Poster

Decline in forced vital capacity (FVC) in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) in consecutive 6-month periods of the SENSCIS trial

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Decline in forced vital capacity (FVC) in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) in consecutive 6-month periods of the SENSCIS trial

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INTRODUCTION

- A decline in FVC in patients with SSc-ILD reflects disease progression and is associated with an increased risk of mortality.[1,2]
- SSc-ILD has a variable course, which may include periods of decline in FVC and periods of stability.[1,3]

AIM

- To assess the prognostic value of change in FVC over 24 weeks for change in FVC over the following 28 weeks in patients with SSc-ILD using data from the placebo group of the SENSCIS trial.

METHODS

Trial design[4]

- Patients had SSc with first non-Raynaud symptom in the prior ≤7 years, extent of fibrotic ILD on HRCT ≥10%, FVC ≥40% predicted.
- Patients taking prednisone ≤10 mg/day and/or stable therapy with mycophenolate or methotrexate for ≥6 months were allowed to participate.
- Patients were randomized to receive nintedanib or placebo.

Analyses

- In *post-hoc* analyses, we analyzed the proportions of patients in the placebo group who had an increase or no decline in FVC % predicted, a decline in FVC <5% predicted, a decline in FVC ≥5% to <10% predicted, and a decline in FVC ≥10% predicted from week 24 to week 52 in subgroups of patients who had these categorical changes in FVC % predicted from baseline to week 24:
  - Patients who died were excluded
  - Missing FVC values at weeks 24 and 52 were imputed using a worst value carried forward approach.
- We used segmented linear mixed effects models, which allowed for different slopes before and after week 24, to analyze the change in FVC % predicted over 52 weeks in the same subgroups.

CONCLUSIONS

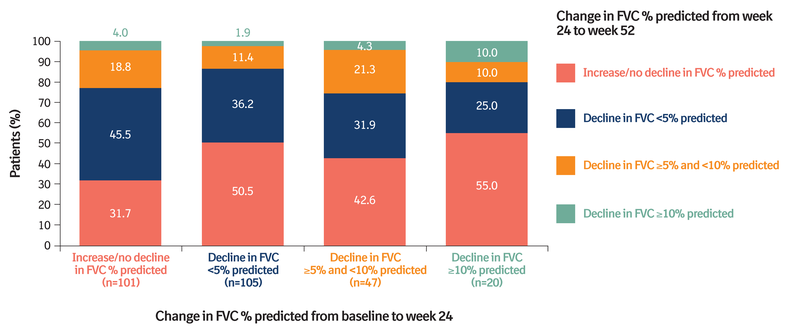
- Among patients with SSc-ILD who received placebo in the SENSCIS trial, change in FVC over 6 months could not reliably be predicted based on monitoring over the prior 6 months.
- These findings highlight the challenges in predicting the course of SSc-ILD and the importance of regular monitoring over a prolonged period.

RESULTS

Change in FVC % predicted from week 24 to week 52 in subgroups by change in FVC % predicted from baseline to week 24

- In the placebo group overall, there was no association between change in FVC % predicted from baseline to week 24 and change in FVC % predicted from week 24 to week 52. Results were similar in subgroups by use of mycophenolate at baseline.

Change in FVC % predicted from week 24 to week 52 in subgroups by change in FVC % predicted from baseline to week 24

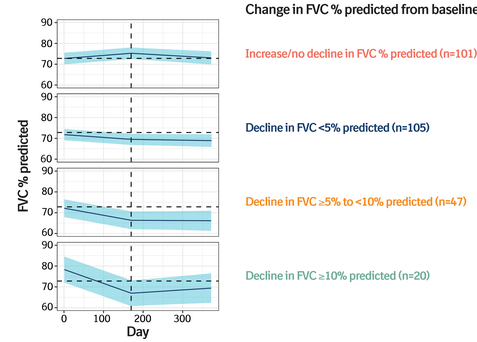


At baseline, mean time since first non-Raynaud symptom was 3.5 years and mean FVC was 72.7% predicted. Missing FVC values at weeks 24 and 52 were imputed using a worst value carried forward approach. p=0.11 for chi-square test of independence; p=0.27 for linear-by-linear test of ordinal associations.

Change in FVC % predicted over 52 weeks based on segmented linear mixed effects models

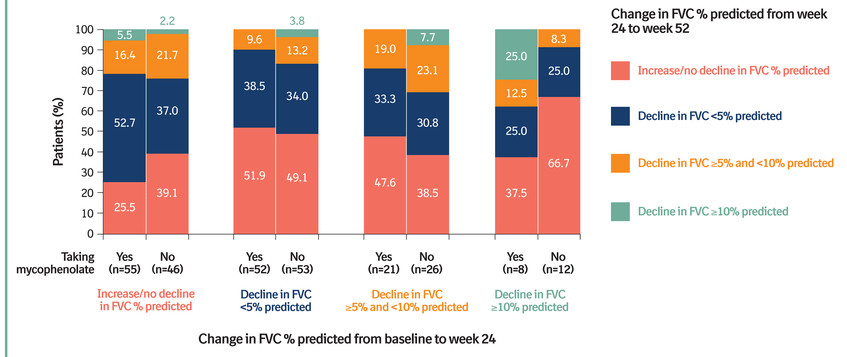
- Patients with a decline in FVC ≥10% predicted between baseline and week 24 tended to have an increase in FVC % predicted between week 24 and week 52, while patients with an increase or no decline in FVC % predicted in the first period tended to have a decline in the second period. Results were similar in subgroups by use of mycophenolate at baseline.

Change in FVC % predicted over 52 weeks in subgroups by change in FVC % predicted from baseline to week 24



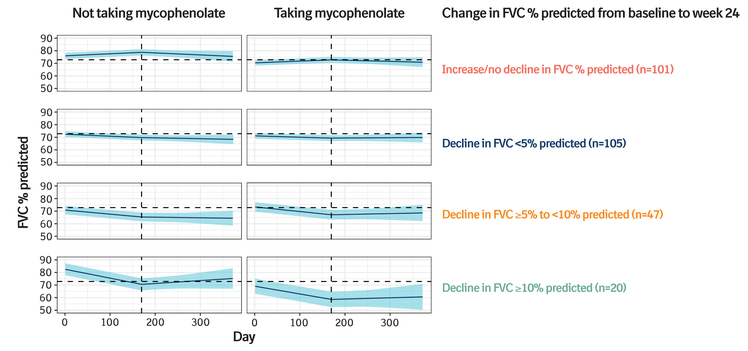
Based on segmented linear mixed effects models. Vertical dashed line indicates week 24. Horizontal dashed line indicates mean baseline FVC % predicted.

Change in FVC % predicted from week 24 to week 52 in subgroups by change in FVC % predicted from baseline to week 24 by use of mycophenolate at baseline



Missing FVC values at weeks 24 and 52 were imputed using a worst value carried forward approach.

Change in FVC % predicted over 52 weeks in subgroups by change in FVC % predicted from baseline to week 24 by use of mycophenolate at baseline



Based on segmented linear mixed effects models. Vertical dashed line indicates week 24. Horizontal dashed line indicates mean baseline FVC % predicted.

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