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## Development and Item Selection of the Inflammatory Bowel Disease Patient-reported Outcomes Scale Based on Theories of Traditional Chinese Medicine

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# Development and Item Selection of the Inflammatory Bowel Disease Patient-reported Outcomes Scale Based on Theories of Traditional Chinese Medicine

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**【Abstract】** Background The prevalence of inflammatory bowel disease (IBD) increases annually in China. The integrated traditional Chinese and western medicine is helpful to alleviate and control symptoms of IBD. Quality of life (QoL) is an important index to evaluate the clinical efficacy of IBD. However, there are few studies about IBD patient-reported outcomes (PROs) based on TCM theories. Objective To determine the framework and items, and then use them to develop the IBD PROs scale using TCM theories. Methods Under the guidance of the TCM theory of “body and mind harmony, and man's adaptation to his total environment”, literature review, focus group discussion and expert consultation were carried out. The conceptual framework and item pool of the draft of an IBD PROs scale were developed, then the corresponding items were determined, forming the draft of the IBD PROs scale. Then the draft scale was pre-tested in IBD patients treated in Department of Spleen and Stomach Diseases, the First Affiliated Hospital of Guangzhou University of Chinese Medicine from January to June 2021. Standard deviation, Cronbach's  $\alpha$  and correlation analysis were used for item selection. Results The final IBD PROs scale is composed of two domains: body and mind harmony (12 body-related items, and 9 mind-related items) and man's adaptation to his total environment (6 items). Conclusion The IBD PROs scale which was developed based on theories of TCM could be used to evaluate the QoL of IBD patients. But further clinical research is still needed to verify its reliability and validity.

**【Key words】** Inflammatory bowel disease; Patient-reported outcomes; TCM theories; Quality of life; Item selection; Construction of scale

**【Chinese Library Classification Number】** R 574 **【Document Identification Code】** A

Inflammatory bowel disease (IBD), including ulcerative colitis (UC) and Crohn's disease (CD), is a kind of intestinal

disease with chronic non-specific inflammation of the intestinal mucosa as the main pathological change. Since 1990, the incidence of IBD continued to rise in newly industrialized countries in Africa, Asia and South America, and IBD has become a global disease<sup>[1]</sup>. The number of IBD cases in mainland China is on the rapid rise<sup>[2]</sup>.

IBD is a chronic disease with low mortality. Compared with mortality, quality of life (QoL) is more suitable to be used as an outcome indicator for clinical efficacy evaluation<sup>[3]</sup>. At present, two scales have been translated into Chinese: The 32-item Inflammatory Bowel Disease Questionnaire (IBDQ-32)<sup>[4]</sup> (including the traditional Chinese version<sup>[5]</sup> and the simplified Chinese version<sup>[6]</sup>) and the Short Health Scale (SHS)<sup>[7-8]</sup>. IBDQ-32 was the most widely used scale in China. Yang et al.<sup>[9]</sup> developed a 56-item quality-of-life scale for ulcerative colitis with traditional Chinese medicine characteristics based on Delphi method, and Ruan et al.<sup>[10]</sup> developed a 22-item IBD quality-of-life questionnaire (IBDQOL-22).

QoL measurement is affected by the social circumstances and cultural background of the subjects. The cultural differences between the East and the West reduce the measurement performance of the scales<sup>[11]</sup>. The theories of traditional Chinese medicine (TCM) which derived from the Huangdi Neijing, inherit the outstanding traditional culture of China. The “harmonization between soma and spirit” and “correspondence between man and universe” are core ideas of TCM on health<sup>[12-13]</sup>. Chinese Quality of Life Instrument<sup>[14-15]</sup>, Health Status Scale of Traditional Chinese Medicine<sup>[16]</sup> etc. which developed on the basis of traditional Chinese medicine theories, have been testified to have good effectiveness of measurement and value of use by clinical practices. Patient-reported outcomes (PROs) are any reports of a patient's health status that comes directly from him or her without interpretation by the clinician or anyone else. PROs are recommended by the Food and Drug Administration (FDA) of the United States as an effective tool to evaluate the benefits and risks of treatment in clinical trials<sup>[17]</sup>. It is also recommended by the International Organization for the Study of IBD as one of the evaluation indicators for treat-to-target strategies of patients with IBD<sup>[18]</sup>. However, there are few reports on IBD PROs scale developed based on theories of traditional Chinese medicine. Therefore, this study developed an IBD PROs scale based on theories of traditional Chinese medicine to provide an effective tool for clinical evaluation on TCM treatments of patients with IBD. The reliability and validity of IBD PROs scale are still in progress. This article focuses on the framework construction and pre-test (item selection) results of IBD PROs scale.

