underwent surgery twice for wound debridement and samples were taken.

After 6 days of empirical treatment, microbiological culture of exudate revealed *Streptococcus pyogenes*, and directed antibiotic therapy with penicillin and clindamycin was given. Skin lesions improved progressively with the treatment and lymphocyte count was 1.12×10×3/µL. However, he had to undergo plastic surgery for loss of granulated substance in the affected tissue. Clindamycin was suspended after 7 days and penicillin G after 14 days of treatment. One month later, a significant improvement in cutaneous injuries caused by baricitinib was observed, although he continued to need daily cures for sequels.

Conclusion and relevance This adverse reaction was reported to the pharmacovigilance centre and caused baricitinib discontinuation.

Immunosuppression caused by baricitinib and probable subsequent infections should be taken into account when starting this treatment in susceptible patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-064 RELATED RISK OF BIOLOGIC DRUGS FOR CROHN'S DISEASE IN PREGNANCY: A CASE REPORT AND REVISION OF THE LITERATURE

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10.1136/ejhpharm-2020-eahpconf.381

Background and importance Adalimumab is a human recombinant monoclonal antibody that is increasingly used in clinical practice for induction of remission in Crohn's disease. It reduces inflammation by binding with tumour necrosis factor (TNFα) so that it cannot interact with its own receptors. Crohn disease has a peak incidence in youth. Patient fertility can be influenced depending on the stage of disease (active or remission phase). There are insufficient data about how adalimumab impacts on fertility and its safety when administered in pregnancy.

Aim and objectives This case report presents a serious adverse reaction in a 33-year-old woman treated with adalimumab during pregnancy.

Material and methods Data were extrapolated from computerised medical records.

Results In 2009, the patient was diagnosed with Crohn ileitis, which required ileocaecal resection (removal of 35 cm of ileus, 7 cm of colon and the appendix). The morphological finding was compatible with the anamnesis: active and stenosing Crohn's disease. Several drugs were prescribed: mesalamine, corticosteroids and azathioprine, although without remission. In 2010, biological therapy with adalimumab was introduced and was interrupted three times: once for pregnancy and twice for relief of symptoms, which then regressed. The patient was in clinical, endoscopic and bio-humoral remission and had been receiving adalimumab since October 2018. On the last follow-up, June 2019, the drug was interrupted: the patient was pregnant and abnormalities were identified in the morphological assessment.

On 12 June, a clinician reported an adverse drug event. The morphological scan performed around the 21st week of pregnancy showed a small ectasia of the fetus's right ureter with a slight increase in right kidney dimensions. At the first scan, there were no problems identified with the fetus and so the patient continued therapy with adalimumab. The biological drug was interrupted on the 24th week of pregnancy. The seriousness of the adverse reaction will be reassessed at the next check-up.

Conclusion and relevance For adalimumab, as for other drugs, limited clinical data are available for exposed pregnancies. A toxicity study conducted in monkeys showed no indication of maternal toxicity, embryotoxicity or teratogenicity. Pharmacovigilance is essential in monitoring the safety of drugs in clinical practice, especially in populations not included in clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-065 PREDICTION OF TOXICITY OF METHOTREXATE BY MEANS OF GENETIC TESTS IN PATIENTS DIAGNOSED WITH MODERATE–SEVERE PSORIASIS

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10.1136/ejhpharm-2020-eahpconf.382

Background and importance Methotrexate is the standard treatment for moderate–severe psoriasis. However, it is a very aggressive treatment which has a high percentage of severe adverse events, such as asthenia, gastrointestinal toxicity, haematological toxicity and nephrotoxicity. This toxicity profile varies from person to person. Various studies have reported that these interindividual differences may be due to genetic factors, such as single nucleotide polymorphisms (SNPs), which are involved in methotrexate pharmacodynamics, metabolism and mechanism of action.

Aim and objectives To determine the utility of ABCB1 C3435T and MTHFR 1298 as prognostic and predictive markers in patients diagnosed with moderate–severe psoriasis treated with methotrexate, and to evaluate the toxicity of methotrexate treatment.

Material and methods A prospective cohort study was performed. Data and DNA were obtained from saliva samples of 64 patients residing in the province of Granada with moderate–severe psoriasis who had been treated with methotrexate. The genotypes were determined by Taqman PCR real time.

Results Mean age of the patients was 46±14 years; 33 men (33/64); 57 had psoriasis plaque (57/64), 56 located in the trunk and extremities and 30 in the scalp and face, 17 had psoriatic arthritis (29/64), 7 with diabetes mellitus (7/64), there were 19 smokers (19/64), 16 occasional drinkers (16/64) and 30 had a family history of psoriasis (30/64). Twenty-eight patients were treated with oral administration of methotrexate (28/64) and 44 for <12 months (44/64). Thirty patients were high responders (30/64), 34 presented with gastrointestinal toxicity (34/64), 25 hepatic toxicity (25/64) and 12 skin toxicity (12/64).

An association between nausea and alcoholism (p=0.06), diarrhoea and diabetes mellitus (p=0.03), age (p=0.02) and treatment duration (p=0.01) was found. Furthermore, a relationship between vomiting and female gender (p=0.016) and smoking (p=0.017) was observed.

