EXPERIENCE OF ANTIFIBROTIC AGENTS IN THE TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS

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Background and importance Antifibrotics are an important alternative for the treatment of idiopathic pulmonary fibrosis (IPF) but long-term follow-up studies of their effectiveness and safety are required.

Aim and objectives To assess the safety and efficacy of pirfenidone and nintedanib in patients with IPF.

Material and methods A retrospective study was conducted in all patients treated with pirfenidone and nintedanib for >3 months. Variables collected were age, sex, forced vital capacity (FVC) at baseline, at 6 and 12 months, and at follow-up visits. The time of the diagnosis of IPF, the time of inclusion in the treatment, the time of the death of the patient, and the age at death were recorded.

Results Ninety-four patients were included, 57 received pirfenidone and 37 nintedanib. Mean age was 67 years (79.8% men). The mean baseline FVC was 69.9% (SD 14.33) for pirfenidone and 68.1% (SD 14.33) for nintedanib. Median duration of pirfenidone and nintedanib treatment was 31.1 months (0.8–56.3) and 16.2 months (5.8–36.8), respectively. Twenty-nine per cent of patients treated with pirfenidone had exceeded 2 years of treatment (2.5–4.7 years) and FVC was stable at the present time compared with 18.9% in the nintedanib group. Of the patients treated with pirfenidone, 45.6% discontinued (33.3% in the first year) due to ADR (17.5%), disease progression (14.0%) or death (7.0% IPF related and 12.3% in total). For nintedanib, 62.2% discontinued (35.1% in the first year) due to ADR (18.2%), disease progression (21.6%) or death (5.4%, all IPF related). ADR related exacerbations per year of treatment rate was 0.19 for pirfenidone and 0.47 for nintedanib; hospitalisations per year of treatment rate was 0.21 for pirfenidone and 0.45 for nintedanib. The average ADR/patient was 1.0 for pirfenidone (19.2% ADR grade 2, 5.1% grade 3) and 0.97 for nintedanib (45% grade 2, 2.7% grade 3). The most frequent ADR in pirfenidone treated patients were gastrointestinal (24.1%), asthenia (22.4%), cutaneous reactions (18.9%), cough (15.5%) and myalgia (8.6%); for nintedanib, the most frequent ADR were gastrointestinal (73.5%, mainly diarrhea), liver enzyme alteration (11.8%) and bleeding (8.8%).

Conclusion and relevance Both drugs had moderate efficacy and high toxicity. Although it was not a comparative study, pirfenidone showed better tolerance than nintedanib and patients had longer courses of treatment with stable disease.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

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No conflict of interest.

5PSQ-104 DESCRIPTION OF A PHARMACOVIGILANCE PROGRAMME IN A TERTIARY HOSPITAL

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Background and importance Pharmacovigilance (PV) is a public health activity in which clinicians are legally and medically involved. Notification of adverse drug reactions (ADRs) is essential to ensure the safety of medications.

Aim and objectives To describe the ADRs notified to the Regional Centre of Pharmacovigilance (RPC).

Material and methods A retrospective study was conducted between January 1992 and December 2018. The hospital pharmacist (HP) was responsible for data collection and notification. PV started up in 1992 accompanied by a strong information and communication campaign. Data were recorded and analysed in Excel 2007: sex and age of patients, total number of reported ADR notifications, detection method, severity and outcome of the ADRs, medications involved and therapeutic group (ATC classification).

Results During the 27 years of the study period, 1246 ADRs were reported (annual average: 46±2.83): 53.6% of patients were men and 54.2% were >65 years old while 10.6% were <30 years old. Regarding the detection method, 59.7% came from the minimum database set for hospital (MDS-H), 34.3% by voluntary notification of health staff and the remaining (6%) were detected by the HP during treatment validation. Mild ADRs accounted for 16.8%, 45% were moderate and severe cases were rare (2%). The outcome of the ADRs, medications involved and therapeutic group (ATC classification).

Conclusion and relevance Both drugs had moderate efficacy and high toxicity. Although it was not a comparative study, pirfenidone showed better tolerance than nintedanib and patients had longer courses of treatment with stable disease.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
In 1992, 19 ADRs were notified, a value that progressively increased over the years, reaching its highest in 2003 (84 ADRs). In 2004 it decreased to 46, remained constant (mean 35.7±9.7) and then declined to 31 in the last year.

**Conclusion and relevance** More than one-third of ADRs were serious, but most patients recovered without sequelae. Most notifications to the RPC come from the MDS-H, but a significant number were detected by health staff and HP. In recent years, reported ADRs has decreased, so the HP could be an essential element to develop the pharmacovigilance programme, which is key to improving the safety of medicines by promoting relevant modifications in the technical data sheets and issuing alerts from the Spanish Agency for Medicines and Health Products.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

No conflict of interest.