

# Development and Validation of the Turkish Version of the Colorectal Anal Distress Scale-8

Serdar AYDIN<sup>1</sup>, Tuğçe İrem PAŞA<sup>2</sup>, Merve BİDAK<sup>2</sup>, Gonca BATMAZ<sup>1</sup>, Ramazan DANSUK<sup>1</sup>

<sup>1</sup>Department of Obstetric and Gynecology, Bezmialem Vakıf University School of Medicine, İstanbul, Turkey

<sup>2</sup>Bezmialem Vakıf University School of Medicine, İstanbul, Turkey

## ABSTRACT

**Objective:** Pelvic floor disorders are common and include a wide spectrum of conditions such as pelvic organ prolapse, urinary incontinence, fecal incontinence, voiding and/or defecation dysfunction, sexual dysfunction, and several chronic pain syndromes. There is a need for a validated and reliable inventory to evaluate colorectal anal distress in women with pelvic floor disorders. The aim of this study was to investigate the reliability and validity of the Turkish version of the CRADI-8 for the evaluation of colorectal distress.

**Methods:** Overall, 101 women, some with pelvic floor disorders, were enrolled in the study. The Turkish version of the CRADI-8 was developed using forward back translation. Cronbach's alpha was used to assess the internal consistency of the Turkish version. Receiver operating characteristic (ROC) analysis was performed to determine the optimal cutoff values for determining the presence of colorectal distress. The discriminant validity was assessed by comparing the mean scores of the rectocele and control groups. Correlation analysis was examined for convergent validity.

**Results:** The Cronbach's alpha value was 0.763. A Spearman correlation coefficient of  $r=0.823$  was found between the POP-Q score and the inventory score ( $p<0.0001$ ). The correlation coefficient of the rectocele stage and CRADI-8 score was calculated to be  $r=0.924$  ( $p<0.0001$ ). The one-factor unidimensional model explained 79.3% of the total variance. Discriminant ROC analysis of the Turkish version of the CRADI-8 demonstrated that the AUC for the total FSDS-R score was 0.76 (0.64–0.88) at the baseline, confirming the moderate discriminant validity of the scale.

**Conclusion:** The Turkish CRADI-8 is a valid, reliable tool for the evaluation of colorectal anal distress and symptoms in women with posterior vaginal wall defects and pelvic floor dysfunction.

**Keywords:** Anal incontinence, fecal incontinence, pelvic floor disorders, pelvic organ prolapse, rectocele

## Introduction

Pelvic floor diseases (PFDs) are common in women and include pelvic organ prolapse (POP), urinary incontinence, fecal incontinence, voiding and defecation disorders, sexual disorders, and many chronic painful syndromes (1). Anal incontinence is the involuntary incontinence of gas, fluid, or solid feces, and fecal incontinence is the involuntary incontinence of liquid or solid feces. Anal and fecal incontinence are common medical problems and significantly affect the quality of life (2). Anal incontinence is reported in 54% of women with POP or urinary incontinence, which reveals a significant relationship between anal incontinence and other PFDs (3). In the evaluation of patients with PFDs, not only the objective confirmation of the condition but also the subjective perception of symptoms and their effect on daily life activities should be obtained. Particularly, the detection and grading of colorectal distress is difficult for this group of patients. Self-administered questionnaires for these patients have been proposed as a standardized and reproducible method to determine the presence of colorectal distress, its severity, and its effects on their quality of life and daily activities (4). They can also be used to identify clinically meaningful psychometric changes that emerge because of the disease progression and treatment (5).

