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ORIGINAL ARTICLE

The validity and reliability of the turkish version of the constipation risk assessment scale in cancers

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SUMMARY

Objectives: Cancer increases the incidence of constipation. The best way to prevent constipation is to detect it before it develops. Therefore, it is very important to use valid and reliable scales that assess the risk of constipation in order to prevent its occurrence in cancer patients. This study aims to assess the validity and reliability of the Constipation Risk Assessment Scale (CRAS) when applied to the Turkish population with cancer.

Methods: A total of 102 outpatients with cancer were included in the study. According to the Rome IV criteria, participants were divided into two groups: constipated and non-constipated. All patients were evaluated using the CRAS. A subset of patients was randomly selected for retesting with the CRAS.

Results: In the evaluation of the test-retest reliability of the CRAS, Cronbach's alpha coefficient and intraclass correlation coefficient (ICC) values were found to be 0.97 (0.93–0.99) for the total CRAS score and between 0.83 (0.64–0.94) and 0.96 (0.92–0.97) for the subscales. The retest reliability was found to be high ($p<0.001$). Significant correlations were observed between the total CRAS score and all subscales with the Rome IV criteria, as well as between the CRAS medication subscale and the Rome IV criteria.

Conclusion: The present study showed that the Turkish version of the CRAS is a valid and reliable tool for use with outpatients with cancer. The CRAS can be effectively utilized to identify individuals at risk of constipation and to develop targeted prevention programs. Healthcare professionals can use the Turkish version of the CRAS as a reliable tool to assess constipation risk among cancer patients.

Keywords: Cancer; constipation; risk assessment; scale.

Introduction

Constipation is defined as difficulty in defecation and decreased frequency of defecation (less than three times a week), resulting from decreased intestinal motility.[1] The prevalence of constipation, which is one of the leading problems of cancer patients, in advanced-stage cancer patients reaches approximately 32–87%.[2] Constipation causes various symptoms such as abdominal pain, abdominal bloating, fatigue, and colic, resulting in a decrease in the quality of life of patients.[3,4] Therefore, preventing constipation is especially important in managing constipation.

Lifestyle-related constipation is caused by reasons such as decreased physical activity, insufficient fluid or fiber intake in the diet, or insufficient privacy when defecating. These situations cause decreased motility of fecal material and increased intestinal transit time.[5] Secondary constipation is caused by pathological conditions such as metabolic and endocrine diseases.[5] Iatrogenic constipation is often caused by medications; chemotherapy drugs and opioid drugs are frequently used, especially in cancer patients.[6] These drugs cause a decrease in peristalsis and an increase in the transit time of feces through the intestine through similar mechanisms.[7]

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Using a constipation risk assessment scale has demonstrated efficacy in reducing the occurrence of constipation among patients. While numerous assessment scales exist for this purpose, none specifically address the needs of cancer patients.[3,8,9] In particular, the Constipation Risk Assessment Scale (CRAS), designed by Richmond and Wright, includes 25 items and four different subscales: lifestyle, hospitalization experience, physiological/psychological conditions, and medications. It encompasses common risk factors like abdominal and metabolic disorders, as well as medications such as opioids and chemotherapy drugs, frequently associated with constipation in cancer patients.[9] This tool offers an objective means to determine individuals at risk of constipation, facilitating the implementation of preventive measures. In addition, CRAS helps patients, physicians, and other healthcare professionals better manage and address constipation. To our knowledge, although CRAS validity and reliability studies have been conducted for many diseases, there is no validity and reliability study of CRAS in patients with cancer in Türkiye. Therefore, the current research aimed to evaluate the validity and reliability of the Constipation Risk Assessment Scale in cancer patients in Türkiye.

Materials and Methods

Study Design and Study Population

The research complied with the ethical guidelines of the Declaration of Helsinki, and written informed consent was secured from all participants. Authorization to employ the CRAS in our investigation was secured from its developer, Richmond. Subsequently, the CRAS underwent translation from English to Turkish following established guidelines. Following approval from the institutional ethics committee (Ethics approval number: 03.02.2023.237), a cross-sectional, cross-cultural adaptation and validation study was undertaken on cancer patients at a tertiary hospital's pain management outpatient clinic, spanning from February 2023 to December 2023.

