Abstract 5PSQ-070 Table 1 Two-hundred and one patients

	Spondyloarthritis n=106	Inflammatory bowel disease (IBD) n=37	Rheumatoid arthritis (RA) n=34	Psoriasis n=24
Males	65 (61.3%)	24 (64.9%)	13 (38.2%)	15 (62.5%)
Age, mean (SD)	52.6 (12.5)	44.7 (12.2)	61.2 (9.3)	50.9 (10.9)
Spanish	88 (83.0%)	28 (75.7%)	29 (85.3%)	24 (100%)
Patients with pain reduction	94 (88.7%)	36 (97.3%)	28 (82.3%)	20 (83.3%)
VASPRE, median (P25, P75)	6 (4–8)	6 (4–8)	6 (4–8)	4 (3.5–6.5)
VASPOST, median (P25, P75)	0 (0–2)	0 (0–2)	2 (0–2)	0 (0–2)

Association of several variables with pain reduction was checked through median regression models.

Results Injection pain reduction (VASPOST–VASPRE) was statistically significant for all pathologies ($p<0.001$).

Statistically significant differences observed for:

VASPRE: RA vs psoriasis ($p=0.0403$): IBD vs psoriasis ($p=0.0207$).

Injection pain reduction (VASPOST–VASPRE): IBD vs psoriasis ($p=0.0117$).

For IBD, antidepressants treatment (four patients, 10.81% of IBD cases) was the variable associated with the pain injection reduction (MD=−4.0; 95% CI: −7.26 to −0.74); $p=0.018$). No variables were identified for the other pathologies.

Conclusion

- Most patients reported better tolerance to the new formulation of original adalimumab, independently of the pathology.
- Pain with the ancient formulation was higher in IBD and RA than in psoriasis patients, and pain reduction was higher in IBD than in psoriasis ones.
- In IBD patients, those receiving antidepressant had a lower perception of pain maybe due to the analgesic action of these drugs.
- It would be interesting to consider these pain reduction results when developing biosimilar adalimumab formulations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

5PSQ-071 EVALUATION OF THE EFFECTIVENESS AND SAFETY OF VEDOLIZUMAB FOR THE TREATMENT OF INFLAMMATORY BOWEL DISEASE

MÁ Amor*, E Lobato-Matilla, Á Giménez-Manzorro, X García-González, E García-Martín, A Melgarejo-Ortuño, JL Revuelta-Herrero, PA Martínez-Ortega, C Ortega-Navarro, A Herranz-Alonso, M Sanjurjo-Sáez. *Servicio de Farmacia, Hospital General Universitario Gregorio Marañón, Madrid, Spain*

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Background Vedolizumab seems to be an alternative in the treatment of inflammatory bowel disease (IBD), but it needs real-world data to assess its utility.

Purpose To evaluate the effectiveness and safety of vedolizumab in patients with IBD in clinical practice and second, in patients with dose intensification.

Material and methods Retrospective observational study. Inclusion criteria: age≥18 years, IBD (including Crohn's disease and ulcerative colitis) treated with vedolizumab for at least 12 months. Period of study: December 2014 to September 2018.

The following variables were recorded: age, gender, previous anti-tumour necrosis factor (TNF) treatments, duration of treatment with vedolizumab, dose intensification (interval shortening from 8 to 4 weeks), effectiveness and safety.

Treatment effectiveness was assessed as follows:

Mayo Score (MS) in ulcerative colitis: patients in clinical remission (CR) in the induction period (IP) week 6 and in the maintenance period (MP) week 52 valued with MS ≤2.

Harvey–Bradshaw index (HBI) in Crohn's disease: patients in CR in the IP and MP, valued with HBI ≤4.

Incidence of drug-related adverse events (AE) reported by the attending physician was used to assess drug safety.

Data was collected from patients' clinical records and from the computerised physician order entry system (Farhos).

