

# Esophageal Involvement and Gastroesophageal Reflux Disease in Patients with SSc-ILD: Data From a Sub-Study of the SENSICIS Trial

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## INTRODUCTION

- Upper gastrointestinal involvement, characterized by structural changes such as esophageal dilatation and manifestations such as gastroesophageal reflux disease (GERD), is frequently observed early in the course of SSc and may be associated with the severity of SSc-ILD.<sup>1-3</sup>
- In an exploratory sub-study of the SENSICIS trial,<sup>4</sup> conducted to investigate the extent of pulmonary involvement on HRCT at baseline and changes over 52-60 weeks, features related to upper gastrointestinal involvement were assessed.

## AIM

- To assess the characteristics of patients with SSc-ILD based on the presence of esophageal distension and GERD and on widest esophageal diameter on HRCT.

## METHODS

### The SENSICIS trial<sup>4</sup>

- Subjects had SSc with first non-Raynaud symptom in the prior  $\leq 7$  years, extent of fibrotic ILD on HRCT  $\geq 10\%$ , FVC  $\geq 40\%$  predicted, diffusing capacity of the lung for carbon monoxide (DLco) 30-89% predicted. Patients with clinically significant pulmonary hypertension were excluded.
- In a sub-study, baseline HRCT scans were assessed by a single radiologist to determine:
  - Presence of esophageal distension (diffuse or focal)
  - Widest esophageal diameter, i.e., largest distance between internal esophageal mucosal limits for three diameter measurements on supine axial images (above aortic arch, between right inferior pulmonary vein and aortic arch, between diaphragmatic hiatus and right inferior pulmonary vein).

- GERD was based on report of "esophageal (dysphagia, reflux)" as SSc-related medical history.

### Analyses

- In descriptive analyses, we assessed the baseline demographics and clinical characteristics of subgroups based on:
  - Presence (yes/no) of esophageal distension and GERD
  - Widest esophageal diameter  $\leq 15$  mm vs  $>15$  mm.

## CONCLUSIONS

- Exploratory analyses of a sub-study of the SENSICIS trial suggest that patients with SSc-ILD who had esophageal involvement and GERD, or a widest esophageal diameter  $>15$  mm, had worse disease severity and quality of life.
- Patients with SSc should be thoroughly evaluated for organ involvement at the time of diagnosis and during follow-up, to ensure that all aspects of the disease can be managed appropriately.

## RESULTS

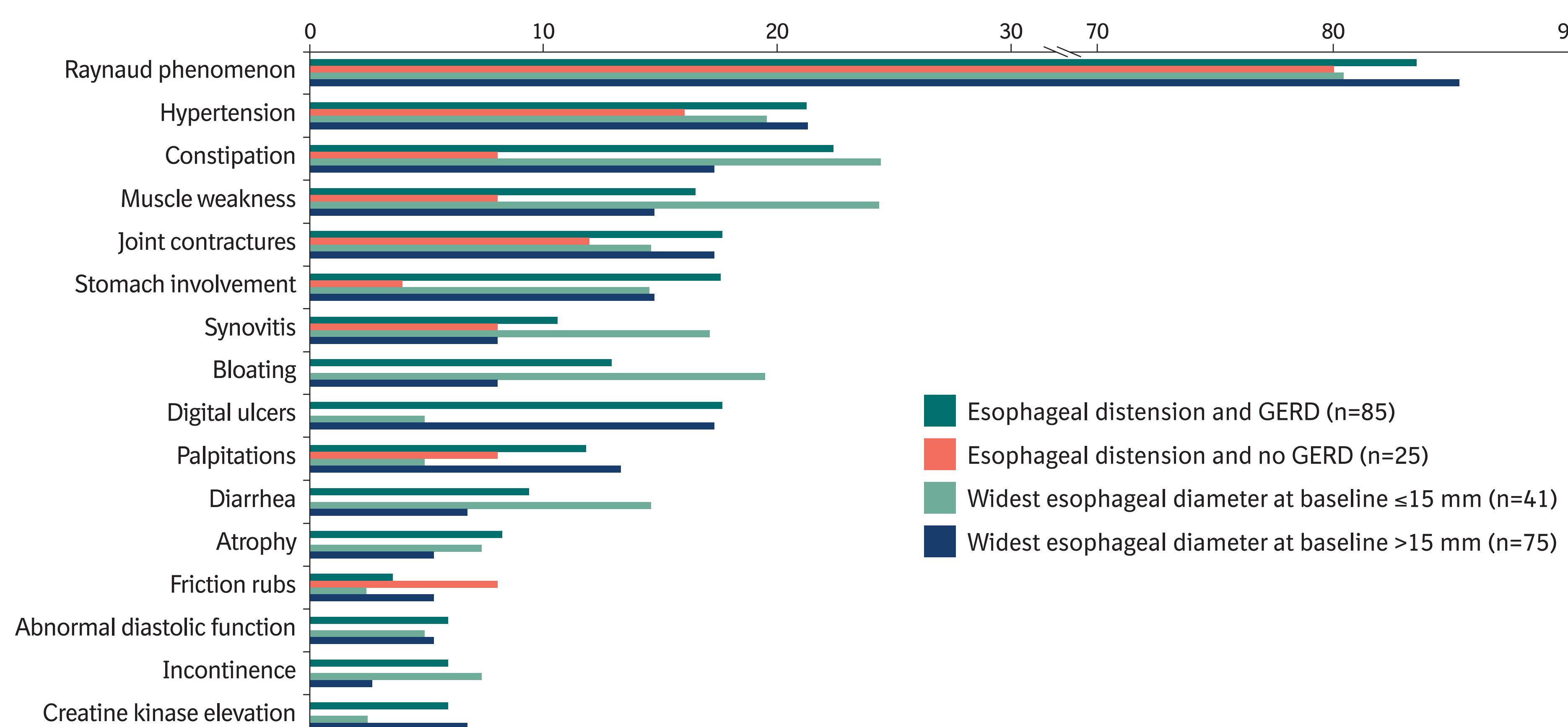
- Of 576 patients in the trial, 150 participated in the HRCT sub-study. Data on esophageal distension and diameter were available in 117 and 116 patients, respectively.

