evaluate associations of SI and pts receiving anti-TNFα agents and immunomodulators (IM). We categorized SI events and evaluated pts who experienced SI within 91 days of IFX, other anti-TNFα exposure, or within 31 days of IM exposure.

**Results:** 4343 pts (7883 pt-ys [PY]) were enrolled as of 6/30/12, 2586 were exposed to anti-TNF biologics, including 2503 who received IFX (4347 PY). 1757 pts received only nonbiologic therapies (3369 PY). Factors associated with significant risk (p < 0.05) of SI were (adjusted hazard ratio, 95% CI): younger age at baseline (0.92, 0.86–0.97), hospitalizations in the year prior to enrollment (1.81, 1.27–2.59), time-dependent IFX use (2.00, 1.38–2.91), time-dependent IM use (1.58, 1.07–2.34), and time-dependent PGA score (1.23, 1.06–1.44) (time-dependent variables reflected status at each 6-month visit for a pt). Pts with anti-TNF exposure in the last 91 days showed a significant increased risk of SI in the categories of number of SI (5.82 vs. 2.89 events per 100 pt yr for exposed vs. nonexposed), especially on the subcategories of superficial infections, & abdominal abscess; & a trend of an increased risk of significant viral infections. IFX exposed pts showed a trend of an increase risk of number of SI (4.88 vs. 3.65 events per 100 pt yr for exposed vs. nonexposed) & a significant increase risk on superficial infections. There were no differences in all categories for IM exposure within 31 days of SI.

**Conclusions:** Time-dependent IFX use and hospitalizations in the year prior to enrollment conferred an approximate 2-fold increased risk for SI. Clinically significant risks for SI are associated with younger age, time-dependent IM use and time-dependent higher PGA score. IFX and anti-TNF exposed pts have an increased risk in general of SI and of superficial infections within 91 days of exposure. Anti-TNF exposure appeared to increase the risk of abdominal abscess and significant viral infections. No difference in SI for IM exposure within 31 days was observed.

16 Relationships between clinical remission, C-reactive protein normalization and mucosal healing in Crohn’s disease: analyses from the SONIC trial

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**Background:** The CDAI has been criticized due to heavy weighting on subjective clinical symptoms, such as abdominal pain and decreased sense of well-being. Biomarker CRP and endoscopic lesions are objective measures of inflammation. We investigated the relationships between clinical remission, CRP normalization, & mucosal healing (MH) in CD in SONIC.

**Methods:** SONIC was a randomized, controlled trial comparing infliximab (IFX) to azathioprine (AZA) and to IFX plus AZA for the treatment of 508 CD pts naive to immunomodulators & biologics. CD activity, measured by CDAI, CRP, and ileocolonoscopy was evaluated at baseline (BL) and at wk26. Mucosal healing was defined as absence of mucosal ulceration at wk26 ileocolonoscopy in a pt who had evidence of ulceration present at BL ileocolonoscopy.

**Results:** 188 pts who had evidence of mucosal ulceration at BL, evaluable ileocolonoscopy, CDAI scores and CRP values at BL and at wk26 were included in this analysis. 140/188 pts (74.3%) had BL elevated FC (FC > 50 mg/dL). Seventy-two of 136 pts (52.9%) who were in clinical remission (CDAI < 150) at wk26 achieved MH, while 54 (39.7%) achieved both CRP normalization (CRP < 0.5 mg/dL) and MH. Sensitivity and specificity of CDAI remission and CDAI moderate-to-severe disease activity to predict MH and CRP normalization in CD are provided (Table). PPV and NPV of CDAI to detect MH using 150 as a cutoff for CDAI were 65.4% & 52.9%, & 80.8% & 39.7% to detect MH and/or CRP normalization, resp. Among the 27 pts (14.4%) who had persistent moderate-to-severe disease (CDAI ≥ 220) at wk26, 8 (29.6%) achieved MH and 6 (22.2%) achieved CRP normalization & MH. PPV & NPV of CDAI to detect MH using 220 as a cutoff for CDAI were 70.4% & 50.9%, & 77.8% & 36% to detect MH and/or biomarker remission, resp.

| Table: Sensitivity and specificity of CDAI remission and CDAI moderate-to-severe disease activity to predict MH & CRP normalization in CD |

