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Pregnancy outcomes in women with IBD treated with biosimilar infliximab

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Background: Anti-TNF therapy in IBD patients during pregnancy has been linked to lower birth weight, shorter gestational term and in some studies also with more frequent birth defects and spontaneous abortions. Recent results indicate that disease severity and activity, rather than anti-TNF therapy per se, are the main determinants of pregnancy outcome, however, negative effect of anti-TNF cannot be ruled out. In case of original infliximab (IFX), it is considered that benefit of treatment outweighs the potential harm, but it remains an open question in case of biosimilar IFX.

Methods: The observational study included 20 women treated with biosimilar IFX (CT-P13) with available pregnancy outcome. Data on disease activity, treatment, and pregnancy and new born outcome were recorded. Cord blood levels of anti-TNF were measured by ELISA.

Results: Twenty pregnant women (16 CD, 4 UC) with mean age of 28.7 ± 4.1 years were included, 53% (11) of them primigravidae. Mean disease duration at the time of pregnancy was 6.0 ± 3.5 years, 70% (14) had history of perianal disease. At the time of conception 30% (6) had active disease, 65% (13) were in remission and 1 was newly diagnosed with acute severe colitis after conception. Besides this patient, to whom rescue IFX therapy was administered during first trimester, all women had already been treated with IFX before getting pregnant (2.3 ± 2.7 years). There were 19 live births (mean weight 3305 ± 493 g), 18 at-term and 1 pre-term (with low birth weight). One pregnancy ended in spontaneous abortion. Disease activity at conception was associated with lower birth weight (3549 ± 392 g in remission vs. 2921 ± 390 g with active disease; p = 0.0043).

Conclusions: This is, to our knowledge, the first report of pregnancy outcomes in women exposed to biosimilar IFX. Under constrains given by limited sample size, no new safety concerns have so far arisen.

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Efficacy of vedolizumab in patients with Crohn’s disease may differ depending on the disease location: The UCLH experience

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Background: Vedolizumab is α4β7 integrin antagonist licenced to treat moderate to severely active Crohn’s disease (CD) as well as ulcerative colitis. The aim of this study was to examine the efficacy of vedolizumab in patients with CD at a single tertiary IBD centre in the UK, and whether efficacy varies depending on disease location in this heterogeneous condition.

Methods: Clinical records of patients with CD commenced on vedolizumab between 11/05/2015 and 01/12/2016 were examined retrospectively. Clinicopathological features and disease activity using Harvey Bradshaw Activity Index (HBAI) were collected at baseline, and at Weeks 14, 30 and at Week 52. Response to vedolizumab was defined as reduction in HBAI score ≤3 compared with baseline, and remission was defined as HBAI score ≤4 at these time points. For patients with a stoma, response was defined as a reduction in CRP ≥ 20% or radiological improvement, and remission was defined as normalisation of CRP ≤ 10 mg/l or radiological resolution of disease activity.

Results: Forty patients with CD were commenced on vedolizumab during the study period. Out of the 40 patients, 8 were excluded from the data analysis due to incomplete data. Eighteen patients (57%) had ileocolonic disease, 11 patients (34%) had colonic disease, and 3 patients (9%) had small-bowel disease. Mean age at the time of first Vedolizumab infusion was 29.3. Mean age at diagnosis was 18.1 with mean time between diagnosis and first vedolizumab infusion of 10.1 years. Twenty-one patients (66%) were taking immunomodulator (IM) and only 1 patient was anti-TNF naïve (3%) at the time of the first vedolizumab infusion. Sixteen patients...
had undergone previous surgery. Mean faecal calprotectin at baseline was 1948 μg/g. At Week 14, 3 patients responded (9%), 14 (44%) were in remission and 15 (47%) did not respond. Out of 23 patients who continued vedolizumab to Week 30, 1 patient responded (4%), 14 were in remission (61%), and 8 (35%) did not show response. Out of 18 patients who continued vedolizumab for 1 year, 10 (56%) were in remission. Out of these 10 patients, 4 had colonic disease and 6 had ileocolonic disease. The three patients with small-bowel disease were all non-responders. The rate of remission at 1 year was lower in the patients with concomitant use of IM (n = 5/21, 24%) compared with IM (n = 5 of 11, 45%). Six patients underwent surgery within 1 year of receiving their first vedolizumab infusion.

