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Translation, Cultural Adaptation and Validation of "PROMIS GI - Disrupted Swallowing" Scale for the Portuguese Language

Tradução, Adaptação Cultural e Validação da Escala "PROMIS GI - Dificuldade em Engolir" na Língua Portuguesa

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ABSTRACT

Introduction: Dysphagia is a prevalent condition (20%), and occurs more frequently in women and in older people. It negatively impacts innumerous aspects of patient's personal and professional lives. Patient-reported outcomes allow patients to directly quantify their experience regarding dysphagia and evaluate its true impact on quality of life. Among the scales available, Patient-Reported Outcomes Measurement Information System Gastrointestinal (PROMIS GI) Disrupted Swallowing stands out because it is a robust instrument that can be applied regardless of the type and etiology of dysphagia. The aim of this study was to translate, culturally adapt and validate PROMIS GI Disrupted Swallowing scale for the Portuguese-speaking population.

Methods: Firstly, the seven items of the scale were translated and transculturally reviewed following the systematic method proposed by the Functional Assessment of Chronic Illness Therapy (FACIT). Afterwards, the pre-test version of the questionnaire was administered to a convenience sample (n = 6) for semantic evaluation, with the aim of detection and subsequent correction of possible problems in the translation. The final translated and certified version of the scale was administered to 200 voluntary adult participants (n = 123 healthy; n = 77 dysphagia) in Portugal, for evaluation of reliability and validity.

Results: The Portuguese version of PROMIS GI Disrupted Swallowing presented acceptable internal consistency (coefficient of Cronbach's α of 0.919) and adequate test-retest reliability (intraclass correlation coefficient of 0.941). The translated version of the scale revealed a strong correlation with both Eckardt score ($p < 0.001$; $\rho = 0.782$) and the quality-of-life questionnaire EuroQol-5D ($p < 0.001$; $\rho = -0.551$), demonstrating evidence of convergent validity.

Conclusion: The Portuguese version of PROMIS GI Disrupted Swallowing scale presented conceptual, semantic, cultural and measurement equivalence relatively to the original items. The results attained demonstrated that the translation of this scale to Portuguese is reliable and valid for use both in clinical practice and for research purposes.

Keywords: Deglutition Disorders; Portugal; Reproducibility of Results; Surveys and Questionnaires; Translation

RESUMO

Introdução: A disfagia é uma condição prevalente (20%), mais frequente nas mulheres e nos idosos, que tem um marcado impacto negativo na qualidade de vida pessoal e profissional dos afetados. Os resultados reportados pelo doente (*patient-reported outcomes*) permitem quantificar a sua experiência perante a disfagia e avaliar o impacto real na qualidade de vida. Entre as escalas disponíveis, a *Patient-Reported Outcomes Measurement Information System Gastrointestinal* (PROMIS GI) *Disrupted Swallowing* destaca-se por ser um instrumento robusto e aplicável independentemente do tipo e causa de disfagia. Neste estudo os autores procedem à tradução, adaptação cultural e validação da escala PROMIS GI *Disrupted Swallowing* na população de língua portuguesa.

Métodos: Numa primeira fase, os sete itens da escala foram traduzidos e revistos transculturalmente de acordo com o método sistemático proposto pelo *Functional Assessment of Chronic Illness Therapy* (FACIT). A versão pré-teste do questionário foi aplicada a uma amostra de conveniência (n = 6) para avaliação semântica, para deteção e correção subsequente de possíveis problemas na tradução. A versão final traduzida e certificada foi aplicada a 200 indivíduos adultos voluntários (n = 123 saudáveis; n = 77 disfagia) em Portugal, para avaliação da confiabilidade e validade.

Resultados: A versão portuguesa da escala PROMIS GI *Disrupted Swallowing* apresenta uma consistência interna aceitável (coeficiente α de Cronbach de 0,919) e uma confiabilidade teste-reteste adequada (coeficiente de correlação intraclasse de 0,941). A versão traduzida da escala apresentou uma correlação forte com o *score* de Eckardt ($p < 0,01$; $\rho = 0,782$) e com o questionário de qualidade de vida EuroQol-5D (EQ-5D) ($p < 0,01$; $\rho = -0,551$), evidenciado validade convergente.

