



Reliability and validity of the Korean version of the University of California–Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract instrument in patients with systemic sclerosis

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Received: May 1, 2020

Revised: June 4, 2020

Accepted: June 8, 2020

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Background/Aims: Systemic sclerosis (SSc) is associated with a wide range of gastrointestinal (GI) changes. The University of California–Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract (UCLA SCTC GIT 2.0) instrument is a self-administered GI assessment instrument for patients with SSc. We developed a Korean version of the UCLA SCTC GIT 2.0 instrument and evaluated its reliability and internal consistency.

Methods: The participants were 37 Korean patients with SSc. Translation and cross-cultural adaptation of the UCLA SCTC GIT 2.0 were performed according to international standardized guidelines. We evaluated reproducibility by calculating the intraclass correlation coefficients and assessed the internal consistency of the Korean version of the UCLA SCTC GIT 2.0. We assessed its construct validity by evaluating its correlations with the Short Form Health Survey version 2 and EQ-5D scores by means of Spearman correlation analyses.

Results: Patients with SSc were mostly women (89.19%) with a mean age of 52.2 years, median disease duration of 24 months, and median modified Rodnan total skin score of 4. The median total GIT score on the UCLA SCTC GIT 2.0 was 0.3. The UCLA SCTC GIT 2.0 Korean version showed excellent internal consistency (Cronbach's α of total GIT score = 0.863). Most domains of the UCLA SCTC GIT 2.0 were correlated with those of the EuroQol (EQ)-5D score.

Conclusions: The Korean version of the UCLA SCTC GIT 2.0 has acceptable internal consistency, reliability, and validity. Therefore, it can be used to assess GIT involvement in Korean patients with SSc.

Keywords: Reliability; Validity; Korean; Gastrointestinal tract; Systemic sclerosis

INTRODUCTION

Systemic sclerosis (SSc) is an autoimmune disease characterized by endothelial dysfunction, immune dysreg-

ulation, and excessive collagen deposition, and is of unknown etiology. Individual patients manifest these three components to varying degrees, resulting in a heterogeneous clinical presentation [1]. A recent Korean na-

tionwide population-based study reported a prevalence of SSc of 77.7 per million population [2]. The gastrointestinal tract (GIT) is the most commonly involved organ and affects the health-related quality of life (HRQoL) of patients with SSc. High-resolution manometry (HRM) shows a high level of diagnostic accuracy and reproducibility for esophageal involvement even in asymptomatic patients with SSc [3].

Outcome measurements are important in clinical trials and patient-reported outcomes (PROs) can be useful for monitoring symptoms of SSc [4]. Khanna et al. [5] developed the University of California–Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract Instrument (UCLA SCTC GIT) 2.0, a comprehensive self-administered survey, which has been translated and validated in the United Kingdom, Canada, France, The Netherlands, Romania, Italy, Turkey, and Singapore [5–12]. The UCLA SCTC GIT 2.0 has been used in randomized placebo-controlled trials to evaluate gastrointestinal symptoms and immune parameters in SSc [13]. It was developed to assess the severity of GIT symptoms and their impacts on HRQoL and consists of 34 items with seven subscales, assessing reflux (eight questions), distension/bloating (four questions), fecal soilage (one question), diarrhea (two questions), social functioning (six questions), emotional well-being (nine questions), and constipation (four questions) [5]. Ethnic and geographical differences are closely related to the prevalence of GIT symptoms in the general population [14,15]. Conceptual differences between quality of life (QoL) domains and attitudinal differences toward GIT features according to ethnicity exist among patients with SSc [16]. However, to date, few Asian adaptations of the UCLA SCTC GIT 2.0 questionnaire are available.

We translated the instrument into Korean and assessed the acceptability, feasibility, reliability, and construct validity of it for evaluating perception of GIT symptoms.

METHODS

Patients and data collection

This was a two-phase cross-sectional study involving translation and adaptation into the target language, followed by validation. Thirty-seven patients with SSc were

consecutively recruited between July and October 2017. The patients were diagnosed using the 2013 American College of Rheumatology SSc criteria in the SSc Clinic of Soonchunhyang University Seoul Hospital [17]. For proper sample size calculation, the number of subjects was determined according to a previous study [5]. Two-sided tests ($\alpha = 0.05$, power = 80% [$\beta = 0.2$]) were performed with the correlation coefficient ρ set to 0.2 to 0.6. A ρ value of 0.2 indicated a minimum number of subjects of 30. Taking into consideration a 20% dropout rate, 37 subjects were included in this study.

