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Validation of the Chinese version of the low anterior resection syndrome score for measuring bowel dysfunction after sphincter-preserving surgery among rectal cancer patients

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A B S T R A C T

Purpose: The low anterior resection syndrome (LARS) score is a simple and valid instrument for measuring bowel dysfunction after sphincter-preserving surgery (SPS) among rectal cancer patients. We aimed to translate the LARS score into Chinese, and to test its reliability and validity among Chinese rectal cancer patients.

Methods: The LARS score was translated into Chinese by using internationally recognized forward- and back-translation procedures. In total, 102 patients completed the questionnaire; a subgroup of 20 patients answered the survey twice. The reliability was estimated through the test-retest reliability method. The convergent and discriminant validities were confirmed by measuring the relation of the LARS score with the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 and QLQ-CR29 domains, respectively, and testing its ability to differentiate among patients with different clinical characteristics.

Results: The Spearman correlation coefficient of the LARS-scores at the two surveys was 0.86 ($p < .001$), and the linear-weighted kappa values of the five items of the LARS score were 0.38, 0.76, 0.79, 0.77, and 0.78, respectively. The LARS score showed significant correlations with all the assumptive domains of QLQ-C30 and QLQ-CR29, especially flatulence, fecal incontinence, and stool frequency (all $p < .05$). It could also detect differences between female and male patient groups ($p = .033$), patients who had/had not undergone radiation therapy ($p = .007$), those who had undergone surgery in the last <12.0 or ≥12.0 months ($p = .002$), and those with low or high tumor edge level ($p = .017$).

Conclusions: The Chinese version of the LARS score had good psychometric properties and can be used in clinical and research settings in the Chinese population.

Introduction

Rectal cancer is one of the most common gastrointestinal cancers worldwide (International Agency for Research on Cancer, 2008), and the morbidity rate in China has shown an increasing trend in the last several decades (Chen et al., 2013, 2014). With the improvements in surgical technology and the increasing demand for a higher quality of life (QoL), the number of rectal cancer patients undergoing sphincter-preserving surgery (SPS) with low or ultra-low anastomosis, to avoid permanent colostomy, has increased. Although bowel continuity is maintained in such cases, many factors such as anal sphincter damage, rectal capacity decrease, and adjuvant therapy may lead to bowel dysfunction in 70–90% of patients, resulting in various symptoms including frequent bowel movement, fecal urgency, incontinence, and fractional defecation—collectively known as the (low) anterior

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resection syndrome (ARS/LARS) (Bryant et al., 2012; Ziv et al., 2013). Studies (Cornish et al., 2007; Pachler and Wille-Jørgensen, 2012; How et al., 2012; Emmertsen and Laurberg, 2013; Juul et al., 2014a) have shown that after SPS, patients with low rectal cancer do not have better QoL than patients with permanent stoma, and ARS/LARS proved to be the main reason for the lower QoL.

In Chinese patients, rectal cancer develops at the middle or low section of the rectum in approximately 70% of cases (Gu, 2006). SPS has become a routine operation in China, suggesting that an increased number of Chinese rectal cancer patients may experience ARS/LARS after the surgery. To develop effective interventions and improve symptom management in these patients, oncology nurses should first perform an assessment of bowel function. However, because the consultation time is limited during outpatient follow-up owing to the large number of patients in China, a simple, specific, and valid instrument to assess bowel function after rectal resection is urgently needed.

Currently, there are a variety of instruments used for the assessment of bowel function after SPS, such as the Wexner incontinence score (Jorge and Wexner, 1993), Vaizey scoring system (Vaizey et al., 1999), Williams classification (Williams et al., 1991), Fecal Incontinence Severity Index (Rockwood et al., 1999), Memorial Sloan Kettering Cancer Center Bowel Function Instrument (Temple et al., 2005), and the LARS score (Emmertsen and Laurberg, 2012). Among these instruments, the LARS score is a newly developed international tool for the quick evaluation of the presence and severity of ARS/LARS that has undergone systematic and rigorous validation. The LARS score consists of only five symptom items weighted according to impact on patients' QoL, which makes it simple but relatively comprehensive for bowel function assessment. Moreover, all the response options for these five items correspond to the exact number of frequencies of the symptoms, which allows patients to give an accurate answer easily. Besides, the patients can be divided into groups with no, minor, and major LARS on the basis of the total score; thus, oncology nurses could provide specific supportive care based on the group to which the patient belongs. Therefore, the LARS score could be used by health-care professionals to assess bowel function in rectal cancer patients after SPS, quickly and relatively comprehensively, in the hospital or even during telephone follow-up if necessary.

