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Development of a Burden Scale for Colonoscopy Experienced by Patients with Inflammatory Bowel Disease

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Keywords
Colonoscopy · Crohn's disease · Inflammatory bowel disease · Burden · Scale development · Ulcerative colitis

Abstract
Introduction: This study aimed to develop and validate a burden scale for colonoscopy-specific experiences among patients with inflammatory bowel disease (IBD) and to assess its reliability and validity. ***Methods:*** Building upon previous research on patient experiences and perceptions of colonoscopy, a 33-item pain scale was developed. Content validity was assessed to refine the questionnaire. An online survey was conducted through an IBD patient community. The reliability of the scale was evaluated using Cronbach's α coefficient and test-retest reliability. Validity was examined through factor analysis to assess construct validity and correlation coefficients with external criteria for criterion-related validity. ***Results:*** Of the 371 distributed questionnaires, 176 were returned, and data from 173 participants were included in the analysis. Item analysis and exploratory factor analysis yielded a 21-item scale with four distinct factors: pain during colonoscopy, burden with bowel preparation, anxiety and symptoms after colonoscopy, and difficulty in taking time off to receive colonoscopy. The scale demonstrated strong internal consistency (Cronbach's α = 0.875) and test-retest reliability (intraclass correlation coefficient = 0.879). Criterion-related validity was supported by correlations with external measures, including the cognitive appraisal rating scale (r = 0.615), anxiety related to colonoscopy (r = 0.582), pain during colonoscopy (r = 0.544), and satisfaction with colonoscopy (r = −0.333). ***Conclusion:*** The newly developed burden scale for colonoscopy in patients with IBD demonstrated robust reliability and validity, indicating its potential utility as a clinical instrument for assessing the burden in this patient population.

Introduction

Inflammatory bowel disease (IBD) is a chronic autoimmune disease characterized by inflammation of the gastrointestinal tract, primarily encompassing ulcerative colitis and Crohn's disease. The incidence of IBD has risen dramatically in Japan, with an estimated prevalence per 100,000 individuals, increasing from 0.08 in 1965 to 4.8 in 2000 for ulcerative colitis and from 0.003 in 1965 to 1.3 in 2000 for Crohn's disease [1].

Colonoscopy remains the gold standard for diagnosing IBD, monitoring disease activity, and assessing treatment efficacy because it allows for direct and accurate visualization of intestinal inflammation [2]. The incidence of

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colorectal cancer associated with IBD has also risen, particularly among patients with long-term disease [3], underscoring the critical role of colonoscopy in early cancer detection and prognosis improvement.

Despite its diagnostic value, colonoscopy is associated with significant patient discomfort due to its invasive nature, including the bowel preparation process. Patients with IBD are required to undergo frequent colonoscopies to assess disease progression, treatment effectiveness, and cancer surveillance. Many patients report that repeated colonoscopies are burdensome, interfere with daily life, and serve as a constant reminder of their chronic condition [4]. Commonly reported experiences during colonoscopy include "physical and mental burden of bowel preparation," "pain during colonoscopy," "fear of colonoscopy," "discomfort with opposite-gender healthcare providers," "fatigue and disease aggravation after colonoscopy," "anxiety about test results," and "the burden of time and cost" [5]. Therefore, healthcare professionals must recognize that patient discomfort during colonoscopy extends beyond physical pain to include psychological distress and social burdens, such as disruption of daily life and financial costs.

Previous studies have quantitatively assessed the degree of pain experienced by patients with IBD during colonoscopy using visual analog scales (VASs) [6, 7]. However, a VAS primarily evaluates singular aspects, such as pain or discomfort, without capturing the multidimensional nature of the patient's experience during the colonoscopy process. A comprehensive measurement of the physical, psychological, and social pain or discomfort encountered by patients with IBD during colonoscopy would allow healthcare professionals to implement more targeted care strategies aimed at alleviating the specific burdens experienced by individual patients.

Therefore, this study aimed to develop a burden scale to assess the physical, psychological, and social discomfort experienced by patients with IBD during colonoscopy and to evaluate the scale's reliability and validity. For the purposes of this study, the burden associated with colonoscopy is defined as the physical, psychological, and social discomfort experienced by the patient from the time of appointment scheduling to the receipt of colonoscopy results from a gastroenterologist.

Methods

The scale was developed using a cross-sectional research design comprising two phases: (1) item generation and (2) reliability and validity testing. The study procedure is illustrated in Figure 1.

Phase 1: Item Generation

The development of items was informed by findings from previous studies addressing the experiences and perceptions of patients with IBD undergoing colonoscopy [4, 5, 8, 9]. Specifically, the burden associated with colonoscopy in patients with IBD (BSC-IBD) was conceptualized across the following six domains: physical and mental burden related to bowel preparation, burden of time and cost, pain and fear during colonoscopy, perplexity in the relationship with healthcare professionals, fatigue and disease aggravation after colonoscopy, and anxiety regarding investigation results and the future. The preliminary draft scale consisted of 43 items.

Content validity of the 43 items was assessed by two groups: 6 adult patients with IBD who had undergone at least one colonoscopy within the past 5 years, and six nurses with a minimum of 3 years of colonoscopy nursing experience. Both groups were asked to match each item with one of the six domains and rate its relevance using a 4-point Likert scale (1 = not relevant to 4 = very relevant) [10]. Additionally, participants were invited to provide qualitative feedback on item revision and overall scale enhancement. The content validity index (CVI) was calculated for each item (I-CVI) as well as for the entire scale (S-CVI). The I-CVI represented the proportion of participants who rated an item as 3 (quite relevant) or 4 (very relevant). Items with an I-CVI exceeding 0.78 for I-CVI and an S-CVI exceeding 0.90 were retained [11]. Consequently, 11 items with an I-CVI below 0.78 were excluded, resulting in a revised scale of 32 items, with an S-CVI average of 0.94.

The qualitative responses regarding item revisions were reviewed by researchers following two primary criteria for item selection: (1) content validity, assessing whether the item appropriately reflected the burden associated with colonoscopy in patients with IBD, and (2) general applicability, evaluating whether the item could be broadly applied to patients with IBD who had undergone colonoscopy. Based on this feedback, one additional item, "I am afraid I will wake up if the sedative effect wears off during colonoscopy," was incorporated. The final draft of the scale consisted of 33 items distributed across six domains: physical and mental burden related to bowel preparation, burden of time and cost, pain and fear during colonoscopy, perplexity in the relationship with healthcare professionals, fatigue and disease aggravation after colonoscopy, and anxiety regarding investigation results and the future.