<table>
<thead>
<tr>
<th>CDAI &lt; 150 (N = 136)</th>
<th>CDAI ≥ 150 (N = 52)</th>
<th>CDAI ≥ 220 (N = 27)</th>
<th>CDAI ≥ 220 (N = 161)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete MH</td>
<td>72/136 (52.9%)</td>
<td>8/27 (29.6%)</td>
<td></td>
</tr>
<tr>
<td>Sensitivity/Specificity (%)</td>
<td>80.0/34.7</td>
<td>91.1/19.4</td>
<td></td>
</tr>
<tr>
<td>CRP normalization (&gt;0.5 mg/dL)</td>
<td>88/136 (64.7%)</td>
<td>13/27 (48.2%)</td>
<td></td>
</tr>
<tr>
<td>Sensitivity/Specificity (%)</td>
<td>81.5/40</td>
<td>88.0/17.5</td>
<td></td>
</tr>
<tr>
<td>CRP normalization &amp; MH</td>
<td>54/136 (39.7%)</td>
<td>6/27 (22.9%)</td>
<td></td>
</tr>
<tr>
<td>Sensitivity/Specificity (%)</td>
<td>84.4/33.9</td>
<td>90.6/16.9</td>
<td></td>
</tr>
</tbody>
</table>

**Conclusions:** Half of CD pts in clinical remission have endoscopic and/or CRP evidence of residual active CD, whereas other pts with endoscopic and CRP normalization have persistent clinical symptoms. These findings demonstrate that CD clinical symptoms scored by CDAI are not a reliable measure of underlying inflammation. Objective outcome measures of CD activity beyond clinical symptoms need to be further evaluated.

17 Optimising the use of faecal calprotectin for early diagnosis of IBD in primary care

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**Background:** Faecal calprotectin ELISA (FC) is an exquisitely sensitive and specific test of intestinal inflammation and may have a role in distinguishing early IBD from other GI disorders (IBS) presenting in primary care. Previous data has shown that diagnostic uncertainty for symptomatic patients with FC between 50–150 µg/g might be resolved by a strategy of repeat testing 6–8 weeks later. The AIM of this study was to evaluate the safety and diagnostic utility of this strategy in patients with elevated FC levels in primary care.

**Methods:** Study population: All patients with a FC results within the pathology faecal calprotectin data set from June 2009–2012 (n = 9123). Patient data were cross checked with electronic patient records, radiology (PACS), endoscopy and histology data sets for SnoMed CT codes for IBD (T655260, T67000–6893). Exclusion criteria: previous diagnosis of IBD, and aged <16 yr at study entry.

**Results:** Of 9123 results, 2663 (29%) were from primary care and met the inclusion criteria. 62% were female, median age 52 yr (range 18–88yr), 56% were <55 yr old, and diarrhoea (50%) was the most frequent indication for FC testing. 1710 (65%) had FC values <50 µg/g and were negative and not retested. 483 (18%) had FC values between 50–150 µg/g and 440 (17%) had FC values >150–3000 µg/g. In the latter population, there were 13 new diagnoses of IBD (9 female, 7 with UC), in whom mean FC increased from 933 to 1666 µg/g (sem ±200) (ns) on repeat testing prior to specialist referral. In contrast, FC values fell rapidly in 37 patients with presumed infectious enteritis: initial mean FC decreased from 682 to 53 µg/g (sem ±155) (p < 0.05).

In 66 patients with minimally elevated FC levels (50–150 µg/g),
The European Crohn’s and Colitis Organisation

1.61]. In contrast, the RR crude and for women

2010. Diagnoses of CVD were obtained from the Danish

2.52] and RRadjusted: 1.42 [95% CI: 0.82

2.45]. The

2.30] in women.

Abstracts of the 8th Congress of ECCO – the European Crohn’s and Colitis Organisation

1. The quality of care for inpatients with inflammatory bowel disease in the UK over a six year period


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Background: Since 2005, three national audits have been conducted to assess the quality of Inflammatory Bowel Disease inpatient care in the UK. Our aim is to examine the quality of care provided for inpatients with IBD in the UK in the last 6 years.

Methods: NHS trusts/ Health boards in the UK which routinely admit IBD patients were invited to participate in three national audits. Data were collected on adult patients with IBD admitted to hospital between 01/06/2005 to 31/05/2006; 01/09/2007 to 31/08/2008; and 1/9/2010 to 31/08/2011 if the primary reason for admission was inflammatory bowel disease. Data related to individual patient care, services resources and organization were collected for the three audit rounds. The audits data were based on national standards. Comparisons across the three rounds of audit were made using chi-square test, with a p value of <0.05 taken to be statistically significant.

