



# Development and Assessment of a Novel Ulcerative Colitis-Specific Quality of Life Questionnaire: A Prospective, Multi-Institutional Study

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**Purpose:** Interest in the quality of life (QoL) of patients with inflammatory bowel disease (IBD) has recently increased. Although measurement tools have been devised for IBD in general, there is no specific tool for measuring the QoL of patients with ulcerative colitis (UC). Therefore, we developed a QoL questionnaire specifically for patients with UC.

**Materials and Methods:** The Korean Ulcerative Colitis-Specific Questionnaire (K-UCSQ) was developed through item generation, raw-scale construction, focus group meetings, and multi-center field tests. Two hundred patients with UC were recruited for a field test of the K-UCSQ, and subsequent responses to the Inflammatory Bowel Disease Questionnaire (IBDQ) were also obtained. After performing factor analyses to ensure construct validity, the K-UCSQ was finalized as a four-domain, 28-item questionnaire. Subsequent analyses evaluated the reliability of the K-UCSQ in terms of Cronbach's alpha, concurrent validity in comparison with the pre-established IBDQ, and predictive validity of the area under the ROC curve (AUC) for clinically relevant QoL outcomes.

**Results:** A Cronbach's alpha of 0.94 showed excellent reliability. Furthermore, correlation analyses demonstrated the concurrent validity of the K-UCSQ in comparison with the IBDQ. The K-UCSQ also showed high validity in predicting the perceived overall health (AUC of 0.812 vs. 0.797 using the IBDQ) and past 2-week QoL (AUC of 0.864 vs. 0.859 using the IBDQ).

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**Conclusion:** The newly developed K-UCSQ is concise, bathroom problem-emphasizing, and UC-specific, suggesting that it could be a valid and reliable UC-specific instrument for QoL measurement.

**Key Words:** Ulcerative colitis, quality of life, questionnaire

## INTRODUCTION

Inflammatory bowel disease (IBD) is characterized by chronic inflammation of the gastrointestinal tract. The two major types of IBD are ulcerative colitis (UC) and Crohn’s disease (CD).<sup>1</sup> UC is characterized by continuous inflammation of the gastrointestinal tract from the rectum to the colon and is associated with symptoms such as mucoid stool, bloody stool, diarrhea, and urgency, whereas CD is commonly characterized by skipped inflammation anywhere from the mouth to the anal canal.<sup>2</sup> Inflammation in UC is confined to the mucosa, whereas that of CD is transmural and more often associated with symptoms such as abdominal pain, cramping, and weight loss.<sup>2</sup> Therefore, the two diseases differ in terms of symptoms and impact on quality of life (QoL).

Patients with IBD experience recurrent exacerbation and improvement of symptoms throughout their lives and require various medications for the induction and maintenance of disease remission.<sup>3</sup> Recently, the International Organization for the Study of IBD updated the therapeutic goals for treat-to-target strategies in IBD, emphasizing symptomatic remission, laboratory remission, endoscopic remission, and normalized QoL.<sup>4</sup> QoL and disability were designated as long-term targets for the first time in this statement, demonstrating that improving the QoL of patients with IBD is of paramount importance.<sup>5-7</sup>

The 32-item Inflammatory Bowel Disease Questionnaire (IBDQ-32) is the most frequently used tool in clinical trials for measurement of QoL in patients with IBD.<sup>8</sup> This questionnaire was developed in 1989, and the items were categorized into four domains: 1) bowel symptoms, 2) systemic symptoms, 3) emotional function, and 4) social function.<sup>9</sup> Previous studies have demonstrated that IBDQ is a reliable, valid, and responsive tool for patients with IBD.<sup>10</sup> Nevertheless, CD and UC are different disease entities and have distinct symptoms; and until now, no specific questionnaire has been developed to measure the QoL of patients with UC. Therefore, we aimed to develop a novel QoL questionnaire specifically for patients with UC and evaluate its reliability and validity.

