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Minimally Important Differences of the UCLA Scleroderma Clinical Trial Consortium Gastrointestinal Tract Instrument

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Abstract

Purpose—To provide minimally important difference (MID) estimates for the UCLA Scleroderma Clinical Trial Consortium Gastrointestinal Tract 2.0 (UCLA SCTC GIT 2.0) in a longitudinal observational cohort.

Methods—We administered the UCLA SCTC GIT 2.0 to 115 patients with SSc at 2 time points 6 months apart. UCLA SCTC GIT 2.0 has 7 multi-item scales: Reflux, Distention/Bloating, Diarrhea, Fecal Soilage, Constipation, Emotional Well-being, and Social Functioning and a Total GIT score. All scales are scored from 0 (better HRQOL) to 3 (worse HRQOL) except the diarrhea and constipation scales (ranges are 0–2 and 0–2.5, respectively). Patients also rated their overall, upper, and lower GIT involvement during the 2nd visit using a “*Much better, somewhat better, almost the same, somewhat worse, or much worse*” response scale. The minimally changed group was defined by those reporting they were somewhat *better* or somewhat *worse compared to 1st visit*.

Results—Study participants were 84% female and 81% white with a mean disease duration of 6.9 years. The MID estimates for improvement ranged from 0.07 for the Social Functioning scale to 0.36 for Emotional Well-Being scale. For worsening, the MID estimates ranged from 0.06 for Fecal Soilage scale to 0.21 for the Social Functioning Scale.

Conclusion—We provide MID estimates for the UCLA SCTC GIT 2.0 scales. This information can aid in interpreting scale scores in future RCTs and observational studies.

Keywords

gastrointestinal; scleroderma; systemic sclerosis; UCLA SCTC GIT 2.0; minimally important differences; minimal clinically important differences

Gastrointestinal tract (GIT) involvement occurs in approximately 90% of patients with systemic sclerosis (SSc)(1, 2) and has a negative impact on health-related quality of life (HRQOL)(3, 4). The UCLA Scleroderma Clinical Trial Consortium GIT 2.0 [UCLA SCTC 2.0](5) includes 34 items and 7 multi-item scales (reflux, distention/bloating, diarrhea, fecal soilage, constipation, emotional well-being, and social functioning) and a total GIT score to assess HRQOL and GIT symptoms severity in SSc. All scales are scored from 0 (better HRQOL) to 3 (worse HRQOL) except the diarrhea and constipation (range from 0–2 and 0–2.5, respectively). The GIT 2.0 takes 6–8 minutes to complete and was found to have acceptable feasibility, reliability (test-retest and internal consistency) and validity in a large observational study. This study estimates minimally important differences (MIDs) — the smallest change in score that patients perceive as beneficial—for the GIT 2.0 scales (6). MID estimates provide a benchmark for the future design of gout clinical trials by helping researchers and clinicians understand whether HRQOL score differences between two treatment groups or if changes within one group over time are meaningful (7)

MID estimates are obtained using an anchor-based approach. An “anchor” is a clinically relevant indicator of change that is used to evaluate change on a patient-reported outcome measure. Anchors include clinical indicators of response to treatment (disease severity) and patient or physician subjective reports.

Subjects and methods

Patient characteristics and study methods have been published elsewhere(5, 8). In brief, patients with SSc and GIT involvement were invited to participate at the following 3 Scleroderma centers in the United States: UCLA, Los Angeles, CA; University of Michigan, Ann Arbor, MI; and University of Texas at Houston, Houston, TX. The protocol was approved (UCLA approval #07-08-004-04) by the IRB at each institution and each subject signed a consent form prior to completing the questionnaires. In addition to completing the paper-and-pencil UCLA SCTC 2.0 questionnaire(9), patients reported their age, gender, race/ethnicity, and level of education. Each physician did a physical examination to determine the type of SSc (limited or diffuse cutaneous) and provide their GIT diagnoses.