Conclusão: A escala PROMIS – Sintomas Gastrointestinais - Dificuldade em Engolir apresentou equivalência conceptual, semântica, cultural e de medição relativamente à escala original. Os resultados obtidos demonstraram que a versão portuguesa desta escala aparenta ser fiável e válida para aplicação tanto na prática clínica como em contexto de investigação.

Palavras-chave: Distúrbio da Deglutição; Inquéritos e Questionários; Portugal; Reprodutibilidade dos Testes; Tradução

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INTRODUCTION

Dysphagia consists in the difficulty of liquids or solids to pass from the oral cavity to the stomach. It can be classified as oropharyngeal or esophageal. The prevalence of dysphagia in the general population is around 20%,[1] and it is estimated to affect up to 50% of people over 60 years old, occurring more frequently in women and in older people than in men and in younger people.[1-3] However, it is very challenging to accurately quantify the true prevalence of this symptom.[4] Oropharyngeal dysphagia is typically due to structural, anatomic or neuromuscular abnormalities. On the other hand, esophageal dysphagia arises after swallowing and causes include intrinsic structural disease, disruption in normal motility or extrinsic compression.[1,2]

This condition can have nefarious consequences in terms of physical health such as malnutrition, dehydration, aspiration pneumonia or death caused by asphyxia,[5-6] which increase in-hospital mortality, hospital length of stay, inpatient costs and likelihood of discharge to a post-acute care facility.[4,8,9] However, the impact of dysphagia is much wider, with consequences also in terms of psychological well-being and innumerous aspects of the personal and professional lives of patients, thus reinforcing the need of an early and multidisciplinary approach.[4,10-13] In a study performed in patients with dysphagia following chemoradiation for head and neck cancer, roughly 40% reported anxiety during meals and 36% avoided eating in front of other people.[11]

The assessment of dysphagia can be performed using simple tests designed to rapidly detect signs and symptoms of swallowing disorders, such as the Eating Assessment Tool (EAT-10) and the Functional Oral Intake Scale (FOIS).[13] Patient-reported outcome (PROs) scales offer a method of quantifying the patient experience regarding his/her illness in a structured format and can be helpful for use in comparative effectiveness studies.[14-16] The measurement of PROs can improve clinical outcomes by successfully aiding in the detection and management of conditions, improving satisfaction with care and enhancing the patient–provider relationship.[17] The Patient-Reported Outcomes Measurement Information System (PROMIS®) is a standardized set of PROs that cover physical, mental, and social health. The PROMIS vision is to create highly efficient and short questionnaires that are feasible to implement in busy clinical settings while preserving reliability and validity.[17]

A recent meta-analysis identified a total of 34 dysphagia-related PROs scale studies,[15] mostly conceived for specific conditions such as achalasia or Parkinson's disease.[18-21] Among the available scales for general dysphagia, PROMIS Gastrointestinal (PROMIS GI) Disrupted Swallowing is a robust instrument when evaluating all the different domains (conceptual model, content validity, reliability, construct validity, scoring and interpretation, and burden and presentation).[15] It was validated in the North American population, it is easy to use, and it was developed with the goal of evaluating the impact caused by dysphagia in an individual patient, regardless of etiology or type of dysphagia.[17] PROMIS GI scales have not been validated, to the present moment, in a Portuguese population.

Since the original items of PROMIS were developed in English a translation is necessary in order to allow the use of these scales in countries with other native languages.[16] The PROMIS standards stipulate that all PROMIS translations should be carried out using the rigorous Functional Assessment of Chronic Illness Therapy (FACIT) translation methodology, which includes cross-cultural adaptation and linguistic validation, before allowing the application of PROMIS scales in clinical trials, multicentric studies and clinical practice.[16] Additionally, our study has included rigorous reliability verification procedures.