## 1 Materials and methods

### 1.1 Forming of the draft of IBD PROs scale

#### 1.1.1 Literature research study “Inflammatory bowel disease, ulcerative colitis, Crohn's disease, quality of life” were used

as keywords to search on the CNKI, and “inflammatory bowel disease, quality of life” to search on the PubMed, Embase for retrieving articles on disease-specific scales of IBD, UC or CD. The search period was from the inception of the databases to October 31th 2020. Inclusion criteria: (1) study objects: patients with establish diagnosis of IBD, UC and CD; (2) research contents: development, translation or validation on reliability or validity of quality-of-life scales of IBD. Exclusion criteria: (1) articles without full-text accessory or scale items; (2) articles on General QoL instruments. A total of 18 instruments for adults with IBD were acquired, excluding the Quality-of-Life Index for Pediatric Inflammatory Bowel Disease (IMPACT)<sup>[30]</sup>, the IMPACT- II<sup>[31]</sup> and the IMPACT- III<sup>[32]</sup>, 3 instruments of pediatric IBD. Details of these IBD disease-specific QoL instruments, such as publication date, the first author, country, number of domains, number of items and number of items in each domain etc. are shown in Table 1.

**Table 1** IBD-specific health-related quality of life instruments

Abbreviation of scale	Year of publication	First author	Nation	Number of domains	Number of items	IBD-related symptoms (Number of items)	Physical functioning or general wellbeing (Number of items)	Emotional functioning (Number of items)	Social functioning (Number of items)
IBDQ-32 <sup>[4]</sup>	1989	GUYATT	Canada	4	32	Bowel symptoms (10), Systemic symptoms (5)	-	Emotional functioning (12)	Social function (5)
RFIPC <sup>[19]</sup>	1991	DROSSMAN	USA	4	25 <sup>a</sup>	Impact of disease (13), complications of disease (4)	Body stigma (2), Sexual intimacy (3)	-	-
IBDQ-36 <sup>[20]</sup>	1992	LOVE	Canada	5	36	Bowel symptoms (8), Systemic symptoms (7)	Functional impairment (7)	Emotional functioning (8)	Social function impairment (6)
CCQIBD <sup>[21]</sup>	1992	FARMER	USA	4	47	Medical/symptoms (9)	Affect/life in general (11), Functional/economic (12)	-	Social function/recreational (15)
PIBDQL <sup>[22]</sup>	1995	MARTIN	Italy	4	29	Bowel symptoms (8), Systemic symptoms (7)	-	Emotional functioning (9)	Social function (5)
SIBDQ <sup>[23]</sup>	1996	IRVINE	Canada	4	10	Bowel symptoms (3), Systemic symptoms (2)	-	Emotional functioning (3)	Social function (2)
CGQL <sup>[24]</sup>	1999	FAZIO	USA	3	3	-	Quality of life (1), quality of health (1), physical activity level (1)	-	-