SSc is classified as limited cutaneous (lc) or diffuse cutaneous (dc) systemic disease according to the distribution of skin involvement [18]. For each patient, the following data were collected: demographic characteristics, body mass index (BMI), Raynaud's phenomenon, and the extent of skin thickening. The extent of skin thickening was evaluated using the modified Rodnan total skin score (mRSS). Laboratory findings, including serum levels of anti-nuclear, anti-centromere, anti-topoisomerase, and anti-RNP antibodies, were also recorded. We investigated internal organ involvement including digital ulcers, SSc-associated interstitial lung disease (as represented by pulmonary function), gastroesophageal reflux disease (GERD; by esophagogastroduodenoscopy, EGD) [19], scleroderma renal crisis (defined as malignant hypertension with acute renal insufficiency occurring during the course of SSc) [20], and heart involvement including pulmonary arterial hypertension (defined as a mean pulmonary artery pressure ≥ 20 mmHg, pulmonary artery wedge pressure < 15 mmHg, and pulmonary vascular resistance > 3 Wood units measured during right-heart catheterization at rest according to the Sixth World Symposium on Pulmonary Hypertension) [21]. Pulmonary function was assessed by determining the functional vital capacity (FVC; % predicted) and diffusion capacity of the lung for carbon monoxide (DLCO; % predicted) (corrected for hemoglobin). Patients with an incomplete clinical assessment were excluded. This study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board for Human Research of Soonchunhyang University Seoul Hospital (IRB no. SCH 2017-07-029). Written informed consent was obtained from all participants.

Translation of the Korean version of the UCLA SCTC GIT 2.0

The English-language version of the instrument is available at https://umich.qualtrics.com/jfe/form/SV_3eBP4A-4umBwnSvj/ and was used in this study with the permission of Professor Khanna. Translation and cross-cultural adaptation of the instrument were performed according to the published recommendations [22,23]. The proposed steps were synthesis of translation, back translation, expert committee review, and pre-testing. First, three people of different backgrounds (e.g., one medical and two non-medical) independently performed a forward translation of the instrument from the English-language to the Korean language. The adjustments made were combined by consensus among the translators. Then back translation was performed by two independent bilingual native speakers of English, who were blinded to the original English-language version. The two (forward and back) non-medical translators are very familiar with cross-cultural adaptation. The final version (Supplementary Table 1) was, with the approval of the Expert Committee, preliminarily administered to patients with SSc attending the hospital. After patients answered, each question was discussed with them to check whether all items had been fully understood.

Study instruments

The UCLA SCTC GIT 2.0 is a 34-item questionnaire with seven subscales (reflux, distension/bloating, fecal soilage, diarrhea, social functioning, emotional well-being, and constipation). Each item scores the frequency of symptoms over a recall period of 7 days from 0 to 3, where 0 indicates no GI problems and three indicates worse health. The exceptions are questions 15 (diarrhea subscale) and 31 (constipation subscale), which are scored from 0 (no matter) to 1 (worse health). The score of six subscales (excluding constipation) is summed as the total score, which captures the overall burden of disease (the possible scores range from 0 to 2.83).

The Short Form Health Survey version 2 (SF-36v2) is the most widely used measurement of general health and QoL [24]. It is based on norm-based scoring algorithms standardized by the same average (i.e., 50) and the same standard deviation. The survey has eight aspects: physical functioning (PF), physical role (RP), bodily pain (BP), general health (GH), vitality (VT), social role func-

tioning (SF), emotional role functioning (RE), and mental health (MH). The physical (PCS) and mental component scores (MCS) are calculated based on those aspects; higher scores indicate a higher QoL [25].

The EQ-5D questionnaire is one of the most widely used instruments for measuring utility, and is available in several languages including Korean [26]. It consists of five health dimensions: mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. The questionnaire also comprises a visual analogue scale domain, which measures the overall HRQoL on a scale of 0 (worst health state) to 100 (best health state).

Statistical analysis

The reliability of the UCLA SCTC GIT 2.0 was assessed by the test-retest method at a 1-week interval in all 37 patients. This yielded an estimate of the instrument's reproducibility over time as measured by intraclass correlation (ICC). The test-retest reliabilities were interpreted as appropriate if the ICCs were > 0.7 and 0.9 for group and individual comparisons, respectively.

Internal consistency was evaluated using the Cronbach's α method for the seven subscales and the total score of the Korean version of the UCLA SCTC GIT 2.0 questionnaire. A Cronbach's α coefficient > 0.7 indicates a good correlation. Floor and ceiling effects were defined as the proportion of patients with the minimum (floor, representing absence of symptoms) and maximum (ceiling, representing the worst symptoms) possible scores. These proportions were calculated for each scale and an effect was considered present if more than 15% of patients had the maximum or minimum score. We assessed the construct validity of the UCLA SCTC GIT 2.0 questionnaire by examining its correlations with the SF-36v2 and EQ-5D scales by Spearman correlation [8-10,12]. Correlations (rho) \leq 0.29 were considered small, 0.30 to 0.49 were moderate, and those \geq 0.50 were considered large. SPSS version 26.0 software (IBM Co., Armonk, NY, USA) was used for statistical analyses. Continuous variables were analyzed using the Wilcoxon signed-rank test and categorical variables were assessed using the chi-square or Fisher exact tests. Simple relationships were assessed using Spearman rank-correlation analyses. Differences were considered statistically significant at $p < 0.05$.

