scores, duration, site and concomitant medications were recorded. Pregnancy outcomes including mode of delivery, minute of delivery, intrauterine or neonatal complications, age at conception and need for escalation of IBD treatment during pregnancy were also assessed. Neonatal outcomes including low birth weight, pre-term delivery, NICU stays or perinatal infection and timing of vaccines were also recorded. Data were analysed using t testing, contingency and logistic regression analyses.

Results: From an IBD population of over 2,500 patients, 31 individual females who underwent anti-TNF treatment during pregnancy from 2008–2013 were identified with a total of 36 pregnancies. Median disease duration at time of pregnancy was 12 years (IQR 3–17). 85% had Crohn’s Disease, 15% Ulcerative Colitis. Median Harvey–Bradshaw index pre-pregnancy was 4.5 (IQR 2–13). Median Mayo score was 1 (IQR 0–3). 57.3% received infiximab, 38% adalimumab, 4.7% certolizumab. 53.8% were on concomitant immunomodulators. The majority of patients stopped biologic treatment at the start of the third trimester. 67% had treatment reinstated in the postpartum period. Median age at conception was 30.5 (IQR 25–35). 19% had previous miscarriages. 92% had successful term pregnancies. 22% required escalation of treatment during pregnancy. 19.3% had a pregnancy complication including emergency section. 16% neonates had a low birth weight with 2 preterm deliveries and one case of NICU stay for meconium ileus. No perinatal infections were reported. 20% mothers breastfed. The majority of mothers delayed live vaccination of their children. Interestingly, there was a significant independent association between disease activity at time of conception and low birthweight (p < 0.01). There was no association between adverse outcomes or neonatal infections and anti-TNF use noted in this cohort.

Conclusions: Disease control at time of conception and through pregnancy should be the main goal of treatment in this patient cohort and the use of TNF alpha antagonists to achieve this appears to warrant improvement to pregnancy outcomes though definitive safety has yet to be proven.

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TNF-alpha as induction therapy for Crohn’s disease: a comparison of adalimumab and infiximab – a prospective observational study in Germany


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Background: The nationwide BioCrohn Registry (Biological Registry with Crohn’s Disease Patients in Germany) of the German Competence-Network IBD is a five-year prospective registry of about 1.500 patients with Crohn’s disease (CD) in Germany. This is a sub-study of the BioCrohn Registry reporting the induction therapy steroid-free remission rates in 392 anti-TNF-naive CD-patients with adalimumab (ADA) or infliximab (IFX).

Methods: Within the framework of this non-interventional prospective online documentation, data on the course of disease, on psychosocial burden of disease, on health economics and on the genetic profile were examined. End of 2012 the recruitment was stopped having 1,525 CD-patients included by 59 different gastroenterology practices and had 3 years with IBD-experience. All patients have a 5 year follow-up period. The databank for baseline and 6-months data has been closed in 07/2013 and after databank cleansing now we have the finalized data including the 6-months visit. Results after 6 months are calculated only on the basis of an interim analysis.

Results: 392 TNF-naïve CD-patients (ADA: n = 263; IFX: n = 128) have been analysed (average age: 36 years; female: 52%; smokers 34%; disease duration: 9.4 years; bowel resection: 33%; prior immunosuppressive therapy: 75%). Baseline characteristics were in the two groups. The IBD-therapy followed an accelerated step-up management. The indication for TNF-therapy has been steroid-dependent or steroid-refractory course of disease or patients haven’t responded or were intolerant to an immunosuppressive therapy. Immunosuppressants were used in 19% at 6 months, in 23% after 12 months and 17% after 24 months. Accordingly to the TNF therapy, the use of systemic glucocorticoids dropped over time (baseline until 6 months) from 22.3% to 6.3% and 9.2%, respectively (p < 0.001). The remission rate (PGA) at 6 months was 70.7% and 70.1% after 12 months. In spite of the TNF-induced clinical remission (>70%) the psychosocial impairments with anxiety/depression (EQ-5D) show only minor improvement and remain on a relatively high level (baseline: 37%, 6 months: 31%, 12 months: 29%). In the induction therapy with TNF we found a steroid-free remission (HBI <5) in 66.7% at 6 months. Evaluating the efficacy of ADA vs. IFX as an induction therapy we do not find any difference in steroid-free remission rates at month 6 (ADA: 67.5%; IFX: 65.2%; p = n.s.).