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EIBDQ <sup>[25]</sup>	2002	SMITH	UK	3	13 <sup>b</sup>	Bowel-specific symptoms (6), Disease-specific symptoms (5)	-	-	-
IBDQ-9 <sup>[26]</sup>	2004	ALCALÁ	Spain	1	9	-	-	-	-
SHS <sup>[7]</sup>	2006	HJORTSWAN G	Sweden	4	4	Symptom burden (1)	General wellbeing (1)	Disease-related worry (1)	Social functioning (1)
CUCQ <sup>[27]</sup>	2015	ALRUBAIY	UK	1	8	-	-	-	-
QOLS of TCM for UC <sup>[9]</sup>	2015	Yang Ling	China	4	56	-	Physical Factors (25), Overall evaluation (2)	Psychological factors (9)	Independent factors (1), Social factors (10)
CLIQ <sup>[28]</sup>	2015	WILBURN	-	2	36	-	-	-	-
IBDQOL-22 <sup>[10]</sup>	2017	RUAN	China	4	22	Bowel symptoms and influences (6), Symptoms and discomfort (5)	-	Emotional function (6)	Social function (5)
PROBE <sup>[29]</sup>	2019	THOMAS	USA	4	6	Bowel symptoms (1), systemic symptoms (1)	-	Emotional functioning (2)	Social functioning (2)

Notes: IBDQ-32: the 32-item Inflammatory Bowel Disease Questionnaire, RFIPC: the Rating Form of IBD Patient Concerns, IBDQ-36: the 36-item Inflammatory Bowel Disease Questionnaire, CCQIBD: the Cleveland Clinic Questionnaire for Inflammatory Bowel Disease, PIBDQL: the Padova Inflammatory Bowel Disease Quality of Life, SIBDQ: the Short Inflammatory Bowel Disease Questionnaire, CGQL: the Cleveland Global Quality of Life, EIBDQ: the Edinburgh Inflammatory Bowel Disease Questionnaire, IBDQ-9: the 9-item Inflammatory Bowel Disease Questionnaire, SHS: the Short Health Scale, CUCQ: the Crohn's and ulcerative colitis questionnaire, QOLS of TCM for UC: the Quality of Life Scale of Traditional Chinese Medicine for Ulcerative Colitis, CLIQ: the Crohn's Life Impact Questionnaire, IBDQOL-22: the 22-item IBD Quality-of-life Questionnaire, PROBE: the PRO-based evaluation; <sup>a</sup> represents 3 items can not be divided into these domains for low factor loading; <sup>b</sup> represents 2 items of the EIBDQ on information can not be divided into these domains; - represents content is missing.

1.1.2 Developing the Conceptual Framework In accordance with the World Health Organization's definition of QoL, referencing to the international process and guidance of PROs instruments development, co-opted the conceptual framework of the Spleen and Stomach disease PRO scale (SSDPRO) and the Myasthenia gravis-PRO scale (MG-PRO), "unity of body and spirit" "correlation of five zang organs" "unity of nature and human" and "correlation of seven emotions". Combined with the TCM etiology and pathogenesis of IBD, the conceptual framework of the IBD PROs with TCM characteristics was constructed.

1.1.3 Generating item pool To generate item pool, items of the internationally widely used IBD instruments were referenced. Meanwhile, literatures on treating IBD with Chinese medicine or western medicine were retrieved from the SinoMed, CNKI, Wangfang Data, VIP Chinese Journal Database, by using key words “IBD, UC, CD, treatment, syndrome differentiation, symptom”. Search period was from the inception of the databases to October 31th 2020. Common subjective symptoms or signs of patients with IBD, such as abdominal pain, diarrhea, tenesmus, fatigue, emaciation, sleeplessness etc. were abstracted from these literatures.

1.1.4 Core-group discussion Core-group was composed of 2 clinical experts of spleen and stomach diseases with associate senior titles or above, 2 experts of scale development, and 4 undergraduate students of integrated traditional Chinese and Western medicine from Guangzhou University of Chinese Medicine. Members of the core-group had a discussion on the conceptual framework, item inclusion, and the clarity of the item semantics, based on the item pool generated from the theories of Chinese medicine, the composition of QoL and literature research, combined with the theory of traditional Chinese medicine and the clinical manifestations of IBD patients. The conceptual framework and items of the draft scale were protocoled.

