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Background: We aimed to describe the real-world effectiveness of tofacitinib in ulcerative colitis (UC).
Methods: We analysed a retrospective, multi-centre cohort from six centres in the USA. UC patients started on tofacitinib (10 mg BID) for active disease were included. Primary outcome was clinical response (>50% reduction in symptoms) at Week 8 as determined by physician global assessment. Secondary outcomes included clinical remission (no symptoms) at Week 8, clinical response/remission at Week 16 and endoscopic healing (defined as Mayo endoscopic score ≤1 or absence of erosions/ulcerations) within 6 months of initiating tofacitinib. Descriptive statistics and Fisher exact tests were performed. Logistic regression assessed predictors of Week 8 response. A multi-variable model was created using backward elimination.
Results: A total of 123 UC patients were included with a median age of 38 years (IQR 27–46) and 5 years disease duration (IQR 2–9). 56.1% were men and 60.2% had pancolitis. 28.5% were bio-naïve while 40.7% had been exposed to both anti-tumour necrosis factor (anti-TNF) biologics and vedolizumab (VDZ). Ninety-six patients completed 8 weeks of tofacitinib. 60.8% had clinical response and 13.5% clinical remission at Week 8. At Week 16 (total n = 74), 55.4% had clinical response and 48.6% clinical remission. 64.9% (total n = 57) had endoscopic healing. A larger proportion of bio-naïve patients achieved clinical response with no difference between those exposed to both anti-TNF and VDZ or either alone (Table 1). Patients with prior exposure to 2 biologic classes (anti-TNF and VDZ) had lower rates of endoscopic healing compared with bio-naïve and 1 biologic class exposure (Table 1). Bio-naïve status and higher albumin were associated with greater chance of Week 8 response while pancolitis, baseline endoscopic Mayo score 3, concomitant steroids at start of tofacitinib, and male gender were associated with lower chance of response (Table 2). In multi-variable analysis, bio-naïve status (aOR 5.50, 95% CI 1.71–17.65), concomitant steroids (aOR 0.25, 95% CI 0.07–0.83), and male gender (aHR 0.25, 95% CI 0.08–0.83) were associated with Week 8 response.
Conclusions: Tofacitinib is effective at inducing clinical response in a real-world clinical setting. Prior exposure to biologics is associated with reduced chance of clinical response and endoscopic healing.

Table 1. Tofacitinib response rates by prior biologic exposure. (*p = 0.007, **p < 0.001, *** p < 0.001. Patients who discontinued tofacitinib before Week 8 or 16 were considered non-responders.)

Prior biologic exposure status	Clinical response Week 8*	Clinical response Week 16**	Endoscopic healing by 6 months***
Bio-Naïve	81.8% (total n = 33)	81.3% (total n = 32)	87.1% (total n = 31)
Prior exposure to 1 class (Anti-TNF or VDZ)	44% (total n = 25)	36.4% (total n = 22)	57.1% (total n = 14)
Prior exposure to 2 classes (Anti-TNF and VDZ)	55.3% (total n = 38)	35% (total n = 20)	16.7% (total n = 12)

Table 2. Baseline variables significantly associated with tofacitinib clinical response at Week 8 OR: odds ratio; CI: confidence interval.

Univariable logistic regression variable	OR (95% CI)	p-value
Bio-Naïve	4.50 (1.64–12.37)	0.004
Pancolitis (ref = limited colitis)	0.34 (0.14–0.86)	0.02
Albumin (g/dl)	2.63 (1.02–6.80)	0.046
Mayo endoscopic score 3 (ref=score 2)	0.27 (0.10–0.72)	0.01
Male (ref=female)	0.28 (0.11–0.70)	0.007
Concurrent steroids at start of tofacitinib	0.22 (0.08–0.58)	0.002

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Risk of long-term post-operative recurrence (POR) in Crohn's disease patients with a first postoperative normal endoscopic assessment under thiopurine prevention

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Background: Endoscopic post-operative recurrence (PORe) in Crohn's disease (CD) occurs between 30 and 50% after intestinal resection with anastomosis under preventive treatment within the first 6–12 months after surgery. The natural history of those patients who do not present PORe in the first endoscopy is not known and no recommendations about PORe monitoring beyond the first year after surgery in this population are available. Objective: To evaluate the natural history of the PORe in those patients who do not present PORe in the first endoscopic assessment.
Methods: From a specific database including all patients with CD who underwent resection with anastomosis at our institution since 1998 were prospectively included and followed, we identified those who initiated AZA within the first month after surgery and who underwent a first endoscopic assessment showing no PORe (Rutgeerts score i1) and who had at least a further endoscopic assessment. PORe was defined by Rutgeerts score i2, clinical POR (PORc) as the appearance of symptoms requiring changes in CD treatment, and surgical recurrence (PORs) as the need for a new resection. We defined a combined outcome (CO) as the occurrence of any of the following events: need for biological agents, PORc, or PORs during the follow-up.
Results: From 291 patients undergoing ileocolic resection and anastomosis, 94 patients (29%) had a first post-surgery endoscopy with Rutgeerts score i1. Regarding PORe risk factors: 52% penetrating pattern, 48% smokers at surgery, 12% previous resections and 22% perianal disease. Twenty-one per cent of patients received metronidazole in the first 3 months postop. The median follow-up was 84 (IQR 49–156) months. Thirty-seven per cent developed PORe (median 45 [IQR 30–60] months), of whom 65% were i2 and 35% were i3-i4, whereas only 14% PORc and 3.6% PORs. The accumulated probability of developing PORe during the follow-up was 0%, 16%, 40% and 50% at 1, 3, 5, and 10 years from the first postop endoscopic assessment, while the cumulative probability of CO was 1%, 2.5% 12%, and 19% at 1, 3, 5, and 10 years. No factors were associated with PORe.
Conclusions: The risk of PORe in patients without significant lesions in a first endoscopic assessment under thiopurine prevention is relatively low but steady over time, suggesting that monitoring remains necessary. In these patients PORs is very low in the long-term.