

Safety profile of pirfenidone and nintedanib in a real life setting: assessment of suspected adverse drug reactions in the Emilia-Romagna Region, Italy.

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BACKGROUND AND IMPORTANCE

» Idiopathic pulmonary fibrosis (IPF) is a progressive and fatal form of fibrosing interstitial pneumonia with poor prognosis, characterized by lung functional decline, reduction in forced vital capacity (FVC), worsening of dyspnea and quality of life.

» Pirfenidone and nintedanib are the only two drugs with antifibrotic effects approved for the treatment of IPF. They both block the receptors of pro fibrotic growth factors such as vascular endothelial growth factor (VEGF), platelet-derived growth factor (PDGF) and fibroblast growth factor (FGF).

» Because of their critical safety profile, many patients are forced to dose reduction or treatment interruption, in order to manage side effects like gastrointestinal disorders (diarrhoea, nausea and vomiting), bleeding (epistaxis and contusions), liver enzyme elevation, rash and photosensitivity.

AIM AND OBJECTIVES

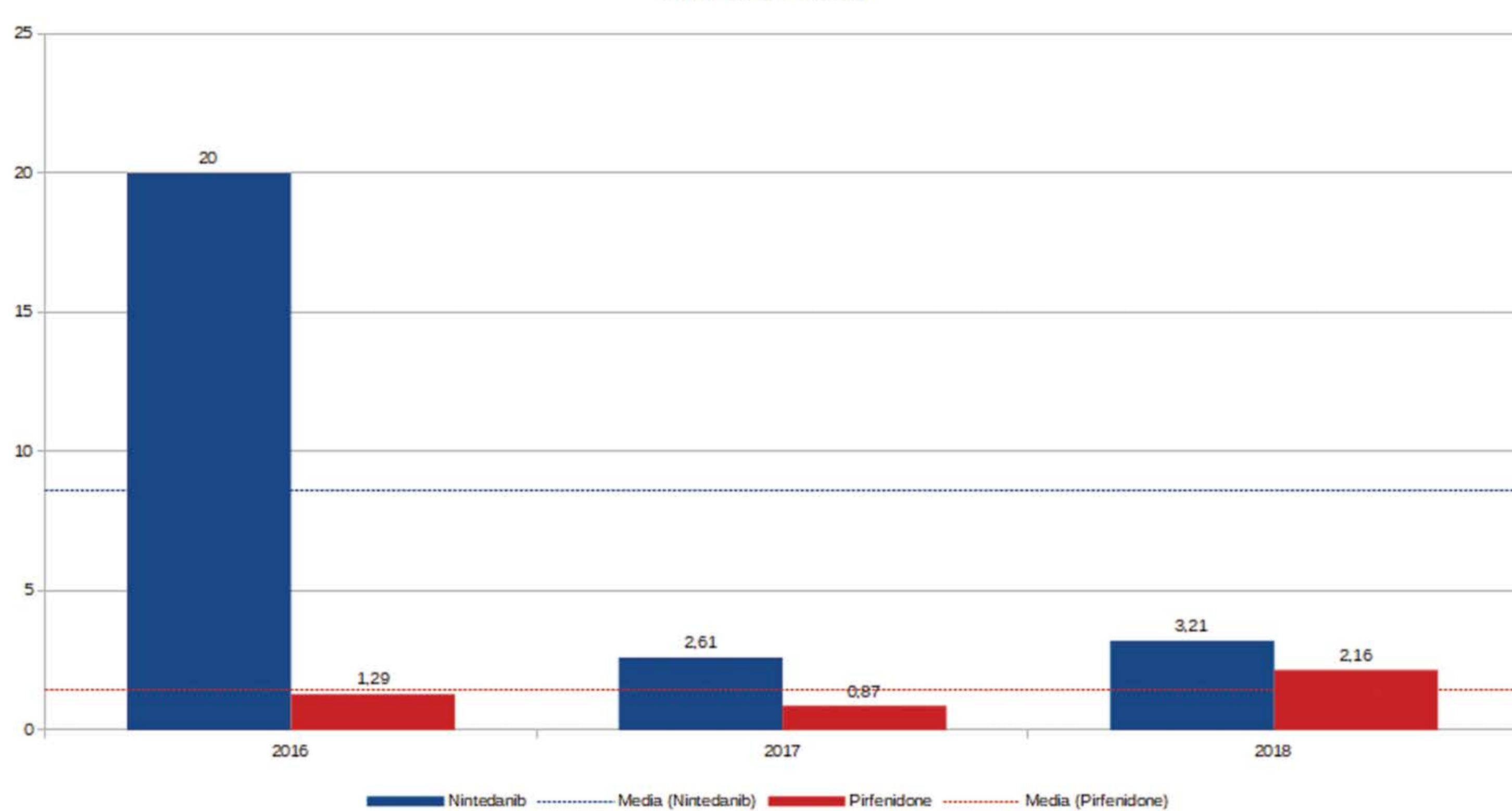
The aim of this study was to evaluate the safety profile of pirfenidone and nintedanib in a real life setting of Emilia-Romagna Region (RER), Italy.

