

(optimised prescriptions of a drug/prescriptions of that drug). Data were collected from the electronic prescription software.

**Results** In September 2016, 246 patients were treated with SBT: 22% patients had their prescription optimised. Higher percentages for optimisation were observed for tocilizumab, adalimumab and etanercept (44%, 34% and 22%, respectively). Golimumab, certolizumab and abatacept had lower percentages for optimisation (15%, 11% and 8%, respectively).

In September 2019, 337 patients were treated with SBT: 32% patients had their prescription optimised, 10% more than in 2016. A higher percentage of optimisation was observed for tocilizumab, etanercept and adalimumab (55%, 45% and 44%, respectively). Golimumab, certolizumab and abatacept had a lower percentage of optimisation (32%, 27% and 27%, respectively). Optimisation of secukinumab was very limited (2016, 0%; 2019, 3%). No prescriptions for ustekinumab or sarilumab were optimised.

**Conclusion and relevance** The rise in patients treated with SBT for chronic inflammatory arthropathies has been accompanied by a rise in the optimisation percentage over time, showing how rheumatologists consider BTO effective and safe. This strategy pursues the minimal effective dose with a consequent reduction in adverse events and economic savings. Optimisation was performed mainly for drugs that have been commercialised longer (adalimumab and etanercept) and drugs with a frequent dosing interval (etanercept and tocilizumab). Future comparisons will show if drugs with longer dosing intervals could also be optimised.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

#### 5PSQ-103 EXPERIENCE OF ANTIFIBROTIC AGENTS IN THE TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS

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10.1136/ejhpharm-2020-eahpconf.420

**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 (2.5–4.7 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). 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 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 (73.53%, 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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10.1136/ejhpharm-2020-eahpconf.421

**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:  $46 \pm 2.83$ ): 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 the rest 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% and M (musculoskeletal system) 19.6%, followed by C (cardiovascular system) 16.6% and J (anti-infectives for systemic use) 15.6%.