
Development and validation of French version of the UCLA Scleroderma Clinical Trial Consortium Gastrointestinal Tract Instrument

S. Bae¹, Y. Allanore², B. Coustet², P. Maranian¹, D. Khanna¹

¹David Geffen School of Medicine at UCLA, Los Angeles, CA, USA;

²Université Paris Descartes, Rhumatologie A, Hôpital Cochin, APHP, Paris, France.

Sangmee Bae, MBBS
Yannick Allanore, MD, PhD
Baptiste Coustet, MD
Paul Maranian, MS
Dinesh Khanna, MD, MS

Please address correspondence and reprint requests to:

Dinesh Khanna, MD, MS,
Division of Rheumatology,
1000 Veteran Avenue, Rm 32-59,
Rehabilitation Building,
Los Angeles, CA 90095, USA.
E-mail: dkhanna@mednet.ucla.edu

Received on November 15, 2010; accepted in revised form on February 14, 2011.

Clin Exp Rheumatol 2011; 29 (Suppl. 65): S15-S21.

© Copyright CLINICAL AND EXPERIMENTAL RHEUMATOLOGY 2011.

Key words: Systemic sclerosis, scleroderma, gastrointestinal, quality of life, questionnaire, French, UCLA-SCTC-GIT 2.0, UCLA scleroderma gastrointestinal

ABSTRACT

Objective. The UCLA Scleroderma Clinical Trial Consortium Gastrointestinal Tract Instrument (UCLA-SCTC-GIT) 2.0 was developed to assess systemic sclerosis (SSc) associated gastrointestinal tract (GIT) symptoms severity and its impact on patients' well-being. Our objective was to translate the UCLA-GIT 2.0 from English to French and to evaluate the reliability and validity of the French version.

Methods. UCLA-GIT 2.0 was adapted into French using a formal forward-backward translation method and administered to 76 French speaking patients with SSc. The patients also completed the SF-36. We evaluated the internal consistency reliability and construct validity by exploring associations between the UCLA SCTC GIT 2.0 and SF-36 scales. Patients were also classified into two groups based on unintended weight loss within the past 6 months ($\geq 5\%$ vs. $< 5\%$ of total body weight).

Results. Participants were mostly white (90%), female (81%) and had limited SSc (50%). Mean score of the UCLA-GIT 2.0 scales were: 0.35 for faecal soilage, 0.44 for diarrhoea, 0.45 for emotional well-being, 0.48 for both constipation and social functioning, 0.52 for reflux, and 0.95 for distention/bloating. The instrument had acceptable reliability (defined as Cronbach alpha ≥ 0.69) except for the diarrhoea scale (alpha = 0.56). The majority of hypothesized correlations were of moderate magnitude (coefficient ≥ 0.30) and were in the appropriate direction. Patients with $\geq 5\%$ unintended weight loss had worse UCLA-GIT scores in all scales ($p < 0.05$ for distention/bloating scale).

Conclusion. The French version of the UCLA-GIT 2.0 has acceptable psychometric properties and can be used in French speaking SSc patients.

Introduction

Systemic sclerosis (scleroderma; SSc) is a multisystem connective tissue disorder characterised by inflammation, fibrosis, and a diffuse vasculopathy. Approximately 90% of patients develop gastrointestinal tract (GIT) manifestations (1) which involve both upper and lower GI tract – a pattern unique to SSc compared to other GIT diseases. GIT symptoms in patients with SSc may be associated with decrements health-related quality of life (HRQOL) (2-4). We have recently developed a SSc-GIT instrument called the University of California, Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract Instrument (UCLA GIT 2.0) (5, 6). UCLA GIT 2.0 consists of 34 items with 7 scales: reflux, distention/bloating, diarrhoea, faecal soilage, constipation, emotional well-being, and social functioning and was developed to assess GIT symptoms severity and its impact on HRQOL. The instrument is feasible and showed acceptable reliability and validity in one study (5). UCLA 2.0 is also being incorporated in the ongoing clinical trials and observational registries of SSc.

