(ReNaSFO) established a joint action to update existing data on QoL and its correlation with use of disease modifying drugs in Italian patients. The results will be helpful as reference for future studies using PRO.

Aim and objectives The primary endpoint was QoL score in MS patients. Secondary objectives included QoL correlation with pharmacological therapy and clinical characteristics of patients.

Material and methods We designed a multicentre, observational, cross sectional study. Every patient had to complete a questionnaire on QoL (MS-QoL54) and the pharmacist collected the following data: sex, age, MS type, expanded disability status scale (EDSS) and history of pharmacological treatments. The study was approved by an ethic committee in each centre and patients provided signed informed consent. As MS-QoL54 scores were not normally distributed, we used Spearman's correlation test, ANOVA on ranks for multiple comparisons and the Mann-Whitney test for simple comparisons.

Results We enrolled 341 patients from 16 centres (median age 44.1 years; 68.9% women) with relapsing-remitting MS from May 2018 to June 2019 (median 20 per centre). The composite indexes of physical and mental well being were correlated with each other ($R=0.826$; $p<0.001$) according to a direct proportionality, and both had an inverse correlation with the degree of EDSS disability ($R=-0.511$, $p<0.001$ and $R=0.344$, $p<0.001$, respectively). Although there was no correlation between QoL and route of administration of the drug, we found significantly lower scores for patients treated with teriflunomide compared with other oral drugs (54.24 points vs 67.64 for fingolimod and 78.25 for dimethyl-fumarate; $p=0.002$).

Conclusion and relevance The study achieved primary and secondary endpoints and indicated a relevant decrease in QoL related to physical health associated with teriflunomide, which deserves further investigations. We also demonstrated that joint action by a scientific society and a student association was a valuable method to perform a no profit, multicentre, observational study in real practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-060 EFFECTIVENESS AND SAFETY OF USTEKINUMAB IN CLINICAL PRACTICE FOR CROHN'S DISEASE

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Background and importance Ustekinumab is a monoclonal antibody that inhibits the bioactivity of IL-12 and IL-23 causing a decrease in inflammatory markers in Crohn's disease (CD), used in patients in whom conventional treatment or anti-TNF is insufficient to control the disease or are contraindicated.

Aim and objectives To evaluate the efficacy and safety of ustekinumab in patients diagnosed with CD in a real clinical setting.

Material and methods This was a retrospective observational study, in two regional hospitals, in patients with CD who received an induction dose of ustekinumab between January 2018 and September 2019, inclusive. The data were obtained from the PRISMA-APD outpatient care programme, and by reviewing medical records in Diraya. To assess efficacy, the Harvey-Bradshaw index (HBI) was considered, for which the following variables were recorded: general condition of the patient, abdominal pain, number of daily liquid bowel movements, presence or absence of abdominal mass and other associated symptoms. Remission of the disease was considered if HBI was 1–6. Other clinical variables included were: age, sex, previous treatments with anti-TNF, concomitant use with immunomodulators and/or corticosteroids, need for intensification and treatment interruption. To assess safety, adverse effects associated with ustekinumab were considered.

Results Thirty-seven patients were included in the study: 21 women and 16 men. Median age was 45 years. With the exception of three patients, all had received prior therapy with one or more anti-TNF. Twenty of the patients had received concomitant corticosteroid and immunosuppressive medication. In 4 patients ustekinumab was withdrawn due to lack of action but 29 patients presented with an HBI <6, of whom 23 had an intensified pattern (90 mg every 8 weeks). The only adverse reaction recorded was atypical erythema nodosum in a patient.

Conclusion and relevance Ustekinumab seemed to have good efficacy in CD with an intensified regimen, as the disease was in remission (HBI 1–6 points) in most patients. Its safety profile was optimum as only one patient experienced an adverse reaction and withdrawal of the drug was not necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-061 ALEMTUZUMAB FOR RELAPSING-REMITTING MULTIPLE SCLEROSIS: EFFECTIVENESS AND SAFETY

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Background and importance Alemtuzumab is a humanised monoclonal antibody that selectively targets CD52, indicated in adult patients with relapsing-remitting multiple sclerosis (RRMS).

Aim and objectives To assess the effectiveness and safety of alemtuzumab for RRMS in the clinical setting.

Material and methods A retrospective observational study of all patients with RRMS treated with at least one course of alemtuzumab from July 2016 to March 2019 was carried out. The drug was administered by intravenous infusion on 5 consecutive days at baseline and on 3 consecutive days 12 months later. All patients received prophylaxis with methylprednisolone, antihistamines, antipyretics and acyclovir.

Alemtuzumab was started in adults with active disease, defined by clinical or imaging features despite the use of immunomodulating therapies, or having a fast and aggressive course. The variables studied were sex, age, time from diagnosis, expanded disability status scale (EDSS), previous treatment, number of cycles, adverse events (AE) and number of relapses

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