To date, the LARS score has been translated and validated into Danish, Spanish, German, and Swedish (Juul et al., 2014b), but has not yet been introduced in China. Thus, in the present study, we aimed to thoroughly translate the LARS score into Chinese and to test its psychometric properties in a Chinese population, to develop a scientific instrument for future research and clinical practice in China.

Methods

Translation process

The LARS score consists of five items: “incontinence for flatus,” “incontinence for liquid stool,” “frequency of bowel movements,” “clustering of stools,” and “urgency.” On the basis of the symptoms of bowel dysfunction and their impact on the patients' QoL, each item has three to four response choices that are assigned with different score values. The third item has four choices, including “>7 times per day,” “4–7 times per day,” “1–3 times per day,” and “less than once per day,” assigned with values of 4, 2, 0, and 5, respectively. All the other four items have three choices, including “no, never,” “yes, less than once per week,” and “yes, at least once per week,” and are assigned with the values of 0, 4, and 7 for the first item; 0, 3, and 3 for the second item; 0, 9, and 11 for the fourth item; and 0, 11, and 16 for the fifth item, respectively. (Please refer to the Appendix for the Chinese version of the LARS score and its value assignment.) The total score by summing all five items ranges from 0 to 42, with values of 0–20 representing “no LARS”; 21–29 representing “minor LARS”; and 30–42 representing “major LARS.”

After obtaining permission from the original authors, we conducted the forward- and back-translation procedures in accordance with the translation guideline provided by the authors. First, two Chinese researchers who had a master's degree in surgical nursing and were fluent in both Chinese and English independently translated the English version into Chinese. The two translators checked and discussed the two translations for any inconsistency, and eventually established a single provisional Chinese version. Thereafter, the Chinese version was back-translated into English by a Chinese-American researcher engaged in clinical nursing who had never seen the original English version before. The three translators compared the English back-translated version against the original and did not find any conceptual discrepancies.

Finally, a pilot test was conducted in the gastrointestinal surgery clinic. Ten patients who met the inclusion criteria were administered the Chinese version of the LARS score. These patients were chosen according to their representativeness; they represented a wide range of socio-demographic and clinical characteristics. In total, six male patients and four female patients were administered the questionnaire. Three of these patients had primary level education, four had secondary level education, and three had college level or higher education. Seven patients had undergone surgery <12 months previously and three patients had undergone surgery >12 months previously. Three patients had tumor stage I, five patients had tumor stage II, and two patients had tumor stage III. Their age ranged from 48 to 85 years, with a mean age of 62.2 (SD, 12.5) years. Furthermore, two of the patients had a history of temporary stoma. The patients were asked whether each item in the questionnaire was clear and easily understandable, and whether they experienced any difficulty or confusion when filling out the questionnaire; they stated that the questionnaire was acceptable and easy to understand.

The final Chinese version (please see Appendix) and the whole translation process mentioned above were then sent to the original author of the LARS score for approval.

Participants and data collection

The participants were recruited from a tertiary general hospital in Beijing between October 2013 and June 2014. The inclusion criteria were as follows: (i) age 18 years or older; (ii) a diagnosis of rectal cancer through colonoscopy or pathological evaluation; (iii) underwent stoma-free rectal resection surgery or reversal surgery of temporary stoma $\geq$1 month previously; and (iv) voluntarily participated in the study. Patients were excluded if they had undergone palliative surgery, were receiving adjuvant therapy, had confirmed recurrence or metastasis, had other diseases of bowel dysfunction (Crohn's disease, irritable bowel syndrome, and others), or had cognition/language problems.

Data collection was performed according to the following procedures. (i) The researchers identified eligible participants by reviewing the medical records of rectal cancer patients who were hospitalized in the gastrointestinal surgery department during the period from January 1, 2010, to September 30, 2013. (ii) The eligible