Patients with mesalazine therapy including those who received only a short steroid course for the first flare. Group 2: Patients who received more than mesalazine-monotherapy at diagnosis and/or step-up-therapy during follow-up. All patients with mesalazine-monotherapy or no treatment at diagnosis (42/103 patients) were included into a statistical survival analysis for time until step-up-therapy.

Results: 103 patients (47% male, 53% female; mean age 37.7 years) with newly diagnosed CD were followed-up for a median of 46 months. Group 1 consisted of 28 patients (27.2%), of which 15 received mesalazine-monotherapy (14.6%) over the whole observation period. 13 patients received one initial steroid course. Predictive factors for a mild course of the disease were age (group 1: 43.3 vs. group 2: 35.5 years; p = 0.027), CRP (group 1: 1.35 mg/dl vs. group 2: 3.64 mg/dl; p = 0.019) and endoscopic findings at the diagnosis: patients with mild endoscopic alterations represented a proportion of 21.4% in group 1 while group 2 comprised 6.8% of those patients (p = 0.03). The adapted Rutgeerts score showed a trend (ns) towards a lack of severe mucosal lesions in group 1 (25.0% of the patients of group 1 had a Rutgeerts score of <2 vs 17.6% of the patients of group 2). 42/103 CD-patients (40.7%) received mesalazine-monotherapy at time of diagnosis and were included into the statistical survival analysis. 20 of these patients (47.6%) remained on mesalazine for at least 48 months without step-up-therapy.

Conclusion: More than a quarter of patients with CD experienced a mild long-term course of the disease not requiring other treatment than mesalazine. Predictive factors for mild CD are higher age, lower CRP and lack of severe mucosal alterations. Those factors should serve for further prospective trials with mesalazine in CD.

P184 Adalimumab in the treatment of active luminal and perianal Crohn’s disease: a single center experience in 100 patients

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Introduction: Adalimumab is effective in inducing and maintaining remission in active steroid-dependent Crohn’s disease (CD). A post hoc analysis has also shown its effectiveness in perianal CD.

The aim of the study was to evaluate the effectiveness of Adalimumab in the treatment of active and perianal MC.

Materials and Methods: From January to July 2008, 100 consecutive patients were enrolled (44f/56m, mean age 35.7 years, range 16–67, 33 smokers). The patients presented active luminal CD (n = 54) and/or perianal fistulising disease (n = 46). The patients were age (group 1: 43.3 vs. group 2: 35.5 years; p = 0.027), CRP (group 1: 1.35 mg/dl vs. group 2: 3.64 mg/dl; p = 0.019) and endoscopic findings at the diagnosis: patients with mild endoscopic alterations represented a proportion of 21.4% in group 1 while group 2 comprised 6.8% of those patients (p = 0.03). The adapted Rutgeerts score showed a trend (ns) towards a lack of severe mucosal lesions in group 1 (25.0% of the patients of group 1 had a Rutgeerts score of <2 vs 17.6% of the patients of group 2). 42/103 CD-patients (40.7%) received mesalazine-monotherapy at time of diagnosis and were included into the statistical survival analysis. 20 of these patients (47.6%) remained on mesalazine for at least 48 months without step-up-therapy.

Conclusion: More than a quarter of patients with CD experienced a mild long-term course of the disease not requiring other treatment than mesalazine. Predictive factors for mild CD are higher age, lower CRP and lack of severe mucosal alterations. Those factors should serve for further prospective trials with mesalazine in CD.

P185 Granulocyte, monocyte adsorptive (GMA) apheresis in UC: is the treatment efficacy dose-dependent? Results of a randomized comparison of 5 versus 10, the CESA 5.10 study

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CESA 5.10 is a randomized, multicenter, dose-controlled trial to compare 5 weekly GMA apheresis treatments to 10 treatments over 8 weeks in patients with active UC. A total of 186 patients were enrolled, and 162 could be evaluated in the ITT analysis.

Primary endpoint was changes in disease activity, monitored by CDAI, Rachmilewitz score, from baseline to Week 12. Secondary endpoints were remission and response rates over time, endoscopic changes from baseline to Week 12, and changes in fecal calprotectin and in QoL. The intention was to test non-inferiority of 5 versus 10 treatments.

CDAI changed from 8.7 (5) and 8.8 (10) at baseline to 5.6 (5) and 5.4 (10) at Week 12. Group differences were statistically not significant. Significant differences between the 2 groups could also not be detected for any other parameter monitored. The overall response rates were 56.1% and 58.8% at Week 12.

GMA apheresis treatment has not shown a dose dependency in this setting. However there was a consistent trend to show a faster onset of treatment effects under the more intense treatment regimen.

P186 Long-term prevention of post-operative recurrence in Crohn’s disease is not affected by mesalazine

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Background: Prevention of post-operative recurrence has a central role in the management of Crohn’s disease (CD). Many drugs have been assessed in prospective randomised controlled trials (RCTs) but the results are disappointing. Mesalazine, the drug more extensively evaluated, has been shown to be effective for preventing recurrence in the short-term; however, the overall benefit is small and no data are available on the long-term effectiveness.

Aim: To compare the long-term occurrence of post-operative recurrence in patients who received regular prophylactic treatment with mesalazine and in patients who did not receive prophylaxis after the first radical resection for ileo-cecal CD.

