# **Cross-cultural adaptation and validation** of the Constipation Scoring System for the Brazilian population

Thiago Masashi TANIGUCHI, Glicia Estevam de ABREU, Matheus Mascarenhas PORTUGAL and Ubiraiara BARROSO JUNIOR

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ABSTRACT - Background - Beyond Rome IV Criteria, the assessment of functional constipation in clinical practice can also be obtained by the Constipation Scoring System (CSS). By accessing the CSS, health professionals are able to measure this dysfunction, guiding initial therapeutic approach and post-treatment response. In addition, the CSS enables the standardization of results concerning functional constipation research. Objective - To promote translation, cross-cultural adaptation and validation of the CSS for the Brazilian population. Methods - To attain the score in Portuguese, the adaptation was accomplished in four steps (translation, back translation, application and adjustments). Afterward, the validation and adaptation to the Brazilian population was performed through test-retest. Results - For adults, the convergent validity of the Brazilian version of the CSS showed a significant correlation to the Rome IV Criteria evinced by the positive Spearman correlation (r<sup>2</sup>) of 0.816 (P<0.001). Between the test-retest responses, the translated version of the score had a Cronbach's Alpha of 0.972. A high level of internal consistency was also obtained when each item of the questionnaire was assessed separately, revealing an adequate internal reliability. Conclusion - The CSS was well adapted and accepted by the Brazilian population, demonstrating the linguistic and psychometric validity of this Portuguese version of the score.

Keywords - Functional constipation; questionnaires; validation study.

## INTRODUCTION

Affecting nearly 15% of the general adult population<sup>(1-3)</sup>, constipation is the most prevalent digestive symptom in general population<sup>(1)</sup>. It is related to high costs for health services<sup>(1,4,5)</sup> and impacts negatively on patients' quality of life<sup>(6)</sup>. Functional constipation (FC) is a functional bowel disorder characterized by the predominance of obstruction defecation symptoms and/or reduced spontaneous bowel movements<sup>(7)</sup>.

The major problem in FC research is the dependence on patients' perception of their bowel habits and the range of variations accepted as a normal pattern for each one<sup>(8)</sup>. Consequently, FC diagnosis tends to be interpretated in different concepts between patients and health professionals, and symptoms of constipation are underestimated in many times by patients themselves<sup>(8-10)</sup>. For this reason, the current diagnosis of FC and others functional gastrointestinal disorders is obtained in a standardized manner, using clinical aspects listed as Rome Criteria<sup>(7,11,12)</sup>, with Rome IV being the most recent one, published in 2016<sup>(7,11,12)</sup>.

Beyond Rome IV Criteria, the Constipation Scoring System (CSS) can also get FC's assessment in clinical practice. This score is usually used for adult population and that evaluates eight clinical aspects, varying from 0 to 30 points<sup>(13)</sup>. The advantage of this tool is to quantify the intestinal dysfunction, what guides the initial therapeutic approach and post-treatment response<sup>(14)</sup>. In addition, the CSS enables the standardization of results on FC research.

However, those scores require linguistic and cultural adjustments to personalize the approach to each population. Although the CSS seems to have a good applicability and acceptance in studies with the Brazilian population<sup>(15,16)</sup>, it has never been translated and adapted for this usage. Therefore, the aim of this study is to promote translation, cross-cultural adaptation and validation of the CSS for the Brazilian population.

## **METHODS**

This is an adaptation and validation study conducted with patients over 18 years receiving care at an outpatient clinic specializing in the diagnosis and treatment of colorectal diseases between July to November 2019. This medical service receives patients referred by gastroenterologists, other specialties or spontaneous demand. Patient with anatomical abnormalities (anorectal and colonic diseases), neurological diseases (central nervous system lesions, Parkinson disease), gastrointestinal tract neuropathy (autonomic neuropathy, Hirschsprung disease, amyloidosis), metabolic disorders (diabetes, hypothyroidism, hyperparathyroidism, metabolic and electrolytes imbalance) or evident psychiatric changes were excluded. All patients enrolled in the study denied receiving a

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Corresponding author: Glicia Estevam de Abreu. E-mail: gliabreu@hotmail.com

previous diagnosis of constipation or treatment for constipation or being referenced with the diagnosis of constipation refractory to the initial treatment. Moreover, they were not submitted to any anorectal physiological examination or radiological exam to differentiate the subtypes of intestinal constipation.

