Safety and tolerability of nintedanib in patients with autoimmune disease-related interstitial lung diseases (ILDs) in subgroups by sex and age

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11.5 (2.3)

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INTRODUCTION

- The efficacy and safety of nintedanib in patients with autoimmune disease-related ILDs have been investigated in two placebo-controlled trials: the SENSCIS trial in patients with systemic sclerosis-associated ILD (SSc-ILD) and the INBUILD trial in patients with progressive fibrosing ILDs other than idiopathic pulmonary fibrosis (IPF). 1-4
- The tolerability of a drug may vary in patients of different sex and age.^{5,6}

To assess the safety and tolerability of nintedanib in patients with autoimmune disease-related ILDs by sex and age.

METHODS

Data were pooled from all patients in the SENSCIS trial and patients with autoimmune disease-related ILDs in the INBUILD trial.

Key inclusion criteria

SENSCIS trial¹ Age ≥18 years Diagnosis of diffuse fibrosing ILD other than IPF Age ≥18 years Diagnosis of SSc based on ACR/EULAR classification criteri honeycombing) on HRCT with first non-Raynaud symptom in prior ≤7 years Predominant features on HRCT consistent with SSc-ILD Fibrotic ILD of ≥10% extent on HRCT

- FVC ≥40% predicted
- DLco 30–89% predicted

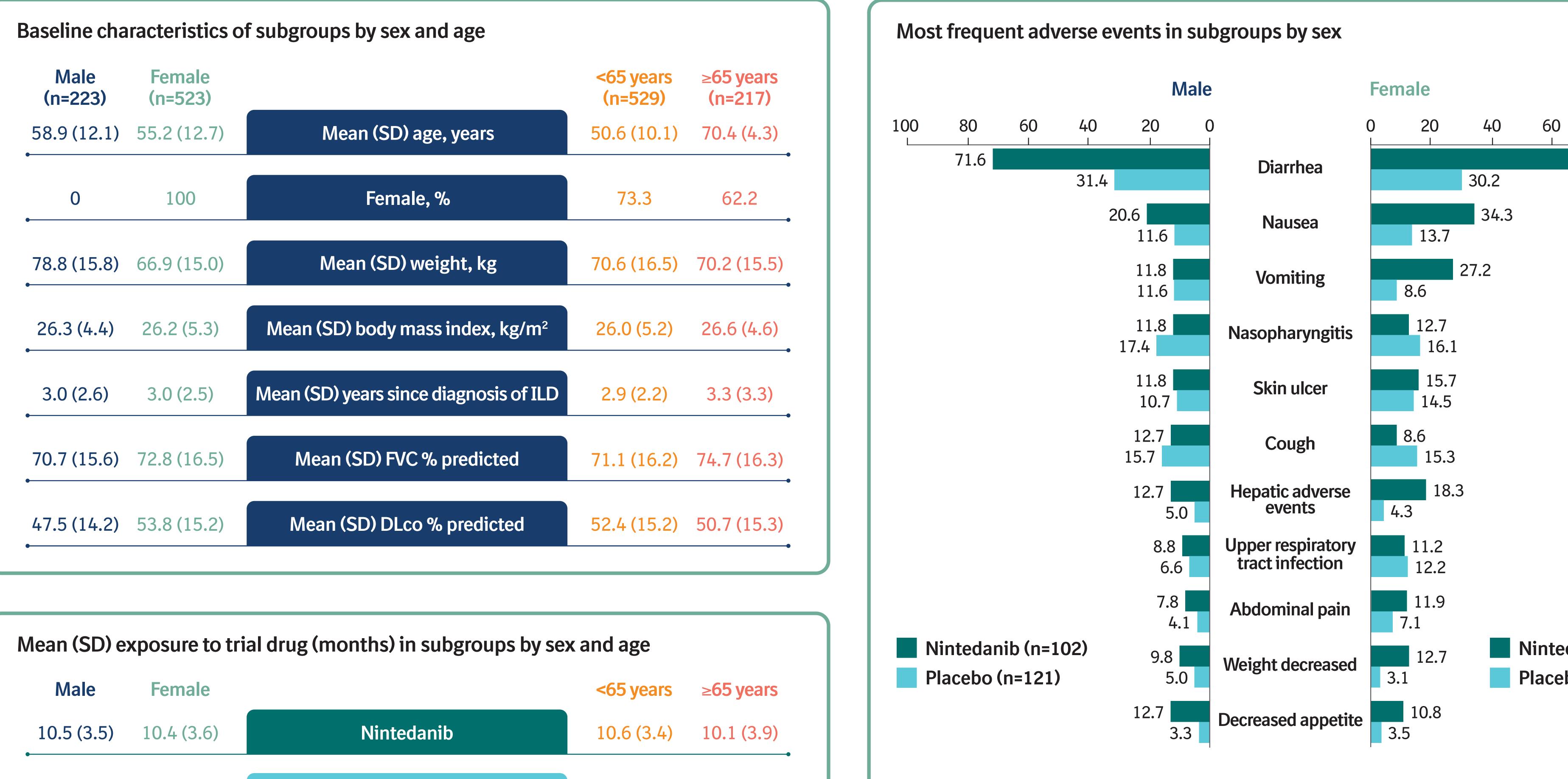
INBUILD trial²

- Reticulation with traction bronchiectasis (with or without
- Progressive ILD defined by worsening in lung function, symptoms, or imaging, despite management in clinical
- Fibrotic ILD of ≥10% extent on HRCT
- FVC ≥45% predicted DLco 30-80% predicted
- In both trials, patients were randomised to receive nintedanib or placebo.
- Recommendations were provided for the management of adverse events using symptomatic therapy, dose adjustment and treatment interruption.^{3,4}
- Adverse events reported by the investigators irrespective of causality were coded according to the Medical Dictionary for Regulatory Activities (MedDRA) version 23.0.
- We analysed adverse events reported over 52 weeks in subgroups based on sex and age (<65 and ≥65 years) at baseline.