Phase 2: Reliability and Validity Testing

Participants and Procedure

Participants were included in the study if they met all of the following inclusion criteria: (1) adults enrolled in the G community, an online platform for patients with

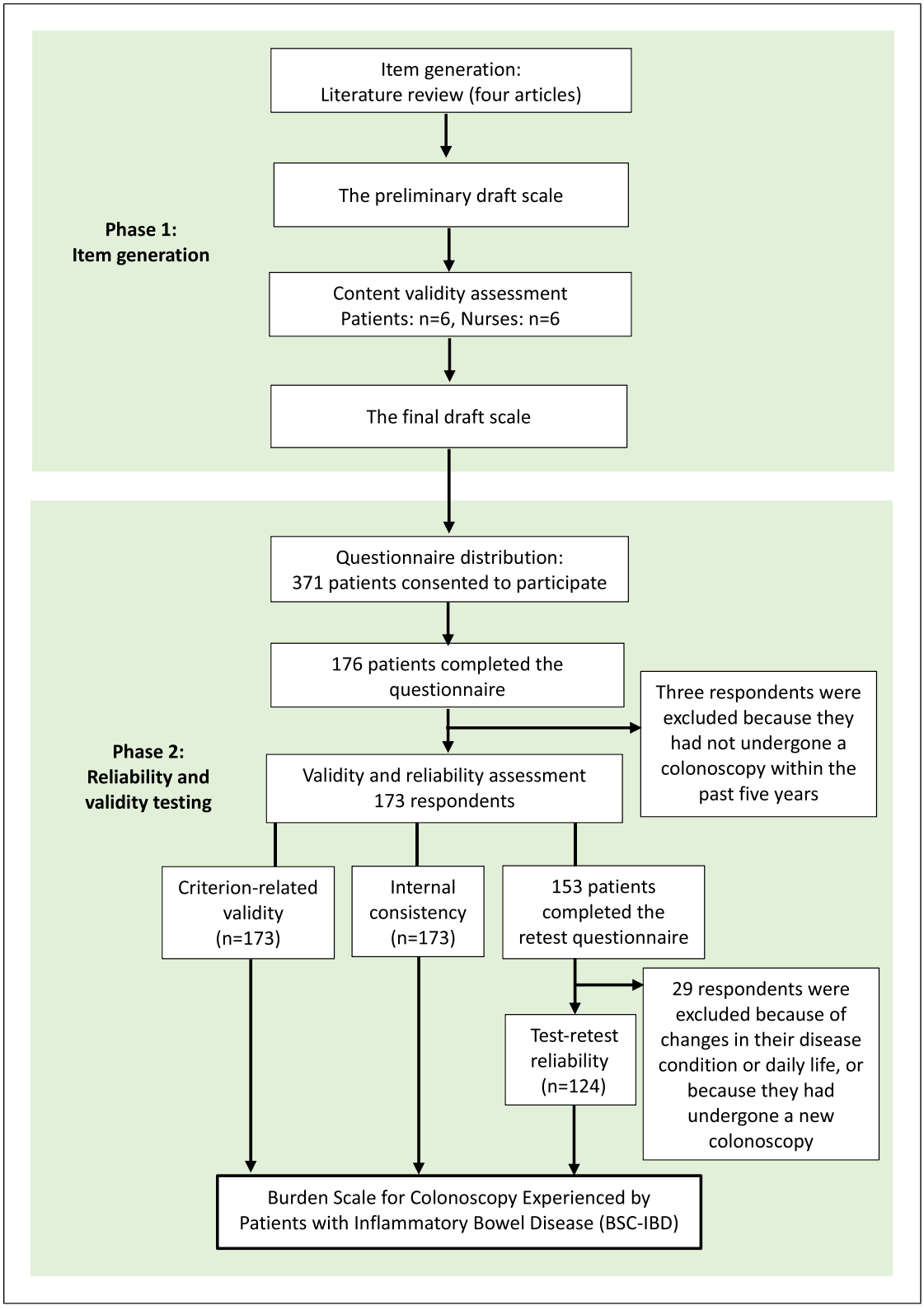


Fig. 1. Summary of study flow.

IBD; (2) individuals diagnosed with IBD, either Crohn's disease or ulcerative colitis, who had undergone colonoscopy more than once in the previous 5 years; (3) individuals with sufficient proficiency in the Japanese language to comprehend the questionnaire; and (4) individuals who provided informed consent via an online confirmation form. In scale development, it is recommended that the sample size be seven times the number of scale items [12]. Because the draft scale comprised 33 items, we aimed to recruit a minimum of 231 participants.

To minimize bias related to the colonoscopy methods used at specific medical institutions, the survey was conducted through the G community to gather responses from a broad range of patients, irrespective of the institution where they received their colonoscopy. The G community is a closed online forum consisting of patients with IBD, their family members, and healthcare professionals. As of 2023, it is the one of the largest domestic online communities for intractable diseases, with over 2,000 registered members. To recruit participants, we requested the G community manager to include a link to the study explanation document and the informed consent confirmation form in the biweekly newsletter distributed to community members. The first author then sent the questionnaire via email to individuals who had completed the consent form. The questionnaire was administered using Google Forms (Google LLC, Mountain View, CA, USA), and a retest survey form was sent 4 weeks after the initial test to the same email addresses. Data collection took place between April 2024 and May 2024.

Measures

Participant characteristics assessed included age, sex, diagnosis, disease duration, number of prior colonoscopies, history of abdominal surgery, presence of intestinal complications, use of sedative and/or painkillers during the most recent colonoscopy, and employment status. To measure the burden experienced during colonoscopy among patients with IBD, we employed a draft version of the BSC-IBD, consisting of 33 items. The scale used a 6-point Likert scale ranging from 1 (not applicable at all) to 6 (very much applicable), with participants rating their experiences during their most recent colonoscopy.

The criterion-related validity of the BSC-IBD was assessed using the cognitive appraisal rating scale (CARS) [13], developed and validated by Suzuki and Sakano [13], which evaluates an individual's cognitive appraisal of stressful situations. The CARS consists of 10 items divided into four subscales: commitment, appraisal of effect, appraisal of threat, and controllability. Higher scores reflect a higher cognitive appraisal of the stressor. The CARS has demonstrated stability in factor structure across various ages and stress situations. In this study, the stressor was defined as the participants' most recent colonoscopy. Permission to use the CARS was obtained from the original authors. Additionally, we used the VAS to further assess the criterion-related validity of the scale. Participants were asked to rate their anxiety, pain, and satisfaction with colonoscopy using a numerical scale ranging from 0 to 100. These items were adapted from a previous study [14]. In the retest phase, we collected data on changes in disease status, daily life, or the most recent colonoscopy to assess for any changes in participant characteristics since the initial survey.