Conclusions: In this real life setting anti-TNF therapy could induce steroid-free remission in about 70% with the relatively early escalation of therapy in IBD-experienced centres. In comparison there is no difference in steroid-free remission between ADA vs. IFX.

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Systematic versus endoscopy-driven treatment with azathioprine to prevent postoperative ileal Crohn’s disease recurrence

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Background: Preventing postoperative Crohn’s disease (CD) recurrence remains challenging. Prophylactic therapy with azathioprine (AZA) has been shown efficacious, but it is unclear whether it should be started immediately after surgery in all patients. Therefore, we compared systematic versus endoscopy-driven therapy with AZA in preventing CD recurrence at 24 months.

Methods: Patients with CD undergoing curative ileal resection with ileocolonic anastomosis and at high risk of recurrence (smoker, perforating disease, age <30 years, previous resec-
PP analysis

21.6%, 45/90 mg q12wk
ileal 16.2%, 54 years. The patients were randomized between 2005–2011 and included in the intention-to-treat (ITT) analysis. Eighteen of the 59 patients withdrew prematurely from the study (7 clinical recurrence, 5 adverse events due to AZA, 6 patient’s preference). Of the 30 patients included in the ED-AZA group, 10 and 4 patients initiated AZA at months 6 and 12, respectively. Both ITT and PP analyses revealed no difference in the primary and secondary endpoints between the SYS-AZA and ED-AZA group (Table). In the ITT analysis, endoscopic remission was achieved by 52% in the SYS-AZA and 43% in the ED-AZA group (p = 0.519).

Conclusions: Although this study was underpowered, we could not observe a benefit of systematic post-operative prophylactic therapy with AZA in patients at high risk of post-operative CD recurrence. Early post-operative endoscopic evaluation to guide further therapy seems most appropriate, but more studies are warranted.

Table: Study outcome

<table>
<thead>
<tr>
<th>ITT analysis</th>
<th>SYS-AZA</th>
<th>ED-AZA</th>
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<th>PP analysis</th>
<th>SYS-AZA</th>
<th>ED-AZA</th>
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<td></td>
<td>n = 29</td>
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<td></td>
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<tr>
<td>0/10 at m24</td>
<td>7 (24%)</td>
<td>9 (30%)</td>
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<td>7 (20%)</td>
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<td>0/10 at m24</td>
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<td>13 (43%)</td>
<td>0.519</td>
<td>15 (45%)</td>
<td>13 (52%)</td>
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<tr>
<td>0/10 at m24</td>
<td>17 (59%)</td>
<td>17 (57%)</td>
<td>0.879</td>
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<td>17 (68%)</td>
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<td>17 (68%)</td>
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<tr>
<td>CDAI &lt; i0 at m24</td>
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<td>13 (43%)</td>
<td>0.519</td>
<td>15 (45%)</td>
<td>13 (52%)</td>
<td>0.353</td>
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<td>Radiology normal at m24</td>
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<td>16 (50%)</td>
<td>0.447</td>
<td>13 (37%)</td>
<td>16 (59%)</td>
<td>0.684</td>
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</table>

P340 Subcutaneous ustekinumab for the treatment of anti-TNF resistant Crohn’s disease – the McGill experience

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Background: Ustekinumab is a fully human IgG1 monoclonal antibody that blocks the p40 subunit of interleukin-12/23. Ustekinumab is approved for treatment of plaque psoriasis. It was reported to be effective for induction and maintenance treatment of anti-TNF resistant CD.