No significant association was found between toxicity and the MTHFR 1298 and ABCB1 C3435T polymorphisms examined.

Conclusion and relevance In conclusion, gastrointestinal toxicity events were associated with alcoholism, diabetes mellitus, age, treatment duration, female gender and smoking. No significant association was found between toxicity and the SNPs examined.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-066 ANALYSIS OF POTENTIALLY INAPPROPRIATE MEDICATIONS IN ELDERLY ONCOLOGIC PATIENTS BY THE CHECK THE MEDS APP

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10.1136/ejhpharm-2020-eahpconf.383

Background and importance Elderly patients are fragile and often polymedicated. These characteristics, added to an oncologic process, could generate an increased risk of adverse effects of drugs.

Aim and objectives The aim of this study was to identify potentially inappropriate medications (PIM) in oncological elderly patients treated with oral chemotherapy dispensed at the hospital pharmacy.

Material and methods This was a 6 week observational, cross sectional study. PIM included inappropriate drugs in the elderly population, clinically relevant interactions, opportunities for de-prescription, duplicity, contraindications and other necessary pharmacological dose adjustments. All outpatients treated with active antineoplastic oral drugs provided by the hospital pharmacy service during that period were included. The inclusion criteria were: age >60 years and polypharmacy with more than six drugs. Unified medication order (UMO) was used to identify the patient's chronic medication. UMO joins specialised and primary prescriptions into a single visual screen for both attention levels. Check the Meds (V.3.6.0) is a software programme that facilitates optimisation of drug therapy, reviewing each treatment globally. It can also include patient dependent variables. A combination of both tools, UMO and Check-the-meds, was used to review completed prescription orders. All variables are described as number (percentage).

Results A total of 26 patients were analysed and 65.3% were men. Mean age was 72.69 years (60–90). Most common tumour location was colorectal (53.7%), prostate (19.23%) and both breast and lung cancer (11.5%). The prevalence of polypharmacy was 66.66% in those >60 years. The mean number of medicines was 10.15 (6–16). A total of 264 prescriptions were assessed. In 65% (172) some type of potentially inappropriate drug was identified according to the following distribution: 41.86% treatment duration, 33.14% proposed de-prescriptions, 8.14% clinically significant interactions and 16.86% related to out of range doses, duplicity or contraindication.

In 12 patients (46%), 14 clinically relevant interactions were identified. In 8 patients (57%), antineoplastic treatment was involved. In 88% of cases this medicine was metamizol. In the other relevant interactions, anti-inflammatory drugs were responsible for 66%.

Conclusion and relevance Technological tools improved the safety of pharmacotherapy in elderly oncological patients. It is necessary to reconsider the usefulness of metamizol based on its unfavourable safety profile, even more so as it is not available in Europe, apart from Spain.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-067 SAFETY PROFILE OF PIRFENIDONE AND NINTEDANIB IN A REAL LIFE SETTING: ASSESSMENT OF SUSPECTED ADVERSE DRUG REACTIONS IN THE EMILIA ROMAGNA REGION, ITALY

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10.1136/ejhpharm-2020-eahpconf.384

Background and importance Idiopathic pulmonary fibrosis (IPF) is a progressive and fatal form of fibrosing interstitial pneumonia with a poor prognosis, characterised by a decline in lung function, reduction in forced vital capacity (FVC), and worsening of dyspnoea and quality of life. Pirfenidone and nintedanib are the only two drugs with antifibrotic effects approved for the treatment of IPF. They both block the receptors of profibrotic growth factors, such as vascular endothelial growth factor (VEGF), platelet derived growth factor (PDGF) and fibroblast growth factor (FGF). Because of their critical safety profile, many patients are forced to have dose reductions or treatment interruption to manage side effects such as gastrointestinal disorders (diarrhoea, nausea and vomiting), bleeding (epistaxis and contusions), liver enzyme elevation, rash and photosensitivity.

Aim and objectives The aim of this study was to evaluate the safety profile of pirfenidone and nintedanib in the real life setting of the Emilia-Romagna region (RER), Italy.

Material and methods We examined all spontaneous adverse drug reaction (ADR) reports for pirfenidone and nintedanib entered into the National Pharmacovigilance Network by RER healthcare professionals and patients from January 2016 to December 2018 and combined these records with consumption data. We compared the ADR/DDDs ratio of the two drugs and characterised the type and rate of ADRs.

Results From January 2016 to December 2018, we found 22 ADR reports for pirfenidone and 19 for nintedanib, with an ADR/DDDs ratio of 1.44 and 8.61, respectively. The most frequent ADRs reported were photosensitivity reactions (50%) for pirfenidone and gastrointestinal disorders (53%) for nintedanib; the rate of hepatotoxicity was similar between the two drugs (18% and 16%, respectively). Three records (16%) about nintedanib concerned lack of efficacy.

Conclusion and relevance Our results showed that nintedanib had a worse safety profile than pirfenidone, even though the reporting rate is higher in the first years of marketing and pirfenidone has been on the market for longer. The safety