Statistical Analysis

Item Analysis

Descriptive statistics for each item of the BSC-IBD were calculated. The exclusion criteria for item removal were defined as follows: (1) any item exhibiting skewness and/or kurtosis exceeding ±1.5 or demonstrating significant ceiling or floor effects, (2) an item with a correlation coefficient between item scores of >0.8, and (3) an item with an item-total correlation coefficient of >0.8 or <0.3.

Validity Assessment

Exploratory factor analysis (EFA) was performed to evaluate the structural validity of the BSC-IBD. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy (MSA >0.5) and Bartlett's test of sphericity ($p < 0.05$) were applied to verify the appropriateness of the EFA. Maximum likelihood estimation with promax rotation was utilized. The number of factors was determined based on the scree plot and eigenvalues of ≥1.0. Items with factor loadings exceeding 0.40 and loading exclusively on a single factor were retained. Criterion-related validity of the BSC-IBD was assessed by comparing it to the total CARS score, as well as VAS scores for anxiety, pain, and satisfaction with colonoscopy, using Pearson's correlation coefficient.

Reliability Assessment

The internal consistency of the scale was evaluated by calculating Cronbach's alpha coefficient, with values exceeding 0.7 considered acceptable [15, 16]. To assess interrater reliability and the stability of scale ratings, the test-retest method was employed. Test-retest reliability was determined using intraclass correlation coefficients (ICCs), with an ICC of ≥0.5 regarded as acceptable [17].

Demographic Characteristics Related to Scale Scores

After completion of data normality tests using the Shapiro-Wilk test, demographic characteristics such as sex and diagnosis related to the BSC-IBD scores were assessed using *t* tests. All statistical analyses were performed using SPSS version 29.0 (IBM SPSS Statistics for Windows, Armonk, NY, USA), and statistical significance was set at $\alpha = 0.05$.

Results

Demographic Characteristics of the Respondents

The demographic characteristics of the 173 respondents are shown in Table 1. Of the respondents, 62.4% ($n = 108$) were women, 30.1% ($n = 52$) were between the ages of 30 and 39 years, and 63.0% ($n = 109$) had been diagnosed with ulcerative colitis. Additionally, 69.9% ($n = 121$) had undergone colonoscopy more than five times.

Item Analysis

The results of the item analysis are shown in Table 2 and Figure 2. Four items (Nos. 9, 17, 25, and 27) exhibited a skewness and/or kurtosis exceeding ±1.5, as well as a ceiling effect. Four items (Nos. 2, 5, 21, and 29) showed an item-total correlation coefficient of <0.3. Based on these findings, eight items were excluded from further analysis, leaving 25 items for subsequent evaluation.

Assessment of the Scale's Validity

EFA was performed on 25 items to assess the scale's validity. The overall MSA from the KMO test was 0.84, indicating a suitable level for factor analysis. Bartlett's test of sphericity was statistically significant ($\chi^2 = 1{,}819.37$, df = 300, $p < 0.001$), confirming the adequacy of the correlation matrix for factor analysis. Based on the scree plot and eigenvalues criteria, four factors were identified. Items with factor loadings of >0.40 and contributing to only one factor were retained, leading to the exclusion of four items and the selection of 21 items. The results of the EFA are shown in Table 3.

Factor 1 consisted of six items related to "pain and fear during colonoscopy" and "perplexity in the relationship with healthcare professionals," focusing on physical pain and the perceived lack of understanding from healthcare professionals. This factor was labeled "pain during colonoscopy." Factor 2 comprised five items addressing the "physical and mental burden related to bowel preparation," focusing on both physical and psychological discomfort experienced during the preparation process. This factor was named "burden with bowel preparation." Factor 3 included seven items derived from "pain and fear during colonoscopy," "fatigue and disease aggravation after colonoscopy," and "anxiety regarding investigation results and the future." It was characterized by anxiety and concerns related to the colonoscopy procedure and post-procedural symptoms, leading to its designation as "anxiety and symptoms after colonoscopy." Finally, factor 4, composed of three items related to the "burden of time and cost," focused on social challenges such as difficulties in taking time off from work for the procedure and inconveniencing colleagues or family members. This factor was labeled "difficulty in taking time off to receive colonoscopy." A question list of the BSC-IBD is shown in Figure 3.

Table 4 presents the correlation coefficients used to assess criterion-related validity. The factor scores of the BSC-IBD exhibited significant positive correlations with the CARS. The total and factor scores of the BSC-IBD also showed significant positive correlations with the VAS for anxiety regarding colonoscopy. Additionally, all factors except factor 4 showed significant positive correlations with the VAS for pain associated with colonoscopy, while all factors except factor 4 showed significant negative correlations with the VAS for satisfaction with the colonoscopy experience.

Assessment of the Scale's Reliability

The reliability of the BSC-IBD was assessed using Cronbach's alpha and ICC values, as shown in Table 4. The Cronbach's alpha coefficients for the total score and the four factors of the BSC-IBD were 0.875, 0.811, 0.835, 0.750, and 0.841, respectively, indicating good internal consistency. The ICC values for the test-retest reliability of the total and factor scores ranged from 0.821 to 0.879, demonstrating strong test-retest reliability across all factors.

Demographic Characteristics Related to the Scale Scores

The respondents' demographic characteristics and corresponding BSC-IBD scores are summarized in Figure 4. The total BSC-IBD scores, as well as the scores for factor 3 ("anxiety and symptoms after colonoscopy") and factor 4 ("difficulty in taking time off to receive colonoscopy"), were significantly higher among respondents without than with a history of abdominal surgery ($p = 0.042$, 0.020, and 0.008, respectively). The scores for factor 1 ("pain during colonoscopy") were significantly higher among respondents who had undergone more than five prior colonoscopies than in those who had undergone four or fewer ($p = 0.009$). Similarly, the scores for factor 2 ("burden with bowel preparation") and factor 4 were significantly higher among respondents aged <40 than ≥40 years ($p = 0.047$ and 0.026, respectively). Respondents who used sedatives and/or

Table 1. Demographic characteristics of the respondents (n = 173)

Characteristic	*n*	%
Age		
20–29 years	34	19.7
30–39 years	52	30.1
40–49 years	44	25.4
50–59 years	29	16.8
>60 years	14	8.0
Sex		
Women	108	62.4
Men	64	37.0
Other	1	0.6
Diagnosis		
Crohn's disease	64	37.0
Ulcerative colitis	109	63.0
Disease duration		
<5 years	60	34.7
5–9 years	54	31.2
10–19 years	31	17.9
>20 years	28	16.2
Previous abdominal surgery	53	30.6
Intestinal complications	44	25.4
Previous colonoscopies		
1–2	16	9.2
3–4	36	20.7
>5	121	69.9
Sedative and/or painkiller use in most recent colonoscopy	130	75.1
Employment status		
Regular employee	105	60.7
Part-time employee	21	12.1
Self-employed	6	3.5
Student	9	5.2
Unemployed at present	32	18.5

painkillers during their most recent colonoscopy had significantly higher factor 3 scores than patients who did not ($p < 0.001$).

