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Research Paper

Cross-culturally Adaptation, Validity, and Reliability of the Persian Version of the Constipation-related Disability Scale

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ABSTRACT

Background and Objectives: Chronic functional constipation is a common condition that declines the quality of life (QoL). The constipation-related disability scale (CRDS) precisely measures the disability caused by constipation and its effect on daily activities. In this study, we translated the CRDS into Persian and evaluated its reliability and validity.

Methods: We used the international QoL assessment procedure to translate the CRDS into Persian. The translation was then given to 145 patients (59 men and 86 women) with chronic functional constipation. Also, 130 healthy individuals completed the questionnaire to assess its discriminant validity. The Cronbach α was calculated to assess the internal consistency, and the intra-class correlation coefficient showed the tool's reproducibility. In addition, five gastroenterologists or internists reviewed the translated version to evaluate its acceptance and content validity. The content validity ratio and content value index were calculated in this regard. Finally, the Pearson correlation test assessed the tool's convergent validity by correlating the CRDS with the 36-item short-form survey (SF-36).

Results: The Cronbach α coefficient for total scores was found to be 0.86, indicating high internal consistency. The intra-class correlation coefficient was found to be 0.98 (95% CI, 0.96%, 0.99%), demonstrating excellent test re-test reliability. The total score of CRDS showed a strong negative correlation with the total scores of SF-36 (r=-0.89), showing its construct validity. All items of the Persian CRDS had a content validity index higher than 0.78 and a content validity ratio higher than 0.75, indicating good content validity. Furthermore, the independent t-test revealed a statistically significant difference ($P < 0.05$) between the healthy and diseased groups in questionnaire scores. This finding shows the tool's ability to discriminate between healthy and sick groups.

Conclusion: The Persian version of CRDS is suitable for evaluating constipation associated with disabilities in Persian-speaking individuals.

Keywords: Disability, Quality of life, Reliability, Validity, Persian, Functional constipation

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What is "already known" in this topic:

In the field of investigating the impact of constipation on the quality of life, several questionnaires have been designed so far, among which we can mention the questionnaire for PAC-QOL (patient assessment of constipation quality of life) and the PAC-SYM (patient assessment of constipation symptoms) which despite the fact that Research has shown that the decrease in a person's ability to complete daily activities is related to the decrease in the quality of life and the increase in mental pressure, but until now, a questionnaire that can measure the disability specific to constipation was not designed, which was created in response to the existing gap in this questionnaire. And due to the fact that its validity and reliability had not been determined in Iran so far, this was done in this study so that Iranian researchers can use it as a valid and reliable tool.

What this article adds:

In the field of examining the impact of constipation on the quality of life, several questionnaires have been designed so far, but the constipation related disability scale is the first tool that provides a more comprehensive and specialized evaluation of the impact of constipation on daily life and the degree of disability caused by constipation compared to other questionnaires.

Introduction

Constipation is one of the most prevalent gastrointestinal tract diseases, especially in developed countries [1]. While constipation is often seen as harmless and can be cured with minimal treatment, chronic constipation can create various complications, from mild to severe disability, that require medical attention [2]. Functional constipation occurs when incoordination exists between the relaxation of the pelvic floor muscles, especially the puborectalis muscles, and the contractions of the abdominal wall muscles essential for normal defecation [3]. Constipation is diagnosed based on the Rome IV diagnostic criteria [4].

Chronic functional constipation (CFC) affects both genders of all age groups in the general population, with a prevalence of up to 27%. However, it is more common in females, older people, and low socioeconomic class [5, 6]. In the future, the prevalence of constipation patients may increase due to the recent changes in people's lifestyles and inactivity [7, 8].

Constipation also imposes a significant economic burden on the patient and society. This burden is partly related to using resources for outpatient visits, hospitalization, laboratory tests, the cost of medicines, and the reduction of people's work productivity due to constipation [9].

CFC seriously impacts the quality of life (QoL) and performing daily activities [10]. Reducing physical activity is associated with many illnesses, such as diabetes, high blood pressure, obesity, osteoporosis, heart and vascular diseases, breast and colon cancer, depression, and anxiety [11].

