

The aim of this study was to validate the Ureteral Stent Symptom Questionnaire (USSQ), developed by the Bristol Urological Institute in the United Kingdom (UK), for the Brazilian reality, through translation and cultural adaptation. The instrument contains 38 questions divided into six health areas: urinary symptoms, body pain, general health, work performance, sexual matters, and additional problems.[11] The USSQ instrument was validated in studies similar to this one in Japan, Spain, Korea, France, Italy and Saudi Arabia. It was chosen because it is specific tool that has been proven effective for evaluating the impact of ureteral stent placement on patients' quality of life.

Methods

The translation, cultural adaptation and validation of the USSQ was performed according to the Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures, which was specially developed by Beaton to optimize the semantic, idiomatic, experiential and conceptual adaptation of instruments, in order to ensure content validity between the source language and the target language.[12] This methodology is considered the gold standard for this type of study, and has been used for translation, adaptation and validation of instruments in Brazil and abroad. Methodological rigor can be observed at every stage of the study, which is divided into five phases, as shown in figure 1.

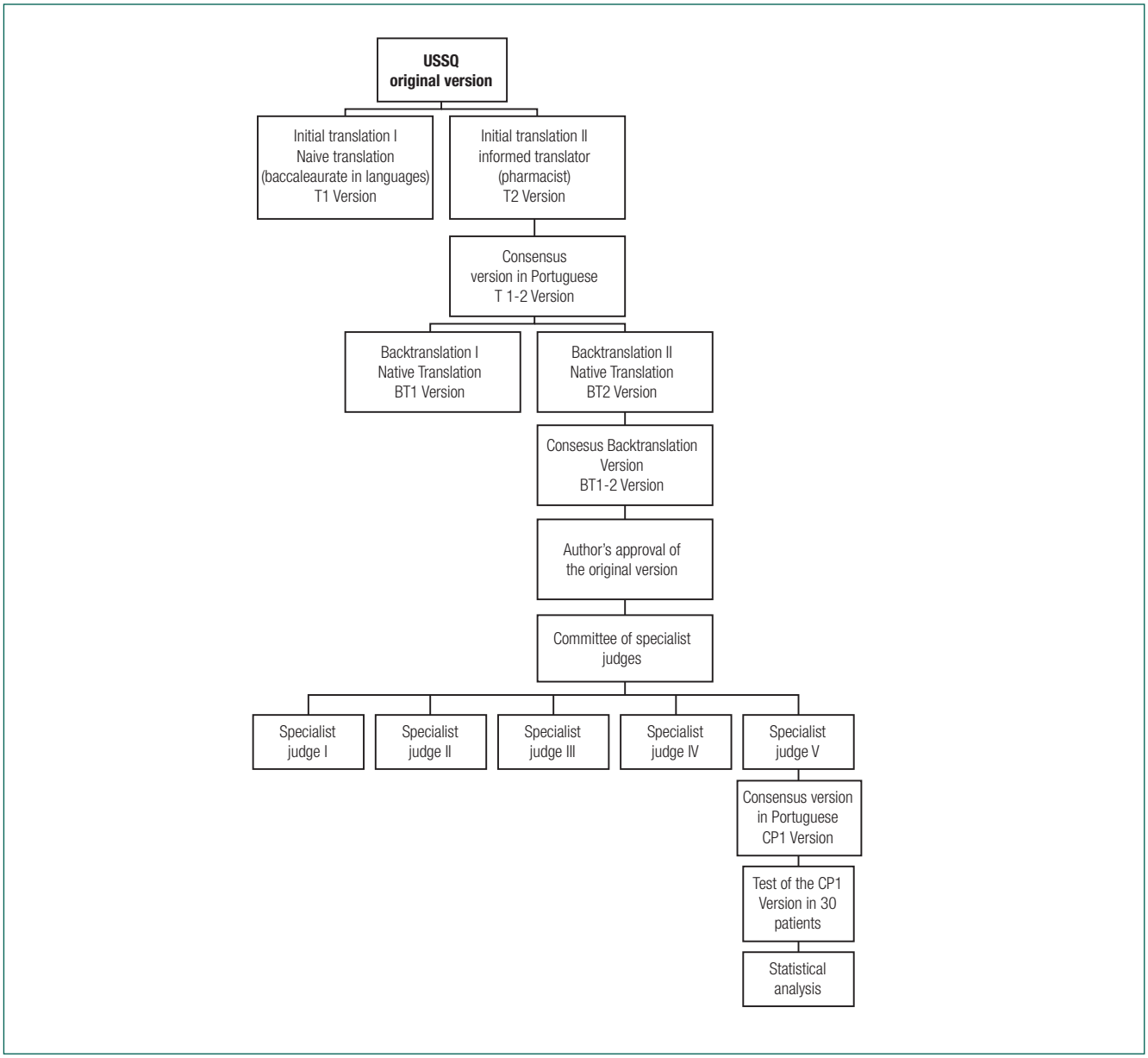

Figure 1. Flow chart of the translation, cultural adaptation and validation process of the USSQ-Brazil instrument