Discussion

Validity of the Scale

The construct validity of the BSC-IBD was evaluated through EFA, which revealed a four-factor structure. Although the initial draft included six subscales, several items were consolidated based on thematic overlap. Specifically, items related to "physical and mental burden related to bowel preparation" were grouped into the "burden with bowel preparation" factor; items pertaining to "burden of time and cost" were combined into the "difficulty in taking time off to receive colonoscopy" factor; items regarding "pain and fear during colonoscopy" and "perplexity in the relationship with healthcare professionals" were merged into the "pain during colonoscopy" factor; and items related to "pain and fear during colonoscopy," "fatigue and disease aggravation after colonoscopy," and "anxiety regarding investigation results and the future" were grouped into "anxiety and symptoms after colonoscopy."

In this study, 75% of participants reported the use of sedatives and/or painkillers during colonoscopy, a significantly higher proportion than the 25% sedative use rate among the general population [18]. These findings suggest that the utilization of sedatives and/or painkillers during colonoscopy is substantially higher in patients with than without IBD. Despite this high rate of sedative and painkiller usage, previous studies have reported that patients with IBD experience more intense pain during colonoscopy than those without IBD [8, 19]. Patients with

Table 2. Results of item analysis (n = 173)

Select item	Item number	Mean	SD	Distortion	Kurtosis	Ceiling effect	Floor effect	I-T CC
✓	1	4.2	1.5	−0.3	−1.1	5.7	2.7	0.516
	2	5.0	1.6	−1.4	0.6	6.6	3.4	0.202
✓	3	4.7	1.3	−1.1	0.7	6.0	3.4	0.618
✓	4	4.5	1.5	−0.8	−0.3	5.9	3.0	0.558
	5	4.7	1.2	−0.7	0.0	5.8	3.5	0.183
✓	6	4.0	1.4	−0.2	−0.8	5.4	2.6	0.583
✓	7	3.9	1.5	−0.3	−0.9	5.4	2.3	0.408
✓	8	4.1	1.4	−0.5	−0.6	5.4	2.7	0.485
	9	5.1	1.3	−1.5	1.6	6.3	3.8	0.571
✓	10	3.0	1.6	0.4	−1.0	4.6	1.3	0.329
✓	11	4.1	1.6	−0.3	−1.0	5.7	2.5	0.620
✓	12	4.6	1.5	−0.8	−0.4	6.0	3.1	0.508
✓	13	4.7	1.4	−0.8	−0.3	6.1	3.2	0.554
✓	14	4.8	1.3	−1.0	0.3	6.1	3.5	0.618
✓	15	4.2	1.4	−0.7	−0.3	5.6	2.7	0.402
✓	16	3.4	1.8	0.2	−1.3	5.1	1.6	0.439
	17	5.3	1.0	−1.5	2.6	6.3	4.3	0.654
✓	18	2.9	1.4	0.4	−0.6	4.4	1.5	0.478
✓	19	4.5	1.6	−0.7	−0.6	6.0	2.9	0.623
✓	20	4.3	1.4	−0.5	−0.6	5.7	2.9	0.411
	21[a]	2.5	1.1	0.9	1.1	3.6	1.4	0.016
✓	22	4.9	1.1	−1.0	0.8	5.9	3.7	0.401
✓	23	3.6	1.5	0.0	−1.1	5.1	2.1	0.611
✓	24	3.8	1.4	−0.1	−0.9	5.2	2.4	0.619
	25	5.2	1.1	−1.6	2.8	6.3	4.0	0.584
✓	26	4.5	1.4	−0.7	−0.2	5.8	3.1	0.498
	27	5.2	0.9	−1.3	2.5	6.1	4.3	0.428
✓	28	4.1	1.6	−0.4	−1.0	5.7	2.6	0.479
	29[a]	1.7	0.9	1.5	2.9	2.6	0.8	−0.069
✓	30	4.5	1.4	−0.8	−0.2	5.9	3.1	0.688
✓	31	3.3	1.5	0.3	−0.9	4.8	1.7	0.445
✓	32	3.9	1.4	−0.2	−0.8	5.3	2.5	0.553
✓	33	4.9	1.2	−1.3	1.4	6.1	3.7	0.549

SD, standard deviation; I-T CC, item-total correlation coefficient. [a]Reversal item.

IBD, particularly those with intestinal inflammation or complications, such as anal stenosis, fistula, or adhesions, experience a considerable amount of physical pain during the procedure [5]. These findings are likely related to factor 1 of the BSC-IBD, "pain during colonoscopy." Additionally, this factor includes an item indicating that patients feel that their pain is not adequately recognized by healthcare professionals, even when they explicitly

