Linear regression using the ordinary least squares method examined the relationship between cumulative dose, period of diagnosis, age, gender and category of IBD.

Results: The mean cumulative effective radiation doses for the earlier and later periods were 4.7mSv (95% CI, 1.86 to 7.54) and 7.4mSv (95% CI, 3.60 to 11.26) respectively.

No significant relationship was demonstrated between age (-0.03mSv, 95%CIs: -0.20, 0.12), male gender (0.69mSv, 95%CIs: -4.00, 5.39), or later referral period (3.06mSv, 95%CIs: -1.67, 7.78) and cumulative dose. A diagnosis of Crohn's (as opposed to UC) had a strongly positive relationship with total radiation dose (5.89, 95%CI: 1.07, 10.70).

12 MRI small bowels were completed during period 2, none during period 1.

Conclusion: Our evaluation shows an upward trend, failing to meet statistical significance, in the radiation doses to which patients with new diagnoses of IBD were exposed to by our service.

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Which biomarkers have an effect on therapeutic vedolizumab drug levels? A retrospective analysis from a London Tertiary Centre.

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Background: Vedolizumab is a humanised monoclonal antibody that binds to the $\alpha_4\beta_7$ integrin and is an established treatment for both Crohn's Disease (CD) and Ulcerative Colitis (UC). Drug levels for anti-tumour necrosis factor-α inhibitors such as infliximab and adalimumab have been used routinely for therapeutic drug monitoring (TDM). Target therapeutic levels for vedolizumab are yet to be established. Correlations with vedolizumab levels have been found in prospective and retrospective studies with a number of biomarkers such as C-Reactive Protein (CRP), albumin and Body Mass Index (BMI). However, these have failed to replicate consistently among studies of vedolizumab drug levels.

Methods: Trough serum vedolizumab drug levels were taken for 81 patients through a period of 3 months. These were analysed using a drug tolerant assay (IDKMonitor Drug level ELISA and IDKMonitor vedolizumab Free anti-drug antibody ELISA) run on a Dynex DS2 ELISA processor. These were collected from 33 CD patients, 46 UC patients and 2 patients with unclassified Inflammatory Bowel Disease (IBD-U). Faecal calprotectin (FCP) was collected in a subset of patients. Serum CRP, albumin, and haemoglobin (Hb) levels were also taken alongside levels. BMI was recorded at our infusion unit before receiving the infusion.

Results: 81 patients had drug levels taken: CD patients (mean drug level Q8w - 7.8 mcg/ml, Q4w - 18.6 mcg/ml, 9 patients with concomitant immunomodulators (CIM)), UC patients (mean drug level Q8w - 9.4 mcg/ml, Q4w – 22.0 mcg/ml, 5 patients with CIM), IBD-U (mean drug level Q8w - 15.2 mcg/ml, no patients with CIM). One patient developed anti-drug antibodies. Correlation was analysed using simple linear regression. A positive correlation was found with vedolizumab levels and albumin (correlation coefficient (r) = 0.11; p=0.03) but not with CRP (p=0.49), Hb (p=0.56), BMI (p=0.33) or FCP (p=0.08).

Conclusion: Our results indicate that albumin positively correlates with a higher vedolizumab drug level, which suggests that drug levels will be lower and perhaps less effective in patients with a low albumin level. Further studies should look at larger numbers of patients to identify whether the correlations identified with other biomarkers are significant and identify therapeutic target levels for vedolizumab. These will help guide TDM for patients and inform clinicians of when to switch as well as recognising likely non-responders and thus provide a personalised approach to biologic choice.

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Anti-TNF therapy for Ulcerative Colitis in Brazil: a comparative real-world national multicentric study from the Brazilian Study Group of IBD (GEDIIB).

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Background: Anti-TNF therapy represented a landmark in medical treatment of ulcerative colitis (UC). There is lack of data on the efficacy and safety of these agents in Brazilian patients, as public reimbursement is relatively recent. The present study aimed to analyze rates of clinical and endoscopic remission comparatively, between adalimumab (ADA) and infliximab (IFX), in Brazilian UC patients, and evaluate possible factors associated with remission after 1 year of treatment.

Methods: A national retrospective multicenter study (24 centers) was carried out including patients with moderate-to-severe UC treated with anti-TNF therapy. Disease activity was categorized using Mayo score at baseline, weeks 8, 26 and 52. Clinical remission was defined as a partial Mayo score ≤ 2. Endoscopic remission was defined as a Mayo endoscopic subscore ≤ 1. Patients were allocated in 2 groups (ADA and IFX) and a comparative efficacy study was performed. Statistical analysis: logistic regression model was used to study effects of predictor variables on categorical outcomes, such as presence or absence of remission at week 52. Statistical significance was assumed if $p < 0.05$.

