

# Significant gastrointestinal unmet needs in patients with Systemic Sclerosis: insights from a large international patient survey

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## Rheumatology key message

- GI symptoms are complex and multifaceted in SSc and there are many current unmet needs.

DEAR EDITOR, The gastrointestinal (GI) tract is affected in the vast majority (>90%) of patients with SSc and is associated with significant disease-related morbidity and mortality [1–6]. However, the aetiopathogenesis of SSc-related GI disease currently remains ill-defined, and therefore treatment is usually informed by a symptomatic approach [7]. Furthermore, in the absence of large, SSc-specific randomized controlled trials, recommendations are largely based on expert opinion or the extrapolation of data from other GI patient populations [8]. Clinical experience clearly demonstrates that patients consider this to be an important unmet need, as their work and personal lives are often highly impacted by SSc-related GI complications.

Against this background, we sought to refine the list of SSc GI research priorities by incorporating the viewpoints of patients living with this condition. Here we present a dedicated analysis of data acquired from a broader-ranging international survey that examined SSc patient perspectives related to the use of proton pump inhibitors (PPIs). This survey was developed in collaboration with a patient research partner with the aim of shaping the SSc GI research agenda. It included questions concerning the prevalence, impact and perceived unmet needs of SSc patients with GI disease and was disseminated through social media and SSc-focused patient organizations.

We report the perspectives of 301 SSc patients ('respondents') from 14 countries who completed the survey. The majority (95%) were female, and most were between 30 and 70 years of age (84%) and identified as white (86%) ([Supplementary Table S1](#), available at *Rheumatology* online). Respondents reported that a broad range of clinicians were involved in their care including general rheumatologists (local hospital 21% or private practice 26%), SSc specialists in an academic medical centre (26%), or a combined care from a general rheumatologist and a SSc specialist (26%). The majority (UK 88% and USA 93%) reported taking PPIs for SSc-related GI symptoms. However, a significant proportion (31% UK and 46% USA) reported that other non-PPI medication(s) had been prescribed for gastroesophageal reflux disease, including combination therapy.

We specifically questioned respondents about the presence of *any gastrointestinal symptoms*. The majority (97%) experienced 'heartburn or acid reflux'. Two-thirds of respondents (67%) reported experiencing 'a sensation of food getting stuck in their chest', 'bloating, nausea or vomiting' (63%), 'regurgitating food or phlegm' (61%), and 'trouble swallowing solid or liquid food' (59%). Around half of respondents reported 'early fullness after eating' (55%), 'diarrhoea' (52%), or 'constipation' (51%). Symptoms such as having 'a metallic taste in your mouth' or 'incontinence of stool' were experienced less commonly by patients (20% and 10.5%, respectively). Importantly, GI symptoms were considered to cause unintentional weight loss in 41% of respondents.

Nearly three-quarters (72%) of respondents reported that GI involvement has a significant impact on their *quality of life*, and most (84%) considered the impact to be either

**Table 1.** Most commonly reported gastrointestinal symptoms and their effect on quality of life in patients with systemic sclerosis (n = 301)

	n (%)
<b>Gastrointestinal symptom</b>	
Heartburn or acid reflux	216 (72)
Bloating, nausea or vomiting	101 (34)
Trouble swallowing solid or liquid food	97 (32)
Sensation of food getting stuck in your chest	95 (32)
Diarrhoea	89 (30)
Incontinence of stool	74 (25)
Regurgitating food or phlegm	70 (23)
Early fullness after eating	69 (23)
Constipation	61 (20)
A metallic taste in your mouth	7 (2)
<b>Most affected daily life activities</b>	
Sleeping	198 (66)
Social interactions/embarrassment	180 (60)
Travelling	147 (49)
Intimate relationships	96 (32)
Working	90 (30)

‘moderate’ or ‘severe’. The most common symptoms that were perceived to negatively impact quality of life were ‘heartburn or acid reflux’ (72%), ‘bloating, nausea or vomiting’ (34%), and a ‘sensation of food getting stuck in the chest’ or ‘trouble swallowing solid or liquid food’ (both 32%) (Table 1). The two aspects of daily life that were most negatively impacted by GI symptoms were sleeping (66%) and social interactions/embarrassment (60%) (Table 1). Furthermore, half (48%) of respondents considered that GI symptoms have a significant impact on their family life.

We present the results of a large international survey that has benchmarked and identified key unmet clinical GI needs in SSc. Potential limitations include the following: (i) there could be a potential selection bias from the use of social media and patient organizations for participant recruitment; for example, patients with more severe GI disease may have been more likely to participate; and (ii) the survey was only distributed in the English language; however, due to the high frequency of GI involvement in SSc, it is likely that our findings are generalizable among most SSc patients.

Our data confirm and highlight the significance of GI disease in SSc. These findings are relevant to practicing clinicians as they interview patients with SSc because they may generate a more comprehensive review of GI symptoms. Further research is urgently needed to address the burdensome and complex multifactorial manifestations of GI involvement in patients with SSc.

## Supplementary material

Supplementary material is available at *Rheumatology* online.

## Data availability

The data underlying this article will be considered to be shared on reasonable request to the corresponding author.

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**Ethics:** All subjects gave their informed consent for using their anonymous responses before starting the survey. The study was conducted in accordance with the Declaration of Helsinki and it was impossible at any time to link responses to individuals.

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