Translation, cross-cultural adaptation, and validation of the UCLA Scleroderma Clinical Trial Consortium Gastrointestinal Tract Instrument (SCTC GIT) 2.0 into Dutch

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ABSTRACT

Objective. *To translate and adapt the University of California, Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract Instrument 2.0 (UCLA SCTC GIT 2.0) into Dutch and validate it among Dutch systemic sclerosis (SSc) patients.*

Methods. *First, the UCLA SCTC GIT 2.0 questionnaire was translated and adapted according to international guidelines. The resulting Dutch GIT 2.0 was, in combination with the SSc Health Assessment Questionnaire (SHAQ) and Short Form-36 (SF-36) administered to SSc patients participating in a standardised medical assessment. Moreover, all previous clinical examinations and confirmed medical diagnoses related to GIT were extracted from the medical records. Internal consistency was determined by calculating Cronbach's alpha. To determine the reliability, the questionnaire was re-administered with an interval of two weeks to a subgroup of patients and the intraclass-correlation coefficient (ICC) was computed. Spearman correlation coefficients between GIT scores, SF-36 and SHAQ were computed. GIT scores were compared among patients with and without previous gastrointestinal examinations and/or diagnoses.*

Results. *Eighty-nine patients with a mean age of 53.6 (SD 12) years, and predominantly female (76%) were included. The median total GIT score was 0.17 (Cronbach's alpha 0.921). The test-retest reliability of the total GIT score was good (n=27; ICC 0.749). Overall, the GIT total scores correlated significantly with the SHAQ visual analogue scale intestinal complaints and the SF-36. Significant differences between GIT total and subscale scores of patients with and without previous gastrointestinal examinations and diagnoses were present.*

Conclusion. *The Dutch GIT 2.0 questionnaire showed good internal consistency, construct validity and test-retest reliability.*

Introduction

Systemic sclerosis (SSc) is a rare multisystem connective tissue disorder, affecting primarily the skin but also internal organs (1). SSc affects the gastrointestinal tract (GIT) in approximately 90% of the patients and leads to a decrease in health-related quality of life (HRQOL) (2-3). It is important to identify and evaluate GIT involvement in SSc patients, since it is probable that earlier detection and treatment prevent serious GIT and microvascular complications like pulmonary arterial hypertension (4, 5).

Objective assessments of GIT involvement included for example manometry, scintigraphy, gastro esophageal endoscopy, barium esophagram, measuring gastric emptying, computed tomography (CT), colonoscopy, x-ray and breath test (6-10).

To subjectively assess GIT involvement in SSc patients, Khanna *et al*. developed the SSc-GIT 1.0 (11) in 2007. First, a 52-item questionnaire was generated by extensive literature search, expert opinions and two focus groups. In 2009 Khanna *et al*. made a shorter and improved version; the University of California, Los Angeles (UCLA) Scleroderma Clinical Trail Consortium (SCTC) GIT 2.0 (12), comprising 34 items. The UCLA SCTC GIT 2.0 was shown to have a good test-retest reliability (13). Moreover, the total and the subscale scores were found to discriminate between patients with mild, moderate and severe self-rated GIT involvement (12). Therefore, its usage in clinical trials and day-to-day care was advocated (11, 12).

In 2011 Bae *et al*. translated the UCLA

SCTC GIT 2.0 questionnaire into French and validated this questionnaire among French SSc patients (13). However, no Dutch GIT questionnaire has been available until now. Moreover, the original English questionnaire and the French version were validated using the Short Form-36 (SF-36), which is a generic instrument to asses health related quality of life. Neither Khanna nor Bae assessed construct validity with the GIT complaints objective measurements or confirmed diagnoses. Recently, Bae validated two subscales of the original English UCLA SCTC GIT 2.0, namely the reflux and distention/bloating subscale, with objective evaluations (14).

In order to improve the management of (Dutch speaking) SSc patients with GIT involvement, it is important to have a validated and reliable screening measurement of GIT involvement. Therefore, the aim of this study was first to translate the UCLA SCTC GIT 2.0 from English into Dutch. Secondly, this translation was validated not only by using the SF-36, but also by correlating the items of the subscales with objective measurements on GIT involvement and GIT diagnoses.

Patients and methods

Study design

The study had a cross-sectional design and was carried out in two phases, first the translation and adaptation into the target language were made, and second, a validation of the translated UCLA SCTC GIT 2.0 was carried out.

The study was performed as part of a larger prospective cohort study aiming to describe the course of the disease in patients with SSc, for which ethical approval was obtained from the Institutional Review Board of the Leiden University Medical Center. All participants gave written informed consent.

Translation and cross-cultural adaptation

The questionnaire UCLA SCTC GIT 2.0 is consisting of 34 items on 7-multi-item subscale; reflux (8 questions), distention/bloating (4 questions), fecal soilage (1 question), diarrhoea (2 questions), social functioning (6 questions), emotional well-being (9 questions) and constipation (4 questions). The items are scored from 0 to 3, with lower values indicating fewer gastrointestinal complaints (11, 12, 15), except for questions 15 (diarrhoea subscale) and 31 (constipation subscale), which are scored on 0 (better health) and 1 (worse health) possible range. The total score averages 6 of 7 scales (excluding the constipation subscale) and is scored from 0 to 2.83 (16).

