Short Health Scale: a Valid and Reliable Quality of Life Scale for Chinese Patients With Inflammatory Bowel Disease

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Research
Abstract

**Background:** The aim of our study was to translate and validate the Chinese version of the Short Health Scale (SHS), a disease-specific quality of life (QoL) scale for the patients with inflammatory bowel disease (IBD).

**Methods:** The SHS was translated and validated according to the standard process: a translation and back-translation procedure, culture adaptation and a validation study. Patients with IBD were enrolled, and their QoL were assessed using the SHS and the short inflammatory bowel disease questionnaire (SIBDQ). Reliability (internal consistency reliability, split-half reliability and test-retest reliability) and validity (content validity, construct validity, criterion validity and discriminant validity) analysis were performed to evaluate the psychometric characteristics of the SHS.

**Results:** A total of 95 patients with IBD (62 ulcerative colitis and 33 Crohn's disease) completed the Chinese version of the SHS, and 40 patients completed the SHS within 1-4 weeks once again. Cronbach's alpha value of the SHS was 0.91, and its split-half coefficient was 0.83. Intraclass correlation coefficients of four items ranged from 0.55 to 0.75. All four items of the SHS were significantly associated with the corresponding domains of the SIBDQ, with correlation coefficients ranging from -0.47 to -0.63 ($P < 0.001$). Exploratory factor analysis showed that the cumulative contribution rate of variance reached 68%, and the factor loading of all the items were greater than 0.8. The scores of four items were significantly different for the patients of different Bristol stool form scale ($P < 0.001$). The scores of function, worry and general well-being were significantly different among the patients with different smoking status ($P < 0.05$).

**Conclusions:** The SHS is a simple and quick scale. The SHS had good validity and reliability, and was suitable to evaluate the QoL of patients with IBD in Chinese.

**Background**

Inflammatory bowel disease (IBD) is a chronic nonspecific bowel disease of unknown etiology, which includes Crohn's disease (CD) and ulcerative colitis (UC). IBD usually occurs in adolescence and young adulthood, and is characterized by prolonged nonunion and remitting-relapsing disease course (1). IBD is a global disease that poses a great challenge to healthcare systems around the world. In accordance with epidemiological data, the incidence of UC in Europe was as high as 24/100,000, and the CD was 11.5/100,000 in 2015 (2). Ng et al. reported that the incidence of IBD has risen rapidly in Eastern countries while plateauing in Western countries (3). In addition, the long-term symptoms caused significant distress, and worsen prognosis. The long-term symptoms and treatments influenced patients’ physiology, emotions, functional status, and social capabilities (4, 5). It suggested that clinicians should pay more attention to the quality of life (QoL).

The health-related quality of life (HRQoL) has been widely used to assess clinical efficacy of the patients with IBD in recent years (6, 7). HRQoL is defined as a broad multidimensional concept, covering questions
related to patient’s perception, experience, daily function and so on (8). A large number of scales were developed and verified to assess the HRQoL for patients with IBD. Fifteen IBD-specific instruments were developed for the patients with IBD (9). The specific instruments mainly contained the IBD Questionnaire (IBDQ) (10), the short inflammatory bowel disease questionnaire (SIBDQ) (11), the Rating Form of IBD Patient Concerns (RFIPC) (12) and the Short Health Scale (SHS) (13). Among them, IBDQ has been widely used for the patients with IBD. The reliability and validity of the Chinese version of IBDQ has been initially validated (14).

The SHS was a rapid, sensitive and specific measurement tool to assess the QoL of patients with IBD in clinical trials and practices (13, 15). The SHS was developed by Dr. Henrik from Switzerland in 2006, (13). It was a self-report tool for IBD using opening-ended questions, so that the patients could consider some aspects important to them in their life. Up to now, The SHS has been translated, validated and used in Sweden (13, 15), Norway (16), Ireland (17), Korea (18) and Netherlands (19). The SHS has been proved to be a rapid, valid, reliable and sensitive instrument with the ability to assess the QoL of patients with IBD in these countries. However, the SHS was not translated into Chinese, and not used in Chinese patients with IBD. Therefore, the purpose of this study was to cross-culturally translate and validate the SHS for Chinese patients with IBD.