The aims of the present study were; 1) to translate and adapt the UCLA GIT 2.0 from English to French, and 2) to assess reliability and construct validity of the French version of UCLA GIT 2.0. We assessed the construct validity by: a) exploring the correlations between the UCLA-GIT 2.0 and the SF-36 scales, and b) comparing UCLA-GIT 2.0 scale scores between patients with $< 5\%$ of unintended weight loss vs. $\geq 5\%$ weight loss in the last 6 months.

Subjects and methods

We recruited 76 consecutive patients with SSc referred to the "Rheumatology A" Department at Cochin Hospital (Paris) over a 6-month period for clini-

Competing interests: Dr D. Khanna has received grant/research support from the NIH, SCTC, and Scleroderma Foundation; the other co-authors have declared no competing interests.

cal care. All patients provided written informed consent and the study was approved by the local ethics committee. We collected the following data: age, sex, cutaneous SSc subtype as defined by LeRoy (7), disease duration (date of first non-Raynaud symptom), serum C-reactive protein (CRP), modified Rodnan skin score, digital ulceration (past or current) and medication use (antisecretory, prokinetics, oral low-dose corticosteroids calcium channel blockers, antibiotics, antidepressants, immunosuppressant therapy-hydroxy-chloroquine, azathioprine, methotrexate, mycophenolate mofetil and rituximab). We also asked the patients if they had any unintended weight loss and if the weight loss was $<5\%$ vs. $\geq 5\%$ weight loss during the last 6 months. Pulmonary fibrosis was assessed by high-resolution computed tomography (HRCT) scan and pulmonary function tests (forced vital capacity and carbon monoxide diffusion capacity divided by alveolar volume). All patients were tested for antinuclear antibodies by indirect immunofluorescence. We also analysed anti-centromere antibodies (ACA) based on their distinctive immunofluorescence pattern and anti-topoisomerase I antibodies by counter-current immunoelectrophoresis.

Health Related Quality of Life (HRQOL) Instruments

Patients completed the UCLA GIT 2.0 and Medical Outcomes Short Form (SF)-36. UCLA GIT 2.0 is a validated, patient-reported outcome measure to assess HRQOL and GIT symptoms severity in SSc (5, 6). This 34-item instrument has seven scales: reflux, distention/bloating, diarrhoea, faecal soilage, constipation, emotional well-being, and social functioning and a total GI score. All scales are scored from 0 (better HRQOL) to 3 (worse HRQOL) except diarrhoea and constipation scales that ranges from 0–2 and 0–2.5, respectively. The total GI score is the average of 6 of 7 scales (excludes constipation) and total GI score are scored from 0 (better HRQOL) to 3 (worse HRQOL). The English version is available online at: <http://uclascderma.researchcore.org/>. The SF-36 is a generic health status

measure consisting of 36 items assessing 8 domains (8, 9). The SF-36 consists of 4 physical health scales (physical functioning [10 items], bodily pain [2 items], role limitations due to physical health perceptions [4 items], and general health perceptions [5 items]), 4 mental health scales (mental health [5 items], role limitations due to emotional problems [3 items], vitality [4 items], and social functioning [2 items]), and a health transition scale [1 item]. The 4 physical health scales are summarised into Physical Component Summary (PCS) and 4 mental health scales are summarised into Mental Component Summary (MCS) scores. The summary scores are normalised to the US general population, for whom the mean \pm SD score is 50 ± 10 . In a previous study, the French norms were found to be very similar to those obtained in the US population (10–12). Therefore, we used US general population norms for SF-36 scales and summary scores. We used a standard (4-week) recall period.