## MATERIALS AND METHODS

### Devising the items of the Korean Ulcerative Colitis-Specific Questionnaire (K-UCSQ)

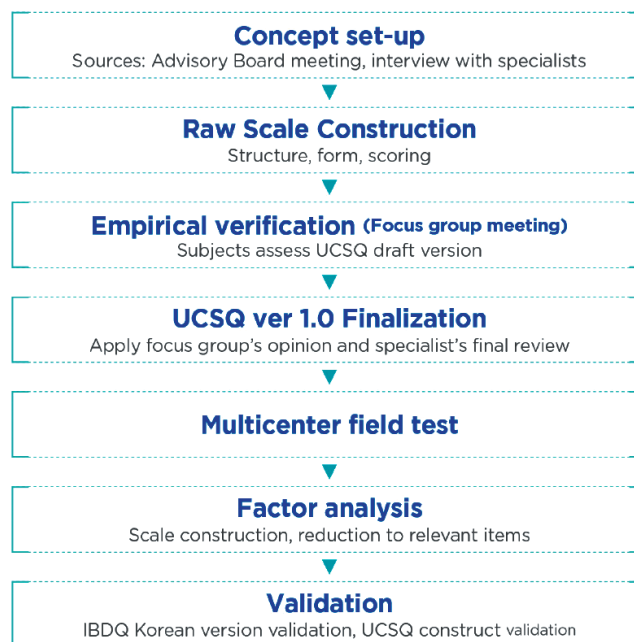
To meet the needs of a questionnaire specific to patients with

UC, the K-UCSQ was developed through procedures that included item generation and reduction, raw scale construction, focus group meetings for empirical verification, and multicenter field tests for initial validation (Fig. 1).

More specifically, advisory board (AB) meetings were held among seven members (six gastroenterology department professors and one biostatistician), and the initial items were generated through a review of existing questionnaires and expert opinions pertaining to the underlying concepts of UC signs and symptoms, systemic symptoms, coping with UC, personal and social daily life impact, and emotional impact (Supplementary Material, only online). This was followed by item reduction through in-depth interviews with two gastroenterologists. Only a Korean version of the questionnaire has been developed to date.

### Devising the draft version of the K-UCSQ (ver. 1.0)

Crude domain composition and Likert-scale construction were performed by the AB biostatistician to prepare for pilot testing, and empirical verification was conducted via a focus group meeting with four UC patients. The patients completed the pi-



**Fig. 1.** Flowchart depicting the development process of the Korean Ulcerative Colitis-Specific Questionnaire. IBDQ, Inflammatory Bowel Disease Questionnaire; UCSQ, Ulcerative Colitis-Specific Questionnaire.

**Table 1.** Demographic and Disease-Related Characteristics of Patients with UC Enrolled in the Development of the Korean Ulcerative Colitis-Specific Questionnaire (n=200)

Variables	Value
Hospitals from where patients were enrolled	
Asan Medical Center	35 (17.5)
Kangbuk Samsung Medical Center	35 (17.5)
Samsung Medical Center	35 (17.5)
Seoul National University Hospital	35 (17.5)
Severance Hospital	60 (30.0)
Age at study enrollment, yr	43.7±13.1
Sex	
Male	123 (61.5)
Female	77 (38.5)
Marital status	
Married	123 (61.5)
Unmarried	77 (38.5)
Smoking status	
Never	138 (69.0)
Former/past	39 (19.5)
Current (within last 6 months)	22 (11.0)
Missing	1 (0.5)
Alcohol consumption	
None	119 (59.5)
3 drinks or less per week	56 (28.0)
4–14 drinks per week	16 (8.0)
15 or more drinks per week	9 (4.5)
Work or school participation	
Yes	139 (69.5)
No	61 (30.5)
UC duration in years	6.7±5.4
UC severity	
Remission	114 (57.0)
Mild	67 (33.5)
Moderate	17 (8.5)
Severe	2 (1.0)

UC, ulcerative colitis.

Data are presented as mean±standard deviation or n (%).

lot test and gave their personal opinions regarding the items answered. Using the focus group meeting results and expert opinions from a second AB meeting, the draft version of the K-UCSQ (ver. 1.0) was developed (Fig. 1).

### Enrollment of UC patients for preliminary validation of the K-UCSQ ver. 1.0

A total of 200 patients with UC were recruited from five major university hospitals in Korea in a competitive enrollment process (Table 1) to participate in a field test of the K-UCSQ ver. 1.0. These patients were instructed to concurrently complete the pre-existing Korean version of the IBDQ<sup>9,11</sup> for additional validation. The disease severity of the patients was assessed

using the Mayo scoring system.