The UCLA SCTC GIT 2.0 questionnaire was translated and cross-culturally adapted according to international guidelines by Beaton *et al*. (17). First, two bilingual, native Dutch speaking translators, one rheumatologist [A.A.S.] and one uninformed person (naive translator) [J.V.] translated the UCLA SCTC GIT 2.0 from English into Dutch. Secondly, the two translators synthesised the results of the translations and reached consensus on one draft version in Dutch. Thirdly, this draft Dutch version was back translated into English by two native English speaking translators, one rheumatologist [J.M.] and one naive translator [T.R.]. Then, an expert panel consisting of all translators, a methodologist [T.V.V.] and one rheumatologist [A.J.M.S.] evaluated the preliminary version of the questionnaire regarding grammatical issues, cultural relevance and content validity for the Dutch population, with decisions on adjustments made by consensus.

Field-testing

Aiming to obtain comments from at least 15 patients, 17 patients with SSc who were regularly visiting the outpatient clinic and were fluent in Dutch were invited for the field-testing. They received the Dutch questionnaire by regular mail and were asked to fill in the questionnaire, to record the time needing to fill in the questionnaire (minutes) and to give written comments to every item of the preliminary Dutch UCLA SCTC GIT 2.0. Respondents were also asked if they felt the question was inappropriate or too difficult to answer or that any important issues had been omitted. Patients could clarify their comments in a telephone interview that was performed after two weeks. The comments and suggestions resulting from the field-testing were subsequently discussed with the expert panel and the developer of the original questionnaire [D.K.], resulting in a final Dutch questionnaire.

Validation

Patients

Consecutive patients with SSc who were treated in the LUMC and who took part in a standardised clinical assessment programme between January 2012 and June 2013 were invited to participate in the present study. All patients had a diagnosis of diffuse cutaneous SSc (DcSSc) or limited (cutaneous) SSc (LcSSc) and were classified according to the American College of Rheumatology (ACR) classification criteria (18) or LeRoy classification of early or limited systemic sclerosis (19). The comprehensive assessment included an extensive medical evaluation as well as an assessment of physical and psychosocial functioning and quality of life.

Assessment methods

All patients were asked to complete the final Dutch UCLA SCTC GIT 2.0 during their visit to the hospital (patients visiting the hospital between January and June 2013) or at home (all other patients). The latter group was also asked to complete the questionnaires on quality of life and physical functioning from the routine annual assessment again, in order to date all questionnaires from the same time period.

Sociodemographic and disease characteristics

Sociodemographic and clinical data were derived from the medical records, which included all data gathered in connection with the routine yearly examination (physical and additional medical examinations and questionnaires).

The laboratory investigations included the presence of the autoantibodies ANA (antinuclear antibody), anti-topoisomerase I (anti-Scl70) and anti-centromere measured at baseline and the laboratory values haemoglobin (Hb), C-reactive protein (CRP), creatinin and creatine phosphokinase (CPK). Cardiopulmonary investigations included HRCT-thorax, lung function, Cardio-

pulmonary Exercise Test (CPET), echocardiography and electrocardiography (ECG). The presence of alveolitis and fibrosis on HRCT-thorax were scored by a radiologist.
For all of these measures, the results obtained at the visit closest to filling out the questionnaire were used.

Gastrointestinal symptoms and diagnoses
The history of any gastrointestinal investigations and/or diagnoses as confirmed by a gastroenterologist were obtained from the patients' medical records. Investigations included esophagography, manometry, scintigraphy, breath test (lactulose/glucose), gastroesophageal endoscopy, colonoscopy, x-ray (with or without adding barium), CT scan and Magnetic Resonance Imaging (MRI) of the abdomen.
Diagnoses included hiatus hernia (oesophagei or diaphragmatica), esophagitis, gastritis, gastroparesis (delayed gastric emptying), dysphagia, motility disorders, gastric antral vascular ectasia, small intestinal bacterial overgrowth and intestinal pseudo-obstruction. No malignancies were reported.

Quality of life and physical functioning
Quality of life was measured with the SF-36, which contains eight subscales: physical functioning, role limitation due to physical problems, bodily pain, general health perception, vitality, social functioning, role limitation due to emotional problems, and mental health (20). The scoring range of the SF-36 subscales is [0-100], with higher scores indicating better quality of life. The subscales can be converted into two summary scales: the physical component summary (PCS) and mental component summary (MCS) scale, standardised to a score with a mean of 50 and a standard deviation of 10 in the general population. For that purpose, the scores from an age- and sex-matched, normative sample, drawn from a large, random, nationwide sample of adults (n=1742) from the general Dutch population Frequency Table and factor score coefficients were used (21). The psychometric properties of this questionnaire have been found to be adequate in SSc patients (22).
In addition, patients were asked to fill in the Scleroderma Health Assessment Questionnaire (SHAQ); a 20-item questionnaire comprising eight domains of activities of daily living, with the final score ranging from 0 (no disability) to 3 (severe disability) with scleroderma-symptom visual analogue scales (VAS 0-100 mm) in addition; Raynaud's disease, digital ulcers, intestinal complaints, pulmonary complaints, overall complaints, and pain (23). The SHAQ has been found to be a reliable outcome measure for disease severity in SSc (24).