Translation

We developed the French version of UCLA GIT 2.0 instrument using the “forward-backward method” (13). Two initial forward translations were made independently by two translators (Allanore Y, Coustet B). The two translators were native speakers of the target language (French). Following this, 2 translators reviewed each item and discussed items that were confusing in interpretation or vague items and reached a consensus. The translated (intermediate) instrument was administered to 10 nonbilingual SSc subjects. No concerns were raised regarding clarity/understanding of the items. We also assessed for clarity of the instrument in 15 healthcare professional at the Cochin Hospital. No ambiguities were highlighted. This version was then back-translated by two independent bilingual translators, and this English version was critically evaluated by 2 native English speakers without any additional modification (Appendix).

Statistical methods

Mean scores, standard deviations (SD), ranges, and percentages of respondents

scoring the minimum (floor) and maximum (ceiling) possible scores were calculated to evaluate scale score distributions. Internal consistency reliability was estimated using Cronbach's alpha (14). We assessed the construct validity by exploring the association between the UCLA SCTC GIT 2.0 and SF-36 scales. Correlations ≤ 0.29 were considered to be small, between 0.30 and 0.49 moderate, and ≥ 0.50 as large (15). We hypothesized *a priori* moderate product-moment correlations (coefficient ≥ 0.30) between the social functioning scale of the UCLA GIT 2.0 and social functioning of the SF-36, the emotional well-being scale of the UCLA GIT 2.0 and the role-emotional and mental health scales of the SF-36. In addition, we recently showed that depressed mood is associated with reflux and constipation scales of the UCLA GIT 2.0 (2). Therefore, we hypothesized that reflux and constipation scales will have at least moderate correlations with mental health scales of the SF-36.

We also examined the ability of the UCLA SCTC-GIT 2.0 to differentiate among patients with $<5\%$ unintended weight loss vs. $\geq 5\%$ weight loss during last 6 months. We hypothesized that patients with $>5\%$ unintended weight loss will have higher (worse HRQOL) scale scores and were compared using unpaired *t*-test.

All analyses were performed by using STATA software version 10.2 (College Station, Texas) and $p < 0.05$ was considered statistically significant.

Results

A total of 76 patients with SSc were recruited with a mean (SD) age of 58(13) years, the large majority of whom were white (90%), female (81%), and had limited SSc (50%; Table I). The mean (SD) disease duration of SSc was 10(9) years. HRQOL, as assessed by SF-36 showed decrement of 1.2 SD in the SF-36 PCS and 0.4 in the SF-36 MCS when compared to the US general population.

Mean (SD) score of the UCLA SCTC-GIT ranged from 0.35 (0.71) for the faecal soilage scale to 0.95 (0.80) for the distension/bloating scale (Table II). The patients with limited SSc had sig-

Table I. Baseline characteristics of our patients.

Variable	n=76
Age, mean (SD)	58.1 (12.9)
Female, n. (%)	62 (81.6)
Ethnicity, n. (%)	
White	67 (88.1)
African	7 (9.2)
Unknown Maghr	2 (2.6)
Type of SSc, n. (%)	
Limited	37 (50.0)
Diffuse	29 (39.2)
Overlap	8 (10.8)
Disease duration (years), mean (SD)	10.2 (9.3)
Autoantibodies positive, n. (%)	
Antinuclear antibody	60 (78.9)
Anticentromere antibody	20 (30.8)
Anti-topoisomerase-1 antibody	19 (28.8)
Digital ulcers, n. (%)	
None	49 (67.1)
Active	9 (12.3)
Past	15 (20.6)
Modified Rodnan skin score, mean (SD)	14.4 (12.6)
Height (cm), mean (SD)	163.6 (8.0)
Weight (kg), mean (SD)	65.2 (13.2)
Unplanned weight loss, n. (% of total body weight)	
<5%	32 (76.2)
≥5%	10 (23.8)
C-Reactive protein (mg/l), mean (SD)	4.6 (7.7)
Medications, n. (%)	
Ongoing PPI	73 (89.0%)
Ongoing prokinetics	26 (31.7%)
Low dose corticosteroids	37 (45.7%)
Calcium channel blockers	70 (92.1)
Antibiotics	8 (10.5)
Antidepressants	15 (19.7)
Immunosuppressants	26 (34.2)
Forced Vital Capacity % predicted, mean (SD)	100.0 (20.7)
Diffusion Capacity (DLCO) % predicted, mean (SD)	66.9 (18.3)
High Resolution CT ground glass opacity, n. (%)	11 (18.0%)
HRQOL, mean (SD)	
SF-36 Physical component summary (PCS)	38.5 (9.1)
SF-36 Mental component summary (MCS)	46.4 (13.2)

