Conclusions: All the patients had inflammatory bowel disease during exacerbation has reduced quality of life. The results indicate a higher quality of life in patients with IBD who had received biological therapy – mesenchymal stromal cells and infliximab, than in patients treated with standard anti-inflammatory therapy.

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Adalimumab in active ulcerative colitis: A "real-life" observational study

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Background: The effectiveness of adalimumab (ADA) in the treatment of ulcerative colitis (UC) is under debate. Controlled trials have shown that ADA is significantly better than placebo, but the absolute benefit is small. We report data on the effectiveness of ADA in a large cohort of patients with active UC.
Methods: Patients with active UC treated with ADA in 21 Italian referral centres have been collected. Clinical characteristics before and after ADA treatment were reported in a common database. Active UC was defined as a partial Mayo score $\geqslant$2. All patients received ADA induction and maintenance regimen and concomitant medications according to clinical judgement. Co-primary endpoints were clinical remission (partial Mayo score $\leqslant$1) at 4, 12, 24 and 54 weeks. Secondary endpoints were sustained clinical remission, steroid discontinuation, endoscopic remission and need of colectomy.
Results: Eighty patients (median age 39 years, IQR 31–47) have been enrolled. Main indications for ADA treatment were steroid-dependency (45%), steroid-resistance (24%) and extraintestinal manifestations (14%). Most of patients (79%) received previous infliximab treatment. Median partial Mayo score at baseline was 6 (IQR 4–7). ADA induction regimen was 160/80 mg (90%) or 80/40 mg (10%) and maintenance treatment was 40 mg every other week for a median time of 11 months (IQR 4–16). During follow up 30% of patients required dose-escalation. Clinical remission at 4, 12, 24 and 54 weeks was achieved in 13/80 (16.2%), 20/76 (26.3%), 25/73 (34.2%) and 23/57 (40.3%) patients, respectively. Sustained clinical remission at 12, 24 and 54 weeks was achieved in 10/57 (17.5%) patients. 33 of 55 patients (60%) receiving steroids at baseline were able to discontinue them. 47 patients underwent baseline and follow-up endoscopy after a median of 11 months (IQR 3–13). Endoscopic remission was achieved in 21/47 patients (45%). During the study period, 18 patients (22.5%) underwent colectomy after a median of 5.5 months (IQR 2–14). No significant differences in remission rates at 4, 12, 24 and 54 weeks and colectomy rates were observed between anti-TNF alpha naïve and non-naïve patients.
Conclusions: In this large "real-life" experience ADA appeared to be effective in active UC. One fourth of patients achieved clinical remission within three months. In patients receiving scheduled maintenance treatment for one year the remission rate was 40%. Although ADA shows a steroid-sparing effect, the probability of colectomy for treatment failure is high.

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Efficacy of hepatitis B vaccination and re-vaccination and factors impacting on the response in inflammatory bowel disease patients

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Background: Vaccination against hepatitis B (HBV) is recommended in patients with inflammatory bowel disease (IBD). However, only a few studies have addressed the response to HBV vaccination in these patients.
Aims: (i) to assess the HBV vaccine efficacy in a large sample of patients with IBD; (ii) to evaluate the influence of the treatment with immunosuppressors and anti-TNF drugs; and (iii) to assess the success rate after the re-vaccination in patients who failed to the first attempt.
Methods: Patients diagnosed with IBD were vaccinated against HBV with a quick, double dose schedule (Engerix B® double dose at 0, 1 and 2 months). Anti-HBs titers were measured two months after the last vaccine dose. A multivariate analysis was performed to identify predictive factors of response to the vaccine. In non-responders, a second vaccination was administered with the same dosage and schedule.
Results: 241 patients (mean age, 44 years; 62% Crohn's disease, and 38% ulcerative colitis) were included. 40% were on immunomodulators, and 20% on anti-TNF therapy when the vaccination was administered. 59% of patients (95%CI = 52–65%) had anti-HBs >10 IU/l after the vaccination, while 39% (95%CI = 32–45%) had anti-HBs >100 IU/l. In the univariate analysis, the response rate (anti-HBs >10 IU/l) to the vaccine was lower among patients under anti-TNF therapy: 46% vs. 62% ($p < 0.05$). In the multivariate analysis, the age and being under anti-TNF therapy were the only factors associated with the response to the vaccine (anti-HBs >10 IU/l), with a lower response rate in older patients (OR = 0.96; 95%CI = 0.94–0.98; $p < 0.001$) and in those receiving anti-TNF drugs (OR = 0.39; 95%CI = 0.2–0.76; $p < 0.01$). The response rate (anti-HBs >100 IU/l) after the re-vaccination in patients who had previously failed was 42% (95%CI = 29–54%). Therefore, adequate anti-HBs antibody level (anti-HBs >100 IU/l) was finally reached, overall, in 65% of the patients.
Conclusions: The response rate to the HBV vaccination, even when a double dose schedule is administered, is very low in IBD patients, mainly in those receiving anti-TNF therapy. However, treatment with immunosuppressors does not seem to impact on the efficacy of the VHB vaccine. A considerable, although still insufficient, success rate may be obtained when two consecutive vaccination courses, with 3-dose vaccine series each one, are administered.