The objective of our study was to conduct the translation, cultural adaptation and validation of the PROMIS GI Disrupted Swallowing scale in the Portuguese language and in an adult population. The validation of the Portuguese version of PROMIS GI Disrupted Swallowing is vital for a more standardized evaluation and intervention in dysphagia, contributing for its subsequent application in research and clinical practice.

METHODS

We conducted a cross-sectional study of translation, cultural adaptation, and validation of the PROMIS GI Disrupted Swallowing scale to the Portuguese language, after obtaining permission from the PROMIS Health Organization (PHO).

PROMIS GI Disrupted Swallowing comprises seven items (questions GISX31 to GISX37) that assess the frequency of swallowing-related symptoms during the past seven days on a scale of "never" to "always".[17] It encompasses an array of symptoms described by patients ranging from pain or difficulty swallowing solid and soft foods, liquids and pills, to food getting stuck in the throat or chest when eating.[17] Each item is scored between 0 and 5 and the overall score ranges from 7 to 35 (summed score). This scale uses item-level calibrations to produce a T-score, based on the United States general population, where 50 is an estimate of the general population mean and 10 is the standard deviation. This type of scoring scale uses a response pattern scoring and is more accurate, especially when there is missing data or different groups of participants responded to different items. The participants completed the questionnaire through pen-and-paper or electronically. Participants were instructed to respond to all items.

The study was developed in three phases. The first phase included the translation process and cultural adaptation of the PROMIS GI Disrupted Swallowing scale to the Portuguese language, with verification of semantic equivalence, according to the guidelines for the process of cross-cultural adaptation of self-reported instruments.[22] The translation followed the universal and systematic method proposed by FACIT, as required by PHO.[23]

The questionnaire underwent two forward translations that were performed by two researchers, one being a native speaker of European Portuguese and the other being a native speaker of Brazilian Portuguese, and both were fluent in the Portuguese and English languages. Afterwards, a third translator, who was a native speaker of European Portuguese and was also fluent in both Portuguese and English, reconciled the two initial translations. A retro-translation of this reconciliated version was conducted by a native speaker of American English, and who was also fluent in Portuguese and uninformed about the English source of the questionnaire.

Afterwards, three independent reviewers (one linguist and two health-related quality of life research experts), two native speakers of European Portuguese and one native speaker of Brazilian Portuguese, analyzed all the previous steps and selected the most adequate translation for each one of the seven items. The translated version was sent to the PROMIS Translation coordinating center in the Department of Medical Social Sciences of Northwestern University in the United States of America for appraisal and further revision. The translation history was verified by the PROMIS Translation Director, and the Portuguese translation was harmonized with the versions in other languages. Finally, the ultimate English to Portuguese translated version was approved and submitted to the pre-test stage, in collaboration with the linguistic coordinator in Portugal.

The second phase of the process included the semantic evaluation to confirm the suitability of the translation to Portuguese-speaking populations. The approved pre-test version of the questionnaire was administered to a convenience sample of six voluntary adult participants followed in Centro Hospitalar de Lisboa Ocidental, for detection of possible problems in the translation and subsequent correction. All participants had at least basic reading and writing skills and were native speakers of Portuguese (both individuals born in Portugal and in Brazil were considered eligible participants). Participants were asked to complete the questionnaire on their own and were then asked some debriefing questions about the translated items to assess comprehension. Following the process of linguistic validation, the translation was certified by the PROMIS Translation Director at Northwestern University.

During the third phase of the process, the final version of the Portuguese PROMIS GI Disrupted Swallowing scale was applied to 200 voluntary adult participants whose native language was European Portuguese. The purpose of this phase was the evaluation of reliability and validity of the translated version of the scale. These participants were individuals from the general population or patients with dysphagia followed in Centro Hospitalar de Lisboa Ocidental. The size of the sample was considered fair according to Comrey and Lee.[24,25] The patients were also asked to fill a sociodemographic form (age, gender, education and ethnicity), Eckardt score (if dysphagia) and the Portuguese version of the quality-of-life questionnaire EuroQol-5D (EQ-5D).