### Demographics and SSc characteristics

Esophageal distension and GERD (n=85)	Esophageal distension and no GERD (n=25)		Widest esophageal diameter at baseline $\leq 15$ mm (n=41)	Widest esophageal diameter at baseline $>15$ mm (n=75)
53.7 (12.5)	58.2 (11.8)	Age, years	56.3 (11.6)	54.0 (12.8)
65.9	76.0	Female	82.9	60.0
69.4	44.0	White	65.9	64.0
20.0	56.0	Asian	26.8	26.7
8.2	0	Black or African-American	4.9	6.7
1.2	0	Other	0	1.3
26.0 (4.8)	25.7 (4.5)	BMI, kg/m <sup>2</sup>	26.9 (5.9)	25.8 (4.3)
3.2 (1.5)	2.3 (1.2)	Years since onset of first non-Raynaud symptom	2.9 (1.4)	3.1 (1.5)
47.1	24.0	Diffuse cutaneous SSc	22.0	52.0
58.8	52.0	ATA positive	43.9	62.7
9.0 (8.0)	7.1 (5.3)	mRSS	6.1 (6.9)	9.6 (7.6)
36.9 (19.4)	34.8 (24.0)	Extent of fibrotic ILD on HRCT, %*	29.1 (18.5)	39.1 (20.7)
89.4	56.0	Drugs for gastric acid-related disorders	80.5	81.3

Data are mean (SD) or % of patients. Seven patients had GERD and no esophageal distension. \*Assessed visually in the whole lung to the nearest 5%. Pure (non-fibrotic) ground-glass opacity was not included.

### SSc-related medical history



Data are % of patients with the characteristic at screening. SSc characteristics reported in  $>5\%$  of patients in any subgroup are shown.

### Lung function

Esophageal distension and GERD (n=85)	Esophageal distension and no GERD (n=25)		Widest esophageal diameter at baseline $\leq 15$ mm (n=41)	Widest esophageal diameter at baseline $>15$ mm (n=75)
73.9 (16.0)	80.6 (16.5)	FVC % predicted	78.0 (15.6)	73.7 (16.5)
98.0 (1.5)	97.5 (2.6)	SpO <sub>2</sub> , %	97.5 (2.5)	97.9 (1.7)
51.2 (13.7)	59.3 (17.4)	DLco % predicted	56.0 (17.3)	51.7 (13.7)

