P080
MAINTENANCE INFLIXIMAB TREATMENT FOR CROHN'S DISEASE OVER 54 WEEKS: OUR EXPERIENCE

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Background: The efficacy and safety of repeated infusions of Infliximab in the treatment of Crohn's disease (CD) is recognized by international clinical trials (ACCENT I and II study) for a maintenance time of 54 weeks. Long term Infliximab therapy results in a reduction of a rate of complications, hospitalizations and surgeries associated with CD. Literature data are not available for a longer period of time.
Aim: Our experience was conducted to monitoring the efficacy, safety and steroids tapering of patients affected by CD, already well responded to Infliximab, for more than 54 weeks.
Matherial and Methods: Twenty patients (pts), 11M, 9F, average 38 years (yrs), affected by CD with a long history of illness (median 9 yrs) were enclosed. All pts were parted into: fistulazing 9/20, refractory 8/20, stenosing 3/20 without occlusive symptoms; 5/20 pts had previous surgical intestinal resections. Extraintestinal manifestations were arthralgia in 6/20, rheumatoid arthritis in 1/20, uveitis in 2/20 pts. Since the beginning of the treatment concomitant steroids were in every pts, Azatioprine (12/20), Tacrolimus (3/20), and MTX (1/20) only in few. All pts, already in treatment with Infliximab for more than 54 weeks and in remission CD (CDAI<150) were subjected to repeated infusions, every 8 wks, thereafter until 126 wks. At predefined study visits CDAI, IBDQ, C-reactive protein values and steroid tapering were assessed.
Results: Five pts (25%) stopped the treatment for infusion reactions in 3/5 at the time of 66 and 106 wks and for surgical treatment in 2/5 fistulazing CD at 86 and 106 wks respectively. The other pts continued to the end of the study and showed from 56 to 126 wks a sustained clinical remission with CDAI <150 and IBDQ >165 (p=0.012 and p=0.006 respectively); the C-reactive protein values decreased with significant results only at 126 wk (p=0.07). Moreover 14/20 (70%) pts were not receiving steroids at baseline continued without, the other 6pts (30%) with low dose of steroids didn't get the withdraw, but kept periodically assuming.
Conclusions: Our preliminary experience explains a maintenance Infliximab treatment, safe and efficacy, for MC in remission for a time of 126 weeks. Only 40% of the pts interrupted the treatment before the end of the study. A longer time of Infliximab treatment didn't increase the steroid tapering in those pts previously assuming. Further studies would be encouraged to better define the outcome of maintenance Infliximab treatment in pts with CD for a longer time.

P081
TREATMENT OF ULCERATIVE COLITIS WITH A COMBINATION OF LACTOBACILLUS RHAMNOSUS AND LACTOBACILLUS ACIDOPHILUS. RESULTS OF A RANDOMISED, DOUBLE-BLIND, AND PLACEBO CONTROLLED TRIAL

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Introduction: In recent years, there has been an increasing interest in the relationship between the gastrointestinal flora and gut function. Several studies have shown promising results for the use of probiotics in the treatment of patients with inflammatory bowel disease.
Aims: Aim of the current study was to evaluate the effect of a probiotic containing Lactobacillus rhamnosus and Lactobacillus acidophilus for the induction and maintenance of remission in patients with active ulcerative colitis.
Methods: The study was a two-centre, randomised placebo-controlled, and double-blind trial. Patients above the age of 18 years with known ulcerative colitis with a clinical and endoscopic documented relapse could be included in the trial. Patients were randomised to treatment with a combination of Lactobacillus rhamnosus strain 19070-2 and Lactobacillus acidophilus strain 18911-2 (10EE9 colony forming unit/ml) 1ml daily or an identical placebo. Patients were stratified according to whether or not they received systemic glucocorticoid treatment at inclusion. From inclusion and to remission patients were treated according to the physician's standard guidelines and probiotics/placebo for 4-16 weeks. Patients achieving remission continued with maintenance treatment and probiotics/placebo for six months. Treatment with probiotics/placebo was stopped and patients were followed for another six months after this. The primary end-point was the number of patients without relapse (clinical and endoscopic documented) 6 months after remission had been achieved; secondary endpoint was the number of patients achieving remission.
Results: 102 patients (47 Males/55 Females) with a mean age of 38 years (range 21-75) were included in the trial. Fifty (49%) were randomised to treatment with probiotics, 52 (51%) to treatment with placebo. Sixtythree patients (62%), 35 treated with probiotics and 28 with placebo achieved remission, (p=0.07, n.s.). Six months after remission had been achieved there was no difference in the number of patients in remission in the probiotic and placebo treated group; 12 vs 13, (p= 0.47).
Conclusion: a suspension containing Lactobacillus rhamnosus strain 19070-2 and Lactobacillus acidophilus strain 18911-2 had no effect on the number of patients achieving remission or the number of patients in remission after 6 months.

