THE IMPORTANCE OF MONITORING ADVERSE DRUG REACTIONS: DATA FROM THE TREATMENT OF A RARE DISEASE

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Background and importance

Idiopathic pulmonary fibrosis (IPF) is a rare disease characterized by scar tissue formation in the lungs. The prevalence is higher in males (20/100,000), compared to females (13/100,000). The average age at onset is 66 years. Nowadays nintedanib and pirfenidone are used to treat IPF. They have an anti-fibrotic and anti-inflammatory activity, slowing down the progression of the disease. It’s very important to report any suspected adverse drug reaction (ADR) to better understand the efficacy and safety profiles of both.

Aim and objectives

We analysed the adverse drug reaction (ADRs) reported in the year 2018 of pirfenidone and nintedanib in our hospital.

Material and methods

Suspected ADRs reported by patients and sent to the national pharmacovigilance network (RNFV) are analyzed.

Results

11 ADRs have been recorded for each molecule. Considering that the number of patients treated with pirfenidone was 19 and with nintedanib was 25, the number of ADRs reported appears quite relevant. Pirfenidone ADR reports were: 5 (45.4%) at the skin level, like dermatitis, erythema and photosensitivity; 3 for gastrointestinal disorders (27.2%), such as diarrhea, nausea, dysgeusia and inappetence; 2 at the level of the nervous system (18.2%), with sleepiness and confusion and in 1 case (9%) there have been an increase in the levels of aspartate aminotransferase, with a probable onset of hepatic alteration. The reports of nintedanib were: 7 (63.6%) for the gastrointestinal system, of which 4 consisted in diarrhea, the others in asthenia and nausea; 4 (36.4%) related to toxic hepatitis, of which 1 reported as serious. The pulmonologists, therefore, reduced the daily dose for 12 patients (54.5%), for 2 patients (9%) they changed therapy from pirfenidone to nintedanib and for the remaining ones they temporarily suspended the treatment (36.4%).

<table>
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<tr>
<th>Drugs for IPF treatment</th>
<th>Number of patients</th>
<th>Number of ADRs recorded</th>
<th>Classification of ADRs for anatomical systems</th>
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| Pirfenidone 267 mg       | 19                 | 11                      | Skin diseases: 5  
Gastrointestinal diseases: 3  
Neurological diseases: 2  
Hepatic diseases: 1          |
| Nintedanib 100 mg e 150 mg | 25                 | 11                      | Gastrointestinal diseases: 7  
Hepatic diseases: 4           |

Conclusion and relevance

Initially IPF had been treated with cortisone drugs, azathioprine and cyclophosphamide, while in the last 10 years, the development of novel more specific medicines prolonged significantly life expectancy. Nevertheless, it is essential to carry out continuous monitoring of drugs to ensure that patients are treated as effectively and safely as possible. The pharmacist plays a central role in this activity, through the direct interaction with the patients during medicine dispensing.