The Eckardt score was used for evaluation of the severity of dysphagia. It attributes 0 to 3 points to each of the major symptoms of achalasia (dysphagia, regurgitation, chest pain and weight loss).[26]

EQ-5D is a quality-of-life index developed by the EuroQoL group that contains two pages: the EQ-5D descriptive system and the EQ-5D visual analogue scale (VAS). The first comprises five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels of severity, which implicates a total of 243 distinct health states,[24] that can be converted to a value between -1 and 1 according to the Portuguese general population time trade-off (TTO) values for EQ-5D. VAS records the patient's self-rated health on a vertical visual analogue scale (from 0 to 100), where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'. The VAS can be used as a quantitative measure of health outcomes that reflects the patient's own judgement.

Approximately half of the study population (115 participants, both healthy and with dysphagia) did a retest 15 days after the first administration of the Portuguese version of PROMIS GI Disrupted Swallowing scale, in order to allow the subsequent study of test-retest reliability.

Statistical analysis

Descriptive statistics (central tendency and dispersion measures) were used for characterization of the sociodemographic variables of the study population and for analysis of the PROMIS GI Disrupted Swallowing initial test and retest, Eckardt score and EQ-5D (TTO and VAS values).

Testing for dimensionality was skipped due to the fact that both versions of the scale (original and Portuguese) are directly comparable. In terms of reliability, internal consistency of the items of the PROMIS GI Disrupted Swallowing scale was assessed by using Cronbach's α, with values higher than 0.5 indicating an acceptable level of reliability.[27] The test-retest reliability was analyzed by using the intraclass correlation coefficient (ICC). ICC values higher than

0.75 were considered adequate.[28]

Spearman's rank correlation coefficient was used to evaluate the relationship between the score attained in the PROMIS GI Disrupted Swallowing scale with the value of EQ-5D TTO and with Eckardt score. Coefficient estimates lower than 0.29 were deemed weak and those higher than 0.5 were considered strong.[29] Statistical tests with *p*-value less than 0.05 were considered statistically significant.

RESULTS

Translation and cultural adaptation process

The seven items of the original PROMIS GI Disrupted Swallowing scale were translated and transculturally reviewed following the systematic method proposed by FACIT. The process of translation and cultural adaptation is summarized in Fig. 1. The researchers and the certified translator discussed some specific technical concepts of the first two forward translations in order to reconcile them. A few adaptations were made to make the concepts more discernible and appropriate for Portuguese speakers both in Portugal and in Brazil. For example, in Brazilian Portuguese the term for "ice cream" is "sorvete", while in European Portuguese the term is "gelado". The consensus version includes both terms ("gelados/sorvete"). Similarly, the word "mashed" (from mashed potatoes) is spelled "purê" in Brazil and "puré" in Portugal. The solution for a universally acceptable version was to use both diacritic marks ("puré(ê) de maçã ou puré(ê) de batata").

The reconciled Portuguese version then underwent retro-translation by an independent translator without