Table 1. Baseline characteristics of the study population

Characteristic	All patients (n = 37)	lcSSc (n = 12)	dcSSc (n = 25)	p value ^a
Age, yr	52.2 ± 13.0	58.4 ± 8.9	49.2 ± 13.7	0.019
Female sex ^b	33 (89.2)	10 (83.3)	23 (92)	0.582
Weight, kg (%) ^c	55 (50.7–60)	58.5 (55–61.0)	53 (49.8–58.8)	0.036 ^d
BMI, kg/m ²	22.1 ± 2.5	23.7 ± 2.0	21.4 ± 2.3	0.004 ^e
Meet the classification diagnosis				
1980 Criteria ^b	27 (73.0)	8 (66.7)	19 (76.0)	0.696
2013 Criteria	37 (100)	12 (100)	25 (100)	NA
Disease duration, mon ^c	24 (10–48)	15.5 (10–27)	36 (10–50)	0.199
Raynaud's phenomenon				
Yes	37 (100)			
RP duration, mon ^c	36 (18–63)	38 (21.3–63.3)	35 (18–60)	0.948
mRSS	4 (3–11)	4.5 (2–7.8)	4 (3–12)	0.415
Autoantibodies				
Anti-nuclear Ab	37 (100)	12 (100)	25 (100)	NA
Anti-centromere Ab ^b	13 (35.1)	10 (83.3)	3 (12)	< 0.001 ^e
Anti-scl70 Ab ^f	15 (41.7)	1 (8.3)	14 (58.3)	0.012 ^d
Anti-RNP Ab ^b	7 (19.0)	1 (8.3)	6 (24)	0.49
Anti-dsDNA Ab ^b	2 (5.4)	0	2 (8)	NA
Anti-Sm Ab	0	0	0	NA
Pattern of capillaroscopy				
Normal ^b	1 (2.7)	1 (8.3)	0	0.289
Early pattern of SSc	14 (37.8)	6 (50)	8 (32)	
Active pattern of SSc	8 (21.6)	2 (16.7)	6 (24)	
Late pattern of SSc	14 (37.8)	3 (25)	11 (44)	
Organ involvement				
Digital ulcer ^b	10 (27.0)	1 (8.3)	9 (36)	0.119
Interstitial lung disease	30 (81.1)			
FVC	86.2 ± 18.6	99.5 ± 9.3	79.8 ± 18.7	< 0.001 ^e
FEV ₁	92.7 ± 18.3	107.3 ± 10.8	85.6 ± 17.1	< 0.001 ^e
FEV ₁ /FVC	81.0 ± 5.8	79.1 ± 6.7	82.0 ± 5.2	0.205
DLCO	71.0 ± 15.6	81.3 ± 16.5	66.1 ± 12.8	0.011 ^d
Recent EGD ^b	13 (35.1)	5 (41.7)	8 (32)	0.716
GERD in EGD ^b	7 (53.9)	0	7 (87.5)	0.005 ^d
Scleroderma renal crisis	0	0	0	NA
Heart involvement ^b	1 (2.7)	0	1 (4)	> 0.99
Previous medication				
PPI	24 (64.9)	6 (50)	18 (72)	0.345
Mean duration ^c	9 (2–20.3)	9 (3.75–15.75)	9.5 (2–24.5)	0.789
Prokinetics ^f	14 (37.84)	5 (41.67)	9 (36)	> 0.99
Mean duration ^c	8.5 (3–20.25)	9 (7–18)	8 (1–26)	0.893
Steroid ^e	32 (86.49)	9 (75)	23 (92)	0.367
Mean dose, mg/day ^c	5 (2.5–5)	2.5 (2.5–5)	5 (5–5)	0.014 ^d

Table 1. Continued

Characteristic	All patients (n = 37)	lcSSc (n = 12)	dcSSc (n = 25)	p value ^a
CYC ^f	15 (40.54)	2 (16.67)	13 (52)	0.091
Total dose of CYC, mg ^c	4,750 (2,850–7,575)	2,875 (2,312.5–3437.5)	5,000 (3,250–9,900)	0.269
MMF ^f	13 (35.14)	3 (25)	10 (40)	0.598
Mean dose, mg/day ^c	1,500 (1,000–2,000)	1,500 (800–1,500)	1,250 (1,000–2,000)	0.534
Tacrolimus ^b	1 (2.7)	0	1 (4)	> 0.99
Mean dose, mg/day	2 (2–2)		2 (2–2)	NA
IVIg ^b	2 (5.41)	0	2 (8)	> 0.99
Total dose, g	685 (584–786)		685 (584–786)	NA

Values are presented as mean ± standard deviation, number (%), or median (interquartile range).

lcSSc, limited cutaneous systemic sclerosis; dcSSc, diffused cutaneous systemic sclerosis; BMI, body mass index; NA, not available; RP, Raynaud’s phenomenon; mRSS, modified Rodnan’s skin sclerosis score; Ab, antibody; dsDNA, double-stranded DNA; SSc, systemic sclerosis; FVC, functional vital capacity; FEV₁, forced expiratory volume in 1 second; DLCO, diffusion capacity of the lung for carbon monoxide; recent EGD, esophagogastroduodenoscopy within 6 months; GERD, gastroesophageal reflux disease; PPI, proton pump inhibitor; CYC, cyclophosphamide; MMF, mycophenolate mofetil; IVIG, intravenous immunoglobulin.