After patient signed the informed consent, a trained researcher applied a sociodemographic characteristic's questionnaire, the CSS's translated version, Rome IV Criteria, as well as a picture of the Brazilian version of Bristol Stool Chart<sup>(17)</sup>. The study was submitted to the Ethics Committee and obtained approval under the reference of CAAE 15331819.10000.5544.

# **Diagnostic tests**

# Gold standard test

The gold standard test for the diagnosis of FC in adults was Rome IV Criteria<sup>(12)</sup>. Patients were constipated when they presented at least two positive criteria: straining during more than 25% of defecations, lumpy or hard stools (Bristol types 1 or 2) more than 25% of defecations, sensation of incomplete evacuation for more than 25% of defecations, sensation of anorectal obstruction/blockage for more than 25% of defecations, manual maneuvers to facilitate more than 25% of defecations, less than three spontaneous bowel movements per week. Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis.

# **Comparing test**

The CSS is a score developed by Agachan et al.<sup>(13)</sup> that consists in a questionnaire with eight questions about symptoms and clinical signs related to the bowel habits. The usage and the validation of this tool have been authorized by one of the authors of the CSS.

# Steps of the study

This study was developed in three steps (FIGURE 1): (1) assessment of equivalence, (2) application in the target population, (3) final evaluation of the pre-test version and final version.

# Step 1: assessment of equivalence

Two independent certified translators (translators one and two) produced a Portuguese version from the CSS original English version. The comparative analysis of these translations originated a Portuguese score version, which was translated back to English by a medical professional that was native to the English language and fluent in Portuguese (translator three). Therefore, translator three performed the translation without prior knowledge of the original version.

Subsequently, the original text of the CSS was compared to the one translated from Portuguese, which allowed the inference on the quality of the Portuguese version of CSS. A multidisciplinary team composed of specialists in Pediatric Urology, Coloproctology, pelvic floor physiotherapy, psychology, portuguese and grammar discussed this preliminary version. This preliminary version was modified based on the consensus among the experts' opinions.

Because the original CSS utilizes technical terms not commonly used by the Brazilian population, to expressions like "bowel movements", "abdominal pain" and "constipation" (on topics 1, 4 and 8) were added synonyms such as "evacuations", "bellyache" and "irregular intestinal habit", respectively. Frequency terms were also modified by the consensus of experts and words previously translated as "occasionally" and "regularly" were replaced by expressions more commonly used by Brazilians, such as "sometimes" and "often", respectively. Following the same idea, the term "enema" (on item 6) was substituted for "intestinal lavage", and the term "never" (on item 7) was replaced for "no attempt".

# Step 2: application in the target population

The second Portuguese version was adapted by adding an extra alternative answer to each question, which was "I did not understand". After that, a primary test was carried out in a group of 40 patients in order to define the incidence of responses indicating incomprehension about the questionnaire, and the version obtained by this method, denominated as pre-test version, was subsequently evaluated in the third step of this study, in which were assessed the validity and reliability of the Brazilian version of CSS, in Portuguese.

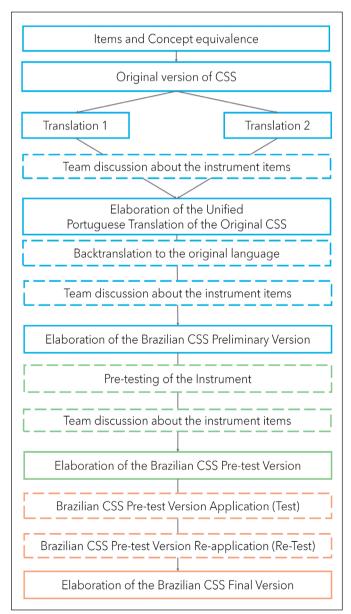


FIGURE 1. Steps of the study.

## Step 3: final evaluation of the pre-test version

In the third step, the Brazilian CSS was applied in all patients that fulfilled the study's criteria from the general medical school clinic. The score was applied during medical consults in a private room by a trained researcher. Since the Rome IV Criteria is the gold standard test for the diagnosis of FC in adults, it was applied on the sample and the results of both tests were compared in order to evaluate the correlation between them.

The internal consistency of the Brazilian CSS was assessed by the test-retest method. Patients were submitted to an interview with an examinator who applied the translated version of CSS, and this first evaluation was denominated "First Score". 30 days after, without any further intervention, patients were re-interviewed by a telephone call and this second evaluation was denominated "Second Score".

The protocol used to attempt telephone contact was based on three calls per day, in three different days, and in different times, in a bid to make it possible for patients to participate in the survey. In cases the contact was not succeeded, it was considered loss of follow-up. After evaluating the correlation and the internal consistency, this final version of the Brazilian CSS was considered validated.