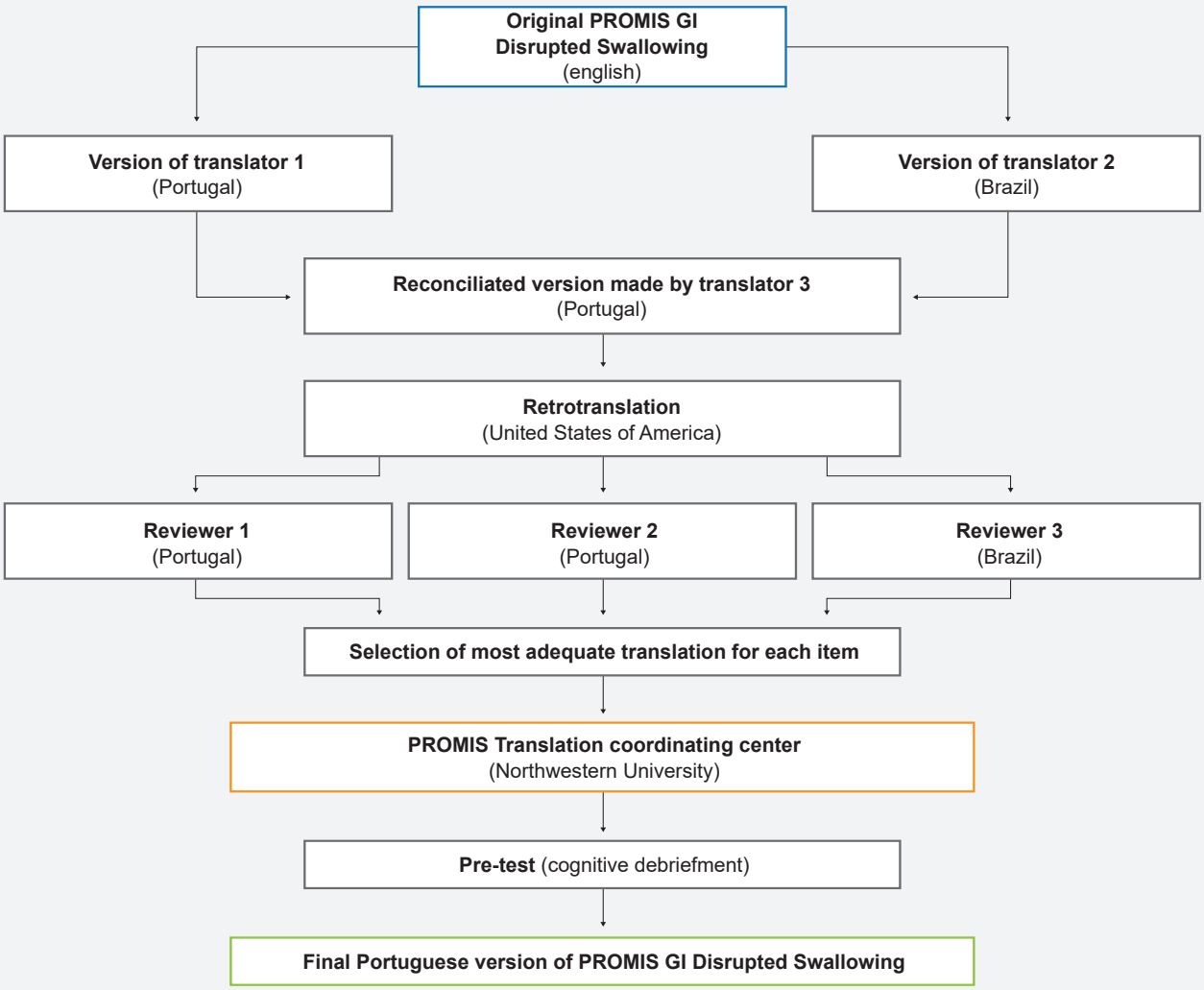

Figure 1 – Flowchart of the process of translation and cultural adaptation of PROMIS GI - Disrupted Swallowing scale to European Portuguese

access to the English source. Afterwards, three independent reviewers analyzed all the previous steps and selected the most adequate translation for each one of the seven items. Finally, the translated version was evaluated and revised by the PROMIS translations coordinating center in Northwestern University in the United States of America. Both the PROMIS Translation coordinating center and the linguistic coordinator in Portugal approved the final version of the PROMIS GI Disrupted Swallowing scale after discussion of clinical and linguistic issues (the translated questionnaire can be obtained at https://www.healthmeasures.net/explore-measurement-systems/promis/intro-to-promis/available-translations). This final version was submitted to the pre-test phase.