Evaluating the disabilities caused by constipation is crucial in order to manage the treatment effectively and reduce complications and disabilities. Physiotherapy plays a significant part in this regard [12].

Several tools have been devised to evaluate the effects of constipation on the QoL. However, the constipation-related disability scale (CRDS) stands out as the most effective tool for evaluating the impact of constipation on daily activities [2]. It is a more comprehensive assessment tool compared to previous questionnaires like PAC-QOL (patient assessment of constipation QoL) [13] and PAC-SYM (patient assessment of constipation symptoms) [14, 1].

The original version of CRDS was reviewed and developed in Canada and English. Although strong evidence supports the validity and reliability of this questionnaire, due to the cultural and linguistic differences in different societies, it is recommended to use valid culturally-adapted tools [15]. Therefore, the cultural adaptation of the CRDS in the Persian-speaking population can facilitate the comparison of research findings in different clinical conditions.

To address this matter, the current research aims to develop the Persian version of the CRDS and compare its psychometric properties with the original version. The

Table 1. CRDS

Activity	No Difficulty 0	Some Difficulty 1	Much Difficulty 2	Unable to Do 3	Does Not Apply
1. Doing activities that require you to sit for long periods (i.e. car rides, meetings, sitting at a computer)					
2. Doing activities that require you to bend over, like gardening, cleaning, athletics					
3. Shopping or doing errands					
4. Taking care of family members or people closest to you					
5. Doing things with or for your children or grandchildren					
6. Going to social events, parties, or celebrations					
7. Having people in your home					
8. Visiting friends or family members in their homes					
9. Walking					
10. Concentrating/maintaining focus on tasks					
11. Travelling out of town					
12. Participating in recreational activities, such as bicycling, swimming, walking, or taking part in sports					
13. Participating in leisure activities, such as going to movies, club meetings, or restaurants					

study outcomes will provide valuable insights for assessing different interventions' effectiveness in clinical and research settings.

Materials and Methods

This methodological study was conducted on a group of Iranian individuals diagnosed with CFC, based on the Rome IV criteria, to assess the reliability and validity of the Persian version of CRDS. The participants were recruited from public and private hospitals and gastroenterology and colorectal physician offices in Arak City, Iran, from April 2022 to August 2022. The study sampling method was purposive. The sample included 145 patients who met the inclusion criteria: Being ≥18 years old, fulfilling the Rome IV criteria for chronic functional constipation, and having the ability to read and speak Persian [15]. The exclusion criteria were as follows: Having secondary constipation, suffering from any systemic disease and psychological disorders, undertaking previous pelvic surgery, and lacking the mental disability to complete the questionnaire [16].

To assess the discriminant validity of the Persian version of CRDS, 130 healthy individuals were selected to participate. These healthy volunteers were recruited through ads, and to be eligible for participation, the healthy subjects were required to be at least 18 years old and proficient in speaking and reading Persian.

This questionnaire consists of 13 items in two subscales: Work/leisure activities (7 items) and daily life activities (6 items). The items are scored on a 4-point Likert scale, ranging from 0 (no difficulty) to 3 (unable to do). Additionally, a fifth response option called 'does not apply' was included for activities that participants did not do due to reasons unrelated to their bowel problems. These items were not considered in the scoring process (Table 1).

Cultural adaptation

At first, permission to translate the questionnaire into Persian was obtained from its authors. In this study, the cultural adaptation of the CRDS questionnaire to the Persian language was carried out according to the international QoL assessment (IQOLA) project presented by Bollinger et al. The project includes the following steps: Translation of the original version into Persian, evaluation of the quality of the translation, back-translating the Persian version into English, comparing the English back-translation with the original version, and assessing

the conceptual consistency between the two. Adjustments will be made to the English-translated version if needed [17].

To qualitatively examine face validity, we gave the Persian version to 15 patients with CFC, who were asked to read the items and express their understanding to the researcher. They were also asked about their comprehension, ability to answer the questions, and appearance and arrangement of the questionnaire items. Considering the patients' understanding of the questions, amendments were made to the questionnaire's text to make the items clear and understandable. For example, in the translation of item number 4, the word "care" was replaced with "nursing" to better convey the concept to the patients.