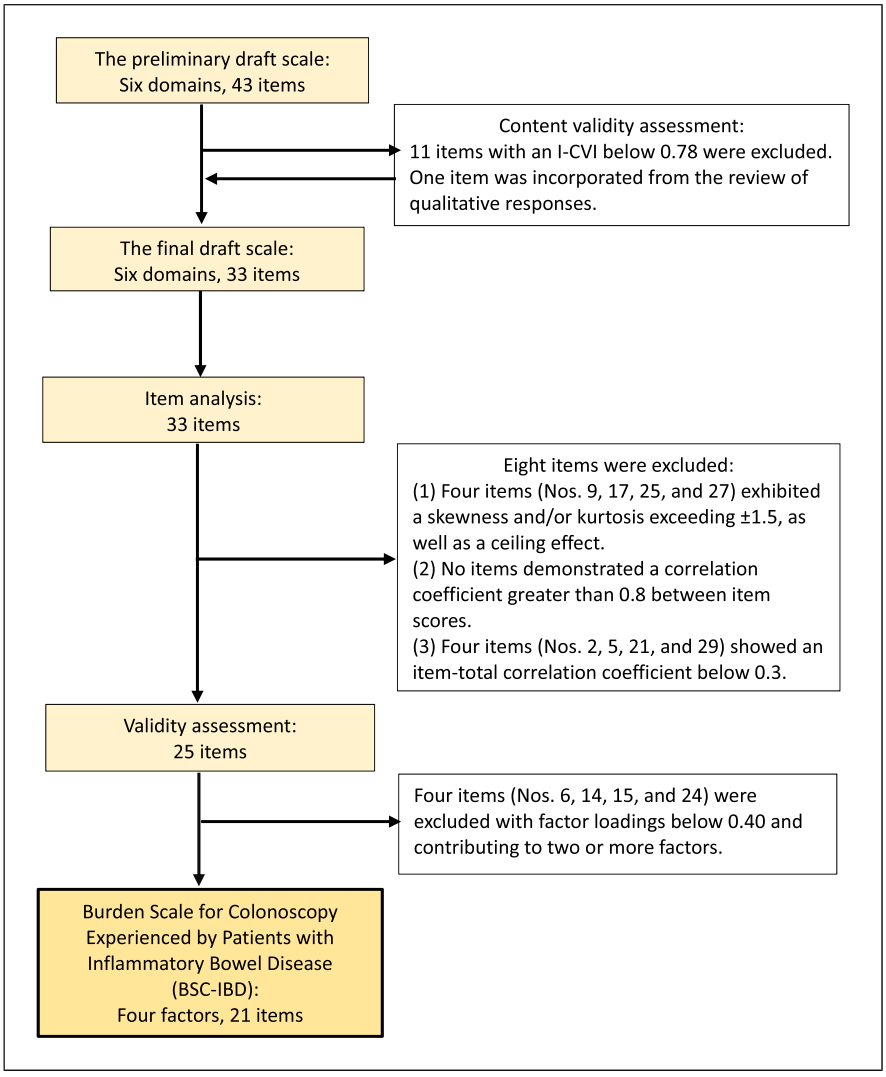


Fig. 2. Chart of scale item selection. I-CVI, item-level content validity index.

express it. This suggests that the pain experienced by patients with IBD during colonoscopy may encompass both physical and psychological dimensions, exacerbated by a perceived lack of empathy or understanding from healthcare professionals.

Factor 2, "burden with bowel preparation," addresses the challenges patients face during bowel preparation. Previous studies have demonstrated that bowel preparation, particularly the ingestion of laxatives, is often regarded as the most burdensome aspect of the colonoscopy procedure [20, 21]. Patients with IBD report a significantly greater burden during this phase compared with other patient groups [8]. Denters et al. [8] suggested that because of the chronic nature of their condition, patients with IBD are more accustomed to undergoing frequent bowel preparations, which contributes to their increased sense of burden. In our study, 90% of participants reported having undergone more than three colonoscopies, further underscoring the repetitive nature of the burden they experience during bowel preparation. Additionally, patients with IBD often experience symptoms such as abdominal pain, diarrhea, anal discomfort, and bowel urgency prior to bowel preparation because of intestinal inflammation, which may exacerbate the discomfort and pain caused by laxative ingestion. Moreover, bowel incontinence and urgency are frequently reported as symptoms that patients with IBD feel embarrassed to discuss with healthcare professionals. Among these, bowel incontinence is the most commonly cited, followed by bowel urgency and a sense of incomplete evacuation [22]. Despite their concerns about bowel urgency or incontinence during bowel preparation, patients with

Table 3. Factor loadings in the exploratory factor analysis (EFA) (n = 173)

Items	Factor loading				h^2
	F1	F2	F3	F4	
Factor 1: pain during colonoscopy					
12. I have pain when the colonoscope reaches flexion of the large intestine	**0.958**	−0.024	−0.255	0.094	0.757
11. I feel fear of the pain during colonoscopy before receiving it	**0.716**	−0.060	0.214	−0.045	0.645
13. I have abdominal tension and pain from the air supply	**0.675**	0.103	−0.038	0.019	0.505
28. I have pain because it is hard to insert a colonoscope at the time of bowel inflammation	**0.582**	0.019	0.134	−0.145	0.415
18. I am not understood by healthcare professionals even if I appeal for my pain during colonoscopy	**0.451**	−0.002	0.123	0.061	0.293
10. I have pain at the time of inserting the colonoscope due to anal fistula, stenosis, and adhesion	**0.426**	−0.073	0.090	−0.049	0.192
Factor 2: burden with bowel preparation					
19. It is hard to take the laxative, and I seem to become ill-conditioned	−0.052	**0.927**	−0.030	−0.100	0.739
1. It is hard for me to take the laxative orally because it tastes bad	−0.074	**0.852**	−0.106	−0.014	0.596
3. I am worn out by frequent evacuation when I take the laxative	0.026	**0.654**	−0.024	0.110	0.492
30. I experience abdominal pain, diarrhea, anal ache, and bowel urgency when taking the laxative	0.174	**0.480**	0.196	−0.039	0.481
4. I worry about bowel incontinence on the way to the hospital or during colonoscopy	0.157	**0.450**	−0.004	0.161	0.377
Factor 3: anxiety and symptoms after colonoscopy					
33. I am afraid when pain has been experienced during colonoscopy once	0.079	−0.009	**0.673**	−0.087	0.469
32. I worry about bleeding or perforation caused by colonoscopy	−0.009	−0.058	**0.635**	0.141	0.440
20. I am afraid of cancer being detected by colonoscopy	0.004	−0.039	**0.540**	−0.060	0.256
22. I worry about future treatment following colonoscopy	0.014	−0.090	**0.522**	0.098	0.279
26. I feel residual sleepiness or tiredness after colonoscopy	−0.172	0.292	**0.442**	0.040	0.344
16. I am afraid I will wake up if the sedative effect wears off during colonoscopy	0.055	−0.055	**0.428**	0.054	0.204
23. I experience symptoms such as abdominal pain, bleeding, or diarrhea after colonoscopy	0.155	0.130	**0.411**	−0.036	0.330
Factor 4: difficulty in taking time off to receive colonoscopy					
31. It is hard for me to take time off to receive a colonoscopy	0.072	−0.037	−0.069	**0.874**	0.731
7. I trouble my co-workers or family members when I take time off to receive colonoscopy	−0.123	−0.027	0.125	**0.791**	0.654
8. It is difficult for me to adjust my schedule for receiving colonoscopy	0.003	0.099	0.041	**0.705**	0.586
Cumulative contribution ratio, %	26.443	35.175	41.341	46.591	
Factor correlations					
F2	0.436				
F3	0.493	0.510			
F4	0.217	0.369	0.356		

Factor loadings of ≥0.4 are shown in bold. Calculations were performed using the maximum likelihood method and promax rotation. F1, factor 1; F2, factor 2; F3, factor 3; F4, factor 4; h^2, commonality.

