

Title:

Fecal incontinence in systemic sclerosis: prevalence, clinical correlates, and impact on quality of life

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Fecal Incontinence in Systemic Sclerosis: Prevalence, Clinical Correlates, and Impact on Quality of Life

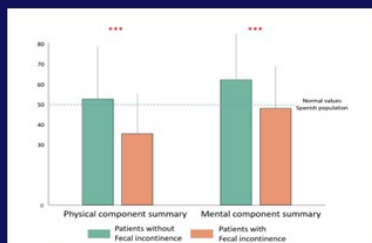
Fecal incontinence prevalence

Post-hoc case-control analysis within a cohort of 166 patients with systemic sclerosis



Prevalence 30.1%
(n=50)

Health related quality of life (SF-36)



Fecal incontinence is linked to impaired Health related quality of life

Fecal incontinence associated factors



Diffuse cutaneous subset
OR 2.61
(95% CI; 1.12-6.07)



Telangiectasias
OR 2.45,
(95% CI; 1.31-12.0)



Late pattern-capillaroscopy
OR 2.63,
(95% CI; 1.12-6.14)

Multivariable logistic regression
Adjusted: age, sex, BMI, disease duration, BCS 6-7 and opioids

Felix-Tellez, et al.

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Fecal incontinence in systemic sclerosis: prevalence, clinical correlates, and impact on quality of life

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Abbreviations:

SSc: Systemic sclerosis, UCLA SCTC GIT 2.0: University of California Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract 2.0, SF-36: Short Form-36 Health Survey Questionnaire, HADS: Hospital Anxiety and Depression Scale, HrQoL: Health-related quality of life, FI: Fecal incontinence, GI: Gastrointestinal, lcSSc: Limited cutaneous systemic sclerosis, dcSSc: Diffuse cutaneous systemic sclerosis, RP: Raynaud's phenomenon, ILD: Interstitial lung disease, PAH: Pulmonary arterial hypertension, ACR: American College of Rheumatology, EULAR: European League Against Rheumatism, QoL: Quality of life.

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DATA SHARING STATEMENT: Data are available upon reasonable request.

AUTHOR CONTRIBUTIONS

All authors meet all four ICMJE criteria. LGAG and FAFT: study management, study design, data extraction, data analysis and manuscript preparation. AGDC, AA, CB, CC, AMG, CM, CPA data extraction, data analysis and manuscript preparation, and JSP revised the final version of the manuscript for important intellectual content.

LAY SUMMARY

Fecal incontinence is frequent but underrecognized in systemic sclerosis. Among 166 patients, prevalence was 30%, associated with worse physical and mental health, higher gastrointestinal burden, and greater anxiety and depression. It was independently linked to diffuse cutaneous subtype and telangiectasias. These findings highlight fecal incontinence as a common, clinically relevant manifestation that warrants systematic screening and specialized care.

ABSTRACT

Introduction: Fecal incontinence is a frequent underrecognized complication of systemic sclerosis. It has been associated with reduced quality of life and increased psychosocial burden, but its clinical determinants remain poorly characterized.

Methods: We performed a post-hoc case-control analysis within a cohort of patients with SSc at a tertiary care center with prospectively collected clinical data. Fecal incontinence was defined by the fecal soilage subscale of the University of California Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract 2.0. Patient-reported outcomes included the Short Form-36 and Hospital Anxiety and Depression Scale. We compared patients with and without fecal incontinence and used logistic regression to identify associated factors.

Results: Fecal incontinence was reported by 30.1% of patients. Patients with fecal incontinence had significantly lower physical and mental component scores (Physical: 35.4 ± 23.2 vs. 52.6 ± 26.2 ; Mental: 48.0 ± 21.0 vs. 62.1 ± 19.8 ; $p < 0.001$). HrQoL impairment extended across almost all subdomains except for vitality ($p < 0.05$ for all). Fecal incontinence was independently associated with the diffuse cutaneous subset (OR 2.61, 95% CI 1.12–6.07), telangiectasias (OR 2.45, 95% CI 1.31–12.0) and Late pattern-capillaroscopy (OR 2.63, 95% CI 1.12–6.14 $p = 0.02$). Liquid stools and obstructive defecation symptoms were more frequent in patients with fecal incontinence ($p < 0.05$). Despite its clinical relevance, only half of patients with fecal incontinence had been evaluated by a gastroenterologist.

