



Turkish Reliability of National Institutes of Health (NIH) patient-reported outcomes measurement information system (PROMIS®) Gas/Bloating Scale

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Abstract

Many other methods are used to diagnose gas and bloating in addition to invasive methods. Scales are one of these methods. In this study; our aim was to perform reliability study of the Turkish version of National Institutes of Health (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS®) Gas/Bloating Scale. The Gas/Bloating scale was translated into Turkish by three researchers, and a consensus meeting was held after the translation process. The Turkish text on which the researchers agreed was translated into English by an independent professional translator. The researchers decided that there was no difference between the translated English text and the source text after they compared the two texts in terms of meaning and comprehensibility. As a result of this process, the researchers obtained the final version on which they agreed and the accuracy of which was proved by back translation. A total of 60 patients took part in this study. 29 of them (48.3%) were male, 31 of them (51.70%) were female. Mean age of participants was 39,5±17,1 years. Cronbach's alpha coefficient was found to be 0.914 for 12 scale question. This study shows that Turkish version of PROMIS-Gas/Bloating scale is reliable. We believe that this scale may be used for the objective assessment of patients with gas and bloating in clinical practice.

Keywords: NIH PROMIS GI Symptom Scale, Gas and Bloating, Turkish Reliability

Introduction

Bloating –commonly seen in all age groups– is one of the most common gastrointestinal symptoms. It occurs in 96% of those with functional gastrointestinal disorders and in 10-30% of the general population [1-3].

The term “bloating” can be defined as a feeling of discomfort due to gas in the intestines of patients. Swelling or abdominal distension refers to an actual increase in abdominal circumference. They may not always be together [1].

Amongst patients having bloating, 54% of them stated that it prevented their daily activity and 43% had to use medication while more than 65% described their symptoms as moderate and severe [4].

Abdominal bloating may be caused by abnormal bowel flora, intestinal bacterial overgrowth, intestinal gas accumulation, impaired bowel motility, abnormal abdominal and diaphragmatic reflexes, visceral hypersensitivity, food intolerance, constipation, psychological factors and female gender [5].

Many other methods are used to determine the cause and severity of gas and bloating in addition to invasive methods. Scales are one of these methods. Scales were developed for objective assessment of symptoms. Scales related to gas and bloating generally question the symptoms' frequency, severity and, in some cases, effects on quality of life in the last 7 days [6,7].

Objective

Our aim is to perform reliability study of the Turkish version of Gas/Bloating Scale of National Institutes of Health (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS®) Gastrointestinal Symptom Scales.

Material and Methods

PROMIS, developed by NIH, provides patient-reported outcome measures for the assessment of diseases, including GI disorders. The PROMIS Gas/Bloating, one of the eight categories in the PROMIS GI item banks, is designed to measure the frequency, severity, impact of and discomfort caused by main Gas/Bloating symptoms, based on the assumption that the complaints continue for at least seven days. PROMIS Disrupted Swallowing scale has 12 items [6].

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The questionnaire consisted of 12 questions, and in each question, the answers were scored from 0 to 4. The points for each question were summed. According to the scoring system in the original questionnaire, 0 point refers to not symptomatic, 1 point to least symptomatic, 2-5 points to mild symptomatic, 6-13 points to moderately symptomatic and 14 and more points to most symptomatic.

Translation process

The Gas/Bloating scale was translated into Turkish by three researchers, and a consensus meeting was held after the translation process. The Turkish text on which the researchers agreed was translated into English by an independent professional translator. After the researchers compared the English text, a product of back translation, and the source text in terms of meaning and comprehensibility, they decided that there were no differences between the two texts. As a result of this process, the researchers obtained the final version on which they agreed and the accuracy of which was proved by back translation.

In order to test reliability of the questionnaire form, Cronbach's alpha coefficient was calculated for each question. In the case that Cronbach's alpha coefficient was minimum 0.70, it was considered that the questions were consistent with each other (8).

Patient collection

This study was conducted prospectively in the outpatient clinic of Family Medicine at Osmangazi University Faculty of Medicine between the dates of 15 June and 30 September 2016 after approval from ethical committee was received. The scale was administered to patients that above 18 years who presented to the outpatient clinic with gas and bloating complaints lasting for at least one week. Patients below 18 years, above 18 years but have a cognitive disorder that prevents answering the questions and unvolunteers were not included to the study. A consent form has been taken from all the patients who will participate in the study.