#### Statistical analysis

Categorical variables were expressed in absolute and percentage values. Quantitative variables were described in mean and standard deviation or median and interquartile range, according to their distribution pattern (normal or non-normal) assessed by Kolmogorov-Smirnov test.

The convergent validity of the questionnaire was assessed analyzing the correlation between First CSS score and the quantity of positive variables of the Rome IV by using Spearman or Pearson (r) coefficient, depending on the distribution pattern of variables. Moreover, the internal consistency of the score was evaluated by obtaining a Cronbach's Alpha for First and Second CSS scores, and also for the eight questions that compose the score.

Furthermore, expecting a positive correlation between Rome IV and the Brazilian CSS, it was necessary a sample of 62 patients to obtain a correlation coefficient (r) of 0.35, with bilateral  $\alpha$  of 0.05 and  $\beta$  of 0.20 (statistical power of 80%), and thereby validate the tool for the adult population. For precaution, predicting a probable loss of follow-up of about 10% of patients, recruitment of 68 patients was estimated.

Statistical analysis was accomplished by SPSS Statistics for Windows, version 25.0. Armonk, NY: IBM Corp. and MedCalc for Windows, version 15.0 (MedCalc Software, Ostend, Belgium). The level of significancy was set at 5% for all tests.

## RESULTS

## Application in the target population

Of the 120 patients enrolled in the study, between July 01, 2016 and November 30, 2019, a total of 40 participated in the step 2 (application in the target population) and 80 in the step 3 (final evaluation of the pre-test version).

In this step, age ranged from 18 to 77 years old (mean =49.55 $\pm$ 15.0) and 27 (67.5%) participants were female. Regarding the comprehension of the score, questions 1, 2, 4, 6 and 8 were understood by 100% of patients. In contrast, questions 3, 5 and 7 had a comprehension rate of 85%, 97.5% and 75%, respectively.

In view of that, since the level of incomprehension of items three and seven was high, those questions were modified, generating the pre-test version of the Brazilian CSS, in Portuguese.

#### Final evaluation of the pre-test version

During the final evaluation, 80 patients evaluated in this phase, age ranged from 19 to 84 years old (mean  $=39.38\pm15.0$ ) and 66 (82.5%) participants were female.

In convergent validity analysis, the pre-test version of Brazilian CSS showed a significant agreement with the Rome IV criteria for constipation (FIGURE 2), with a positive correlation (r) of 0.816 (*P*<0.0001). Individual scoring of each Rome IV Criteria is available in TABLE 1.

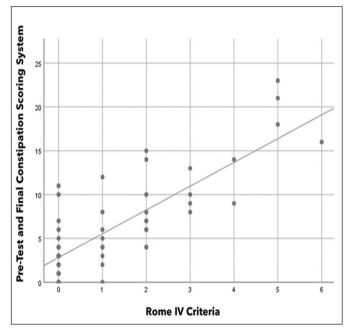


FIGURE 2. Correlation between The Rome IV criteria and the pre-test version of Brazilian Constipation Scoring System.

 TABLE 1. Individual criteria scoring at the Rome IV Criteria during the final evaluation of the pre-test version.

Rome IV Criteria	N of patients with positive criteria (%)
Straining	24 (30%)
Lumpy or hard stools	12 (15%)
Sensation of incomplete evacuation	23 (29%)
Sensation of anorectal obstruction/ blockage	6 (7.5%)
Manual maneuvers to facilitate defecation	8 (10%)
<3 spontaneous bowel movements per week	8 (10%)

N: number.

In test-retest phase, 14 (17.5%) patients did not complete the second application of the questionnaire. Cronbach's Alpha of the translated version of the scale was 0.972 (TABLE 2). A high concordance was also observed when each item of the questionnaire was assessed separately. The final version of the CSS validated for the Brazilian population is available in TABLE 3.

TABLE 2. Internal consistency of Constipation Scoring System between first and second Scores, and for each question of the scale, obtained by Cronbach's Alpha.

Variables	Test	Correlation
First and Second Scores (total)	Cronbach's Alpha	0.972
First and Second Scores for each question:		
Frequency of bowel movements	Cronbach's Alpha	0.797
Difficulty: painful evacuation effort	Cronbach's Alpha	0.769
Completeness: feeling incomplete evacuation	Cronbach's Alpha	0.780
Pain: abdominal pain	Cronbach's Alpha	0.793
Time: minutes in lavatory per attempt	Cronbach's Alpha	0.798
Assistance: types of assistance	Cronbach's Alpha	0.809
Failure: unsuccessful attempts for evacuating	Cronbach's Alpha	0.798
Per 24 hours		
History: duration of constipation	Cronbach's Alpha	0.797

## DISCUSSION

The results obtained by this study showed that the CSS, translated to Portuguese and adapted to the Brazilian population, has a high level of internal consistency and an excellent reliability as an instrument to evaluate constipation in clinical practice.