Table 1 – Sociodemographic characteristics of the study population (n = 200)

Characteristics	Value
Age (average ± DP)	49.8 ± 16.6 years
Gender	
Male	59 (29.5%)
Female	141 (70.5%)
Education	
Primary	44 (22.0%)
Secondary	58 (29.0%)
University	85 (42.5%)
Unknown/undisclosed	13 (6.5%)
Ethnicity	
White	160 (80.0%)
Black	12 (6.0%)
Asian	1 (0.5%)
Unknown/undisclosed	27 (13.5%)
Type of participant	
Healthy	123 (61.5%)
Esophageal dysphagia	59 (29.5%)
Oropharyngeal dysphagia	18 (9.0%)

Pre-test (semantic equivalence)

The pre-test aimed to assess the cultural and semantic equivalence and the comprehension of the wording of the questions and the scale. The PROMIS GI Disrupted Swallowing instrument was tested in six individuals from the general population (three women and three men) with ages between 27 and 73 years (average age of 51 years). Five participants were native Portuguese speakers, born in Portugal, and one participant was born in Brazil and spoke Brazilian Portuguese. One participant had completed the fourth grade, one participant was a high school graduate, one had a college degree, one had a technical degree and two participants had advanced degrees. None of the participants reported any items to be difficult to understand, irrelevant or offensive. None of the participants felt the need to add anything else to the questionnaire. Cognitive debriefing for content validity was performed and no translation changes were recommended. Conceptual and semantic equivalence were confirmed in relation to the original version.

Test (measurement equivalence)

Among the 200 voluntary participants that participated in the final phase of translation, cultural adaptation and validation process of the Portuguese PROMIS GI Disrupted Swallowing scale, 123 were healthy (61.5%) and 77 had esophageal or oropharyngeal dysphagia (59 and 18 individuals, respectively). The average age was 49.8 ± 16.6 years, and most individuals were female (n = 141; 70.5%). Regarding education, nearly half of the participants did not have a college degree (n = 102; 51%) while 85 individuals went to university (42.5%). White ethnicity was the most frequently reported (n = 160; 80%). Table 1 summarizes the sociodemographic characteristics of the study population.

Table 2 shows the results attained in PROMIS GI Disrupted Swallowing test and retest (summed scores), Eckardt score and EQ-5D (TTO and VAS) among the three different groups of our study (healthy, esophageal dysphagia and oropharyngeal dysphagia). The average summed scores of PROMIS GI Disrupted Swallowing test and retest

Table 2 – Results attained in PROMIS GI Disrupted Swallowing test and retest (summed scores), Eckardt score and EQ-5D (TTO and VAS) among the three different groups of the study (healthy, esophageal dysphagia and oropharyngeal dysphagia) (n = 200)

	n	PROMIS GI Disrupted Swallowing test (summed score)*	PROMIS GI Disrupted Swallowing retest (summed score)*	Eckardt score*	EQ-5D (TTO)*	EQ-5D (VAS)*
Healthy	123 (61.5%)	8.56 ± 8.00	8.21 ± 5.21	0.1 ± 2.3	0.853 ± 2.193	85 ± 18
Esophageal dysphagia	59 (29.5%)	17.00 ± 6.32	15.39 ± 5.43	3.7 ± 2.5	0.630 ± 0.269	72 ± 19
Oropharyngeal dysphagia	18 (9.0%)	18.17 ± 5.79	16.20 ± 5.24	2.9 ± 1.8	0.481 ± 0.272	58 ± 19
Total	200 (100%)	11.92 ± 6.15	10.97 ± 5.21	1.5 ± 2.5	0.754 ± 0.266	79 ± 19

*: average ± DP

Table 3 – Distribution of the answers given to the seven questions (GISX31 to GISX37) that compose PROMIS GI Disrupted Swallowing (n = 200)