Results

A total of 60 Mean age patients took part in this study. 29 of them (48.3%) were male while 31 of them (51.7%) were female. of participants was $39,5 \pm 17,1$ years. 10 of patients (16.7%) were using NSAID (3 were diclofenac, 4 flurbiprofen, 1 metamizole, 2 etodolac). 6 of patients were using PPI (5 were lansoprazole, 1 rabeprazole).

Mean questionnaire score was $17,06 \pm 7,07$. The results indicate that 3 people was mildly symptomatic, 15 persons were moderately symptomatic and 42 persons fell under the category of most symptomatic. The Cronbach's alpha coefficient of the scale was 0.914 for 12 questions. When evaluated separately for each question, the Cronbach's alpha coefficient was 0,899 at least and 0,919 at most for

each question. These results indicate that the Turkish version of the instrument was quite reliable. The distribution of Cronbach's alpha values by questions are provided in table 1.

Table 1: Distribution of Cronbach's Alpha values of questions

Questions	Cronbach's Alpha
Question-1	0.908
Question-2	0.904
Question-3	0.902
Question-4	0.899
Question-5	0.902
Question-6	0.907
Question-7	0.906
Question-8	0.911
Question-9	0.904
Question-10	0.910
Question-11	0.912
Question-12	0.919

Discussion

In addition to invasive methods, scales are important method to diagnose gas and bloating. Scales were developed for objective assessment of symptoms and give information about severity of symptoms (6).

NIH developed PROMIS at 2004 to provide patient-reported outcome measures for the assessment of diseases, including GI disorders. PROMIS tools are suitable for both traditional and electronic data collection methods. Reliable and easily applicable PROMIS tools allow users to set collective language criteria for symptoms and determine clinical thresholds. Various users including patients, researchers and organizers can use these tools as guidelines for clinical decision making, clinical research and drug approval. Despite the development of more than 100 PRO related to GI symptoms, there is still a need to develop standardized, detailed, and electronic PRO measurement tools for clinical and research purposes that cover all GI symptoms (6). Turkish reliability study of this system's section regarding gastroesophageal reflux was performed before (9).

The PROMIS-Gas/Bloating Scale is a short and easy-to-apply questionnaire that consists of 12 questions and allows us to evaluate each gas and bloating symptom individually. The PROMIS Gas/Bloating, one of the eight categories in the PROMIS GI item banks, is designed to measure the frequency, severity, impact of and discomfort caused by main Gas/Bloating symptoms, based on the assumption that the complaints continue for at least seven days (6). The physician can question the complaints of gas and bloating, and assess its severity through this easy-to-apply questionnaire by taking a short amount of time.

This study shows that Turkish version of PROMIS-Gas/Bloating scale is reliable. We believe that this scale may be used for the objective assessment of patients with gas and bloating in clinical practice.

PROMIS- Gas/Bloating Scale (Turkish Reliability Version)

		Hiç kötü değil	Çok az kötü	Biraz kötü	Oldukça kötü	Çok kötü
GI9 5	Bağırsaklarınızdaki şişkinlik ne kadar kötüleşti?					
		Hiç	Çok az	Biraz	Oldukça	Çok fazla
GI9 6	Bağırsaklarınızdaki şişkinlik günlük aktivitelerinizi ne kadar etkiledi?					
GI9 7	Bağırsaklarınızdaki şişkinlik sizi ne kadar rahatsız etti?					
GI99	Genel olarak karmanızdaki şişkinlik ne kadar şiddetliydi?					
GI GI10 3	Karmanızda şişkinlik hissetmeniz günlük aktivitelerinizi ne kadar etkiledi?					
GI GI10 4	Karmanızda şişkinlik hissetmeniz sizi ne kadar rahatsız etti?					
		Hiç şiddetli değil	Çok az şiddetli	Biraz şiddetli	Oldukça şiddetli	Çok şiddetli
GI10 0	Karmanızdaki şişkinlik en kötü haliyle ne kadar şiddetliydi?					
GI10 1	Genel olarak karmanızdaki şişkinlik hissi ne kadar şiddetliydi?					
		Hiçbir zaman	Nadiren	Bazen	Sık	Her zaman
GI98	Ne kadar sıklıkta karmanızda şişkinlik hissettiniz?					
GI10 2	Ne kadar sıklıkta karmanızda şişkinlik olacağını olmadan önce hissettiniz?					
GI10 9	Ne kadar sıklıkla aç değilken karmanızda guruldama oldu?					
		Hiçbir zaman	Nadiren (günde sadece bir veya iki kez)	Yaklaşık 3-4 saatte bir	Yaklaşık 2 saatte bir	Yaklaşık saatte bir
GI10 5	Ne kadar sıklıkla gaz çıkardınız?					

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