Background: Tofacitinib (TFC) is an oral, small-molecule Janus kinase inhibitor, which was recently approved for moderate to severe ulcerative colitis (UC). The aim of the current real-life study was to determine efficacy of TFC induction therapy regarding the clinical response and remission in patients with active UC. We evaluated short-term efficacy data in a Hungarian cohort with prior exposure to other biological agents such as anti-TNF drugs and vedolizumab.

Methods: In this single-centre retrospective study, patients with TFC introduction were included. Since January 2019, a total of 16 patients received an oral TFC induction therapy in a dose of 10 mg twice daily for 8 weeks. Endoscopic activity was evaluated by endoscopic Mayo (eMayo) score before the introduction of TFC and in case of an inadequate therapeutic response to the 5-mg-therapy to confirm therapeutic decision-making. Based on the evaluation of clinical symptoms and laboratory parameters, we either kept the dosage or reduced the dose to 5 mg according to local regulations. We also collected data from the 16. and 24. weeks of the therapy. Primary endpoints were a clinical response (as a reduction in partial Mayo Score [pMayo] by minimum 3 points) or remission (as a Mayo score of the maximum of 2 points and without blood in stool) at week 8.

Results: Sixteen patients had received the induction therapy (mean age: 36 years, 7 males and 9 females) in our centre. After 8 weeks, 12 (75%) patients responded to the TFC induction therapy and 6 (37.5%) of them were in remission. Four patients were primary non-responders (25%). Corticosteroid therapy (18 ± 7 mg) was required during the induction in 4 responder cases, which could be stepped down by week 8. As a continuous maintenance therapy, 4 patients have already reached the 16th week and 8 have completed the 24th week. By the end of the follow-up, 12 patients responded and 10 was in remission. During the observation period, 3 patients had to remain on 10 mg TFC dose, 6 patients required dose escalation from 5 mg to 10 mg and 5 mg was sufficient in case of only 3 patients after the introduction. Endoscopic activity showed a moderate decrease from 2.5 ± 0.5 eMayo score to 2 ± 1 (n = 7) until week 16. In respect the responder patients, CRP levels decreased from the mean of 7.23 to 5.02. No serious side-effects were observed during the follow-up.

Conclusion: After the 8-week TFC induction therapy, the response rate was high and only every fourth patients were non-responder. A low number of patients had adequate reactions to the 5 mg-therapy after the introduction, but TFC is effective with dose-escalation in respect of clinical response and remission in patients with UC, who have had an inadequate response to previous biological therapy.

Table 1.

	6 weeks (n = 121): 26 (21.5) ≥ 1 EIM				6 months (n = 113): 26 (23%) ≥ 1 EIM				1 year (n = 104): 17 (16.3%) ≥ 1 EIM			
n(%)	Stable	Worse	New	Total	Improved	Stable	Worse	New	Total	Stable	Worse	New	Total
Arthropathy	4 (66.7)	0	2 (33.3)	6	2 (25)	5 (62.5)	0	1 (12.5)	8	8 (100)	0	0	8
Arthralgia	3 (30)	1 (10)	6 (60)	10	1 (10)	5 (50)	0	4 (40)	10	4 (100)	0	0	4
Skin EIM	0	1 (25)	3 (75)	4	1 (33.3)	0	0	2 (66.7)	3	0	0	1 (100)	1
Liver EIM	5 (100)	0	0	5	0	0	5 (83.3)	1 (16.7)	6	5 (100)	0	0	5
Myalgia	0	0	2 (100)	2	0	1 (50)	0	1 (50)	2	1 (50)	1 (50)	0	2

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The impact of vedolizumab on extra-intestinal manifestations in inflammatory bowel disease patients: A real-life experience of a single-centre cohort

