Review of Disease-Specific Instruments for Measuring Patient-Reported Outcomes and Quality of Life in Irritable Bowel Syndrome: Post-Print

Authors: Wu Xiaoyu, Chonghua Wan, Chen Ying, Ruan Yanqin, Weng Yijie, Xu Xiaojiang, Wan Chonghua

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Abstract

Scale assessment has been widely applied in clinical practice, and selecting appropriate assessment tools is of crucial importance. Based on this, this paper employs a literature search methodology to identify scales specific to irritable bowel syndrome (IBS) patients, summarizes their main contents and psychometric properties, and proposes recommendations for scale selection. A total of 35 specific scales commonly used for quality of life assessment in IBS patients were retrieved. Existing IBS-specific scales have been demonstrated to possess satisfactory reliability, validity, and responsiveness, and can be effectively applied in clinical practice. In clinical application, appropriate scales should be selected according to different purposes and research content.

Full Text

Preamble

A Review of Studies on Reported Outcomes and Specific Scales for Quality of Life in Patients with Irritable Bowel Syndrome

WU Xiao-yu, WAN Chong-hua*, CHEN Ying, et al.

Abstract Scale assessment has been widely used in clinical practice, and selecting appropriate assessment tools is crucial. This paper employed a literature search method to identify specific scales related to patients with irritable bowel syndrome, summarized their main contents and measurement properties, and proposed guidelines for scale selection. A total of 35 specific scales commonly used to measure quality of life in patients with irritable bowel syndrome were retrieved. Existing IBS-specific scales have demonstrated good reliability, validity, and responsiveness, and can be effectively applied in clinical practice. When

applying these scales clinically, the appropriate instrument should be selected based on different purposes and research content.

[**Key words**] irritable bowel syndrome; quality of life; specific scale; measurement characteristic

Irritable Bowel Syndrome (IBS) is a condition characterized by abdominal pain, bloating, or discomfort associated with altered bowel habits, including frequency and/or stool form changes, without identifiable organic disease through routine clinical examination. Due to its insidious course and recurrent symptoms, IBS causes significant inconvenience to daily life, work, and study. With the shift toward a bio-psycho-social medical model, patient-reported outcomes and health-related quality of life have received increasing attention. Scales for assessing IBS patient-reported outcomes and quality of life fall into two categories: generic and disease-specific. Commonly used generic scales include the Medical Outcomes Study Short-form 36 (SF-36), European Quality of Life Index (EQ-5D), and Nottingham Health Profile (NHP). While generic scales are suitable for evaluating interventions across different diseases and populations, they are less responsive for assessing quality of life in specific disease patients or capturing subtle changes. In such cases, disease-specific scales are more appropriate for evaluating quality of life in IBS patients. Therefore, this review focuses on the research progress of specific scales.

1. Methods

1.1 Inclusion and Exclusion Criteria

Inclusion criteria: (1) Study subjects were patients with irritable bowel syndrome or functional gastrointestinal disorders; (2) Assessment was conducted using specific scales; (3) Outcome measures were patient-reported outcomes and quality of life scores.

Exclusion criteria: (1) IBS or functional gastrointestinal disorders combined with other diseases; (2) Duplicate publications.

1.2 Literature Search

A comprehensive literature search was conducted across CNKI, Wanfang, VIP, CBM, and PubMed databases for the most recent 31 years (January 1990 to December 2021) using Chinese search terms including "肠易激综合征/功能性胃肠病" and "患者报告结局/健康相关生命质量/生命质量 (生活质量、生存质量)", and English search terms including "Irritable Bowel Syndrome/Functional Gastrointestinal Disorders" and "Patient Reported Outcomes/Health-Related Quality of Life/Quality of Life" . The search identified specific scales for patient-reported outcomes and quality of life in IBS patients, and information on scale reliability, validity, and responsiveness was compiled.

1.3 Evaluation Indicators

1.3.1 Basic Scale Information This included the Chinese and English names and abbreviations of specific scales, number of items, dimensions, dimension content, scale administration method, total scoring, scoring method, and survey time.

