DI-082

ADVERSE EVENTS OF PIRFENIDONE AND CAUSE OF SUSPENSION IN CLINICAL PRACTICE

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BACKGROUND

In 2011, **pirfenidone** was the **first drug** to be approved for the treatment of **idiopathic pulmonary fibrosis** (IPF) in Europe after reduced decline in percent-predicted forced vital capacity (FVC) in the two phase III trials

PURPOSE

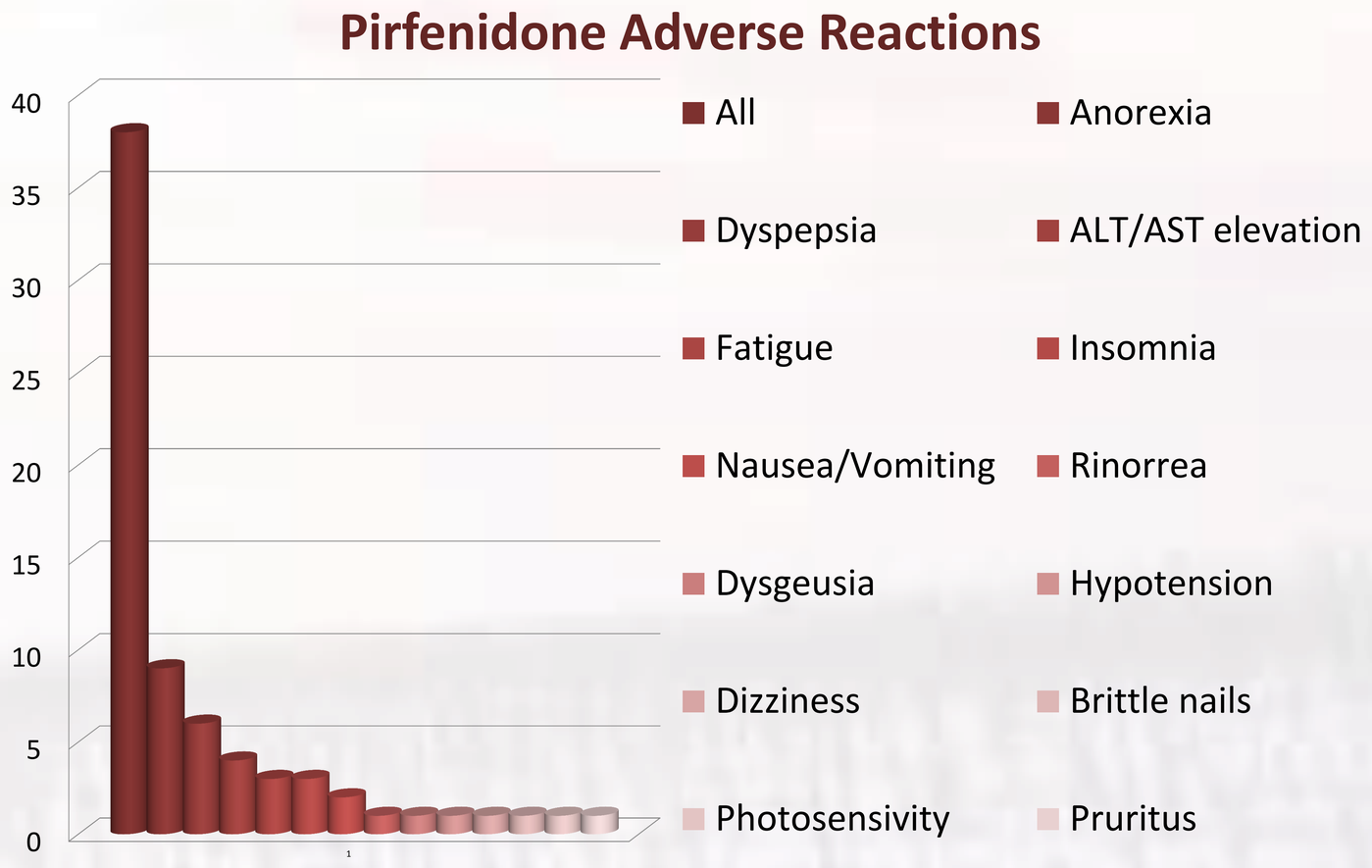
1. Describe the **adverse events** of the patients on treatment with pirfenidone in the **pharmaceutical consultation**
2. Describe the time of regimen treatment with pirfenidone and the **cause of his suspension** if there was
3. **Compare** the results obtained with the published in the **clinical trials**

MATERIAL AND METHODS

- **Prospective**, descriptive and observational study
- Assess the **safety** and **duration** of the treatment with pirfenidone
- **Patients** on treatment with pirfenidone were eligible for the study
- **Main variable** is the **adverse events** notified by the patient during the pharmaceutical interview at the outpatient unit of pharmacy

RESULTS

- 16 patients (4 women , 12 men)
- Mean age: 72,8 years
- 38 adverse events in 12 (75%) patients
- 4 patients that did not report any adverse event
- The **most common** adverse events were **gastrointestinal disorders** (18 events)
- **5 patients (31,5%) needed to discontinued** pirfenidone due to adverse events (3 women and 2 men)
- Mean duration patients stop drug: 103,4 days
- Reasons to discontinue:
  - Gastrointestinal disorders (60%)
  - AST elevation (20%)
  - Asthenia (20%)



CONCLUSIONS

Adverse reactions found in our study are similar to those of clinical trials

Women have less tolerance to pirfenidone and need lower dose in maintenance treatment

There is a significant percentage of dropouts due to adverse events