nificantly higher (worse) mean scores on distention/bloating (1.16 vs. 0.72), constipation (0.48 vs. 0.27) and total GIT (0.65 vs. 0.38) scales ($p < 0.05$ for all; data not shown in tabular form). Cronbach's alpha was ≥ 0.70 for all scales except diarrhoea (alpha=0.56) and social functioning (alpha=0.69; Table II). Ceiling effect ranged from 20% for the distention/bloating scale to 76% for the faecal soilage scale. As hypothesized, we found moderate correlation between emotional well-being scale of the UCLA GIT 2.0 and the role-emotional and mental health scales of the SF-36 (correlation coefficient 0.50 and 0.38, respectively; Table III). In addition,

reflux and constipation scales of the UCLA GIT 2.0 and mental health scales of SF-36 also showed a moderate correlation (correlation coefficient 0.37 and 0.32, respectively). Social functioning scales of the UCLA GIT 2.0 and the SF-36 had a correlation coefficient of 0.27.

We further explored correlation coefficients between other UCLA GIT 2.0 and SF-36 scales. We found more substantial associations (correlation coefficient ≥ 0.30) between the symptom scales of the UCLA GIT 2.0 and the mental health scales of the SF-36 including the SF-36 MCS, compared to the physical health domains, with the exception of

role limitations due to physical health. To further explore construct validity, we divided patients into two groups based on the presence or absence of significant unintentional weight loss ($<5\%$ vs. $\geq 5\%$ of total body weight) in the past 6 months. All scales as well as the Total GIT score had numerically higher (worse) GI symptoms in patients that had lost $\geq 5\%$ of their body weight compared to patients with $<5\%$ loss (Table IV). In addition, there was a statistically significant difference between the two groups in the distention/bloating scale (1.43 vs. 0.87, $p = 0.04$).

Discussion

Gastrointestinal tract (GIT) involvement is seen in 90% of all patients with systemic sclerosis (SSc) and is associated with a decline in the health-related quality of life (HRQOL) (16). Every part of the GIT can be involved in SSc, including the mouth (xerostomia), oesophagus (dysmotility, acid reflux), stomach (vascular ectasia, gastroparesis), intestines (vascular lesions, hypomotility, bacterial overgrowth, toxic megacolon), and anorectal system (faecal incontinence). Moreover, correlation between histological or physiological tests and GIT symptoms have been poor in recent studies (17). Given the impact of GIT involvement in patients with SSc on morbidity, mortality and HRQOL, a feasible and reliable instrument that captures GIT symptoms severity and its impact on HRQOL is needed. We have translated the UCLA Scleroderma Clinical Trial Consortium (UCLA-GIT) 2.0 instrument into French language and found acceptable reliability (as assessed by Cronbach's alpha) and construct validity.

The original English version of the UCLA-GIT 2.0 was developed to capture GIT symptoms activity and severity (5). The original version had a satisfactory reliability and validity. We found that French version had adequate reliability (defined as Cronbach alpha ≥ 0.69) except for the diarrhoea scale. The two authors (YA and BC) reviewed the 2 diarrhoea items after the study was completed and found the translation to be appropriate. Although we do not know the exact reason for this low