The study encompassed 102 cancer patients meeting specific criteria. The inclusion criteria were patients aged 18 years and older with a cancer diagnosis. Exclusion criteria included patients unable to complete the questionnaire, those with gastrointestinal diseases other than cancer, and psychiatric disorders like psychosis and bipolar disease. We collected patient data including demographic information, cancer type, cancer duration, constipation duration, and medical treatments. Patients were categorized according to the Rome IV criteria based on whether they had constipation or not.

Based on the Rome IV criteria, chronic constipation is characterized by the persistence of symptoms for the last three months (having started at least six months ago) and the absence of organic gastrointestinal pathology. It manifests with two or more of these conditions: straining in more than one-fourth of defecations, passing lumpy or hard stools in more than one-fourth of defecations, feeling of not being able to fully evacuate the stool in more than one-fourth of defecations, having anorectal obstruction/obstruction sensation in more than one-fourth of defecations, needing to assist with defecation through physical methods in more than one-fourth of defecations, and experiencing less than three natural stool passages per week.[10]

The CRAS comprises 25 items grouped into four distinct subscales. The lifestyle subscale, consisting of five items, covers aspects such as mobility, sex, consumption of fiber, bran intake, and fluid intake. The experience of hospitalization subscale includes two items tailored for ward patients or those needing access to a toilet/sink. Additionally, the physiological/psychological conditions and medications categories include seven types of diseases and 11 types of medications known to increase the risk of constipation (Appendix 1). The total cumulative score, ranging from 1 to 33, reflects the risk level. A higher score indicates greater susceptibility to constipation. Scores below 11 indicate a low risk, scores between 11 and 15 indicate a moderate risk, and scores of 16 or higher indicate a high risk of constipation. Notably, scores of 16 or higher demonstrated the strongest ability to accurately identify individuals with and without constipation risk, with sensitivity of 0.849 and specificity of 0.854. Additionally, the scale is well-regarded for its content validity and interrater reliability.[9,11]

Translation and Cultural Adaptation Process

CRAS was translated into Turkish according to standard guidelines for adapting surveys to different cultures. Initially, two bilingual speakers translated the

survey independently, resulting in two further translations. Subsequently, the consensus version of the survey was obtained from the forward translation procedure. The consensus version was subsequently translated back into English by two additional bilingual experts who had not seen the original version. A committee of four pain medicine specialists and four interpreters then deliberated to resolve any remaining discrepancies. Following this discussion, the preliminary final version of the Turkish CRAS was created with minor edits made by the committee. In this pre-post version, cognitive debriefing interviews were conducted with 20 cancer patients to ensure clarity and relevance.

Statistical Analysis

Statistical analyses were performed using SPSS version 20.0 software (IBM Corp., Armonk, NY, USA). Descriptive analysis, including mean, frequency and standard deviation, was employed to analyze sociodemographic data. The Shapiro-Wilk test, probability plots and histograms were used to assess the distribution of the data. Quantitative data were used as mean, standard deviation or median. Concurrent validity was evaluated by examining the correlation between CRAS subgroups and the Rome criteria using Spearman's rank correlation coefficients. Test-retest reliability validated all subsections except "experience of hospitalization." Internal consistency was assessed through the utilization of Cronbach's alpha. Differences between the two groups were analyzed using the Student's t-test for normally distributed data and the Mann–Whitney U test for non-normally distributed data. Changes over time with treatment were analyzed using repeated measures ANOVA, with adjustments made for multiple comparisons using the Bonferroni method. The chi-square test was employed to analyze differences in categorical data. A p-value of less than 0.05 was considered significant.