Statistical analysis
According to their distribution, continuous variables were either presented as mean and standard deviation (SD) or medians with interquartile range (p25-p75).
In case of more than 10% missing questions, the questionnaires were excluded. For all other missing items the method imputation using the overall sample median was applied (25), resulting in a zero for every missing question. The subscale constipation was excluded for imputation, since this subscale was not included in the calculation of the total GIT score.
The internal consistency was determined by calculating Cronbach's alpha of the total score and seven subscales of the UCLA SCTC GIT 2.0. The internal consistency was considered to be good when Cronbach's alpha is between 0.70 and 0.95 (26). Floor and ceiling effects were considered present if 15% of the respondents achieved the lowest or highest possible score (26). In order to test the reliability, intraclass correlation coefficients (ICC) were computed between the scores of questionnaire completed at baseline and after two weeks. A value of >0.70 was considered the minimum acceptable value (26).
Two aspects of construct validity were used: discriminative or divergent validity (to be able to distinguish between groups with expected differences in scores) and construct or convergent validity (how strongly a measure correlates with other related measures) (26). In order to test divergent validity, GIT scores of the subscales and a total score were compared among patients with and without previous gastrointestinal examinations and/or diagnoses. In order to test convergent validity, correlations of the GIT scores and SF-36 and SHAQ were examined.
The following hypotheses for convergent construct validity were tested with Spearman's correlation coefficient:
a) The GIT subscales and total score correlate strongly with the VAS intestinal complaints of the SHAQ;
b) The GIT total score correlates moderately with the PCS scale;
c) The GIT total score correlates weakly with the MCS scale;
d) The GIT subscale social functioning correlates strongly with the social functioning subscale of the SF-36;
e) GIT total score correlates strongly with unintended weight loss >10% during the last year;
f) GIT subscale reflux correlates strongly with alveolitis and/or fibrosis on HRCT (27-29).
All statistical analyses were executed using SPSS 20.0 software (SPSS Inc., Chicago, USA).

Results
Translation
The discussion on the preliminary version of the translation of the UCLA SCTC GIT 2.0 and the backward translations did not yield any significant changes.
The field-testing of the resulting Dutch version was done among 17 SSc patients between August and October 2012. The mean and median reported times needed to fill in the questionnaire were 18 and 20 minutes, respectively with a range of 5 to 30 minutes. Three patients preferred a comment line in the questionnaire. None of the questions were thought to be ambiguous. Four persons noted that some questions showed overlap: Questions 2 and 3 (n=1), 14 and 15 (n=1), 26 and 28 (n=1) and 31 and 33 (n=1). Five persons argued that a one-week time interval was too short, because of having no complaints in the past week, but they had experienced severe complaints in the last month.

Table I. Sociodemographics and disease characteristics of patients with systemic sclerosis, DcSSc and LcSSc.