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

UCLA GIT 2.0 Scale	n.	Mean (SD) score	Minimum score	Maximum score	Cronbach's α	% with ceiling effect	% with floor effect
Reflux	76	0.52 (0.51)	0.0	2.0	0.71	22.4	0.0
Distention/bloating	76	0.95 (0.80)	0.0	3.0	0.70	19.7	4.0
Diarrhoea	73	0.44 (0.74)	0.0	2.0	0.56	65.8	2.7
Constipation	67	0.48 (0.74)	0.0	2.5	0.79	44.8	0.0
Faecal soilage	75	0.35 (0.71)	0.0	3.0	Not applicable	76.0	2.7
Emotional well-being	70	0.45 (0.61)	0.0	2.6		38.6	0.0
Social functioning	69	0.48 (0.57)	0.0	2.0		36.2	0.0
Total GIT score	76	0.53 (0.50)	0.0	2.3	0.88	6.6	0.0

All scales and Total GIT score are scored from 0 (better HRQOL) to 3 (worse HRQOL) except diarrhoea and constipation scales that ranges from 0–2 and 0–2.5, respectively.

Table III. Pearson correlation coefficients between UCLA GIT 2.0 vs. SF-36 scales.

GIT 2.0 / SF-36	PF	BP	RP	GH	MH	RE	VT	SF	PCS	MCS
Reflux	0.15	0.25*	0.43*	0.12	0.37*	0.31*	0.36*	0.36*	0.32*	0.34*
Distention/bloating	0.17	0.26*	0.47*	0.07	0.28*	0.29*	0.31*	0.34*	0.39*	0.29*
Diarrhoea	0.05	0.15	0.14	0.10	0.09	0.29*	0.10	0.15	0.13	0.20
Constipation	0.27*	0.26*	0.41*	0.08	0.32*	0.43	0.26*	0.25	0.22	0.28*
Faecal soilage	0.23	0.02	0.22	0.18	0.29*	0.41*	0.36*	0.38*	0.18	0.43*
Emotional well-being	0.25	0.25*	0.47*	0.16	0.38*	0.50*	0.27*	0.38*	0.27	0.45*
Social functioning	0.18	0.21	0.43*	+0.03	0.30*	0.36*	0.21	0.27*	0.28*	0.30*
Total GIT score	0.24*	0.32*	0.52*	0.17	0.41*	0.46*	0.39*	0.43*	0.43*	0.45*

All negative values unless marked (+);* indicate $p \leq 0.05$.

PCS: physical health component summary; MCS: mental health component summary; 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.

reliability, it is possible that 2-item diarrhoea scale is suboptimal to capture this construct in the French population. We noticed a very high ceiling effect (65.8%) for this scale that can also affect the reliability. Also, subtle differences in the translation can lead to significant differences in interpretation of the items.

For convergent construct validity, associations were explored between the

French UCLA-GIT instrument and the SF-36 and we found a moderate correlation (correlation coefficient ≥ 0.30) between the emotional well-being scale of the UCLA-GIT 2.0 and the mental health scale of the SF-36 ($r = -0.38$, $p < 0.05$). The social functioning scales between the two instruments had a statistical association, but the correlation coefficient was less than 0.30 ($r = -0.27$, $p < 0.05$).

Exploratory analyses of other correlation coefficients showed that the UCLA-GIT had stronger association with the mental health scales of the SF-36, compared to the physical health scales, with the exception of the SF-36 role-physical scale. Previous analysis by our group showed that greater symptom severity as reflected by the reflux and constipation scales are associated with depressed mood (2). Current analyses support these data and suggest that GI involvement has greater impact on mental compared to physical health. The only exception is role limitations due to physical health. Although UCLA-GIT scale scores did not significantly correlate with physical functioning, it is conceivable that GI symptoms may interfere with accomplishing daily activities related to physical activities.

In comparison to our original study of the English version, several baseline differences in the study population were noted (5). The French version assessment was done on a smaller patient

Table IV. Construct validity of the UCLA GIT 2.0.

