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Background: In real-world clinical practice, biologics may be discontinued due to variety of reasons, including discontinuation by gastroenterologists, in the UK. The aim of the study was to report on outcomes after discontinuation in IBD patients after a minimum follow-up of 24 months.
Methods: All IBD patients who discontinued their first-use biologics between January 2013 and Dec 2016 were identified from the EMR at a tertiary referral centre to ensure at least 24 months follow-up. Reasons for discontinuation and pre-defined adverse outcomes (steroid and other rescue therapies, hospitalisations, surgery including perianal) were recorded. The data were analysed using multivariable and univariable logistic regressions within a machine learning technique in order to predict adverse outcomes within the stated timeframe. We performed Kaplan-Meier survival analysis for those patients who had biologics electively discontinued.
Results: In total, 147 IBD patients who discontinued biologics (*M* = 74.median age 39 years; CD = 110) were identified. Follow-up ranged from 24 to 60 months (median 40 months). One hundred and forty-four patients (98%) discontinued anti-TNF (1% biosimilar anti-TNF and 1% vedolizumab) and 69 (47%) were on thiopurines at start of biologics. Fifty-nine patients (40%) had biologics electively discontinued by their gastroenterologists and they were analysed separately. Of the 59 elective discontinuations, 22(37%) continued thiopurines after biologic stoppage; 37/59 (63%) patients had at least one adverse outcome (AO) within 6 months of discontinuation and 42/59 (71%) patients restarted biologics.

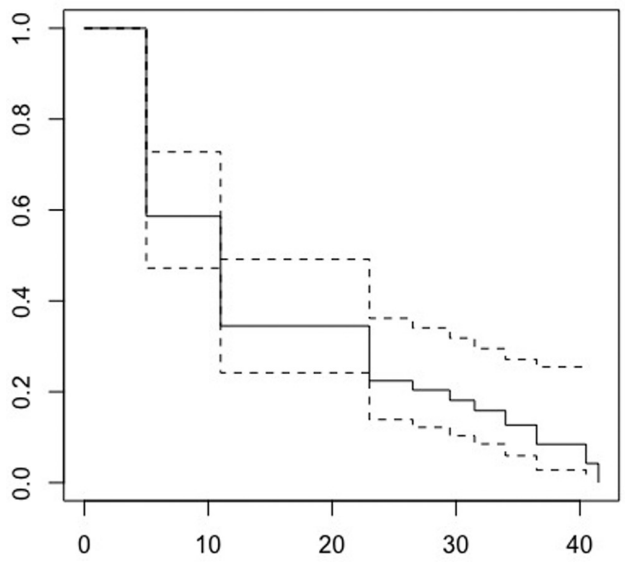

Figure 1. the Kaplan–Meier survival curve after elective discontinuation.

Conclusion: The majority of patients who electively discontinued biologics had IBD-related AO rapidly after the stoppage and needed to restart biologics. Almost all patients had AO by the end of the study follow-up period. This should be discussed with patients when considering discontinuation of biologics.

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Evaluation of targeted vitamin D supplementation regimen in postoperative patients with Crohn's disease

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Background: Vitamin D with a serum 25(OH)D concentration above 100 nmol/l was associated with disease remission in patients with IBD and suggested that targeted administration may be an anti-inflammatory drug. This study was designed to assess the effectiveness, safety, and predictive measures of a vitamin D regimen in postoperative patients with Crohn's disease to achieve the above goals.
Methods: In a prospective study, patients with Crohn's disease and serum 25(OH)D concentrations <75 nmol / L were prescribed an oral vitamin D supplement at a dose of one year, and adjusted 4-weekly to aim for a serum 25(OH)D level of 100–125 nmol/l.
Results: Thirty-two postoperative patients with Crohn's colitis had an average 25(OH)D concentration of 51.5 (range 25–74 nmol / L). 25 patients reached the target level and six patients reached 90–94 nmol / L. Because of the reoperation, one patient withdrew in 6 months. Patients with BMI <30 kg / m2 could reach the target dose (p = 0.006), and the total dose was negatively correlated with the initial serum 25(OH)D (Spearman r = 0.86, p = 0.002). One patient developed a high level (146 nmol/L) at 2 months and the other had new hypercalciuria. There are no serious adverse events attributable to treatment. Clinical disease activity continued to decline (p = 0.015), but faecal calprotectin (p = 0.264), inflammatory cycle markers (p = 0.513) and Rutgeerts score (p = 0.428) did not decrease.
Conclusion: Specific oral vitamin D regimens can successfully and safely reach or approach target levels, improve symptom-based activity scores, but do not alter objective indicators of intestinal or systemic inflammation. A modified version of this dose-escalation protocol is suitable for randomised placebo-controlled trials, and the further randomised controlled trial was needed.

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Anti-TNF α antibodies in patients with inflammatory bowel disease naive to anti-TNF therapy treated with biosimilar infliximab (CT-P13): a prospective single-centre real-life study

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Background: There are several tests for detecting antibodies to infliximab. The tests differ in sensitivity and therefore the detection of antibodies varies significantly between clinical trials, and less data is available for induction compared with the maintenance therapy.
The aim of the study was to determine the incidence of anti-drug antibodies (ADAs) in patients during induction and maintenance therapy using the Enzyme-Linked Immunosorbent Assay (ELISA) and to analyse the risk factors for their occurrence.
Methods: It was a prospective single-centre study involving 84 patients with IBD during treatment with biosimilar infliximab (CT-P13) at the Tertiary IBD Center in South-eastern Poland between 2016 and 2019. All participants were naive to previous anti-TNF α therapy (80 patients). ADAs serum testing was only performed when IFX levels below 3 μg/ml were found during induction or maintenance therapy. The incidence of ADAs was analysed, and the relationship between the presence of ADAs and selected variables

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was assessed: gender, type of disease, immunosuppressive therapy, and undetectable drug level at week 6. The relationship between response to induction treatment and high//low ADAs titers was also compared using Fisher's exact test.