After applying the changes, we submitted the revised English version of the questionnaire to the questionnaire authors for their approval. They reviewed and approved it, ensuring it maintained conceptual compatibility with the original version.

Reliability

The internal consistency of the tool was assessed through a reliability test using the Cronbach α coefficient. A coefficient value equal to or greater than 0.7 was deemed acceptable [18, 19].

To evaluate the test re-test reliability, 30 patients completed the questionnaire again two weeks later, while they had not received any new treatment for their constipation symptoms and had not changed their diet and nutrition. Also, the intra-class correlation coefficient was calculated as 0.8 to 1.0, indicating its perfect reproducibility [20].

Validity

The translated version was offered to 5 gastroenterologists or internists to assess the acceptance and content validity. Then, the content validity ratio and index were calculated.

We used the physical health composite of the medical outcomes study short form-36 (SF-36) to establish convergent validity for the CRDS due to its association with reduced QoL caused by disease-related disability [2]. A total of 145 patients were given the final Persian version of the CRDS. Additionally, they were asked to complete the SF-36, which consists of 36 questions assessing the overall health of individuals. These 36 items have 8 subscales: Physical functioning, role-physical, bodily pain, general health (physical health composite), vitality, social functioning, role-emotional, and mental health (mental health composite). The Persian version of the SF-36 was translated and culturally adapted by Montazeri et al. [21]. It was assessed by measuring the Pearson correlation coefficient (r) between the CRDS total score and the scores of the physical health section of SF-36.

To evaluate the discriminant validity questionnaire, 130 healthy people also completed it. Then, an independent t-test was used to check the difference between constipated patients and healthy groups.

A committee of 8 gastroenterologists and internists evaluated the instrument's content validity. Content validity ensures the instrument contains appropriate examples to demonstrate the desired structure. Each expert provided a score of 1 to 3 for each question (1=necessary, 2=useful but not necessary, 3=not necessary). The content validity ratio was then calculated. With 8 experts, a minimum acceptable item content validity ratio of approximately 0.75 was established [22]. Additionally, each question was evaluated by experts on a scale of 1 to 4, with 1 indicating no relevance, 2 indicating relevance but requiring significant revisions, 3 indicating some need for revision, and 4 indicating close relevance. Subsequently, the content validity index for each item was computed, whose value exceeding 0.78 signifies strong content validity [23]. The effect of a ceiling or flooring was also evaluated. If more than 15% of the participants attained the maximum or minimum score, it confirms a ceiling or flooring effect.

Results

Participants

This study involved the participation of 145 patients suffering from CFC; 86(59.3%) were women, and 59(40.7%) were men. The mean age of men and women was 49.05 years (30 to 73 years) and 46.88 years (range: 32 to 72 years), respectively.

Also, 130 healthy people completed the questionnaire; 82(63%) were women, and 43(37%) were men, and their Mean±SD age was 39.83±12.74.

Reliability

The reliability of the Persian version of CRDS was assessed by internal consistency and reproducibility measures.

Table 2. The ICC of CRDS scale

Items	No.	Mean±SD	95% CI		
			ICC	Lower Bound	Upper Bound
CRDS score 1 (test) CRDS score 2 (re-test)	30 30	25.13±3.34 26.57±3.51	0.98	0.96	0.92
Work/ leisure activities subscale score1 (test) Work/ leisure activities subscale score 2 (re-test)	30 30	14.03±1.71 14.70±1.74	0.92	0.82	0.96
ADL subscale score 1 (test) ADL subscale score 2 (re-test)	30 30	11.10±1.71 11.90±1.74	0.96	0.92	0.98

ADL: Activities of daily life.

We calculated the Cronbach α value to analyze the internal consistency and found the reliability of the CRDS questionnaire. The Cronbach α coefficients for all items of the CRDS, as well as the work/leisure activities subscale and the ADL subscale, were 0.86, 0.77, and 0.75, respectively. These results indicate a high level of internal consistency for the CRDS questionnaire.