^aStudent’s *t* test.

^bFisher exact test.

^cWilcoxon rank-sum test.

^d*p* < 0.05.

^e*p* < 0.005.

^fChi-square test.

RESULTS

Patients

Patients with an incomplete clinical assessment were excluded from the analyses. Complete data were available for 37 patients (12 lcSSc and 25 dcSSc) with consecutive scheduled study instruments. Those patients’ characteristics are listed in Table 1. Most of the patients with SSc (n = 37) were women (89.19%), and they had a mean age of 52.2 years, BMI of 22.1 kg/m², median disease duration (interquartile range [IQR]) of 24 months, and median mRSS of 4 points. The lcSSc subtype was diagnosed in 12 patients (32.4%) and the dcSSc was documented in 25 (67.6%). The patients with dcSSc were more frequently anti-Scl70 positive; had higher GERD on EGD, and had lower FVC, forced expiratory volume in 1 second (FEV₁), and DLCO than those with lcSSc. The HRQoL instruments in patients with SSc are shown in Table 2. The median total GIT score was 0.3 and did not differ between the lcSSc and dcSSc subtypes.

Reliability and internal consistency

The Korean UCLA SCTC GIT 2.0 questionnaire showed

good and reproducible reliability; the ICC values were close to 0.7 and statistically significant for all subscales (Table 3). For most subscales, Cronbach’s α was ≥ 0.7 ; the exceptions were the diarrhea and social function subscales (Cronbach’s $\alpha = 0.551$, $\alpha = 0.421$), suggesting good internal consistency. There was floor effect for both the scale itself and all of the subscales, ranging from 16% (total GIT score) to 89% (fecal soilage); however, there was no ceiling effect (Table 4).

To assess construct validity, the UCLA SCTC GIT 2.0 was compared to the SF-36v2 and EQ-5D. The reflux domain of the UCLA SCTC GIT 2.0 was moderately correlated with the SF-36v2 (PF, RP, BP, VT, SF, RE, MH, and MCS). The emotional well-being domain of the was negatively correlated with that of the SF-36v2, except the PCS. The total GIT score of the UCLA SCTC GIT 2.0 was negatively correlated with that of the SF-36v2, except RP, BP, and GH (Table 5). However, most domains of the UCLA SCTC GIT 2.0 were not correlated with those of the EQ-5D. The emotional well-being domain was significantly correlated with that of the EQ-5D, except usual activities and pain. The total GIT score of the UCLA SCTC GIT 2.0 was significantly correlated with that of

Table 2. Health-related quality of life instruments in patients with systemic sclerosis

Variable	lcSSc (n = 12)	dcSSc (n = 25)	p value
UCLA SCTC GIT 2.0 ^a			
Reflux	0.12 (0.09–0.39)	0.25 (0–0.35)	0.947
Distention/bloating	0.62 (0.19–0.81)	0.75 (0–1)	0.574
Fecal soilage	0 (0–0)	0 (0–0)	0.833
Diarrhea	0 (0–1)	0 (0–1)	0.971
Social function	0.16 (0–0.5)	0.16 (0–0.5)	0.946
Emotional well-being	0.5 (0–0.8)	0.11 (0–0.66)	0.396
Constipation	0 (0–0.25)	0.25 (0–0.75)	0.184
Total GIT score	0.3 (0.2–0.4)	0.4 (0.06–0.64)	0.974
SF-36v2 ^b			
PF	79.17 ± 18.2	72.4 ± 17.33	0.295
RP ^a	62.5 (37.5–100)	50 (50–100)	0.973
BP	78.17 ± 17.71	59.2 ± 24.24	0.012 ^c
GH	46 ± 14.02	44.32 ± 16.68	0.751
VT ^a	40 (30–50)	40 (40–55)	0.321
SF ^a	93.75 (75–100)	62.5 (37.5–87.5)	0.038 ^c
RE ^a	83.33 (50–100)	100 (33.33–100)	0.888
MH	52.67 ± 21.83	62.4 ± 17.85	0.195
PCS	49.97 ± 8.79	44.07 ± 9.13	0.072
MCS	31.23 ± 15.39	35.71 ± 15.57	0.417
EQ-5D ^a			
Mobility	1 (1–2)	1 (1–2)	0.891
Self-care	1 (1–1)	1 (1–1)	0.272
Usual activities	1 (1–1)	2 (1–2)	0.023 ^c
Pain/discomfort	2 (1–2)	2 (2–2)	0.101
Anxiety/depression	2 (1–2)	1 (1–2)	0.318
VAS ^a	70 (55–76.25)	60 (40–70)	0.420

Values are presented as median (interquartile range) or mean ± standard deviation.

lcSSc, limited cutaneous systemic sclerosis; dcSSc, diffused cutaneous systemic sclerosis; UCLA SCTC GIT 2.0, The University of California–Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract; GIT, gastrointestinal tract; SF-36v2, Short Form Health Survey version 2; PF, physical functioning; RP, physical role functioning; BP, bodily pain; GH, general health perceptions; VT, vitality; SF, social role functioning; RE, emotional role functioning; MH, mental health; PCS, physical health component summary; MCS, mental health component summary; EQ-5D, EuroQol-5 dimensions; VAS, visual analogue scale.