Material And Methods

Translation and back-translation procedure

The researcher contacted Dr. Henrik, the original author of the SHS, and developed the Chinese version after obtaining permission of the SHS. The Chinese version of the SHS was translated and back-translated according to the Brislin's guidelines for the translation and back-translation method and the standard process for translating instruments (20, 21). First, two bilingual (Chinese and English) native researchers independently translated the original text into Chinese. The translation coordinator (one of the authors) integrated and debugged the two Chinese translation versions to form the first draft of the Chinese version of the SHS. Then, the first draft of the Chinese version of the SHS was back-translated to English by another two bilingual researchers, who was not involved in the translation section. The back-translation coordinator (one of the authors) integrated and debugged the two English translation versions to form the English back-translated version. Finally, the research team coordinated and discussed the differences between the English back-translated version and the original English-translated version of the questionnaire. After language and cultural adaptation, the Chinese version of SHS was finally formed.

Validation study

The reliability and validity of the SHS were measured using a cross-sectional study method. The patients with IBD were enrolled from the First Affiliated Hospital of Guangzhou University of Traditional Chinese Medicine, the First Affiliated Hospital of Sun Yat-sen University and Shanghai TCM-Integrated Hospital between June 1st and December 1st, 2020. The study was approved by the Ethics Committee of the First
The inclusion criteria were patients aged 16-75 years with a definite diagnosis of IBD. The exclusion criteria were (i) non-IBD patient, (ii) severe cognitive impairment who could not understand the questionnaire and (iii) patients with IBD who refused to participate in the study. Eligible participants completed the questionnaire on their mobile phone or on paper.

The trained researchers explained the purpose of our study to the patients with IBD. After obtaining informed consent of participants, the researchers ask the patients to complete a self-filled case report form (CRF). The CRF contained socio-demographic characteristics, the SHS, and the SIBDQ. The socio-demographic characteristics included age, gender, education, family history, smoking status, drinking history, diagnosis, lesion location and the Bristol stool form scale (BSFS). According to the BSFS, the patients was classified into three groups: hard stools (types 1-2), normal stools (types 3-5) and loose stools (types 6-7) (22). If the patients had any question about the CRF, the researchers would explain the CRF and help to solve the problem. Some participants were also required to complete the SHS again, within one week to four weeks after the first survey.

The SHS

The SHS was a 4-item self-administered questionnaire, which measured the QoL of patients with IBD (13). It consisted of four items: Symptoms, Function, Worry and General well-being. Each item represented a QoL domain. It used open-ended items, which was easily understood by the patients. The items were graded on a 100-mm visual analogue scale (VAS) correlating with score range of 0 to 100. The higher values of VAS indicated worse QoL. The 100-mm VAS was changed into 10-mm VAS (Figure 1). The patients with IBD were asked to mark the position deemed appropriate on the 10 mm visual analogue scale. In addition, patients with IBD were encouraged to reported other concerns, such as high costs for treatment. These concerns, which did not include in the SHS was also recorded. The result was used to evaluate the content validity of the SHS.

The SIBDQ

The SIBDQ was a shortened version of the IBDQ, which was responsive to important changes in disease activity (11). The SIBDQ consisted of ten items, each having seven answer categories (all of the time, most of the time, a good bit of the time, some of the time, a little bit of the time, hardly any of the time, and none of the time). The items were clustered into four domains: symptoms, systematic symptoms, social function and emotional function. The score of the SIBDQ ranged from 10 (worst QoL) to 70 (best QoL). Higher score represented more higher QoL. The SIBDQ was one of the most commonly specific scale for measuring QoL of IBD, which had been translated and verified in German and Canadian patients with IBD (10, 23).

