

# Validation survey of the impact of urinary incontinence (IIQ-7) and inventory of distress urogenital (UDI-6) – the short scales – in patients with multiple sclerosis

Validação da escala curta do questionário de impacto da incontinência urinária (IIQ-7) e do inventário de angústia urogenital (UDI-6) em pacientes com esclerose múltipla

Lívia Palma Stievano<sup>1</sup>, Guilherme Sciascia do Olival<sup>1</sup>, Raquel Ataíde Peres da Silva<sup>1</sup>, Vania Balardin Toller<sup>1</sup>, Eduardo Gregorin Carabetta<sup>1</sup>, Eliana Tomomi Shimabukuro da Cunha<sup>1</sup>, Raphael de Jesus Moreira<sup>1</sup>, Marina Eloi<sup>2</sup>, Charles Peter Tilbery<sup>1</sup>

## ABSTRACT

Cross-cultural adaptation and validation of the Impact Questionnaire of Urinary Incontinence (IIQ-7) and Urogenital Distress Inventory (UDI-6) - short scale - in the Brazilian population with multiple sclerosis. The IIQ-7 and UDI-6 were translated into Portuguese, called IIQ-7-BR and UDI-6-BR. The questionnaires were administered in 211 individuals selected randomly. Of these, 140 had MS according to McDonald criteria and 71 were included in the control group. In both questionnaires, the Cronbach's alpha coefficient was above 0.7. The IIQ-7-BR showed 94.31% concordance between the evaluated studies and UDI-6-BR, 93.33%. Thus, the instruments of this study were presented according to the standards proposed by the Instrument Review Criteria, reliability, validity and sensitivity, maintaining the original scales characteristics.

**Keywords:** urinary incontinence, multiple sclerosis, questionnaires.

## RESUMO

Adaptação transcultural e validação da escala curta do Questionário de Impacto de Incontinência Urinária (IIQ-7) e do Inventário da Angústia Urogenital (UDI-6) na população brasileira com esclerose múltipla (EM). O IIQ-7 e o UDI-6 foram traduzidos para a língua portuguesa, obtendo-se IIQ-7-BR e UDI-6-BR. Os questionários foram aplicados em 211 indivíduos selecionados aleatoriamente. Destes, 140 apresentavam EM nos critérios de McDonald, e 71 foram incluídos no grupo controle. Em ambos os questionários aplicados nos grupos, o coeficiente alpha de Cronbach apresentou-se acima de 0,7. O IIQ-7-BR apresentou 94,31% de concordância entre os estudos avaliados e o UDI-6-BR, 93,33%. Sendo assim, os instrumentos desse estudo apresentaram-se, segundo as normas propostas pelo *Instrument Review Criteria*, confiabilidade, validade e sensibilidade, mantendo as características das escalas originais.

**Palavras-chave:** incontinência urinária, esclerose múltipla, questionários.

Multiple sclerosis (MS) is an inflammatory demyelinating disease which affects the spinal cord (especially posterior cords), causing several symptoms, including urinary dysfunction, which affects up to 85% of the population<sup>1,2</sup>, leading to a decline inequality of life (QOL)<sup>3</sup>.

Urinary incontinence (UI) causes severe changes in patient's lives, making it stressful and debilitating and generate high morbidity, affecting the psychological, occupational, physical and

sexual level<sup>4</sup>. For this reason, the International Continence Society (ICS) has recommended that quality life measurement assessment, included in all studies, as a complement to clinical measures<sup>5</sup>. The effectiveness of urinary incontinence's treatment has been usually assessed according to objective parameters (urodynamic study, absorbent test and stress test). These parameters, however, fail to evaluate the impact of the disease and its treatment cause from the patient's view.

<sup>1</sup>Faculdade de Ciências Médicas, Santa Casa de São Paulo, Sao Paulo SP, Brazil;

<sup>2</sup>Universidade Federal de São Paulo, Sao Paulo SP, Brazil.

**Correspondence:** Guilherme Sciascia de Olival; Rua Cesário Mota Júnior, 112; 01221-020 São Paulo SP, Brasil; E-mail: guilherme.olival@einstein.br

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Because of these difficulties, generic and specific questionnaires for measuring quality of life have been created to access both the subjective aspects of disease. The Impact Urinary Incontinence (IIQ-7) and Urogenital Distress Inventory (UDI-6) questionnaires were developed and combined to assess the impact of urinary incontinence on QOL<sup>6</sup>. Both questionnaires are recommended by ICS<sup>7</sup>. In Portuguese, there is no validated instrument that measures the impact of urinary incontinence. Thus, the aim of this study was to adapt and validate the IIQ-7 and UDI-6 in Brazilian population and to check its measurement properties so they can be used as a tool for evaluating the impact of urinary incontinence in patients Brazilians with multiple sclerosis.

