ANALYSIS OF PRESCRIBING AND CLINICAL OUTCOMES OF VEDOLIZUMAB TREATMENT IN A UNIVERSITARY CARE HOSPITAL

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OBJECTIVES

The aim of this study was: to describe the clinical outcomes of vedolizumab uses and to verify that had been followed up the Spanish Agency for Drugs and Health Products recommendations about its prescription criteria.

METHODS

A An observational retrospective analysis of all patients treated with vedolizumab in a universitary hospital was done. Patients were identified from june-2015 to june-2017 with the diagnosis of CD or UC and treated with vedolizumab; Patients were only eligible if they received, at least, complete induction therapy (four doses).

Data analysed: sex, age, start reason, previous treatment, diagnosis, surgeries, heath-care needed before/after vedolizumab began, evolution of the main analytical parameters, clinical response, and stop-rule adherence. Additionally, the reason for discontinuation was analyzed in those patients who discontinued treatment. Data were collected from electronic clinical history.

RESULTS

19 patients were identified: 10 men (6 UC,4 CD) with a mean age of 46,2 years and 8 women (8 CD, 1 UC) with a mean age of 43,7 years. Infliximab and adalimumab were used prior to vedolizumab in 87% of our patients. There was one patient without other biologic agent previously used. In 87% of the patients vedolizumab was initiated because of failure and/or intolerance of two different anti-TNF.

Vedolizumab was used with a mean duration of 35 weeks in UC and 40,6 in CD.
In 6 patients, after a mean 32 weeks-period of time, treatment had to be stopped: 4 loss of response,1 none response,1 surgery needed. Doses regimen reduction was needed, being useful only temporarily in 1.

In 13 patients, the drug was useful after a followed up mean period of time of 37 weeks. Nonetheless, in 6 patients a doses regimen reduction was needed, being useful in 5. Vedolizumab allowed a corticoids reduction or suppression in 5 patients and Immunosuppressant drugs in 3.

There was no relationship observed between the diagnosis and clinical outcomes. 16 patients had a successful induction. Only in 3 cases with (2 UC, 1 EC) it was not useful. 3 patients with UC reached clinical remission and maintenance with a dosage regimen every 8 weeks. In 7 cases, having obtained remission, a dose regimen reduction to every 4 weeks was needed in order to keep the response.

The national recommended stop-rule was not followed up in 3 patients, with 7 more doses used (14.196 €) without clinical benefit.

In 7 patients (36,84 %) it was observed a decrease of health care provider needed: visits to family doctor, emergency department, or hospital admissions.

CONCLUSION

Vedolizumab has shown to be useful in patients previously treated with anti-TNF; nonetheless, most of them required a doses regimen reduction. Suppression of corticoids or immunosuppressant drugs is an important goal that can be achieved.
A reduced number of patients, without other pharmacological alternatives, remain treated with vedolizumab unless it has to be stopped while surgery is going on.