P131
Induction and maintenance of clinical response and remission with certolizumab pegol in patients with inflammatory or fistulizing Crohn’s disease: a referral center experience of compassionate use

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Introduction: Certolizumab pegol (CZP) is a pegylated Fab’ fragment of a humanized anti-TNFα monoclonal-antibody, effective in the treatment of Crohn’s disease (CD). A recent report showed its efficacy in patients who had previously received and responded to infliximab, but who no longer have a sustained response and/or toleration to infliximab.

Aim and Methods: We report the experience of a referral centre concerning the short and long-term efficacy of CZP in the treatment of moderate to severe CD (Harvey Bradshaw Index (HBI) > 4). Nine patients (4 with intolerance and 5 with loss of response to infliximab) were enrolled. Patients received 400 mg of CZP subcutaneously at week 0, 2, 4 (induction); responders maintained a scheduled regimen of 400 mg every 4 weeks. We evaluated the efficacy and safety of CZP at the end of the induction (week 6), and 6 to 12 months later. Remission was defined as HBI < 4 or a complete fistulas closure; response was defined as a reduction of HBI < 3 or a reduction of at least 50% of drainage trough the fistulas.

Results: Five males/4 females (mean age 40.4 years, range 18–54) were enrolled; mean disease duration 14.1 years (range 4–22). The median baseline HBI score was 9.2 (range 7–16). Involved intestinal areas were: ileum (2 patients), colon (2), ileum–colon (5). Three patients were treated with CZP for fistulizing CD (evaluated with MRI) and 6 for inflammatory CD. At week 6, among the patients treated for inflammatory CD, 3 of 6 (50%) were in remission, while 2 of 6 (33%) achieved clinical response; the mean HBI was 6.2 (range 3–16). At month 6, 3 of 5 (60%) responder patients were in clinical remission: 2 maintained the remission achieved at week 6, and 1 improved from response to remission. At month 12, 2 patients were in remission and 1 relapsed. In patients with fistulizing disease CZP was ineffective: 2 patients underwent surgery for abdominal abscesses, and another one is waiting for surgery although received only 1 injection because of infusion reaction. No patients treated for disease activity had adverse events; among patients with fistulizing disease, 2 developed an abdominal abscess and 1 discontinued the treatment for skin rash.

Conclusion: In our experience, CZP was effective in inducing clinical response and remission in patients with moderate to severe inflammatory CD who had responded to infliximab and then lost that response or were intolerant to the agent. This efficacy was confirmed at 6, and partly, at 12 months. For fistulas healing CZP was ineffective. Abscesses developed in 2 patients with fistulas suggesting an accurate screening for abdominal sepsis before starting therapy. Further experiences with placebo-controlled trials will definitively address the efficacy of CZP in similar population of CD patients.

P132
Clinical experience with adalimumab in a multicenter Swiss cohort of patients with Crohn’s disease

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Introduction: Adalimumab (ADA) is a fully human monoclonal antibody which binds with a high affinity and specificity to tumor necrosis factor (TNFα). Controlled clinical trials have demonstrated its efficacy and safety in the treatment of moderate-to-severe Crohn’s disease (CD). However, long term experience with ADA in real-life clinical practice has rarely been reported.

Objective: To assess the long term effectiveness and the safety of ADA in a multicenter cohort of patients with moderate-to-severe CD.

Methods: Fifty-five patients (21 men, 34 women), mean age 37.5 years (±11.4 years), median disease duration 12.7 years (range 1–41 years) were treated with ADA and followed up over a period of 52 weeks (range 12–96 weeks, median 50 weeks). Thirty-eight patients had previously been treated with infliximab (IFX). The ADA induction regimen was 160/80 mg in 31 patients and 80/40 mg in 24 patients. The clinical evolution during treatment was evaluated with the Harvey–Bradshaw Index (HBI) at week (W) 4–6, 12, 24 and 52.

Results: On week 4–6, a response was demonstrated in 83.6% of patients and remission was obtained in 52.7%. The remission was maintained in 89.6% and 72.4% of the patients at W12 and W24, respectively. In per protocol analysis at W52, half of patients were still in response and half had stopped ADA: 5/19 because of adverse events and 14/19 because of no response or loss of response. Thirteen patients (23.6%) needed a dose escalation after a mean interval of 7 months (range 1–24 month). The response rate at W4–6 was not influenced by gender, smoking status, disease duration, localisation of disease, previous surgery, previous IFX treatment, the first month total ADA dose, or the first month ADA dose divided by body weight. Interestingly, however, the remission rate at W4–6 was significantly higher in patients intolerant (78.9%) to IFX, as compared to those who had lost response to IFX (42.1%; p = 0.02). Overall ADA was well tolerated, 54.5% patients didn’t report any side effects. The most common side effect was pain at the injection site (10.9%), followed by anaemia (9%) and infections (7.2%).

Conclusion: ADA was effective and safe in clinical practice as induction and maintenance therapy for patients with moderate-to-severe CD.