## METHOD

### Instrument

Questionnaires IIQ-7 and UDI-6 are composed by 30 and 19 questions, respectively, and although they have been evaluated and classified as effective in the evaluation of treatment effectiveness, they proved to be impractical due to long period of time to be answered<sup>6</sup>. Therefore, short versions of IIQ-7 and UDI-6, composed by 7 and 6 questions, respectively, were developed together to measure the impact of urinary incontinence. The UDI-6 can also be divided into three subscales: the first evaluates irritation symptoms (urgency, frequency and pain) (questions 1 and 2), the second stress symptoms (questions 3 and 4) and the third evaluates obstruction/discomfort or symptoms of voiding difficulty (questions 5 and 6). We also applied the Expanded Disability Status Scale - Kurtzke Expanded Functional Disability Scale (EDSS) to assess the progression of the disability caused by MS.

### Translation and cultural adaptation

The translation, cultural adaptation and validation protocol was prepared according to some proposed steps on literature which addresses the methodology of translation of questionnaires into other languages<sup>8</sup>. Initially, the items of the English version were translated into Portuguese by two English teachers, independent Brazilians aware of the objective of this research. The two translations were compared by translators and researchers of the study and modifications were made to obtain a consensus. This translation was rendered into English by a native English teacher who was not part of the previous step. The comparison between the back-translated English version and the original questionnaires (IIQ-7 and UDI-6) was performed and no significant discrepancies were noted.

For pretest analysis of cultural equivalence, a pilot study was conducted in which the scale was administered to a group of 11 MS patients, without cognitive impairment.

They were selected randomly at the Centre of Care and Treatment of Multiple Sclerosis of *Santa Casa de Misericórdia of São Paulo* (CATEM). The purpose of this process was to identify issues that were not understood by the population and therefore were deemed culturally inappropriate, however, no question was framed in these parameters. Thus the final versions of the scales translated into Portuguese, named IIQ-7-BR and UDI-6-BR were generated.

### Subjects

140 patients with MS treated at CATEM, including 104 women and 36 men were selected. In the control group 71 healthy individuals - 47 women and 24 men - were included. Patients with MS were randomly selected among CATEM patients. The inclusion criteria were: confirmed diagnosis of MS according to the revised McDonald criteria 2010<sup>9</sup> and no other pathological conditions suffer that can lead to UI. The exclusion criterion for individuals with MS was being in times of disease outbreak. The 71 healthy individuals were randomly selected among MS patients at CATEM whose exclusion criteria were having MS or other pathology which could cause UI.

The study was approved by the Ethics and Research of the Santa Casa de Sao Paulo Brotherhood (Project no. 072 / 12). All subjects were informed about the purpose of the study and signed a consent form.

The questionnaires were conducted in a quiet and private environment minimizing the possible constraints. Were collected socio demographic data (gender, age and education), disease duration and form of MS, neurological examination and EDSS. After 30 days, the same researcher performed the re-test with 55 patients with the aim of analyzing the stability and reliability of the scale.

### Statistical analysis

The descriptive analysis was developed by the frequency of categorical variables and measures of position and dispersion of continuous variables. A multivariate analysis of variance was performed for socio-demographic data, disease duration and EDSS, to identify factors that could possibly influence the results of each dependent variable. The playability of the instrument was estimated by calculating the averages and standard of the final result and the partial results of each group of survey questions deviations. The results were calculated and compared between the control group and patients with MS in order to understand the significance of the final score.

To validate the instrument, the standards proposed by Instrument Review Criteria (SAC) to analyze the reliability, validity and sensitivity. The reliability of the questionnaire was assessed by internal consistency and test-retest stability, respectively obtained by Test Statistics Cronbach's alpha and Pearson correlation analysis. The validity of the instrument

Table 1. Socio-demographic and clinical data of the control group and the MS group.