1.1.5 Experts consultation After the draft scale were protocoled, 2 senior TCM doctors with rich clinical experience specialized in spleen and stomach diseases (one of them is an expert in TCM scale development) were consulted. The two experts made language adjustments to the item stem and response options of the draft scale. The framework and items of the draft scale were finally determined.

1.2 Pre-testing Patients with IBD who visited the Department of Spleen and Stomach Diseases of the First Affiliated Hospital of Guangzhou University of Chinese Medicine from January to June 2021, were pre-tested using the draft scale. Patients of this study were enrolled consecutively. Inclusion criteria: (1) In line with the diagnostic criteria of UC or CD in the Chinese consensus on diagnosis and treatment of inflammatory bowel disease (Beijing, 2018) [\[2\]](#); (2) Age between 16~75 years old; (3) Able to communicate normally, and to complete the questionnaires solely or with the assistance of others. Exclusion criteria: With concurrent diseases, such as cancer or heart disease, which seriously affect QoL. A total of 113 questionnaires were distributed and all were recovered. One questionnaire with incomplete demographic data was excluded, and 112 cases were finally included, including 72 males and 40 females; mean of age was (38.9±13.6) years; 69 cases were patients with UC, and 43 cases were patients with CD.

1.3 Item selection

1.3.1 Dispersion tendency analysis Dispersion tendency was measured by the standard deviation calculated by the score of each item. Greater dispersion tendency represents better discriminant ability of the item. Standard deviation < 0.9 was consider as the criterion for excluding item.

1.3.2 Cronbach's  $\alpha$  coefficient The Cronbach's  $\alpha$  coefficient of a domain was calculated, and the change of  $\alpha$  coefficient after retaining and deleting an item was compared. If the  $\alpha$  coefficient increased significantly after deleting an item, the item was deleted; otherwise, it was retained.

1.3.3 Correlation coefficient The correlation coefficient between item and domain was evaluated by calculating the correlation coefficient  $r$  of each item and domain score. The criterion for deleting item was  $r < 0.5$ .

1.4 Statistical analysis The SPSS 22.0 software was used for statistical analysis. Measurement data were expressed as  $(\bar{x} \pm s)$ , and count data were expressed as the number of cases.  $P < 0.05$  was considered statistically significant.

**2 Results**

2.1 The Draft IBD PROs Scale The conceptual framework of the draft IBD PROs Scale includes 2 domains of “harmonization between soma and spirit” and “correspondence between man and universe”, in which “harmonization between soma and spirit” is composed of two aspects: “soma” and “spirit”. The “soma” aspect, based on the theory of “correlation theory of Zang-fu vicera”, measures the symptoms of visceral systems related to the pathogenesis of IBD. The “spirit” aspect measures the emotion and psychological states of patients with IBD from the perspective of joy, sorrow, sadness, fear and so on. The “correspondence between man and universe” domain measures how disease affect the life, work and interpersonal relationship of IBD patients. The draft scale included 28 items (Table 2). A 5-point Likert scale was used as response options, including “very serious”, “heavy”, “moderate”, “mild” and “not at all”.

**Table 2** Conceptual framework and items of the first draft of the IBD PROs

Domains	Aspects	Items
harmonization between soma and spirit	soma	abdominal pain, diarrhea, abdominal distension, tenesmus (feeling of urgency to defecate, but with incomplete defecation), bloody stool, loss of appetite, nausea and vomiting, weight loss or marasmus, malnutrition, fatigue and tired, palpitations (heartbeat gets louder), decreased sexual function
	spirit	depression, upset, being annoyed, worry about the disease being passed on to future generations, recurrent episodes of the disease, the damage of the disease, food aggravating the condition, developing cancers, having surgery, being satisfied with the effectiveness of treatment
correspondence between man and universe		influence on the relationship with family, friends or colleagues, influence daily life, working capability, social activities, being a burden on others