Results Forty-eight patients with IBD were included (62.5% Crohn's disease and 37.5% ulcerative colitis). The median age was 43.5 years (IQR=19.5) and 62.5% were males. 66.7% of patients had been previously treated with two or more anti-TNF, 22.9% with one anti-TNF and 10.4% were receiving vedolizumab as first-line treatment. The median duration of treatment with vedolizumab was 1.97 years (IQR=0.83). 33.3% of the patients required dose intensification.

Effectiveness: 20.8% of patients achieved CR in the IP and 50% achieved CR in the MP (47.4% in patients with dose intensification and 51.7% with no intensification).

Safety: 27.1% of patients experienced a grade 1 or 2 AE, higher in dose intensification vs no intensification (36.8% vs 20.7%). No severe AE and no treatment discontinuations due to toxicity were reported.

Conclusion Vedolizumab has shown to be a mildly effective drug in clinical practice for the treatment of IBD and is well-tolerated. Patients with dose intensification experienced similar response but a higher AE incidence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

http://www.aulamedica.es/fh/pdf/8981.pdf

No conflict of interest.

5PSQ-072 ACUTE PROMYELOCYTIC LEUKAEMIA AFTER INFLIXIMAB THERAPY IN A CROHN'S DISEASE PATIENT: A CASE REPORT AND A REVIEW OF THE LITERATURE

L Camuffo*, MV Lucatelli, G Pieri, C Bacci, G Inzalaco, R Puzziferri, C Di Carlo, M Fazio. *Humanitas Research Hospital, Pharmacy, Rozzano, Italy*

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Background In the post-marketing setting, only cases of leukaemia have been reported in patients treated with infliximab. There is also an increased background risk for lymphoma and leukaemia in patients with long-standing, highly active, inflammatory disease, which complicates risk estimation.

Purpose We wanted to report a case of acute promyelocytic leukaemia (APL) in a patient with Crohn's disease (CD) after infliximab therapy. We also reviewed the available literature.

Material and methods In June 2018 the patient's data were collected from the electronic medical records (Whospital) in our hospital: the literature was reviewed using the Pubmed database.
Results A 50 years' old male, with perianal CD since 2000, was diagnosed with APL in March 2018 after a bone marrow biopsy for grade 3/4 neutropaenia during an episode of pulmonary embolism and deep vein thrombosis. Infliximab therapy began in 2003 and was intermittent, with discontinuation in 2004 and 2006 because of good therapy response. He was unresponsive to these prior therapies: steroids, azathioprine and adalimumab. In 2015 he was enrolled for a few months, without good response, in a clinical trial with ustekinumab. After APL diagnosis, infliximab was discontinued and induction therapy for APL with arsenic trioxide and tretinoin (ATO +ATRA) was started. Remission began in April 2018, maintenance ATO +ATRA therapy was started and was still continuing in June 2018. The review of the literature found five reports of leukaemia cases after infliximab therapy in patients with CD (three), rheumatoid arthritis (one) and ankylosing spondylitis (one); three were males and two were females; the mean age of the patients was 46. The review also showed a higher risk of the occurrence of malignancies in patients on immunosuppressive therapy and/or with autoimmune/inflammatory disorders.
Conclusion Our patient presented APL after a long exposure to infliximab, which raises the concern that infliximab may be involved in leukaemia development. The presence of an autoimmune disease, such as CD, and prior immunosuppressive therapies, such as azathioprine and TNF-alfa inhibitors, may also have caused the development of leukaemia. Risk estimation is difficult. However, we suggest prompt evaluation for patients who develop haematological abnormalities when treated with infliximab.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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5PSQ-073 MUCORMYCOSIS INDUCED BY INAPPROPIATE USE OF ORAL CORTICOIDS – A CASE REPORT