**Address for Correspondence:** Serdar AYDIN; Bezmialem Vakıf Üniversitesi Tıp Fakültesi, Kadın Hastalıkları ve Doğum Anabilim Dalı, İstanbul, Türkiye E-mail: seaydin@bezmialem.edu.tr

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The Pelvic Floor Distress Inventory (PFDI) has been developed to measure the breakdown of symptoms and the severity of the disturbances that occurs due to the large array of pelvic symptoms. The PFDI-20 consists of three subgroups: the Pelvic Organ Prolapse Distress Inventory (POPDI-6), the Colorectal-Anal Distress Inventory (CRADI-8), and the Urinary Distress Inventory (UDI-6) and includes 20 questions in total that were developed in 2005 (6). The PFDI-20 has been translated into and validated in many languages to be used as a common tool for evaluating PFDs in different populations and cultures (7-13). The PFDI-20 has been validated in two Turkish studies (9, 13). However, deficiencies in the validity of the CRADI-8 section were reported in the psychometric analysis of the latest published study (13). Although the validation of the Turkish version of UDI-6 has been performed, and the version is being used for urinary incontinence, there is a need for the validation of colorectal anal distress that is a frequently encountered part (14). The present study aimed to translate the CRADI-8 questionnaire into Turkish and validate it. To our knowledge, such a validation has not yet been performed.

## Methods

This study was conducted between January 2015 and June 2012 in a tertiary urogynecology unit. Female patients with PFDs who appeared to have rectoceles and were older than 18 years were included in the study. The study was conducted in three stages. The first stage included the translation of the questionnaire into Turkish and its cultural adaptation, and the second stage included the evaluation of psychometric appropriateness. The final stage included the measurement of the results of the questionnaire administered to nulliparous pregnant women without pelvic floor injuries. The study protocol was approved by the local ethics committee. All women were informed and their written consent was obtained before including them in the study.

The PFDI-20 consists of 20 questions divided into three subgroups: the POPDI-6, the CRADI-8, and the UDI-6. In the first phase of our study, the CRADI-8 was translated and cultural adaptation was performed. A multistep approach was followed in the translation process using the guide recommended by Guillemin and Beaton (15, 16). Further translation was performed by two bilingual translators whose mother tongue was Turkish. The first translator was the author of the study who had the relevant experience, and the other translator had no medical background and was not aware of the concepts covered by the survey. The two translators developed a mutually translated version in Turkish.

A written report that shows the translators' interpretations of any difficulties and the reasons for the choices they made in the event of problematical questions was prepared. The translation of these Turkish versions into English was performed by

a translator whose mother tongue was English and who was completely blind to the original model. Lastly, original and rejected surveys were compared by clinical researchers. Corrections were made before the questionnaire was presented to the patients. The final version of the questionnaire was tested by interviewing 10 patients whose mother tongue was Turkish and who had posterior vaginal compartment prolapse. The patients were asked whether they understood the meaning of each question, and each difficulty and comment was recorded. With the completion of the last phase, clinical researchers developed the final version of the CRADI-8 questionnaire in Turkish. The questionnaires were applied to literate women who were not directed by trainee doctors.

The reliability of the Turkish version of the CRADI-8 questionnaire was tested for internal consistency. Cronbach's alpha ( $\alpha$ ) coefficient was used as an indication of internal consistency. Cronbach's  $\alpha$  coefficient of  $\geq 0.70$  was considered as an acceptable measure of internal consistency (17). To evaluate the factor structure and the structural reliability, a single basic component analysis was applied to all eight questions. For distinguishing between those with and without colorectal anal distress, the receiver operating characteristic (ROC) curve was used to determine the optimal cutoff value. The area under the curve (AUC) of  $< 0.5$  indicates inadequacy to measure the difference between groups, and the AUC of 1.0 indicates an excellent discriminant validity (18). Whether there was discriminant validity in patients with and without rectoceles was evaluated by comparing the averages of two groups within the groups. Considering that the colorectal distress increases with the increase in rectocele degree, component validity was tested by performing correlation analysis between the CRADI-8 score and rectocele degree.

## Statistical analysis

The Statistical Package for the Social Sciences (SPSS 21.0, IBM Corp, Armonk, NY, USA) was used for all statistical analyses made in this study. The distribution of the data was evaluated by performing histogram and the Kruskal-Wallis test. Student's *t*-test was used for continuous variables with normal distribution, and the Mann-Whitney U test was used for those not consistent. The chi-square test or Fisher's exact test was used to compare the categorical data. A *p*-value of  $< 0.05$  was considered statistically significant.

