A Romanian version of the UCLA Scleroderma Clinical Trial Consortium Gastrointestinal Tract Instrument

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ABSTRACT

Objective. *UCLA Scleroderma Clinical Trial Consortium Gastrointestinal Tract (UCLA SCTC GIT 2.0) Instrument is a comprehensive, self-administered survey for the assessment of gastrointestinal involvement in scleroderma patients, developed and validated in English. Our objective was to translate and validate a Romanian version of UCLA SCTC GIT 2.0.*

Methods. *Translation from English into Romanian has been made using the forward-backward method. Sixty-four patients, attending a referral centre as part of an extensively studied cohort, were approached in a consecutive manner over a period of two years for administration of the questionnaire. We evaluated the reproducibility, internal consistency, construct validity and discriminative capacity of the translation (Romanian GIT).*

Results. *Fifty-four patients returned completed questionnaires. Internal consistency was demonstrated by Cronbach's alpha coefficient (0.931). Construct validity is supported by moderate, but significant correlations of Romanian GIT total score with the Mental Component Summary (MCS) of SF-36 (r=0.541, Spearman correlation) and among subscales, by significant correlations with SHAQ total score (r=0.559, Spearman correlation) and by strong correlations with gastrointestinal subscale of SHAQ (SHAQ GI) (r=0.726, Spearman correlation). Reproducibility was also good. Divergent validity was supported by significant differences between patients with or without a clinical diagnosis of gastrointestinal disease. Other differences in the Romanian GIT total score were tested among subgroups of patients.*

Conclusion. *The Romanian GIT has acceptable reliability and validity. This questionnaire can be used for the assessment of gastrointestinal involvement in scleroderma patients.*

Introduction

Systemic sclerosis or scleroderma is a connective tissue disease, affecting the skin and visceral organs, with significant mortality and a high impact on quality of life (1-3). The disease is characterised by a unique combination of immunological abnormalities, vascular disease and fibrosis (4), while smooth muscle atrophy and replacement fibrosis are the main pathological features in the gastrointestinal tract (5, 6). These pathological changes correlate with a decrease in motility, most frequently noted in the oesophagus (7), and are responsible for a variety of symptoms, depending on the affected segment (8, 9).

The involvement of the digestive tract in scleroderma is of great interest, since its presence can be detected in nearly all scleroderma patients. Before the introduction of proton pump inhibitors (PPIs), clinically 'significant' gastrointestinal involvement was estimated to occur in approximately 50% of cases (10). Investigations using sensitive methods, especially classical manometry, demonstrated the presence of abnormalities in up to 90% of cases (8, 9), thus indicating a lack of symptoms in some patients or a more subtle disease. A systematic application of a symptom questionnaire in a large hospital cohort recently suggested that gastrointestinal symptoms are very frequent in scleroderma, with only 10% of patients reporting daily symptoms, but just 3% having no symptoms at all (11).

Khanna *et al.* developed the UCLA Scleroderma Clinical Trial Consortium Gastrointestinal Tract Instrument (UCLA SCTC GIT) 2.0, a comprehensive self-administered survey, translated and validated in the recent years in English (12, 13), French (14) and Dutch (15). Our objectives were to translate and validate the UCLA SCTC GIT 2.0 instrument in Romanian lan-

guage, as a potential useful tool in the clinical evaluation of gastrointestinal symptoms in scleroderma patients.

Patients and methods

Patients

We approached 64 patients with a confirmed diagnosis of scleroderma, attending a referral centre over a period of two years, from November 2011 to November 2013, in a consecutive manner. The patients were part of a hospital cohort of scleroderma cases, each consented in writing before taking part in this cohort and with responsible ethics committee approval in place for this research. Patients in the cohort regularly attended the hospital, at least for a yearly evaluation, which included a detailed clinical assessment, annual pulmonary function tests (PFTs), annual echocardiography for pulmonary hypertension screening and additional tests, depending on clinical status of each patient. All patients fulfilled ACR classification criteria (16) or LeRoy classification criteria for early or limited systemic sclerosis (17). All patients also fulfilled the 2013 classification criteria applied in retrospect (18). All questionnaires were filled in by patients during a visit in the hospital. Socio-demographic and clinical data were systematically collected, by using a standardised assessment, including but not limited to patient general characteristics (age, sex, education level, work capacity), disease subtype, disease duration (defined as duration since appearance of first non-Raynaud symptom), body mass index, weight loss, lab results, autoantibodies status, physical and mental health assessments, functional tests, clinical diagnoses, comorbidities, current and previous treatments. One patient has been excluded due to history of extensive gastric resection for duodenal ulcer. Gastrointestinal (GI) diagnoses by clinician were documented at each visit and included: gastro-esophageal reflux disease, gastritis, diarrhoea, fecal incontinence and constipation. There was no case of pseudo-obstruction noted in this cohort. Gastrointestinal tests performed at each visit were retrieved from patient's files and consisted in oesophagogastroduodenoscopy, x-ray studies including barium transit studies and colonoscopy.

