Material and methods We analysed 148 patients treated with pirfenidone (72% men; 28% women) and 120 treated with nintedanib (77% men; 23% women) from September 2016 to September 2019. The average age of the patients treated with pirfenidone and nintedanib was 72.7 and 74.4 years, respectively. Drug tolerability was compared by a Student's t test considering the average number of days of treatment (DOT) for patients who started the therapy since September 2016 (n=88 pirfenidone; n=120 nintedanib). The safety of the two treatments was compared by analysing the adverse drug reactions (ADRs) reported. ADRs were classified as: nausea/vomiting (NV), diarrhoea, rash, weight loss (WL) and non-specific gastrointestinal disturbance (nsGID). We also considered the type of action taken (interruption, reduction of dosage) and compared the frequencies using a χ^2 test.

Results The Student's t test showed no statistically significant difference in the average DOT between the two treatments ($t=0.9803$, $df=206$, $p=0.3281$). We detected 30 ADRs in 148 patients treated with pirfenidone (4 of which were severe) and 66 in 120 patients treated with nintedanib (1 severe). Nintedanib showed a greater percentage of ADRs at the gastrointestinal level (NV 18%, diarrhoea 42%, WL 23%, nsGID 39%) compared with pirfenidone (NV 17%, diarrhoea 7%, WL 13%, nsGID 20%). Pirfenidone instead showed a greater percentage of rash (43%) compared with nintedanib (8%). The χ^2 test carried out on type of action taken showed a statistically significant difference in the distribution of patients who suspended or reduced the dosage for the two drugs (χ^2 (96)=9.329, $p\leq 0.0023$, $df=1$). Nintedanib showed a higher percentage of patients who reduced the dosage (70%) compared with pirfenidone (37%), probably due to the different dosage titrations. The percentage of patients who suspended therapy was higher for pirfenidone (63%) than for nintedanib (30%).

Conclusion and relevance Although the tolerability of the drugs was comparable, nintedanib showed a higher incidence of ADRs compared with pirfenidone but with a lower severity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-101 DRUG-DRUG INTERACTIONS AND POTENTIALLY RELATED ADVERSE CLINICAL EVENTS IN PATIENTS WITH CARDIOVASCULAR DISEASES

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10.1136/ejhp-pharm-2020-eahpconf.418

Background and importance Several studies have estimated that about 60% of patients present at least one potential drug-drug interaction (DDI) at discharge. Considering that DDIs are predictable, a review of DDIs conducted by pharmacists and physicians would be ideal.

Aim and objectives The aim of this analysis was to measure the frequency and nature of DDIs in a cardiovascular unit and investigate whether any adverse events after discharge could be associated with these DDIs.

Material and methods This was an observational retrospective study involving patients discharged between December 2016

and December 2017. The discharge medication list within the electronic medical record was used to determine the presence of moderate or severe DDIs at discharge. To check if any adverse events were associated with DDIs, we reviewed the causes of each hospitalisation or access to the emergency department (ED) within 3 months after discharge.

Results Among 2715 patients screened, 624 (23%) were exposed to at least one potential DDI. A total of 1108 DDIs were recorded, 834 (75.3%) were classified as moderate and 274 (24.7%) as severe. The median number of DDIs per patient was 1.8 (range 1–11). The most frequent severe interaction was the combination of some selective serotonin reuptake inhibitors and furosemide (38%). Among the most frequent moderate interactions, we registered an association between warfarin and acetylsalicylic acid (10.2%). Of the 624 patients with at least one DDI, follow-up data were available for 593 (95.0%). Among them, 144 (24.3%) had at least one adverse clinical event within 3 months after discharge. A total of 212 events were recorded (hospitalisations=179; ED attendance=33). For approximately 12% of these events, the cause of hospitalisation or ED attendance was potentially associated with a DDI.

Conclusion and relevance From this analysis it emerged that a remarkable number of patients had been discharged with at least one DDI and a considerable portion of the included patients might have experienced an adverse event due to these DDIs. The next step will be the involvement of a clinical pharmacist within a multidisciplinary team to highlight to the physician any potential DDIs before discharge and minimise the occurrence of their related risk.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-102 AMBULATORY SUBCUTANEOUS BIOLOGIC THERAPY OPTIMISATION IN RHEUMATOLOGY: IMPLEMENTATION OVER TIME

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10.1136/ejhp-pharm-2020-eahpconf.419

Background and importance Biologic treatment optimisation (BTO) consists of reducing the dose and/or increasing the interval between doses in patients who have maintained their therapeutic goal for at least 6 months. In 2013, our hospital created a BTO protocol for chronic inflammatory arthropathies, based on the consensus established between the Spanish Rheumatology Society and the Hospital Pharmacy Society.

Aim and objectives To analyse the percentage development of BTO for subcutaneous biologic therapy (SBT) in patients with chronic inflammatory arthropathies, and to determine the drugs involved after implementation of the protocol.

Material and methods This was an observational retrospective study comparing patients with chronic inflammatory arthropathies being treated with SBT and BTO in 2016 and 2019. Optimisation was defined as any prescription with a lower dose or a longer administration interval than usual. Variables measured were number of patients being treated with SBT, optimisation percentage (patients with optimised prescriptions/patients treated) and optimisation percentage for each drug

(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/ehjpharm-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/ehjpharm-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 ± 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%.