Conclusions: Fecal incontinence is a common and clinically relevant complication that significantly impairs HrQoL. Our findings highlight the need for systematic screening of fecal incontinence in routine care of patients with systemic sclerosis.

INTRODUCTION

Systemic sclerosis (SSc) is a chronic autoimmune connective tissue disease characterized by immune dysregulation, microvascular injury, and fibrosis.[1,2] Visceral involvement is common, particularly in the pulmonary, gastrointestinal (GI), and cardiac systems, and is associated with substantial disability and impaired quality of life.[3–6] Over recent years, advances in the management have improved survival, shifting the focus from early mortality toward long-term morbidity and health-related quality of life (HrQoL).

The GI tract is frequently affected in SSc, with up to 90% of patients reporting symptoms, primarily related to dysmotility.[3] Clinical manifestations are heterogeneous and may involve any segment of the digestive tract.[7] While most research has centered on esophageal disease, lower GI manifestations also contribute substantially to morbidity. Among these, fecal incontinence (FI) is a particularly frequent yet underrecognized

complication. A recent scoping review reported highly variable prevalence rates (0.4–77%), and consistently demonstrated that FI impairs social functioning and general health in patients with SSc.[8] In a recent Spanish survey, 41% of patients reported FI[9]; however, these data lacked of clinical or immunological correlates. We conducted, in a well-characterized Spanish SSc cohort, a cross-sectional study to evaluate the impact of FI on patient-reported HrQoL, and examine clinical and immunological correlates to identify features that may inform patient care.

MATERIALS AND METHODS

Study design

We conducted a retrospective, post-hoc case–control analysis nested within a previously published cross-sectional study of GI symptoms, psychological distress, and HRQoL in patients with SSc .[10] The parent study included consecutive patients with SSc evaluated at the Hospital Universitari Vall d’Hebron (Barcelona, Spain) between October 2021 and July 2022. For the analysis, we stratified patients according to the presence or absence of FI, as defined by the fecal soilage subscale of the University of California Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract 2.0 (UCLA SCTC GIT 2.0) questionnaire.

Study population

The parent cohort included 166 patients, all participants fulfilled the 2013 ACR/EULAR and/or the LeRoy classification criteria for SSc.[11,12] Baseline data was obtained from a prospectively maintained database of the study center, as previously described.[3,6,10,13] Patients were classified into three subsets: limited cutaneous SSc (lcSSc), diffuse cutaneous SSc (dcSSc), and sine-scleroderma. Disease onset was defined as the date of the first symptom attributable to SSc, including Raynaud’s phenomenon (RP). Peripheral vascular involvement included RP, digital ulcers, or telangiectasias. Interstitial lung disease (ILD) was diagnosed by high-resolution computed tomography. Pulmonary arterial

hypertension (PAH) was diagnosed by right heart catheterization. The presence of objective GI involvement was categorized as present or not and relied on GI tests results including the esophageal hypomotility by manometry, gastroparesis by gastric scintigraphy, gastric antral vascular ectasia, radiological signs of intestinal pseudo-obstruction, or confirmed small intestinal bacterial overgrowth. Myopathy was diagnosed when proximal muscle weakness or myalgia was associated with elevated serum creatine kinase, myopathic changes on electromyography, or histological evidence of myositis. Calcinosis cutis was defined as localized or diffuse soft-tissue calcification. Joint involvement included arthritis or tendon friction rubs. Cardiac involvement encompassed pericarditis, pericardial effusion, ischemic cardiomyopathy in the absence of conventional risk factors, or cardiac abnormalities attributable to SSc as assessed by echocardiography, cardiac magnetic resonance imaging, or gated myocardial perfusion single-photon emission computed tomography. Finally, capillaroscopy findings were categorized according to the patterns described by Cutolo et al.[1] For immunophenotyping, antinuclear antibodies were detected by indirect immunofluorescence using the Hep-2 cell line (INOVA, San Diego). Systemic sclerosis-specific autoantibodies were assessed with a commercial line blot assay (Systemic Sclerosis Profile Euroline Blot test kit, Euroimmun, Lübeck, Germany). Anti-U1-RNP and anti-Ro52 antibodies were measured by chemiluminescence immunoassay (INOVA, San Diego), following the manufacturer's recommendations.