Translation and field-testing

UCLA SCTC GIT 2.0 questionnaire is a validated 34-items questionnaire with 7 subscales, assessing reflux (8 questions), distension/bloating (4 questions), fecal soilage (1 question), diarrhoea (2 questions), social functioning (6 questions), emotional well-being (9 questions) and constipation (4 questions) (12). Each item scores the frequency of symptoms over a recall period of 7 days, on a 0 to 3 possible range, where 0 indicates better health and 3 indicates worse health, with the exception of questions 15 (diarrhoea subscale) and 31 (constipation subscale), scored on 0 (better health) to 1 (worse health). The average of items in each subscale can be calculated as a separate subscale score (for reflux, distention/ bloating, fecal soilage, diarrhoea, constipation, social functioning, emotional well-being), with scores ranging from 0 to 3, except diarrhoea and constipation, with ranges 0–2 and 0–2.5, respectively. A combined score of 6 subscales (excluding constipation) is calculated as a total score, to capture the overall burden of disease (possible scores from 0 to 2.83). The English version of UCLA SCTC GIT 2.0 is available at http://uclascleroderma.researchcore.org/ and it was used in this study with kind permission from the author (Dr D. Khanna).

The UCLA SCTC GIT 2.0 was translated from English into Romanian by an independent translator and a rheumatologist (MG), then agreement on the draft translation was reached among the two. The back-translation of the draft was performed by another rheumatologist (CM) and a second independent translator (See Appendix). Adjustments were made by consensus among all translators. To assess the time needed for completion and the choice of some terms, the questionnaire was preliminarily administered and discussed with five patients attending the hospital.

Statistical methods

The questionnaires were excluded in cases of more than 50% missing answers for a scale or more than 10% overall missing answers. All statistical analyses were carried in SPSS 20.0 software and a few missing values were imputed by using the overall sample median (except for constipation scale, which does not contribute to the total score). *Reproducibility* was assessed by retesting the questionnaire over a period varying from 8 to 14 days in a group of 16 patients, with correlations $r > 0.7$, considered as acceptable.

Internal consistency as a measure of reliability was evaluated by applying Cronbach's alpha method for the seven subscales and the total score of the Romanian GIT questionnaire. For a good correlation, the minimum Cronbach's alpha coefficient should be 0.7. The proportion of patients scoring the worst possible score (the maximum possible value of the instrument) was defined as floor effect. The proportion of patients scoring the best possible score of the instrument (absence of symptoms) was defined as ceiling effect (19). These proportions were calculated for each scale and an effect was considered present if more than 15% of patients gave maximum or minimum scores, respectively.

Construct validity: convergent validity was tested by examination of Spearman correlation coefficients 1) between Romanian GIT scores and Short Form (36) Health Survey (SF-36) and 2) between Romanian GIT scores and Scleroderma Health Assessment Questionnaire (SHAQ). Correlations ≤ 0.29 were considered to be small, 0.30 to 0.49 moderate, and ≥ 0.50 strong.

The Short Form (36) Health Survey (SF-36) is a generic health survey, widely used for estimating disease burden. The instrument provides an 8-scale profile of functional health and well-being, as well as two summaries, physical and mental component scores (PCS and MCS). The Physical Functioning, Physical Role functioning and Bodily Pain scales contribute mostly to the scoring of Physical Component Summary (PCS), while Mental Health, Emotional Role functioning and Social Functioning scales contribute mostly to the Mental Component Summary (MCS). Vitality and General Health perceptions scales each contribute to

Table I. Patients' characteristics.