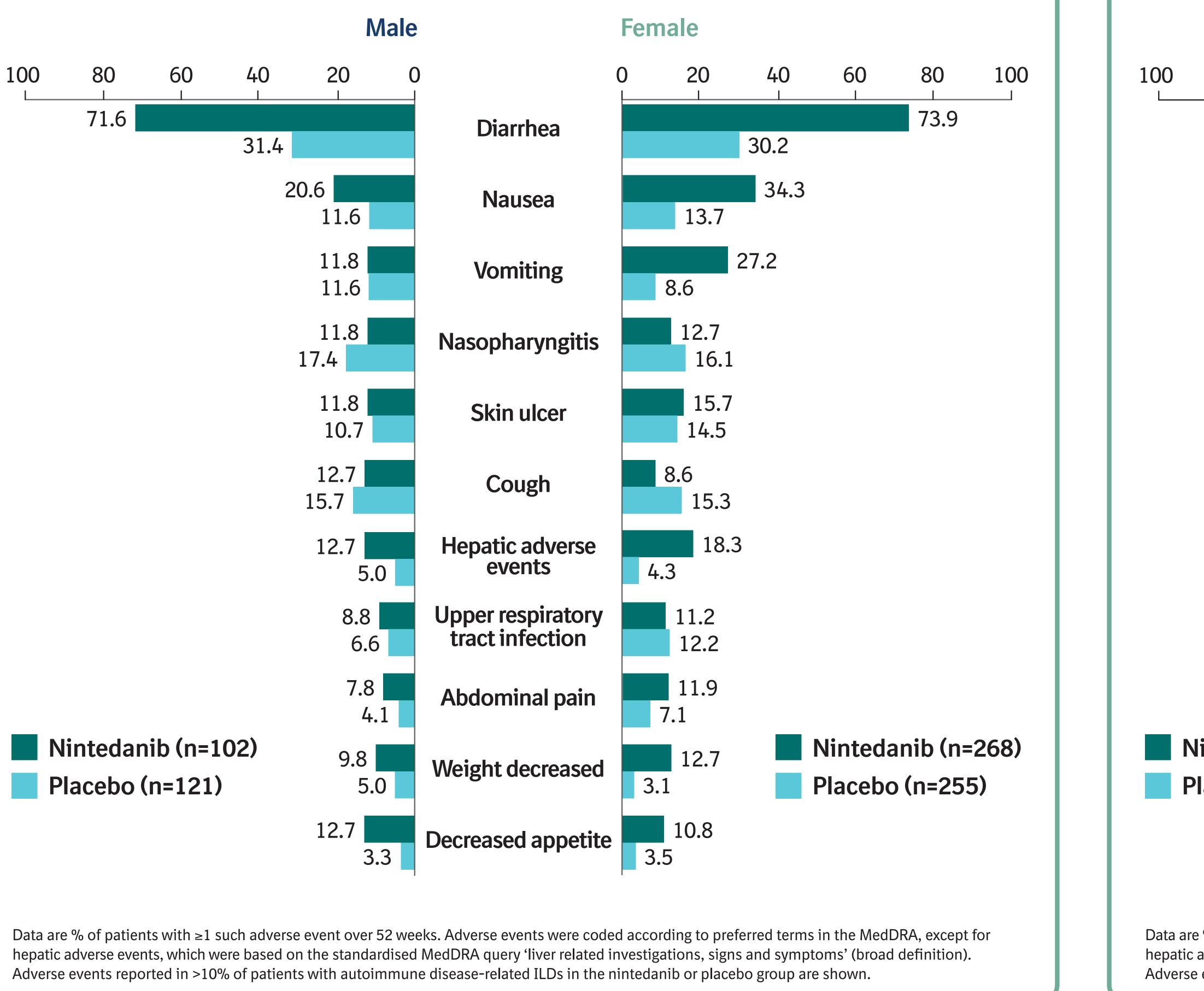
CONCLUSIONS

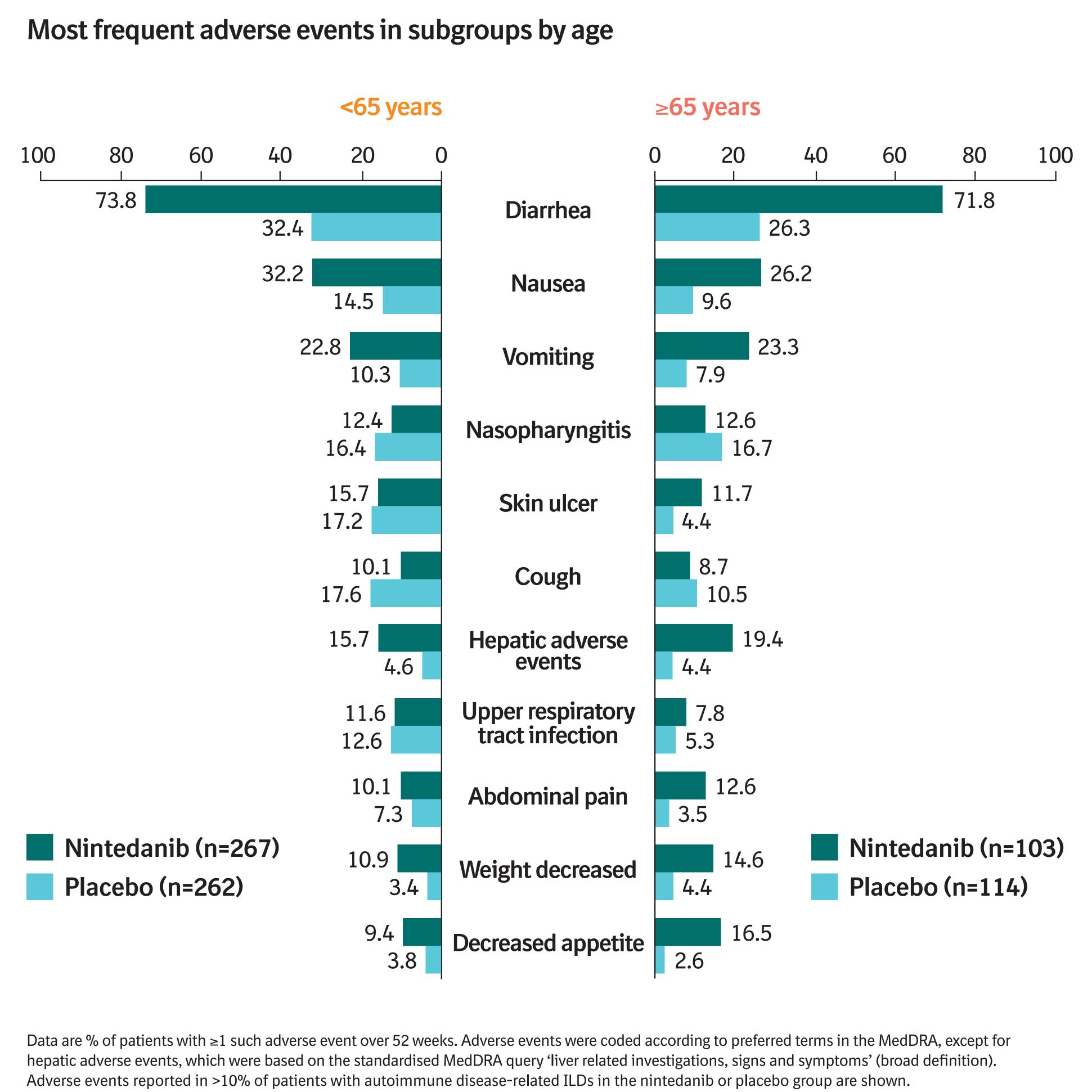
- In patients with autoimmune-disease related ILDs, the safety profile of nintedanib was similar between male and female patients, but nausea, vomiting and hepatic adverse events and dose reductions were more frequent in female patients, while serious adverse events were more common in male patients.
- The safety profile of nintedanib was similar between patients aged <65 and ≥65 years, but decreased appetite was more frequent in nintedanib-treated patients aged ≥65 years. Serious adverse events and adverse events leading to treatment discontinuation were more frequent in patients aged ≥65 years in both treatment groups.

