

### 5PSQ-057 ANALYSIS OF THE INCIDENCE OF HEPATOTOXICITY ASSOCIATED WITH THE USE OF TOCILIZUMAB

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**Background and importance** Prolonged treatment with tocilizumab has been associated with cases of severe hepatotoxicity with liver failure and hepatitis, characterised by elevated hepatic transaminases (GOT/AST and GPT/ALT).

**Aim and objectives** To analyse the incidence of elevation of liver enzymes and the presence of severe liver damage in patients treated with tocilizumab, in a third level hospital.

**Material and methods** A descriptive, observational, 10 year study that included all patients treated with tocilizumab for more than 6 months, from January 2009 to August 2019, was carried out. Patients in whom the drug was used under special conditions of use and those with abnormal transaminase values prior to the start of treatment were excluded. The variables recorded were age, sex and duration of treatment. Liver function values (GOT/AST and GPT/ALT) were analysed every 4 weeks in the first 6 months of treatment and every 12 weeks after 6 months of treatment. Alterations in these values were classified as mild (1–3×normal upper limit (NAL)), moderate (3–5×NAL) and severe (>5×NAL). Data were collected from a database in Excel format.

**Results** During the study, a total of 135 patients were treated, 84 intravenously and 51 subcutaneously. Fifty-six patients were excluded from the study: 28 for receiving treatment for <6 months, 19 for off-indication regimens and 9 for elevation of liver enzymes prior to drug initiation. The study population was 77 patients: 11.7% (n=9) men and 88.3% (n=68) women; mean age was 55.13 years (12–83).

Mean duration of treatment was 40.44 months: 48.1% (n=37) showed alterations in liver parameters during treatment. In the first 6 months of treatment, 22.1% of patients (n=17) showed an increase in levels (82.4% mild (n=14), 11.8% moderate (n=2) and 5.9% severe (n=1)). After 6 months of treatment, in 44.2% of cases (n=34) levels increased (88.2% mild (n=30), 11.8% moderate (n=4)).

**Conclusion and relevance** Our study showed that the rate of liver toxicity in patients treated with tocilizumab was about 50%. Severe toxicity was identified in only one patient. These results, as indicated by the European Medicines Agency, show the need for liver function monitoring in patients treated with tocilizumab.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

### 5PSQ-058 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 characterised by scar tissue formation in

the lungs. The prevalence is higher in men (20/100 000) than women (13/100 000). The average age at onset is 66 years. Currently, nintedanib and pirfenidone are used to treat IPF. They have an antifibrotic and anti-inflammatory activity, slowing down the progression of the disease and are subjected to additional monitoring. It is very important to report any suspected adverse drug reaction (ADR) to better understand the efficacy and safety profiles of both of these drugs.

**Aim and objectives** We analysed the ADRs reported in the year 2018 for pirfenidone and nintedanib in our hospital.

**Material and methods** Suspected ADRs reported by patients and sent to the national pharmacovigilance network (RNFV) were analysed.

**Results** Eleven ADRs were recorded for each drug. Considering that the number of patients treated with pirfenidone was 19 and with nintedanib 25, the number of ADRs reported appeared to be quite relevant. Pirfenidone ADR reports were: 5 (45.4%) skin disorders, such as dermatitis, erythema and photosensitivity; 3 gastrointestinal disorders (27.2%), such as diarrhoea, nausea, dysgeusia and inappetence; 2 nervous system (18.2%), with sleepiness and confusion; and in 1 case (9%) there was an increase in levels of aspartate aminotransferase, with a probable onset of hepatic alteration.

**The reports for nintedanib were 7 (63.6%)** for the gastrointestinal system, of which 4 consisted of diarrhoea, and the others asthenia and nausea; and 4 (36.4%) related to toxic hepatitis, of which 1 was 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 treatment (36.4%).

**Conclusion and relevance** Initially IPF had been treated with cortisone drugs, azathioprine and cyclophosphamide, while in the past 10 years the development of novel more specific medicines significantly prolonged 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 direct interaction with patients during dispensing of medicines.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

### 5PSQ-059 PHARMACIST-LED OBSERVATIONAL STUDY ON QUALITY OF LIFE IN RELAPSING-REMITTING MULTIPLE SCLEROSIS: EVIDENCE FROM THE QOSMOS STUDY

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**Background and importance** Patient reported outcomes (PRO) are increasingly used to evaluate effectiveness of treatments for multiple sclerosis (MS) and they often include an evaluation of health related quality of life (QoL). In 2017, the Italian Society of Clinical Pharmacy and Therapeutics (SIFaCT) and the National Association of Hospital Pharmacy Students