^aWilcoxon rank-sum test.

^bStudent's *t* test.

^c*p* < 0.05.

Table 3. Reliability of the Korean version of the UCLA SCTC GIT 2.0 as assessed by intraclass correlation

UCLA SCTC GIT 2.0 (n = 37)	No. of items	First time	Second time	ICC	95% CI	p value
Reflux	8	0.46 ± 0.51	0.42 ± 0.35	0.690	0.269 to 0.869	0.004 ^a
Distention	4	1.23 ± 0.81	1.10 ± 0.71	0.867	0.686 to 0.944	< 0.001 ^b
Fecal soilage	1	0.04 ± 0.21	0.22 ± 0.60	0.573	-0.006 to 0.819	0.026 ^a
Diarrhea	2	0.30 ± 0.47	0.37 ± 0.50	0.753	0.417 to 0.895	0.001 ^b
Social function	6	0.51 ± 0.49	0.38 ± 0.42	0.639	0.148 to 0.847	0.010 ^a
Emotional well-being	9	0.47 ± 0.60	0.54 ± 0.64	0.809	0.549 to 0.919	< 0.001 ^b
Constipation	4	0.48 ± 0.58	0.68 ± 0.78	0.906	0.777 to 0.960	< 0.001 ^b
Total GIT score	30	0.50 ± 0.36	0.50 ± 0.39	0.842	0.627 to 0.933	< 0.001 ^b

Values are presented as mean ± standard deviation. Data were analyzed using Student's *t* test. A two-way random effects model was used and the ICC using a consistency definition.

UCLA SCTC GIT 2.0, The University of California–Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract; ICC, intraclass correlation coefficient; CI, confidence interval; GIT, gastrointestinal tract.

^a*p* < 0.005.

^b*p* < 0.05.

Table 4. Descriptive statistics and internal consistency of the Korean version of the UCLA SCTC GIT 2.0

UCLA SCTC GIT 2.0 (n = 37)	No. of items	Mean ± SD	Median	Q1	Q3	Min	Max	Floor effect, %	Ceiling effect, %	Cronbach's α
Reflux	8	0.30 ± 0.40	0.25	0.00	0.35	0.00	2.00	35	3	0.762
Distention	4	0.72 ± 0.69	0.75	0.00	1.00	0.00	2.75	27	3	0.688
Fecal soilage	1	0.16 ± 0.55	0.00	0.00	0.00	0.00	3.00	89	3	NA
Diarrhea	2	0.39 ± 0.52	0.00	0.00	1.00	0.00	1.50	59	5	0.551
Social function	6	0.28 ± 0.31	0.16	0.00	0.50	0.00	1.00	41	5	0.421
Emotional well-being	9	0.42 ± 0.48	0.22	0.00	0.72	0.00	1.55	43	3	0.793
Constipation	4	0.32 ± 0.47	0.00	0.00	0.50	0.00	2.00	54	3	0.711
Total GIT score	30	0.38 ± 0.30	0.32	0.11	0.63	0.00	1.01	16	3	0.863

A Cronbach's α coefficient ≥ 0.7 indicates a good correlation. The floor and ceiling effects were defined as the proportion of patients with the minimum (floor, representing absence of symptoms) and maximum (ceiling, representing the worst symptoms) possible scores.

UCLA SCTC GIT 2.0, The University of California–Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract; GIT, gastrointestinal tract.

the self-care domain of the EQ-5D (rho = 0.385, *p* = 0.019) (Table 5).

DISCUSSION

The UCLA SCTC GIT 2.0 of Khanna et al. [5] was the first validated 34-item questionnaire for assessing GIT involvement. The total score is the average of six of the seven subscales (excluding constipation), and the 2.0

version was developed using 52 items from the SSc-GIT 1.0 and 1 rectal incontinence item, grouped into the reflux, distention/bloating, diarrhea, fecal soilage (rectal incontinence), constipation, pain, emotional well-being, and social functioning scales. Version 2.0 includes 34 items and is scored from 0 to 3, with lower values indicating a better HRQoL. The measures have been validated in terms of manometry and for esophageal and gastric transit time [4].

