compared with those of patients who underwent screening colonoscopy. We retrospectively analyzed the prevalence of colonic diverticulosis in 100 patients with known left, extensive or total UC and compared them with 100 age/gender-matched controls without colitis. Patients with distal UC were excluded. All patients and controls underwent pancolonoscopy and biopsies were taken for histopathological evaluation.

Results: Colonic diverticulosis was present only 1 of 100 patients with and in 28 of 100 patients without ulcerative colitis ($p < 0.0001$).

Conclusions: Patients over 50 years of age with UC show a significantly lower prevalence of colonic diverticulosis, UC might prevent diverticulosis coli due to motor alterations caused by chronic bowel wall inflammation.

P160

Anti-TNF therapy prior to intestinal resection for symptomatic stenotic small bowel Crohn's disease

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Introduction: Intestinal resection for stenotic Crohn's disease (CD) is usually discussed after failure or intolerance to steroids and/or immunosuppressants. In these situations, anti-TNFs are usually contraindicated because of a hypothetic risk to increase the stenosis. Moreover, recent use of steroids, denutrition and/or hypoalbuminemia are associated with an increased risk of stoma or extensive bowel resection. The aim of this pilot study was to evaluate the tolerance and the effectiveness of a preoperative treatment with an anti-TNF to reverse surgical decision and/or to improve the surgical outcome in patients with an stenotic CD unresponsive to conventional treatments.

Aims and Methods: All patients planned to have an intestinal resection for symptomatic stenotic CD were prospectively discussed for a preoperative induction treatment with an anti-TNF from January 2006 to December 2007. Patients without any inflammatory patterns (CRP $< 10$ mg/l and/or absence of enhancement of bowel wall in MRI or CT scan) were excluded ($n = 14$). In the other cases, after informed consent, patients received an induction anti-TNF treatment prior to surgery.

Disease evolution, reconsideration of indication of surgery, surgical characteristics, 60-day complications and mortality for patients treated with an anti-TNF (ATF) within 8 weeks preoperatively was compared with a cohort of 22 patients matched for age, sex and type of surgery, who underwent intestinal resection for stenotic CD without previous anti-TNF treatment (NATF).

Results: Both groups ATF and NATF were similar according to steroid treatment, immunosuppressant, body mass index and albumin level. Thirteen patients were preoperatively treated with an anti-TNF [infliximab ($n = 9$) or adalimumab ($n = 4$)] for ileal stenosis ($n = 6$), duodenal ($n = 1$) or multiple small bowel stenosis ($n = 6$). Surgery was not mandatory in two patients because of anti-TNF efficacy on the obstructive symptoms [duodenal stenosis $n = 1$, multiple intestinal stenosis ($n = 1$)], an event-free follow-up of 8 and 20 months, respectively. For the 11/13 patients who were operated on, the mean number of anti-TNF infusions/injections was 2.7 ($\pm 0.9$) and the mean time between the last treatment administration and surgery was 25.3 ($\pm 9.8$) days. No death occurred. Statistical analysis showed that length of post-operative hospital stay, post-operative complications (18% and 20%) and stoma confection [2/11 (18% and 4/22 (18%)] were not significantly different in the ATF and NATF groups, respectively.

Conclusions: An anti-TNF treatment in the 8 weeks prior to planned intestinal resection for symptomatic stenotic CD allowed us to avoid surgery in some cases, without increase of postoperative complications. A randomized controlled trial is mandatory to evaluate this strategy.

P161

Newly diagnosed neoplasia in a cohort of Crohn's disease patients treated or untreated with infliximab followed up in the long term: a multicenter matched-pair study


Background: The widespread use of Infliximab in Crohn's disease (CD) rises concerns about cancer risk in the long term. In a cohort of matched-pair CD patients we reported that the frequency of newly diagnosed neoplasia did not differ between infliximab-treated and untreated patients matched for clinical variables (Gut 2006; 55: 228–33). The long-term risk of developing neoplasia in CD patients treated with infliximab is undefined.

Aims: To assess, in a multicenter, matched-pair study, whether Infliximab use is associated with an increased frequency of neoplasia in the long term. At this purpose, the frequency of newly diagnosed neoplasia was assessed in the same cohort of infliximab-treated or untreated CD patients, followed up for additional 4 years.