UCLA GIT 2.0 Scale	<5% of Total body weight loss			$\geq 5\%$ of Total body weight loss			p -value
	n.	mean	SD	n.	mean	SD	
Reflux	32	0.46	0.51	10	0.63	0.52	0.38
Distention/bloating	32	0.87	0.87	10	1.43	0.85	0.04
Diarrhoea	32	0.50	0.83	10	0.75	0.95	0.24
Constipation	29	0.28	0.40	9	0.64	0.63	0.07
Emotional well-being	30	0.33	0.56	10	0.71	0.82	0.10
Social functioning	30	0.37	0.55	10	0.66	0.71	0.11
Faecal soilage	32	0.41	0.71	10	0.50	0.97	0.90
Total GIT	32	0.50	0.50	10	0.78	0.66	0.16

All scales and Total GIT score are scored from 0 (better HRQOL) to 3 (worse HRQOL) except diarrhoea and constipation scales that ranges from 0–2 and 0–2.5, respectively.

population ($n=76$ vs. 152); the patients were older (mean age = 58.1 vs. 50.9 years); and the French study included less patients with diffuse type SSc (39.2% vs. 55.3%). The HRQOL, as captured by the SF-36 showed a mean SF-36 PCS and MCS score of 38.5 and 46.4, respectively, compared to 36.7 and 47.1 in our original study. The French version of our instrument showed higher mean scores in the following scales: constipation (0.48 vs. 0.43), faecal soilage (0.35 vs. 0.30) and social functioning (0.48 vs. 0.26) suggesting somewhat higher severity of the lower GI involvement. Conversely, the other scales including the total GIT score had lower mean scores: reflux (0.52 vs. 0.69), distention/bloating (0.95 vs. 1.07), diarrhoea (0.44 vs. 0.56), emotional well-being (0.45 vs. 0.49) and total GIT score (0.53 vs. 0.66). Both studies showed a high ceiling effect, ranging from 19.7% in distention/bloating to 76.0% in faecal soilage.

In this study, we also classified patients based on unintended weight loss ($\geq 5\%$ vs. $< 5\%$ of total body weight) and found that all scale scores were higher (worse HRQOL) in the $\geq 5\%$ weight loss group. Since gastroparesis and small intestine bacterial overgrowth is associated with weight loss in SSc (18), we postulated that these patients will have worse scores in the distention/bloating scale. This was confirmed based on the analysis where we found statistically significant difference in the distention/bloating scale. In addition, patients with unintentional weight loss of $\geq 5\%$ also had higher scores for all other GI scales.

Our study has certain limitations. First, our construct validity was not assessed with objective measures (e.g. endos-

copy, barium swallow, gastric emptying), or clinical diagnoses (e.g. gastroesophageal reflux disease, ileus, etc.). Second, our study included a relatively small number of patients ($n=76$) from a single clinical centre. Also, this is a cross-sectional study and further longitudinal studies should assess the predictive validity.

In conclusion, we found acceptable reliability and validity of the French version of the UCLA -GIT 2.0 to assess GIT symptoms in French speaking patients with SSc.

Key messages:

- The French version of the UCLA-GIT 2.0 has acceptable reliability and validity.
- UCLA GIT 2.0 can be used to assess patients with systemic sclerosis and gastrointestinal involvement.