MATERIAL AND METHODS

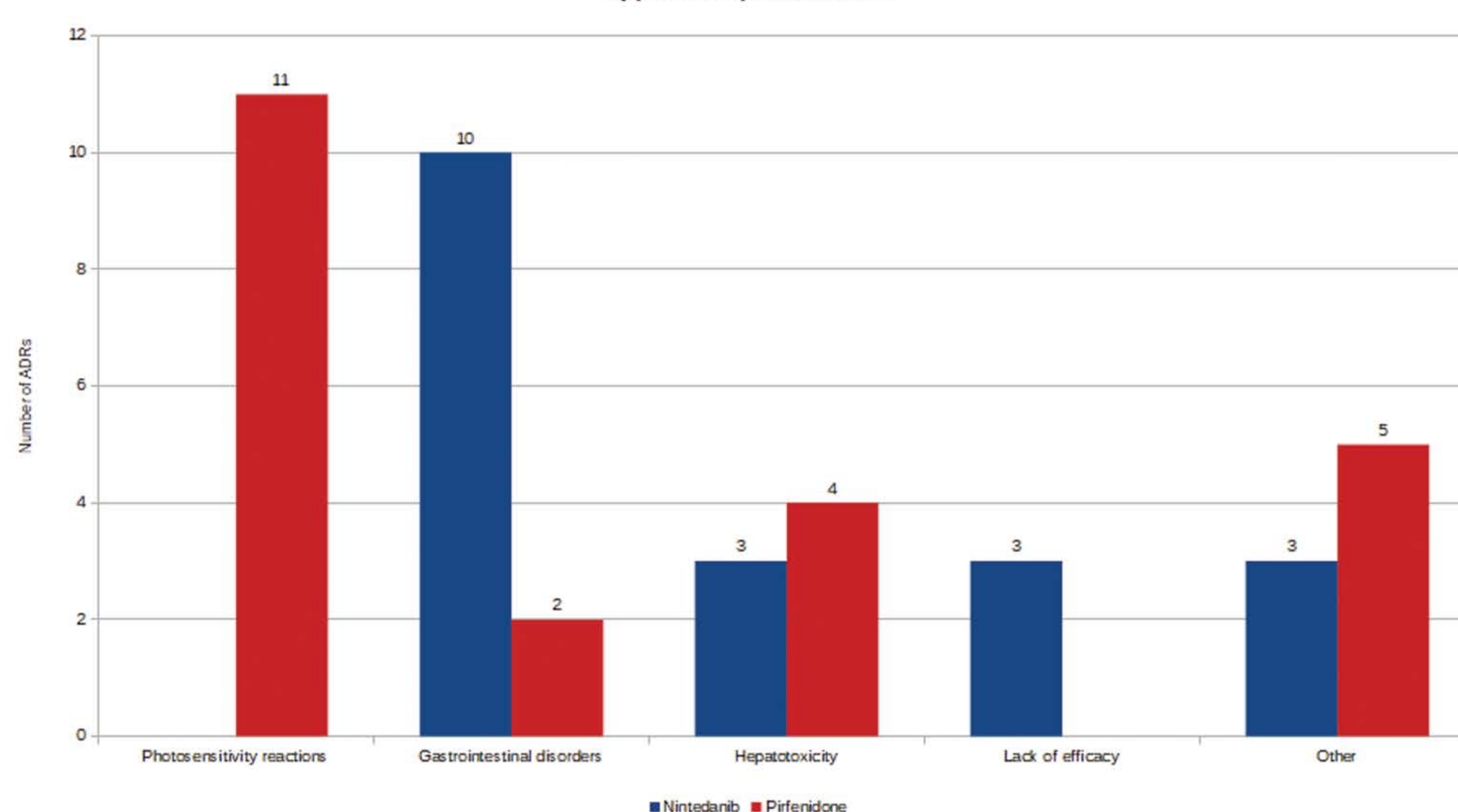
We examined all spontaneous ADR reports about pirfenidone and nintedanib entered into the National Pharmacovigilance Network by RER healthcare professionals and patients from January 2016 to December 2018 and combined these records with consumption data. We compared the ADR/DDDs ratio of the two drugs and characterized type and rate of ADRs.