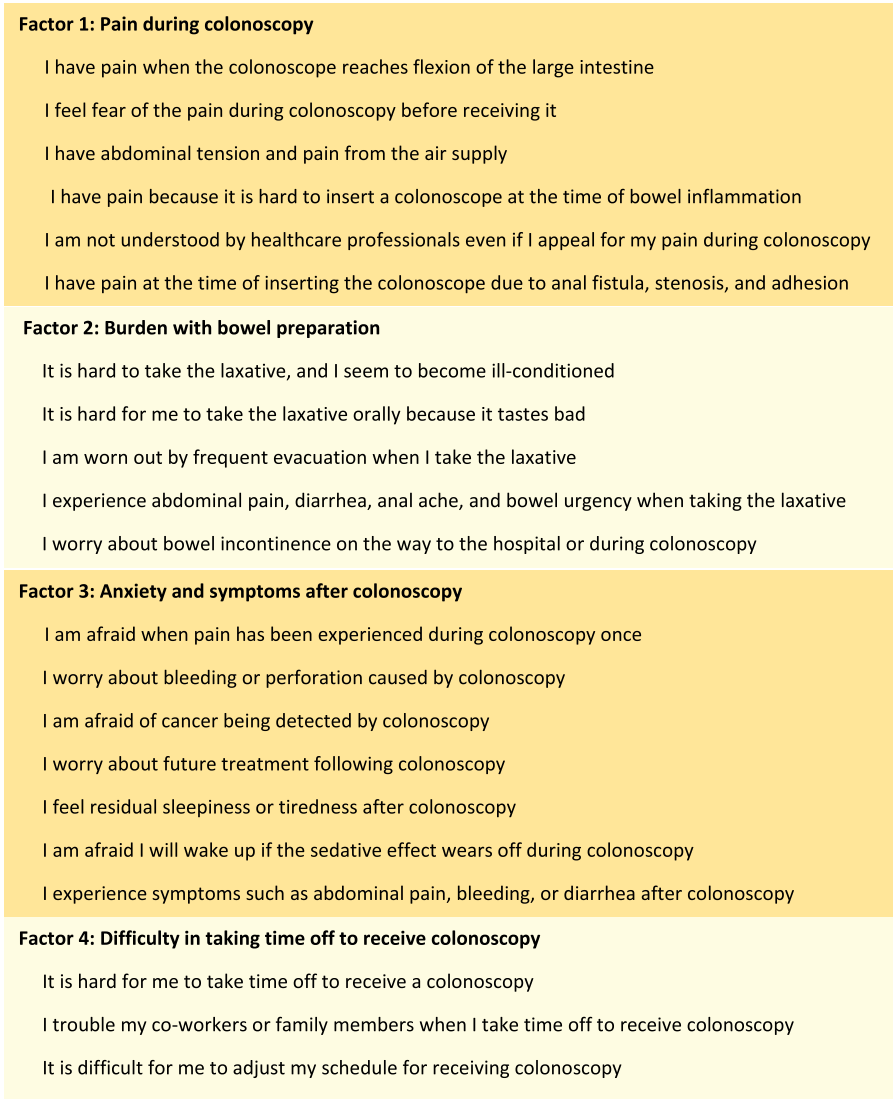


Fig. 3. Question list of burden scale for colonoscopy in patients with inflammatory bowel disease (BSC-IBD).

IBD may avoid seeking advice from healthcare professionals due to feelings of shame. Factor 2 of the BSC-IBD includes these types of symptoms, highlighting the psychological burden associated with hesitation to seek medical consultation for such distressing issues.

Patients with IBD are at increased risk of complications such as bleeding and perforation during colonoscopy, particularly when the disease is active because of the weakened mucosa of the large intestine. Additionally, the cumulative risk of colorectal cancer among Asian patients with IBD has been reported as 0.02% at 10 years, 4.81% at 20 years, and 13.91% at 30 years [23]. Therefore, patients with IBD may experience heightened anxiety related to both the potential complications associated with colonoscopy and their long-term risk of colorectal cancer. This anxiety corresponds to factor 3 of the BSC-IBD, "anxiety and symptoms after colonoscopy." Moreover, the use of sedatives among patients with IBD is higher than that in the general population, which may contribute to a higher incidence of post-colonoscopy symptoms such as drowsiness and fatigue, based on the result that the factor 3 score was significantly higher for respondents who did than did not use sedatives.

In this study, 76% of participants were employed, a rate consistent with findings from previous research [24]. Advances in medical treatments, including the use of molecularly targeted therapies, have enabled many patients with IBD to achieve remission and maintain employment. However, data from the Intractable Disease Consultation Support Center show that patients with IBD account for the largest proportion of consultations from

Table 4. Estimation of the reliability and criterion-related validity coefficients

BSD-IBD	α	Test-retest ICC (95% CI)	Criterion scales			
			cognitive appraisal rating scale	VAS of anxiety with colonoscopy	VAS of pain with colonoscopy	VAS of satisfaction in colonoscopy
n	173	124	173	173	173	173
Total score	0.875	0.879 (0.832–0.913)	0.615**	0.582**	0.544**	−0.333**
Factor 1	0.811	0.821 (0.754–0.871)	0.441**	0.493**	0.669**	−0.359**
Factor 2	0.835	0.832 (0.768–0.879)	0.449**	0.309**	0.303**	−0.231**
Factor 3	0.750	0.854 (0.798–0.895)	0.523**	0.589**	0.370**	−0.253**
Factor 4	0.841	0.825 (0.760–0.874)	0.365**	0.238**	0.142	−0.062