Patient reported outcomes assessment

GI symptom burden was assessed with the Spanish version of the UCLA SCTC GIT 2.0, a validated instrument that evaluates seven symptom domains and provides a global GI score, reflecting burden over the preceding two weeks and widely used in SSc.[14]

HrQoL was assessed with the Spanish version of the SF-36, a validated 36-item questionnaire covering eight domains. Results were summarized into Physical (PCS) and Mental (MCS) Component Scores, standardized to the Spanish population (mean 50, SD 10).[15]

Psychological status was assessed using the Hospital Anxiety and Depression Scale (HADS, Spanish version), a 14-item questionnaire divided into two subscales of seven items each, measuring anxiety and depression.[16]

All participants completed a non-standardized questionnaire assessing bowel movement frequency, Bristol Stool Form Scale, and defecation-related symptoms.

Outcomes

The primary outcome was the difference in HrQoL between patients with and without FI. Secondary outcomes, in hierarchical order, included (1) identification of clinical and immunological factors associated with FI, and (2) differences in GI symptom burden and psychological distress.

Ethical considerations

The study protocol was approved by the Clinical Research Ethics Committee of Hospital Universitari Vall d'Hebron [PR(AG)312/2021]. All patients provided informed consent and the study was conducted in accordance with the Declaration of Helsinki.

Statistical Methods

Statistical analyses were performed using JASP version 0.19.3 (JASP Team, Amsterdam, The Netherlands). Categorical variables were compared using the χ^2 test. Continuous variables were assessed for normality using the Shapiro–Wilk test. Normally distributed variables were compared using Student's t-test, with Welch's correction applied when variances were unequal. Non-normally distributed variables were compared using the Mann–Whitney U-test. To explore independent associations with FI, univariate analyses were first conducted. Significant variables in univariate analysis, as well as relevant covariates (age, sex, BMI, disease duration, watery stools and opioid use), were entered into multivariable logistic regression models.

The sample size was determined using the classical formula for estimating proportions with a 95% confidence level, considering an expected prevalence of fecal incontinence of

27.2% based on values reported in the literature and an absolute margin of error of $\pm 4\%$. Based on these parameters, the theoretical sample size was 476 participants, which would have allowed for a precise prevalence estimate with a narrow confidence interval. In the present study, 166 patients were included, achieving an actual precision of approximately $\pm 7\%$, which is considered acceptable for descriptive studies of low-prevalence diseases.

Effect sizes for all patient-reported outcome comparisons were calculated using Cohen's d , and p -values were adjusted for multiple testing using the False Discovery Rate (FDR) correction according to the Benjamini–Hochberg procedure.

Results

General overview

A total of 166 patients were included; 82.5% were women, mean age was 58 ± 12 years, and mean disease duration 13.9 ± 9.6 years. Cutaneous subsets were lcSSc (57.8%) and dcSSc (23.5%). Based on UCLA GIT 2.0, 50 patients (30.1%) reported FI (21.1% mild, 4.8% moderate, 4.2% severe). Table 1.

Quality of life and psychological burden in patients with systemic sclerosis and fecal incontinence

Patients with FI had significantly lower SF-36 PCS (35.4 ± 23.2 vs. 52.6 ± 26.2 , $p < 0.001$) and MCS (48.0 ± 21.0 vs. 62.1 ± 19.8 , $p < 0.001$) compared with those without FI. Figure 1. When evaluating HrQoL subdomains, patients with FI had significantly worse scores in all except vitality. Figure 2.

Evaluating the differences in digestive-related QoL using the UCLA-GIT 2.0 subdomains, patients with FI had lower scores in both the GI specific emotional well-being and social functioning related to GI function. Figure 3

Regarding psychological distress assessed by HADS, patients with FI had higher anxiety scores (HADS Anxiety: 9.0 ± 4.6 vs 6.3 ± 4.3 , $p = 0.001$) and depression scores (HADS Depression: 8.3 ± 4.8 vs. 4.3 ± 3.7 , $p = 0.001$) compared with the non-FI group. Table 1.