Patients were re administered UCLA SCTC GIT 2.0 during their 2nd clinic visit. We used 3 different patient-reported anchors. Patients rated their overall, upper, and lower GIT involvement: 1. “Compared to your LAST VISIT, how would you rate your overall gastrointestinal symptoms?”; 2. “Compared to your LAST VISIT, how would you rate your upper gastrointestinal symptoms? (such as heartburn, nausea, vomiting, bloating or gas or air in the stomach)?”; and 3. “Compared to your LAST VISIT, how would you rate your lower gastrointestinal symptoms? (such as diarrhea or constipation)?” Responses were provided using a categorical response scale: “*Much better, somewhat better, almost the same, somewhat worse, or much worse.*”

For Reflux and Distention Bloating scales, we used the overall and upper GI items as anchors to estimate the MID. For Diarrhea, Constipation, and Fecal Soilage scales, the overall and lower GI scales were used as anchors. For Emotional Well-Being and Social Functioning Scales and the Total GIT score, we used all 3 rating items as anchors. The MID was estimated by examining change in scores of different GI scales ($\text{time}_2 - \text{time}_1$) in subjects who reported they were *somewhat better* or *somewhat worse*. MIDs have been found to range between effect sizes of 0.20 to 0.50.(10). ES is the ratio of observed change to a measure of variance (11) and was defined as $(\text{mean score for individual scale at time}_2 - \text{mean score for individual scale time}_1) / \text{SD baseline}$. Because we had multiple anchors for each scale, we present individual MID estimates and as an average across different anchors.

To assess the usefulness of an anchor, previous research has recommended reporting the correlation between the anchor and the change score; for example, a correlation of zero will make the anchor useless and a correlation of at least 0.30–0.35 has been suggested (10, 12). We assessed the association between the anchors and the change scores for scales using the Spearman rank-order correlations to account for the ordinal-level of measurement of the anchors.

All analyses were performed by using STATA software version 10.2 (College Station, Texas).

Results

Study Population

The participants had a mean age of 51 years, 84% were female and 81% were white; 55% had diffuse SSc(5, 8) with a disease duration of 6.9 (7.4) years.. The majority of patients had a diagnosis of GERD (91%) followed by small intestinal bowel bacterial overgrowth, gastroparesis, and diarrhea (11% each). Of 152 patients, 115 patients returned for their second visit at a mean (SD) of 6 (3) months later. Of these, 10 patients were started or dose was increased of proton-pump inhibitor, 8 were started or dose was increased for pro motility agents, and 1 each was started on antibiotics and laxatives during the 2 time points.

Spearman correlation coefficients for 3 anchors vs. 7 scales ranged from 0.04 for Constipation scale with the upper GI anchor to 0.41 for Reflux scale with the upper GI anchor (Table 1). Only the Constipation scale had non-significant correlations with its anchors (overall and lower GI). The other correlations were statistically significant (Table 1).

There were no significant changes in the mean scores of GIT scales and total GI score from baseline to second visit (Appendix Table 1). In 8 patients who started or increased their dose of proton pump inhibitors (PPIs), their mean (SD) change score was 0.09 (0.46) compared to 0.05 (0.39) in patients with no change in their PPIs ($p=0.7$). In 8 patients who were started on promotility agents, their mean (SD) change score was -0.61 (0.78) compared to $+0.01$ (0.69) in patients in whom it was not started ($p=0.03$).

The mean MID estimates for improvement ranged from 0.07 for Social Functioning scale to 0.36 for Emotional Well-Being scale (Table 2). Except for Distention/Bloating and Social Functioning scales, ES for MID estimates ranged from 0.20 to 0.58. For the Distention/Bloating scales, MID estimates for improvement were 0.04 (0.05 ES) for overall GI anchor and 0.24 (0.26 ES) for upper GI anchor. For Social Functioning scale, the MID estimates ranged from 0.04 (0.10 ES) to 0.11 (0.33 ES) for all 3 anchors. For worsening, the mean MID estimates ranged from 0.06 for Fecal Soilage scale to 0.21 for Social Functioning Scale. ES were generally smaller for worsening than for improvement group and ranged from 0.00 to 0.43. All MID estimates for improvement and worsening were larger than “no change” group.