2.2 Result of item selection The standard deviation of all 28 items were  $> 0.9$ , representing good dispersion tendency. As it is shown in results, the Cronbach's  $\alpha$  coefficient of the "soma" and the "spirit" aspects and the "correspondence between man and universe" domain were 0.92, 0.92 and 0.89 respectively. The Cronbach's  $\alpha$  coefficient of "spirit" aspect increased from 0.91 to 0.93 when item 22 was excluded. Except for the item 22 "Being satisfied with the effectiveness of treatment", the correlation coefficients of items and domains (aspects) scores and total scores were  $>0.50$  ( $P < 0.001$ ). Details of the analysis result for item selection are shown in Table 3. The IBD PROs scale was composed of two domains: "harmonization between soma and spirit" and "correspondence between man and universe". The "soma" aspect of the domain "harmonization between soma and spirit" included 12 items, while the "spirit" aspect included 9. Domain "man's adaptation to his total environment" contained 6 items.

**Table 3** Item selection of the IBD PROs

Domains/Aspects		Score (Mean $\pm$ SD, Points)	Cronbach's $\alpha$ coefficient	r values (items and domains)			
				soma	spirit	correspondence between man and universe	Total scores
soma			0.92				
	1. abdominal pain	3.63 $\pm$ 0.96	0.91	0.71	0.54	0.50	0.66
	2. diarrhea	3.34 $\pm$ 1.23	0.91	0.76	0.61	0.59	0.73
	3. abdominal distension	3.78 $\pm$ 1.03	0.92	0.60	0.50	0.49	0.59
	4. tenesmus	3.50 $\pm$ 1.20	0.91	0.69	0.47	0.48	0.62
	5. bloody stool	3.69 $\pm$ 1.30	0.92	0.68	0.44	0.44	0.60
	6. loss of appetite	3.98 $\pm$ 1.14	0.91	0.79	0.47	0.59	0.69
	7. nausea and vomiting	4.38 $\pm$ 1.01	0.91	0.71	0.44	0.47	0.61
	8. weight loss or marasmus	3.52 $\pm$ 1.34	0.91	0.81	0.56	0.63	0.75
	9. malnutrition	3.46 $\pm$ 1.31	0.91	0.84	0.62	0.66	0.79
	10. fatigue and tired	3.32 $\pm$ 1.20	0.91	0.77	0.55	0.68	0.74
	11. flustered	3.83 $\pm$ 1.13	0.91	0.70	0.53	0.54	0.66
	12. decreased sexual function	3.96 $\pm$ 1.12	0.92	0.65	0.55	0.48	0.63
spirit			0.92				
	13. depression	3.59 $\pm$ 1.13	0.91	0.74	0.80	0.69	0.82
	14. upset	3.56 $\pm$ 1.15	0.91	0.74	0.80	0.74	0.83
	15. annoyed	3.43 $\pm$ 1.15	0.91	0.74	0.80	0.74	0.84
	16. worry about the disease being passed on to future generations	2.94 $\pm$ 1.30	0.92	0.48	0.71	0.50	0.62

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	17. worry about recurrent episodes of the disease	2.08 ± 1.00	0.91	0.48	0.79	0.55	0.66
	18. worry about the damage of the disease	2.16 ± 1.04	0.91	0.52	0.88	0.60	0.73
	19. worry about food aggravating the condition	2.45 ± 1.18	0.91	0.59	0.84	0.58	0.74
	20. worry about developing cancers	2.44 ± 1.16	0.91	0.45	0.78	0.49	0.63
	21. worry about having surgery	2.31 ± 1.18	0.91	0.49	0.83	0.52	0.68
	22. being satisfied with the effectiveness of treatment	3.63 ± 0.95	0.93	0.27	0.44	0.37	0.39
correspondence between man and universe			0.89				
	23. influence relationship with family	3.19 ± 1.10	0.89	0.57	0.55	0.72	0.66
	24. influence your relationship with friends or colleagues	3.40 ± 1.05	0.87	0.59	0.58	0.80	0.69
	25. influence daily life	2.72 ± 1.07	0.87	0.67	0.64	0.83	0.76
	26. influence working capability	2.84 ± 1.17	0.87	0.56	0.63	0.83	0.71
	27. influence social activities	3.14 ± 1.16	0.87	0.59	0.59	0.83	0.71
	28. being a burden on others	3.36 ± 1.25	0.87	0.65	0.66	0.82	0.76