Clinical characteristics associated with fecal incontinence

Patients with FI were more likely to present with the DcSSc subset (36.0% vs. 18.2%, $p=0.013$), telangiectasias (90.0% vs. 73.3%, $p=0.016$), and a capillary loss/destructive pattern (30.0% vs. 14.7%, $p=0.018$). No significant differences were observed in disease duration (13.7 ± 9.9 vs. 14.0 ± 9.4 years, $p=0.859$). Significant differences were observed in the reflux, bloating, diarrhea, social functioning, and well-being subscales of the UCLA SCTC GIT 2.0, with constipation being the only subscale not affected.

In the adjusted multivariable logistic regression model, FI remained independently associated with DcSSc (OR 2.61, 95% CI 1.12–6.07; $p=0.02$), telangiectasias (OR 2.45, 95% CI 1.31–12.0; $p=0.01$) and with Late pattern-capillaroscopy (OR 2.63, 95% CI 1.12–6.14 $p=0.02$). Figure 4.

When evaluating other GI clinical features, liquid stool was more frequently in patients with FI (50.0% vs. 25.0%; $p=0.002$). Symptoms suggestive of obstructive defecation were also more common among patients with FI, with higher prevalence of anorectal blockage sensation and incomplete evacuation. Fifty-three patients had a treating gastroenterologist, the remaining patients were treated by internal medicine or rheumatology specialists, only 48% of patients with FI had been evaluated by a gastroenterologist, and just 26% had undergone colonoscopy.

Discussion

FI is highly prevalent in Spanish patients with SSc and was strongly associated with impaired HrQoL, greater gastrointestinal symptom burden, and increased psychological distress. It clustered with disease-specific features, being more common in DcSSc and in patients with telangiectasias.

FI prevalence was present in 30.1%, considerably higher than in the general population (8.0%, 95% CI 6.8–9.2).[8] In a scoping review of FI in SSc including 61 studies, prevalence was reported as high as 77%.[17] Our findings, are consistent with previously published

data, confirming that FI is an important unmet need in the care of patients with SSc.

FI in SSc had a significant impact beyond GI symptoms. Patients with FI showed lower HrQoL, higher GI symptom burden, and greater psychological distress. These findings emphasize the physical and psychosocial consequences of FI in SSc and support prior evidence that GI involvement is a major driver of disability and reduced well-being.[6] Our findings are consistent with international studies on the impact of FI in SSc. Richard N. et al. reported an inverse correlation between FI severity and QoL, and Franck-Larsson K. et al. showed that SSc patients with bowel dysfunction had significantly lower HrQoL compared to controls.[18,19] Using Spanish population reference values, patients without FI showed normal HrQoL, unlike those with FI. Although the cross-sectional design precludes causal inference, FI appears to be a major GI driver of impaired HrQoL. Early identification and management may improve HrQoL and overall well-being.

FI was independently associated with dcSSc and telangiectasias, as well as GI features such as liquid stools and obstructive defecation symptoms. These hypothesis-generating results support prior reports linking dcSSc with FI, possibly reflecting a more aggressive phenotype with fibrosis-driven GI dysmotility and sphincter dysfunction.[20–22] The association with telangiectasias, a marker of microvascular injury, suggests a vasculopathic role in FI pathophysiology in SSc. Its link with obstructive symptoms may reflect overflow diarrhea, pelvic floor akinesia, or rectal sensory disorders. Although no significant associations with antibodies were found, a higher anti-Ku prevalence was observed. Up to 33.3% of anti-Ku-positive patients develop generalized muscle weakness, suggesting broader muscular involvement affecting both smooth (internal anal sphincter) and striated muscle (levator ani, external anal sphincter).[23] This aligns with proposed mechanisms of FI in SSc described in studies using anorectal manometry.[24–26] Future studies linking these clinical features with objective anorectal function tests may clarify mechanisms of FI in SSc. Clinically, patients with SSc, especially those with dcSSc and telangiectasias, should be proactively screened by directly inquiring about FI during consultations.