	Total n=89	DcSSc n=39	LcSSc n=50	*p*-value
Age, years, mean (SD)	53.6 (11.9)	51.4 (12.0)	55.2 (11.6)	0.776
Female, n (%)	67 (75.3)	24 (61)	43 (86)	0.000
Disease duration, months, median (25-75th percentile)	71 (30-133)	95 (50-138)	50 (15-123)	0.111
Onset of Raynaud's phenomenon, years, median (25-75th percentile)	10.5 (8-17)	10 (7.5-14)	16.5 (9-23)	0.487
Onset of non-Raynaud's phenomenon, years, median (25-75th percentile)	7.5 (5-11)	9.0 (6-12)	6.5 (4-11)	0.041
Caucasian origin, n (%)	63 (70.8)	28 (71.8)	35 (70)	0.853
Education level, n (%)				0.916
Low	33 (39.3)	14 (36.8)	19 (41.3)	
Medium	32 (39.1)	15 (39.5)	17 (37.0)	
High	19 (22.6)	9 (23.7)	10 (27.7)	
Lifestyle, n (%)				
Paid employment	33 (39.8)	17 (47.7)	15 (33.3)	0.193
Practicing sport	45 (54.2)	16 (42.1)	29 (64.4)	0.042
Diet	25 (28.7)	9 (21.3)	16 (33.3)	0.293
Physical examination				
MRSS, median (25-75th percentile)	4 (0-6)	6 (2-7)	2 (0-5)	0.001
Pulmonary crackles, n (%)	28 (31.8)	13 (33.3)	15 (30.6)	0.946
Autoantibodies, n (%)				
ANA	77 (89.5)	32 (82.1)	45 (95.7)	0.039
Anti-Scl70**	22 (24.7)	16 (41.0)	6 (12.0)	0.005
Anti-centromere **	22 (24.7)	2 (5.1)	20 (40.0)	0.000
Laboratory results				
Hb, g/L, mean (SD)	133.0 (12.0)	131.5 (13.7)	134.1 (10.4)	0.146
CRP, mg/dl, median (25-75th percentile)	3 (3-4)	3 (3-5)	3 (3-3)	0.267
Creatinin, umol/l, median (25-75th percentile)	73 (59-86)	72 (63-79)	72 (62-82)	0.147
CPK, mg/dl, median (25-75th percentile)	99.7 (59-114)	113.9 (64-144)	87.0 (54-99)	0.014
Pulmonary investigations				
Vital capacity, % of expected, mean (SD)	97 (108)	90 (21)	103 (19)	0.634
DLCO, % of expected, mean (SD)	66 (17)	64 (16)	67 (18)	0.448
Fibrosis (HRCT), n (%)	31 (34.8)	17 (43.6)	14 (28.0)	0.178
Alveolitis (HRCT), n (%)	40 (44.9)	26 (66.7)	14 (28.0)	0.001
Current treatment, n (%)				
Azathioprine	6 (5.7)	1 (2.6)	5 (10.0)	0.165
Methotrexate	5 (5.6)	3 (7.7)	2 (4.0)	0.453
Prednisone	12 (13.5)	6 (15.4)	6 (12.0)	0.643
Proton-pump inhibitor	66 (74.2)	29 (74.4)	37 (74)	0.969
Prokinetics	3 (3.4)	2 (5.1)	1 (2)	0.417
NSAID	10 (11.2)	4 (10.3)	6 (12)	0.796
Calcium channel blocker	54 (60.7)	19 (48.7)	15 (30)	0.041
Previous treatment, n (%)				
Cyclophosphamide	10 (11.6)	10 (25.6)	0 (0)	0.000
Autologous stem cell transplantation	12 (14.0)	12 (30.8)	0 (0)	0.000
SHAQ (0-3), median (25-75th percentile)	0.38 (0.13-0.88)	0.38 (0.13-0.88)	0.44 (0.13-0.88)	0.509
VAS Raynaud's disease (0-100)	52 (17-74)	33 (3-74)	54 (28-74)	0.027
VAS digital ulcers (0-100)	3 (0-44)	1 (0-30)	8 (1-49)	0.172
VAS intestinal complaints (0-100)	11 (1-48)	5 (1-27)	18 (2-55)	0.042
VAS pulmonary complaints (0-100)	6 (1-48)	4 (1-51)	7 (1-47)	0.313
VAS overall complaints (0-100)	32 (12-89)	28 (8-54)	34 (20-62)	0.905
VAS pain (0-100)	22 (4-48)	6 (2-29)	28 (15-38)	0.425
SF-36 (0-100), median (25-75th percentile)				
Physical Component Summary Scale	42.8 (36.4-51.8)	44.7 (37.1-52.2)	42.0 (35.5-50.61)	0.920
Mental Component Summary Scale	51.7 (43.2-56.8)	52.3 (43.9-57.5)	50.7 (43.0-55.8)	0.211
Physical functioning	48.1 (41.1-55.1)	45.8 (36.4-54.6)	49.3 (41.1-55.1)	0.421
Role-physical	42.9 (29.2-56.7)	49.8 (29.2-56.7)	36.1 (29.2-56.7)	0.992
Bodily pain	49.0 (43.9-54.1)	53.3 (44.74-58.4)	49.0 (39.6-53.3)	0.091
General health	39.3 (32.4-48.5)	39.3 (32.4-43.9)	39.3 (32.4-50.8)	0.668
Vitality	43.1 (35.7-53.0)	45.6 (35.7-53.0)	41.9 (35.8-53.0)	0.631
Social functioning	46.9 (41.5-52.4)	52.4 (41.5-57.8)	46.9 (41.5-52.4)	0.518
Role-emotional	55.4 (45.6-55.4)	52.9 (46.3-59.4)	55.4 (45.6-55.4)	0.230
Mental health	50.7 (44.1-57.3)	52.8 (46.3-59.4)	50.7 (44.1-50.1)	0.080
GIT Diagnosis, n (%)	27 (30.3)	8 (20.5)	19 (38.0)	0.104
GIT Investigations, n (%)	50 (56.2)	19 (48.7)	31 (62)	0.282

MRSS: Modified Rodnan Skin Score; SHAQ: SSC Health Assessment Questionnaire, VAS: visual analogue scale; SF-36: Short Form-36; GIT: gastrointestinal tract. *1% missing; **20-25% missing.

After consultation of the expert panel and the developer [D.K.], one adjustment to the questionnaire was made as a result of the field testing. This concerned question 1, asking about difficulty with swallowing. Initially, swallowing was translated as 'slikken', which does however not cover the esophageal phase. To better cover the construct swallowing, the Dutch word 'zakken' was added was added to the translation.
The resulting final version of the Dutch UCLA SCTC GIT 2.0 (Dutch GIT 2.0) is shown in the Appendix. The questionnaire is freely available and will be published on the official UCLS SCTC GIT 2.0 website (30).