	Total (n=54)	dSSc (n=14)	lSSc (n=40)	*p*-value
Age, years, mean (SD)	52.4 (12.1)	47.3 (10.8)	54.2 (12.2)	0.070
Female, n, %	49 (90.7)	12 (85.7)	37 (92.5)	0.595
Disease duration, months, median (25^{th}-75^{th} percentile)	78.5 (43-148)	64 (43-106)	80.5 (47.5-164)	0.465
BMI, median (25^{th}-75^{th} percentile)	24.4 (21.9-27.1)	24.6 (22.8-25.0)	24.4 (21.8-27.2)	0.739
mRSS, median (25^{th}-75^{th} percentile)	4 (2-9)	9 (6-13)	3 (2-7.5)	0.003
Pulmonary function tests				
FVC, % of predicted, mean (SD)*	91.3 (20.4)	79.5 (20.4)	95.4 (19.0)	0.019
DLCO, % of predicted, mean (SD)**	66.7 (18.8)	59.5 (19.3)	69.2 (18.3)	0.127
Autoantibodies, n, %				
ANA*	40 (85.1)	10 (76.9)	40 (88.2)	0.377
Anti-Scl70**	28 (60.9)	11 (91.7)	17 (50.0)	0.015
Anti-centromere***	9 (21.4)	0 (0.0)	9 (29.0)	0.083
Laboratory results, median (25^{th}-75^{th} percentile)				
Hb, g/dL	12.9 (12.0-13.6)	13.5 (13.0-13.8)	12.6 (11.9-13.5)	0.010
CRP, mg/dL	2.90 (1.63-6.62)	2.90 (1.63-5.10)	2.92 (1.46-7.33)	0.780
creatinin, mg/dL	0.66 (0.55-0.72)	0.58 (0.50-0.69)	0.68 (0.60-0.76)	0.048
Medications, n, %				
Calcium blockers	31 (57.4)	7 (50.0)	24 (60.0)	0.736
PPI	40 (74.1)	9 (64.3)	31 (77.5)	0.479
Prokinetics	14 (25.9)	4 (28.6)	10 (25.0)	1.000
NSAIDs	15 (27.8)	4 (28.6)	11 (27.5)	1.000
Azathioprine	7 (13.0)	4 (28.6)	3 (7.5)	0.065
Methotrexate	9 (16.7)	1 (7.1)	8 (20.0)	0.418
Corticosteroids	11 (20.4)	3 (21.4)	8 (20.0)	1.000
Cyclophosphamide	10 (18.5)	4 (28.6)	6 (15.0)	0.424
GI tests (EDS, barium studies), n, %	34 (63.0)	10 (71.4)	24 (60.0)	0.659
GI clinical diagnosis, n, %	38 (70.4)	13 (92.9)	25 (62.5)	0.043
SF-36 (0-100), median (25^{th}-75^{th} percentile)				
Physical Functioning	35.1 (25.7-44.6)	32.0 (25.7-48.8)	36.2 (28.8-44.6)	0.488
Role Physical	28.0 (28.0-49.2)	28.0 (28.0-42.1)	31.5 (28.0-49.2)	0.280
Bodily Pain	37.5 (29.3-46.0)	37.5 (29.3-37.9)	37.5 (31.2-46.2)	0.511
General Health	33.6 (28.9-41.5)	30.0 (24.2-36.8)	34.7 (29.3-41.5)	0.103
Vitality	45.9 (39.6-56.2)	44.3 (32.5-49.1)	46.7 (39.6-56.2)	0.352
Social Functioning	40.9 (30.0-51.7)	35.4 (30.0-46.3)	40.9 (30.0-51.7)	0.437
Role Emotional	34.3 (23.7-55.3)	23.7 (23.7-44.8)	34.3 (23.7-55.3)	0.254
Mental Health	39.1 (30.0-50.4)	34.5 (27.7-48.2)	39.1 (33.6-51.5)	0.255
Physical Composite Summary Score (PCS)	32.6 (26.3-42.1)	27.6 (25.2-46.2)	33.3 (27.2-41.3)	0.244
Mental Composite Summary Score (MCS)	42.8 (34.0-50.4)	38.0 (31.4-53.0)	44.4 (34.2-50.1)	0.229
SHAQ total score (0-3), median (25^{th}-75^{th} percentile)	1.038 (0.615-1.462)	1.423 (0.692-1.769)	0.961 (0.576-1.308)	0.119

*13% missing; **14.8% missing; ***22.2% missing. BMI: body mass index; mRSS: modified Rodnan skin score; FVC: forced vital capacity; DLCO: diffusion lung capacity for carbon monoxide; Hb: hemoglobin; CRP: C-reactive protein; PPI: proton pump inhibitors; NSAIDs: non-steroidal anti-inflammatory agents; EDS: esofagogastroduodenoscopy.