Results

The study included 102 patients, with an average age of 62 years. There was male predominance in the study with 60 patients. The patients' BMI was found to be 27.01 (16.84). The rates of patients being married and employed were 76 (74.5%) and 64 (62.7%), respectively. The frequency and duration of constipation in the patients were found to be 57 (55.9%) and 15.09 (1–120), respectively (Table 1).

Table 1. Patients' baseline demographic characteristics and clinical findings

Variables	
Female, n (%)	42 (41.2)
Married, n (%)	76 (74.5)
Employed, n (%)	64 (62.7)
Education >12 years, n (%)	26 (25.5)
BMI, Mean (±SD)	27.01 (16.84)
Cancer duration (months)	45.66 (1–252)
Age (years), Mean (±SD)	62.35 (12.7)
Constipation, n (%)	57 (55.9)
Constipation duration	15.09 (1–120)
CRAS lifestyle, Mean (±SD)	5.90 (1.70)
CRAS Physiological/psychological conditions, Mean (±SD)	2.51 (1.01)
CRAS medications, Mean (±SD)	5.63 (3.15)
CRAS overall scale, Mean (±SD)	14.07 (5.18)
Cancer type	
Lung cancer, n (%)	19 (18.6)
Breast cancer, n (%)	11 (10.8)
Colon cancer, n (%)	11 (10.8)
Pancreatic cancer, n (%)	9 (8.8)
Prostate cancer, n (%)	7 (6.9)
Multiple myeloma, n (%)	5 (4.9)
Rectal cancer, n (%)	4 (3.9)
Stomach cancer, n (%)	4 (3.9)
Others, n (%)	32 (31.4)

BMI: Body Mass Index; CRAS: Constipation Risk Assessment Scale.

Significant differences were observed between patients with and without constipation in terms of CRAS total score, laxative use and risk of constipation. In patients with a high risk of constipation according to CRAS, the rate of constipation was found to be higher according to the Rome IV criteria (Table 2).

There were no notable differences between groups regarding age, sex or education levels when classifying constipation risk. According to CRAS, mobility and difficulty evacuating bowels were found to be significantly higher in the high-risk subgroup compared to other groups (Table 3).

The test-retest reliability of the CRAS total score was measured to be 0.97 (0.93–0.99). In the subgroups,

Table 2. Comparisons of the overall CRAS scores between constipated and nonconstipated groups and criterion validity of the CRAS cutoff values according to the Rome IV criteria

	Constipated group (n=57)	Control group (n=45)	p
CRAS overall score	15.72 (4.86)	12.02 (5.02)	<0.001
Laxative use			<0.001
Yes (33)	17.72 (5.26)	24.01 (5.58)	
No (69)	14.40 (6.22)	12.58 (5.41)	
Risk of constipation			<0.001
Low (23)	8.50 (1.87)	6.71 (2.30)	
Medium (40)	13.21 (2.31)	11.93 (1.18)	
High (39)	16.07(5.07)	12.01 (4.98)	

CRAS: Constipation Risk Assessment Scale.

Table 3. Comparison of the characteristics of patients and risk levels of the CRAS

	Low risk n (%)	Medium risk n (%)	High risk n (%)	Chi-square/ ANOVA
Age	62.82 (13.88)	61.42 (11.67)	63.20 (13.13)	0.780
Gender				0.362
Female	7 (30.4)	16 (40.0)	19 (48.7)	
Male	16 (69.6)	24 (60.0)	20 (41.3)	
Education				0.538
Low	15 (65.2)	32 (80.0)	29 (74.3)	
High	8 (34.8)	8 (20.0)	10 (25.7)	
Mobility				0.032
Active	16 (69.6)	22 (55.0)	15 (38.5)	
Passive	7 (30.4)	18 (45.0)	24 (61.5)	
Difficulty evacuating bowels				0.030
Yes	5 (21.7)	17 (42.5)	27 (69.2)	
No	18 (78.3)	23 (57.5)	12 (30.8)	

CRAS: Constipation Risk Assessment Scale.