When created, questionaries are intended to be applied in a specific population, what means that American scores, produced in English, are developed based on American characteristics<sup>(13)</sup>. Globalization may facilitate the access to these tools. However, since professionals cannot guarantee that aspects are being explored in the right way, literal translations during the clinical practice may represent an error, especially when it comes to symptoms or its impacts on the quality of life<sup>(18)</sup>.

Although constipation is a very prevalent symptom, its definition is quite difficult once it depends on cultural aspects that varies with each population<sup>(19,20)</sup>. Because of that, the creation of a simple, practical, effective and objective criterion for the diagnosis of this condition is extremely important for clinical practice. Rome IV criteria could satisfy these demands and it standardized the definition of constipation worldwide<sup>(7,21,22)</sup>. However, it stills has limitations. The inflexibility of dichotomous criteria hampers the diagnosis of constipation as it hinders quantification and comprehension of symptoms impact on quality of life.

CSS was developed in 1996<sup>(13)</sup>, and although it is a simplified tool, this score complements Rome IV Criteria because it quantifies clinical aspects of constipation, allowing health professional to understand and individualize therapeutics approaches for each patient. Besides that, because of its score structure, CSS could also be used as a tool of post-treatment evaluation, monitoring improvement, maintenance or even worsening of cases<sup>(14)</sup>.

TABLE 3. Final Portuguese version of Constipation Scoring System.

Sistema de Pontuação de Constipação	Pontuação*
3	3
Frequência de evacuações (fazer cocô)	
1 a 2 vezes a cada 1 a 2 dias	0
2 vezes por semana	1
1 vez por semana	2
Menos do que uma vez por semana	3
Menos que uma vez por mês	4
Dificuldade: esforço com dor para evacuar	-
Nunca	0
Raramente	1
Às vezes	2
Quase sempre	3
Sempre	4
Completude: sensação de evacuação incompleta	1
Nunca	0
Raramente	1
Às vezes	2
Quase sempre	3
Sempre	4
Tempo: minutos no banheiro por tentativa (para fazer c	-
Menos que 5 minutos	0
5 a 10 minutos	1
10 a 20 minutos	2
20 a 30 minutos	3
Mais que 30 minutos	4
Assistência: ajuda para evacuar	1
Sem assistência	0
Laxantes estimulantes	1
Assistência digital ou lavagem intestinal	2
Fracasso: tentativas malsucedidas de evacuação por 24 l	
Nenhuma tentativa	0
1 a 3 tentativas	1
3 a 6 tentativas	2
6 a 9 tentativas	3
Mais que 9 tentativas	4
Histórico: duração da constipação (prisão de ventre)	-
<1 ano	0
1 a 5 ano(s)	1
5 a 10 anos	2
10 a 20 anos	3
Mais que 20 anos	4
*Pontuação mínima: 0; pontuação máxima: 30	-

Despite being an excellent tool, the use of CSS had never been validated for the Brazilian context. Aspiring to guarantee the same effectiveness of the score among our population, the core of this study was to adapt the CSS not only to the Brazilian linguistic aspects, but also to their cultural specifications. For this reason, the methodology of this article was carefully planned and based on the opinion of health experts and a Portuguese language specialist, what allowed us to structure the questionnaire conciliating technical issues with the peculiarities of Brazilian culture, and that was reflected on the high level of comprehension observed during the pre-test.

Similar results were also found on studies that aimed to validate other scales for the Brazilian population. The Bristol Stool Scale was validated by Martinez et al. (2012)<sup>(17)</sup>, while the Wexner Incontinence Score was adapted by Meinberg (2014)<sup>(23)</sup>. Methodology utilized in these studies were quite similar to ours and both of them obtained a good internal consistency with significant correlation between the adapted version and the gold standard test that was adopted. Furthermore, this study demonstrated a positive linear correlation of 0.816, which is higher than the obtained on the validation of Wexner Incontinence Score (negative linear correlation of 63%) that adopted the Fecal Incontinence Quality of Life (FIQL) as the gold standard test<sup>(23)</sup>.