Validation

Response

All 46 patients visiting the annual assessment programme between January 2013 and July 2013 agreed to participate and completed the Dutch GIT. In addition, 56 patients who had had their annual visit in the previous months were invited by post, of whom 50 returned the questionnaire. Thus, the initial response rate was 94% (96/102). In 21 of the 96 questionnaires (22%) one or more answers were missing. In seven questionnaires more than 10% of the answers was missing, so these patients were excluded from the study, finally resulting in 89 patients. There were no significant differences between included and excluded patients regarding sex, age and type of SSc (data not shown).

Patients

Table I shows the characteristics of the patients. They were mostly women (75.3%), Caucasian (70.8%) and 53% had LcSSc. Patients were on average 53.6 (11.9 SD) years old and had a median disease duration of 71 months. Patients with DcSSc had a significant longer duration of non-Raynaud phenomenon, were more frequently Anti-Scl70 positive and were more frequent diagnosed with alveolitis.

Gastrointestinal examinations and diagnoses

Fifty (56%) patients had undergone one or more gastrointestinal examinations, with esophagography (n=34, 40%) and gastroscopy (n=17, 19%) being the most common procedures. With respect to gastrointestinal diagnoses, one or more confirmed diagnoses were recorded in 27 (30%) of the patients. Of these, motility disorders (n=14, 16%) and hiatus hernia (n=11, 12%) were most frequent (data not shown).

Internal consistency and floor and ceiling effects of the Dutch GIT

Table II shows the results of the Dutch GIT. The median total score was 0.17, with a good internal consistency for all subscales, except for the diarrhoea scale (0.418)
The proportions of patients with the maximum score ranged from 0% to 3%, indicating that no ceiling effect was present. The proportions of patients with the minimum score ranged from 27% to 89%, demonstrating a clear floor effect.

Validity

Analyses of correlation coefficients of the Dutch GIT total score and the MCS and PCS scores of the SF-36 showed that the Dutch GIT was slightly stronger associated with the MCS score (Table III). Furthermore, the total GIT score is strongly correlated with physical role functioning and social functioning.
A weak yet significant association (correlation coefficient ≥0.30) between the VAS GIT-complaints of the SHAQ and the subscale reflux of the Dutch GIT, but not with the other GIT subscale scores or the total score was found (as shown in Table III).
Moderate correlations between emotional well-being subscale of the Dutch GIT and the role-emotional and mental health subscales and the MCS score (correlation coefficient 0.494, 0.640 and 0.620, respectively; Table III) were found. Moreover, the social functioning subscale of the Dutch GIT and social functioning subscale of SF-36 showed a good correlation (0.517).
In order to calculate the divergent validity differences between patients with and without previous GIT examinations and diagnoses were examined (Table IV). Patients who had had one or more GIT examinations scored significantly higher on VAS intestinal complaints, all SF-36 subscales including PCS and MCS scores, on the GIT total score and on all subscales except soiling, social functioning and constipation.
Patients with one or more GIT diagnoses had significantly higher scores than patients without GIT diagnoses on all GIT subscales, except for constipation. There was no difference in SF-36 subscale scores and PCS and MCS score between patients with and without a GIT diagnosis. It was not possible to calculate a correlation between GIT scores and weight loss, since only

Table II. Descriptive statistics and internal consistency reliability of the Dutch UCLA SCTC GIT 2.0.

Scale	Sample size	no. of questions	Mean	SD	Median	Minimum-maximum	25-75th percentile	Floor effect, %	Ceiling effect, %	Cronbach's alpha	ICC (N=27)
Reflux	89	8	0.41	0.47	0.25	0.00-2.50	0.00-0.50	27	0	0.777	0.860
Distention/ bloating	8	4	0.58	0.76	0.25	0.00-3.00	0.00-0.75	41.6	3.4	0.835	0.625
Fecal soilage	89	1	0.2	0.62	0	0.00-3.00	0.00-0.00	88.8	2.2	NA	0.642
Diarrhoea	89	2	0.23	0.43	0	0.00-2.00	0.00-0.50	69.7	2.2	0.418	0.706
Social functioning	89	6	0.16	0.33	0	0.00-1.33	0.00-0.17	69.7	0	0.731	0.390
Emotional well-being	89	9	0.28	0.46	0.13	0.00-2.13	0.00-0.38	44.9	0	0.851	0.752
Constipation	87	4	0.31	0.56	0	0.00-2.50	0.00-0.50	64	2.2	0.817	0.605
Total GIT scoreΔ	89	30	0.31	0.39	0.167	0.00-1.73	0.04-0.40	18	0	0.921	0.749

ICC: intraclass correlation coefficient; NA: not applicable; Δ excluding constipation scale.

Table III. Spearman's correlation coefficients between the Dutch UCLA SCTC GIT 2.0 and SHAQ, VAS GIT-complaints and SF-36 scales.