PROMIS GI Disrupted Swallowing	1	2	3	4	5	Median (Q1 - Q3)
GISX31	125 (62.5%)	24 (12.0%)	29 (14.5%)	18 (9.0%)	4 (2.0%)	1 (1 - 3)
GISX32	111 (55.5%)	44 (22.0%)	30 (15.0%)	12 (6.0%)	3 (1.5%)	1 (1 - 2)
GISX33	121 (60.5%)	32 (16.0%)	35 (17.5%)	8 (4.0%)	4 (2.0%)	1 (1 - 2)
GISX34	118 (59.0%)	25 (12.5%)	32 (16.0%)	14 (7.0%)	11 (5.5%)	1 (1 - 3)
GISX35	149 (74.5%)	23 (11.5%)	17 (8.5%)	7 (3.5%)	4 (2.0%)	1 (1 - 2)
GISX36	137 (68.5%)	25 (12.5%)	23 (11.5%)	13 (6.5%)	2 (1.0%)	1 (1 - 2)
GISX37	122 (61.0%)	36 (18.0%)	24 (12.0%)	10 (5.0%)	8 (4.0%)	1 (1 - 2)

were 11.92 ± 6.15 and 10.97 ± 5.21, respectively (the median summed score is 9 in both cases).

Table 3 displays the absolute and relative frequencies and the first quartile (Q1), median and third quartile (Q3) of the answers given to the seven items of PROMIS GI Disrupted Swallowing. Most of the inquired participants answered "1", which corresponds to "Never" in all of the items.

The set of items of the Portuguese PROMIS GI Disrupted Swallowing scale presented a coefficient of Cronbach's α of 0.919, indicating an acceptable level of reliability (shown in Table 4).

The ICC obtained regarding the test-retest reliability was 0.941 ($p < 0.001$; 95% CI: 0.916 - 0.959).

Convergent validity

Regarding the results of the other questionnaires administered to the 200 individuals, the mean Eckardt score was 1.5 ± 2.5 (median 1, minimum 0 and maximum 12). Concerning EQ-5D, the mean TTO was 0.754 ± 0.266 (median 0.767, minimum -0.035 and maximum 1) and the mean value of VAS was 79 ± 19 (median 83, minimum 5 and maximum 100) (Table 2).

The spearman's rank correlation coefficient was used to assess for convergent validity. The correlation between PROMIS GI Disrupted Swallowing and Eckardt score was positive and statistically significant ($p < 0.001$; $\rho = 0.782$).

Table 4 – Internal consistency of the Portuguese version of PROMIS GI - Disrupted Swallowing scale: Cronbach's α if item deleted

Internal consistency	n	Cronbach's α if item deleted
GISX31	200	0.905
GISX32	200	0.911
GISX33	200	0.912
GISX34	200	0.901
GISX35	200	0.901
GISX36	200	0.903
GISX37	200	0.913
Total	200	**0.919**

The values of EQ-5D TTO were also statistically correlated with PROMIS GI Disrupted Swallowing ($p < 0.001$; $\rho = -0.551$). However, the correlation was negative.

DISCUSSION

The aim of this study was to describe the process of translation, cultural adaptation and validation of PROMIS GI Disrupted Swallowing questionnaire in Portuguese, in agreement with the rigorous recommended methods proposed by international literature and including representation from major Portuguese-speaking regions.

Even though dysphagia is a prevalent symptom with major impact in the quality of life of patients, its etiology is extremely variable and the patients that report this symptom represent a very heterogeneous population. Older people are more likely to report dysphagia, with an estimated prevalence of 50% to 66% in this group and with a higher likelihood of neurologic causes, such as stroke or neurodegenerative diseases.[1,2,4] In younger populations, however, dysphagia is often associated with an underlying systemic illness, such as autoimmune diseases or eosinophilic esophagitis.[2] The use of a standardized tool in a structured format that measures the outcomes of this population in a more objective way is obviously very advantageous for epidemiological characterization and clinical intervention.

