during the study period. Median follow-up was 9 (IQR: 7–16) months; 28 (92%) had at least 6 months of clinical follow-up. Serum alkaline phosphatase activities did not significantly decrease with vedolizumab therapy (median 268 (IQR: 105–551) IU/L at baseline versus 249 (IQR: 183–634) IU/L, p=0.9899 at week 30). Of the 18 patients with an abnormal alkaline phosphatase at baseline (>120IU/L), 11 (61%) had improvement with treatment. In these patients, alkaline phosphatase trended down from 475 IU/L (IQR: 241–757) at baseline to 283 IU/L (IQR: 207–658), p=0.267 at week 30 but none of these normalized (Figure 1). Median alkaline phosphatase changes remained similar when patients exposed to UDCA were excluded. Of the 8 patients (31%) with normal alkaline phosphatase at baseline, 4 (50%) had a subsequent increase to abnormal levels by week 30, from a baseline median of 98 IU/L (IQR: 77–102) to 146 IU/L (IQR: 90–203), p=0.036 at week 30 (Figure 2). No significant changes in other liver biochemistries or the Mayo PSC Risk Score were demonstrated at week 30. 55% of Crohn's disease and 21% of ulcerative colitis patients achieved clinical remission at week 30. Seven patients (21%) ceased vedolizumab therapy; one for a deterioration in liver biochemistry thought to be a drug reaction and six for IBD primary non-response. Two patients developed ascending cholangitis but continued vedolizumab.

Conclusions: Vedolizumab therapy in patients with IBD-PSC has little overall effect on liver biochemistry, but is safe and does improve IBD clinical activity. Treatment earlier in the disease course of PSC and assessment of longer-term exposure of lymphocyte trafficking blockade in IBD-PSC remains of interest.

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Drug persistence and need for dose intensification to adalimumab therapy; the importance of therapeutic drug monitoring in inflammatory bowel diseases

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Background: Therapeutic drug monitoring (TDM) measuring drug trough levels (TL) and antidrug antibodies (ADA) may aid the therapeutic decision in patients with inflammatory bowel disease (IBD) who loose response to anti-TNF therapy. Our aim was to evaluate the frequency and predictive factors of loss of response to adalimumab therapy and the role of the therapeutic drug monitoring to predict the loss of response in adalimumab treated IBD patients.

Methods: 112 IBD patients (with 214 TDM measurements, CD/UC 84/28, male/female 50/62, mean age CD/UC: 36/35 years, mean duration of adalimumab therapy CD/UC: 157.8/70.1 weeks) were enrolled in this consecutive cohort from two referral IBD centres in Hungary. Demographic data were comprehensively collected and a harmonized monitoring strategy was applied. Previous and current therapy, laboratory data and clinical activity at the time of the TL and ADA measurement were recorded. Patients were evaluated either at the time of suspected LOR or during follow-up. TDM measurements were done by commercial ELISA (LISA TRACKER, Theradiag, France).

Results: Among 112 IBD patients, LOR/drug persistence was 25.9%/74.1%.The probability of ADA positivity and low TL (<4.0 μg/mL) was 12.1% and 17.8% in the first year and 17.3% and 29.5% and in the second year after start of adalimumab therapy in Kaplan-Meier analysis. Dose intensification was needed in 29.5% during the study period. There was an association between female gender, ADA positivity and LOR (female gender: p<0.001, OR: 7.770 CI95%: 2.483–24.315, ADA positivity: p=0.007 OR: 3.616 CI95%: 1.374–9.518)), while no other parameters, including TL was associated with LOR or dose intensification.

Table 1. ADA and TL status in IBD patients treated with adalimumab

	Normal TL	Low TL
ADA negative	58%	21.4%
ADA positive	10.7%	9.8%

Conclusions: Our results suggest that ADA development, low TL and need for dose intensification are frequent during adalimumab therapy and support the use of routine TDM assessment in IBD patients. Female gender, and ADA positivity were predictors of loss of response.

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The Sicilian network of biological therapy in inflammatory bowel disease: preliminary data on efficacy

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Background: The monitoring of appropriateness, costs, and clinical outcomes of biological therapy in inflammatory bowel disease (IBD) is a relevant need. We aimed to evaluate all these issues in Sicily through a web based network of all prescribing centers.

Methods: From January 2013, all IBD patients starting a biological agent (incident cases) or already on treatment (prevalent cases) were entered in a web based software. Herein we report data of incident

cases about the efficacy of biological therapy after twelve weeks and one year of treatment.

