ORIGINAL ARTICLE

Turkish reliability of National Institutes of Health (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS®) constipation scale

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Abstract

Objective: Scales can be used to determine the cause of constipation which is one of the gastrointestinal symptoms. 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®) Constipation Scale.

Materiel and Methods: The Constipation 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.

Results: A total of 63 patients took part in this study. 32 of them (50.8%) were male, 31 of them (49.2%) were female. mean age of participants was 40,25±16,18 years. Mean questionnaire score was 11,38 ± 2,95. Cronbach's alpha coefficient was found to be 0.758 for 9 scale question.

Discussion: This study shows that Turkish version of PROMIS-Constipation scale is reliable. We believe that this scale may be used for the objective assessment of patients with constipation in clinical practice.

Keywords: NIH PROMIS GI Symptom Scales; Constipation; Turkish Reliability.

INTRODUCTION

Constipation is not a diseases but a symptom that differs from person to person (1,2). The number of stools that varies from three in a day to once in three days is considered normal. In general, two or less defecation in a week is described as constipation. But the number of defecation alone is not a sufficient criterion. Amount of stool is also important as the number of defecation (2-4). Constipation is a very common gastrointestinal problem in the community (ranging from 2% to 28%) (2,5,6). According to studies conducted in Turkey, the rate of constipation varies between 22-40% (4). According to different studies, it is seen more frequently in women, children and elderly people (5,7,8).

In women; constipation rate increases with factors such as chronic immobility, inadequate fluid intake, inadequate/inappropriate diet, illnesses, psychological problems, and side effects of medications (7-9).

Scales can be used to find the cause of constipation. Scales were developed for objective assessment of symptoms. Constipation related scales generally question symptoms' frequency, severity and, in some cases, effect on quality of life within the last 7 days. (10).

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®) Constipation Scale.

MATERIALS and METHODS

PROMIS, developed by NIH, provides patient-reported outcome measures for the assessment of diseases, including GI disorders. The PROMIS Constipation, one of the eight categories in the PROMIS GI item banks, is designed to measure the frequency, severity, impact and discomfort caused by main Constipation symptoms, based on the assumption that the complaints continue

for at least seven days. PROMIS Constipation scale has 9 items (10).

The questionnaire consisted of 9 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, 1-3 points to least symptomatic, 4-7 points to mild symptomatic, 8-15 points to moderately symptomatic and 16 and more points to most symptomatic. The questionnaire was administered prospectively to patients equal and above 18 years that presented to Family Medicine outpatient clinic of Eskisehir Osmangazi University

Translation process: The Constipation 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 (11).

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 constipation 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 un volunteers 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 63 patients took part in this study. 32 of them (50.8%) were male, 31 of them (49.2%) were female. Average age of participants was 40,25±16,18 years. 12 of patients (%19,0) were using NSAID (1 were diclofenac, 2 flurbiprofen, 2 metamizole, 1 etodolac, 5 dexketoprofen trometamol, 1 naproxen). 3 of patients were using PPI (2 were lansoprazole, 1 pantoprazole).

PROMIS- Constipation Scale (Turkish Reliability Version)

		Hiç	Çok az	Biraz	Sık	Çok fazla
GI64	Sert veya topaklı gaita sizi ne kadar rahatsız etti?					
GI66	Tuvaletinizi yapmaya çalışırken ne kadar zorluk hissettiniz?					
GI67	Rahatsız edici barsak hareketleri sizi ne kadar rahatsız etti?					
		Hiçbir zaman	Bir gün	2-6 gün	Günde bir	Günde birden fazla
GI63	Ne kadar sıklıkta sert veya yumrulu gayta yaptınız?					
		Hiçbir zaman	Nadiren	Bazen	Sık	Her zaman
GI65	Tuvaletinizi yaparken ne kadar sıklıkta zorlandınız?					
GI68	Tuvaletinizi yaparken rektum veya anüste ne kadar sıklıkta ağrı hissettiniz?					
GI72	Barsak hareketiniz sonrasında ne sıklıkta boşaltımın bitmediği- yani bir miktar daha gaitanız kaldığını hissettiniz?					
GI74	Gaytanızı çıkarmak için ne sıklıkta parmağınızı veya tuvalet kağıdını kullandınız?					
		Hiç değil	Çok az kötü	Biraz kötü	Oldukça kötü	Çok kötü
GI69	Tuvaletinizi yaparken rektum veya anüste (makatta) ağrınızı en kötü haliyle nasıl derecelendirirsiniz?					

Mean questionnaire score was 11,38 ± 2,95. The results indicate that 1 person was least symptomatic, 7 persons were mildly symptomatic, 49 persons were moderately symptomatic and 6 persons fell under the category of most symptomatic. The Cronbach's alpha coefficient of the scale was 0.758 for 9 questions. When evaluated separately for each question, the Cronbach's alpha coefficient was 0,700 at least and 0,768 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	0.735
Question-2	0.712
Question-3	0.703
Question-4	0.761
Question-5	0.724
Question-6	0.700
Question-7	0.741
Question-8	0.760
Question-9	0.768

DISCUSSION

In addition to invasive methods, scales are important methods to diagnose constipation. Scales were developed for objective assessment 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, valid 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 (10).

The PROMIS-Constipation Scale is a short and easy-to-apply questionnaire that consists of 9 questions and allows us to evaluate each constipation symptom individually. The PROMIS Constipation, 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 Constipation symptoms, based on the assumption that the complaints continue for at least seven days (10). The physician can question the complaints of constipation, 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-Constipation scale is reliable. We believe that this scale may be used for the objective assessment of patients with constipation in clinical practice.

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