Methods: In a multicenter matched-pair study, the same cohort of 404 CD patients treated with infliximab (CD-IFX) matched with 404 CD never receiving Infliximab (CD-C) included in the previous study, was followed up for additional 4 years (October 2004-October 2008). Cases and controls were already matched for sex, age ($\pm 5$ yrs), CD site, age at diagnosis ($\pm 5$ yrs), immunosuppressants (ISS) use and follow up. Data recorded included: newly diagnosed neoplasia, outcome of neoplasia, new Infliximab or ISS use.

Results: When compared with the 404 CD-IFX and 404 CD-C enrolled from April 1999 to October 2004 ($n = 808$), a lower number of patients are in follow up after additional 4 years (up to October 2008), including 274 CD-IFX (67.8%) and 259 CD-C (64%) (total $n = 533$). Drop outs included patients lost at follow up from both 2004-2008 and from 1999-2004. On October 2008, among the total 533 patients in follow up, still matched couples included 187 CD-IFX and 187 CD-C. When considering the entire study period from April 1999 to October 2008 in all the 533 patients in follow up, the frequency of newly diagnosed neoplasia did not significantly differ between CD-IFX (10/274; 3.6%) and CD-C (10/259; 3.8%; $p = n.s.$). Also when considering only the 374 still matched CD-IFX ($n = 187$) and CD-C ($n = 187$) couples in follow up on October 2008, the frequency of newly diagnosed neoplasia did not significantly differ between CD-IFX (8/187; 4.2%) and CD-C 7/187 (3.7%; $p = n.s.$). Newly diagnosed neoplasia from October 2004 to October 2008 were detected in 4 patients in the CD-IFX (3 breast cancers, 1 HL; ISS use in 3/4) and 4 patients in the CD-C group (1 duodenal adenocarcinoma, 1 prostatic adenocarcinoma, 1 breast cancer, 1 lung cancer; ISS use in 2/4).

Conclusion: Present findings from a multicenter matched-pair long-term study support that the frequency of newly diagnosed neoplasia is comparable in a cohort of CD patients treated or untreated with IFX, matched for clinical variables.

P162

Patients' evaluation of dietary advice in ulcerative colitis (UC): results of a pilot study

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Background: The subject of diet and ulcerative colitis is controversial. Patients believe that dietary factors are
important. Some research suggests that nutrition can bring real benefit to patients with UC. However, recognised dietary guidelines for use in UC do not exist.

A newly developed dietary educational booklet for ulcerative colitis patients “Diet and ulcerative colitis” (Flesch-Kincaid Reading Ease 65) developed from preliminary focus group data (supported by an educational grant from P&G pharmaceuticals), provided some dietary principles and advice for UC flare-ups.

**Methods:** This standardised dietary advice booklet “Diet and ulcerative colitis”, was given to 57 UC patients. The mean age of participants was 48 with a range from 22 to 81 years. 54% of participants were male. The ethnicity of the sample was 74% Caucasian, 26% South Asian.

A pilot study was undertaken, firstly, to evaluate the written material by the target audience for readability and comprehension level, and, secondly, to ascertain whether dietary intervention could be determined as helpful in UC management.

Two validated questionnaires Visceral Sensitivity Index (VSI), Simple Clinical Colitis Activity Index (SCCAI) were completed and the evaluation of a design questionnaire completed by UC patients was performed.

**Result:** 61% of study participants had a high VSI – the level of gastrointestinal symptom-specific anxiety, 35% have a moderately high VSI and only 3% (2 people) did not show any symptom-specific anxiety. Correlation between SCCAI and VSI was significant (p < 0.01). It appeared that patients’ symptom-anxiety level is directly dependent on the severity of symptoms in UC.

After receiving the booklet, 74% of study participants found dietary advice helpful and 42% of UC patients reported feeling more confident about controlling the diarrhea, bloating and pain. Twelve out of 24 patients (50%) with the highest clinical activity noted a significant reduction of bowel frequency and urgency of defecation, as a result of using the dietary advice. 56% of patients also reported that information given in the booklet was easy to read and comprehend and a further 42% evaluated the booklet content as moderately easy to read and understand.