Almost 90% of patients with SSc suffer from GIT

Table 5. Spearman's correlation coefficients of the Korean version of the UCLA SCTC GIT 2.0, SF-36v2, and EQ-5D

Variable	Reflux		Distention		Fecal soilage		Diarrhea		Social function		Emotional well-being		Constipation		Total GIT score		
	rho	p value	rho	p value	rho	p value	rho	p value	rho	p value	rho	p value	rho	p value	rho	p value	
SF-36v2																	
PF	-0.473	0.003 ^a	-0.386	0.018 ^b	-0.216	0.200	0.284	0.181	0.284	-0.554	<0.001 ^a	-0.423	0.009 ^b	-0.178	0.293	-0.531	0.001 ^a
RP	-0.440	0.007 ^b	-0.330	0.046 ^b	0.053	0.757	0.383	0.148	0.383	-0.258	0.124	-0.415	0.011 ^b	-0.120	0.478	-0.310	0.062
BP	-0.434	0.007 ^b	-0.472	0.003 ^a	-0.195	0.248	0.268	0.187	0.268	-0.526	0.001 ^a	-0.494	0.002 ^a	-0.429	0.008 ^b	-0.533	0.001
GH	-0.198	0.239	-0.238	0.156	0.282	0.091	0.084	0.084	0.623	-0.112	0.510	-0.418	0.010 ^b	-0.364	0.027 ^b	-0.233	0.165
VT	-0.365	0.026 ^b	-0.308	0.063	-0.069	0.686	0.801	0.043	0.801	-0.443	0.006 ^b	-0.563	<0.001 ^a	-0.465	0.004 ^a	-0.405	0.013 ^b
SF	-0.412	0.011 ^b	-0.300	0.072	0.173	0.305	0.281	0.182	0.281	-0.261	0.120	-0.445	0.006 ^b	-0.351	0.033 ^b	-0.376	0.022 ^b
RE	-0.531	0.001 ^a	-0.181	0.283	0.318	0.055	0.272	0.185	0.272	-0.261	0.118	-0.583	<0.001 ^a	-0.323	0.052	-0.353	0.032 ^b
MH	-0.346	0.036 ^b	-0.045	0.790	-0.040	0.815	0.209	0.215	0.246	0.143	-0.246	-0.562	<0.001 ^a	-0.275	0.100	-0.334	0.044 ^b
PCS	-0.300	0.071	-0.456	0.005 ^b	-0.182	0.280	0.688	0.068	0.688	-0.401	0.014 ^b	-0.221	0.189	-0.130	0.443	-0.368	0.025 ^b
MCS	-0.524	0.001 ^a	-0.143	0.399	0.159	0.346	0.129	0.254	0.129	-0.275	0.099	-0.666	<0.001 ^a	-0.400	0.014 ^b	-0.406	0.013 ^b
EQ-5D																	
Mobility	0.286	0.086	0.251	0.134	-0.079	0.643	0.749	0.054	0.749	0.167	0.325	0.341	0.039 ^b	0.220	0.191	0.229	0.174
Self-care	0.412	0.011 ^b	0.333	0.044 ^b	-0.168	0.320	0.125	0.460	0.227	0.177	0.372	0.372	0.024 ^b	0.381	0.020 ^b	0.385	0.019 ^b
Usual activities	0.215	0.202	0.393	0.016 ^b	0.010	0.953	0.873	0.027	0.873	0.280	0.093	0.241	0.150	0.296	0.075	0.281	0.092
Pain/discomfort	0.317	0.056	0.334	0.044 ^b	-0.203	0.229	0.353	0.157	0.353	0.334	0.044 ^b	0.292	0.080	0.340	0.039 ^b	0.213	0.206
Anxiety/depression	0.289	0.083	0.117	0.492	-0.177	0.294	0.313	0.170	0.313	0.153	0.365	0.378	0.021 ^b	0.320	0.054	0.216	0.198
VAS	-0.238	0.156	-0.252	0.132	0.165	0.328	0.011	0.951	-0.216	0.198	-0.357	0.030 ^b	-0.276	0.098	-0.285	0.088	0.088

A p value by Spearman correlation analysis.

UCLA SCTC GIT 2.0, The University of California–Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract; SF-36v2, Short Form Health Survey version 2; EQ-5D, EuroQol-5 dimensions; GIT, gastrointestinal tract; PF, physical functioning; RP, physical role functioning; BP, bodily pain; GH, general health perceptions; VT, vitality; SF, social role functioning; RE, emotional role functioning; MH, mental health; PCS, physical health component summary; MCS, mental health component summary; VAS, visual analogue scale.

^ap < 0.005.

^bp < 0.05.

symptoms, which include malabsorption, GERD, nausea, vomiting, diarrhea, and constipation. GIT symptoms are diagnosed by specific tests and can manifest as various degrees of severity and from the mouth to the anus in SSc patients [1]. These symptoms, if severe, can impose a large burden in terms of mortality, morbidity, and HRQoL [27]; thus, insightful assessments are necessary. The frequency of GIT involvement in patients with SSc is reportedly 2% to 95%; the wide range is likely due to different studies using different diagnostic tools [28]. A physical examination for GIT manifestations can be less specific than for other organs. The present HRM and EGD provide insight into the perception of GIT symptoms and may improve the clinical management of patients with SSc with neither dysmotility nor erosive esophagitis. However, some aspects are insufficient to reflect the symptoms or evaluate the response to treatment. Patient questionnaires can help to establish a more patient-oriented approach and assess the social and psychological contribution to symptoms; therefore, they are an important aspect of clinical decision making [29,30]. The importance of PROs is emphasized by the increasing frequency of assessment of GIT involvement in clinical trials. PROs have the advantages that the questionnaire does not require the time of a physician and can be completed by the patient and returned by mail without the patient attending the hospital. The UCLA SCTC GIT 2.0 instrument can be used to determine a PROs in randomized controlled trials of SSc-associated GIT involvement [5,31]. Self-reported GI QoL tools may be specific for issues related to SSc and could be used to monitor changes over time or during a trial.