1.3.2 Reliability Reliability reflects the internal stability and consistency of an instrument, indicating the degree of measurement variation caused by random error. Common methods include test-retest reliability (calculating the correlation coefficient r between two measurements) and internal consistency reliability (commonly calculated using Cronbach' s α coefficient).

1.3.3 Validity Validity refers to the degree to which an instrument measures the intended construct. Common methods include content validity (generally judged based on experience; good content validity is assumed if items cover various aspects of the measured concept in appropriate proportions), construct validity (commonly reflected through correlation and factor analysis methods), and criterion validity (represented by the correlation coefficient between measurement scores and criterion standards).

1.3.4 Responsiveness Responsiveness refers to the degree to which survey results reflect changes when the subject's condition changes. Common indicators include Effect Size (ES) and Standardized Response Mean (SRM).

2. Results

2.1 Literature Search Results

Following the search strategy, 7,976 Chinese articles and 31,186 English articles were retrieved from various databases. Using Endnote X9 software, 15,783 duplicate publications were removed, yielding 23,379 articles for initial screening. After reviewing titles and abstracts, 19,302 articles that did not match the topic were excluded, leaving 4,077 articles. After full-text review and application of inclusion and exclusion criteria, 4,040 additional articles were excluded, resulting in a final inclusion of 37 articles (6 Chinese and 31 English).

2.2 Scale Overview

Based on the database search and compilation, 37 specific scales were identified for measuring patient-reported outcomes and quality of life in IBS patients. The specific content and psychometric characteristics of these scales are presented in and . Additionally, two scales developed by domestic and international scholars that are widely used and have good psychometric properties are described in detail.

TABLE:1 presents the basic information of specific scales, including scale names, dimensions, scoring methods, and administration details. **TABLE:2** presents the psychometric characteristics, including reliability, validity, and responsiveness data.

2.2.1 Irritable Bowel Syndrome-Quality of Life Measure (IBS-QOL)

The IBS-QOL scale was developed in 1998 by Patrick et al. to create a quality of life measurement method specifically for IBS. Items were generated using a conceptual model and qualitative interviews with IBS patients diagnosed using Rome criteria. The scale comprises 8 dimensions and 34 items, with higher scores indicating better health-related quality of life. Patients use a 30-day recall period for descriptive statements and a 5-level response scale (“not at all,” “slightly,” “moderately,” “quite a bit,” “extremely”) to assess how well each statement describes their feelings. Total scores are calculated by summing all items. Validation studies demonstrated good reliability (Cronbach’ s $\alpha = 0.95$, ICC = 0.86) and validity (r = 0.33-0.45). Leeanne et al. used the IBS-QOL scale to investigate the effects of gender and weight on quality of life in 41 IBS patients and 74 healthy controls through ANOVA and multiple regression. Results showed that IBS patients reported lower QOL scores across all subscales compared to healthy controls, with normal-weight women ($M = 74.60 \pm 18.63$) and overweight men ($M = 77.21 \pm 17.33$, $P < 0.05$) reporting the greatest quality of life impairment. The differences in QOL scores across gender and weight groups among IBS participants may reflect different social pressures experienced by normal and overweight women and men, suggesting that psychological, cultural, and healthcare-seeking behaviors are potential contributing factors. Future research should examine how these factors influence QOL in these subpopulations. The reliability and validity of the IBS-QOL scale have been tested in multiple countries including the United States and Mexico. However, research on the scale’ s responsiveness is limited. Bian Lizun et al. noted that the IBS-QOL scale primarily assesses quality of life, which may not show clear relationships with symptoms in the short term, but its value deserves further investigation for clinical studies with longer treatment courses or follow-up periods.

