

(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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10.1136/ejhp-pharm-2020-eahpconf.377

**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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10.1136/ejhp-pharm-2020-eahpconf.378

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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