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Background: Vedolizumab (VDZ), a gut-specific anti-integrin, is approved as a treatment for moderate to severe Crohn's disease (CD) and ulcerative colitis (UC). Extra-intestinal manifestations (EIMs) are frequently associated with inflammatory bowel disease (IBD). However, the effect of VDZ on EIMs remains unknown. The aim of the current study was to describe the prevalence of EIMs in IBD patients at VDZ initiation, the evolution during continued treatment as well as the occurrence of new EIMs.
Methods: A single-centre study was performed in IBD patients who were started on VDZ between May 2010 and February 2019. Retrospectively, the physician-reported EIMs and intestinal disease activity (clinical and endoscopic) were assessed at baseline, 6 months and 1 year after the start of VDZ.
Results: The cohort consisted of 134 patients, including 77 CD patients, 56 UC patients and 1 patient with unclassified IBD. At VDZ initiation EIMs were assessed in 127 patients and 17.3% had ≥ 1 EIM: 9 hepatic EIMs (2 patients with toxic hepatitis, 2 with autoimmune hepatitis and 5 with PSC), 7 arthropathies (6 patients with axial spondyloarthropathy and 1 with peripheral arthritis), 3 non-further specified axial or peripheral arthralgias and 3 cutaneous EIMs (urticaria, psoriasis and erythema nodosum). Clinical evolution of the EIMs is reported in Table 1, assessment of intestinal disease activity in Table 2. During follow-up, 23 new EIMs were seen, mainly arthralgia, which was often transient. VDZ was stopped in 39/130 (30%) patients due to active intestinal disease in 32 patients, patients' choice (n = 1) or because of deep disease remission (n = 1). In five patients, VDZ was stopped because of insufficient control of EIM.

Table 2.

Clinical, *n* (%)	**6 months (*n* = 109)**	**1 year (*n* = 106)**
No response	13 (11.9)	10 (9.4)
Response	34 (31.2)	24 (22.6)
Remission	62 (56.9)	72 (67.9)
Endoscopic, n (%)	**Post induction (n = 81)**	**1 year (n = 44)**
No response	24 (29.6)	12 (27.3)
Response	35 (43.2)	7 (15.9)
Remission	22 (27.2)	25 (56.8)

Conclusion: A good clinical intestinal response was observed. However, the clinical evolution of EIMs appears unaffected by the use of VDZ in our cohort. Prospective data are needed to confirm these results.

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Which second-line biologic after anti-TNF failure during Crohn's disease: Ustekinumab or vedolizumab, a multicentre retrospective study

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Background: Anti-TNF antibodies treatments are the only first-line reimbursed biologics for Crohn's disease (CD) in several countries. Recently, Vedolizumab (VDZ) and Ustekinumab (UST) were added to the therapeutic armamentarium for CD refractory to a first anti-TNF antibody. However, studies comparing these two compounds remain unavailable. Our aim was to compare their efficacy in second-line treatment in CD after failure of one TNF antagonist.
Methods: All patients with CD refractory (primary or secondary non-responders) to first anti-TNF treatment and receiving UST or VDZ as a second biologic were included retrospectively in 10 French tertiary centres. The remission and clinical response were assessed at week 14. On the long-term, the cumulative probabilities of being in remission were estimated using the Kaplan–Meier method and the associated factors using a Cox proportional risk model. The drug survival to assess efficacy as well as side effects was assessed by actuarial analysis.
Results: 88 patients were included, 50 (57%) females (mean age: 41 ± 15 years), 61 (69%) being treated with UST and 27 (31%) with VDZ. The first anti-TNF was discontinued for primary or secondary non-response in 66 (75%) patients and for side effects in 22 (25%) patients, without any difference between the anti-TNF antibody previously used. Among the 55 patients with endoscopic data at baseline, 55 (98%) had ulceration, a CRP above 5mg/l for 33/71 (46%) patients and a faecal calprotectin > 250 µg/g for the 12 patients tested. At week 14, no difference was observed for clinical response and clinical remission according to the type of treatment: the rate of clinical response and remission were 74% (UST)/58% (VDZ) (p = 0.20) and 33% (UST)/26% (VDZ) (p = 0.56), respectively. The only factor associated with short-term remission was the lack of optimisation prior to anti-TNF discontinuation (p = 0.038) regardless of the type of second-line therapy (UST, p = 0.02; VDZ, p = 0.03). After a mean follow-up of 67 weeks, the cumulative probabilities of being in remission at 6 and 12 months were 16% and 34% for UST and 25% and 44% for VDZ, respectively (p = 0.24 for UST vs. VDZ). The drug survival was higher in the UST group as compared with the VDZ group (HR (UST vs. VDZ) = 2.36 [1.02–5.5], p = 0.04).
Conclusion: Our preliminary results suggest that VDZ and UST have similar efficacy in the short- and long-term response when used as a second-line biologic therapy in CD refractory to a first anti-TNF antibody. These results will be complemented for the congress by the inclusion of additional patients recruited into this registry.

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Neutropenia in inflammatory bowel disease patients on TNF inhibitors: A single-centre, retrospective cohort study

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Background: Tumor necrosis factor-α inhibitors (TNFi) have become the mainstay of treatment in moderate to severe cases of IBD. The haematological safety profile of these agents has been documented in multiple clinical trials and post-marketing registries.