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Persistence and efficacy of Ustekinumab in Crohn’s disease after antiTNF failure. May the response of the second biologic therapy be better than the first one?
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Background: After antiTNF failure, a second antiTNF in Crohn’s disease (CD) is effective to achieve and maintain remission, but only 50% remain with the drug after 12 months of treatment. Ustekinumab (UST) has a better persistence as second-line treatment and is effective to induce and maintain long-term remission.

Methods: Retrospective and observational study retrieved from a prospective database of Crohn’s disease patients treated with UST, after approval of Research Ethics Committee. Data were collected at the beginning of treatment and after 4, 8, 16, 24 weeks, 12, 24, 36, 48, 60 months and at the end of follow-up (UST discontinuation or March 2023 if treatment continues).

Primary Objective: evaluate the persistence with UST and clinical (Harvey-Bradshaw index (HBI)<4) and biological remission (C-reactive protein (CRP)<5 mg/dl and/or fecal calprotectin (FC)<250 mg/kg) in each period of follow up.

Clinical remission in perianal disease was defined as absence of drainage both spontaneous and after soft pressure. Persistence of the first biologic therapy, reasons of treatment change, dose optimization, surgery, hospitalizations and adverse events were also evaluated.

Results: 68 patients were included (Table 1).
Median survival of antiTNF is 1.65 years (IC95% 1.18-2.56). 72.06% patients receive antiTNF 1 year, 45.59% 2 years, 30.88% 3 years and only 8.82% are treated during 10 years.
Persistence with UST was longer than with antiTNF. 93.2% of patients receive UST 1 year, 89.4% 2 years and 86.1% 3 years.
There was a significant reduction of fecal calprotectin values during follow-up (p=0.0002).
7 patients with perianal disease achieved clinical remission (70.00%) and 4 complete fistula healing in magnetic resonance enterography (40.00%) at the end of follow-up.
60.29% patients received 90 mg every 8 weeks, but 36.76% required dose optimization (23.50% 90mg sq/4 weeks and 13.24% 130mg/4 weeks ev).
86.76% continue UST at the end of follow-up, with a mean duration of treatment of 27.65 months (SD 18.27). 9 patients (13.24%) stopped treatment (1 primary non response, 5 loss of response, 3 adverse events).
11 patients (16.18%) needed surgery and hospitalization during follow up; 63.60% of them had stricturing disease.

Conclusion: Persistence with UST as a second line therapy was superior to antiTNF in first-line. 86.76% continued treatment with UST after 2 years.
UST achieved early and long-term clinical remission in approximately two thirds of patients. 36.76% of patients required dose optimization. UST was effective in perianal disease after antiTNF failure.

Figure(s)/Table(s): see next page
Figure 1 shows clinical remission in patients with basal HBI>4.