The original version of the instrument belongs to the Bristol Urological Institute - Ureteric Stent Symptom Group - and is protected by copyright. The study started after permission was received from the Bristol Urological Institute and the author of the instrument, and after approval of the research project by the Ethics and Research Committee of the Federal University of São Paulo - Paulista School of Nursing - through the Brazil Platform, under protocol 11378813.3.0000.5505. All volunteers and judges invited to participate in the study agreed to sign the Terms of Free and Informed Consent form.

The inclusion criteria were the same used to develop the original version of the instrument: age equal to or greater than 18 years, with diagnoses of unilateral ureteral stones or obstruction of the ureteropelvic junction, using an ureteral stent. Patients with other urological diseases using an ureteral stent as part of therapy were excluded from the sample.[11,12]

Phase I - Initial translation

According to the chosen methodology, the translations were performed by two native speakers of the target language, i.e., two Brazilians, also fluent

in the instrument source language, i.e., English. Only one of the translators had academic training in health.[13,14]

At this stage, the translators were instructed to perform the translation focused on the culture of the target language, i.e., translations were transcultural and not literal.

Translator I can also be called naive translator because he was not informed about the purpose of translation and had no academic training in health (English Teacher). The translated version produced by the first translator is called T.1.

Translator II was informed of the purpose of translation and had academic training in health (Pharmacist). The translated version produced by the second translator is called T.2.

Phase II - Synthesis of translations

The synthesis of T.1 and T.2 versions was produced by the author, the advisor and a licensed professional in languages. At this stage it was essential to observe the semantic equivalence between the original version and the versions produced in phase I.

Semantic equivalence is the translation of the original instrument, not only conserving the meaning of words between two different languages, but also seeking to achieve the same effect in different cultures.[15]

This phase yielded a consensus version entitled T.1-2, which was used in the next phase of the study.

Phase III - Back translation into English

Two translators without prior knowledge of the project, without academic training in health, who were native English speakers produced the BT-1 and BT2 versions in the source language, using the T.1-2 version.[13]

The consensus version was developed, based on the BT-1 and BT-2 versions, and was named BT.1-2. At this stage, it is recommended that the back translation (BT.1-2) is sent to the original author in order for it to be reviewed and approved.

Upon review and approval of BT.1-2 version by the original author, the versions obtained in phases II and III were ready to be provided to the committee of expert judges.

Phase IV - Committee of expert judges

The committee consisted of medical, nursing and psychology professionals. The invitation to participate in the committee came from the author and the advisor. The choice of judges was based on the following criteria: knowledge of the addressed subject, domain of Portuguese and English, as well as the methodology used to perform the translation, cross-cultural adaptation and validation of instruments.

The expert committee assessed semantic, idiomatic, cultural and conceptual equivalence. This procedure aims to ensure that all items of the instrument are easily understood by the target population of the study.

The judges had access to the original versions of the USSQ - in situ and post removal versions, and to the versions produced in phase II – the consensus version in Portuguese (T1-2). According to the method chosen, the judges were free to suggest changes, and these were further analyzed by the author and the study advisor, culminating in the consensus version in Portuguese I (CVP I), which was used in the next phase of the study.

Phase V - Test of the version synthesized in phase IV

According to international recommendations for validation studies, the USSQ - Brazil was administered to 30 patients who underwent ureteral stent implantation between 1-4 weeks and readministered four weeks after removal of the ureteral stent.[15] All the subjects who answered the USSQ - Brazil were interviewed to clarify their understanding of the questions and their chosen responses, which allowed for the assessment of whether the new version retained the semantic, idiomatic and conceptual equivalences of the original version, as recommended in the literature.[16]

The instrument was administered during the nursing appointment, and had a mean duration of 16 minutes in the first administration and 12 minutes in the second.

Because the original version of the instrument is protected by copyright, the study began after receiving the author's permission.

Table 1. Spearman's correlation coefficients between the domains of USSQ - Brazil

Domains	Urinary symptoms	Pain	General health	Quality of the work	Quality of sex	Trade-off
Urinary symptoms	1.00	0.63	0.45	0.38	-0.27	0.45
Pain		1.00	0.53	0.17	-0.15	0.59
General health			1.00	-0.11	-0.23	0.51
Quality of work				1.00	-0.13	0.05
Quality of sex					1.00	-0.19
Trade-off						1.00

Results

The post-translation validation step was performed by a predominantly female sample (61.3%) and most subjects were between 30 and 59 years of age. The mean age was 40.4 ± 12 years.