We calculated the intra-class correlation coefficient to determine the reproducibility of the CRDS. This coefficient value for the total scale score of the CRDS was 0.98 (95% CI, 0.92%, 0.96%) (Table 2). The coefficient values for the work/leisure activities subscale and the ADL subscale were 0.92 and 0.96, respectively.

Validity

An independent t-test was conducted to evaluate the discriminant validity of CRDS. The results revealed a significant difference between the healthy and patient groups in the scores obtained. Specifically, the constipated sample had a higher CRDS total score (Mean±SD 25.60±2.71) compared to the healthy controls (Mean±SD 4.02±3.6), t (273)=- 55.62, P<0.001. This finding suggests that CRDS can distinguish between the two groups effectively.

Furthermore, the total score and subscales of CRDS were found to be significantly correlated with the physical health composite score of SF-36 (R=-0.84 to -0.89, P<0.001) (Table 3). This result indicates that individuals with higher levels of disability tend to have lower ratings of QoL.

Regarding content validity, the Lawshe content validity ratio for all items of the Persian CRDS was higher than 0.75, and the CVI for all items of the Persian CRDS was higher than 0.78. There was no ceiling/floor effect for the total score of the Persian CRDS and its subscales.

Discussion

The study results prove the reliability and validity of the Persian version of the CRDS to measure constipation's impact on Iranian people's daily activities. Although cross-cultural validity studies are challenging, they yield precious results. The provision of standard health tools enables the comparison of health status between countries. It provides reliable measurements to monitor health at the population level, estimate the disease burden, examine the consequences in clinical performance, and evaluate the therapeutic outcomes.

In this questionnaire, disability questions were simple and understandable. It makes it easy for people with a low literacy level, who comprise the most affected people, to complete the questionnaire. All patients completed all items of the Persian version of the CRDS, and no item was left unanswered. This high level of responsiveness indicates the patients' good understanding of the questions, a sign of the acceptability of the Persian translation in this study.

Table 3. CRDS

CRDS Subscale	Total Score of Physical Health Composite SF-36
Work/Leisure	-0.84
ADL	-0.85
CRDS total	-0.89

A similar study [24] suggests that it is better to consider the type of chronic constipation and its cause in affected people because irritable bowel syndrome can also lead to chronic constipation. This syndrome results from the interaction between the brain and the intestine. The irritable bowel syndrome causes disability and affects people's QoL differently. Thus, for the sake of homogeneity of the studied sample, patients with irritable bowel syndrome were excluded from the study, and only people with chronic functional constipation remained.

The Cronbach α and intra-class correlation coefficient values for the Persian version of CRDS and its subscales were lower than the English version, which can be due to the countries' cultural differences and the translation and cultural adaptation processes. However, Cronbach α values in this study are also good and acceptable, which indicates good internal consistency of the Persian version of this questionnaire.

The intra-class correlation coefficient was measured by test re-test reliability over time. The coefficient value varies from 1 (the highest level of reliability) to 0 (the lowest level of reliability). Based on the findings of the statistical tests, the repeatability of the overall scores of the questionnaire and the subscales were 0.98, 0.92, and 0.96, respectively. According to the study of Hart et al. [2], the values are 0.88 and 0.87, respectively, and in both studies, the intra-class correlation coefficient values were greater than 0.85, indicating the good internal consistency of the questionnaire.

The correlation between the CRDS and SF-36 questionnaire scores was investigated to check the convergent validity. The Pearson correlation coefficient between the total score of the CRDS questionnaire and its subscales with the total score of the physical health composite of the SF-36 questionnaire was between -0.84 and -0.89 (high correlation). This coefficient has been obtained in a previous study [2] between -0.31 and -0.53 (moderate correlation). The reason for the lower correlation values in the English study is the separation of the subscales of the physical health composite of the SF-36 questionnaire. However, in this study, the total score from the physical health composite of the SF-36 questionnaire was considered, and its correlation with the total score of the CRDS questionnaire and its subscales was investigated. Negative correlation values indicate that higher levels of disability in people are associated with lower QoL.