### 3 Discussion

With the rapid development of economy in China, the lifestyle and eating habits of Chinese residents are westernized gradually, and the number of patients with IBD is increasing yearly. As a chronic disease, there is no radical cure for IBD in western medicine. The goal of treatment is to alleviate symptoms, delay the progression of the disease and reduce complications, improve the QoL of patients, and ultimately reduce medical costs<sup>[37]</sup>. Integrated traditional Chinese and western medicine can help to induce deep remission and achieve treat-to-target, which can provide optimized treatments for patients with IBD<sup>[38]</sup>. More and more TCM practitioners have carried out clinical trials of TCM or integrated Chinese and Western medicine in the treatment of IBD. When searching for safe and effective treatments, attention should also be paid to

the loss of QoL caused by IBD at the same time. To develop a suitable QoL measurement instrument based on China's national conditions and the life experience and actual needs of Chinese IBD patients. Although the definition of QoL has never been clearly proposed in TCM, the understanding of health implies the thinking of QoL in TCM. The scale established under the guidance of theories of TCM can better reflect the expectations and habits of the domestic population<sup>[39]</sup>.

The IBD PROs scale was developed based on the theories of TCM. It has the same theoretical basis with the SSDPRO and the MG-PRO, so the conceptual framework is similar. The studies of the SSDPRO and the MG-PRO have confirmed that the scale based on TCM theories can be used to measure QoL of Chinese patients. The IBD PROs includes two domains, “harmonization between soma and spirit” and “correspondence between man and universe”. Domain “harmonization between soma and spirit” is subdivided into two aspects: “soma” and “spirit”, corresponding to physiology and psychology respectively. The conceptual framework of the IBD PROs conforms to the Biopsychosocial model and the WHO’s definition of QoL. In order to ensure the representativity of the included items, the item pool was formed by referring to internationally widely used IBD-specific instruments (including IBDQ-32, the short inflammatory bowel disease questionnaire, the SHS, the RFIPC etc.) and combining the key points of IBD syndrome differentiation. After the discussion and language adjustment by experienced TCM clinical experts of spleen and stomach disease and experts of scale development, a total of 27 items were finally included through pre-testing, integrating dispersion tendency analysis, Cronbach's  $\alpha$  coefficient and correlation coefficient method to ensure the practicability of the items.

The IBD PROs included 27 items, and the number of items was reasonable. All the participants completed the questionnaire within 10 minutes. Moreover, the IBD PROs is guided by the theories of TCM to construct the conceptual framework and included items, with UC and CD patients enrolled. The IBD PROs may be more suitable to be used as an outcome evaluation index for clinical research on IBD treatment with TCM when compared with the IBDQ-22.

The reliability, validity, and responsiveness of the IBD PROs have not been verified, which is the deficiency of this study. Therefore, it is necessary to conduct field investigation and clinical validation with larger sample size to evaluate the measurement performance of the IBD PROs, so as to further improve the IBD PROs. After the performance evaluation is completed, the IBD PROs developed based on the theories of TCM can be used to measure the QoL of patients with IBD in China, and can be used as the clinical effectiveness evaluation of IBD, especially the outcome evaluation index of clinical studies of TCM in the treatment of IBD.

Author Contributions: LUO Jianfeng participated in the design, conduct, statistical analysis and writing of the study. HOU Jiangtao, HOU Zhengkun, PENG Bin, LI Huibiao, LIU Shiyong, and ZHANG Shijing participated in the study design

and survey implementation. HE Zhenfan and ZHONG Jiamin were responsible for data entry and management. LIU Fengbin and CHEN Xinlin proposed the research concept, designed and undertook the project management and supervision, and were responsible for the review and proofreading of the paper. Both of them take overall responsibility for the article

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