Statistical Methods
All the data was inputted to Microsoft Office Excel 2016 and analyzed by SPSS software (version 25.0) and R software (version 4.0). The normally distributed continuous data were expressed as mean and standard deviation (SD), while the non-normal distribution continuous data were expressed as median and interquartile range (IQR). The categorical variables were presented as percentages (%). The preset p-value for significance was set to 0.05. The correlations between non-normal distribution data were analyzed using Spearman's rank correlation coefficient ($r_s$).

The validity analysis contained criterion validity, construct validity and discriminant validity. The SIBDQ was used as a criterion scale. Criterion validity were assessed using Spearman correlation coefficient between the SHS and the SIBDQ. The construct validity was estimated using exploratory factor analysis (EFA). Discriminant validity was measured by comparing the QoL of the SHS among different demographic characteristics using Wilcoxon test.

Reliability analysis included internal consistency reliability, split-half reliability, and test-retest reliability. Cronbach's α value was used to assess internal consistency reliability. Split-half reliability was assessed by Pearson's correlation coefficients between two halves of the items. Test-retest reliability was evaluated using Spearman rank correlation coefficients ($r_s$) and intra-class correlation coefficient (ICC) between test–retest scores. Test-retest reliability was evaluated using ICC.

**Results**

**Patient characteristics**

A total of 96 patients were enrolled to fill in the CRF. One patient was excluded due to incomplete information, and finally 95 patients were included for analysis (Table 1). Among them, 65.3% of the patients were UC and 34.7% were CD. Sixty-two participants (65.3%) were male, with mean age 38.9 ± 13.8 years. More than half of the patients had normal stools, followed by loose stools and the least was hard stools.
Table 1
Demographic and clinical factors presented with IBD (N = 95) [n (%)].

| Variable                      | n (%)  |
|-------------------------------|--------|
| Gender                        |        |
| Female                        | 33 (34.7) |
| Male                          | 62 (65.3) |
| Age (year) (mean [range]) *   | 39.3 (17–73) |
| Marital status                |        |
| Unmarried                     | 30 (31.6) |
| Married                       | 65 (68.4) |
| Education                     |        |
| Primary                       | 14 (14.7) |
| Secondary                     | 26 (27.4) |
| Tertiary                      | 55 (57.9) |
| Past medical history          |        |
| No                            | 52 (54.7) |
| Yes                           | 43 (45.3) |
| Food allergy history          |        |
| No                            | 87 (91.6) |
| Yes                           | 8 (8.4) |
| Family history                |        |
| No                            | 94 (98.9) |
| Yes                           | 1 (1.1) |
| Drinking history              |        |
| No                            | 73 (76.8) |
| Yes                           | 22 (23.2) |
| Smoking status                |        |
| Non-smoker                    | 59 (62.1) |

* The continuous data were indicated as mean and range.
| Variable                               | n (%) |
|----------------------------------------|-------|
| Ex-smoke                               | 28 (29.5) |
| Smoker                                 | 8 (8.4) |
| Diagnosis                              |       |
| CD                                     | 33 (34.7) |
| UC                                     | 62 (65.3) |
| Disease location of UC                 |       |
| Proctitis                              | 31 (50.0) |
| Left sided                             | 18 (29.0) |
| Pancolitis                             | 13 (21.0) |
| Disease location of CD                 |       |
| Colon                                  | 18 (54.5) |
| Small bowel                            | 7 (21.2) |
| Colon + Small bowel                    | 8 (24.2) |
| BSFS                                   |       |
| Hard (Types 1–2)                       | 3 (3.2) |
| Normal (Types 3–5)                     | 65 (68.4) |
| Loose (Types 6–7)                      | 27 (28.4) |

* The continuous data were indicated as mean and range.

Validity

Content validity was assessed using other concerns reported by the patients with IBD. According to the results, the Chinese version of the SHS almost reflected the actual concerns of Chinese patients with IBD. Twelve Chinese patients with IBD also reported other concerns: (1) A quarter of the patients worried IBD would lead to other diseases affecting their careers and the life after marriage. (2) Besides, one patient was concerned that the symptoms of abdominal pain or increased frequency of defecation would hinder from going out. (3) About half of the patients were afraid that the medicine would cause aggravation or recurrence of IBD and its side effects would lead to low immunity and affect fertility. (4) In addition, some patients wanted to be cured, while another patient concerned about whether he can afford the cost.