The Inclusion criteria for patients with UC were as follows: 1) patients of either sex aged ≥19 years who had already been diagnosed with UC at the time of enrollment; 2) patients who thoroughly understood the purpose and related procedures of the current study and voluntarily agreed to participate; and 3) individuals who were able to read, comprehend, and complete the K-UCSQ and IBDQ.

Informed consent was obtained from all of the enrolled patients, and a detailed participation manual was distributed, which included the purpose and duration of the study, voluntary participation/withdrawal, and strict confidentiality agreements. The study protocol was approved by the Institutional Review Boards of the Yonsei University Health System (No. 2-2018-0300), Seoul National University Health System (No. H-1812-043-993), Samsung Medical Center (No. SMC 2018-09-104), Kangbuk Samsung Medical Center (No. KBSMC 2018-09-039), Asan Medical Center (No. 2018-1137), and the Korea University Health System (No. 2018AN0360). All of the procedures performed in this study were in accordance with the tenets of the Declaration of Helsinki.

### Development of the current version of the K-UCSQ (ver. 1.1)

A field test of the K-UCSQ ver. 1.0 was conducted among the enrolled patients with UC (n=200). The enrollment target of 60 patients from Severance Hospital and 35 each from the remaining four university hospitals were met. Based on the field test results, items that did not contribute to the main domains identified by factor analysis (Table 2) were removed from the questionnaire. After a third AB meeting, the K-UCSQ ver. 1.1 was finalized as having four domains and 28 items.

The newly developed K-UCSQ ver. 1.1 is a 28-item questionnaire specific to the health-related QoL of patients with UC. Each item is scored on a five-point Likert scale, with a higher score corresponding to a better medical and/or psychosocial outcome. The overall score ranges from a minimum of 28 to a maximum of 140. The questionnaire can be divided into four conceptual domains: 1) bowel symptoms (items 1–5); 2) lavatory (items 6–10); 3) functional symptoms (items 11–17); and 4) impact on life (items 18 to 28), which emphasize the patient’s routine physical, emotional, and social encounters.

### Statistical analysis

#### Descriptive statistics

Mean and standard deviation values were used for continuous variables, such as age at study enrollment and UC duration (Table 1),<sup>12</sup> while frequencies and percentages were used for other categorical variables. Nonparametric measures, such as the Spearman rank-correlation coefficient, were used for the K-UCSQ or IBDQ item-score comparisons in total and by domains. The enrollment sample size of 200 was based on the ra-

**Table 2.** Factor Analysis (Construct Validity) of the K-UCSQ Draft Version 1.0

K-UCSQ draft version 1.0 <sup>†</sup>	Rotated factor pattern with promax rotation <sup>‡</sup>			
	Bowel symptoms (factor 1)	Lavatory (factor 2)	Functional symptoms (factor 3)	Impact on daily life (factor 4)
Q1	<b>43*</b>	8	-1	8
Q2	<b>50*</b>	26	5	5
Q3	37	-1	-22	<b>59*</b>
Q4	<b>62*</b>	0	12	-6
Q5	<b>62*</b>	8	16	-14
Q6	31	-11	16	<b>45*</b>
Q7	23	3	34	13
Q8	<b>43*</b>	7	-6	26
Q9	31	-4	<b>51*</b>	5
Q10	4	12	<b>47*</b>	-5
Q11	-6	5	<b>48*</b>	6
Q12	6	16	<b>69*</b>	-25
Q13	22	<b>65*</b>	5	14
Q14	12	<b>81*</b>	-5	5
Q15	13	<b>82*</b>	2	1
Q16	26	<b>67*</b>	3	5
Q17	0	<b>87*</b>	0	3
Q18	8	-8	<b>75*</b>	10
Q19	8	-15	<b>73*</b>	25
Q20	4	<b>47*</b>	31	7
Q21	-11	39	24	11
Q22	2	22	<b>47*</b>	26
Q23	15	36	19	38
Q24	7	25	25	<b>43*</b>
Q25	-33	26	19	<b>55*</b>
Q26	<b>-42*</b>	25	2	<b>61*</b>
Q27	-17	0	30	<b>67*</b>
Q28	29	23	-12	<b>56*</b>
Q29	27	5	-6	<b>69*</b>
Q30	12	-2	1	<b>65*</b>
Q31	16	1	10	<b>49*</b>
Q32	31	1	-1	<b>54*</b>

K-UCSQ, Korean Ulcerative Colitis-Specific Questionnaire.