## Results

One hundred one sexually active women were included in this study. While 23 women with stage 2 or more according to the Rectal POP-Q evaluation were included in the study, 78 women did not have any significant rectoceles. In the evaluation of urogynecologic POP, those with  $\leq$ stage 1 rectocele were designated as the control group. The mean age in the rectocele group was  $48.1 \pm 10.7$  years. The mean

**Table 1.** Basic features and demographic data in rectocele and control groups

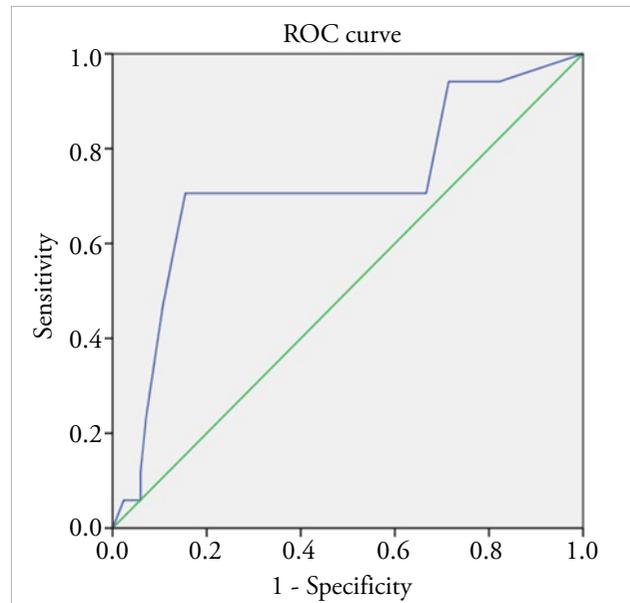
	Rectocele (n=23)	Control (n=78)	p
Age, year (mean±SD) <sup>a</sup>	48.1±10.7	32±13.5	<0.0001
BMI (mean±SD) <sup>a</sup>	28.1±3.7	23.3±4.1	<0.0001
Cystocele, N (%) <sup>c</sup>	13 (56.5)	6 (7.7)	<0.0001
Uterine prolapse, N (%) <sup>d</sup>	13 (56.5)	3 (3.8)	<0.0001
Urinary incontinence, N (%) <sup>c</sup>	14 (60.9)	7 (9)	<0.0001
Gravida, N (%) <sup>b</sup>	4.6±1.3	1.5±2.1	<0.0001
Parity, N (%) <sup>b</sup>	3.8±1.1	1.1±1.3	<0.0001
Nulliparity, N (%) <sup>c</sup>	-	41 (52.6)	<0.0001
Cesarean section, N (%) <sup>c</sup>	-	15 (18.2)	0.04
Educational level, N (%) <sup>c</sup>			
Primary education	17 (73.9)	17 (21.8)	<0.0001
Secondary education	6 (26.1)	30 (38.5)	
University	-	31(39.7)	
Pulps food, N (%) <sup>d</sup>	4 (17.4)	10 (12.8)	0.6
Smoking, N (%) <sup>d</sup>	1 (4.3)	16 (20.5)	0.07
Alcohol, N (%) <sup>d</sup>	1 (4.3)	8 (10.3)	0.4

BMI: body mass index; SD: standard deviation; a Student's t-test; b: Mann-Whitney U test; c: chi-square test; d: Fisher's exact test

**Table 2.** Single basic component analysis of the Turkish version of the colorectal anal distress inventory 8 (CRADI-8)

Question items	Factor 1
Question 1	0.80
Question 2	0.88
Question 3	0.45
Question 4	0.84
Question 5	0.33
Question 6	0.43
Question 7	0.65
Question 8	0.38
Eigenvalue	7.13
Percentage of the presented variance	79.3%

age of the control group was 32±13.5 years. The women with rectocele were significantly older than those in the control group ( $p<0.0001$ ). The demographic data and basic sociocultural characteristics of the women participating in the study are shown in Table 1. The body mass index in the rectocele group (28.1±3.7 kg/m<sup>2</sup>) was significantly higher than that of the control group (23.3±4.1 kg/m<sup>2</sup>) ( $p<0.0001$ ). As expected, the accompanying cystocele (56.5%) and uterine prolapse (56.5%) were more frequent than the control group. The education level was higher in the control group.