Moreover, the validation of Bristol Stool Scale also counted with the inclusion of health professionals on test-retest phase<sup>(22)</sup>, which was not done in this study because our objective was to adapt CSS in terms of complexity and linguistic adequacy, in order to guarantee the comprehension by patients and professionals. On the other hand, Leite et al.  $(2018)^{(24)}$  assumed to get a satisfactory validation once the internal consistency was about 0.8. Since this study showed an internal consistency of 0.972, it is possible to admit an excellent functionality of the CSS adapted version.

Difficulty of follow-up can be highlighted as the major limitation of this study. Once the second application of the questionnaire was accomplished by a telephone call, 17.5% of the sample did not complete this tool. However, this was a predicted limitation, and some measures were taken to contain it: the protocol of telephone contact involved different days and times, and sample calculation was done with a safety margin of 10%. The small sample size could also be taken as a limitation, but 80 patients was sufficient when considering sample calculation based on the expected correlation, allowing analysis with significance and satisfactory statistical power. Moreover, it is important to mention that despite of its large usage in Brazil, the Rome IV Criteria, adopted as the gold standard, have not been officially translated to Portuguese yet. However, we emphasize that the Rome IV criterion is a score of dichotomous responses. In turn, the CSS, evaluating the intensity of the symptoms, presents about five response options. Thus, respondents may find it more difficult to understand its literal translation.

Besides, despite the significant correlation between the CSS and the Rome IV Criteria for Functional Constipation, is not possible to affirm that this same correlation significance would be applicable to each bowel constipation subtype (FC, defecatory dysfunction, and colonic inertia). However, none of the patients included in this study had a medical record of FC refractory of any initial constipation management that indicated further examination with anorectal physiology workup or radiological exams. This approach is consonant with the American Gastroenterological Association (AGA) medical position statement on constipation which indicates additional examination when there is an inadequate response to the therapeutic trial (fiber  $\pm$  laxatives)<sup>(25)</sup>. Moreover, in a large cohort study with more than 1.400 adults with FC<sup>(26)</sup>, the normal transit constipation represented the most frequent subtype (65%), followed by the dyssynergic defecation type (30%), and colonic inertia, which represents only (5%) of the constipation subtypes<sup>(26)</sup>.

In conclusion, this study demonstrated the linguistic and psychometric validity of the Brazilian CSS, reinforcing the importance of this tool for diagnosis and management of constipated patients in Brazil. The translation to Portuguese had an excellent adequacy and it was well accepted by the population due to it's simplified structure associated with questions more immersed in symptoms impact on quality of life.

## Authors' contribution

Taniguchi TM: data collection, survey execution, writing of text, statistical analysis. Abreu GE: data collection, survey execution, review. Portugal MM: writing of text, translation and review. Barroso Junior U: writing of text, review.

## Orcid

Thiago Masashi Taniguchi: 0000-0003-3458-510X. Glicia Estevam de Abreu: 0000-0003-3170-2294. Matheus Mascarenhas Portugal: 0000-0003-3258-7267. Ubirajara Barroso Junior: 0000-0002-1067-2463.

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RESUMO – Contexto – Além dos Critérios de Roma IV, a avaliação da constipação funcional também pode ser obtida por meio do *Constipation Scoring System* (CSS). Ao acessar o CSS, o profissional de saúde consegue mensurar a constipação funcional, orientando a abordagem terapêutica inicial e a resposta pós-tratamento. Além disso, o CSS possibilita a padronização dos resultados das pesquisas sobre esta disfunção. Objetivo – Promover a tradução, adaptação transcultural e validação do CSS para a população brasileira. Métodos – Para obtenção da versão do CSS em português, a adaptação foi realizada em quatro etapas (tradução para o inglês, retrotradução para o português, aplicação e ajustes). Posteriormente, foi realizada a validação e adaptação para a população brasileira por meio de teste-reteste. Resultados – Para adultos, a validade convergente da versão brasileira do CSS apresentou correlação significativa com os critérios de Roma IV evidenciada pela correlação de Spearman positiva (r) de 0,816 (*P*<0,001). Entre as respostas do teste-reteste, a versão traduzida do escore apresentou um Alpha de Cronbach de 0,972. Um alto nível de consistência interna também foi obtido quando cada item do questionário foi avaliado separadamente, revelando uma confiabilidade interna adequada. Conclusão – O CSS foi bem adaptado e aceito pela população brasileira, demonstrando a validade linguística e psicométrica da versão em português do escore.</p>

Palavras-chave – Constipação funcional; questionários; estudo de validação.

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