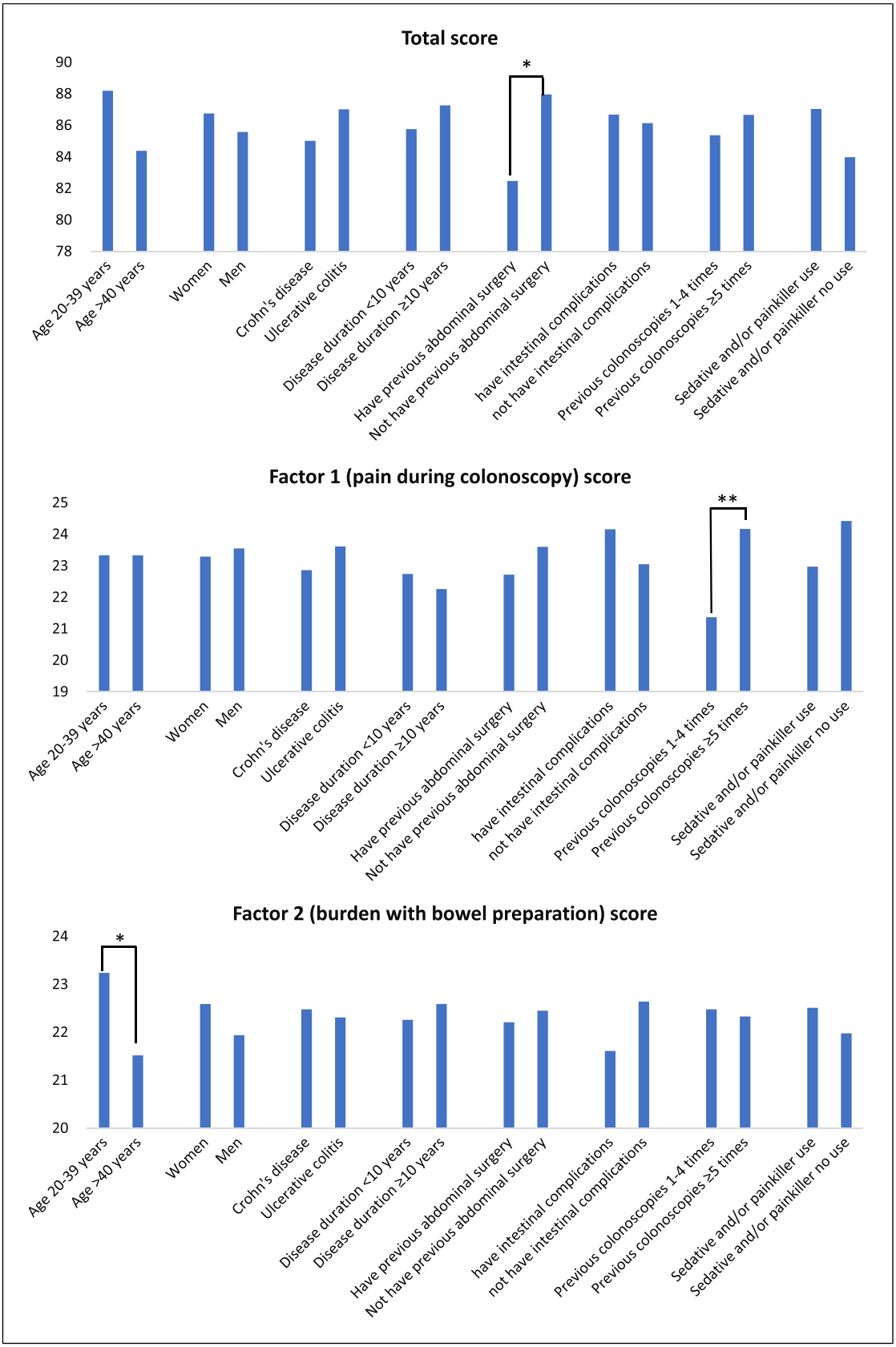
Factor 1, pain during colonoscopy; factor 2, burden with bowel preparation; factor 3, anxiety and symptoms after colonoscopy; factor 4, difficulty in taking time off to receive colonoscopy. BSD-IBD, burden scale with colonoscopy experienced by patients with inflammatory bowel disease; ICC, intraclass correlation coefficient; CI, confidence interval; VAS, visual analog scale. $^{**}p < 0.01$.

patients with intractable diseases, with 30%–40% of these consultations focusing on issues related to employment [25]. These findings suggest that despite being in remission, many patients with IBD face significant challenges in balancing their treatment needs with work obligations. This difficulty aligns with factor 4 of the BSC-IBD, "difficulty in taking time off to receive colonoscopy." Patients may experience challenges in adjusting their schedules for colonoscopy appointments and feel concerned about burdening colleagues or family members.

The burden factor structure identified in this study is considered appropriate for capturing the burden experienced by patients with IBD during colonoscopy. It encompasses the entire process, from scheduling the appointment to receiving the results, and addresses physical, psychological, and social discomfort, reflecting the unique characteristics of IBD.

Demographic Characteristics Related to the Scale Scores

The demographic factors associated with the scale scores were previous abdominal surgery, prior colonoscopies, age, and use of sedatives and/or painkillers. While abdominal surgery can lead to adhesion formation, which increases the difficulty of colonoscopy insertion and amplifies pain due to mesenteric stretching [26], this study showed no significant association between the score for factor 1 ("pain during colonoscopy") and previous abdominal surgery. Interestingly, the total BSC-IBD score was significantly higher among respondents without a history of abdominal surgery. Thus, patients who have undergone abdominal surgery might perceive colonoscopy as less burdensome when compared with the risks and challenges of surgery. Regarding prior colonoscopies, earlier studies on patients without IBD reported mixed results, with some showing no influence on patient comfort [27] and others noting greater fear and anxiety in first-time than experienced patients [28]. In this study, however, respondents who had undergone more than five colonoscopies reported significantly higher factor 1 scores than those with fewer procedures. Therefore, repeated colonoscopies might be perceived as a cumulative and potentially traumatic burden for some patients, as reflected in the scale item: "I feel fear of the pain during colonoscopy before receiving it." For age, previous research on patients without IBD indicated that younger age is associated with a higher risk of discomfort or pain during colonoscopy [27, 29]. In this study, however, factor 1 scores were not associated with age. Instead, younger respondents reported significantly higher scores for factor 4 ("difficulty in taking time off to receive colonoscopy"). Younger patients with IBD might feel a greater social or professional burden, such as concerns about inconveniencing colleagues or family members when scheduling colonoscopy appointments.