**Conclusion:** Responses to standardised dietary advice were largely positive. This advice was viewed by patients as a beneficial tool to overcome symptom-specific anxiety and helpful with UC self management especially during flare-ups. Study participants also favorably evaluated the format and content of the booklet. Further research is needed on the effectiveness of dietary intervention.

**P163**

**Fistulizing Crohn’s disease**

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**Introduction:** Fistulas (F) are serious and frequent complication in Crohn’s disease (CD). They occur in approximately one-third of patients, mostly as perianal F. Some types of F seldom develop like urinary F which affect 2–8% of patients. Gastrocolonic and duodenocolonic F are particularly rare. The risk of fistula formation increases with the duration of the disease. It has been reported that therapeutic management of external F is easier than in case of internal fistulation. Presence of F not only makes the treatment of CD more difficult but it also may cause malnutrition and it decreases the quality of life.

**Aim:** The aim of this study was to estimate the frequency of different types of F and to assess if and how the nutritional status depends on their number and location in CD patients.

**Materials and methods:** Medical case records of fistulizing CD patients hospitalized in the Department of Gastroenterology and Hepatology of the Medical University in Wroclaw, Poland in years 2004–2008 were analyzed retrospectively. The study group consisted of 50 subjects with F (21 female, 29 male; mean age 39.4±12.4 yrs) among 289 patients hospitalized with the diagnosis of CD at that time. Data on disease duration and activity, number and location of F and nutritional status (based on BMI and blood parameters) were collected.

**Results:** Perianal and enterocutaneous F found in 44% and 28% patients respectively, were the most frequent type of fistulous connections (table). Thirty seven external F constituted 66% of all diagnosed F (n =56). Enteroenteric and ileocolonic F followed by duodenocolonic and gastrocolonic F were disclosed less frequently. More than one fistula was observed in only 6 patients. The nutritional status in patients with numerous F proved to be worse than in those with a single site of fistulation (mean BMI 18.6±2.17 kg/m² vs 20.9±2.96 kg/m², p < 0.05).

**Table. The site of fistulation in Crohn’s disease patients**

<table>
<thead>
<tr>
<th>Type of fistula</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perianal</td>
<td>22</td>
</tr>
<tr>
<td>Enterocutaneous</td>
<td>15</td>
</tr>
<tr>
<td>Enteroenteric and ileocolonic F</td>
<td>9</td>
</tr>
<tr>
<td>Enterovesical</td>
<td>5</td>
</tr>
<tr>
<td>Enterovaginal</td>
<td>2</td>
</tr>
<tr>
<td>Duodenocolonic</td>
<td>2</td>
</tr>
<tr>
<td>Gastrocolonic</td>
<td>1</td>
</tr>
</tbody>
</table>

**Conclusions:**

1. External F with predominant perianal location are frequent manifestation of complicated CD.
2. Duodenocolonic and gastrocolonic F are less frequent and their presence is often connected with malnutrition.
3. Patients with numerous F have worse nutritional status as compared with patients with a single fistula.

**P164**

**Clinical pharmacology of vedolizumab (MLN0002) in patients with active ulcerative colitis**

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**Objectives:** Vedolizumab (MLN0002) is a humanized monoclonal antibody in phase 3 trials for moderate to severe ulcerative colitis (UC) and Crohn’s disease. Vedolizumab inhibits the binding of α4β7 integrin to the mucosal addressin cell adhesion molecule-1 (MAdCAM-1) on endothelial cells. The α4β7 integrin is expressed by subsets of leukocytes and guides inflammatory cells to the gut. Vedolizumab demonstrated efficacy in both ulcerative colitis and Crohn’s disease trials. The study reported here was a phase 2, randomized, placebo-controlled, double-blind study designed to evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of multiple IV doses (2, 6, or 10 mg/kg) of vedolizumab or placebo in patients with active UC.

**Materials and methods:** Patients were randomized (4:1) to receive vedolizumab (2, 6, or 10 mg/kg) or placebo on Days 1, 15, 29, and 85. Patients were monitored through Day 253. To support PK and PD evaluation, blood samples were collected at multiple time points during the study period through Day 253. Vedolizumab serum concentrations were determined by ELISA and saturation of α4β7 was determined by FACS. Response to vedolizumab was assessed by the partial Mayo score.

Exploratory analyses were performed to correlate