For continuous variables normally distributed, mean and standard deviation (SD) are listed and differences were tested by independent samples t-test; for continuous variables non-normally distributed, medians and interquartile ranges (25-75^{th} percentiles) are listed and differences between groups were tested with Mann-Whitney U-test. For categorical variables, differences were tested by Pearson chi-square (with continuity correction) or Fisher's exact test. *p*-values <0.05 are considered significant.

both PCS and MCS. Norm-based scoring transforms all scales to have the same average score (50) and the same standard deviation (10 points) (20, 21). We used the standard form of SF-36 (4-week recall period).

Scleroderma Health Assessment Questionnaire (SHAQ) was developed by addition to the HAQ disability index (HAQ-DI) of five visual analogue scales (VAS), each assessing the functional impact of Raynaud phenomenon, digital ulcers, gastro-intestinal symptoms, respiratory symptoms and the global impact of the disease. SHAQ is validated for its use in scleroderma (22) and a validated Romanian version is available and was used in this study (23). The five VAS are replaced with Likert scales, with possible values ranging from 0 (no impact) to 3 (maximum impact).

Discriminative (divergent) validity was assessed by comparing total and subscales scores of the Romanian GIT questionnaire in patients with or without a clinical GI diagnosis (Mann-Whitney U-test; $p<0.05$ was considered significant).

Results

The Romanian version of the UCLA SCTC GIT 2.0 questionnaire is reproduced in the appendix. During preliminary discussions, two patients remarked a complete avoidance of 'acidic' foods

due to severe heartburn. A total of 54 patients returned completed questionnaires. Patients' characteristics are summarised in Table I. All patients were Caucasians, 49 (90.7%) were women and 40 (74%) had the limited form of the disease (lSSc). The patients with a diffuse form (dSSc) were more frequently anti-Scl70 positive and had a lower FVC (% predicted) than those with lSSc.

The Romanian GIT questionnaire showed a good *internal consistency* (Table II), with Cronbach's alpha 0.931. For all subscales Cronbach's alpha was ≥0.7, with the exception of diarrhoea subscale (alpha 0.581). The median total GIT score was 0.35. Strong corrected item-total correlations were noted for all items in the reflux subscale, with only item 6 ('...sleeping in a raised or seated position') showing a moderate correlation (r=0.353). Corrected item-total correlation was low for item 20 on the social functioning subscale ('... worrying of accidentally soiling the underwear'), r=0.003, most probably due to the very low prevalence of fecal incontinence in our cohort. Except for the reflux scale and the total GIT score, there was a clear ceiling effect in all other subscales, with a maximum effect in fecal incontinence scale (89%). No floor effect was noted.

Table III presents the results of analysis of correlation between Romanian GIT with SF-36 subscales and summaries, as well as with total SHAQ score and with the gastrointestinal SHAQ subscale (SHAQ-GI). Romanian GIT total score showed significant correlations with all SF-36 subscales, but not with the physical functioning subscale (PF) or with PCS. Fecal soilage and constipation correlated significantly with PF scale. We found strong correlations of Romanian GIT total score with the MCS and between the social functioning and emotional well-being subscales of Romanian GIT with the social functioning (SF), emotional role functioning (RE), bodily pain (BP) and mental health perception (MH) subscales of SF-36, as well as with the MCS score.

Instead, we found a strong correlation of Romanian GIT total score with SHAQ total score (r 0.559). Reflux, distension/bloating, social functioning and emotional well-being subscales all had moderate to strong correlations with SHAQ total score. An excellent correlation has been found between Romanian GIT total score and SHAQ-GI subscale (r=0.726). Reflux, distension/bloating, diarrhoea, social functioning, emotional well-being and constipation subscales demonstrated moderate to excellent correlations with SHAQ-GI subscale.

Patients with a clinical GI diagnosis scored significantly higher on the Romanian GIT total score compared with patients with no clinical GI diagnosis; significant differences were found for all subscales, except fecal incontinence and constipation subscale (Table IV).