Results: Participation in these audits by UK hospitals rose from 75% in the first round to 93% and 90% in the second and third rounds respectively. The total numbers of inpatients were 2767, 2981, and 3049 patients with ulcerative colitis and 2914, 3154 and 3122 patients with Crohn’s disease in the 1st, 2nd and 3rd audit rounds respectively. For ulcerative colitis, the inpatient mortality rate fell from 1.7% in the 1st round, 1.5% in the 2nd round, to 0.8% in the 3rd round (p = 0.034). For Crohn’s disease the inpatient mortality dropped from 1.3% in the 1st round, 1.1% in the 2nd round to 0.8% in the 3rd round (p = 0.226). There have been specific improvements in many areas covered by the National Service Standards for Inflammatory bowel disease. The number of admissions remained almost the same in the last few years, but the number of admissions per patient has reduced. The collection of stool samples; use of prophylactic heparin; prescription of bone protection agents; and use of anti-TNF therapy as a rescue therapy has increased. There has been a reduced frequency of surgery in non-elective admissions with a significant increase in the percentage of operations performed laparoscopically. A significant increase in the percentage of inpatients reviewed by the IBD specialist nurses during their admission. High proportion of patients was not reviewed by dietetic services.

Conclusions: It is clear that the care of patients with inflammatory bowel disease, severe enough to warrant admission, is improving, and suggests regular national audit against clear standards is an effective catalyst for change.

Tumor necrosis factor-alpha antagonists and cardiovascular disease in inflammatory bowel disease

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Background: It is suggested that patients with inflammatory bowel disease (IBD) have an increased risk of cardiovascular disease (CVD), potentially due to systemic inflammation. Tumour necrosis factor-alpha (TNF-α) antagonists are increasingly used in the treatment of IBD, being highly effective in reducing the inflammatory burden. However, data on the potential impact of this anti-inflammatory effect on risk of CVD in IBD remains limited. We conducted a nationwide, population-based, cohort study of risk of CVD, subdivided into ischemic heart disease (IHD) and cerebrovascular event (CVE), among patients with IBD followed for up to 11 years after exposure to TNF-α antagonists.

Methods: The cohort consisted of 50,756 IBD patients of whom 3,109 had been exposed to TNF-α antagonists during 1999–2010. Diagnoses of CVD were obtained from the Danish Patient Register. Using Poisson regression and adjusting for age, calendar year, disease duration, propensity scores that included cardiovascular risk factors, and use of other IBD medications, we calculated rate ratios (RR) with 95% confidence intervals for IHD and CVE among TNF-α exposed and non-exposed.

Results: During 386,367 person-years of follow-up, 31 TNF-α antagonist-exposed patients and 2,641 unexposed patients developed IHD, yielding a crude RR of 0.83 [95% CI: 0.58–1.18] and an unchanged adjusted RR of 0.85 [95% CI: 0.59–1.24]. For men the RRadjusted was 0.71 [95% CI: 0.41–1.26] and for women RRadjusted: 0.98 [95% CI: 0.60–1.61]. In contrast, the RR for CVE (n = 15) associated with TNF-α antagonists was 1.51 [95% CI: 0.90–2.52] and RRadjusted: 1.42 [95% CI: 0.82–2.45]. The RRadjusted was 1.93 [95% CI: 0.94–3.94] in men and 0.98 [95% CI: 0.42–2.30] in women.

Conclusions: Our nationwide cohort study of patients with IBD found no significant associations between TNF-α antagonist-exposure and risk of IHD and CVE. Nonetheless, the point estimates indicate that there might be decreased risk of IHD and increased risk of CVE in men exposed to TNF-α antagonists. These findings need further evaluation.

Mortality and causes of death in ulcerative colitis: results from a Norwegian population based study during a twenty years period of follow-up (the IBSEN study)


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Background: There is a lack of studies addressing mortality and causes of death in unselected cohorts of patients with ulcerative colitis (UC). This study aimed to evaluate mortality and causes of death during the first 20 years after diagnosis in a well-characterised population based UC cohort.

Methods: The study group on Inflammatory Bowel Disease in South East Norway (IBSEN) has prospectively followed all patients diagnosed with inflammatory bowel disease from four geographically well defined areas in the period from January 1990 to December 1993. In total 519 UC patients were enrolled in the inception cohort. Each patient was sex and age matched with 25 controls selected at random from the background population within the same county. Data on death and causes of death were collected from the Norwegian Cause of Death...