<sup>†</sup>The K-UCSQ draft version 1.0 consists of 32 questions, from which four factors (domains) were derived via factor analysis, and 28 questions most relevant to the four factors (domains) were retained for the newly developed K-UCSQ version 1.1; <sup>‡</sup>The table values above are standardized regression coefficients of each factor (domain) regressed upon the 32 questions, multiplied by 100 and rounded to the nearest integer. Values >0.4 are marked in bold font and flagged by an asterisk (\*).

tionale that at least five times the number of items were needed to validate the questionnaires.<sup>13</sup>

All statistical tests were two-sided, and *p*-value <0.05 was considered statistically significant. The analyses were conducted using SAS ver. 9.4 (Cary, NC, USA) and R ver. 4.0.4 (The R foundation for statistical computing).

*Construct validity*

Factor analysis was used to estimate the construct validity of the K-UCSQ items, that is, the extent to which the questionnaire measured the theoretical constructs it intended to measure. Factor analysis shows how the correlations among the question-

naire items can be explained by each item’s correlation with an underlying latent “construct.” The basis of factor analysis is a regression model that links the questionnaire items to a set of unobserved “constructs” or questionnaire domains,<sup>14</sup> and a set of items that highly contributed to a construct in terms of a factor loading ≥0.4 were given domain membership (Table 2).

*Reliability (internal consistency)*

Cronbach’s alpha,<sup>15</sup> conceptually defined as the average correlation of all possible split-half pairs in a questionnaire or survey, was used to gauge the reliability (internal consistency) of the K-UCSQ. The usual standard of Cronbach’s alpha ≥0.7 was

applied to determine the reliability of the items devised, while considering alpha as a function of both item inter-relatedness and the number of items itself.<sup>16</sup>

**Concurrent validity**

To evaluate the concurrent validity of the newly developed K-UCSQ, patients with UC enrolled in the current study provided answers to both the K-UCSQ and the IBDQ. The IBDQ is a 32-item questionnaire on a seven-point Likert scale, with scores ranging from 32 to 224, with a higher score indicating better QoL for patients with IBD. Spearman’s rank correlation coefficient was calculated between the K-UCSQ and IBDQ scores, and a generalized version of the McNemar test (Stuart-Maxwell test, Bhapkar test) was used to assess marginal homogeneity of the K-UCSQ.<sup>17,18</sup> In addition, the correlation between the mean standardized K-UCSQ and IBDQ scores by severity of UC (remission, mild, or moderate-to-severe) was measured (Fig. 2).

**Predictive validity**

Predictive validity evaluates the degree to which clinical endpoints correlate with measures derived from the survey, such as when the endpoint is regressed upon the survey scores. Among pre-survey background information collected from the enrolled patients, a patient’s “perceived overall health” and “past 2-week QoL” were chosen to be the relevant clinical outcomes of interest. To compare the sensitivity of the K-UCSQ and IBDQ questionnaires’ scores, the predictive ability of the scores in the subgroup of UC patients currently in remission were compared in terms of their area under the receiver operating characteristic curve (AUC) in two logistic regression models (Fig. 3 with the log-odds of “perceived overall health” being bad or very bad as the outcome, Fig. 4 with the log-odds of “past 2-week QoL” being satisfied or happy as the outcome), with either the standardized K-UCSQ total score or standardized IBDQ total score as the predictor variable in both models. The statistical significance of AUC differences was also evaluated.<sup>19</sup>