Table 4. Test and retest scores of the CRAS scores, intraclass correlation (ICC), and change scores in the first week

	Mean (SD) of test (n=102)	Mean (SD) of re-test (n=20)	ICC with 95% CI	p
CRAS lifestyle	5.90 (1.70)	6.05 (1.98)	0.83 (0.64–0.94)	<0.001
CRAS physiological/psychological conditions	2.51 (1.01)	2.90 (1.50)	0.95(0.84–0.97)	<0.001
CRAS medications	5.63 (3.15)	5.40 (2.90)	0.96 (0.92–0.97)	<0.001
CRAS overall scale	14.07 (5.18)	14.20 (5.60)	0.97 (0.93–0.99)	<0.001

CRAS: Constipation Risk Assessment Scale; ICC: Intraclass correlation coefficient; CI: Confidence interval.

the ICC score varied between 0.83 (0.64–0.94) and 0.96 (0.92–0.97), and high test-retest reliability was detected (Table 4).

Table 5 illustrates the correlation analysis among the CRAS subgroups, total score and Rome IV criteria. A weak correlation was observed between the CRAS

Table 5. Correlation among CRAS subscale scores and Rome IV criteria

	CRAS lifestyle	CRAS physiological/ psychological conditions	CRAS medications	CRAS total score	Rome criteria
CRAS lifestyle	1	0.070	0.075	0.357	-0.051
CRAS physiological/ psychological conditions		1	0.328	0.625	-0.018
CRAS medications			1	0.802	-0.327
CRAS total score				1	-0.257
Rome IV criteria					1

CRAS: Constipation Risk Assessment Scale.

total score, lifestyle scores and Rome IV criteria. A moderate positive correlation was identified between the CRAS total score and CRAS physiological/ psychological conditions. Lastly, a significant positive relationship was detected between the CRAS total score and CRAS medications.

Discussion

The primary objective of the current study was to assess the psychometric properties of the Turkish adaptation of the CRAS among cancer patients. Employing a risk assessment tool for constipation aids in mitigating its occurrence in patients. Originally designed by Richmond and Wright for this specific purpose, CRAS evaluates the risk of constipation with questions regarding lifestyle, physiological/psychological conditions, personal beliefs, medications and frequency of bowel movements.[9] The findings of this research indicate that the Turkish version of CRAS exhibits satisfactory reliability and validity in the context of cancer patients.

The prevalence of constipation in the general population is reported to be 14%, with estimates ranging from 1.9% to 40.1%. In cancer patients, the rate of constipation varies between 32% and 87%. In advanced cancer patients using opioids, this rate can reach up to 97% in some studies.[12–14] A literature review conducted in Türkiye found that the prevalence of constipation in cancer patients ranged from 19.5% to 69%, and in our study, 55.89% of cancer patients had constipation.[15]

In the current research, the overall CRAS score, which indicates the risk of developing constipation, was 14.07, with sub-scores of 5.90 for CRAS lifestyle, 2.51 for CRAS diseases and 5.63 for CRAS medications. These scores are consistent with those reported in the original validity study and other validation studies in the literatüre.[11,16,17] In a study conducted on Chinese cancer patients, the CRAS overall score was 12.31, CRAS lifestyle was 5.0, CRAS diseases was 3.0 and CRAS medications was 5.0. While the CRAS scores in our study were higher across all subcategories, similar to the literature, the overall CRAS score of 14.07 in cancer patients in our study indicates a moderate risk for constipation development.[17]

To assess the reliability of the Turkish version of CRAS, test-retest reliability and internal consistency were evaluated. Test-retest reliability was measured using the intraclass correlation coefficient (ICC) for numerical variables and the rate of agreement for categorical variables. Additionally, interrater reliability, which indicates the consistency among different assessors using the same scale on the same sample, reflects the scale's equivalence.[18] An ICC exceeding 0.8 signifies robust consistency.[19] In our study, the ICC values obtained for CRAS total, CRAS lifestyle, CRAS physiological/psychological conditions and CRAS medications are 0.97, 0.83, 0.95 and 0.96, respectively, and these values are similar to the original validity article.[11] The present study's results demonstrated that the Turkish version of CRAS has good reliability.