Results: Overall, 393 patients were included (111 ADA and 282 IFX). The mean age was 41.86 ± 13.60 y, 61.58% women, most patients had extensive colitis (62.40%) and 19.39% previous exposure to biological agent. Overall, clinical remission rate was 66.78%, 71.62% and 82.82% at weeks 8, 26 and 52, respectively. Remission rates were higher in the IFX group at weeks 26 (75.12% vs. 62.65 %, p <0.0001) and 52 (65.24% vs. 51.35%, p <0.0001) – figure 1. Overall, endoscopic remission was observed in 50% of patients at week 26 and in 65.98% at week 52, with no difference between the two groups (p = 0.114). Colectomy was performed in 23 patients (5.99%). The variables associated with clinical remission after 1 year of treatment were age, non-prior exposure to biological therapy, use of IFX, endoscopic remission at week 26 and no need for optimization (table 1). The variables associated with endoscopic remission after 1 year were non-prior exposure to biological therapy, clinical and endoscopic remission at week 26 and no need for optimization.

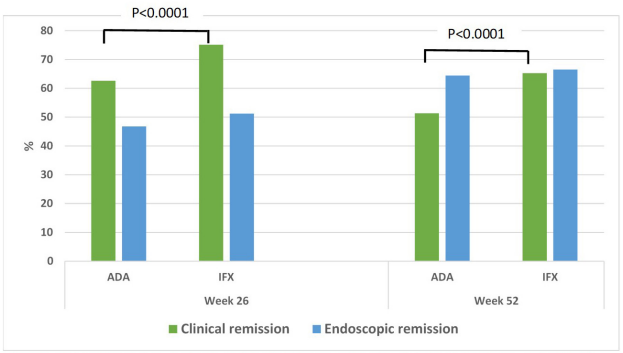

Figure 1. Clinical and endoscopic remission at weeks 26 and 52 according to use of adalimumab (ADA) or infliximab (IFX).

Table 1. Logistic regression for clinical and endoscopic remission at week 52 of treatment in UC patients.

	Clinical remission			Endoscopic remission		
	OR	CI	P-value	OR	CI	P-value
Age (y)	1.052	1.026-1.080	0.0001	1.008	0.990 - 1.026	0.3998
Azathioprine use	1.105	0.528-2.314	0.7908	1.158	0.641 - 2.093	0.6274
Non-prior exposure to biologic	2.903	1.423-5.922	0.0034	2.000	1.056 - 3.787	0.0333
Infliximab x Adalimumab	1.980	1.040-3.759	0.0378	1.0941	0.6325-1.8939	0.7472
Clinical remission at week 26	4.778	2.208-10.339	<0.0001	7.341	3.228 - 16.695	<0.0001
Endoscopic remission at week 26	4.909	2.295-10.500	<0.0001	8.280	4.138 - 16.571	<0.0001
Optimization (no x yes)	4.913	2.458-9.819	<0.0001	6.355	3.651 - 11.064	<0.0001

Conclusion: In this national multicentric study, overall efficacy of anti-TNF therapy was similar to real world data with IFX and ADA. IFX treatment was associated with higher rates of clinical remission after 1 year in comparison to ADA. Patients naive to biological therapy presented higher rates of clinical and endoscopic remission. This is the first real world national study analyzing efficacy of anti-TNF agents in UC in Brazil.

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Costs savings associated with ferric maltol and the reduced use of intravenous iron based on real world data

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Background: Intravenous (IV) iron is frequently used in patients with iron deficiency (ID) when conventional oral ferrous products are ineffective or cannot be used (e.g. due to poor tolerability). Oral ferric maltol is a new iron ferric product registered in Europe and US. The aim of this study was to quantify the use of IV iron before and after the introduction of the new oral ferric maltol in real world settings and extrapolate the overall costs involved.

Methods: Data were collected from a single centre German clinical practice, MVZ für Immunologie, in inflammatory bowel disease (IBD) patients treated with iron therapy for ID with or without anaemia between 2013 and 2019 through the systematic CEDUR IBD registry and local medical records. The first cohort was formed of patients treated between 2013 and 2015, receiving only IV iron as ferric carboxymaltose (FCM). The second cohort was formed of patients treated between 2017 and 2019, receiving either oral ferric maltol only or ferric maltol in combination with FCM. Costs involved in each cohort were extrapolated using a societal perspective.

Results: Following the introduction of oral ferric maltol, the actual total number of FCM infusions observed was 138, showing a decrease of 70% compared to the first cohort in which oral ferric maltol was not available. This decreased number of infusions between the two cohorts was associated with total costs-savings of €56,933. In the first cohort, the administration costs were €44,536, the drug acquisition costs were €59,536 and the productivity loss were €30,944. In the second cohort, the administration costs were €13,597 the drug acquisition costs were €55,028 and the productivity loss were €9,447. A secondary scenario strictly applying the doses taken from respective SmPCs was tested and resulted in greater costs-savings.

Noteworthy, the mean (SD) haemoglobin (Hb) level at baseline in the first cohort was lower with 11.5g/dl (1.19) vs. 12.2g/dl (1.18) in the second cohort. Three to six months after the treatment had been stopped, the mean (SD) Hb level was 13g/dl in both the first and second cohort with a SD of 1.31 and 1.37 respectively, showing that Hb levels were maintained in both cohorts.

Conclusion: The introduction of the new oral ferric maltol resulted in a decrease of 70% in terms of number of FCM infusions which was associated with costs-savings of €56,933 in terms of administration, drug acquisition and productivity loss costs. Considering that

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