**RESULTS**

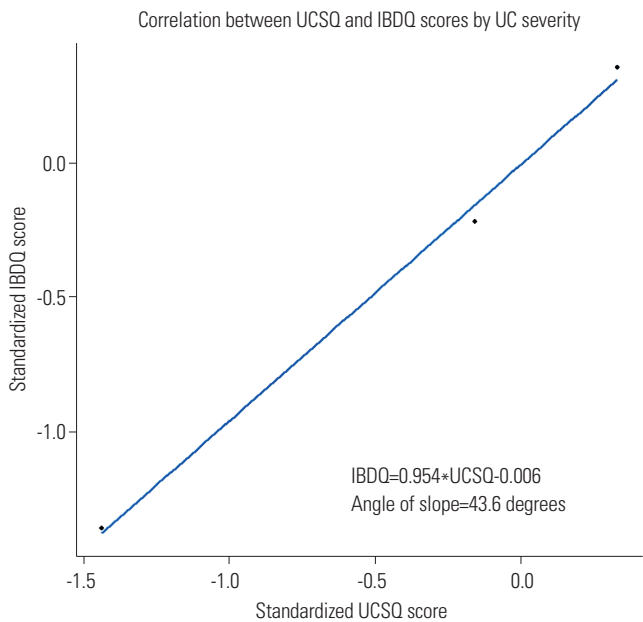
**Descriptive statistics**

Table 1 shows the demographic characteristics of the patients with UC who participated in the development of the K-UCSQ. The mean age of the study population was 43.7 years (standard deviation 13.1), and it comprised of 61.5% males. As shown in Table 1, 69.5% of the study population participated in either work or school, 69.0% were never-smokers, and 59.5% did not consume alcoholic beverages. The average UC duration was 6.7 years (standard deviation 5.4). UC was in remission in 114 patients (57.0 %), while the disease activity was mild in 67 (33.5%), moderate in 17 (8.5 %), and severe in 2 (1.0%) patients.

ucsqDeciles	ibdqDeciles										Total
	1	2	3	4	5	6	7	8	9	10	
1	18	2	0	0	0	0	0	0	0	0	20
2	3	10	7	3	0	0	0	0	0	0	23
3	0	3	4	9	1	0	0	0	0	0	17
4	0	4	5	4	4	2	2	0	0	0	21
5	0	1	1	3	7	2	4	3	1	0	22
6	0	0	1	0	1	8	3	3	1	0	17
7	0	0	1	1	3	3	2	9	3	1	23
8	0	0	0	1	2	4	3	6	3	1	20
9	0	0	0	0	1	0	1	1	7	12	22
10	0	0	0	0	2	3	0	0	4	6	15
<b>Total</b>	<b>21</b>	<b>20</b>	<b>19</b>	<b>21</b>	<b>21</b>	<b>22</b>	<b>15</b>	<b>22</b>	<b>19</b>	<b>20</b>	<b>200</b>

Test	p value
Stuart-Maxwell text	0.647
Bhapkar test	0.615

**Fig. 2.** Marginal homogeneity test results, comparing the composition of K-UCSQ and IBDQ score deciles, from the responses provided by ulcerative colitis patients enrolled in the current study (n=200). IBDQ, Inflammatory Bowel Disease Questionnaire; K-UCSQ, Korean Ulcerative Colitis-Specific Questionnaire.



UC severity	Remission (n=114)	Mild (n=67)	Moderate or severe (n=19)
Mean standardized UCSQ scores	0.332	-0.157	-1.436
Mean standardized IBDQ scores	0.354	-0.218	-1.358

**Fig. 3.** Correlation between the mean standardized K-UCSQ and IBDQ scores by UC severity of remission, mild, moderate, or severe, from the responses provided by UC patients enrolled in the current study (n=200). IBDQ, Inflammatory Bowel Disease Questionnaire; K-UCSQ, Korean Ulcerative Colitis-Specific Questionnaire; UC, ulcerative colitis.

