Background and importance Adalimumab (ADA), an anti-TNF agent, has been shown to effectively induce and maintain remission in patients with inflammatory bowel disease (IBD). The usual recommended dose in the maintenance phase is 40 mg every 14 days. The formation of anti-adalimumab antibodies (AAA) reduces plasma ADA serum concentrations (ADAsc), as well as its efficacy.

Aim and objectives The aim of the study was to analyse ADAsc and the presence of AAA in patients with IBD prior to the implementation of dose optimisation through therapeutic drug monitoring (TDM). The secondary objectives were to evaluate changes in the posology and to characterise the symptoms of IBD.

Material and methods A retrospective observational study was conducted in patients with Crohn’s disease (CD) or ulcerative colitis (UC) on maintenance therapy with ADA during a follow-up period of 3 years (July 2016 to April 2019) before applying TDM in a tertiary referral centre. The concentrations of ADA and AAA were determined by enzyme linked immunosorbent assay. The therapeutic range (TR) of ADA, according to the hospital protocol, is 8–12 mg/mL. Biodemographic, analytical and clinical data were collected from the clinical history.

Results 165 patients (53.0% women) were included, 132 (80.0%) with CD. Mean age was 40.00 (SD 12.4) years. At the beginning of the study, 119 (72.1%) patients received ADA 40 mg every 14 days and 46 (27.1%) intensified regimens. The average concentration of ADA was 7.24 (SD 3.6) mg/mL and 82 (49.7%) patients had ADAsc outside the TR. We observed AAA in 16 (9.7%) patients. Of these, 15 (93.7%) had ADAsc outside the TR. During the study, regimen intensification was conducted in 34 (20.6%) patients. Finally, regarding patients with ADAsc outside the TR, 35 (42.7%) presented with abdominal symptoms and/or systemic manifestations.

Conclusion and relevance ADAsc outside the TR were observed in half of the patients, in approximately 1 in every 10 patients AAA were detected and 42.7% of patients with ADAsc outside the TR presented with symptoms. Implementation of a TDM might be a useful tool for managing patients with IBD on biologic therapy to reduce the number of patients with ADAsc outside the TR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest