EXPERIENCE OF ANTIFIBROTIC AGENTS IN THE DESCRIPTION OF A PHARMACOVIGILANCE

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 16.98) 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 (2.5–7 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). IPF 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 was gastrointestinal (21.4%), 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 diarrhoea), 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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5PSQ-103 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 observational 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 the end of treatment, duration of treatment, disease progression (absolute decline in%FVC >10%), exacerbations and deaths due to IPF, hospitalisations due to respiratory causes and adverse drug reactions (ADR).

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 16.98) 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 (2.5–7 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). IPF 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 was gastrointestinal (21.4%), 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 diarrhoea), 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.

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, detection method, severity and outcome of the ADR, 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 4% were severe. The outcome of the ADRs reported was recovered without sequelae in 92.8% of cases; 14 patients died (1.1%). A total of 1353 drugs were involved (median 42 per year (IQR 33–76.3)). The major therapeutic groups were N (nervous system) with 20.2%, followed by C (cardiovascular system) 16.6% and J (anti-infectives for systemic use) 15.6%.
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.

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**5PSQ-105 PREVENTING FALLS IN ORTHOGERIATRIC PATIENTS BY MANAGING THEIR THERAPEUTIC PROFILES**

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**Background and importance** Elderly people are polymedicated due to their multiple comorbidities. The risks of polypharmacy can be higher than the benefits. Some medicines, labelled ‘increasing risk of fall drugs’, such as benzodiazepines, antidepressants and antipsychotics, are among the major causes of falls. Thus in order to prevent unnecessary falls and their consequences, there is an urgent need to review patients’ therapeutic profiles and to adapt to the real needs of each patient. The orthogeriatric hospital unit was created to provide multidisciplinary care to patients aged >65 years with a hip fracture admitted to hospital.

**Aim and objectives** To review and optimise the therapeutic profile of patients admitted to the orthogeriatric unit, during hospital admission and follow-up appointments, to prevent the recurrence of falls and fractures.

**Material and methods** An observational, retrospective, cohort study was conducted in patients aged >65 years admitted to the emergency service with a hip fracture, between the 1 January 2019 and 30 June 2019. These patients were admitted to the orthogeriatric unit during hospitalisation and scheduled for follow-up appointments. Their medication profile was obtained via the digital medical record and the national platform of healthcare. Descriptive statistics was used to summarise the data.

**Results** A total of 162 patients met the criteria, 75% were women (n=121) and median age was 84 years. The average length of stay was 12.4 days. In 30% (n=48), inappropriate medicines were considered the most likely cause of the fall. During hospitalisation, 316 drugs were suspended and 516 were initiated. Of the 162 patients, 80 already attended follow-up appointments with the general practitioner. From these, 19% (n=15) restarted the inappropriate drugs that were suspended.

**Conclusion and relevance** It is possible to conclude that the majority of patients had inappropriate drugs in their therapeutic profile. Although only 30% of the patients had medicines as a precipitant factor for the fall, almost every patient had one or more ‘increasing risk of fall drugs’. Therefore, these drugs were discontinued to prevent new falls.

A considerable percentage of patients restarted the suspended drugs. Consequently, there is a need to find a better strategy to prevent this occurrence.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

No conflict of interest.