### Construct validity

The 200 recruited patients subsequently participated in field tests of the draft version of the K-UCSQ (ver. 1.0), and also provided answers to the pre-established IBDQ for further validation. Table 2 shows the factor analysis results for the responses to the 32 items of the K-UCSQ ver. 1.0, excluding the additional seven items of UC drug compliance (Q33 to Q39), which were deemed less relevant to the patient’s health-related QoL. The four identified factors were defined as the four domains of the K-UCSQ: 1) bowel symptoms, 2) lavatory, 3) functional (or abdominal and systemic) symptoms, and 4) impact on daily life. Four items (Q7, Q20, Q21, and Q23) of the K-UCSQ ver. 1.0 ei-

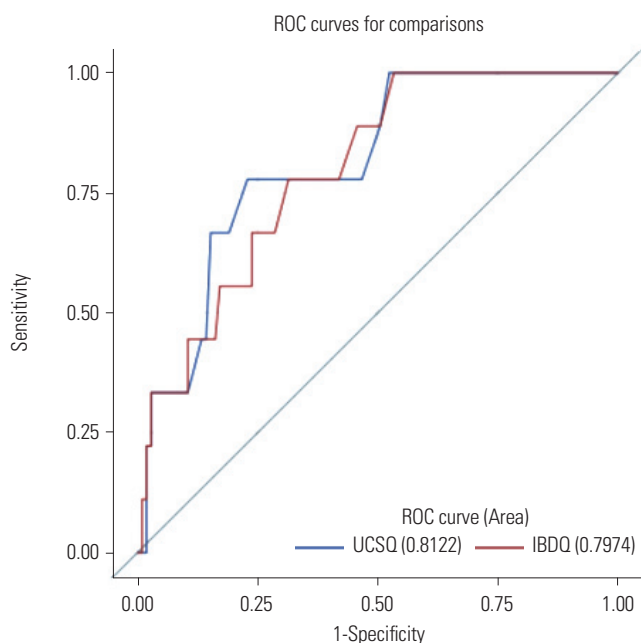
ther did not have any factor loadings >0.4 or were not conceptually pertinent to any specific factor or domain, and were thus removed from the revised questionnaire. Consequently, the newly developed K-UCSQ ver. 1.1 was finalized as a 28-item questionnaire with four conceptual domains. The item generation and reduction process and a Korean version of the K-UCSQ are further provided in Fig. 1 and Supplementary Material (only online).

### Reliability (internal consistency)

After finalizing the K-UCSQ ver. 1.1, its reliability in terms of internal consistency was evaluated using Cronbach’s alpha for each domain and in total, as shown in Table 3. With Cronbach’s alpha ranging between 0.75 (bowel symptoms domain) and 0.94 (lavatory domain), domain-wise reliability was considered sufficient. Furthermore, the 0.94 alpha in total also demonstrated the high internal consistency of the K-UCSQ.

### Concurrent validity

We evaluated the concurrent validity of the K-UCSQ in comparison with the pre-established IBDQ. First, the K-UCSQ total score was 119.5±17.1 with a range of 66–140, for possible scores of 28–140. Second, the IBDQ total score was 178.8±31.5 with a range of 64–224, for possible scores of 32–224. The Spearman rank-correlation coefficient between the K-UCSQ and IBDQ total scores was 0.875 (*p*-value<0.001). In addition, K-UCSQ score groups by decile (patients grouped by their K-UCSQ scores from lowest to highest into 10 groups) were compared against IBDQ score groups by decile to test for marginal homogeneity. For example, patients who scored high on the K-UCSQ (deciles 9 or 10, for example) correspondingly scored high on the IBDQ (also of deciles 9 or 10). Fig. 2 shows that such marginal homogeneity could not be rejected, and the K-UCSQ decile groups were in good agreement with the IBDQ decile groups, with a *p*-value of 0.615 for the relatively high-power Bhapkar’s test. The number of patients with perfect agreement between the K-UCSQ and IBDQ decile groups is further highlighted in Fig. 2’s decile by decile table with a red line along the diagonal. In addition, the mean standardized K-UCSQ scores by UC severity were highly correlated with the mean standardized IBDQ scores by UC severity. The best-fit linear regression line of the mean standardized K-UCSQ scores upon those of the IBDQ by UC severity showed a nearly perfect linear correlation of 0.954,