We compared Romanian GIT scores and SHAQ total score between different subgroups of patients. ACA-positive patients tended to have significantly higher scores for reflux (p=0.016) and distension/ bloating subscales (p=0.011), while anti-Scl70 positive patients tended to have a lower reflux

Table II. Descriptive statistics and internal consistency of the Romanian GIT.

Scale	No. of items	Mean (SD)	Median (25^{th}-75^{th} percentile)	Minimum- maximum range of scores	Ceiling effect, %	Floor effect, %	Cronbach's Alpha
Reflux (n=54)	8	0.62 (0.63)	0.375 (0.125 - 0.875)	0.00 - 2.50	13	0	0.835
Distension/ bloating (n=54)	4	0.90 (0.76)	1.00 (0.00 - 1.25)	0.00 - 3.00	26	4	0.741
Fecal soilage (n=54)	1	0.11 (0.31)	0.00 (0.00 - 0.00)	0.00 - 1.00	89	0	NA
Diarrhoea (n=54)	2	0.22 (0.44)	0.00 (0.00 - 0.00)	0.00 - 1.50	76	0	0.581
Social functioning (n=54)	6	0.32 (0.42)	0.16 (0.00 - 0.50)	0.00 - 1.50	41	0	0.707
Emotional well-being (n=54)	9	0.64 (0.79)	0.33 (0.00 - 1.00)	0.00 - 3.00	39	2	0.926
Constipation (n=50)	4	0.60 (0.64)	0.50 (0.00 - 1.00)	0.00 - 2.50	34	2	0.755
Total GIT score (n=54)	30	0.47 (0.39)	0.35 (0.17 - 0.67)	0.00 - 1.51	4	0	0.931

NA: not applicable.

Table III. Spearman correlation coefficients – Romanian GIT, SHAQ, SHAQ-GI, SF-36.

	SHAQ	SHAQ-GI	PF	RP	BP	GH	VT	SF	RE	MH	PCS	MCS
Reflux (n=54)	0.361**	0.418**	-0.216	-0.140	-0.287*	-0.172	-0.274*	-0.218	-0.249	-0.150	-0.121	-0.215
Distension / bloating (n=54)	0.313*	0.446**	-0.140	-0.190	-0.213	-0.177	-0.204	-0.231	-0.360**	-0.232	-0.052	-0.324*
Fecal soilage (n=54)	0.214	0.219	-0.284*	-0.167	-0.162	-0.061	-0.101	-0.158	-0.279*	-0.167	-0.174	-0.187
Diarrhoea (n=54)	0.246	0.451**	0.066	-0.160	-0.221	-0.111	-0.126	-0.234	-0.416**	-0.255	0.105	-0.403**
Social functioning (n=54)	0.493**	0.648**	-0.162	-0.192	-0.354**	-0.219	-0.290*	-0.312*	-0.459**	-0.431**	-0.041	-0.477**
Emotional well-being (n=54)	0.638**	0.739**	-0.285*	-0.274*	-0.517**	-0.461**	-0.467**	-0.516**	-0.493**	-0.551**	-0.196	-0.604**
Constipation (n=50)	0.272	0.308*	-0.322*	-0.056	-0.203	-0.193	-0.177	-0.224	-0.213	-0.241	-0.126	-0.208
Total GIT score (n=54)	0.559**	0.726**	-0.261	-0.280*	-0.429**	-0.329*	-0.376**	-0.420**	-0.541**	-0.438**	-0.136	-0.541**

Physical Functioning (PF), Role Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role Emotional (RE), Mental Health (MH), Physical Component Summary (PCS), Mental Component Summary (MCS).
*Correlation is significant at the 0.05 level (2-tailed); **Correlation is significant at the 0.01 level (2-tailed).

Table IV. Romanian GIT scores and total SHAQ score for patients with/without clinical diagnosis.