Discussion

MID estimates provide a benchmark for interpretation of results by helping researchers and clinicians understand whether HRQOL-score differences between two treatment groups are meaningful, or if changes within one group over time are meaningful (7). For example, an average change of 0.15 points (on a 0–3 scale) for a patient-reported measure may be statistically significant in a clinic trial, but may not be perceived as beneficial by the subjects. It is also important to note that MID estimates are applicable at the group level and

not at the individual level. Other statistical tests have been recommended to assess statistical significance at an individual level (13, 14). The UCLA SCTC GIT 2.0 was developed to assess SSc-related GIT symptoms severity and impact of GIT symptoms on emotional and social functioning (5, 8). In this study, we present MID estimates for improvement and worsening that are applicable for interpretation of scores in clinical trials and observational studies. Our study is in alignment with other studies that have shown that an effect size 0.20 to 0.50 corresponds to the MID for patient-reported outcome measures (14–16). Also, the MID estimates were larger than the “no change” group providing confidence in our estimates.

Previous published literature has shown that the MID estimates may differ for worsening vs. improvement groups (14, 17, 18). Therefore, we decided to present the MID estimates separately for improvement and worsening groups. Our results are in agreement with the published data. On average, our MID estimates for improved group were larger than worsened group. The only exception was the Social Functioning scale where MID estimates were 0.07 for improved group vs. 0.21 for worsened group.

Although we show that an improvement of 0.26 points (on a 0–3 scale) in Reflux scale is the MID estimate, this should not be interpreted that a change of less than 0.26 points is not clinically important as there is an inherent uncertainty around MID estimates. Previous studies have reported this uncertainty around the MID estimates (19, 20), hence, experts recommend using several anchors. In addition, they suggest gathering data from both observational and clinical trials to gather confidence in MID estimates (10), as it is unlikely that a single MID estimate is applicable to all patient populations. Despite this uncertainty, these data can be used to interpret clinical trial data and observational studies.

Our study has several strengths. Our MID estimates are based on a large sample size in patients at 3 Scleroderma centers. Second, we prospectively incorporated anchors in order to estimate the MIDs.

Our study also has limitations. As previously pointed out (5), we only used patient-reported anchors to estimate MIDs. We did not include radiological tests measures such as the gastro-esophageal endoscopy, breath test in this study. Future studies should corroborate our estimates using these tests and different anchors. Second, our study population generally had mild-to-moderate GIT disease (self rated) with only 9% of patients stating severe-to-very severe GIT disease. The estimates may differ by severity of illness (10). In addition, as previously reported (14, 21), the majority of patients considered themselves *about the same* between the 2 time points. Therefore, these data should be considered preliminary and confirmed with larger cohorts and/or clinical trials.

In conclusion, we provide MID estimates for the UCLA SCTC GIT 2.0 scales. This information can aid in interpreting scale scores in future RCTs and observational studies.

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Key Point

We provide MID estimates for the UCLA SCTC GIT 2.0 scales that can aid in interpreting scale scores in future RCTs and observational studies.

Table 1

Spearman Correlation Coefficients between the UCLA SCTC GIT 2.0 Scales and Ratings of Overall GI, Upper GI and Lower GI involvement

Scales*	Overall GI Involvement	Upper GI Involvement	Lower GI Involvement
Reflux	0.40	0.41	0.28
Distention/Bloating	0.25	0.24	0.21
Diarrhea	0.27	0.25	0.23
Constipation	0.05	0.04	0.11
Fecal Soilage	0.20	0.09	0.17
Emotional Well-Being	0.34	0.31	0.36
Social Functioning	0.31	0.37	0.28
Total GIT score	0.48	0.52	0.40

P 0.05 are not highlighted.