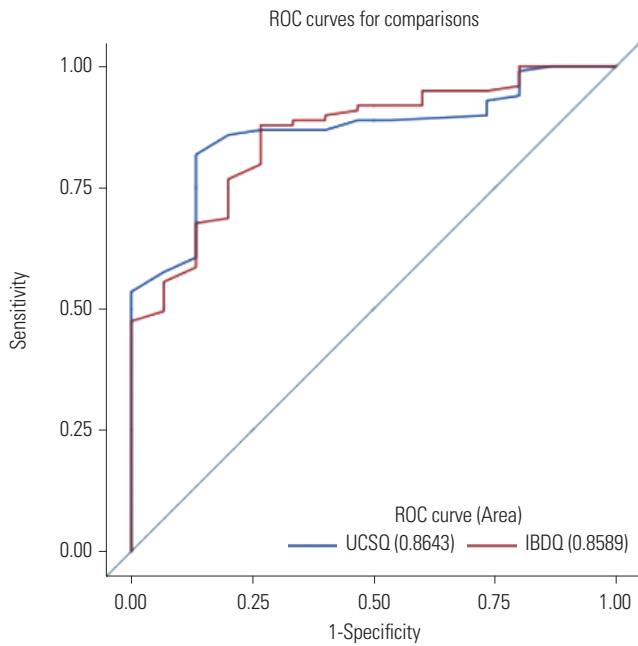
AUC		AUC difference (95% CI)	<i>p</i> value
UCSQ	IBDQ		
0.812	0.797	0.015 (-0.102–0.073)	0.740

**Fig. 4.** Comparison of the area AUC for the outcome of “perceived overall health” being bad or very bad, in a logistic regression model with either the standardized K-UCSQ or IBDQ total score as the predictor variable, from the responses provided by UC patients enrolled in the current study (n=200). AUC, area under the ROC curve; CI, confidence interval; IBDQ, Inflammatory Bowel Disease Questionnaire; K-UCSQ, Korean Ulcerative Colitis-Specific Questionnaire; ROC, receiver-operator characteristic curve; UC, ulcerative colitis.

**Table 3.** Cronbach’s Alpha (Internal Reliability) of the Newly Developed K-UCSQ (version 1.1)

K-UCSQ	Number of questions	Cronbach’s alpha	95% CI
Bowel symptoms domain	5	0.75	0.69–0.80
Lavatory domain	5	0.94	0.93–0.95
Functional symptoms domain	7	0.85	0.82–0.88
Impact on daily life domain	11	0.90	0.87–0.92
Total	28	0.94	0.93–0.95

K-UCSQ, Korean Ulcerative Colitis-Specific Questionnaire; CI, confidence interval.



AUC		AUC difference (95% CI)	p value
UCSQ	IBDQ		
0.864	0.859	0.005 (-0.050-0.040)	0.815

**Fig. 5.** Comparison of the AUC for the outcome of “past 2-week quality of life” being satisfied or happy, in a logistic regression model with either the standardized K-UCSQ or IBDQ total score as the predictor variable, from the responses provided by UC patients enrolled in the current study (n=200). AUC, area under the ROC curve; CI, confidence interval; IBDQ, Inflammatory Bowel Disease Questionnaire; K-UCSQ, Korean Ulcerative Colitis-Specific Questionnaire; ROC, receiver-operator characteristic curve; UC, ulcerative colitis.

demonstrating the K-UCSQ’s high concurrent validity in comparison with the IBDQ (Fig. 3).

**Predictive validity**

Figs. 4 and 5 present further evaluations of the predictive validity of the newly developed K-UCSQ in comparison with that of the IBDQ. In Fig. 4, the clinically relevant outcome of a UC patient’s perceived overall health (the log-odds of perceived overall health being either bad or very bad compared to being so-so, good, or very good) was regressed upon the standardized K-UCSQ and IBDQ total scores separately. The AUC was 0.812 and 0.797 for the K-UCSQ and IBDQ, respectively. Although the AUC point estimate of the K-UCSQ was slightly higher than that of the IBDQ, the difference in AUCs of 0.015 was not statistically significant (*p*-value=0.740), thus demonstrating comparable predictive validity between the two instruments. Similarly, in Fig. 5, a UC patient’s past 2-week QoL (the log-odds of past 2-week QoL being either satisfied or happy compared to being so-so, unsatisfied, or unhappy) was regressed upon the standardized K-UCSQ and IBDQ total scores separately. Again, the K-UCSQ’s AUC point estimate of 0.864 was slightly higher than that of the IBDQ (0.859), but the difference in AUCs was not sta-

tistically significant (*p*-value=0.815), demonstrating comparable predictive validity between the K-UCSQ and IBDQ.