The English-language version of the UCLA SCTC GIT 2.0 has been validated in Western cohorts in the US and Canada and has been adapted for use in a number of European countries. The overall burden of GIT symptoms markedly differs by country. East Asian patients with SSc have a lower frequency of erosive esophagitis, dysmotility, and GERD compared with Western patients [32]. Recent HRM studies of Western patients with SSc have demonstrated diverse esophageal motility patterns, with absent contractility being the most prevalent. It is plausible that underlying ethnic differences affect the prevalence of erosive esophagitis; these may include differences in the frequency of *Helicobacter pylori* infection, gastric acid secretion, dietary habit, obesity preva-

lence, and unspecified genetic factors that predispose to erosive esophagitis [33]. The difference is a fundamental problem that requires a trans-cultural adaptation and validation process, particularly in East Asia. Our findings show that the Korean UCLA SCTC GIT 2.0 questionnaire has good internal consistency and test-retest reliability indicating generally acceptable construct validity with SF-36v2 and EQ-5D. Our enrolled patients had a shorter median disease duration (24 months) and lower skin-hardening score (mRSS) than those of other similar studies. For this reason, our patients had a low total GIT score and few complaints of digestive symptoms. In further studies, longitudinal follow-up of patients is needed to monitor development of severe skin and involvement of other organs, including the GIT. Moreover, to apply the Korean UCLA SCTC GIT 2.0 instrument in real-world settings, it is necessary to match the HRM, EGD, and esophageal/gastric transit time in patients with SSc.

In conclusion, the Korean translation of the UCLA SCTC GIT 2.0 instrument has good test-retest reliability and could support a novel PROs GIT assessment for research and routine practice in Korean patients with SSc.

KEY MESSAGE

1. The Korean version of the University of California–Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract (UCLA SCTC GIT 2.0) questionnaire showed good and reproducible reliability.
2. In clinical trials, the UCLA SCTC GIT 2.0 can be used to assess gastrointestinal tract (GIT) involvement in systemic sclerosis (SSc) in Korean patients.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

Acknowledgments

We thank Prof. Inwon Kim (Department of Mathematics, University of California, Los Angeles) and Prof. Haegeun Chung (Department of Environmental Engineering, Konkuk University) for the forward and backward

translation of the instrument.

This study was supported by the Korean Association of Internal Medicine and Soonchunhyang University.

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Supplementary Table 1. The Korean translation form of the UCLA SCTC GIT 2.0

(설문 날짜 년 월 일)

한국판 UCLA SCTC GIT 2.0

	지난 한 주간 당신은 얼마나 자주...	각각의 질문에 해당하는 답을 체크해주세요.				
		하루도 없다 (0)	1-2일 (1)	3-4 일(2)	5-7 일(3)	
역 류	1. 딱딱한 음식을 삼키기가 어려웠나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1/8= 0.125 2/8= 0.25 3/8= 0.35 4/8= 0.5 5/8= 0.625 7/8=0.825 8/8=1.0
	2. 가슴쪽에서 불쾌하게 찌르거나 타는듯한 느낌이 있었나요? (속쓰림)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9/8=1.1125 10/8=1.25 11/8=1.375 12/8=1.5
	3. 쓰거나 신 맛이 위에서부터 올라와 입에서 느껴졌나요? (위산 역류)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13/8=1.625 14/8=1.75 15/8=1.875 16/8=2.0
	4. 토마토나 오렌지 같은 신 음식을 섭취할 때 속쓰림이 있었나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17/8=2.125 18/8=2.25 19/8=2.375 20/8=2.5
	5. 삼킨 음식의 역류 증상이 있었나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	21/8=2.625 22/8=2.75 23/8=2.875 24/8=3.0
	6. 상체를 올리거나 앉은 상태로 잠을 잤나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	7. 구역, 구토할 것 같은 느낌이 있었나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SCORE R=
	8. 구역질이나 구토를 했나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
팽 만	9. 부푼 느낌 (위에 공기가 찬 느낌) 이 있었나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1/4= 0.25 2/4= 0.5 3/4= 0.75 4/4= 1.0 5/4= 1.25 6/4= 1.5 7/4= 1.75 8/4= 2.0 9/4= 2.25 10/4= 2.5 11/4= 2.75 12/4= 3.0
	10. 배가 팽팽하게 나온 것 때문에 벨트나 바지 또는 셔츠를 풀어야 했나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	11. 적은 양의 식사만으로 배가 부른 느낌이 있었나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	12. 부글거리는 느낌이 있거나 잦은 방귀를 뀌었나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SCORE D/B=