GRAPHICS

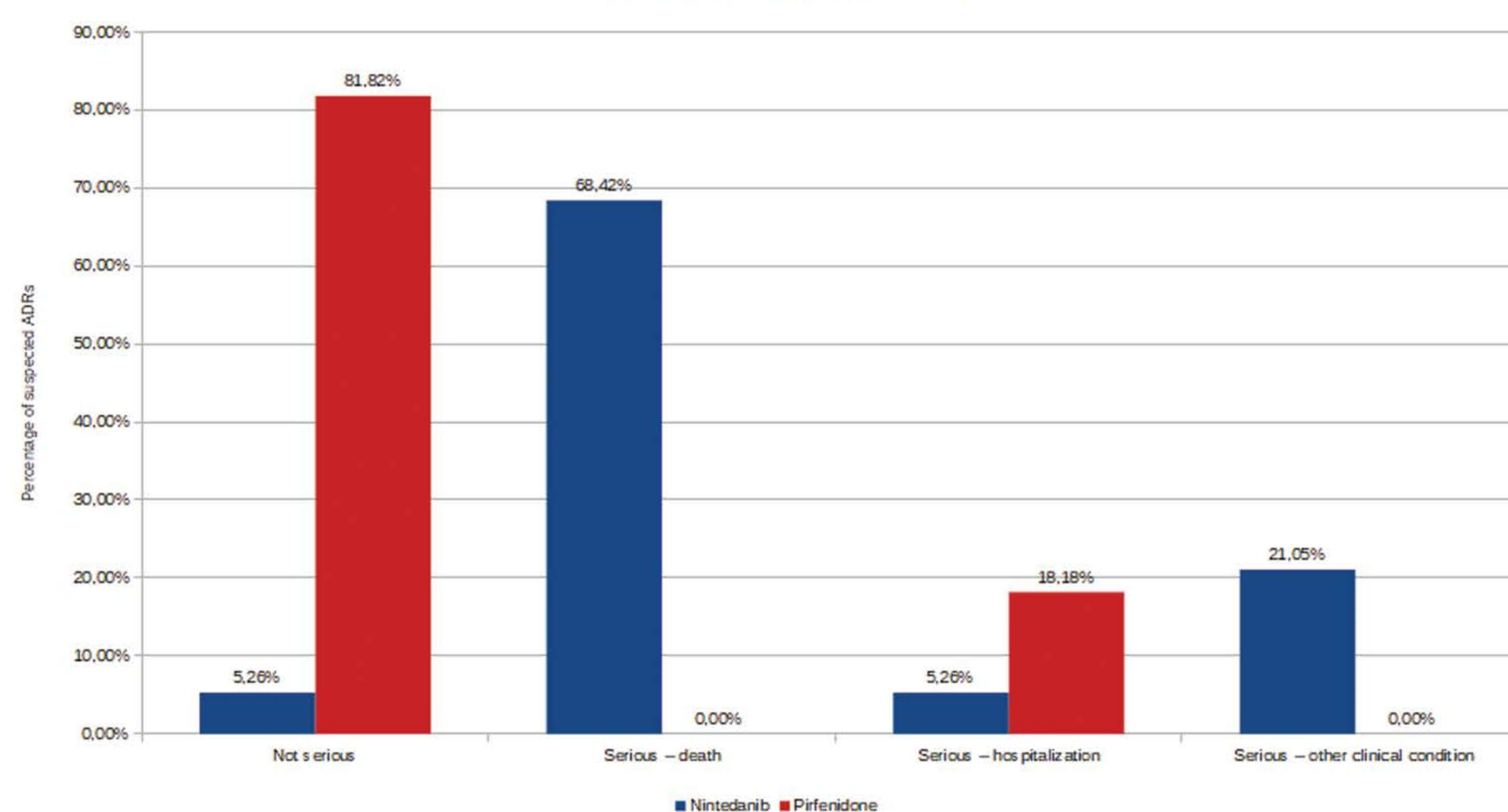
ADRs/DDDs ratio



Type of suspected ADRs



Seriousness of suspected ADRs



RESULTS

From January 2016 to December 2018 we found 22 ADR reports for pirfenidone and 19 for nintedanib, with an ADR/DDDs ratio of 1,44 and 8,61 respectively. The most frequent ADRs reported were photosensitivity reactions (50%) for pirfenidone and gastrointestinal disorders (53%) for nintedanib; the rate of hepatotoxicity was similar between the two drugs (respectively 18% and 16%). Three records (16%) about nintedanib concerned the lack of efficacy.