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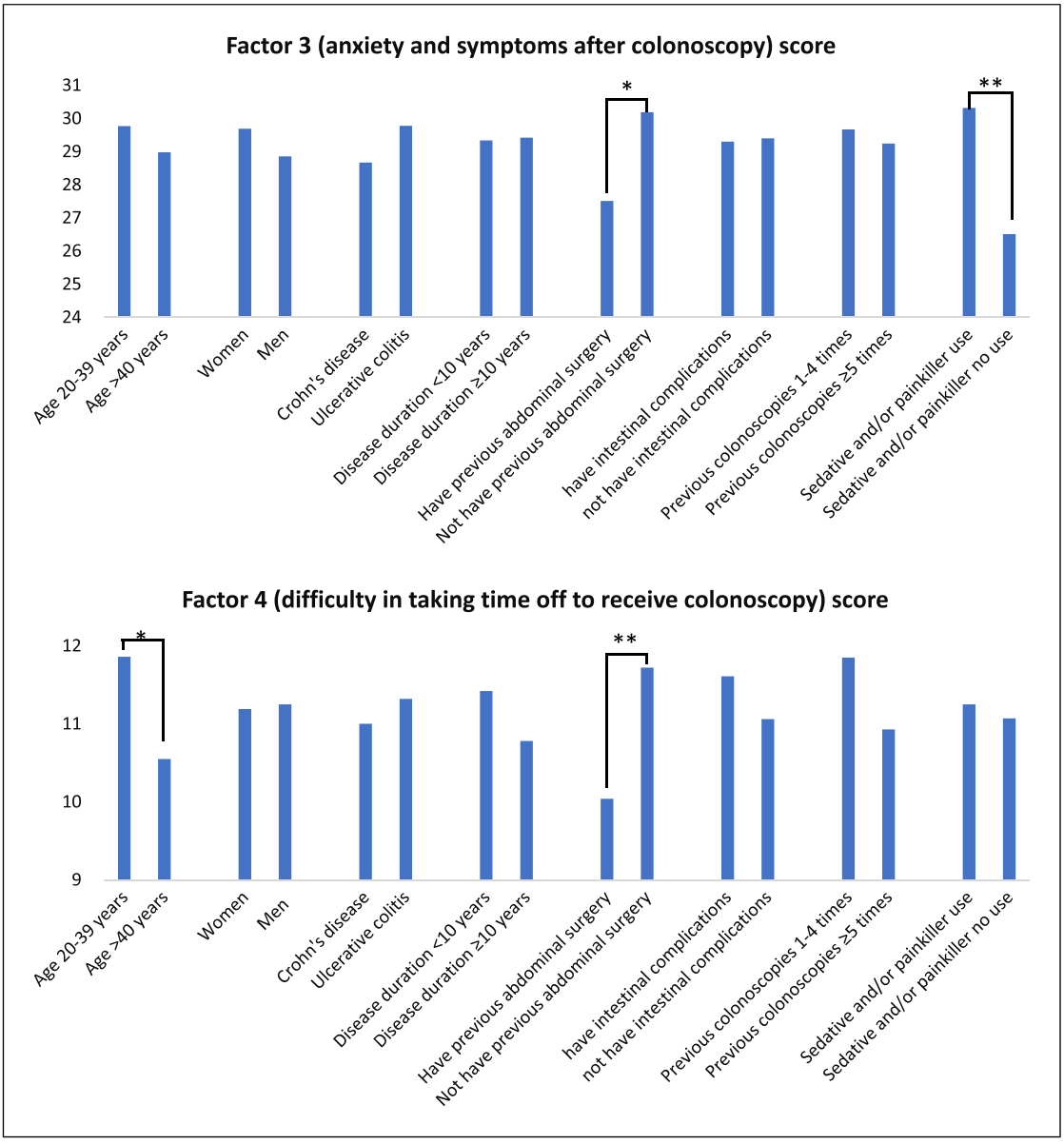

Fig. 4. Demographic characteristics related to the scale scores (n = 173). Demographic characteristics related to the scale scores were assessed by using t test. *$p < 0.05$; **$p < 0.01$.

Possible Utility in Clinical Practice

The BSC-IBD scale demonstrates potential clinical utility for assessing the pain experienced by patients with IBD during colonoscopy. Healthcare professionals, particularly nurses, can utilize the results obtained from this scale before colonoscopy to gain insight into patients' recent colonoscopy experiences and explore strategies to minimize discomfort. Additionally, post-colonoscopy results can guide nurses in evaluating their practices and making adjustments to improve patient care for future procedures. For example, before colonoscopy, patients scoring high on factor 2 ("burden with bowel preparation") may benefit from a collaborative evaluation of their bowel preparation regimen. Involving both the patient and the gastroenterologist in this process can help identify more suitable options. Similarly, after colonoscopy, patients scoring high on factor 1 ("pain during colonoscopy") may benefit from discussions with healthcare providers about the techniques and approaches used during colonoscopy. This feedback can help reduce their pain in the next colonoscopy.

Limitations and Future Directions

This study has some limitations that should be acknowledged. First, although the KMO MSA supports the appropriateness of the sample for this study, the overall sample size was relatively small. Second, while the EFA confirmed the construct validity of the scale, a confirmatory factor analysis with a larger sample size is necessary to further validate the scale and its factor structure. Finally, further research is needed to identify factors beyond patient characteristics that may influence the scale scores, such as those related to healthcare professionals or endoscopic procedures.

Conclusion

To meet the need for a reliable tool to assess the burden experienced by patients with IBD during colonoscopy, we developed the BSC-IBD and evaluated its psychometric properties. Our findings indicate that the BSC-IBD captures the physical, psychological, and social dimensions of the burden associated with colonoscopy and is a stable, reliable measure. The BSC-IBD holds promise for use in research to further explore its validity and to investigate its relationship with clinical outcomes. Additionally, healthcare providers can employ the scale to assess patients' burden during colonoscopy and implement interventions aimed at reducing discomfort, thereby improving the overall patient experience.

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Statement of Ethics

This study protocol was reviewed and approved by the Ethics Committee of Mukogawa Women's University (Approval No. 23-65). All participants were informed about the study's purpose and methods, the voluntary nature of participation, and assurances of privacy and anonymity via an online document. Consent for participation and publication was obtained from all participants through an online form.

Conflict of Interest Statement

M.N. received lecture fees from Takeda Pharmaceutical and Mitsubishi Tanabe Pharma, as well as consulting fees from Takeda Pharmaceutical. M.T. received lecture fees from Mitsubishi Tanabe Pharma. T.M. received event cooperation fees from Takeda Pharmaceutical and is the president of GoodTe Co. This study was conducted independently by T.M., and GoodTe Co. was not involved in the study's execution, analysis, or reporting.

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Author Contributions

All authors contributed to the conception and design of this study. M.N. performed the statistical analysis and drafted the manuscript. M.T. contributed to the development of the scale draft and reviewed the manuscript. T.M. conducted the survey and reviewed the manuscript. All authors read and approved the final manuscript.

Data Availability Statement

The data supporting the findings of this study are not publicly available because of Ethics Committee formalities but are available from the corresponding author (M.N.) upon reasonable request.

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