**Figure 1.** Receiver operating characteristic (ROC) curve of the Turkish version of the CRADI-8 questionnaire

The mean total CRADI-8 score was 28.1±15 for the rectocele group and 15.1±12.3 for the control group. The total score was significantly higher in the rectocele group ( $p<0.0001$ ). This data confirms the discriminative validity of the CRADI-8 inventory.

Single principal component analysis was performed to evaluate the factor structure of the Turkish CRADI-8. Based on this analysis, a one-factor one-dimensional model was established, and this model explained 79.3% of the total variance of the CRADI-8 questionnaire. The factor loadings are shown in Table 2. The fact that each question was clustered as foreseen and had a relatively high factor load supports the factorial validation of the Turkish form of the questionnaire.

The ROC analysis of the CRADI-8 Turkish form indicates that the AUC was 0.76 (0.64–0.88) and that the questionnaire had a moderate discriminant validity. In addition, cutoff values were created to reduce the false positive and false negative errors in the Turkish CRADI-8. When the ideal cutoff value was determined as 7.8, 95.6% sensitivity, a 96.1% specificity, a 88% positive predictive value, and a 98.6% negative predictive value were reached. The ROC curve of the analysis is shown in Figure 1.

The internal consistency reliability of the inventory was assessed by calculating Chronbach's alpha coefficient, which was found to be 0.763. Because this coefficient was higher than 0.70, the inventory was considered as reliable.

Correlation analysis was performed between POP-Q score and rectocele staging to analyze the combined validity of the survey questions. Spearman's correlation coefficient ( $r$ ) between the POP-Q stage and the questionnaire score was

found to be 0.823 ( $p < 0.0001$ ). The correlation coefficient ( $r$ ) between the rectocele stage and the CRADI-8 score was 0.924 ( $p < 0.0001$ ). High correlation score was assessed as the perfect convergent validity.

## Discussion

Although the feeling of being ashamed due to urinary incontinence has been decreasing in recent years, the rates of patients' applications for treatment have been increasing gradually. Unlike urinary incontinence, fecal incontinence still remains a socially and psychologically important area that should be considered as an extremely disturbing condition for patients. Physicians are as reluctant as women to evaluate fecal incontinence (19). The patients are often observed to be feeling ashamed about fecal incontinence even while solving the questionnaires (12). This situation is perceived by the patients as intimate and embarrassing. Various forms of query have been developed to measure colorectal distress and the quality of life of patients with pelvic floor distress.

The quality of life is best measured through self-administered questionnaires (20, 21). Although validated quality-of-life questionnaires have been developed to assess the impact of urinary incontinence on the quality of life and severity of symptoms, there are very few original questionnaires that measure POP and associated anorectal distress. The PFDI-20 is one of the most frequently used questionnaire. The PFDI and PFIQ are query forms designed to measure the change in quality of life caused by infections of the lower urinary tract and lower gastrointestinal tract and POP. The validation and validity of these inventories were demonstrated in previous studies (22, 23). These query forms have been translated into various languages and the methods of translation have been validated (7-13).

Colorectal and anal symptoms are frequent in women with urinary incontinence and POP. In one study, 88% of those who completed the CRADI-8 questionnaire reported at least one colorectal or anal distress (24). The most common symptoms are difficulty in starting bowel movement, not being able to completely empty the bowel, and anal incontinence. Sixty percent of the women reported that they had each of these symptoms.