Spearman correlation coefficients between the four SHS items and corresponding items from the SIBDQ were calculated (Table 2). Among them, correlation coefficient for SHS General well-being and SIBDQ
Systemic symptoms was the highest ($r_s = -0.63$). The correlation coefficient of symptoms item was slightly lower ($r_s = -0.47$). The total score of the SHS was highly correlated with total score of the SIBDQ ($r_s = -0.68$). All correlation coefficients were significant ($P < 0.001$).

Table 2
Spearman correlation coefficients ($r_s$) between the SHS and the SIBDQ.

| The SHS     | The SIBDQ          | $r_s$ |
|-------------|--------------------|-------|
| Symptoms    | Symptoms           | -0.47 |
| Function    | Social function    | -0.53 |
| Worry       | Emotional function | -0.58 |
| Well-being  | Systemic symptoms  | -0.63 |
| Total SHS   | Total SIBDQ        | -0.68 |

According to the result of EFA, one factor was extracted to evaluate construct validity (Table 3). The Kaiser-Meyer-Olkin test (0.76) and Bartlett ball test were performed. The approximate Chi-square value was 238, with $P < 0.001$. The cumulative variance contribution rate was 68%. The loading factor of all the items were greater than 0.7 (Table 3).

Table 3
The result of exploratory factor analysis for the SHS.

| Factor loading | |
|----------------|-------------------------|
| Symptoms       | 0.77                    |
| Function       | 0.87                    |
| Worry          | 0.77                    |
| Well-being     | 0.87                    |

Reliability

To evaluate the reliability, Cronbach's alpha and ICC were conducted. Cronbach's alpha for the SHS was 0.91, and half-split coefficient for the SHS was 0.83. A total of 40 IBD patients (16 CD and 24 UC) completed the SHS again. Test-retest reliability was evaluated using Spearman correlation coefficients ($r_s$) and ICC between test–retest scores (Table 4). ICC was between 0.55 and 0.75. Spearman correlation coefficients ranged from 0.59 to 0.79, with all coefficient's significance ($P < 0.001$). Among them, worry item had the highest correlation coefficient (0.75).
Table 4
Test-retest reliability for 40 IBD patients (16 CD and 24 UC)

|               | Visit 1      | Visit 2      | rs    | P-value | ICC  |
|---------------|--------------|--------------|-------|---------|------|
| Symptoms      | 22.2 (11.1–44.4) | 33.3 (11.1–44.4) | 0.73  | < 0.001 | 0.72 |
| Function      | 22.2 (11.1–44.4) | 22.2 (11.1–47.2) | 0.59  | < 0.001 | 0.55 |
| Worry         | 44.4 (22.2–77.8) | 38.9 (22.2–69.4) | 0.79  | < 0.001 | 0.75 |
| Well-being    | 33.3 (22.2–47.2) | 33.3 (22.2–58.33) | 0.64  | < 0.001 | 0.58 |

SHS scores were performed as medians and IQR (25th-75th percentiles).

Discriminant

Table 5 showed the score of patients with different demographic characteristics and P-value. The scores of four items were significantly different for the patients of different BSFS ($P < 0.001$). The QoL scores of patients with loose stools (Types 6–7) was the highest in four items of the SHS. The scores of functions, worry, well-being items were not significantly different for the patients of different smoking status ($P < 0.05$). There was no significant difference in the scores for the patients of different genders or different diseases (between UC and CD).
Table 5
The score of patients with different demographic characteristics.