Results: The incidence of ADAs in the study population was 10.7%, which is 20.4% of patients with non-therapeutic and 50% of patients with undetectable levels of IFX. The percentage of people with ADAs in the induction treatment group was 11.3% (n = 6) and in the maintenance group 3.9% (n = 3). There was no statistically significant difference in the frequency of finding ADAs in both groups (p = 0.158). In contrast, a statistically significant relationship between the undetectable level of IFX at week 6 and the presence of ADAs was confirmed, 88.9% of patients with ADAs vs. 16.0% patients without ADAs (p <0.001. Comparison of the relationship between response to induction treatment and high//low ADAs titers did not show a statistically significant relationship between these variables (p = 0.381).

Conclusion: The overall incidence of ADAs in patients treated with biosimilar infliximab (CT-P13) naive to previous anti_TNF therapy was relatively low, but in the case of undetectable levels of the drug, the phenomenon of immunogenicity was detected in half of the patients. Undetectable level of infliximab at week 6 was a risk factor for the presence of ADAs. There was no significant association between response to induction therapy and ADAs titers.

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Real-life effectiveness and safety of ABP501, an adalimumab biosimilar, in inflammatory bowel disease: a multicentre Italian study

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Background: Recently, various adalimumab (ADA) biosimilars have been approved by the EMA with the same indications of the reference product (Humira), despite the lack of data in terms of efficacy and safety in patients with inflammatory bowel disease (IBD). The aim of our study was to verify the effectiveness and tolerability of ABP501, an ADA Biosimilar, in IBD in the short-term.

Methods: All consecutive moderate-to-severe IBD patients who completed induction with ABP501 at three Italian IBD Units (Padua, Santorso, Feltre) were included. We collected data on partial Mayo (p-Mayo) Score, Harvey–Bradshaw Index (HBI), C reactive protein (CRP), faecal calprotectin (FC), concomitant steroid and azathioprine therapy at baseline (T_0), after induction (T_1) and at six months (T_2). Information on the need for optimisation and adverse events (AEs) were also collected. Continuous and categorical variables were expressed as mean with standard deviation and frequency with percentages, respectively. Comparisons between variables were conducted using a t-test and chi-square test. Data were analysed using STATA11.1 software.

Results: Thirty-three IBD patients [17 with ulcerative colitis (CU), 18 with Crohn's disease (CD)] that completed induction (T_1) were considered, with 18 of them who completed at least six months of therapy (T_2). Clinical remission was achieved by 14/33 (45.5%) and 8/18 (44.4) patients at T_1 and T_2, respectively. Steroid-free clinical remission was obtained by 14/33 (42.4%) and 8/18 (44.4) patients at T_1 and T_2, respectively. After induction FC tended to decrease from baseline to T_2, without reaching statistical significance (p = 0.1). However, a significant decrease in CRP levels (p < 0.02) was observed. After induction, AEs occurred in 11 (33.3%) patients: 2 had an infection, 8 reported headache or myalgia or arthralgia, and one experienced a local infusion reaction. Moreover, AEs were observed in 6/18 (33.3%) at T_2: 5 had arthralgia and 1 had a local infusion reaction. After induction 4/33 (12.12%) stopped therapy for lack of response, whereas the dropout occurred in 6/12 (33.3%) at six months (4 for loss of response and 2 for adverse events). Finally, 7/33 (21.2%) and 5/18 (27.7%) patients needed therapeutic optimisation at T_1 and T_2, respectively.

Conclusion: ABP501 seemed to be successful in achieving clinical remission and steroid-free clinical remission, but further data are required. Overall the therapy was well tolerated.

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Patient' recruitment for a Phase 3 inflammatory bowel disease (IBD) programme is significantly increased when accessing the CT-SCOUT™ platform

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Background: The main issue when validating new molecules in the field of IBD is insufficient patient recruitment into clinical trials, resulting in a considerable delay and cost increase. The selection of the best recruiting sites is a long and difficult process, especially since study sponsor has no visibility on the activity of the sites, and the sites have no penalties if the objectives are not achieved. The CT-SCOUT™ platform is a web-based solution to help clinicians to pre-screen potential candidate, facilitating the coordination of the research team and providing sponsor and principal investigator visibility into patient recruitment efforts and status on the site. We aimed to compare the recruitment rate in sites using the application according to Premium or Freemium modalities and in sites not equipped with CT-SCOUT™ for IBD clinical trials.

Methods: We conducted a prospective, multicentre, open-label, observational and comparative study in 25 sites participating in a selected phase 3 IBD clinical trials in France. All sites were proposed to be equipped with CT-SCOUT™, and the recruitment rate was compared according to 3 modalities: a) the Premium mode, giving access to all the functionalities of the application (including specific inclusion/exclusion criteria, possibility of sending notification to the

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