	Control group (n = 71)	MS group (n = 140)
Gender F:M	2:1	2.8:1
Age	40.99 (14.85)	41.26 (12.24)
School Index (% with high school)	77.1%	79.9%
Disease duration		6.50 (6.81)
EDSS		2.10 (2.32)

Data are presented as mean +/- SD. SD: Standard deviation; F: Female; M: Male; MS: Multiple sclerosis; EDSS: Expanded Disability Status Scale.

was assessed by comparing the questionnaire results in terms of another measure of clinical evaluation in case the EDSS, also by Pearson correlation. The sensitivity of the scale was assessed by comparing obtained results in four different groups: control group without UI, control group with UI, patients without UI and patients with UI. This subdivision was performed to evaluate the ability of the scale to identify each of these four groups, by applying the Mann-Whitney and Kruskal-Wallis tests.

The level of significance was 0.05 for all statistical tests. The statistical analysis program used was the Statistical Package for Social Sciences (SPSS) version 17.

## RESULTS

211 individuals were evaluated - 71 in control group and 140 patients with MS - by the UDI-6-BR and IIQ-7-BR. The sociodemographic and clinical data are shown in Table 1. A multivariate analysis of variance showed that gender, age and education did not affect the results of both questionnaires and subsequent analysis of the results.

The internal consistency of the subscales and between 7 questions in IIQ-7-BR and 6 issues of UDI-6-BR, was assessed by Cronbach's alpha coefficient, being above 0.7, so the reliability is high for entire sample and separately for the control group and the MS group.

As for the stability of the IIQ-7-BR instrument, it was found a high level of reproducibility, with 94.31% concordance between the studied behaviors. The average test results was 4.26 (5.884) and the re-test 4.28 (5.977). The level of

reproducibility of the UDI-6-BR was also high, with 93.33% concordance between the studied behaviors. The average test results was 5.49 (6,130) and re-test 5.49 (6.145). In both scales the correlation between the outcome in the test and re-test, assessed by Pearson's correlation coefficient showed a strong relationship with a figure above 0.90 and  $p < 0.001$ .

In the validity analysis, it was determined an evaluation of the behavior of the domains of IIQ-7-BR and UDI-6-BR depending on the extent of Disability Status Expanded Scale (DEES), also using the Pearson correlation. Although other studies have demonstrated an association between DEES score and sexual dysfunction<sup>10,11</sup> no significant correlations were observed in this study, a consistent result with the Tzortzis work, et al.<sup>12</sup>.

The sensitivity is a measure of the ability of the scale to identify groups with different characteristics. The study subjects were divided into four groups: control without Urinary Incontinence, control with Urinary Incontinence (UI), MS without UI and MS with Urinary Incontinence, according to the final scores in IIQ-7-BR and also the UDI-6-BR. The average scores of the groups were compared by applying the Mann-Whitney and Kruskal-Wallis tests. The results are shown in Tables 2, 3, 4 and 5.

## DISCUSSION

The translation and cultural adaptation of the instruments IIQ-7 and UDI-6 is very important in clinical practice, because the UI is an issue that affects the patient's quality of life. Everyday activities such as work, study, physical exercise

Table 2. Sensitivity analysis of the IIQ-7-BR in control and MS groups, with and without UI.

Questions	Control without UI (n = 57)	Control with UI (n = 14)	MS without UI (n = 83)	MS with UI (n = 57)	Significance (p)
Q1	0.04 (0.186)	0.71 (0.825)	0.14 (0.354)	1.43 (1.076)	$p < 0.0001$
Q2	0.02 (0.132)	1.14 (0.949)	0.19 (0.426)	1.64 (1.128)	$p < 0.0001$
Q3	0.02 (0.132)	0.93 (0.917)	0.12 (0.329)	1.65 (1.110)	$p < 0.0001$
Q4	0.04 (0.186)	1.50 (0.855)	0.16 (0.366)	1.74 (1.142)	$p < 0.0001$
Q5	0.04 (0.186)	1.07 (1.072)	0.13 (0.341)	1.56 (1.134)	$p < 0.0001$
Q6	0.09 (0.285)	1.57 (1.158)	0.17 (0.464)	1.95 (1.007)	$p < 0.0001$
Q7	0.12 (0.331)	1.64 (1.151)	0.23 (0.502)	1.77 (1.118)	$p < 0.0001$
Total	0.35 (0.89)	8.57 (4.50)	1.14 (1.86)	11.65 (5.78)	$p < 0.0001$

Data are presented as mean +/- SD. IIQ-7: Impact Questionnaire Urinary Incontinence; SD: Standard deviation; MS: Multiple sclerosis; UI: Urinary incontinence.

