

**Conclusions:** In UC patients with a severe disease course vedolizumab treatment results in a rapid and persistent absence of rectal bleeding in one third of patients. Normalization of stool frequency occurs less frequently and may reflect chronic alterations/damages of the bowel that may not be reverted by anti-inflammatory treatment strategies in this severely ill patient population. Absence of rectal bleeding is associated with a substantial improvement in patients quality of life. However, a substantial percentage of patients still required steroid-treatment to achieve these endpoints.

#### References:

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#### Evolution after a “de-intensification” strategy with anti-TNF therapy in patients with inflammatory bowel disease in clinical remission: multicenter study

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**Background:** The “de-intensification” of anti-TNF therapy in IBD patients with sustained remission may be considered for cost and safety reasons. Our aims were: 1) to evaluate the risk of relapse after anti-TNF “de-intensification” in clinical remission; 2) to identify predictive factors associated with relapse; 3) to assess the effectiveness of a second “re-intensification”; and 4) to analyze safety of this strategy.

**Methods:** An observational, retrospective and multicenter study was performed. Patients with Crohn's disease (CD) and ulcerative colitis (UC) who achieved remission on intensified anti-TNF therapy and then de-intensified a standard dose being in clinical remission were included. The follow-up after “de-intensification” was at least 6-months.

**Results:** 287 patients were included (50.9% male, mean age 43.1 years, 64.8% CD). Previous anti-TNF intensification was due to loss of response (58.9%) and partial response (35.6%). The reasons of “de-intensification” were: 87.7% medical decision following sustained clinical remission, 6.7% patient decision and 3.5% adverse events. 31.4% of patients relapsed with a median of 8 months (95% CI: 6.14–9.85). The cumulative rate of relapse was 11.5% at 6 months, 23.9% at 1 year, 33.4% at 2 years and 47.9% at 5 years; and the incidence rate of relapse was 18.9% patient-year. At time of “de-intensification”, endoscopy was performed in 32.2% of patients, out of them 66.3% had no activity and 31.5% mild activity. 48.4% continued combination therapy with immunomodulators after “de-intensification”. In the multivariate analysis, the variables associated with a higher risk of relapse were: presence of extraintestinal manifestations (HR=1.72, 95% CI: 1.04–2.85, p=0.032), and previous surgery related to IBD (HR=2.30, 95% CI: 1.21–4.38, p=0.011). The factors associated with a lower risk of relapse: concomitant treatment with immunomodulator after “de-intensification” (HR=0.406; 95% CI: 0.23–0.70, p=0.001) and inflammatory behavior CD vs. structuring-fistulizing pattern (HR=0.385, 95% CI: 0.20–0.72, p=0.003). 74.2% of patients who relapsed were treated with a new anti-TNF intensification, 57.6% achieved remission in early 8 weeks, and 71.2% at the end of follow-up. After that, only 6% had adverse effects, most of them mild.

**Conclusions:** The incidence rate of inflammatory bowel disease relapse after “de-intensification” in patients with clinical remission was 18.9% patient-year. Extraintestinal manifestations and previous surgery for IBD were predictors of relapse; while concomitant treatment with immunomodulator and inflammatory behavior CD were associated with lower risk of relapse. The treatment of relapse with the new “re-intensification” was safe and effective in 3 out of 4 patients.