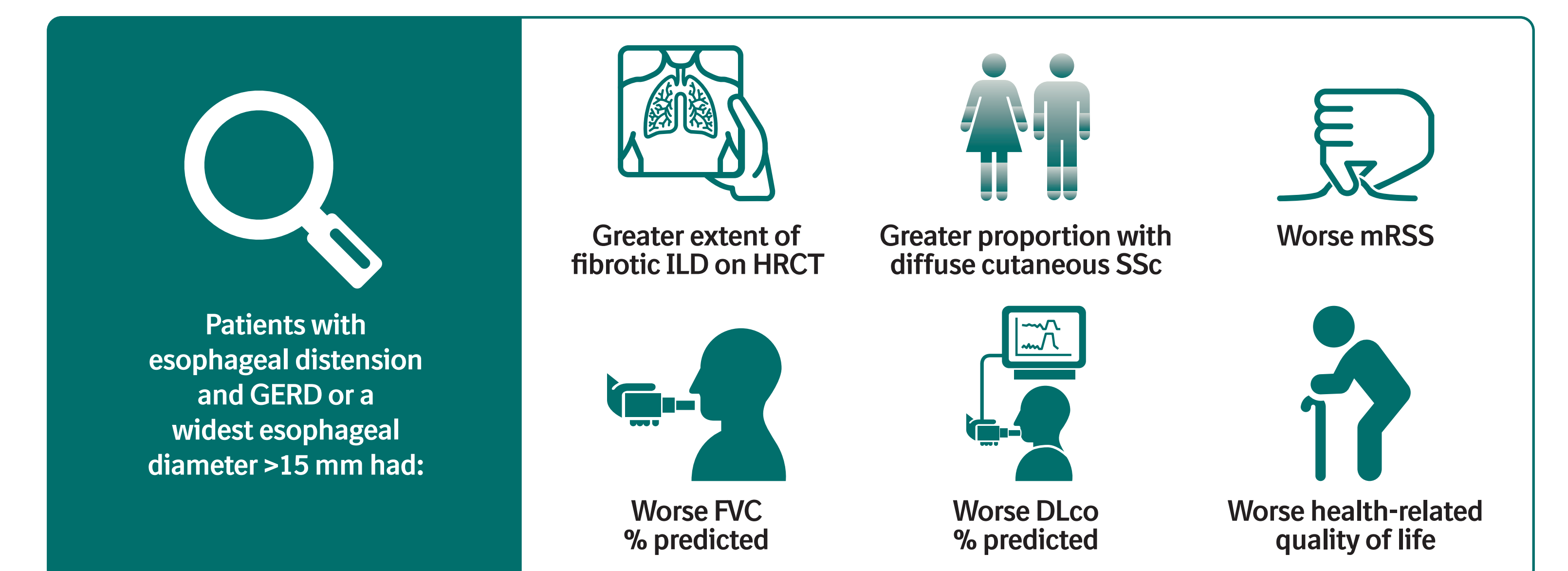
Data are mean (SD). Seven patients had GERD and no esophageal distension.

### Patient-reported outcomes

Esophageal distension and GERD (n=85)	Esophageal distension and no GERD (n=25)		Widest esophageal diameter at baseline $\leq 15$ mm (n=41)	Widest esophageal diameter at baseline $>15$ mm (n=75)
39.0 (20.6)	29.3 (17.0)	SGRQ total score	33.7 (20.4)	39.0 (19.7)
45.1 (8.9)	40.4 (8.5)	FACIT dyspnea score	42.8 (10.0)	45.1 (8.5)
0.49 (0.64)	0.18 (0.31)	HAQ-DI score	0.40 (0.64)	0.46 (0.60)
70.0 (22.0)	78.0 (15.5)	EuroQoL 5D score	76.0 (17.7)	69.7 (22.2)

Data are mean (SD). SGRQ total, FACIT dyspnea, HAQ-DI and EuroQoL 5D scores range from 0-100, 27.7-75.9, 0-3 and 0-100, respectively. Higher SGRQ, FACIT dyspnea and HAQ-DI scores indicate worse impairment/more severe limitations. FACIT, Functional Assessment of Chronic Illness Therapy; HAQ-DI, Health Assessment Questionnaire Disability Index; SGRQ, St George's Respiratory Questionnaire.

### Summary

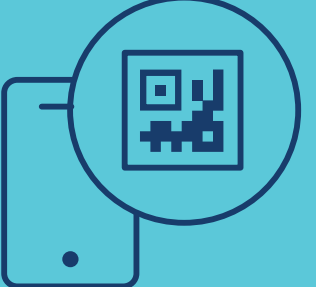


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