This study has limitations. Its cross-sectional design limits causal inference. FI was self-reported without severity instruments, and no objective diagnostic tests were included, which may introduce information bias due to potential underreporting or misclassification of symptoms. Although the study identified significant associations between FI and specific clinical features, it is possible that the limited sample size reduced the statistical power to detect associations of small magnitude. Consequently, subtle relationships with other disease variables may have gone undetected. Strengths include the use of validated questionnaires to assess GI symptoms, HrQoL, and psychological burden, the inclusion of all cohort patients regardless of symptoms or comorbidities, and systematically collected clinical, and immunological data. Despite being exploratory, these findings provide valuable insights and generate hypotheses. Prospective studies combining clinical characteristics, validated instruments, and anorectal function tests are needed to better characterize FI in SSc.

In conclusion, FI is a common, clinically relevant complication of SSc, particularly linked to diffuse cutaneous disease, telangiectasias and destructive capillaroscopy pattern, with significant impact on health-related and GI-specific QoL. These findings highlight the need for systematic screening in routine SSc care

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Table 1. Demographic and clinical characteristics

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	Fecal incontinence n=50	Non-Fecal incontinence n=116	p-value
Age, mean(DS)	58±12	59 ±12	0.734
Sex, n(%)	43(86)	94(81)	0.440
Body mass index, mean(DS)	25.0±5.72	25.0±4.63	0.957
Duration of disease, mean(DS)	13.7±9.95	14.0±9.43	0.859
Smoking status			
Current smoker, n(%)	3(6.0)	22(19)	0.032
Former smoker, n(%)	12(24)	30(25.9)	0.800
Subtype			
DcSSc, n(%)	18(36)	21(18.1)	0.013
LcSSc, n(%)	28(56)	68(58.6)	0.754
Sine-sclerosis, n(%)	4(8.0)	0(0.0)	0.021
Systemic component			
Raynaud phenomenon, n(%)	50(100)	111(95.7)	0.136
Digital ulcers, n(%)	21(42.0)	38(32.8)	0.254
Telangiectasias, n(%)	45(90)	85(73.3)	0.016
Calcinosis, n(%)	7(14.0)	20(17.2)	0.604
Arthritis, n(%)	1(2.0)	17(14.7)	0.049
Tendon friction rubs, n(%)	3(6.0)	5(4.3)	0.659
Myositis, n(%)	7(14)	6(5.2)	0.057
ILD, n(%)	17(34)	49(42.2)	0.261
PAH, n(%)	4(8.0)	11(9.5)	0.736
Lung transplant, n(%)	3(6.0)	10(8.6)	0.586
Scleroderma renal crisis, n(%)	1(2.0)	1(0.9)	0.541
Capillaroscopy late pattern, n(%)	15(30)	17(14.7)	0.018
Antibodies			
Antinuclear antibodies, n(%)	49(98.0)	111(95.7)	0.464
ACA, n(%)	20(40.0)	35(30.2)	0.197
Anti-SCL70, n(%)	9(18.0)	29(25.0)	0.355