	Gastrointestinal (GI) diagnosis			Pulmonary Fibrosis (PF) diagnosis		
	No GI diagnosis	≥1 GI diagnosis	*p*	No PF diagnosis	PF diagnosis	*p*
Reflux	0.250 (0.125-0.375)	0.625 (0.250-1.375)	0.016	0.250 (0.125-0.625)	0.625 (0.250-1.375)	0.033
Distension / bloating	0.500 (0.000-1.000)	1.000 (0.500-1.625)	0.012	0.875 (0.000-1.500)	1.000 (0.500-1.250)	0.542
Fecal soilage	0.000 (0.000-0.000)	0.000 (0.000-0.000)	1.000	NA	0.000 (0.000-0.000)	0.004
Diarrhoea	0.000 (0.000-0.000)	0.000 (0.000-0.500)	0.021	0.000 (0.000-0.000)	0.000 (0.000-0.500)	0.156
Social functioning	0.000 (0.000-0.330)	0.245 (0.000-0.660)	0.022	0.080 (0.000-0.330)	0.330 (0.000-0.660)	0.043
Emotional well-being	0.000 (0.000-0.550)	0.550 (0.000-1.550)	0.021	0.000 (0.000-0.660)	0.605 (0.110-1.385)	0.034
Constipation	0.250 (0.000-0.750)	0.500 (0.000-1.000)	0.208	0.250 (0.000-0.750)	0.500 (0.250-1.250)	0.085
Total GIT score	0.221 (0.042-0.378)	0.589 (0.221-0.839)	0.002	0.250 (0.063-0.540)	0.612 (0.336-0.851)	0.009
SHAQ total score (0-3)	0.884 (0.385-1.154)	1.154 (0.653-1.500)	0.160	0.846 (0.462-1.154)	1.423 (0.923-1.615)	0.007

Medians and interquartile ranges (25-75th percentiles). *p*-values <0.05 are considered significant (Mann-Whitney U-test).

score ((*p*=0.015). There were no significant differences in GIT scores based on disease subsets (data not shown). Interestingly, a significant difference was found in patients with or without current treatment with prokinetics, for the total GIT and distension/ bloating scores, with a higher burden of disease in those patients currently on treatment. There were no significant differences in GIT scores based on other current treatments (proton-pump inhibitors, calcium-channels blockers, NSAIDs, methotrexate, azathioprine, prostanoids) or cyclophosphamide (previous or current) treatment (data not shown). We also noted a significant difference between patients with or without a clinical diagnosis of pulmonary fibrosis, for the total GIT score, reflux subscale and fecal soilage (all patients with fecal soilage also had a diagnosis of pulmonary fibrosis) (Table IV). However, analysis of pulmonary function tests (FVC, DLCO, FVC/DLCO) and PAPs by Spearman correlations showed only higher scores in subjects with a longer disease duration and an increase of reflux scores with age, but did not reveal any significant correlations of GIT scores with PFTs or PAPs, except a small correlation of FVC with distension/ bloating scale (*r* 0.371, Spearman correlation; data not shown).

Discussion

UCLA SCTC GIT 2.0 by Khanna *et al* is the first validated questionnaire available for the assessment of gastrointestinal involvement in scleroderma patients. Our cohort is slightly different from the original cohort (12), with a lower total GIT score and ceiling effects for fecal soilage and diarrhoea, but our results are similar to other recent reports (14-15), possibly reflecting a lower disease burden in our cohort due to increased referral of early cases to this centre within the last years. Nonetheless, esophageal and anorectal dysmotility has been recently demonstrated to be a very early event (24) and we believe that the relationship of total GIT score with disease duration does not imply a lack of GI symptoms in the early stages, but rather more subtle symptoms: our findings are similar to the very high prevalence of digestive symptoms reported by Thoua *et al*. (11), with only 4% of patients reporting no symptoms in our cohort. This is in line with another recent study using a different instrument and objective assessments for evaluation of gastroesophageal disease (25).

The Romanian version of GIT 2.0 had an excellent internal consistency, except for the diarrhoea scale, which is again similar to previous reports (14-15). We found a good correlation with the mental composite score of SF-36, in line with a reported association of depressive and gastrointestinal symptoms (3), and supportive of construct validity. We did not find a correlation with the physical composite score, however we did not adjust for possible confounding variables (13). Instead we found moderate to strong correlations of most scales with the SHAQ total score and with the SHAQ-GI subscale - corroborating the construct validity of the questionnaire.

There are some limitations to our study: objective measurements or tests used for exploration of GI motility or testing for small intestine bacterial overgrowth (SIBO) presence were invasive or unavailable, so we tested construct divergence against clinical GI diagnosis. Due to a limited number of patients with a significant decrease in weight, we did not test construct divergence against weight loss. While esophageal dilation (26) was described in a few CT pulmonary scans, it was not systematically assessed on reports, therefore we did not conduct a separate analysis based on it.