GIT 2.0\SHAQ-SF36	Sample size	SHAQ	VAS GIT	PCS	MCS	PF	RP	BP	GH	VT	SF	RE	MH
Reflux	89	0.297**	0.353**	-0.209	-0.213*	-0.156	-0.212*	-0.315**	-0.204	-0.184	-0.246	-0.228*	-0.242*
Distention/ bloating	89	0.343**	0.236*	-0.361**	-0.295**	-0.317	-0.412**	-0.292**	-0.250*	-0.339**	-0.434**	-0.203	-0.313**
Fecal soilage	89	0.130	0.085	-0.072	-0.119	-0.036	-0.254*	0.074	0.047	-0.040	-0.236*	-0.077	-0.073
Diarrhoea	89	0.065	-0.024	-0.254*	-0.091	-0.128	-0.266*	-0.190	-0.072	-0.160	-0.211*	-0.063	0.013
Social functioning	89	0.263	0.207	-0.189	-0.444**	-0.130	-0.413**	-0.306**	-0.139	-0.335**	-0.517**	-0.359**	-0.383**
Emotional well-being	89	0.201	0.083	-0.219	-0.620**	-0.172	-0.461**	-0.317**	-0.268*	-0.399**	-0.510**	-0.494**	-0.640**
Constipation	87	0.247**	0.191	-0.205	0.045	-0.194	-0.216*	-0.067	-0.072	-0.150	;-0.070	0.061	-0.022
Total GIT score Δ	89	0.347**	0.265*	-0.342**	-0.389**	-0.284**	-0.447**	-0.350**	-0.267*	-0.358**	-0.467**	-0.329**	-0.397**

SHAQ: SSC Health Assessment Questionnaire; VAS GIT: visual analogue scale of gastrointestinal complaints; SF-36: Short Form-36; GH: general health perceptions; PF: physical functioning; RP: physical role functioning; BP: bodily pain; VT: vitality; SF: social role functioning; RE: emotional role functioning; MH: mental health. *Correlation is significant at the 0.05 level (2-tailed); **Correlation is significant at the 0.01 level (2-tailed); Δ excluding constipation scale.

Table IV. Descriptive statistics of SHAQ VAS intestinal complaints and Dutch UCLA SCTC 2.0 for patients with and without GIT examinations and diagnosis.

	No GIT examinations* n=39	≥1 GIT examinations* n=50	*p*-value	No GIT diagnosis n=62	≥1 GIT diagnosis n=27	*p*-value
SHAQ (0-3), median (25-75th percentile)	0.38 (0.13-0.63)	0.5 (0.13-1.0)	0.067	0.44 (0.13-0.88)	0.38 (0.13-0.88)	0.803
VAS intestinal complaints (0-100)	2 (0-20)	23 (4.5-61.5)	0.004	3 (1-24)	49 (11-70)	0.000
GIT scores, median (25-75th percentile)						
Reflux	0.13 (0-0.38)	0.44 (0.13-0.66)	0.024	0.19 (0-0.5)	0.5 (0.13-1)	0.007
Distention/bloating	0 (0-0.25)	0.75 (0.025-1.25)	0.002	0 (0-0.75)	0.75 (0.25-1.5)	0.000
Fecale soilage	0 (0-0)	0 (0-0)	0.095	0 (0-0)	0 (0-1)	0.000
Diarrhoea	0 (0-0)	0 (0-0.5)	0.026	0 (0-0.13)	0 (0-0.5)	0.002
Social functioning	0 (0-0)	0 (0-0.33)	0.081	0 (0-0.04)	0 (0-0.67)	0.004
Emotional well-being	0 (0-0.13)	0 (0.13-0.5)	0.004	0 (0-0.15)	0.38 (0.13-0.88)	0.000
Constipation	0 (0-0.25)	0 (0-0.5)	0.116	0 (0-0.25)	0 (0-0.75)	0.092
Total GIT score Δ	0.04 (0-0.21)	0.12 (0.30-0.56)	0.002	0.10 (0.02-0.30)	0.35 (0.23-0.88)	0.000

SHAQ: SSc Health Assessment Questionnaire; VAS: visual analogue scale; GIT: gastrointestinal tract; Δ excluding constipation scale; *GIT examinations included: esophagography, manometry, scintigraphy, breath test (lactulose/glucose), gastroesophageal endoscopy, colonoscopy, x-ray, CT scan and magnetic resonance imaging (MRI) of the abdomen.

8 SSc patients had lost 10% of their weight in the past year. With regard to the presence of alveolitis and fibrosis on HRCT-thorax, there were no significant correlations (p=0.848) (data not shown).

Test-retest reliability

The test-retest reliability of the total GIT score was acceptable (ICC: 0.749). However, the subscales distention/bloating, fecal soilage and constipation had an ICC lower than 0.7, and the subscale social functioning scored little or absent (ICC<0.4) reliability (Table II).

Discussion

The Dutch UCLA SCTC GIT 2.0 questionnaire showed good internal consistency, high reliability and an acceptable construct validity measured by SF-36 and SHAQ. Furthermore, the Dutch GIT showed a good divergent validity, indicating that this questionnaire is discriminating between patients with and without GIT diagnoses.

Our results are largely in line with the original UCLA SCTC GIT 2.0 and the French version. Both studies found a good reliability and validity. Khanna *et al*. (12) found higher ICC's of the subscales compared to our study where ICC's ranged from small (social functioning subscale) to moderate (distention/bloating, fecal soilage and constipation subscales) to good (reflux, diarrhoea, emotional well-being and total GIT score). This is probably due to the fact that the severity of the GIT complaints is disseminating from week to week, as mentioned by some patients during the field-testing. Probably GIT complaints changed in the patients who were included for the test-retest over a two week period. In case of unstable disease, the ICC will be lower than expected. Unfortunately no data about any change of GIT complaints within those two weeks was available.