| Variable       | Symptoms | Function | Worry      | Well-being |
|----------------|----------|----------|------------|------------|
| Gender         |          |          |            |            |
| Male           | 22.2 (11.1–52.8) | 22.2 (11.1–55.6) | 44.4 (22.2–77.8) | 38.9 (22.2–55.6) |
| Female         | 22.2 (11.1–44.4)  | 22.2 (11.1–44.4)  | 44.4 (22.2–77.8) | 44.4 (22.2–44.4) |
| P-value        | 0.324     | 0.455    | 0.780      | 0.755      |
| Smoking status |          |          |            |            |
| Non-smoker     | 22.2 (11.1–38.9) | 22.2 (11.1–44.4) | 44.4 (22.2–77.8) | 33.3 (22.2–55.6) |
| Ex-smoker      | 22.2 (11.1–69.4) | 22.2 (11.1–61.1) | 44.4 (22.2–69.4) | 33.3 (22.2–44.4) |
| Smoker         | 44.4 (38.9–55.6) | 44.4 (41.7–66.7) | 77.8 (77.8–80.6) | 72.2 (52.8–77.8) |
| P-value        | 0.072     | 0.020    | 0.016      | 0.006      |
| Diagnosis      |          |          |            |            |
| UC             | 22.2 (11.1–44.4) | 27.8 (11.1–52.8) | 44.4 (22.2–77.8) | 38.9 (22.2–55.6) |
| CD             | 22.2 (11.1–44.4) | 22.2 (11.1–44.4) | 44.4 (22.2–77.8) | 44.4 (22.2–55.6) |
| P-value        | 0.797     | 0.357    | 0.531      | 0.997      |
| BSFS           |          |          |            |            |
| Hard (Types 1–2) | 11.1 (5.6–16.7) | 22.2 (11.1–22.2) | 66.7 (38.9–72.2) | 44.4 (22.2–55.6) |
| Normal (Types 3–5) | 22.2 (11.1–33.3) | 22.2 (11.1–33.3) | 33.3 (11.1–55.6) | 33.3 (11.1–44.4) |
| Loose (Types 6–7)| 44.4 (33.3–66.7) | 55.6 (22.2–77.8) | 77.8 (44.4–100.0) | 55.6 (44.4–72.2) |
| P-value        | < 0.001   | < 0.001  | < 0.001    | < 0.001    |

The QoL scores were presented as medians and IQR (25th-75th percentiles). Comparisons were analyzed using Wilcoxon test or Kruskal-Wallis test.

**Discussion**
This is the first study to test and validate the validity and reliability of the SHS for the Chinese patients. The purpose was to provide effective, valid and reliable tools for Chinese patients with IBD.

The SHS is a simple and quick scale for Chinese patients with IBD, which has good operability and acceptability. We changed the visual analogue scale from 10 mm to 0 mm which make it easier for patients to select their own score. The patients with IBD were asked to mark the appropriate position on the 10mm visual analogue scale. The response rate of the scale was 99.0% (95/96). It indicated that the SHS was easy to understand. Moreover, most patients quickly completed the Chinese version of SHS within 1 minute during the investigation. Likewise, the results were consistent with those in other countries (6, 17–19). Accordingly, the SHS is a feasible tool to use for Chinese patients and clinicians.

The Chinese version of the SHS has good content validity. The WHOQOL consisted of six aspects: physical, psychological, independence, social, environment, and spiritual domains (24). According to the results of a review, all the published fifteen IBD-specific scales contained four domains: IBD-related symptoms, physical functioning, emotional functioning and social functioning (9). The structure of the SHS was composed of symptoms, function, worry and general well-being, which was the same as other IBD-specific scales. The items of the SHS reflected the living conditions or concerns of Chinese patients with IBD. In addition, some patients were also worried about the price of drugs, adverse events and exacerbation.

The Chinese version of the SHS had good criterion validity and construct validity. Criteria validity of the SHS was assessed using correlation coefficients between the SHS domains and the corresponding SIBDQ domains. Criteria validity of most items were greater than 0.5, except the symptom item. The symptom item had slightly lower correlation with the corresponding item of the SIBDQ (0.47). The results were consistent with a study using the SIBDQ as the criterion in Dutch-speaking patients, which scores ranged from 0.403 to 0.828 (19). McDermott et al. translated the SHS into Ireland for English-speaking patients. They used the IBDQ as the criterion, and they reported the correlation coefficients of all SHS items ranged from 0.662 to 0.737.

