Poster

Changes in radiological features in patients with progressive fibrosing ILDs treated with nintedanib: a sub-study of the INBUILD trial

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Changes in radiological features in patients with progressive fibrosing ILDs treated with nintedanib: a sub-study of the INBUILD trial

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INTRODUCTION

- In the INBUILD trial in patients with progressive fibrosing ILDs other than idiopathic pulmonary fibrosis (IPF), nintedanib reduced the rate of decline in forced vital capacity (FVC) (mL/year) versus placebo by 57% in the overall population and by 61% in patients with a usual interstitial pneumonia (UIP)-like fibrotic pattern on high-resolution computed tomography (HRCT).[1]
- The effects of nintedanib on markers of lung fibrosis on HRCT were assessed in an exploratory sub-study of the INBUILD trial.

AIM

- To assess the effects of nintedanib on the overall extent of fibrosis and on specific features on HRCT in patients with progressive fibrosing ILDs.

METHODS

INBUILD trial[1]

- Patients in the INBUILD trial had a physician-diagnosed ILD other than IPF with features of diffuse fibrosing ILD (reticular abnormality with traction bronchiectasis, with or without honeycombing) of >10% extent on HRCT. Patients met criteria for ILD progression within the prior 24 months, based on worsening of FVC, abnormalities on HRCT, or symptoms, despite management deemed appropriate in clinical practice.
- Patients were randomized to receive nintedanib or placebo, stratified by HRCT pattern (UIP-like fibrotic pattern or other fibrotic patterns).

HRCT sub-study

- HRCT scans taken at baseline and at week 52 were reviewed by two independent radiologists who were blinded to treatment group and time-point.
- Qualitative changes between baseline and week 52 were assessed as follows:

Overall extent of fibrosis	Worse	Same	Better
Honeycombing	More	Same	Less
Traction bronchiectasis	More	Same	Less
Reticulation	More	Same	Less
Ground glass opacification	More	Same	Less
Volume loss	More	Same	Less

Disagreement between the reviewers in the change in overall extent of fibrosis was resolved by adjudication by a third radiologist. Disagreement between the reviewers in the changes in the individual features was resolved as follows: more and same = more; same and less = same; more and less = discordant.

- An ordinal logistic regression analysis (proportional odds model) was used to compare changes between treatment groups.

CONCLUSIONS

- In a sub-study of the INBUILD trial, based on qualitative visual scoring:
  - Changes in the overall extent of fibrosis and in specific features on HRCT over 52 weeks were small
  - In patients with fibrotic patterns other than UIP, treatment with nintedanib appeared to be associated with a lower risk of worsening in the extent of ground glass opacification.

RESULTS

Patients

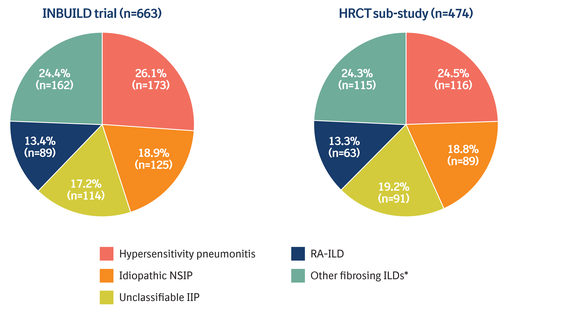
- There were 474 participants in the sub-study, of whom 350 (172 who received nintedanib, 178 who received placebo) had evaluable HRCT scans at baseline and week 52.

Baseline characteristics of patients in INBUILD trial and HRCT sub-study

	INBUILD trial (n=663)	HRCT sub-study (n=474)
Male	53.7	54.2
Age, years	65.8 (9.8)	65.4 (9.8)
White	73.6	70.7
Body mass index, kg/m^2	28.3 (5.3)	28.4 (5.4)
UIP-like fibrotic pattern on HRCT	62.1	61.6
Time since diagnosis of ILD, years	3.8 (3.8)	3.8 (3.7)
FVC % predicted	69.0 (15.6)	68.9 (15.3)
DLco % predicted	46.1 (13.6)	46.2 (14.1)

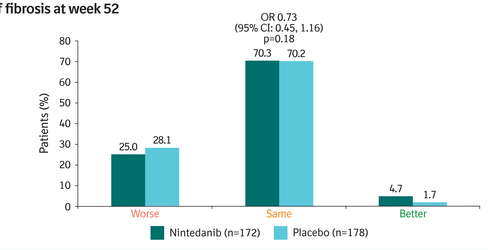
Data are mean (SD) or % of patients.

ILD diagnoses in INBUILD trial and HRCT sub-study

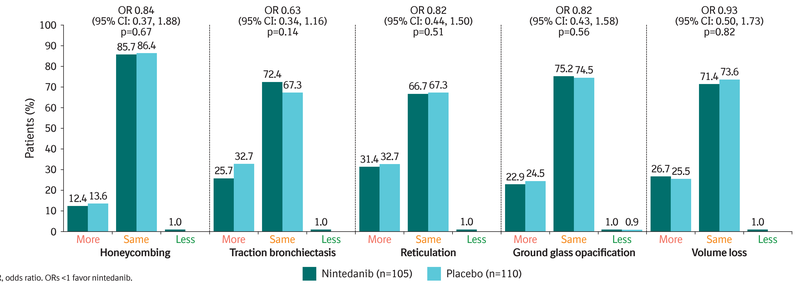


*Included SSc-ILD, MCTD-ILD, other autoimmune ILDs (e.g. Sjögren's syndrome-associated ILD, systemic lupus erythematosus-associated ILD), exposure-related ILDs, sarcoidosis, and other IIPs (e.g. pleuroparenchymal fibroelastosis, cryptogenic organising pneumonia, desquamative interstitial pneumonia).
IIP, idiopathic interstitial pneumonia. RA, rheumatoid arthritis.

Change in overall extent of fibrosis at week 52

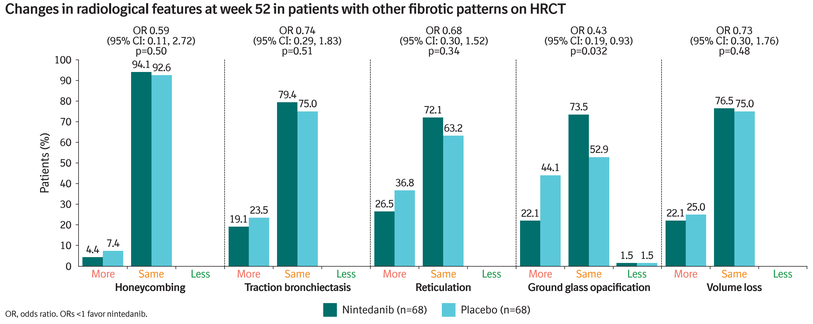


Changes in radiological features at week 52 in patients with UIP-like fibrotic pattern on HRCT



OR, odds ratio. ORs <1 favor nintedanib.

Changes in radiological features at week 52 in patients with other fibrotic patterns on HRCT



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1. Flaherty KR et al. N Engl J Med 2019;381:1718–1727.

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