References

1. LOCK, G, HOLSTEGE A, LANG B, SCHOLMERICH J: Gastrointestinal manifestations of progressive systemic sclerosis. *Am J Gastroenterol* 1997; 92: 763-71.
2. BODUKAM, V, HAYS RD, MARANIAN P *et al.*: Association of gastrointestinal involvement and depressive symptoms in patients with systemic sclerosis. *Rheumatology* (Oxford); 2010.
3. THOMBS BD, HUDSON M, TAILLEFER SS, BARON M: Prevalence and clinical correlates of symptoms of depression in patients with systemic sclerosis. *Arthritis Rheum* 2008; 59: 504-9.
4. NIETERT PJ, MITCHELL HC, BOLSTER MB *et al.*: Correlates of depression, including overall and gastrointestinal functional status, among patients with systemic sclerosis. *J Rheumatol* 2005; 32: 51-7.
5. KHANNA D, HAYS RD, MARANIAN P *et al.*: Reliability and validity of the University of California, Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract Instrument. *Arthritis Rheum* 2009; 61: 1257-63.
6. KHANNA D, HAYS RD, PARK GS *et al.*: Development of a preliminary scleroderma gastrointestinal tract 1.0 quality of life instrument. *Arthritis Rheum* 2007; 57: 1280-6.
7. LEROY EC, BLACK C, FLEISCHMAJER R *et al.*: Scleroderma (systemic sclerosis): classification, subsets and pathogenesis. *J Rheumatol* 1988; 15: 202-5.
8. WARE JE JR, SHERBOURNE CD: The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992; 30: 473-83.
9. KHANNA D, FURST DE, CLEMENTS PJ *et al.*: Responsiveness of the SF-36 and the Health Assessment Questionnaire Disability Index in a systemic sclerosis clinical trial. *J Rheumatol* 2005; 32: 832-40.
10. LEPLEGE A, ECOSSE E, VERDIER A, PERNEGER TV: The French SF-36 Health Survey: translation, cultural adaptation and preliminary psychometric evaluation. *J Clin Epidemiol* 1998; 51: 1013-23.
11. GEORGES C, CHASSANY O, MOUTHON L *et al.*: [Quality of life assessment with the MOS-SF36 in patients with systemic sclerosis]. *Rev Med Interne* 2004; 25: 16-21.
12. WARE JE JR, GANDEK B, KOSINSKI M *et al.*: The equivalence of SF-36 summary health scores estimated using standard and country-specific algorithms in 10 countries: results from the IQOLA Project. International Quality of Life Assessment. *J Clin Epidemiol* 1998; 51: 1167-70.
13. BEATON DE, BOMBARDIER C, GUILLEMIN F, FERRAZ MB: Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine* (Phila, PA 1976); 2000; 25: 3186-91.
14. BLAND JM, ALTMAN DG: Cronbach's alpha. *BMJ* 1997; 314: 572.
15. COHEN J: Applied multiple regression/correlation analysis for the behavioral sciences. 3rd ed. 2003, Mahwah, NJ: Erlbaum L Associates. xxviii, 703 p.
16. JOHNSON SR, GLAMAN DD, SCHENTAG CT, LEE P: Quality of life and functional status in systemic sclerosis compared to other rheumatic diseases. *J Rheumatol* 2006; 33: 1117-22.
17. SALLAM H, MCNEARNEY TA, CHEN JD: Systematic review: pathophysiology and management of gastrointestinal dysmotility in systemic sclerosis (scleroderma). *Aliment Pharmacol Ther* 2006; 23: 691-712.
18. KHANNA D, DENTON CP: Evidence-based management of rapidly progressing systemic sclerosis. *Best Pract Res Clin Rheumatol* 2010; 24: 387-400.

Appendix

UCLA SCTC GIT 2.0 QUESTIONNAIRE

Les questions suivantes concernent vos symptômes gastro-intestinaux (œsophage, estomac, intestin) et leur retentissement sur votre vie concernant les 7 derniers jours. Répondez aux questions en sélectionnant la réponse qui correspond. Si vous n'êtes pas sûr(e) de la manière de répondre, donnez la meilleure réponse possible.

Veillez à bien cocher la case qui correspond et ne pas répondre Oui ou Non.