Aim: To describe a real-life experience with open-label use of subcutaneous ustekinumab in anti-TNF resistant CD patients, in a tertiary referral center setting.

Methods: A retrospective observational study. Clinical response was defined by physician’s global assessment combined with decision to continue therapy. Clinical endpoints were over 12 months of follow-up or discontinuation of ustekinumab. The primary outcome was clinical response by 3 months. Secondary outcomes included clinical response at 6 and 12 months and steroid-free response at each time-point.

Results: Patient characteristics: 37 patients were treated with subcutaneous ustekinumab between 2/2011 to 7/2013 (median follow up: 5 (3–12) months). The demographic and clinical characteristics of the patients were as follows: male 50%, age 37 (21–62) years, age at diagnosis 20.5 (2–54) years. The disease characteristics were as follows: location – ileal 16.2%, colonic 18.9%, ileocolonic 64.9%; disease phenotype – luminal 46%, penetrating 43.2%, strictureing 10.8%; 40.5% had perianal involvement; 27.5% had previously undergone total proctocolectomy. Previous treatment included at least one biologic in all patients. The total biologics in 86.7% and three biologics in 18.9%. A loading dose was administered in 89% of the patients: 90 mg at weeks 0, 1, 2 – 80%; 45 mg at weeks 0 and 4 – 12%, 90 mg at weeks 0 and 4 – 8% of the patients. Initial maintenance dosing included: 90 mg q8 wk – 73%, 90 mg q4 wk – 21.6%, 45/90 mg q12wk – 12.5% of the patients. The mean duration of follow-up was 6.1–3.9 months. Follow-up data was available for 37, 24 and 16 patients at 3, 6, and 12 months, respectively.

Treatment outcomes: Clinical response at 3 months was achieved in 22/37 (59.5%) of the patients; 11 (50%) of these patients were steroid-dependent at treatment onset, 7/11 (63.6%) were able to discontinue corticosteroids and 18.2% to decrease the dose by at least 50%. At 6 months, among

P339 Surgical treatment of female genital fistula in Crohn’s disease

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Background: Treatment of female genital fistula in Crohn’s disease remains challenging with exasperating results. Moreover the considerable variety in the clinical presentation as well as the need of several operations necessary to attain definitive healing, homogeneous literature data and guidelines concerning optimal treatment are not available.

In this study we summarize surgical results of female genital fistula treatments in a large consecutive series of patients.

Methods: All patients with anorectal or rectovaginal fistula due to Crohn’s disease requiring surgery in our institution between 2005 and 2015 were included. Patient’s characteristics, type of fistula and interventions, functional results, and recurrences were classified and analyzed. All data were retrieved from a prospectively collected database.

Results: During the study period, 34 patients with RVF underwent 43 surgical procedure. The patients’ median age was 39±8 years; the median follow-up period was 34 months. Surgeries included: endorectal advancement flap (14), endorectal advancement flap with dermal collagen matrix injection (n = 6), advancement vaginal flap (n = 10), martius flap (n = 5), transverse perineal biological mesh repair (n = 3), ligation of intersphincteric fistula tract-LIFT (3), anocutaneous flap (2). Diverting ileostomies/colostomies were created in 12 patients (35%).

Definitive healing after the initial repair was achieved in 20 patients (59%). Considering repeated procedures, the overall healing rate increased to 68% (23 patients). Recurrence rate was 42%, being immediate after surgery in 24% of the patients. Among the various surgical procedures, the higher success rate was observed after endorectal advancement flap (75%). Number of previous surgery correlates with failure (>3, 100%). At the end of follow-up proctectomy rate was 9%.

Conclusions: This series confirms that recurrence rates after repair of complex fistulas for Crohn’s disease are high and continuously increase over time. Sphincter saving approaches should be considered as first attempt.