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Serological response to the 23-valent pneumococcal polysaccharide vaccine in patients with Crohn’s disease: preliminary results of a prospective, multicentre study
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Background: Recent studies have reported that anti-tumour necrosis factor (anti-TNF) blockers alone or in combination with immunomodulators (IM) can impair the serological response to pneumococcal vaccination in patients with inflammatory bowel disease (IBD). However, the type of IBD might have been a potential confounding factor in the previous studies. Therefore, we evaluated the effect of immunosuppressive treatment on the serological response to and safety of the 23-valent pneumococcal polysaccharide vaccine in patients with Crohn’s disease.

Methods: This is part of an on-going prospective, multicentre, observational study. Of 180 patients enrolled, 171 completed the study. The study population belonged to one of the following four treatment groups: 5-aminosalicylate alone (control group, n = 37), IM alone (IM group, n = 70), anti-TNF blocker alone (anti-TNF group, n = 14), and anti-TNF blocker in combination with IM (combination group, n = 50). Anti-pneumococcal IgG antibody titres were measured before and 4 weeks after vaccination. The primary outcome was the serological response rate, defined as the proportion of patients achieving both a ≥ twofold increase in baseline titres and a post-vaccination geometric mean titre (GMT) ≥ 1 mg/mL. The secondary outcome was the difference in the GMTs prior to and after vaccination. All vaccination-related adverse events up to 4 weeks after vaccination were recorded. This study is registered at www.clinicaltrials.gov (NCT01505855).

Results: The overall serological response rate was 70.8% (121/170). Only the combination group had a significantly lower serological response rate than did the control group (58.0% vs. 78.4%, P < 0.05). The post-vaccination GMTs of the immunosuppressed patients were significantly lower than that of the non-immunosuppressed patients (P < 0.001). The post-vaccination GMTs did not differ significantly among the IM, anti-TNF, and combination groups (P > 0.05). Vaccination was generally safe and well-tolerated by all patients.

Conclusions: Only treatment with the combination of anti-TNF and IM led to impaired seroprotection to pneumococcal vaccination in patients with Crohn’s disease. Patients receiving immunosuppressive therapies had significantly lower post-vaccination GMTs than did non-immunosuppressed patients, suggesting that the use of immunosuppressive medications, regardless of their types, could be a potential cause of suboptimal response to pneumococcal vaccination.

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Side effects in inflammatory bowel disease patients treated with biological therapy: our experience
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Background: Both Infliximab and Adalimumab are anti TNF inhibitors monoclonal antibodies that have demonstrated efficacy in the treatment of inflammatory bowel disease (IBD). The aim of this study was to analyze the side effects in patients with Crohn’s disease (CD) and ulcerative colitis (UC) treated with infliximab and adalimumab in our hospital.

Methods: 345 IBD patients were included. From February 2000 to March 2012, 255 patients, 182 with CD and 73 with UC were treated with infliximab (5 mg/kg) while 90 patients, 86 with CD and 4 UC, were treated with adalimumab (40 mg/2 weeks) from January 2006 to April 2012.

Results: From the 255 IBD patients treated with infliximab, 121 (47.5%) abandoned treatment; 27 (10.6%) due to side effects, it consist of 18 patients with CD and 9 UC, with 5.9 years average duration of the disease, with mesalazine and azathioprine as previous treatment and with an average dose of 325.92 mg per 8 weeks of infliximab. They were treated during 17.5 months in average.

Additionally, the most frequent type of side effects were minor (12 patients, 44.4%): headache, arthralgia, vomiting and malaise; 6 patients (22.2%) with urticarial reaction; 5 patients (18.5%) with infections (2 meningitis, 2 tuberculosis, 1 pneumonia); 1 hepatotoxicity (3.7%); 1 lupus-like (3.7%); 1 psoriasis (3.7%), 1 B cell lymphoma (3.7%). From the 90 IBD patients treated with adalimumab, 34 (37.7%) abandoned treatment; 12 (13.3%) due to side, all patients were CD with 5.1 years average duration, with mesalazine and azathioprine as previous treatment and with an average dose 40 mg/15 days. They were treated during 14.3 months in average. Additionally, the most frequent type of side effects were minor (5 patients, 41.1%); headache, malaise; 2 injection site cellulitis (16.7%); 1 plantar psoriasis (8.3%); 1 tuberculous meningitis (8.3%); 1 neuropathy (8.3%); 1 fever (8.3%); 1 intraductal breast papilloma (8.3%).

Conclusions: Anti TNF therapy in IBD patients is secure, with 10–13% of side effects accordingly to our study, where the most frequent type were minor side effects, although there still exist serious complications. It is fundamental a strictly follow up of patient with Anti TNF therapy.

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Short onset of ulcerative colitis predicts the response to cyclosporine (Neoral) as bridge therapy in steroid-refractory ulcerative colitis
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Background: In the past 10 years, the Oxford regimen, based on the use of intravenous corticosteroids, has been modified by the introduction of cyclosporine (CyS) and infliximab (IFX) as treatment options of severe ulcerative colitis (UC). Long term prognosis, in CyS treated patients, is reported to be improved by the introduction of azathioprine (AZA) or mercaptourine (6-MP) in association with oral CyS as bridge therapy. We report long-term follow-up results from an open-label study that assessed the efficacy and safety of oral CyS in steroid refractory-naive patients with moderately to severely active UC.

Methods: 17 patients (pts) (9 male, 8 female, aged 19–72 years), steroids and AZA/6-MP treatment naïve, received oral CyS as rescue therapy for acute UC, following 2–9 days of intravenous steroids (1 mg/kg/per day); pts were commenced on 5 mg/kg/per day of oral CyS (TO). After 2 weeks all the pts received AZA treatment (2 mg/kg/per day); all the pts followed their 5-ASA therapy (dose ranging 2.4–3.6 g/per day) and tapered steroids 5 mg/every week. The clinical assessment was evaluated with Mayo Scoring System for Assessment of UC Activity; clinical remission was defined as an inactive score and response was defined as an improvement of the activity score after 6 weeks of CyS treatment (T6).