

Tofacitinib Adherence and Outcomes in Patients with Refractory Ulcerative Colitis



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BACKGROUND

Unlike other maintenance medications for moderate to severe ulcerative colitis (UC), tofacitinib (TFB), a janus kinase inhibitor, is the first maintenance medication administered orally.

AIM

To report adherence to tofacitinib in patients with UC and assess clinical, endoscopic and histologic outcomes.

METHODS

This is a retrospective study of UC pts started on TFB at a tertiary care inflammatory bowel disease (IBD) center.

Objective Outcome Measures:

- TFB Adherence (as measured by Proportion of Days Covered)
- TFB discontinuation, IBD-related hospitalizations, prednisone use, need for IBD-related surgery
- Endoscopic outcomes (if ≥ 60 d from TFB initiation)
- Clinical biomarkers (ESR and CRP)

Patient-Reported Outcomes:

- Simple Clinical Colitis Activity Index (SCCAI)
- Short IBD Questionnaire (SIBDQ)
- Patient Health Questionnaire (PHQ-9)

Statistical analysis: Wilcoxon signed rank matched pairs test.

Proportion of Days Covered (PDC)

PDC is an objective marker to assess medication adherence using fill data from our center's specialty pharmacy.

$$\text{PDC} = \frac{\text{total days covered by medication fills}}{\text{total days pt was prescribed TFB during the observation period}} \times 100 \%$$

PDC of 80-100% is a marker of adequate adherence.

RESULTS

Table 1. Patient Characteristics.

Total patients, n	43
Age (years, range)	36 (21, 70)
Follow-up Duration (days, range)	293 (37, 2038)
Time on TFB	203 (35, 2038)
Female (n, %)	25 (58.1%)
BMI (kg/m ² , range)	25 (16, 67)
Ulcerative Colitis Location (n, %)	43
Pancolitis	36 (83.7%)
Left-sided	6 (13.9%)
Proctitis	1 (2.3%)
Prior Biologic History (n, %)	43 (100%)
Multiple Biologic History (n, %)	36 (83.7%)
Vedolizumab	32 (74.4%)
Infliximab	31 (72.0%)
Adalimumab	25 (58.1%)
Ustekinumab	5 (11.6%)
Golimumab	1 (2.3%)
IVIG	1 (2.3%)

Table 2. Clinical and Endoscopic Outcomes.

Total Patients, n	43
Tofacitinib Discontinuation (n, %)	17 (39.5%)
Lack of response	10 (23.2%)
Loss of response	4 (9.3%)
Adverse effect	2 (4.6%)
Other	2 (4.6%)
Adverse effects (n, %)	4 (9.3%)
IBD-related Hospitalizations (n, %)	8 (18.6%)
Prednisone Use (n%)	14 (32.5%)
Surgical Intervention (Colectomy)	7 (16.2%)
Endoscopic Response	18/28 (64.2%)
Endoscopic Remission	13/28 (46.4%)
Histologic Remission	10/28 (35.7%)

RESULTS

Mean Proportion of Days Covered (PDC) was $95.7 \pm 8.0\%$ (n=20), with only one PDC less than 80%.

Table 3. Biomarkers and Patient-Reported Outcome Scores at tofacitinib initiation and follow-up.

	Baseline	Follow up	Days Follow up	p-value
Clinical Biomarkers (n=22)				
CRP	5.7 (0.3, 71)	1.5 (0.1, 38.4)	55 d (31, 196)	< 0.05
ESR	20.5 (1, 102)	14.5 (1, 206)	55 d (31, 196)	NS
Patient-Reported Outcomes (n=28)				
SIBDQ	47 (18, 66)	56 (21, 63)	47 (30, 196)	< 0.05
SCCAI	7 (0, 20)	4 (0, 9)	47 (30, 196)	< 0.05
PHQ	6 (0, 21)	2.5 (0, 13)	47 (30, 196)	0.07

CONCLUSION

- Patients in this cohort had refractory Ulcerative Colitis, with all patients having prior treatment with least one biologic agent prior to TFB (83% received two or more)
- Adherence to Tofacitinib, a twice daily oral medication, as measured by PDC was excellent
- TFB demonstrated significant improvement in CRP and patient-reported outcomes scores
- Patients on TFB had adequate endoscopic response and remission rates, though many patients required use of prednisone.