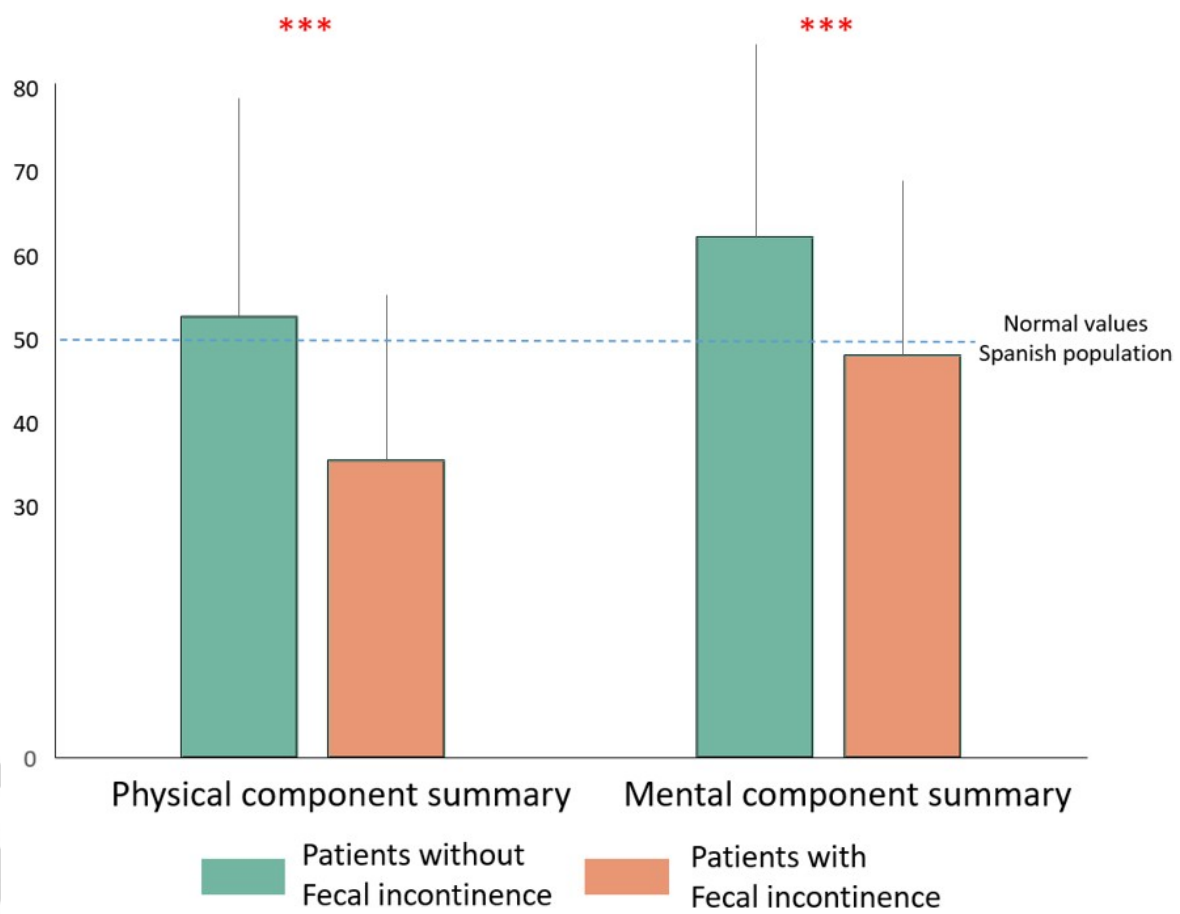


Figure 1. SF-36 component summary scores in patients with and without fecal incontinence.