Internal consistency

Table 1 shows the inter-item correlation coefficients of the USSQ - Brazil domains. In general, the highest coefficients were observed in the 'Pain', 'Urinary symptoms', 'General health' and 'Trade-off' domains (r> 0.5). The 'Quality of sex' domain had the lowest correlation coefficients of the instrument domains, ranging from 0.1 to 0.3.

From a global perspective, the USSQ - Brazil showed moderate internal consistency (alpha=0.61). Only the 'Quality of sex" domain seems to differ from the rest of the instrument, with alow of item-total correlation coefficient (Figure 2).

Sensitivity to change and discriminant properties of the instrument

Significant differences were observed in the distribution of scores obtained by the USSQ - Brazil instrument in all areas both with the stent and after its removal. In general, a decrease in the points (improvement in the score) was found in the following domains: 'Urinary symptoms', 'Pain', and 'General health' (p<0.001). The 'Quality of work' and 'Quality of sex' domains had a significant increase after device removal. The major differences were found in the 'Pain' and 'Urinary symptoms' domains, as shown in Table 2.

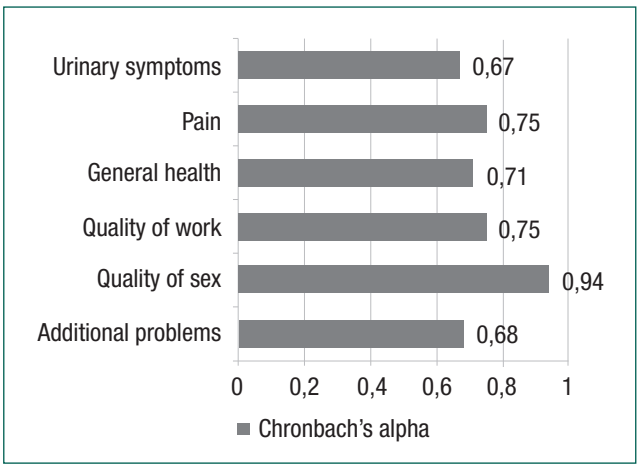

Figure 2. Graph of the synthesis of internal consistency measures of the USSQ - Brazil, according to its domains

Table 2. Median, minimum and maximum values of the USSQ - Brazil, according to its domains

Domains	USSQ - Brazil		p-value**
	in situ	Post	
Urinary symptoms	29.5(19-41)	15.25(12-28.7)	< 0.001
Pain	21(0-56)	5(0-28)	< 0.001
General health	14(6-23)	9(5-25)	< 0.001
Quality of work	1.5(0-11)	3(0-7)	0.03
Quality of sex	0 (0-6)	3 (0-6)	< 0.01

p**= **statistical significance

Discussion

Since it was developed and validated in 2003, the USSQ has been translated, adapted and validated in similar studies for use in Japan, Spain, Korea, France, Italy and Saudi Arabia. The reliability of the USSQ - Brazil Portuguese version was confirmed through statistical analysis. The instrument has moderate to high internal consistency, both in specific areas (Urinary symptoms, Pain, and Additional problems) and in the generic domains (General health, Quality of work, and Quality of sex).

The results obtained in the countries where the USSQ was validated are equivalent to those obtained in the Brazilian version, especially those relating to the domain "sexual performance". According to the author of the Korean version, the low inter-item correlation and weak internal consistency can be attributed to the fact that a few patients had an active sex life and some were still reluctant to talk about sexual matters with health professionals.[17] The authors of the Spanish version of the USSQ states that pain in the genital area, experienced by more than half of the male patients, was the main cause of the low inter-item correlation indicated in the statistical analysis.[18] The tolerance developed during the period when the patient has the ureteral stent implanted is the major variable responsible for the low agreement identified in the domains "additional problems" and "sexual performance," according to the author of the Italian version of the USSQ, thereby ruling out the possibility of methodological bias.[19]

The authors of translated and adapted USSQ versions, and the authors of the original version, are unanimous in stating that the use of the instrument is not feasible in clinical practice because it is comprehensive, but it can be used in comparative studies of ureteral stents of different sizes or those produced with different materials and to test the efficacy of new medicines to reduce adverse effects of the stent.

Conclusion

The adopted methodology has been rigorously applied to make the version of USSQ-Brazil a valid and reliable instrument for the measurement of the impact of various symptoms related to ureteral stents, in Brazilian patients. These results show that the instrument was properly translated, culturally adapted, and validated for Brazilian Portuguese.

Collaborations

Santos RCM, Moreira RSL and Roza BA contributed to the project conception, data analysis and interpretation, drafting of the article, review of its important intellectual content and approval of the final version for publication.

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