Supplementary Table 1. Continued

변실금	13.	화장실에 가기도 전에 실수로 속옷에 지린적이 있나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1/1= 1.0 2/1= 2.0 3/1= 3.0 SCORE S=
설사	지난 한 주간 얼마나 자주...		각각의 질문에 해당하는 답을 체크해주세요.				1/2= 0.5 2/2= 1.0 3/2= 1.5 4/2= 2.0 SCORE D=
			하루도 없다 (0)	1-2일 (1)	3-4 일(2)	5-7 일(3)	
	14.	무른변을 보았나요? (설사)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	지난 한 주간 당신의 대변이...		각각의 질문에 해당하는 답을 체크해주세요.				
			네(1)		아니오(2)		
15.	무르게 변했나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

사회적 기능	지난 한 주간 다음 질문으로 얼마나 자주 사회적 활동에 지장이 있었나요? (친구나 친척 방문 같은)		각각의 질문에 해당하는 답을 체크해주세요.				1/6= 0.16 2/6= 0.33 3/6= 0.5 4/6= 0.66 5/6= 0.83 6/6= 1.0 7/6= 1.16 8/6= 1.33 9/6= 1.5 10/6= 1.66 11/6= 1.83 12/6= 2.0 13/6= 2.16 14/6= 2.33 15/6= 2.5 16/6= 2.66 17/6= 2.83 18/6= 3.0 SCORE SF=
			하루도 없다 (0)	1-2일 (1)	3-4 일(2)	5-7 일(3)	
	16.	구역	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	17.	구토	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	18.	복통	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	19.	설사	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	20.	변을 지릴 것에 대한 두려움	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	21.	팽만감	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Supplementary Table 1. Continued

지난 한 주간 당신은 얼마나 자주...		각각의 질문에 해당하는 답을 체크해주세요.				1/9= 0.11 2/9= 0.22 3/9= 0.33 4/9= 0.44 5/9= 0.55 6/9= 0.66 7/9= 0.77 8/9= 0.88 9/9= 1.0 10/9= 1.11 11/9= 1.22 12/9= 1.33 13/9= 1.44 14/9= 1.55 15/9= 1.66 16/9= 1.77 17/9= 1.88 18/9= 2.00 19/9= 2.11 20/9= 2.22 21/9= 2.33 22/9= 2.44 23/9= 2.55 24/9= 2.66 25/9= 2.77 26/9= 2.88 27/9= 3.0 SCORE EWB=
		하루도 없다 (0)	1-2일 (1)	3-4 일(2)	5-7 일(3)	
감정 행복감	22.	위장 증상 때문에 걱정했나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	23.	위장 증상 때문에 부끄러웠나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	24.	위장 증상 때문에 성관계에 어려움이 있었나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	25.	화장실을 찾지 못할까봐 두려웠나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	26.	위장 증상 때문에 우울하거나 낙담했나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	27.	위장 증상 때문에 여행을 피하거나 미루었나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	28.	위장 증상 때문에 화가 나거나 절망했나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	29.	위장 증상 때문에 수면 장애가 있었나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	30.	위장 증상 때문에 스트레스 받거나 속이 상했나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	지난 한 주간 당신의 대변이...		각각의 질문에 해당하는 답을 체크해주세요.			
		네(1)		아니오(0)		
31.	딱딱해졌나요?	<input type="checkbox"/>		<input type="checkbox"/>		
지난 한 주간 얼마나 자주...		각각의 질문에 해당하는 답을 체크해주세요.				1/4= 0.25 2/4= 0.5 3/4= 0.75 4/4= 1.0 5/4= 1.25 6/4= 1.5 7/4= 1.75 8/4= 2.0 9/4= 2.25 10/4= 2.5 SCORE C=
		하루도 없다 (0)	1-2일 (1)	3-4 일(2)	5-7 일(3)	
32.	변비 때문에 대변을 볼 수 없었나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
33.	딱딱한 대변을 보았나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
34.	배변중 통증이 있었나요?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Supplementary Table 1. Continued

총 점 =	+ 역류	_____
	+ 팽만	_____
	+ 변실금	_____
	+ 설사	_____
	+ 사회적 기능	_____
	+ 감정 행복감	_____
총 점 =	() / 6 =	_____

Scales	None-to-Mild	Moderate	Severe-to-Very severe
역류	0.00-0.49	0.50-1.00	1.01-3.00
팽만	0.00-1.00	1.01-1.60	1.61-3.00
변실금	0.00-1.00	1.01-2.00	2.01-2.50
설사	0.00-0.49	0.50-1.00	1.01-2.00
사회적 기능	0.00-0.49	0.50-1.00	1.01-3.00
감정 행복감	0.00-0.49	0.50-1.00	1.01-3.00
변비	0.00-0.49	0.50-1.00	1.01-3.00
총점	0.00-0.49	0.50-1.00	1.01-3.00

설문에 모두 응해주셔서 대단히 감사합니다.

(SCH Ver 1.0 2017)