Baseline characteristics of patients with improvement or progression of systemic sclerosis-associated interstitial lung disease (SSc-ILD) during the SENSCIS trial

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INTRODUCTION

- The course of SSc-ILD is variable and may include periods of stability or improvement in forced vital capacity (FVC) as well as periods of decline.[1]
- A number of studies have identified characteristics associated with FVC decline in patients with SSc-ILD,[1–3] but the course of disease for an individual patient cannot be predicted.

AIM

- To investigate the baseline characteristics of patients with SSc-ILD in the placebo group of the SENSCIS trial whose ILD improved or progressed over 52 weeks.

METHODS

Trial design[A]

- Patients had SSc with first non-Raynaud symptom in the prior ≤7 years, extent of fibrotic ILD on high-resolution computed tomography (HRCT) ≥10%, FVC ≥40% predicted and DLco 30–89% predicted.
- Patients taking prednisone ≤10 mg/day and/or stable therapy with mycophenolate or methotrexate were allowed to participate.
- Patients were randomised to receive nintedanib or placebo until the last patient had reached week 52 but for ≤100 weeks.

Analyses

- We investigated the baseline characteristics of patients in the placebo group in subgroups based on the course of SSc-ILD over 52 weeks:

Improvement	Stability	Progression	Significant progression
absolute increase in FVC ≥5% predicted	absolute decline or increase in FVC <5% predicted	absolute decline in FVC ≥5% predicted	absolute decline in FVC ≥10% predicted

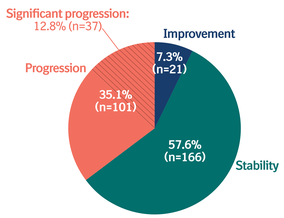
- Missing FVC data at week 52 were imputed using a worst observation carried forward approach.
- P-values based on ANOVA or Chi-squared tests were used to compare the baseline characteristics of the patients who showed improvement, stability, and progression.

CONCLUSIONS

- In the SENSCIS trial, most baseline characteristics were similar across subgroups based on progression of SSc-ILD over 52 weeks, but patients who had higher DLco % predicted or who were taking mycophenolate at baseline were less likely to show progression, while patients with a greater extent of fibrosis on HRCT were numerically more likely to show progression.

RESULTS

Course of SSc-ILD over 52 weeks in placebo group of SENSCIS trial (N=288)



Baseline characteristics of subgroups based on course of SSc-ILD over 52 weeks

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