

administration route (oral/injectable/intravenous), treatment satisfaction and treatment decision-making. This questionnaire was elaborated and validated by an MS expert committee (hospital pharmacists, neurologist, patients' associations: Fundación Esclerosis Múltiple Madrid (nurses) and Esclerosis Múltiple España (clinical psychologists)).

**Results** One-hundred and fifty-seven MS patients (44 males/113 females) were included. The adherence rate was 71% (Morisky–Green scale), and was associated with: older age (mean: 45.2 years compliance; 40.4 years non-compliance), better cognitive status, being married/in-union, more lines of prior treatments, time to diagnosis of 5–10 years, exacerbations absence, clear information about the disease and high treatment satisfaction (table). There were no differences in the adherence rate between oral (63%) and injectable (77%) treatments. Analysing the injectable administration, there was greater adherence in patients with IV (100%) vs SC (68%). There was also a significant difference between IV (100%) vs oral (63%) ( $p=0.001$ ). The main cause for non-compliance was forgetfulness (27%).

**Conclusion** Adherence rate for the MS treatment is acceptable (71%). It is negatively affected by forgetfulness, lower cognitive status and lack of family support. The injectable route shows higher adherence than the oral route, although the latter show the highest patient satisfaction.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-069 ABSTRACT WITHDRAWN

#### 5PSQ-070 INFLUENCE OF PATHOLOGY IN INJECTION PAIN REDUCTION WITH A NEW FORMULATION OF ORIGINAL ADALIMUMAB

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**Background** Drug injection-related pain is associated with a poor treatment adherence.

To reduce it, a new subcutaneous formulation of adalimumab free of citrate and with a smaller volume injection and calibre needle has been brought to the market.

**Purpose** The objective was to assess the influence of the treated pathology and associated factors on the pain reduction due to the switch to the new formulation of original adalimumab.

**Material and methods** Prospective study performed during adalimumab's formulation shift (2017) in the outpatient pharmaceutical care area of a tertiary hospital.

All patients that had received both formulations were included and classified by the treated pathology.

Pain was assessed by the patients through a visual analogue scale (VAS)(0–10 cm).

Data collected: demographic, country of origin, injection site, administration frequency, number of doses before the switch, biologic-naïve, VAS score pre- (VASPRE) and post- (VASPOST) formulation switch, concomitant medication.

Statistics: median and interquartile range for quantitative (except age, mean (SD)), and% for qualitative variables.

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, antidepressant 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

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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  $\geq 18$  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  $\leq 2$ .

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

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

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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.