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.

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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).