Conclusions: CD patients treated with vedolizumab achieved remission in 44% at Week 14, in 44% at 30 weeks and in 31% at Week 52. Vedolizumab was most effective at maintaining remission at 32 weeks in patients with colonic disease (n = 4 of 9, 44%) compared with patients with ileocolic disease (n = 6 of 20, 30%) and patients with small-bowel disease (n = 0 of 3, 0%).

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Utility of zinc protoporphyrin/haem ratio as a marker of iron deficiency with or without anaemia in patients with inflammatory bowel disease

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Background: Iron deficiency anaemia is a common extraintestinal manifestation of inflammatory bowel disease and is usually diagnosed by multiple parameters. Choice of a single iron biomarker for IDA screening remains controversial.1 The most commonly used parameter, ferritin, is an acute-phase protein and may therefore be strongly influenced by inflammatory activity. Zinc protoporphyrin (ZPP) to haem ratio has proved a sensitive and specific marker for functional iron deficiency.2 We evaluated the diagnostic performance of ZPP in ID, IDA, anaemia of chronic disease (ACD) and combined ACD/IDA in patients with IBD.

Methods: Data including blood count, transferrin saturation (TSAT), serum ferritin, CRP, and ZPP were analysed from 101 adults with IBD (62 CD; 40 UC; mean age 36.4 ± 13.1 years, 44% male) who consecutively attended our centre for routine evaluation between 05/2008 and 12/2013. Correlation between iron biomarkers and inflammation was measured by Spearman correlation. Anaemia was defined in accordance with WHO criteria (Hb <13 g/dl males/<12 g/dl females). The most commonly used parameter, ferritin, is an acute-phase protein and may therefore be strongly influenced by inflammatory activity. Zinc protoporphyrin (ZPP) to haem ratio has proved a sensitive and specific marker for functional iron deficiency. We evaluated the diagnostic performance of ZPP in ID, IDA, anaemia of chronic disease (ACD) and combined ACD/IDA in patients with IBD.

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Results: The prevalence of IDA and ACD was 17% (n = 17) and 3% (n = 3), respectively, while mixed anaemia (IDA/ACD) was identified in 23% (n = 23). Absolute ID without anaemia was found in 48 patients (47%). ZPP correlated better with Hb values than ferritin (correlation coefficients: 0.672 and 0.409, respectively, for ZPP and ferritin, p < 0.01). No correlation was found between ZPP und CRP (r = −0.05, p > 0.5), while the acute-phase protein ferritin was found to correlate with CRP (correlation coefficient: 0.329, p < 0.01).

Conclusions: ZPP is a reliable marker of iron-deficient erythropoiesis. Unlike ferritin, ZPP is not influenced by chronic inflammation. We propose that ZPP has utility not only in IBD, but also in patients with other chronic inflammatory conditions.

References

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Single-centre experience with biological treatment in budesonide-refractory microscopic colitis patients

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Background: Microscopic colitis (MC) is an inflammatory bowel disease that causes chronic watery diarrhoea. MC is usually effectively treated with budesonide, however, a few patients become refractory. Data on alternative treatments are sparse. We retrospectively evaluated the outcome of MC patients who have received biological therapy at our centre.

Methods: All patients with MC treated with biological therapy at the Department of Gastroenterology, University hospital Linkoping, Sweden were selected and the outcome recorded. Patients were investigated according to sex, age, disease subtype, clinical remission (defined as < mean 3 and no watery stools/day/week), clinical response (defined as ≥50% reduction of mean stool frequency/day/week), side effects and long-term outcome.

Results: Sixteen patients (12 women) with mean age at diagnosis of 47 years (range 19–76), thereof 14 with collagenous colitis were investigated. All 16 patients had received anti-TNF agents (8 adalimumab (ADA), 4 infliximab (IFX) and 4 both agents). ADA was given as induction treatment (160–80–40 mg) and IFX (5 mg/kg) at Weeks 0, 2, and 6. Eight patients in total achieved clinical remission. Of these, two patients maintained clinical remission for several years after induction treatment with ADA, 1 patient is on maintenance treatment with 40 mg ADA/ew, one patient is on maintenance treatment with 40 mg ADA/ew. Furthermore, one patient is on maintenance treatment on 400 mg IFX every 8 weeks and two patients have recently received IFX induction treatment and are in remission after the second induction dose. Finally, one patient had loss of response and did not gain clinical remission despite the use of a third anti-TNF agent (certolizumab). Four patients had a clinical response but three of them stopped treatment due to side effects.

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