DIARRHEA OCCURRENCE ANALYSIS IN IDIOPATHIC PULMONARY FIBROSIS PATIENTS

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BACKGROUND AND IMPORTANCE

Nintedanib and pirfenidone are the only drugs indicated for the treatment of **idiophatic pulmonary fibrosis** (IPF). Both drugs have diarrhea in 62.4% and 18.8%, respectively, described in the Summary of Product Characteristics (SmPC) as a frequent adverse effect (AE).

In case of diarrhea, it is recommended to follow dietary recommendations and to reduce the dose or stop treatment.

AIM AND OBJECTIVES

To **analyze the frequency of appearance of diarrhea** of the treatment with pirfenidone and nintedanib described in SmPC with that of the patients in the study and to describe the action carried out.

MATERIAL AND METHODS

Retrospective observational study January 2017-August 2022

Patients treated with pirfenidona or nintedanib

- Age, sex
- Drug and duration
- Withdrawal reason
- Diarrea and severity
- Corrective action taken

Collected variables

Stadistical analysis with mean, median and Standard deviation

Odds ratio calculated with data obtained of SmPC

RESULTS

30 patients were included with a mean±SD age of 72±8 years, of which 23.3% (7) were women

80.0% (24) received treatment with nintedanib (duration range: 37 and 1953 days) and 20.0% (6) were treated with pirfenidone (duration range: 124 and 1073 days)

The OR of diarrhea in study patients, compared to described in SmPC, with nintedanib was 1.21 CI95 (0.51-2.86) and with pirfenidone was 0.86 CI95 (0.10-7.47)

Of the patients treated with pirfenidone, 83.0% (5) discontinued treatment (none due to EA).

17% (1) had mild diarrhea that was controlled with loperamide

66.7% (16) of nintedanib patients presented diarrhea (7 severe, 7 moderate, and 2 mild)

Of these, 37.5% (6) were treated with loperamide maintaining the dose, 18.7% (3) discontinued treatment, and 43.8% (7) underwent a dose reduction

This adjustment allowed treatment to be continued in 71.4% (5/7) of the patients

CONCLUSION AND RELEVANCE

- The **appearance of diarrhea** in both drugs is **very frequent**. No statistically significant differences were observed in the frequency of onset of diarrhea in patients at our hospital compared to those described in the SmPC.
- In most cases diarrhea was **controlled by dose reduction or loperamide administration**.

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IAS Institut d'Assistència Sanitària

eahp european association of hospital pharmacists