**Table 3.** Sensitivity analysis of the IIQ-7-BR in the control and MS groups.

Questions	Mann-Whitney U	Significance (p)
Q1	3586.00	p < 0.0001
Q2	3544.00	p < 0.0001
Q3	3560.50	p < 0.0001
Q4	3797.00	p = 0.001
Q5	3761.50	p < 0.0001
Q6	3780.50	p = 0.001
Q7	3906.50	p = 0.004
Total	3209.50	p < 0.0001

IIQ-7: Impact Questionnaire Urinary Incontinence; MS: Multiple sclerosis.

and leisure become difficult to carry out and even generate embarrassing situations which might end up traumatizing the patient with MS. In addition, the UI can also lead to other problems such as psychological disorders (depression), infections and remoteness from social life.

A recent review<sup>13</sup> reported a prevalence of 37%-99% of overactive bladder syndrome characterized by urgency, urinary frequency and/or other irritative symptoms, 34%-79% of obstructive symptoms and 25% with chronic urinary retention in patients with MS. Irritative symptoms and obstruction can coexist and can affect approximately 59% in men and 51% in women. Patients with MS have a higher prevalence of urinary incontinence than the general population, with over 70% of those affected. Symptoms of bladder dysfunction occur an average of six years after diagnosis of MS, but may be present in up to 10% of the initial patients.

As it is known, the UI problems are related to the areas of the anterior cingulate gyrus, with the route of the spinal cord and the medial prefrontal<sup>14</sup> area which are affected by the formation of MS plaques. The use of questionnaires is essential for sorting to be a way for the patient to express their anguish over what they feel, and added to the MRI, it becomes possible to draw a more accurate prognosis and treatments. There are also other ways to assess UI as voiding diaries, pad test and urodynamic parameters. These observations may reflect the severity of the loss, but do not express the changes in daily activities.

The psychometric properties of an instrument (reliability, validity, and sensitivity), either in their development or obligatory ensure that it is easy to apply, quantifiable, presents

**Table 5.** Sensitivity analysis of the UDI-6-BR in the control and MS groups.

Questions	Mann-Whitney U	Significance (p)
Q1	4278.50	p = 0.068
Q2	3614.00	p < 0.0001
Q3	4238.50	p = 0.02
Q4	3842.00	p = 0.001
Q5	3074.00	p = 0.0001
Q6	4783.00	p = 0.555
Total	3487.50	p < 0.0001

UDI-6: Urogenital Distress Inventory; MS: Multiple sclerosis.

sensitivity and specificity and is adapted to the cultural and legal conditions in the country where if you want to use it<sup>15</sup>.

Given the presented data, the use of the IIQ-7-BR and UDI-6-BR is very important for Portuguese language and Brazilian culture, because they are specific clinical questionnaires, which have psychometric properties and applicability in the development of populations in different countries, these important characteristics in selecting a questionnaire to the process of cultural adaptation and validation. All translations and back-translations were performed and evaluated semantically, experimental, idiomatic and conceptual view and few changes were made between the original and the translated questionnaires.

Both instruments of this study are presented according to the rules proposed by the Instrument Review Criteria<sup>16</sup> which states that the validation process of a QOL instrument for patients is applied to evaluate the data obtained internal consistency, reliability or stability of the instrument, validity and sensibility.

All these criteria had to be adequate as demonstrated by the good results. For example, the values of Cronbach's alpha coefficient, in which may vary from 0 to 1.0, and such that follows the variation between 0 and 0.6 corresponds to unsatisfactory reliability rule, from 0.6 to 0.7 reliability satisfactory and between 0.7 to 1.0 high reliability, in both questionnaires and in both groups, the internal consistency was high, maintaining the characteristics of the original scale, which demonstrates the truth of the homogeneity test after translation into the language Portuguese.

Each society has its own beliefs, acts, customs, behavior and social habits, these characteristics give people a guideline

**Table 4.** Sensitivity analysis of the UDI-6-BR in control and MS groups, with and without UI.

Questions	Control without UI (n = 57)	Control with UI (n = 14)	MS without UI (n = 81)	MS with UI (n = 59)	Significance (p)
Q1	0.42 (0.844)	2.64 (1.216)	0.42 (0.576)	2.32 (1.479)	p < 0.0001
Q2	0.25 (0.662)	2.43 (1.453)	0.48 (0.838)	2.80 (1.362)	p < 0.0001
Q3	0.05 (0.294)	1.36 (1.550)	0.15 (0.480)	1.61 (1.801)	p < 0.0001
Q4	0.14 (0.515)	1.29 (1.437)	0.26 (0.667)	2.15 (1.700)	p < 0.0001
Q5	0.35 (0.744)	0.64 (1.082)	0.53 (0.853)	2.76 (1.318)	p < 0.0001
Q6	0.40 (0.863)	1.79 (1.578)	0.16 (0.535)	1.29 (1.619)	p < 0.0001
Total	1.61 (2.11)	10.14 (3.86)	2.00 (2.34)	12.93 (5.24)	p < 0.0001