Sur les <u>7 derniers jours</u> , combien de fois...	(COCHEZ UNE REPONSE POUR CHAQUE QUESTION)			
	Aucune journée ⁰	1-2 jour(s) ¹	3-4 jours ²	5-7 jours ³
1. ...avez vous eu des difficultés pour avaler les aliments solides ? _R				
2. ... avez vous eu une impression de picotements ou de brûlures au creux de l'estomac (brûlures d'estomac) ? _R				
3. ... avez vous eu une sensation de remontée d'un liquide amer ou acide de l'estomac vers bouche (reflux acide) ? _R				
4. ... avez vous eu des brûlures d'estomac en mangeant des aliments acides comme les tomates ou les oranges ? _R				
5. ... avez vous eu des régurgitations (remontée de petites quantités d'aliments qui viennent d'être avalés) ? _R				
6. ... avez vous dormi en position assise ou demi-assise ? _R				
7. ... avez vous été nauséeux(se) ? _R				
8. ... avez vous vomi ? _R				
9. ...vous êtes vous senti ballonné(e) (sensation de gaz ou air dans l'estomac) ? _{D/B}				
10. ...avez vous noté une augmentation de taille de votre ventre nécessitant parfois d'ouvrir votre ceinture, pantalon ou t-shirt ? _{D/B}				
11. ...vous êtes vous senti(e) rassasié(e) après avoir mangé un petit repas ? _{D/B}				
12. ... avez vous eu un excès de gaz ou flatulences ? _{D/B}				
13. ...avez vous accidentellement sali vos sous-vêtements avant de pouvoir aller aux toilettes ? _S				
14. ...avez vous eu des selles liquides ?(diarrhée) _D				
Sur <u>la semaine passée</u> , à quelle fréquence les éléments suivants ont ils interféré avec vos activités sociales (voir vos amis ou autre)	(COCHEZ UNE REPONSE POUR CHAQUE QUESTION)			
	Aucune journée ⁰	1-2 jour(s) ¹	3-4 jours ²	5-7 jours ³
15. Nausées ? _{FS}				
16. Vomissements ? _{FS}				
17. Maux ou douleurs d'estomac ? _{FS}				
18. Diarrhée ? _{FS}				
19. Crainte de salir accidentellement vos sous-vêtements ? _{FS}				
20. Sensation de ballonnement ? _{FS}				

Sur <u>la semaine passée</u> , à cause de vos problèmes intestinaux, à quelle fréquence...		(COCHEZ UNE REPONSE POUR CHAQUE QUESTION)			
		Aucune journée ⁰	1-2 jour(s) ¹	3-4 jours ²	5-7 jours ³
21	...vous êtes vous senti(e) tracassé(e) ou anxieux(se) ? _{BE}				
22	...vous êtes vous senti(e) embarrassé(e) ? _{BE}				
23	...avez vous eu des problèmes lors de vos rapports sexuels ? _{BE}				
24	...avez vous eu peur de ne pas trouver des toilettes ? _{BE}				
25	...vous êtes vous senti(e) triste ou découragé(e) ? _{BE}				
26	...avez vous reporté ou annulé un voyage ? _{BE}				
27	...vous êtes vous senti(e) énervé(e) ou frustré(e) ? _{BE}				
28	...avez vous eu des difficultés de sommeil ? _{BE}				
29	...vous êtes vous senti(e) stressé(e) ou d'humeur contrariée ? _{BE}				
Sur <u>la semaine passée</u> , avez vous remarqué que vos selles étaient devenues...		(COCHEZ UNE REPONSE POUR CHAQUE QUESTION)			
		OUI ¹		NON ⁰	
30.	...liquides ? _D	<input type="checkbox"/>		<input type="checkbox"/>	
31.	...plus dures ? _C	<input type="checkbox"/>		<input type="checkbox"/>	
Sur <u>la semaine passée</u> , à quelle fréquence...		(COCHEZ UNE REPONSE POUR CHAQUE QUESTION)			
		Aucune journée ⁰	1-2 jour(s) ¹	3-4 jours ²	5-7 jours ³
32	...étiez vous constipé(e) ou incapable d'aller à la selle ? _C				
33	...avez vous eu des selles dures ? _C				
34	...avez vous eu des douleurs lors du passage des selles ? _C				

Catégories concernées: C: constipation; D: diarrhée; D/B: distension/ballonnement; BE: bien-être émotionnel; R: reflux; FS: fonctionnement social; S: souillure fécale.