A significant difference for the total GIT and reflux scores was noted among patients with or without a clinical diagnosis of pulmonary fibrosis, and this is a new finding from previous works on questionnaire validation. There is a long-time debate in the field regarding the relationship between pulmonary fibrosis and gastrointestinal disease in scleroderma. Many authors support a contribution of reflux as a perpetrator of fibrosis in the lungs (27, 28), but the relationship between pulmonary disease and dysmotility is more complex, with some reports in support of a relationship and other against it (29, 30). However, most studies relied on classical manometry. The spread of high-performance investigations may bring new data, with some recent reports in support of a relationship among GI disease and the vascular component of lung disease (31).

Previous reports on UCLA SCTC GIT 2.0 conducting factor analysis suggested a primary factor dominated by diarrhoea (and related symptoms) and a secondary factor dominated by con-

stipation (and related symptoms) (12, 13). Using a preliminary version of the UCLA GIT (1.0), Thoua *et al*. reported an inverse relationship among diarrhoea and pulmonary fibrosis (11). A low representation of lower GI tract symptoms in our cohort might be another limitation of the study, so extension of analysis on a larger cohort is needed, as well as a longitudinal assessment.

Detailed algorithms for optimal management of digestive tract involvement in scleroderma have been recently proposed (32). For a thorough assessment of gastrointestinal disease and its impact on quality of life, the application of questionnaires might complement the objective investigations. In conclusion, the Romanian version of the UCLA SCTC GIT 2.0 has acceptable reliability and validity and might prove to be a useful tool to assess the gastrointestinal disease in patients with systemic sclerosis.

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Appendix

ID: _____ Data: _____

Următoarele întrebări se referă la simptomele dumneavoastră gastrointestinale (digestive) şi la modul în care acestea v-au afectat viaţa în ultimele 7 zile. Răspundeţi la fiecare întrebare selectând răspunsul din cele indicate. Dacă nu sunteţi sigur(ă) cum să răspundeţi la o întrebare, vă rugăm alegeţi răspunsul cel mai bun pe care îl puteţi da.

		În ultima săptămână, cât de des...	(ALEGEŢI UN RĂSPUNS PENTRU FIECARE ÎNTREBARE) Nicio Zi 0	1-2 Zile 1	3-4 Zile 2	5-7 Zile 3
REFLUX	1.	...aţi avut dificultăţi să înghiţiţi mâncare solidă?	☐	☐	☐	☐
	2.	...aţi avut o senzaţie neplăcută de usturime sau arsură în piept (pirozis)?	☐	☐	☐	☐
	3.	...aţi avut senzaţia de lichid în gură, amar sau acru, venind înapoi din stomac (reflux acid)?	☐	☐	☐	☐
	4.	...aţi avut pirozis după consumul de alimente 'acide', cum ar fi roşii sau portocale?	☐	☐	☐	☐
	5.	...aţi regurgitat (aţi vomitat sau v-au venit înapoi mici cantităţi din alimentele mâncate)?	☐	☐	☐	☐
	6.	...aţi dormit într-o poziţie ridicată sau în şezut?	☐	☐	☐	☐
	7.	...aţi avut senzaţia de vomă sau vărsătură?	☐	☐	☐	☐
	8.	...aţi vomitat?	☐	☐	☐	☐
DISTENSIE	9.	...v-aţi simtit balonat(ă) (senzaţie de gaze sau aer în stomac)?	☐	☐	☐	☐
	10.	...aţi observat o balonare a abdomenului, uneori trebuind să vă desfaceţi cureaua, pantalonii sau cămaşa?	☐	☐	☐	☐
	11.	...v-aţi simţit plin(ă) după o masă redusă cantitativ ?	☐	☐	☐	☐
	12.	...aţi eliminat gaze în exces?	☐	☐	☐	☐
INCONTINENŢA FECALĂ	13.	...v-aţi pătat accidental lenjeria (cu materii fecale) înainte de a putea ajunge la o toaletă?	☐	☐	☐	☐

1/8= 0.125 2/8= 0.25 3/8= 0.375 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

SCOR R=

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

SCOR D/B=

1/1= 1.0 2/1= 2.0 3/1= 3.0

SCOR IF=

		În ultima săptămână, cât de des...	(ALEGEŢI UN RĂSPUNS PENTRU FIECARE ÎNTREBARE) Nicio Zi 0	1-2 Zile 1	3-4 Zile 2	5-7 Zile 3
DIAREE	14.	...aţi avut scaune moi (diareice)?	☐	☐	☐	☐

