Background and importance Vedolizumab (VDZ) is an alternative in patients with inflammatory bowel disease (IBD) who have an inadequate response or loss of response to previous treatment with tumour necrosis factor-alpha (TNFα) antagonists. Therapeutic drug monitoring (TDM) has allowed optimisation of anti-TNFα therapy but its implications for VDZ are less well known.

Aim and objectives To evaluate the prescribing patterns, effectiveness and VDZ serum levels in clinical practice.

Material and methods This was a retrospective observational study. Inclusion criteria were age ≥18 years and IBD (ulcerative colitis (UC) or Crohn’s disease (CD)) treated with VDZ after anti-TNFα. The study was conducted from October 2015 to April 2019. The following variables were recorded: gender, age, weight, diagnosis, concomitant immunosuppressive treatment, dose and pattern of VDZ, duration of treatment, trough VDZ concentrations and anti-VDZ antibodies (AVA), concentration of C reactive protein (CRP) and faecal calprotectin (FC). Treatment effectiveness was assessed as follows: Mayo score (MS) and Harvey–Bradshaw index (HBI) scores in UC and CD, respectively. Clinical remission (CR) was considered if MS ≤2 or HBS ≤4. Data were collected from the patient clinical records. VDZ levels were determined by enzyme immunoassay.

Results Twenty-five patients (52% men) were included. Median age and median weight were 42 years (range 22–75) and 75 kg (95% CI 67–82), respectively. The diagnosis in 52% (n=13) was UC and in 44% (n=11) CD. At least one immunosuppressant was associated with the initial treatment with VDZ in 60% of patients. Median duration of treatment with VDZ was 79 weeks (95% CI 59–99). In 10 patients the treatment was suspended, mainly because of secondary therapy failure. The maintenance schedule was intensified, increasing to 300 mg/4 weeks in 7 patients (28%); 36% (n=9) of patients needed an extra dose on week 10. A total of 50% and 67% evaluable patients achieved CR in UC and CD, respectively. Clinical remission period were 901 840€ in patients with CRP >5 mg/mL and 1454 µg/g, respectively.

Conclusion and relevance Observed CR rates were modest and nearly a third of patients required intensification of treatment despite not identifying the presence of AVA. Therefore, VDZ TDM can be a useful tool for the physician in the decision making process.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.