Results: From January 2013 to October 2016, 1475 patients were included. Incident cases were 1090. Considering that 16% of patients experienced more than one line of therapy, a total of 1351 treatments were reported. Adalimumab was used in 622 Crohn's disease (CD) patients and in 83 ulcerative colitis (UC)/unclassified colitis patients. Infliximab was prescribed in 275 CD patients (80 biosimilars) and in 279 UC patients (50 biosimilars). Golimumab was used in 32 UC patients, while vedolizumab in 40 CD patients and in 20 UC patients. In patients with CD, after twelve weeks and one year of therapy, the rates of remission with adalimumab were 43.9% and 60.2%, respectively, and the rates of response 40.9% and 25.8%, while the rates of remission with infliximab originator were 46.2% and 50.0%, and the rates of response 40.9% and 32.9% (biosimilars: remission 31.0% and response 51.7% after 12 weeks; remission 45.5% and response 36.4% after one year). In UC, after twelve weeks and one year of therapy, the rates of remission with adalimumab were 43.3% and 57.1%, respectively, and the rates of response 36.7% and 19.0%; the rates of remission with infliximab originator were 41.6% and 48.4%, and the rates of response 35.6% and 32.3% (biosimilars: remission 30.0% and response 63.3% after 12 weeks; remission 20.0% and response 40.0% after one year); the rate of remission after 12 weeks of therapy with Golimumab was 22.2%, and the rate of response was 33.3%. After twelve weeks of therapy with Vedolizumab, 28.6% of CD patients were in remission and 32.0% had a response, while the rates of remission and response in UC patients were 33.3% and 22.0%, respectively. Multivariable logistic regression analysis showed that age >50 years was independently linked to lower rates of remission/response at 12 weeks in CD patients (OR 0.613, p=0.046).

Conclusions: In one of the largest series of IBD patients on biological therapy reported to date, CD patients older than 50 years showed a higher rate of non response at 12 weeks of treatment. Efficacy of biosimilars was overall comparable to that reported for infliximab originator.

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Exclusive enteral nutrition provides an effective bridge to safer interval elective surgery for Crohn's disease

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Background: Despite data reporting that exclusive enteral nutrition (EEN) improves nutritional status and inflammation in patients with Crohn's disease, few studies have reported its systematic use in the perioperative setting. EEN involves the use of a liquid nutrition formula to meet all of an individual's dietary requirements. We sought to test the hypothesis that EEN provides a safe and effective bridge to surgery and reduces post-operative complications in adult patients with Crohn's disease requiring urgent surgery for stricturing or penetrating complications.

Methods: Fifty-one patients who were treated with EEN prior to planned surgery for stricturing or penetrating complications of Crohn's disease were identified from our specialist dietician's database. Thirty eight out of these fifty-one patients had surgery and they were each matched with two control patients for disease behaviour, type of surgery, age at diagnosis and disease duration. Data on disease phenotype, nutritional status, operative course, and post-operative complications were obtained.

Results: Clinical status improved in 25% [13/51] of the EEN patients such that they no longer required surgery. EEN had no effect on pre-operative weight, but it significantly reduced median [interquartile range (IQR)] serum CRP levels (baseline 36 [13–91] vs. pre-operation 8 [4–31] mg/L, p=0.02). The median [IQR] length of surgery was shorter in patients pre-optimised with EEN than controls (3.0 [2.5–3.5] vs. 3.5 [3.0–4.0] hours respectively, p<0.001). Multivariable logistic regression analysis confirmed that going straight-to-surgery compared with EEN pre-optimisation was associated with a nine-fold increase in the incidence of post-operative abscess and/or anastomotic leak (OR 9.1 95% CI [1.2–71.2], p=0.04).

Conclusions: EEN in adult patients presenting with stricturing or penetrating complications of Crohn's disease is associated with a reduction in systemic inflammation, operative times and the incidence of post-operative abscess or anastomotic leak. Further controlled trials are needed to elucidate how EEN may improve operative outcomes and to confirm that EEN provides a safe and effective bridge to surgery.

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Vedolizumab in Pediatric inflammatory bowel diseases: a retrospective multi-center experience from the paediatric IBD Porto group of ESPGHAN

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Background: Vedolizumab (VDZ) has proven as an effective medication in adult Inflammatory Bowel Disease (IBD). There has been increased off-label use of VDZ also in children but with very limited published experience. Therefore we aimed to describe the short-term effectiveness and safety of VDZ in children with IBD in the largest pediatric cohort to date.

Methods: Retrospective review of children (2–18 years) treated with VDZ from 17 centers affiliated with the Paediatric IBD Porto group of ESPGHAN. Baseline characteristics and explicit prior and current clinical data were recorded on a standardized REDcap case-report forms. Primary outcome was treatment success at week 14 and last follow-up, defined as steroid-free remission (i.e. wPCDAI<12.5 or PUCAI<10) without the need for new medications or surgical intervention. Safety data were also explicitly recorded.