Another explanation might be the low variance, *i.e*. floor effects were highly present; our subjects scored lower compared to patients in previous studies (12, 13, 31). We hypothesised that our patients have fewer complaints enhanced by the annual clinical assessment programme. Patients underwent extensive history and examination leading to a change in treatment (if applicable). For example, most of our patients were treated with proton pump inhibitors (PPI) (74% of the patients).

Previous literature showed that higher symptom severity of reflux and constipation was associated with depressive

mental status (3). This is in line with our study, since the scores of the subscales and the total score of the Dutch GIT were stronger associated with the MCS score, compared to the PCS score of the SF-36. This is suggesting that GIT involvement had greater impact on mental health compared to physical health.

To the best of our knowledge, this is the first study that validated the UCLA SCTC GIT 2.0 questionnaire based on clinical examinations and GIT diagnoses. Bae *et al*. (14) found a correlation between the subscales reflux and distention/bloating of the UCLA SCTC GIT 2.0 and objective assessments for gastrointestinal involvement. Our study showed a significant difference of all subscales of the Dutch GIT, except for constipation, between patients with and without GIT diagnoses. This finding is suggesting that the Dutch GIT can be used in clinical practice.

This study has several limitations which should be taken into account.

First, a selection bias cannot be excluded. All patients included in our study were referred to an academically clinical assessment programme. For this study a selection of patients who were treated by a rheumatologist in our university hospital was made. Possibly, only the worst patients were referred to our hospital. The patient population may however be comparable to SSc patients under the care of rheumatologists in general hospitals, as our hospital is the only hospital offering rheumatology services in the Leiden region.

Second, seven patients were excluded from the analysis since more than 10% of the questions were missing. Although these patients were not different in sociodemographic characteristics, bias at indication could not be totally ruled out.

Third, divergent validity could not be confirmed by weight loss due to two main reasons. Only few people had lost weight and therefore no correlation could be found. Furthermore, there was no association found between alveolitis/fibrosis and the Dutch GIT. Our hypothesis was that this is possibly due to the used method, the presence of ILD was scored by using "yes or no" instead of a standardised scoring system, for example the Kazerooni method (32).

Fourth, only half of the patients received additional gastrointestinal examinations, since these investigations were not standardised in the day care programme. For this reason not all patients could have been diagnosed with GIT involvement. We think that patients only suffering a lot of GIT complaints would have had GIT examinations.

Further investigations with regard to the validity would be recommended. We recommend to validate the questionnaire in other SSc populations and to use other objective measurements for divergent validity. In order to analyse the progression of the GIT complaints over time, research on the minimally important differences is recommended. There is an difference in scores found in American SSc patients after 6 months (12, 33). A pilot study found an improvement on the bloating/distention subscale in SSc patients treated with probiotics (34). More research on the additional contribution of the questionnaire at GIT treatment should be done.

In conclusion, the Dutch UCLA SCTC GIT 2.0 questionnaire is a validated questionnaire and thus can be used in day-to-day care of SSc patients.

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VRAGENLIJST MAAG-DARMKLACHTEN BIJ SCLERODERMIE

(THE UCLA SCTC GIT 2.0 QUESTIONNAIRE)

Naam: _____ Datum: _____

De volgende vragen hebben betrekking op uw maag- en darmklachten en hoe deze uw dagelijks leven de laatste 7 dagen hebben beïnvloed. Graag iedere vraag beantwoorden door één van de mogelijkheden aan te kruisen. Als u niet zeker bent hoe de vraag te beantwoorden, kies het antwoord dat het meest op u van toepassing is.

		Hoe vaak heeft u de afgelopen week …	(KRUIS ÉÉN ANTWOORD AAN BIJ ELKE VRAAG)				
			Geen enkele dag[0]	1-2 Dagen[1]	3-4 Dagen[2]	5-7 Dagen[3]	
REFLUX	1.	… moeite gehad met doorslikken van vast voedsel?					1/8= 0.125 2/8= 0.25 3/8= 0.35 4/8= 0.5 5/8= 0.625 6/8= 0.75 7/8= 0.875 8/8= 1.0 9/8= 1.125 10/8= 1.25 11/8= 1.375 12/8= 1.5 13/8= 1.625 14/8= 1.75 15/8= 1.875 16/8= 2.0 17/8= 2.125 18/8= 2.25 19/8= 2.375 20/8= 2.5 21/8= 2.625 22/8= 2.75 23/8= 2.875 24/8= 3.0 SCORE R=
	2.	… een irriterend of brandend gevoel ervaren in de borst/ maagstreek (maagzuur)?					
	3.	… het gevoel gehad dat een bittere of zure vloeistof vanuit uw maag in de mond kwam (zure oprisping)?					
	4.	... last gekregen van maagzuur na het eten van 'zuur' voedsel als tomaat of sinaasappel?					
	5.	… opgeven (uitbraken of omhoog komen van kleine hoeveelheden eerder genuttigd voedsel)?					
	6.	… met verhoogd hoofdeinde of 'zittend' geslapen?					
	7.	… het gevoel gehad te moeten braken of overgeven?					
	8.	… gebraakt of overgegeven?					