This research's limitations were related to the coronavirus disease and the need to gain the participants' trust. It is suggested that in future studies, responsiveness could also be assessed and calculated, and the relationship between the CRDS questionnaire and the severity of constipation should be investigated.

Ethical Considerations

Compliance with ethical guidelines

This study was approved by the University of Social Welfare and Rehabilitation (Code:IR.USWR.REC.1400.338).

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Authors' contributions

All authors equally contributed to the preparation of all aspects of the research.

Conflict of interest

The authors declared no conflict of interest.

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مقاله پژوهشی

شناخت مشکلات و پیامدهای شیوع کووید-۱۹ بر فعالیت‌های بالینی آسیب‌شناسان گفتار و زبان

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چکیده

مقدمه پرسش‌نامه مقیاس ناتوانی مربوط به یبوست (CRDS) به شکل اختصاصی تأثیر یبوست بر فعالیت‌های روزمره فرد و میزان ناتوانی ایجادشده به‌وسیله یبوست را بررسی می‌کند. این مطالعه باهدف ارزیابی روایی و پایایی پرسش‌نامه CRDS جهت آماده‌سازی آن برای استفاده در افراد فارسی‌زبان انجام شد.

مواد و روش‌ها در این مطالعه ابتدا پرسش‌نامه CRDS طبق شیوه‌نامه بین‌المللی IQOLA به زبان فارسی ترجمه شد و سپس تطابق‌های لازم برای بومی‌سازی مفاهیم آن صورت گرفت. ۱۴۵ نفر بیمار مبتلابه یبوست عملکردی مزمن و ۱۳۰ فرد سالم نیز پرسش‌نامه‌های CRDS و SF-۳۶ را تکمیل کردند. ارزیابی پایایی و هم‌خوانی درونی به‌ترتیب از طریق آزمون‌های ICC و آلفای کرونباخ انجام شد. بررسی روایی محتوایی توسط گروهی از متخصصین و با محاسبه آیتم‌های نسبت روایی محتوایی و شاخص روایی محتوایی انجام شد. جهت بررسی روایی همگرایی نیز همبستگی بین نمرات دو پرسش‌نامه از طریق آزمون‌های همبستگی مورد ارزیابی قرار گرفت.

یافته‌ها براساس یافته‌های آزمون‌های آماری، مقادیر آلفای کرونباخ نمره کل پرسش‌نامه CRDS ۰/۹۸ (۰/۹۶-۰/۹۹ با فاصله اطمینان ۹۵ درصد) به دست آمد. هم‌خوانی درونی نیز معادل آلفای کرونباخ ۰/۸۶۶ به دست آمد. نمره کل پرسش‌نامه CRDS همبستگی قابل‌توجهی با نمره کل زیرمقیاس سلامت فیزیکی پرسش‌نامه SF-36 دارد که مقدار ضریب همبستگی پیرسون ۰/۸۹۳- بود که روایی همگرایی خوب پرسش‌نامه را نشان می‌دهد. مقدار آیتم شاخص روایی محتوایی برای تمامی آیتم‌ها بزرگتر از ۰/۷۸ بود که روایی محتوایی خوب پرسش‌نامه را نشان می‌دهد. نتایج حاصل از تست تی مستقل نشان داد که بین دو گروه اختلاف معنی‌دار آماری در نمرات پرسش‌نامه وجود دارد (P<۰/۰۵)؛ به‌نحوی‌که میانگین نمرات پرسش‌نامه در گروه مبتلابه شکل قابل‌توجهی بیشتر از گروه سالم بود که نشان‌دهنده روایی افتراقی خوب پرسش‌نامه می‌باشد.

نتیجه‌گیری به نظر می رسد نسخه فارسی CRDS می‌تواند ابزار مناسبی برای ارزیابی یبوست ناشی از ناتوانی در فارسی‌زبانان ایرانی باشد.

کلیدواژه‌ها:
ناتوانی، کیفیت زندگی، روایی، پایایی، نسخه فارسی، یبوست عملکردی

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