Patients and Methods: The records of 216 patients with ileocaecal CD at their first resection were reviewed: 146 patients (67.6%) received post-operative prophylaxis with mesalazine while 70 patients (32.4%) received no prophylaxis. The mean follow-up after surgery was 132.7 months (range 12–544).

The co-primary endpoints were post-operative clinical and surgical
recurrence. Statistical analysis: Kaplan–Meier survival method, Chi-square, Student t-test.

Results: The two groups were comparable as gender, age at surgery, smoking habits, pattern of CD (perforating / not perforating), and disease duration before surgery. One year after surgery, a small, even if not statistically significant, risk reduction of clinical recurrence was observed in mesalazine treated group (7.6% vs 18.0% to 2.8%). Within 10 years after surgery, the cumulative probability of clinical recurrence and surgical recurrence were similar in the two groups (Log Rank test p = 0.9 and p = 0.1 respectively) (see figure).

Conclusion: Mesalamine prophylaxis is not effective for preventing the long-term post-operative recurrence in ileocaecal Crohn’s disease.

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Predictors of response to infliximab in moderate-to-severe ulcerative colitis


Introduction: Infliximab efficacy in the treatment of moderate-to-severe ulcerative colitis has been demonstrated in several studies, but the proportion of patients achieving remission is lower than 50%. Identification of predictors of remission will be useful for patient selection.

Objectives: To determine predictive factors of response and remission to infliximab treatment in a retrospective cohort study of a tertiary center.

Methods: Clinical data were obtained from a local database of patients with inflammatory bowel disease. We included patients diagnosed of ulcerative colitis treated with infliximab, with a follow-up of at least 3 months. We registered demographic data, clinical data from disease, and previous and concomitant treatment. Assessment of response was made at weeks 4, 8, 30 and 54 using the Mayo index score and requirement of colectomy.

Results: Fifty two patients were included with median follow-up of 16.3 months. Proportion of patients achieving clinical remission at weeks 8, 30 and 54 was 56.8%, 51.1% and 40.5%. Proportion of colectomies at these time points were 9.6%, 19.2% and 23.1%. The only predictor of remission at week 4 was the pre-treatment Mayo score (−0.82, p = 0.01), whereas at week 8 the pre-treatment Mayo (−0.62, p = 0.04) and concomitant treatment with azathioprine (2007, p = 0.04) were independent predictors of remission. With regard to colectomy, previous treatment with cyclosporine (during current or in a previous flare) was associated with a significantly higher proportion of colectomies (16% vs. 45%; p = 0.02).

Conclusions: Disease severity, absence of concomitant immunomodulator therapy and previous treatment with cyclosporine negatively affect the response to infliximab in patients with moderate or severe ulcerative colitis.

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IBD care in Europe: a comparative audit of Crohn’s disease care between Oxford and Milan using the validated National UK IBD Audit Tool

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Introduction: National and European evidence-based guidelines on the management of Crohn’s disease (CD) have been published. The validated National UK IBD Audit tool is an electronic database created to improve the quality and safety of care for IBD patients by auditing individual patient care, service resources and organization against national standards.

Methods: We aimed to compare the organization and process of CD care between 2 IBD centres in Oxford (UK) and Milan (Italy), using the National UK IBD Audit tool, as a pilot study to evaluate its application outside national boundaries. Clinical and demographic data of CD patients consecutively admitted during a 2 month period, were collected using the IBD Audit tool. Data were compared between the 2 centres, to each other and to the UK IBD standards obtained by previous audit analyses performed in Oxford in 2006.

Results: 21 (24% male, age 18–68) and 20 (40% male, age 18–70) patients with CD were admitted in Oxford and Milan, respectively. Most admissions in Milan were planned admissions. No patient died. Median duration of hospitalization was similar (Oxford 8 days, range 3–28; Milan 9 days, range 5–19). Oxford data revealed a higher surgery rate (67% vs 5%) and immunomodulator use (62% vs 20%), while in Milan a higher use of bowel ultrasound (85% vs 5%) over CT scan was found. The following areas did not reach the standards set for the 2006 UK IBD Audit: the lack in Milan of IBD specialist nurses (0% vs 100%) and dietitian visits (15% vs 91%), an unsatisfactory attention to stool sampling for excluding Clostridium difficile infection (57% vs 75%) and outpatient nutritional assessment (45% vs 94%) in Milan. Both centres revealed a high rate of active smokers (29–30%), with little attention to bone protection in steroids users (0–20%) and a preferred use of CRP over ESR for disease monitoring (69–91% vs 31–73%). Since the 2006 audit in Oxford, changes include IBD specialist nurse visits (from 6% to 100%), dietitian visits (44% to 91%), number of active smokers (43% to 29%), stool samples (30% to 75%) of patients) and nutritional assessment included in the outpatient notes (50% to 100%).

Conclusions: The UK IBD Audit tool is an easy instrument to assess the processes and outcomes of care delivery in IBD and can be applied outside UK. It can suggest areas where improvement of care is required. Periodic reauditing may be able to trigger and monitor the outcome of interventional strategies in pivotal areas.

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Is inosine-5’-monophosphate dehydrogenase of importance in thiopurine treated patients who display a “skewed” metabolite profile?

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Aim: Thiopurine efficiency in the treatment of inflammatory bowel disease (IBD) may be predicted from the activity of the polymorphic enzyme thiopurine methyltransferase (TPMT) and the concentration of the metabolites methyl thiopurine