* scores are calculated as the difference between time1 and time2 and anchors are administered at time2.

Table 2
Minimally important differences for UCLA SCTC GIT 2.0 scales and Total GIT Score

UCLA SCTC GIT 2.0		Overall GI Anchor				Upper GI Anchor				Lower GI Anchor			
	Patient-rated*	Mean Change	95% CI	Effect size	Mean Change	95% CI	Effect size	Mean Change	95% CI	Effect size	Mean Change	95% CI	Effect size
Reflux	much better (n = 11–12)	–0.35	(–0.69, 0)	–0.68	–0.26	(–0.54, 0.02)	–0.52						
	somewhat better (n = 15–18)	–0.26	(–0.44, –0.07)	–0.58	–0.27	(–0.56, 0.03)	–0.58						
	about the same (n = 66–71)	0.02	(–0.06, 0.1)	0.03	–0.02	(–0.1, 0.05)	–0.04						
	somewhat worse (n = 15–19)	0.15	(0, 0.29)	0.29	0.22	(0.05, 0.39)	0.32						
	much worse (n = 0–1)	NA		NA	0.41		–0.52						
Distention/Bloating	much better (n = 11–15)	–0.71	(–1.15, –0.27)	–0.74	–0.41	(–0.74, –0.08)	–0.52						
	somewhat better (n = 15–18)	–0.04	(–0.44, 0.37)	–0.05	–0.24	(–0.75, 0.26)	–0.34						
	about the same (n = 66–71)	0.11	(–0.05, 0.26)	0.14	0.04	(–0.11, 0.2)	0.06						
	somewhat worse (n = 13–19)	–0.03	(–0.29, 0.23)	–0.03	0.27	(0.05, 0.49)	0.34						
	much worse (n = 0–1)	NA			0		NA						
Diarrhea	much better (n = 11–15)	–0.41	(–0.74, –0.08)	–0.61							–0.43	(–0.76, –0.1)	–0.64
	somewhat better (n = 16–18)	–0.22	(–0.72, 0.28)	–0.29							–0.16	(–0.7, 0.38)	–0.19
	about the same (n = 66–69)	–0.1	(–0.25, 0.05)	–0.16							–0.03	(–0.16, 0.1)	–0.05
	somewhat worse (n = 12–18)	0.14	(–0.15, 0.43)	0.21							0	(–0.56, 0.56)	0
	much worse (n = 0)										NA		NA
Constipation	much better (n = 11–15)	–0.11	(–0.55, 0.32)	–0.22							–0.11	(–0.43, 0.21)	–0.24
	somewhat better (n = 16–18)	–0.15	(–0.47, 0.16)	–0.28							–0.19	(–0.53, 0.15)	–0.34
	about the same (n = 66–69)	–0.01	(–0.11, 0.1)	–0.02							–0.05	(–0.13, 0.03)	–0.11

