Background: Surgical treatment in Crohn’s disease (CD) is unavoidable in about 70% of patients during the course of the disease. Early intensive therapy is necessary in these patients to reduce the risk of bowel damage leading to surgery like strictures or fistulae. The aim of our study was to assess risk factors for surgery during the course of CD.

Methods: Retrospective analytic study, collecting all patients diagnosed with Crohn’s disease in our department from January 2007 to June 2017. Surgical intervention for perianal disease was excluded from the study. Independent risk factors of surgery were evaluated by univariate and multivariate analysis.

Results: One hundred and twelve CD patients were enrolled with a mean age of 42 years old and a sex ratio (W/M) of 0.96. In total, 41 patients (36.6%) underwent surgery after a mean follow-up of 14.6 months. Thirty patients (73%) had ileal disease, 6 (15%) had colonic disease, and five (12%) had ileo-colonic disease. Indications for surgical treatment were: bowel obstruction in 26 patients, intraabdominal abscess with ileal disease in 9 patients, and acute severe colitis in 6 cases. The presence of obstructed bowel symptoms (p = 0.03), complicated disease at diagnosis (intestinal stenosis, fistula) (p = 0.001), ileal CD affecting >35 cm in extent at diagnosis (p = 0.04), young age (<30 years) at diagnosis (p = 0.012), and Crohn’s disease activity index (CDAI) > 250 (p = 0.03) were independent predictive risk factors for subsequent surgery in CD.

Conclusions: Surgical treatment is a common outcome in luminal CD. Independent risk factors for surgery during the course of the disease were: history of obstructed bowel signs, complicated behaviour at diagnosis, CD involving more than 35 cm of the ileum at diagnosis, young age at diagnosis (<30 years), and CDAI >250.

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Effectiveness and safety of biosimilar infliximab (remsima) in a real-life setting in 84 patients with Crohn's disease and ulcerative colitis

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Background: Over the past decade, biologics has significantly changed the management of Crohn’s disease (CD) and ulcerative colitis (UC). However, their use is limited by their high cost. The introduction of less costly biosimilars can help improving access to well-established therapies while improving healthcare affordability. Biosimilar infliximab (CTP-13) was the first monoclonal antibody biosimilar approved in the EU. The aim of this study was to demonstrate the safety and effectiveness of biosimilar infliximab when administered in a real-life setting in adults with active CD or UC.

Methods: This non-interventional study was conducted in Romania, Czech Republic, and Bulgaria in patients with moderate-to-severe active CD (not responding to steroids and/or immunosuppressive agents) or moderate-to-severe active UC (inadequately responding to conventional therapy). Patients received biosimilar infliximab at baseline, Week 2, Week 6, Week 12, Week 14, Week 22, and Week 30 (end of study visit) as per Summary of Product Characteristics. Safety was assessed by adverse events (AEs) and early withdrawals. Effectiveness was assessed at baseline, at Week 30, and at early withdrawal visits using the Crohn’s Disease Activity Index (CDAI) for CD patients and the partial version (without endoscopy) of the Clinical Activity Index (pCAI) for UC patients. Quality of life was measured by the Short Inflammatory Bowel Disease Questionnaire (SIBDQ).

Results: At December 1, 2017, 84 subjects (58% male, mean [SD] age 41.1 [15.3] years, 55% UC, 45% CD) have been enrolled (median follow-up 210 days). There were 24 AEs: 2 definitely related (i.e. adverse drug reaction (ADR): both of moderate severity) and 22 unrelated to biosimilar infliximab. A total of 17 patients have been withdrawn prematurely. The last available observation carried forward (LOCF) method was used for patients who did not have effectiveness measurement at Week 30 due to early termination. A total of 67 patients (CD: 31; UC: 36) had baseline and follow-up effectiveness measurements. At end of treatment (EOT) patients showed significant improvements in disease activity relative to baseline in terms of pCAI. From all who responded to the induction regimen, nearly 78% maintained their remission at Week 30, except 1 patient with secondary LOR at Week 16 (low TL of IFX, no ADAs detected). Conclusions: Approximately one-fifth of UC patients did not respond to the induction with biosimilar anti-TNF CT-P13 therapy. Although positive correlation of serum trough levels of IFX with the clinical response was found, however the role of ADAs in those who did not archived remission was negligible.

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Frequency of inadequate response to anti-tumour necrosis factor therapy in patients with ulcerative colitis. Preliminary results from POLIBD study

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Background: Therapeutic drug monitoring (TDM) may positively impact therapeutic decisions in patients with inflammatory bowel disease (IBD), especially in those who lose response to anti-tumour necrosis factor (TNF) therapy. The aim of the study was to evaluate the frequency of inadequate response to anti-tumour necrosis factor therapy in polish patients with ulcerative colitis. Mutual relationship between the lack of response, serum trough level of IFX and ADAs was also evaluated.

Methods: In total, 65 UC patients (33 male/32 female, 18-69 age; UC 3.5 years; duration of biosimilar IFX CT-P13 therapy from 6 to 30 weeks) were enrolled in this consecutive cohort from the referral IBD centre in Poland. Previous and current therapy, laboratory data and clinical activity at the time of trough level (TL) and antidrug antibody (ADA) measurement were recorded. All patients received standard immunosuppression with no additional steroid nor antibiotic therapy. TDM was performed before third induction dose, 4 and 6 weeks after it and before the first maintenance dose as well as at the time of suspected loss of response (LOR) using ELISA tests (Janssen Biotech, Horsham, PA, USA).

Results: In total, 65 UC patients who were induced with CT-P13, 51 (78%) responded to therapy. Of those who did not archived remission 22 (33%), 11 (17%) partially responded, in another 11 (17%) no response was noticed. In 3 (4.6%) patients SAE, that forced the withdrawal of treatment, was recorded. From 11 patients with no response, 8 (72%) had an IFX levels below therapeutic values, while the remaining 3 (27%) had IFX levels within the therapeutic values (3-7 µg/ml). Of these patients, 2 (18%) patients had detectable ADAs with the range from 2.8 to 4.2 IU/ml (normal value <2 IU/ml). From all who responded to the induction regimen, nearly 78% maintained their remission at Week 30, except 1 patient with secondary LOR at Week 16 (low TL of IFX, no ADAs detected).