OPGEBLAZEN GEVOEL	9.	… een opgeblazen gevoel gehad (het gevoel dat er lucht in uw maag zat)?					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 SCORE D/B=
	10.	… gemerkt dat uw buik opgezet was, waardoor u soms uw riem, broek of bloes/overhemd moest losmaken?					
	11.	… een vol gevoel gekregen na het eten van een kleine maaltijd?					
	12.	… extreme winderigheid gehad?					

SOILAGE

	Hoe vaak heeft u de afgelopen week …	(KRUIS ÉÉN ANTWOORD AAN BIJ ELKE VRAAG)				
		Geen enkele dag[0]	1-2 Dagen[1]	3-4 Dagen[2]	5-7 Dagen[3]	1/1= 1.0 2/1= 2.0 3/1= 3.0 SCORE S=
13.	… uw ondergoed bevuild omdat U niet op tijd bij een toilet kon komen?					

DIARREE

	Hoe vaak heeft u de afgelopen week …	(KRUIS ÉÉN ANTWOORD AAN BIJ ELKE VRAAG)				
		Geen enkele dag[0]	1-2 Dagen[1]	3-4 Dagen[2]	5-7 Dagen[3]	
14.	… niet-vaste ontlasting (diarree) gehad?					

	Heeft u in de afgelopen week gemerkt dat uw ontlasting …	(KRUIS ÉÉN ANTWOORD AAN BIJ ELKE VRAAG)		1/2= 0.5 2/2= 1.0 3/2= 1.5 4/2= 2.0 SCORE D=
		Ja[1]	Nee[0]	
15.	… waterig is geworden?			

SOCIAAL FUNCTIONEREN

	Hoe vaak werd u in de afgelopen week tijdens sociale activiteiten (zoals het bezoeken van vrienden of familie) gehinderd door?	(KRUIS ÉÉN ANTWOORD AAN BIJ ELKE VRAAG)				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=
		Geen enkele dag[0]	1-2 Dagen[1]	3-4 Dagen[2]	5-7 Dagen[3]	
16.	... misselijkheid					
17.	... overgeven					
18.	... maagpijn					
19.	... diarree					
20.	... angst om per ongeluk uw ondergoed te bevuilen					
21.	... opgeblazen gevoel					

EMOTIONEEL WELBEVINDEN

Hoe vaak heeft u de afgelopen week …		(KRUIS ÉÉN ANTWOORD AAN BIJ ELKE VRAAG)				
		Geen enkele dag[0]	1-2 Dagen[1]	3-4 Dagen[2]	5-7 Dagen[3]	
22.	… maakte u zich zorgen of zenuwachtig over uw darmklachten?					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=
23.	… heeft u zich geschaamd voor uw darmklachten?					
24.	… heeft u problemen gehad in de seksuele omgang door uw darmklachten?					
25.	… was u bang om geen toilet te kunnen vinden?					
26.	… voelde u zich somber of ontmoedigd door uw darmklachten?					
27.	… heeft u activiteiten buitenshuis vermeden of uitgesteld vanwege uw darmklachten?					
28.	… heeft u zich boos of gefrustreerd gevoeld door uw darmklachten?					
29.	… heeft u problemen gehad met slapen door uw darmklachten?					
30.	… heeft u het gevoel gehad dat de darmklachten verergerden doordat u van streek was of last had van ‘stress’?					

VERSTOPPING

Heeft u in de afgelopen week gemerkt dat de ontlasting…		(KRUIS ÉÉN ANTWOORD AAN BIJ ELKE VRAAG)		
		Ja[1]	Nee[0]	
31.	… harder is geworden?			→

Hoe vaak heeft u de afgelopen week…		(KRUIS ÉÉN ANTWOORD AAN BIJ ELKE VRAAG)				
		Geen enkele dag[0]	1-2 Dagen[1]	3-4 Dagen[2]	5-7 Dagen[3]	
32.	… last gehad van verstopping?					1/4= 0.25 2/4= 0.50 3/4= 0.75 4/4= 1.0 5/4= 1.25 6/4= 1.50 7/4= 1.75 8/4= 2.0 9/4= 2.25 10/4= 2.5 SCORE C=
33.	… last gehad van harde ontlasting?					
34.	… pijn gehad bij de stoelgang?					

Dank u voor het invullen van deze vragenlijst

In te vullen door arts

TOTAL SCORE =	Reflux	_____
+	Distention /Bloating	_____
+	Fecal Soilage	_____
+	Diarrhea	_____
+	Social Functioning	_____
+	Emotional well-being	_____
	TOTAL SCORE=	(_____) /6=_____

REMEMBER: CONSTIPATION SCORE IS NOT INCLUDED IN CALCULATION OF TOTAL SCORE

C: Constipation; D: Diarrhoea; D/B: Distention/Bloating; EM: Emotional well-being; R: Reflux; SF: Social Functioning; S: Fecal soilage.