**DISCUSSION**

To the best of our knowledge, this is the first study to develop a UC-specific instrument to measure the QoL. In summary, the K-UCSQ comprises 28 items with four domains: 1) bowel symptoms, 2) lavatory, 3) functional symptoms, and 4) impact on life. The K-UCSQ demonstrated excellent internal consistency and validity through Cronbach’s alpha and validation of the instrument on three potential outcomes, including disease severity, QoL in the past 2 weeks, and perceived overall health, in comparison with the IBDQ. The K-UCSQ was not only comparable to the well-established IBDQ in validation results, but also had the additional strength of being a UC-specific scoring system, especially highlighting bathroom problems in patients with UC.

IBD has a significant impact on the QoL of patients, not only due to the symptoms from the disease itself, but also due to the fear, concern, and other unmet needs of the chronic illness.<sup>20</sup> An effective treatment strategy can achieve and maintain clinical remission, which can effectively restore patients’ QoL.<sup>21,22</sup> It has been shown that timely medical and surgical interventions in patients with IBD can improve their QoL during the first year of disease.<sup>23</sup> Furthermore, physical activity, health education resources, good medical provider relationships, and psychosocial support can also improve the QoL of patients with IBD.<sup>24-26</sup> Therefore, recent treatment strategies have suggested improvement of QoL as a long-term treatment goal for IBD.<sup>27,28</sup> The concept of QoL assessment with its objective measurement was developed by the World Health Organization in 1998 to reach a scientific consensus with high reliability and validity.<sup>29</sup> QoL is often assessed using generic or illness-specific tools.<sup>30</sup> As the importance of QoL in patients with IBD is being emphasized, measurement tools for illness-specific QoL are also being steadily developed,<sup>5</sup> such as the IBDQ-32, Short Inflammatory Bowel Disease Questionnaire, UK-IBD-QoL, IBD-Control, Crohn’s and Ulcerative Colitis Quality of Life Questionnaire-32, and IMPACT questionnaire.<sup>31-35</sup>

The previous QoL measurement tools were developed for IBD in general, but UC and CD are different disease entities with distinct clinical presentations. A recent meta-analysis suggested that QoL scores were lower in patients with CD compared to those with UC in pooled estimates, and suggested separate and independent presentation of data by IBD subtypes.<sup>7</sup> Therefore, we developed the new K-UCSQ questionnaire specifically for patients with UC. This UC-specific questionnaire was created through current consensus and in-depth interviews, and the best indicators were retained by progressively reducing various candidate indicators. The K-UCSQ’s questions were overall more concise than those of the previous questionnaires. The

bathroom problem was highlighted, as poor bowel function control has a dramatic impact on QoL in patients with UC. Since most patients with UC experience bloody stool, diarrhea, frequency, urgency, and incontinence, the K-UCSQ particularly formed a lavatory domain consisting of five questions, including stress, fear, need, frequency, and location check of a bathroom over the past 2 weeks.

Our study had a few limitations. First, although we designed our research as a multi-center study, further validation of the K-UCSQ in different languages is warranted before general use of the questionnaire. Second, since we only enrolled tertiary medical institutions, selection bias may exist. However, our sample size was large and contained various spectra of patients with UC owing to multicenter enrollment. Third, the K-UCSQ was not compared to a generic QoL measurement tool, but with an IBD-specific QoL measurement tool. Fourth, only a small number of patients with severe disease activity were included in this study. Therefore, validation in a cohort with a larger number of clinically active UC may be needed. Fifth, the readability of this tool was not explicitly evaluated, and the tool was not yet tested upon a healthy control group.

In conclusion, the newly developed K-UCSQ demonstrated good validity and reliability as a UC-specific instrument for measuring health-related QoL. We expect the K-UCSQ to serve as a valuable tool in better reflecting the specific aspects of UC patients' QoL.

## DATA AVAILABILITY STATEMENT

A Korean version of the newly developed K-UCSQ is available as online supplementary material.

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