Risk of malnutrition in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD): further analyses of the SENSCIS trial

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INTRODUCTION

- In patients with SSc, gastrointestinal manifestations and reduced functional ability are associated with an increased risk of weight loss and malnutrition.[1,2]
- In the SENSCIS trial in patients with SSc-ILD, nintedanib reduced the rate of decline in forced vital capacity (FVC) (mL/year) over 52 weeks, with an adverse event profile characterised mainly by gastrointestinal adverse events.[3]
- The Malnutrition Universal Screening Tool (MUST) was developed to identify adults who are at risk of malnutrition[4] and has been used in studies of patients with SSc.[2,5]

AIM

- To evaluate nutritional status over 52 weeks in the SENSCIS trial based on a modified MUST score.

METHODS

- Patients had SSc with first non-Raynaud symptom ≤7 years before screening, extent of fibrotic ILD on HRCT ≥10%, FVC ≥40% predicted, and DLco 30–89% predicted. Patients taking prednisone ≤10 mg/day and/or stable therapy with mycophenolate or methotrexate for ≥6 months were allowed to participate.
- Patients were randomised to receive nintedanib 150 mg bid or placebo. Dose reductions to 100 mg bid and treatment interruptions were allowed to manage adverse events.
- We calculated modified MUST scores at baseline and weeks 12, 24, 36 and 52. Baseline MUST score was based solely on BMI.

Step 1. BMI
Based on height at screening, and weight at weeks 12, 24, 36 and 52

BMI	Score
>20 kg/m²	0
18.5–20 kg/m²	1
<18.5 kg/m²	2

Step 2. Weight loss
Calculated between: week 12 vs baseline; week 24 vs week 12; week 36 vs week 24; week 52 vs week 36

Weight loss	Score
<5%	0
5–10%	1
>10%	2

Step 3. Surrogate for acute disease effect
If the patient had any serious adverse event that led to hospitalisation between weight assessments and received ≥1 medication from the WHO classification code for "solutions for parenteral nutrition" for ≥5 days (of which ≥1 day overlapped with the serious adverse event) = score of 2

Scores from Steps 1 to 3 are summed*
The MUST score ranges from 0 to 6:
0: low risk of malnutrition
1: medium risk of malnutrition
≥2: high risk of malnutrition

*In case of missing data, scores were only included if the sum of the available scores was ≥2.

CONCLUSIONS

- In the SENSCIS trial, scores based on a modified MUST indicated that most patients treated with nintedanib were at low risk of malnutrition at baseline and remained at low risk over 52 weeks.
- The proportions of patients at high risk of malnutrition were low but were numerically greater in patients who received nintedanib than placebo.
- Management of disease manifestations and gastrointestinal adverse events that may be associated with weight loss is important to reduce the risk of malnutrition in patients with SSc-ILD treated with nintedanib.

RESULTS

Table 1. Baseline characteristics

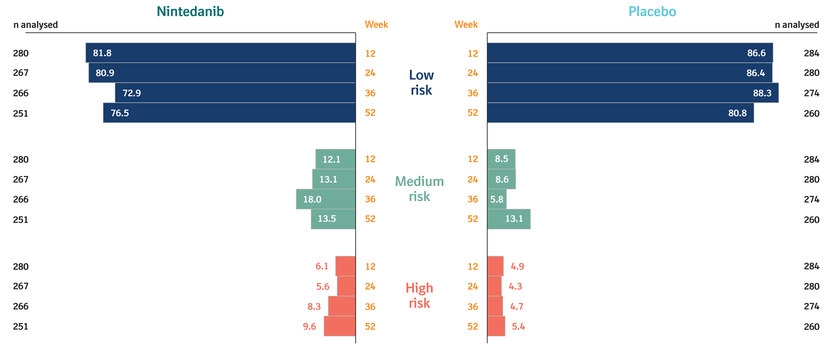
	Nintedanib (n=288)	Placebo (n=288)
Mean age (years)	54.6	53.4
Female, %	76.7	73.6
Mean weight (kg)	69.4	70.0
Mean BMI (kg/m²)	25.9	25.8
Diffuse cutaneous SSc, %	53.1	50.7
Mean FVC % predicted	72.4	72.7
Mean DLco % predicted*	52.9	53.2
Taking mycophenolate, %	48.3	48.6
Predisposition to intestinal events, %†	39.9	39.6

*Corrected for haemoglobin; 7 subjects had missing DLco values.
†History of and/or presence at baseline of diarrhoea, bloating, constipation, or incontinence.

Table 2. Mean modified MUST scores over 52 weeks

	Nintedanib		Placebo	
	n analysed	Mean (SD) score	n analysed	Mean (SD) score
Week 12	280	0.3 (0.6)	284	0.2 (0.5)
Week 24	266	0.3 (0.6)	278	0.2 (0.5)
Week 36	263	0.4 (0.7)	271	0.2 (0.5)
Week 52	250	0.4 (0.7)	258	0.2 (0.6)

Figure. Risk of malnutrition at weeks 12, 24, 36 and 52, % of patients



- MUST scores suggested that 74.0% and 78.1% of patients in the nintedanib and placebo groups, respectively, were at low risk of malnutrition at baseline and remained at low risk at their last measurement.

Table 3. Risk of malnutrition at baseline and at last assessment, n (%) of patients

Nintedanib		Baseline risk: Low	Medium	High	Total
Last assessment of risk	Low	213 (74.0)	1 (0.3)	0	214 (74.3)
	Medium	31 (10.8)	8 (2.8)	0	39 (13.5)
	High	13 (4.5)	8 (2.8)	7 (2.4)	28 (9.7)
	Missing	7 (2.4)	0	0	7 (2.4)
	Total	264 (91.7)	17 (5.9)	7 (2.4)	288 (100)

Placebo		Baseline risk: Low	Medium	High	Total
Last assessment of risk	Low	225 (78.1)	7 (2.4)	0	232 (80.6)
	Medium	20 (6.9)	14 (4.9)	4 (1.4)	38 (13.2)
	High	3 (1.0)	2 (0.7)	10 (3.5)	15 (5.2)
	Missing	3 (1.0)	0	0	3 (1.0)
	Total	251 (87.2)	23 (8.0)	14 (4.9)	288 (100)

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