



## RESEARCH ARTICLE

# Evaluation of the potential complication of interstitial lung disease associated with antifibrotic drugs using data from databases reporting spontaneous adverse effects

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## Abstract

Interstitial lung disease (ILD), as an adverse effect of certain drugs, leads to inflammation and damage in the walls of the alveoli, making it difficult for the alveoli to take up oxygen. Interstitial pneumonia with no identifiable cause is called idiopathic interstitial pneumonia (IIP), and, among the major IIPs, idiopathic pulmonary fibrosis (IPF) is diagnosed in about half of patients. Current treatment options are limited, among which the antifibrotic drugs nintedanib (Ofev) and pirfenidone (Epirsya) are the first-line drugs. In this study, we investigated the incidence of ILD possibly caused by antifibrotic agents using data from the Japanese Adverse Drug Event Report (JADER) database, a database of spontaneous adverse event reports published by the Pharmaceuticals and Medical Devices Agency (PMDA), and the US Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS), published by the FDA. We used the FAERS and JADER to detect the signals of adverse events on the basis of reporting odds ratios. The relationship between indications and adverse events was clarified by separating indications and adverse events using the spontaneous adverse event reporting database with novel drug involvement. Regarding the involvement of nintedanib and pirfenidone in the development of ILD, JADER and FAERS showed signals for both nintedanib and pirfenidone as suspect drugs, and no signals for nintedanib or pirfenidone as concomitant drug interactions were detected. We highlight this because there are only a few effective drugs for IPF, and effective and safe drug therapies should be implemented by taking into consideration drug-induced ILD.

## Study Highlights

### WHAT IS THE CURRENT KNOWLEDGE ON THE TOPIC?

In this study, we aimed to analyze the association of the onset of interstitial lung disease (ILD) as an adverse event with the use of the drugs nintedanib and pirfenidone. These antifibrotic agents are widely used as the first-line treatment for idiopathic pulmonary fibrosis (IPF).

# Drugs In The Workplace Research And Evaluation Data Dhhs Publication

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