4CPS-110 VEDOLIZUMAB: OUTCOMES AND THERAPEUTIC DRUG MONITORING IN INFLAMMATORY BOWEL DISEASE

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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 (TNF α) antagonists. Therapeutic drug monitoring (TDM) has allowed optimisation of anti-TNF α 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-TNF α . 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. Median trough concentration in the induction phase was 45.3 (95% CI 31.0–60.0) $\mu\text{g/mL}$ (6 patients) and during the maintenance phase 25.7 (range 6.40–105) $\mu\text{g/mL}$. In patients with CRP ≤ 5 $\mu\text{g/mL}$, VDZ concentration was higher (mean 34.3 $\mu\text{g/mL}$) than in patients with CRP >5 $\mu\text{g/mL}$ (mean 21.1 $\mu\text{g/mL}$). AVA were not detected in any patient. Patients reduced CRP and FC concentrations by an average of 1.9 $\mu\text{g/mL}$ and 1454 $\mu\text{g/g}$, respectively, during treatment.

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.

4CPS-111 CLINICAL AND ECONOMIC IMPACT OF INFLIXIMAB BIOSIMILAR INFLECTRA IN RHEUMATOID ARTHRITIS, PSORIATIC ARTHROPATHY AND ANKYLOSING SPONDYLITIS NAÏVE AND SWITCHED PATIENTS: 5 YEARS OF FOLLOW-UP

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Background and importance Rheumatoid arthritis (RA), psoriatic arthritis (AP) and ankylosing spondylitis (AS) have a considerable impact on healthcare budgets.

Aim and objectives The aim of this study was to determine the persistence, clinical and economic impact of the use of Inflectra in RA, AP and AS naïve and Remicade switched patients.

Material and methods This was an observational, retrospective cohort study of patients treated with Inflectra for more than 6 months, between June 2015 and September 2019. We collected age, sex, indication and persistence of Inflectra naïve and switched patients. Safety was also assessed. We determined the real cost of Inflectra treatment for each patient from individualised intravenous administration, and correlated dates during the study period were collected from DISPENSA (Oncopharm). We simulated the real cost for these patients if they received Remicade. Cost savings were calculated using official Spanish prices for Inflectra and Remicade.

Results From June 2015 to September 2019, 62 patients (38 women; aged 52 ± 20 years; weight 75 ± 27 kg), 31 with AS, 18 with RA and 13 with AP were treated; 33 (53%) were naïve patients (15 AS, 13 RA, 5 AP) and 29 (47%) were Remicade pretreated patients (16 AS, 5 RA, 8 AP). By September 2019, 33 (54%) patients continued on Inflectra treatment (11 naïve patients and 22 Remicade pretreated patients) in clinical remission (DAS 28 <2.6 or BASDAI <2). Twenty-nine patients discontinued therapy: 24 due to relapse of their rheumatology condition and 5 patients due to adverse reactions. All patients receiving Inflectra presented persistence at 24.4 ± 7.4 months (AS 22.7 ± 3.7 , RA 19.2 ± 5.4 , AP 31.7 ± 6.7). Persistence in naïve patients was 19.1 ± 4.4 months (AS 19.1 ± 4.7 , RA 13.8 ± 3.2 , AP 24.5 ± 10.4) and in Remicade pretreated patients 29.7 ± 5.8 months (AS 26.5 ± 6.5 , RA 24.6 ± 7.2 , AP 37.9 ± 8.1). Total associated costs of Inflectra treatment during the observation period were 901 840€. If these patients had been treated with Remicade, the total cost of therapy would have been 1 099 803€. Implementation of this procedure saved 197 964€ over 5 years.

Conclusion and relevance Inflectra produced cost savings when used in anti-TNF α drug naïve and anti-TNF α pretreated patients. At a time when therapy cost is an unavoidable component of healthcare treatment decisions, Inflectra could be a cost effective option for patients with RA, AP and AS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.