***p= <0.001

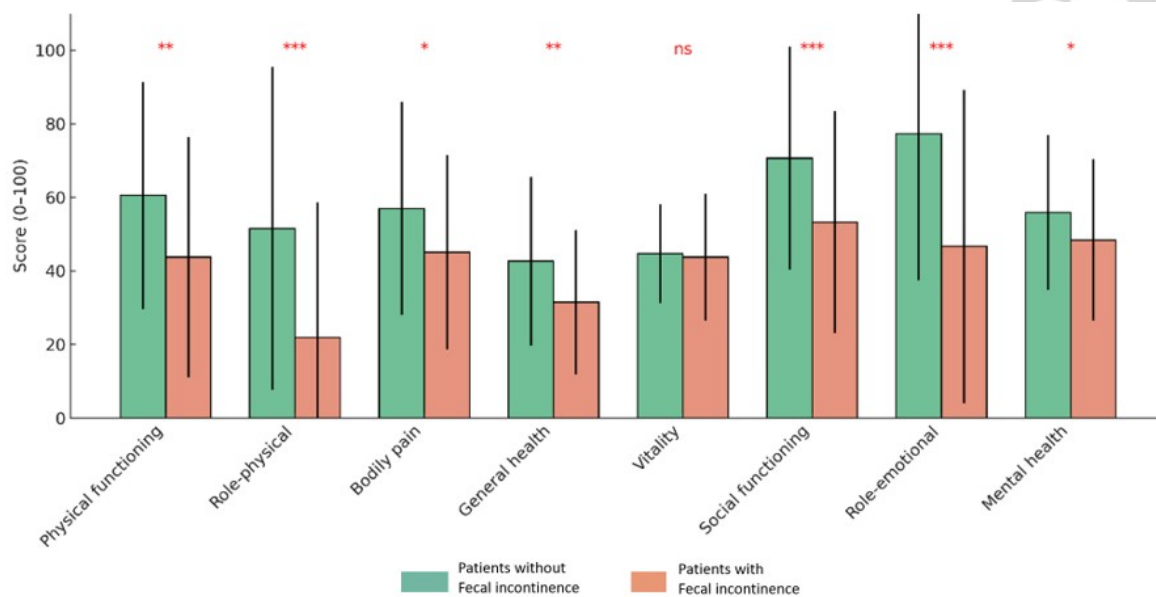


Figure 2. SF-36 subdomain scores in systemic sclerosis patients with and without fecal incontinence.

*p=<0.05, **p= <0.01, ***p= <0.001, ns: Non significance

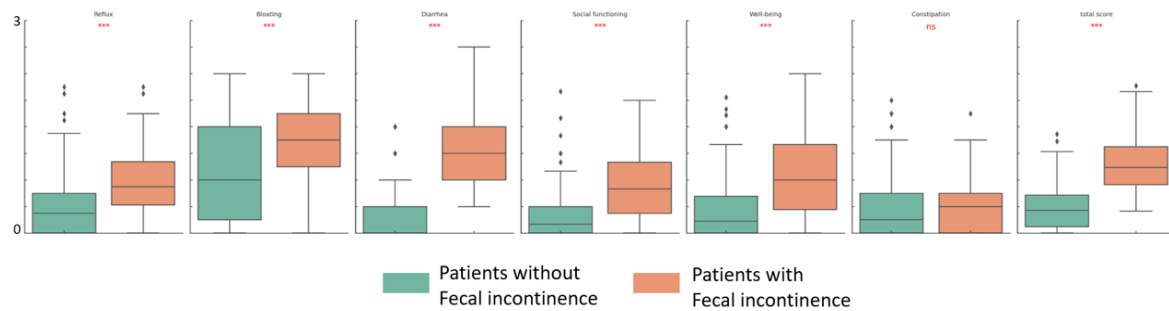


Figure 3. UCLA GIT 2.0 gastrointestinal- symptoms and gastrointestinal related quality of life scores in patients with and without fecal incontinence.

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, ns: Non significance

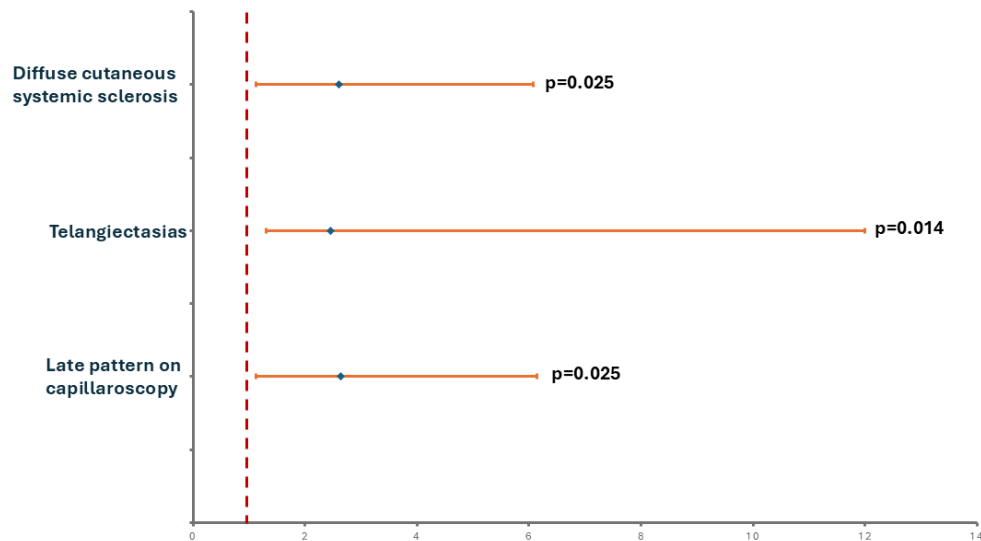


Figure 4. Multivariable logistic regression of factors associated with fecal incontinence