Background and importance Prolonged treatment with tocilizumab has been associated with cases of severe hepatotoxicity with liver failure and hepatitis, characterised by elevated hepatic transaminases (GOT/AST and GPT/ALT).

Aim and objectives To analyse the incidence of elevation of liver enzymes and the presence of severe liver damage in patients treated with tocilizumab, in a third level hospital.

Material and methods A descriptive, observational, 10 year study that included all patients treated with tocilizumab for more than 6 months, from January 2009 to August 2019, was carried out. Patients in whom the drug was used under special conditions of use and those with abnormal transaminase values prior to the start of treatment were excluded. The variables recorded were age, sex and duration of treatment. Liver function values (GOT/AST and GPT/ALT) were analysed every 4 weeks in the first 6 months of treatment and every 12 weeks after 6 months of treatment. Alterations in these values were classified as mild (1–3×normal upper limit (NAL)), moderate (3–5×NAL) and severe (>5×NAL). Data were collected from a database in Excel format.

Results During the study, a total of 135 patients were treated, 84 intravenously and 51 subcutaneously. Fifty-six patients were excluded from the study: 28 for receiving treatment for <6 months, 19 for off-indication regimens and 9 for elevation of liver enzymes prior to drug initiation. The study population was 77 patients: 11.7% (n=9) men and 88.3% (n=68) women; mean age was 55.13 years (12–83).

Mean duration of treatment was 40.44 months: 48.1% (n=37) showed alterations in liver parameters during treatment. In the first 6 months of treatment, 22.1% of patients (n=17) showed an increase in levels (82.4% mild (n=14), 11.8% moderate (n=2) and 5.9% severe (n=1)). After 6 months of treatment, in 44.2% of cases (n=34) levels increased (88.2% mild (n=30), 11.8% moderate (n=4)).

Conclusion and relevance Our study showed that the rate of liver toxicity in patients treated with tocilizumab was about 50%. Severe toxicity was identified in only one patient. These results, as indicated by the European Medicines Agency, show the need for liver function monitoring in patients treated with tocilizumab.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
EFFECTIVENESS AND SAFETY OF USTEKINUMAB IN CLINICAL PRACTICE FOR CROHN’S DISEASE

1M Fages*, 1J García Marín, 1J Romero Puerto, 1Soria Martín, 1MP Quesada Sanz. 1Punta De Europa Hospital, Pharmacy, Algeciras, Spain; 1Hospital De Europa, Hospital de Algeciras, Algeciras, Spain; 1Hospital Punturka, Pharmacy, Hospital de Algeciras, Algeciras, Spain

10.1136/ejipharm-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.

A232

A311. https://ejhp.bmj.com/content/26/Suppl_1/A131.2

No conflict of interest.