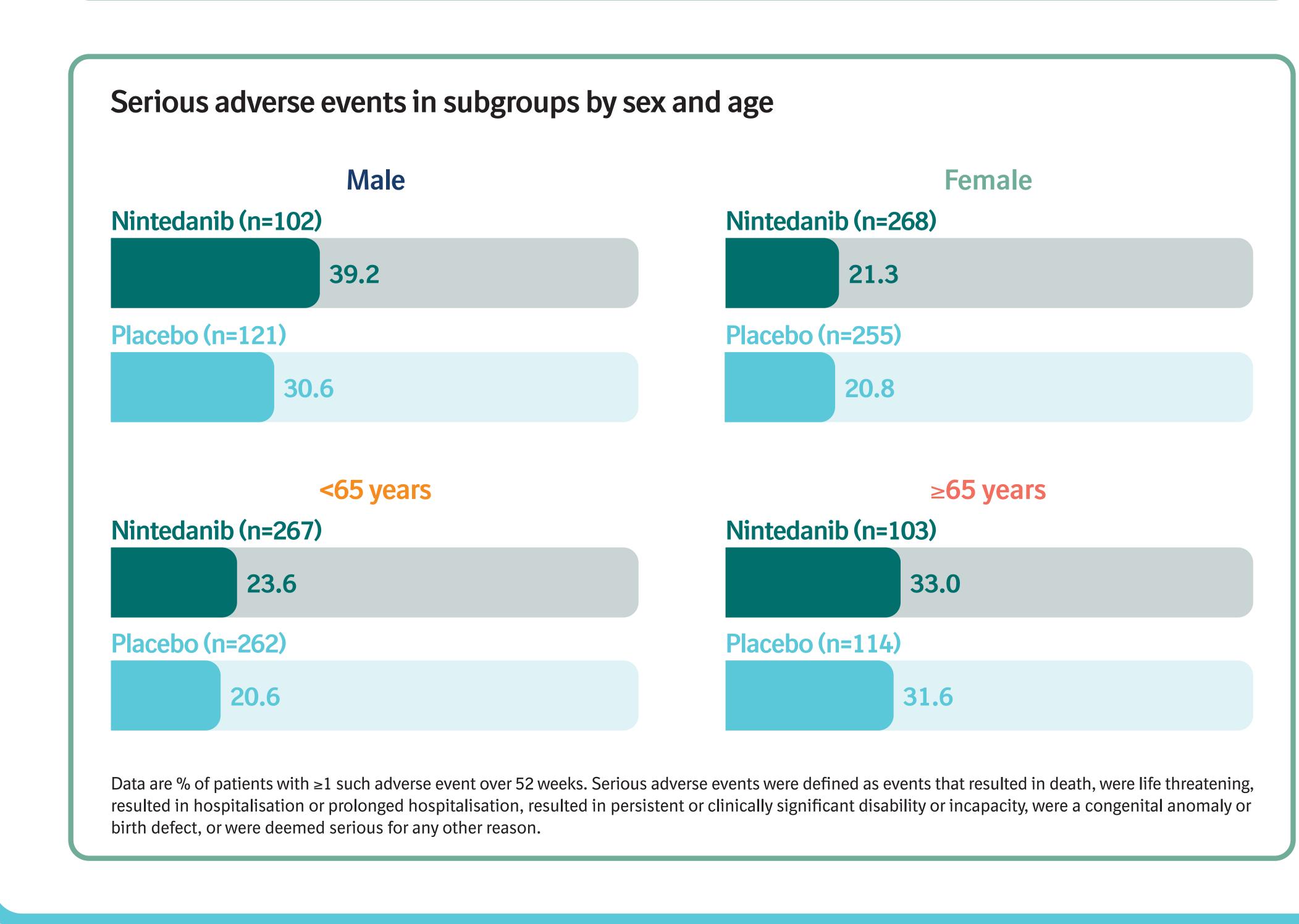
RESULTS



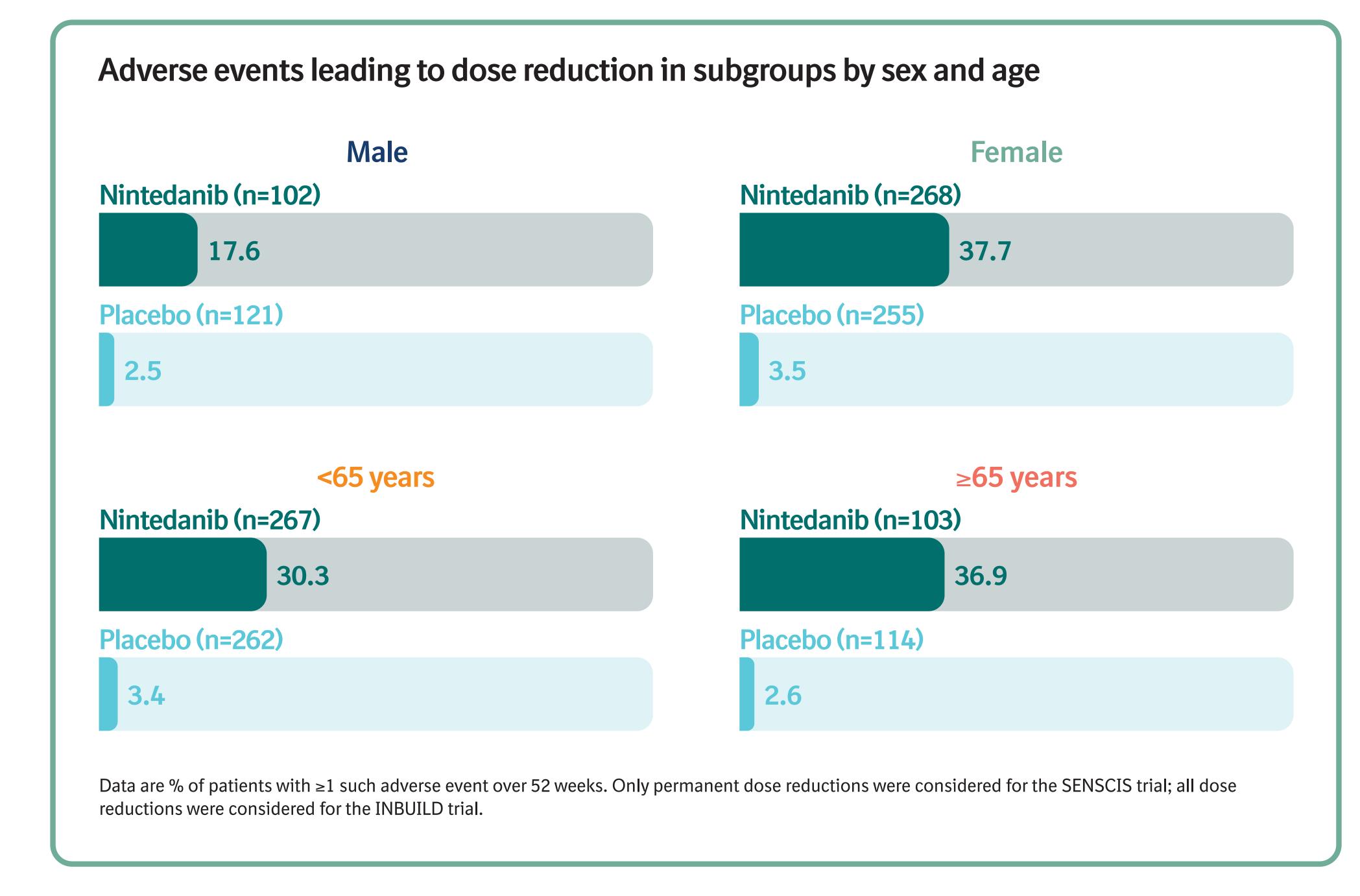