In the current investigation, the mean scores for CRAS overall, CRAS lifestyle, CRAS diseases and CRAS medications were found to be 14.07, 5.90, 2.51 and 5.63, respectively. These CRAS scores closely resemble those reported in the original validation study and other pertinent literatüre.[11,16,17] To assess the reliability of the Turkish version of CRAS, test-retest reli-

ability and internal consistency were evaluated. Test-retest reliability was measured using the intraclass correlation coefficient (ICC) for numerical variables and the agreement rate for categorical variables. Interrater reliability, indicating the scale's consistency among different assessors when measuring the same sample, was also considered.[18] An ICC exceeding 0.8 signifies robust consistency.[19] In our study, the ICC values obtained for CRAS total, CRAS lifestyle, CRAS physiological/psychological conditions and CRAS medications were 0.97, 0.83, 0.95 and 0.96, respectively, mirroring those reported in the original validity article.[11] These results affirm that the Turkish version of CRAS exhibits good reliability.

The validity of the Turkish version of CRAS was assessed through criterion validity and construct validity. Criterion validity, a crucial aspect of clinical performance evaluation, was examined by comparing constipated and non-constipated patients based on the Rome IV criteria, as well as by comparing patient groups in terms of their prior experience with laxatives.[20] Although conventional literature does not typically classify laxative use as a recognized constipation risk factor, we chose to employ this measure as an indirect indicator for constipation in our study and found it to be effective.[9,21]

In the present study, we observed a heightened incidence of constipation, as per the Rome IV criteria, among patients identified as having a high risk of constipation based on the CRAS. Consistent with existing literature, difficulties in bowel evacuation and motility were more prevalent in the high-risk subgroup identified by CRAS in comparison to other groups.[22,23] Significant correlations were identified between CRAS total scores and all subscales and the Rome IV criteria, as well as between CRAS medications and the Rome IV criteria. These findings suggest that the CRAS demonstrates satisfactory construct validity among cancer patients.

A study revealed that inadequate attention from health workers led to a notable decline in bowel function among advanced cancer patients who did not initially present with constipation upon admission but developed it within one week post-admission.[24] Thus, a proactive approach is recommended for healthcare professionals when patients have not yet developed constipation. Screening for constipation risk and implementing personalized preventive measures for those identified as high-risk becomes crucial. Regular reassessment is essential, particularly when constipation risk factors change, such as alterations in the patient's condition or the initiation of new medications. Furthermore, incorporating risk-based constipation prevention strategies into a comprehensive management plan at cancer centers is crucial. Through this approach, the Turkish version of CRAS facilitates increased awareness about constipation among healthcare professionals and contributes to reducing its incidence among cancer patients.

Limitations

This study has several limitations. Although the sample size was adequate for the analyses, its restriction to a single center and inclusion of only cancer patients may limit the generalizability of the findings. Additionally, the study's design does not allow for the assessment of changes in constipation over time, which is crucial for evaluating sensitivity to change using a before-and-after approach. However, a notable strength of this study is that, to our knowledge, it represents the first evaluation of the CRAS's validity and reliability for Turkish-speaking cancer patients.

Conclusion

The current study establishes the reliability and validity of the Turkish version of the CRAS for Turkish outpatients. Reliability was confirmed through test-retest and internal consistency analyses, while validity was assessed through criterion and construct validity, using the Rome IV criteria as a benchmark for constipation. The Turkish CRAS demonstrated high sensitivity in detecting constipation among patients. These findings support the confident use of the Turkish CRAS by clinicians to assess constipation risk in Turkish-speaking cancer patients.

Ethics Committee Approval: The Marmara University Clinical Research Ethics Committee granted approval for this study (date: 03.02.2023, number: 09.2023.237).

Informed Consent: Written informed consent was secured from all participants.

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