The correlation coefficients of their study were higher than ours (17). The reason may be related to the selection of different criteria scales.

The internal consistency reliability and split-half reliability of Chinese version of the SHS were good. Cronbach's alpha value above 0.70 was considered satisfactory (25). Cronbach's alpha of the Chinese version of the SHS was 0.91 (P< 0.001), and it was higher than that of the Norwegian version (0.85) (16). Split-half correlation coefficients of the Chinese version of the SHS was 0.83, which indicated high internal consistencies between the halves. Overall, both the internal consistency reliability and split-half reliability of the Chinese version of the SHS was high.

Test-retest reliability was evaluated using Spearman correlation coefficients (r_s) and ICC between test–retest scores. Spearman correlation coefficients of the SHS ranged from 0.59 to 0.79, with all coefficient's significance. Our result showed that ICC of the SHS was between 0.55 and 0.75. The ICC values of
symptoms and worries items were both greater than 0.7, which was acceptable for test-retest reliability (26). The ICC values of function and well-being were moderate. Our results were better than the Norwegian version of the SHS where ICC ranged from 0.26 to 0.75 (16). Some items of the Chinese version of the SHS had low ICC values, which might be related to the long test–retest period (one to four weeks). The research had pointed out that the test–retest interval was 1 or 2 weeks would be appropriate (26).

In addition, our study showed significant differences in the scores of four items among patients with different stool categories. The SHS could distinguish patients with hard stools, normal stools and loose stools. Likewise, there were significant differences in the scores of functions, worry, well-being items among patients with different smoking status ($P < 0.05$). The SHS could distinguish patients with different smoking status. The similar finding was obtained with other two studies (27, 28).

There were some limitations for this research. (1) The sample size of the study was small. the data of patients with IBD should be collected from wider areas in further studies. (2) In addition, only 40 patients completed the SHS a second time. More patients with IBD should be enrolled to further assess test-retest reliability of the SHS.

**Conclusions**

The SHS is a simple and quick scale for Chinese patients with IBD in clinical research and clinical practice. This study confirmed that the Chinese version of SHS had good validity and reliability, and was suitable to evaluate the QoL of patients with IBD in Chinese.

**Abbreviations**

BSFS: Bristol stool form scal

CD: Crohn's disease

CRF: case report form

EFA: exploratory factor analysis

HRQoL: health-related quality of life

IBD: inflammatory bowel disease

IBDQ: inflammatory bowel disease Questionnaire

ICC: intra-class correlation coefficient

IQR: inter-quartile range
Declarations

Ethics approval and consent to participate

This study was conducted under the Declaration of Helsinki and was approved by the Ethics Committee of the First Affiliated Hospital of Guangzhou University of Traditional Chinese Medicine (Batch number: NO.ZYYECK[2019]160). Written informed consent was obtained from all enrolled patients.

Consent for publication

All of the authors listed have seen the contents of the manuscript and agree with the submission.

Availability of data and materials

Xin-lin Chen and Bin Peng had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare no competing interests.

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**Contributions**

XLC, JTH and BP were involved in construct definition, the validation study and data analysis. BP and SJZ wrote the manuscript. YX Land JZC involved data analysis. YMC and YW were involved in language testing, content validity. JFL, XMZ and SMP were involved in item generation and collected the data. SYL and HM modified the manuscript. XLC and BC designed the study. All authors read and approved the final manuscript.

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Figures

1. How severe are the symptoms you suffer from your bowel disease?

   No symptoms 0—10 Very severe symptoms

2. Do your bowel problems interfere with your activities in daily life?

   Not at all 0—10 Interfere to a very high degree

3. How much worry does your bowel disease cause?

   No worry 0—10 Constant worry

4. How is your general feeling of well-being?

   Very good 0—10 Dreadful

WAS=10mm

Figure 1

The SHS was a 4-item self-administered questionnaire, which measured the QoL of patients with IBD