		În ultima săptămână, aţi observat scaunele dumneavoastra devenind...	(ALEGEŢI UN RĂSPUNS PENTRU FIECARE ÎNTREBARE) Da 1	Nu 0
	15.	...apoase?	☐	☐

1/2= 0.5 2/2= 1.0 3/2= 1.5 4/2= 2.0

SCOR D=

		În ultima săptămână, cât de des au interferat următoarele cu activităţile dvs. sociale (cum ar fi să vă vizitaţi rudele sau prietenii)?	(ALEGEŢI UN RĂSPUNS PENTRU FIECARE ÎNTREBARE) Nicio Zi 0	1-2 Zile 1	3-4 Zile 2	5-7 Zile 3
FUNCŢIONAREA SOCIALĂ	16.	...greaţa?	☐	☐	☐	☐
	17.	...vărsăturile?	☐	☐	☐	☐
	18.	...durerea de stomac?	☐	☐	☐	☐
	19.	...diareea?	☐	☐	☐	☐
	20.	...teama că v-aţi putea păta accidental lenjeria?	☐	☐	☐	☐
	21.	...senzaţia de balonare?	☐	☐	☐	☐

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

SCOR FS=

		În ultima săptămână, cât de des...	(ALEGEŢI UN RĂSPUNS PENTRU FIECARE ÎNTREBARE) Nicio Zi 0	1-2 Zile 1	3-4 Zile 2	5-7 Zile 3
STAREA EMOŢIONALĂ	22.	...aţi fost îngrijorat(ă) sau neliniştit(ă) în legătură cu problemele dvs. digestive?	☐	☐	☐	☐
	23.	...v-aţi simţit jenat(ă) datorită simptomelor dvs. digestive?	☐	☐	☐	☐
	24.	...aţi avut probleme cu relaţiile sexuale datorită simptomelor dvs. digestive?	☐	☐	☐	☐
	25.	...v-a fost teamă că s-ar putea să nu găsiţi o toaletă?	☐	☐	☐	☐
	26.	...v-aţi simţit deprimat(ă) sau descurajat(ă) datorită problemelor digestive?	☐	☐	☐	☐
	27.	...aţi evitat sau aţi amânat să vă deplasaţi datorită problemelor digestive?	☐	☐	☐	☐
	28.	...v-aţi simţit supărat(ă) sau frustrat(ă) datorită problemelor digestive?	☐	☐	☐	☐
	29.	...aţi avut tulburări ale somnului datorită problemelor dvs. digestive?	☐	☐	☐	☐
	30.	...aţi simţit că 'stresul' sau o dispoziţie supărată vă agravează problemele digestive?	☐	☐	☐	☐

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

SCOR SE=

		En ultima săptămână, aţi observat materiile fecale devenind ...	(ALEGEŢI UN RĂSPUNS PENTRU FIECARE ÎNTREBARE) Da 1	Nu 0
CONSTIPAŢIA	31.	...mai tari?	☐	☐

		În ultima săptămână, cât de des...	(ALEGEŢI UN RĂSPUNS PENTRU FIECARE ÎNTREBARE) Nicio Zi 0	1-2 Zile 1	3-4 Zile 2	5-7 Zile 3
	32.	...aţi avut constipaţie sau nu aţi putut să vă goliţi intestinul?	☐	☐	☐	☐
	33.	...aţi avut scaune tari?	☐	☐	☐	☐
	34.	...aţi avut durere în timpul scaunului?	☐	☐	☐	☐

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

SCOR C=

Vă mulţumim pentru completarea chestionarului

A se completa de către medic:

SCOR TOTAL = Reflux	_____
+ Distensie/ Balonare	_____
+ Contenţie Fecală	_____
+ Diaree	_____
+ Funcţionarea socială	_____
+ Starea emoţională	_____
SCOR TOTAL=	(_____) / 6 = _____

DE REŢINUT: SCORUL PENTRU CONSTIPAŢIE NU SE INCLUDE ÎN CALCULAREA SCORULUI TOTAL.

C= Constipaţie; D= Diaree; D/B= Distensie/Balonare; FS= Funcţionarea socială; IF= Incontinenţa fecală; R=Reflux; SE= Starea emoţională.