post-treatment (NRPT). Data were collected from medical records and the electronic prescription programme. Effectiveness was evaluated in terms of NRPT with alemtuzumab. Safety was assessed by reported treatment of AE.

Results Eleven patients, 63.6% women, mean age 38 (24–54) years, were included. Median time from RRMS diagnosis was 10 (4–20) years and mean baseline EDSS was 3.5 (2–5.5).

Patients were previously treated with a median of 3 (2–4) drugs: interferon beta-1a (IFN β -1a) intramuscularly (45.5%), IFN β -1a subcutaneously (27.3%), glatiramer acetate (27.3%), natalizumab (90.9%), fingolimod (27.3%) and dimethyl fumarate (18.2%). Seven patients completed two courses of alemtuzumab, and the second course is pending in three patients. One administration was suspended due to an infusion related reaction (IRR), requiring intensive care. The mean relapse rate was 0.36 (0–2). All patients experienced IRRs: lymphopenia (63.6%) and skin disorders (72.7%). Most were mild and limited in time, except for one patient with skin rash, pruritus and oedema, requiring discontinuation of treatment. Other AE were urinary tract infection (18.2%) and herpes zoster infections (9.1%).

Conclusion and relevance According to our results, alemtuzumab was effective in clinical practice due to a low relapse rate. However, further studies with a larger number of patients are needed to confirm these results. IRRs were frequent. Nevertheless, AE were mild and well tolerated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

5PSQ-062 EFFECTIVENESS OF ADALIMUMAB IN INFLAMMATORY BOWEL DISEASE AND INFLUENCE OF RESPONSE TO FIRSTLINE TREATMENT

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Background and importance Adalimumab is an antitumour necrosis factor- α (anti-TNF) agent indicated in ulcerative colitis (UC) and Crohn's disease (CD). Primary non-response to anti-TNF has been suggested as predictive of poor response to re-treatment with another anti-TNF.

Aim and objectives To assess the effectiveness of adalimumab as the second anti-TNF agent administered, evaluating the influence of response to the first anti-TNF agent.

Material and methods A descriptive retrospective study to July 2019 was conducted. All patients with inflammatory bowel diseases (IBD) treated with adalimumab as the second anti-TNF agent were selected. Variables collected were age, gender, diagnosis, previous anti-TNF therapy, reason for switch, response to anti-TNF, therapy duration and Mayo clinic score (MCS). Effectiveness was measured by MCS at 12, 36 and 60 months. Clinical remission (R) was MCS $\leq$ 2 points, clinical response (CR) was a decrease from baseline in MCS $\geq$ 3 points and lack of response (LOR) was none of the above. Patients with LOR and treatment suspension in 1 week were considered as LOR in the following weeks. Influence of response to the first anti-TNF agent was evaluated using the relationship between types of response to the first and second treatments. Primary non-response to anti-TNF was defined as LOR after induction of anti-TNF treatment: before week 10

for infliximab and before week 4 for adalimumab. Secondary non-response to anti-TNF treatment was considered as LOR after induction therapy.

Results Fifty-eight patients were included: 39.6% men and 60.4% women. Mean age was 41.6 (86–17) years. Diagnoses: 34.5% UC and 65.5% CD. All patients were pretreated with infliximab (first anti-TNF). Switching to adalimumab was caused by: 2 (3.4%) primary non-response, 45 (77.6%) secondary non-response and 11 (19%) intolerance. Mean adalimumab treatment duration was 29.7 (1–120) months. MCS at 12 months: 43.9% R, 19.3% CR and 36.8% LOR. MCS at 36 months: 29% R, 7.9% CR and 63.1% LOR. MCS at 60 months: 22.9% R, 2.8% CR and 74.3% LOR. One patient with primary non-response to infliximab (1/2, 50%) presented primary non-response to adalimumab; and another with secondary non-response to infliximab (1/45, 2.2%) had primary non-response to adalimumab.

Conclusion and relevance Adalimumab showed long term effectiveness in IBD patients pretreated with another anti-TNF, maintaining >20% of patients in clinical remission at 60 months. Adalimumab's primary non-response proportion was lower in patients with secondary non-response to a first anti-TNF than in those who had a primary non-response, but studies with larger sample sizes are necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-063 SERIOUS CELLULITIS IN A PATIENT WITH ATOPIC DERMATITIS TREATED WITH BARICITINIB: A CASE REPORT

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Background and importance Baricitinib is an orally available inhibitor of Janus kinases that is used to treat moderate to severe rheumatoid arthritis. In the literature, baricitinib seems to be an alternative in dermatologic diseases as off-label treatment. The baricitinib technical sheet describes that the most frequent serious infections in clinical trials were herpes zoster and cellulitis.

Aim and objectives To describe a severe case of cellulitis in a patient with atopic dermatitis previously treated with baricitinib.

Material and methods This was a descriptive, retrospective clinical case. The data (diagnostic tests, therapy and clinical course) were obtained by review of electronic medical records.

Results A 63-year-old man with hypertension and diabetes mellitus was diagnosed with severe atopic dermatitis in 2017. Previous treatments for atopic dermatitis were corticosteroids, ciclosporin, methotrexate and apremilast, all suspended due to lack of efficacy or adverse reactions. Treatment with baricitinib was initiated after being processed by our hospital pharmacy and authorised by the medical director, in May 2019.

Four months later, the patient was admitted to the traumatology service for severe extensive cellulitis with associated phascitis and pharmacological immunosuppression (lymphocyte count in the first determination was $0.51 \times 10^3/\mu\text{L}$). Baricitinib was suspended and empirical antibiotic therapy was started with meropenem and linezolid. In addition, the patient

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 $1.12 \times 10^3/\mu\text{L}$. 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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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 (TNF α) 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: mesalazine, 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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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).