2.2.2 Irritable Bowel Syndrome Symptom Severity Score (IBS-SSS)

The IBS-SSS scale was specifically designed in 1997 by Francis et al. to assess IBS severity at specific time points, aiming to facilitate clinical evaluation and research of IBS. The scale contains 5 dimensions and 24 items, with different scores representing different severity levels; higher scores indicate more severe disease and poorer quality of life. Francis evaluated disease severity, scoring system reproducibility, and sensitivity to change using 141 patients and 40 healthy controls. Results showed that mild, moderate, and severe cases were represented by scores of 75-175, 175-300, and >300, respectively. Significant differences were found between control and patient groups ($P = 0.0001$). The question-

naire demonstrated high reproducibility when completed within 24 hours and excellent sensitivity to change ($P < 0.001$), with a response rate of 85% and completion rate of 90%. Su Yidan et al. used the IBS-SSS scale to analyze the efficacy of Bacillus subtilis and Enterococcus faecium enteric-coated capsules in treating IBS patients over 4 weeks. Results showed no significant difference in IBS-SSS scores between groups before treatment ($P > 0.05$), but scores decreased after 4 weeks of treatment, with the combination group showing lower scores than the monotherapy group ($t = 24.333$, $P < 0.001$), indicating that the treatment reduced disease severity and alleviated diarrhea symptoms.

The IBS-SSS scale is an invaluable tool in both clinical and research settings, addressing the challenge of lack of standardization in IBS disease definition and severity assessment. Clinically, it can be used to monitor patient progress or target treatment for particularly severe patients. In research settings, it helps recruit more homogeneous patient populations. However, the stability of its scoring system can be influenced by factors beyond pain, bloating, bowel scores, and quality of life.

2.2.3 Quality of Life Instrument for Chronic Diseases-Irritable Bowel Syndrome (QLICD-IBS)

QLICD-IBS was developed in 2010 by Wan Chonghua' s team from the cultural background of the Chinese population. The instrument consists of a chronic disease generic module (30 items) and an IBS-specific module (15 items). The specific module includes three domains: abdominal pain and bloating, stool condition, and psychological life impact. The scale achieved a response rate of 92% and completion rate of 100%. Subsequent evaluation of quality of life in 99 hospitalized IBS patients before and after treatment demonstrated that the scale has good reliability, validity, responsiveness, and clinical feasibility, and can reflect quality of life changes in IBS patients before and after treatment, making it a suitable quality of life assessment tool for the Chinese population.

QLICD-IBS is part of the Quality of Life Instrument for Chronic Diseases system. It employs a development model combining generic and disease-specific modules. This approach avoids the limitation of generic scales that cannot adequately capture IBS-specific symptoms and psychosocial characteristics, while also addressing the narrow content of disease-specific scales that are only applicable to special patient populations and 不利于 comparison across different samples and treatment methods. The combination of both modules makes research results both comparable and targeted.

2.2.4 Spleen-Stomach Disease PRO Scale-IBS Subscale (SSDPRO-IBS)

This scale was developed in 2011 by Liu Fengbin et al. to align with Chinese culture and medical background for application in modern clinical efficacy evaluation of traditional Chinese medicine. The scale comprises 3 dimensions and

43 items, with higher scores indicating more severe disease and poorer quality of life. The scale achieved a response rate of 95% and completion rate of 100%. Validation studies demonstrated good reliability, validity, discriminative ability, and operability, making it suitable for evaluating clinical efficacy of traditional Chinese medicine and integrated Chinese-Western medicine treatment for IBS.

The SSDPRO-IBS scale adopts a traditional Chinese medicine perspective, using syndrome differentiation and holistic treatment to significantly improve clinical symptoms and enhance patients' quality of life. However, due to limitations in disease distribution and other factors, it has not yet achieved multi-center investigation with large sample sizes. Future research should include additional regions and expand the survey scope.

3. Discussion

Quality of life measurement is a type of psychological measurement. Due to the presence of measurement error, scales must be evaluated for measurement properties before application, including reliability, validity, and responsiveness. Reliability reflects the consistency and stability of repeated measurements, typically quantified using reliability coefficients. It primarily includes test-retest reliability and internal consistency. Generally, test-retest reliability >0.70 indicates good scale stability, while Cronbach' s α coefficient >0.80 for the total scale and >0.70 for subscales suggest good internal consistency. Based on available data in the tables, most scale dimensions have test-retest reliability above 0.70, indicating good stability when used for quality of life measurement in IBS patients. The data also show high Cronbach' s α coefficients across scales, indicating good internal consistency. Scales such as IBS-36, DSSI, and QLICD-IBS have reliability coefficients approaching 0.90, suggesting reliable measurement results in clinical practice.

