Nintedanib Safety Profile and Treatment Persistence in Patients with Fibrosing Interstitial Lung Disease: a Single-centre Retrospective Analysis

I. Vàzquez, M. Oliver, B. Tenas, C. Garcia, V. Insensé, J. Nicolás

Hospital Universitari Mútua Terrassa, Pharmacy, Terrassa, Spain

BACKGROUND AND IMPORTANCE

Nintedanib, a **tyrosine kinase inhibitor** and antifibrotic agent, has been approved for the treatment of **idiopathic pulmonary fibrosis (IPF) and chronic progressive fibrosing interstitial lung diseases (ILD)**. While clinical trials confirm its efficacy, its adverse event (AE) profile, particularly gastrointestinal side effects like diarrhea, has been well-documented. Despite this, there is **limited real-world data on the drug's safety** and treatment persistence. Analyzing AEs and their management in a clinical setting is crucial for optimizing nintedanib treatment.

AIM AND OBJECTIVES

- Evaluate the **incidence** and **types** of **AEs** associated with nintedanib.
- Assess the **clinical impact** of these AEs in patients diagnosed with IPF and ILD.
- Analyze the **persistence** of treatment in these patients under routine clinical practice.

MATERIAL AND METHODS

- Retrospective observational study
- **450-bed university hospital**

Including **all consecutive patients starting nintedanib** for IPF or ILD between March 2015 and August 2025 with at least one follow-up.

Variables collected

- Demographics
- Lung function at baseline
- Treatment data (initial dose, dose reduction, interruption, withdrawal)
- AEs classified by:
  - Organ system (gastrointestinal, hepatic, cardiovascular, general, other)
  - Specific term (diarrhoea, weight loss, nausea, etc.)
- Actions taken (none, dose reduction, interruption, withdrawal)
- Persistence described at 6, 12 and 24 months.

➢ Medians and interquartile ranges were used for quantitative variables; means for time to discontinuation and interruption.

RESULTS

Total N = **39 patients**

- Median age 72 [66–76] years
- 69% male

Diagnose:
IPF 72%
Other ILDs 28%

- FVC 66% [56–84]
- DLCO 41% [31–51]

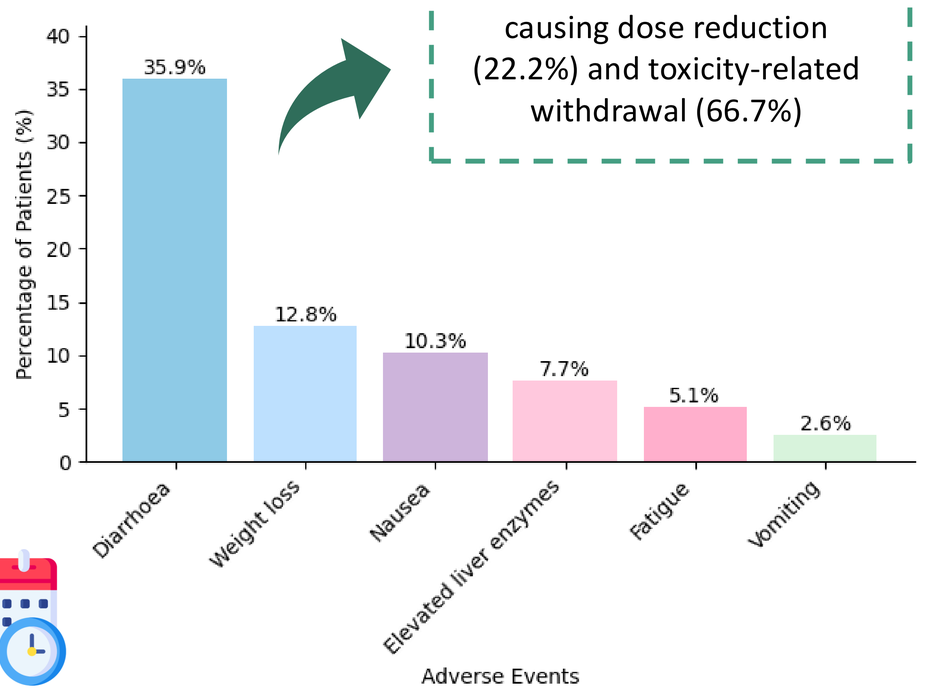
Initial dose:
150 mg/12h 92%
100 mg/12h 8%

- **Dose reduction:** 38.5%
  - Median time to reduction 182 days [71–302]
  - Mean time of dose reduction 32.5 days
- **Temporary interruption:** 10.3% (median time of interruption 30 days [24–45])
- **Discontinuation**: 23.1% (mean time to discontinuation 349.8 days)
  - Due to progression (66.7%) or toxicity (33.3%)

TOP 3 adverse events classified by system

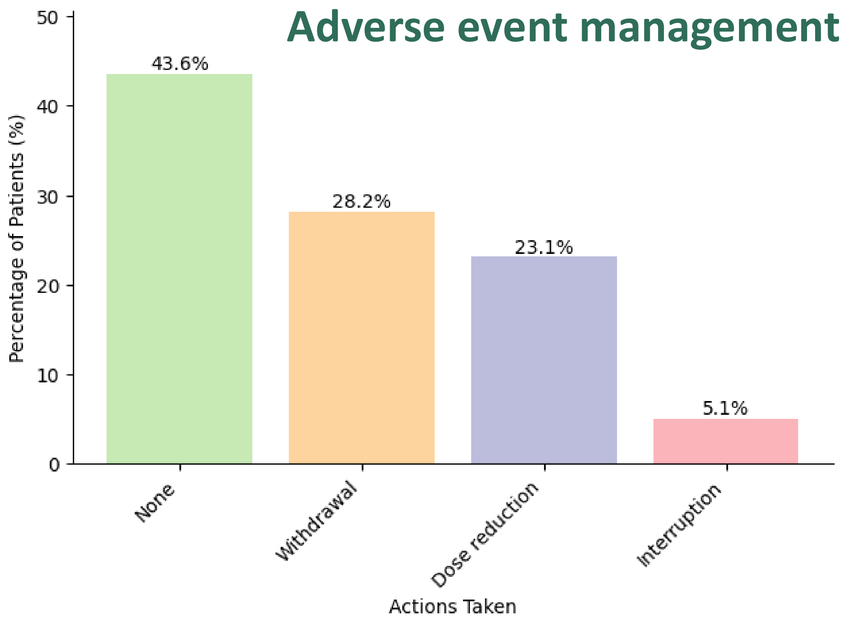
1. Gastrointestinal 46.2%
2. Hepatic 12.8%
3. General 7.7%

Adverse events



Diarrhoea was the **main AE** causing dose reduction (22.2%) and toxicity-related withdrawal (66.7%)

Adverse event management



Treatment persistence

- ≥6 months 84.6%
- ≥12 months 74.4%
- ≥24 months 53.8%

CONCLUSION AND RELEVANCE

Nintedanib showed **frequent but manageable toxicities**, mainly gastrointestinal. Diarrhoea was the main cause of dose modification and withdrawal. Results highlight the need for proactive AE management to optimise persistence in IPF and ILD.

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Ixeia Vàzquez Majó
Hospital Universitari Mútua Terrassa
izvazquez@mutuaterrassa.cat

CONTACT

Authors declare no conflicts of interest