Validation studies of the PFDI were conducted in Greek, Spanish, Arabic, and Turkish (7-13). The lowest ICC values in the Greek version (ICC=0.330) were observed in the CRA-DI-8 section (10). These results are attributed to the fact that patients cannot distinguish intestinal sagging from hemorrhoids and other diseases. The lack of distinctive symptoms in diseases of the lower gastrointestinal system is the shortcoming of the CRADI-8 questionnaire. We recommend adding a question associated with hemorrhoids. In the Arabic version, a question was added to assess the degree of distress related to

worship (11). Swedish researchers have also suggested that a question should be added to assess whether POP affects activities, such as daily tasks, professional skills, and going to work (8). In our study, the majority of patients with hemorrhoids confused rectal prolapse with hemorrhoids.

The responsiveness of the PFDI questionnaire has been tested in patients who underwent POP surgery (9, 10). Although the POPDI-6 and UDI-6 questionnaires showed an excellent responsiveness, the CRADI-8 showed poor responsiveness, and it was proved that there occurred no post-operative changes (10). In the latest validation studies of the Turkish versions of PFDI-20 and PFIQ-7, the CRAIQ-7 showed low responsiveness and the CRADI-8 showed moderate responsiveness (13). The original versions of the PFDI and PFIQ were also associated with low responsiveness in patients undergoing vaginal surgery (5). Based on these results, surgically correcting the anatomy in POP may not result in direct symptom reduction and may not improve the quality of life. Rather than POP, the publications suggesting that abnormal anorectal functions are associated with lower gastrointestinal symptoms also support this (25, 26). No correlation between posterior vaginal wall prolapse and fecal symptoms could be found in the study by Marques da Silva et al. (27).

It is not surprising that, in the study by Barber et al. (5) that involved patients who underwent vaginal surgery, some parts of the questionnaire have generated better results than others because of the complex relationship between pelvic floor compartments and functional diseases (5). Thus, it may be more meaningful to measure the overall quality of life in patients with pelvic floor distress than administering the questionnaires for a single organ. In addition, in these studies, surgical operations have focused more on uterine prolapse than on specific posterior wall surgery or anorectal surgery.

Future studies should examine the psychometric properties of this survey in more detail. In addition, a responsiveness study involving patients undergoing both surgery and conservative treatment modalities, such as pessary and pelvic floor physiotherapy, should be performed. Our study has various limitations. The first is the lack of superficial validity study due to limited patient turnover. The reason for inadequate patient turnover is that the current situation of the patients changes because they have posterior colporrhaphy in a short time and those who undergo operation are not motivated to return to the hospital and they do not accept re-evaluation for a scientific study. The superficial validity study was examined in two Turkish validation studies, and high reliability results were obtained. Thus, we believe that there is no shortcoming that will limit the use of this form of the survey. Another limitation of our study is that minimal clinical significance, which is the smallest difference that greatly affects the treatment or care, was not assessed.

The greatest strength of our work is the translation method, which is the recommended method in cultural adaptation studies. This model includes cognitive interviews and gives the opportunity to reconfigure the translation. Thus, problems related to translation can be detected and tested before starting the statistical validation process. This method enables the selection and the precise adjustment of specific words to provide a larger area of comprehension. The other strength is that unlike other studies, it concentrates only on colorectal anal distress.

## Conclusion

In conclusion, the Turkish form of the CRADI-8 questionnaire is a reliable, understandable, and valid instrument for measuring anorectal symptoms and distress in women with posterior vaginal wall defects and pelvic floor dysfunctions. To our knowledge, this is the first validation study aimed at the posterior compartment to measure anorectal distress associated with pelvic floor distress. The colorectal anal distress inventory that shows low psychometric validation in validation studies evaluating three compartments showed good psychometric reliability in specific population in our study. Future studies should assess the responsiveness of this questionnaire and the minimal clinical significance, and the reliability of the questionnaire should be enhanced by adding questions related to hemorrhoids.

**Ethics Committee Approval:** Ethics committee approval was received for this study from local ethic committee.

**Informed Consent:** Written informed consent was obtained from patients who participated in this study.

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