Data are presented as mean +/- SD. UDI-6: Urogenital Distress Inventory; SD: Standard deviation; MS: Multiple sclerosis; UI: Urinary incontinence.

of who they are, how they should behave and what they should not do. These rules or concepts reflect the country's culture and also differentiates it from others. When we propose a translation of a questionnaire, this should be presented in simple and clear language for that population and keep equivalent with respect to their cultural concepts. Moreover, in situations where the primary goal is not the prolongation of life and specific methods of treatment response are flawed, as is the case of UI in patients with MS, the extent of impact on quality of life of these patients is imperative.

In conclusion, the translation of questionnaires IIQ-7-BR and UDI-6-BR, aim of this study have clinical easy applicability, good sensitivity, specificity and stability, similar to the fact already being used successfully in other countries, demonstrated well adapted to the Brazilian medical practice, and can be used in day-to-day care of patients with MS. Thus, proper evaluation of urinary incontinence allows a more individualized approach to their clinical and biopsychosocial consequences, favoring medical assessment and providing better therapeutic interventions.

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## APÊNDICE

### Questionário de impacto da incontinência urinária (IIQ-7-BR)

Algumas pessoas pensam que a incontinência urinária pode afetar suas atividades, relacionamentos e sentimentos. As perguntas a seguir referem-se a aspectos da sua vida que podem ter sido influenciados ou alterados devido à incontinência urinária. Para cada pergunta, circule o número que corresponde à resposta que melhor descreve o quanto as suas atividades, relacionamentos e sentimentos tem sido afetados pela incontinência urinária.

A incontinência urinária tem afetado...	Nem um pouco	Um pouco	Moderadamente	Muito
Sua habilidade de realizar as tarefas diárias? (tarefas domésticas ou profissionais)	0	1	2	3
Suas atividades físicas? (como caminhar, nadar, dançar, entre outros)	0	1	2	3
Seu lazer? (como ir ao cinema ou a uma festa)	0	1	2	3
Sua habilidade de viajar de carro ou ônibus por mais de 30 minutos?	0	1	2	3
Sua participação em atividades sociais fora de sua casa?	0	1	2	3
Sua saúde emocional? (nervosismo, depressão, ansiedade, medo, etc)	0	1	2	3
Você se sentir frustrado por algum motivo?	0	1	2	3

### Inventário de angústia urogenital (UDI-6-BR)

#### 1. Você urina com uma frequência maior do que considera normal?

SIM

NÃO

Se SIM, o quanto isso te incomoda?

NEM UM POUCO

UM POUCO

MODERADAMENTE

BASTANTE

#### 2. Você usualmente apresenta incontinência urinária associada ao sentimento de urgência, ou seja, uma sensação forte de que precisa ir ao banheiro imediatamente?

SIM

NÃO

Se SIM, o quanto isso te incomoda?

NEM UM POUCO

UM POUCO

MODERADAMENTE

BASTANTE

#### 3. Você usualmente apresenta incontinência urinária associada à tosse, espirros ou risos?

SIM

NÃO

Se SIM, o quanto isso te incomoda?

NEM UM POUCO

UM POUCO

MODERADAMENTE

BASTANTE

#### 4. Você apresenta perda de pequenas quantidades de urina em gotas?

SIM

NÃO

Se SIM, o quanto isso te incomoda?

NEM UM POUCO

UM POUCO

MODERADAMENTE

BASTANTE

#### 5. Você tem dificuldade em esvaziar sua bexiga ou sente que ainda há urina na bexiga após ter ido ao banheiro?

SIM

NÃO

Se SIM, o quanto isso te incomoda?

NEM UM POUCO

UM POUCO

MODERADAMENTE

BASTANTE

#### 6. Você sente dor ou desconforto na região genital ou abdominal baixa?

SIM

NÃO

Se SIM, o quanto isso te incomoda?

NEM UM POUCO

UM POUCO

MODERADAMENTE

BASTANTE