UCLA SCTC GIT 2.0		Overall GI Anchor				Upper GI Anchor				Lower GI Anchor			
	Patient-rated*	Mean Change	95% CI	Effect size		Mean Change	95% CI	Effect size		Mean Change	95% CI	Effect size	
Fecal Soilage	somewhat worse (n = 13–19)	0.03	(–0.14, 0.21)	0.08	Emotional Well-Being					0.23	(–0.14, 0.6)	0.37	
	much worse (n = 0)	0.41								NA		NA	
	much better (n = 11–15)	–0.36	(–0.82, 0.09)	–0.56						–0.2	(–0.57, 0.17)	–0.35	
	somewhat better (n = 15–17)	–0.18	(–0.55, 0.2)	–0.21						–0.2	(–0.57, 0.17)	–0.21	
	about the same (n = 64–67)	0.06	(–0.06, 0.19)	0.11						0.01	(–0.1, 0.13)	0.03	
	somewhat worse (n = 13–19)	0.05	(–0.14, 0.25)	0.07	Social Functioning					0.08	(–0.09, 0.24)	0.09	
	much worse (n = 0)	NA								NA		NA	
	much better (n = 11–15)	–0.28	(–0.56, –0.01)	–0.53						–0.27	(–0.49, –0.06)	–0.56	
	somewhat better (n = 14–18)	–0.4	(–0.79, 0)	–0.57						–0.42	(–0.81, –0.02)	–0.58	
	about the same (n = 66–71)	0	(–0.09, 0.08)	0						0	(–0.09, 0.1)	0.01	
Total GIT score	somewhat worse (n = 13–19)	0.14	(–0.07, 0.35)	0.23						0.2	(–0.07, 0.46)	0.24	
	much worse (n = 0–1)	NA								NA		NA	
	much better (n = 11–15)	–0.23	(–0.5, 0.05)	–0.54						–0.2	(–0.4, 0)	–0.52	
	somewhat better (n = 14–18)	–0.04	(–0.15, 0.08)	–0.1						–0.07	(–0.18, 0.03)	–0.24	
	about the same (n = 64–69)	0.02	(–0.04, 0.07)	0.04						0.09	(0.01, 0.17)	0.31	
	somewhat worse (n = 13–19)	0.24	(–0.1, 0.57)	0.39						0.08	(–0.33, 0.48)	0.08	
	much worse (n = 0–1)	NA								NA		NA	
	much better (n = 11–15)	–0.51	(–0.85, –0.16)	–0.86						–0.33	(–0.48, –0.17)	–0.81	
	somewhat better (n = 15–18)	–0.18	(–0.32, –0.03)	–0.5						–0.16	(–0.32, 0.01)	–0.44	
	about the same (n = 66–71)	0.02	(–0.04, 0.08)	0.04						0.01	(–0.07, 0.1)	0.03	

UCLA SCTC GIT 2.0		Overall GI Anchor			Upper GI Anchor			Lower GI Anchor		
Patient-rated*		Mean Change	95% CI	Effect size	Mean Change	95% CI	Effect size	Mean Change	95% CI	Effect size
somewhat worse (n = 13–19)		0.12	(–0.03, 0.27)	0.22	0.2	(0.09, 0.31)	0.36	0.05	(–0.16, 0.25)	0.07
much worse (n = 0–1)		NA								NA

* n represents patients who are categorized into 5 different responses. n are presented as a range because the number of patients in each category are different based on their responses to the anchors. For Reflux and Distention/Bloating scales, we used overall and upper GI anchor; for Diarrhea, Constipation, and Fecal Soilage, we used overall and lower GI anchors.

† Overall mean change is the average of mean scores for different anchors.

A negative sign indicates improvement in the scale scores. NA=Not applicable

Appendix Table 1

Baseline and follow-up GI scores for 115 patients who completed the UCLA SCTC GIT 2.0 instrument at 2 time points

Scales	Baseline			Follow-up period			P value
	Mean Score	Standard Deviation	Range	Mean Score	Standard Deviation	Range	
Reflux	0.71	0.54	(0, 2.63)	0.66	0.53	(0, 2.75)	0.6
Distention/Bloating	1.09	0.83	(0, 3.00)	1.09	0.83	(0, 3.00)	0.8
Diarrhea	0.57	0.68	(0, 2.00)	0.47	0.56	(0, 2.00)	0.1
Fecal soilage	0.3	0.67	(0, 3.00)	0.28	0.61	(0, 3.00)	0.9
Constipation	0.44	0.50	(0, 2.25)	0.42	0.47	(0, 2.00)	0.5
Emotional well-being	0.49	0.65	(0, 2.78)	0.41	0.60	(0, 2.78)	0.6
Social functioning	0.26	0.51	(0, 3.00)	0.24	0.46	(0, 2.5)	0.8
Total Score *	0.67	0.47	(0, 2.18)	0.62	0.47	(0, 2.01)	0.5

*Total score is sum of 6 of 7 scales (excludes Constipation scale).