P133
Adherence to therapy and use of complementary and alternative medicine in patients with inflammatory bowel diseases

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Introduction: Previous studies have shown a high prevalence of non-adherence the use of CAM in Hungarian patients with IBD. Furthermore a significant number of IBD patients fail to comply with treatment. The aim of our study was to evaluate the prevalence of non-adherence the use of CAM in Hungarian patients with IBD.

Patients: A total of 448 consecutive IBD patients (CD: 234, male/female: 109/125, age: 41.1 (SD 14.0) years, disease duration: 7.8 (SD 7.0) years, last follow up visit by specialist: 6.3 (SD 6.7) months; UC: 214, male/female: 91/123, age: 40.7 (SD 14.5) years, disease duration: 10.3 (SD 8.1) years, last follow up visit by specialist: 8.1 (SD 8.6) months) were
There were 41 non-adherence (UC: 23.8%, CD: 21.8%) and CAM (UC: 34.2%, UC: 31.9%) use was not different between CD and UC. The most common causes of non-adherence were: forgetfulness (14.5%), to many/unnecessary pills (10.9%), being afraid of side effects (8.5%), too complicated administration schedule (1.3%). Most common forms of CAM were: herbal tea use (21.7%), homeopathy (6.7%), special diet (5.6%), acupuncture (4.7%). In CD more advanced age (40 years, OR: 2.02, p = 0.03), lower educational level (high: 10.2% vs low: 37.5%, OR: 0.02) and number of previous surgeries (40 surgery: 26.8% vs >2 surgery: 6.8%, p = 0.02) were predicting factors for non-adherence. In UC, adherence was less in males (OR: 2.4, p = 0.007), in young patients (OR: 2.0, p = 0.037), but not according to the medication type used including local 5ASAs. Alternative medicine use was associated in both diseases with more advanced age (ORUC: 2.8, p = 0.001; ORCD: 1.9, p = 0.03), and in UC with immunosuppressor or steroid use (OR: 2.8 and 2.2, p = 0.001 and 0.014) and urban neighborhood (OR: 2.4, p = 0.029), but not with gender or disease duration.

Conclusions: Non-adherence and CAM use is common in patients with IBD. Special attention should be paid to explore these factors during follow-up visits and to improve adherence to therapy.

P134 Transcolonic specimen removal in laparoscopic ileocolic resection for Crohn’s disease: initial experience


Aim: Ileocolic resections for Crohn’s disease can be done entirely laparoscopically, including devascularisation, transsection and reanastomosing. The only reason to perform a minilaparotomy is to remove the specimen. The present study aims to assess feasibility of endoscopic transcolonic specimen removal obviating the need for minilaparotomy.

Materials and Methods: In a consecutive series of patients, scheduled for laparoscopic ileocolic resection, endoscopic transcolonic specimen removal was attempted. Outcome parameters were: success rate, operating time, reoperation rate, length of hospital-stay, postoperative pain scores as measured by the SF-36. Activity was defined as a score between 6 and 12 in the Mayo Score of at least 1 point or an absolute rectal bleeding subscore of at least 3 point, with a reduction of rectal bleeding subscore of at least 1 points.

Results: From February to September 2008, 10 patients were included. Median age was 31 years (range 19–61), there were seven women and three men. A 4-trocarm approach was used. The right colon was mobilized and the mesentery was devascularised close to the bowel using ultrasonic dissection to minimize the diameter of the specimen. Large bowel and ileum were transsected using endoscopic staplers. After bowel division, the endoscopist introduced the colonoscope up to the area of bowel transection. When the endoscope reached the cross stapled large bowel, the terminal ileum and large bowel were opened to introduce a stapler. The small bowel was clamped to avoid spillage. Using the endostapler a side to side anastomosis was created. Next, the endoscope was advanced through the remaining gap in the anastomosis. The specimen was grasped using an endoscopic snare. During endoscopic removal of the specimen, the laparoscopist facilitated passage of the specimen through the anastomosis for transcolonic retrieval. After this, the remaining anastomotic gap was sutured laparoscopically.

In two patients with a large inflammatory mass (>8 cm in diameter), transcolonic removal was considered not feasible. Overall success rate therefore was 80%. Median operating time was 208 minutes (range 157–327). Median length of resected bowel segment was 25.5 cm (range 16–64), median postoperative hospital stay 5 days (range 2–10). Postoperatively, one patient developed a Douglas abscess, which was drained laparoscopically. One of the two patients in which transcolonic removal was considered not possible developed a sub hepatic abscess. This was drained percutaneously during readmission. Postoperative pain scores quickly decreased after surgery (from median 3.8 after one day to median 0.5 after 28 days). Postoperatively there was a depression in QOL-scores that recovered in four weeks. After 3 months, QOL was better than preoperatively.

Conclusion: With a success rate of 80%, transcolonic removal of the specimen in ileocolic Crohn’s disease is feasible in the absence of a large inflammatory mass and is associated with a fast postoperative recovery. It is however questionable whether the increased complexity of the technique and time consuming logistics are justified by the potential benefit for patients when compared to conventional laparoscopic techniques.