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RITUXIMAB AND ULCERATIVE COLITIS: AN UNEXPECTED BENEFICIAL COLLATERAL EFFECT OF LYMPHOMA TREATMENT

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The etiology of ulcerative colitis (UC) remains unknown, nevertheless there is good evidence that genetic, immunological and environmental factors play a determinant role in the development of the disease. Animal models of the disease and human data stress the role of a T cell-mediated pathology whereas the role of B cell-mediated pathology in UC remains controversial. Rituximab is a chimeric murine/human monoclonal antibody directed against the CD20 antigen found on the surface of normal and malignant B lymphocytes. Its principal indication is the treatment of patients with Non-Hodgkin's Lymphoma and Rheumatoid Arthritis. We report the case of a 33 year old female patient, known for a severe UC for 2 years that developed under methotrexate therapy a large immunoblastic Bcell lymphoma whose treatment with rituximab was associated with a clinical remission of the UC. Methotrexate was introduced as treatment of her severe steroid resistant and ciclosporin dependent UC after the failure of several months of adequately-dosed azathioprine therapy. After 9 months of methotrexate therapy the patient, finally clinically in remission and ciclosporin- as well as steroid-free, developed fever and peripheral lymph node enlargements. The diagnostic work up revealed multiple lymph nodes enlargement at the thoraco-abdominal level that were histologically characteristic for a large immunoblastic Bcell lymphoma in the context of a serological HBV positivity. Methotrexate was immediately stopped and a rituximab based chemotherapy was started with subsequent complete remission of the lymphoma. For the first time in two years the patient did not experienced a UC flare in the absence of any classical immunomodulatory or steroid therapy. A total proctocolectomy performed one and half month later confirmed that the whole colon was macro- and microscopically normal, with the absence of any sign of acute or chronic inflammation such as plasmolymphocytic infiltrates. The patient still remains, 2 years later, in complete remission of her lymphoma. This report gives evidence for the involvement of B cells in the pathophysiology of UC and support in favor of anti-B cell based therapy such as rituximab as a new potential therapeutic weapon in UC.

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LOCAL INJECTION OF INFLIXIMAB IN CROHN'S DISEASE RECURRENCE: A PILOT PROSPECTIVE LONGITUDINAL STUDY IN THE LONG-TERM

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Aim: We aimed to assess the long-term safety and clinical efficacy of local IFX injection into CD recurrence. We also investigated the short-term safety and efficacy in additional CD pts.
Methods: In an open-label study, 14 clinically inactive CD pts with previous ileo-colonic resection requiring colonoscopy (CC) were enrolled. Long-term study. The same 8 CD pts assessed and reported in the short-term study were followed up and assessed in the long-term. Short-term study. Additional 6 CD pts were injected with IFX at the site of recurrence with timing of CC related to the patient's compliance. Inclusion criteria: localized (<5cm) CD recurrence, inflammatory pattern, inactive CD. The endoscopic recurrence was graded according to Rutgeerts score. In all the 14 pts all the involved area was injected with IFX. Long-term study. Among the 8 pts, CC after the first injection was performed at 2 wks in 4 pts (3 performing a second injection followed by CC at 6 wks), at 4 wks in 4 pts (2 performing a second injection followed by CC at 8 wks). Short-term-study. Among the 6 pts, CC after first injection was performed: at 6 (n=3), 12 (n=1),16 (n=1) and 28 wks (n=1).
Results: No pts showed local or systemic side-effects or clinical relapse in the short and long-term. Long-term study. Among the 8 CD pts, 6 remained in follow up > 2 months after the first injection, all 6 pts maintaining clinical remission from the injection to the follow up end(median 24 mths range 1-32). Short-term study. All the 6 pts maintained clinical remission at the fol-