PROMIS GI Disrupted Swallowing is a reliable and validated scale that allows an efficient and quick assessment of the impact of dysphagia in an individual patient.[16] There are currently multiple international scales for evaluation and assessment of dysphagia, but none of those has been linguistically and culturally adapted and validated in Portuguese.[6,15]

The results found suggest that the Portuguese version of PROMIS GI Disrupted Swallowing is reliable and reproductible, as confirmed by the adequate coefficient of Cronbach's α and CCI scores, respectively. Furthermore, the translated version revealed a strong correlation with both the Eckardt score and the EQD-5D TTO with statistical significance, demonstrating evidence of convergent validity. These correlations were expected since individuals with

more symptoms of disrupted swallowing are more likely to have higher Eckardt scores and a more impaired quality of life.

Beyond the purpose of translation and validation, this study contributed to the development of a robust scale that could eventually be used in clinical care in Portugal for the evaluation of dysphagia. It would thus allow the assessment of the true impact of dysphagia in the physical, mental, and social health of the patient, and guide the treatment of benign conditions. Ultimately, the translated version of PROMIS GI Disrupted Swallowing could contribute to the improvement of these patients' quality of life simply by allowing them to better acknowledge the swallowing disorder.[6] There is commonly the perception that eating has a noteworthy social and cultural dimension in Portuguese-speaking countries, and this adapted questionnaire could be useful for future research on this matter.[4,7]

A limitation of the present study is the fact that the sample could have contained more individuals with dysphagia, since more than half of the sample was healthy. Moreover, further cultural adaptation may be needed in order to render the Portuguese version of PROMIS GI Disrupted Swallowing appropriate for use in countries other than Portugal and Brazil where Portuguese is the official language.

Another clear limitation relies on the fact that PROMIS GI Disrupted Swallowing was only validated for use in adults. However, dysphagia is rare in children. Also, the application of this PRO scale in the pediatric population would not be very easy, since children might lack the necessary skills to adequately manifest their own experience through this instrument.

Besides, as with other PROMIS GI scales, the seven-day recall period is a limitation since the symptoms that a patient experienced in the previous week might not reflect the true burden of dysphagia in his/her daily life.[14] Accordingly, the use of this scale for transient evaluations or as a daily diary could be helpful and more accurate in some patients. Finally, this scale is not disease specific, and there could be significant variation in performance regarding the type and etiology of dysphagia.

Finally, it is clear that the use of measures such as PROMIS GI Disrupted Swallowing questionnaire cannot obviously replace the clinical judgment, which is based on a comprehensive assessment and multidimensional evaluation of an individual patient with dysphagia. Moreover, it is essential to define the presence, location, and severity of the swallowing disruption.[13]

CONCLUSION

The translation from English to Portuguese of the PROMIS GI Disrupted Swallowing scale presented conceptual, semantic, cultural and measurement equivalence to the original items in English. The resulting translation history was verified by the PROMIS Translation Director, and the Portuguese translation and proofreading work was performed by native speakers of Portuguese (or English in the case of the back-translator) to the best of their abilities and experience. The results presented demonstrate that this instrument is reliable and valid for both research and clinical use.

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AUTHOR CONTRIBUTIONS

JPR: Study supervision and coordination, writing of the manuscript, translation and cultural adaptation, recruitment the study population and administration of the questionnaires, data analysis; statistical analysis, critical review of the manuscript.

AM: Writing of the manuscript, recruitment the study population and administration of the questionnaires, data collection, data analysis, statistical analysis, critical review of the manuscript.

CF: Translation and cultural adaptation, recruitment the study population and administration of the questionnaires, data analysis.

HC: Translation and cultural adaptation, critical review of the manuscript.

CC: Translation and cultural adaptation, data analysis.

DN: Recruitment the study population and administration of the questionnaires, data analysis.

JDC: Data analysis, statistical analysis.

RTM, MMS: Critical review of the manuscript.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in 2013.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

COMPETING INTERESTS

AM has received payment or honoraria for lectures, presentations, speakers' bureaus, manuscript writing or educational events from Ferring Pharmaceuticals.

All other authors have declared that no competing interests exist.

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