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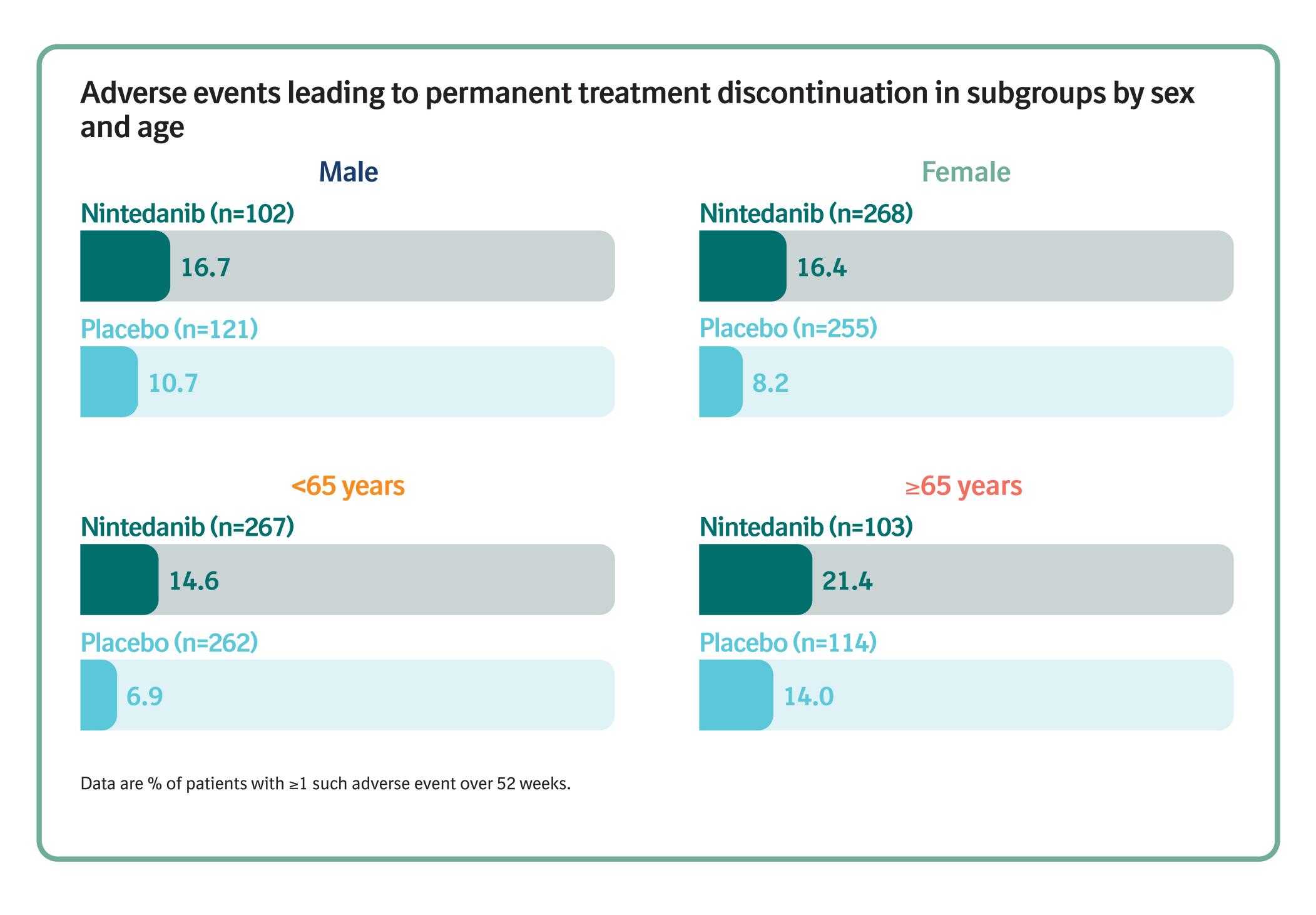






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