Validity reflects the effectiveness of measurement and primarily includes construct validity and criterion validity. Generally, a cumulative variance contribution rate of common factors >40% and factor loadings >0.40 for each item on its common factor indicate good factor interpretation. When using other scales as criteria, Spearman correlation coefficients are typically calculated, with r >0.4 considered moderate correlation and r >0.75 considered high correlation. The data show that cumulative variance contribution rates of common factors for all scales exceed 50%, with factor loadings meeting the >0.40 criterion, indicating good construct validity. Some scales demonstrate high correlation coefficients, such as CR-QOL with SF-36 as the "gold standard" (r = 0.88), RDQ with QOL-RAD as the criterion (r = 0.80), and DSFQ with IBS-SSS as the criterion (r = 0.76), all exceeding 0.75 and indicating high correlation with standard scales.

Responsiveness reflects the sensitivity of scales over time and primarily includes Effect Size (ES) and Standardized Response Mean (SRM). Generally, absolute values $ $0.80 for both indicators suggest good responsiveness. The data show that, except for IBS-36 (ES = 0.31-0.70), absolute values for all other scales

exceed 0.80, indicating good short-term responsiveness.

With over 30 specific scales available for IBS assessment, researchers face challenges in scale selection. Therefore, choosing appropriate scales is critical. For reflecting health status across different populations, generic scales such as SF-36, EQ-5D, and NHP should be selected. For clinical evaluation, specific scales with good psychometric properties should be chosen. For patients with severe conditions or difficulty completing complex scales, brief and easy-to-complete instruments are preferable, such as GSRS-IBS (13 items), LDQ (16 items), PAC-SYM (12 items), SDRH (14 items), SODA (17 items), RDQ (12 items), QOL-PEI (18 items), PADYQ (11 items), VSI (15 items), GIS (10 items), GOS (10 items), CRQOL (18 items), DSFQ (4 items), LPDS (8 items), BSFS (7 items), HKID (12 items), and QLICD-IBS (15 items). For assessing the impact of disease severity on quality of life, scales such as IBS-SSS, FBDSI, GSRS-IBS, PAC-SYM, DSSI, SODA, PAGI-SYM, VSI, DSFQ, and BSFS are appropriate. For comprehensive quality of life assessment, integrated scales such as IBSQOL, IBS-QOL, IBSQ, and IBS-36 can be used. Additionally, scale selection should be based on research content. For example, BSFS may be considered for studies examining the relationship between quality of life and bowel symptom severity in IBS patients. Furthermore, scales developed by foreign scholars may have cultural, dietary, and religious differences that may not suit China' s national conditions. When selecting scales, researchers should verify whether Chinese versions exist and whether they have undergone translation and psychometric evaluation. If not, domestic scales such as the IBS Traditional Chinese Medicine Syndrome Scale, Clinical Outcome Assessment Scale Based on Chronic Gastrointestinal Disease Patient Reports, QLICD-IBS, SSDPRO-IBS, and Functional Dyspepsia Patient-Reported Outcome Scale are excellent alternatives.

In conclusion, irritable bowel syndrome is a psychosomatic disease that significantly reduces patients' quality of life. Clinicians should prioritize research on patients' quality of life, understand measurement tools thoroughly, and apply them judiciously to provide more evidence for selecting effective interventions.

Author Contributions

WU Xiao-yu: data analysis, drafting; WAN Chong-hua: overall design, manuscript revision, quality control and review, overall responsibility; CHEN Ying, RUAN Yan-qin, WENG Yi-jie, XU Xiao-jiang: literature search and data compilation.

Conflict of Interest

The authors declare no conflict of interest.

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Note: Figure translations are in progress. See original paper for figures.