[1]M Ferris Villanueva*, [1]S Martin Clavo, [1]E Garcia Lobato, [1]C Redondo Galan, [2]A Cinza Gonzalez, [3]MDLOCerezo Arias, [1]JF Rangel Mayoral, [4]E Ferris Villanueva. *[1]University Hospital Complex of Badajoz, Hospital Pharmacy, Badajoz, Spain; [2]University Hospital Complex of Badajoz, Maxillofacial and Oral Surgery, Badajoz, Spain; [3]University Hospital Complex of Badajoz, Intensive Care, Badajoz, Spain; [4]San Juan de Dios Hospital, Hospital Pharmacy, Seville, Spain*

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Background Invasive fungal infections such as Mucormycosis are considered opportunistic infections that occur almost exclusively in immunosuppressed patients, causing high morbidity and mortality. The use of long-term steroids may favour the state of immunosuppression, increasing the likelihood of acquiring this type of severe infections. The errors of therapeutic compliance are one of the possible causes of long-term treatment with corticosteroids.
Purpose The aim of the study was to discuss, through a clinical case, the consequences of an error in compliance with corticosteroid therapy.
Material and methods Observational, retrospective and descriptive case report of a patient diagnosed with mucormycosis due to the inappropriate use of corticoids. The data were obtained by review of the electronic clinical history (JARA) and the pharmacy service managing software (FARMATOOLS).
Results The patient was a 47 years' old male with a clinical history of arterial hypertension, dyslipaemia, morbid obesity, with smoking and alcoholic habits. In August 2018, he was operated on for an acute subdural haematoma. After being discharged from the hospital, the doctor prescribed Dexamethasone 4 mg every 12 hours, descending gradually. Due to the patient's misunderstanding, he kept the same medication dose (8 mg Dexamethasone daily) and did not comply with the gradual withdrawal of the medication. Fifty days' later, the patient was admitted to hospital with acute hepatitis, necrotising fasciitis in the right lower limb after trauma and intense palate pain. Suspecting mucormycosis and bacterial infection, the patient was treated with the empirical treatment: liposomal Amphotericin B, Isavuconazole, Daptomycin, Amikacin and CLindamycin. The presence of *Rhizopus spp*. was confirmed and invasive rhinosinusal mucormycosis secondary to immunosuppression due to the continued dose of corticosteroids was diagnosed. Finally, the patient died nine days after hospital admission due to multiorgan failure.
Conclusion In this case, the main cause of the development of mucormycosis came from a medication error in corticosteroid therapy compliance. Aiming to improve this kind of medication error, it is important to highlight the need to enhance pharmacotherapeutic monitoring, information and education for patients with the aim of improving therapeutic compliance.

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5PSQ-074 CANAKINUMAB IN FAMILIAL MEDITERRANEAN FEVER AND SECONDARY AMYLOIDOSIS: A CASE REPORT

V González Rosa*, MI Sierra Torres, S Fernández Espínola, M Zaragoza Rascón, M Pajares Alonso. *Hospital Serrania Ronda, Servicio de Farmacia, Ronda Málaga, Spain*

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Background Familial mediterranean fever (FMF) is an autosomal recessive disease characterised by repeated and self-limited seizures of fever and serositis. Classically, FMF has been treated with colchicine, although currently we have interleukin-1δ inhibitors such as anakinra or canakinumab.
Purpose To describe a case of FMF and secondary amyloidosis in current treatment with canakinumab.
Material and methods Description of a case of FMF, in follow-up in our hospital and in current treatment with canakinumab. Data was collected from the electronic medical record and analytics were reviewed in the laboratory application. The variables analysed were sex, age, neutrophil value, haemoglobin, C-reactive protein (CRP) and renal function before and after treatment with canakinumab and adverse reactions to treatment.
Results A 74-year-old female diagnosed with FMF, chronic kidney disease and hypertensive heart disease was followed up in our hospital since 2006. Treatment with colchicine 0.5 mg daily since then. Febrile episodes in 2009. Period 2010–2014 practically asymptomatic, with some episodes of fever that were self-limited with acetaminophen. She was admitted to hospital in December 2014 due to a fever outbreak and amyloidosis with renal insufficiency. In January 2015, anakinra