Tofacitinib for the Treatment of Pouch-Related Disorders: A Case Series

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Background

- Pouch-related disorders (including chronic pouchitis, cuffitis, or Crohn's-like disease of the pouch (CLDoP)) commonly occur among patients with refractory ulcerative colitis after ileal pouch-anal anastomosis (IPAA).
- The effectiveness of tofacitinib for pouch-related disorders after IPAA is poorly understood.

Aim

- We conducted a retrospective case series of patients receiving tofacitinib for the treatment of pouch-related disorders.

Methods

- **Design:** retrospective case series of adults prescribed tofacitinib for chronic pouchitis (CP), cuffitis, or Crohn's-like disease of the pouch (CLDP) at a large academic medical center after 1/1/2015.
- **Primary outcome:** clinical response determined by provider assessment at first clinical follow-up after tofacitinib initiation.
- **Secondary outcomes**: endoscopic response (determined by endoscopist assessment), tofacitinib discontinuation, need for oral antibiotics or corticosteroids, change in bowel frequency, resolution of rectal bleeding and urgency, IBD hospitalization, need for bowel surgery or ileostomy, and adverse events (AEs).
- **Analysis:** this study is descriptive

Conclusions

- The results of this case series do not support the use of tofacitinib for pouch-related disorders.
- Larger, prospective studies are needed to determine the efficacy of tofacitinib for these conditions.

Results

Table. Baseline characteristics and outcomes

Baseline Characteristics	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Pouch phenotype	Chronic pouchitis	Chronic pouchitis	Chronic pouchitis	Cuffitis	Cuffitis	CLDoP
Age at tofacitinib initiation, y	57	75	61	29	39	50
Sex	Female	Male	Female	Male	Male	Female
Race	Unavailable	White	White	White	Other	White
Ethnicity	Hispanic	Non-Hispanic	Unknown	Non-Hispanic	Non-Hispanic	Unknown
Age at IBD diagnosis, y	45	33	39	25	21	20
Age at colectomy, y	46	60	49	28	24	32
Reason for colectomy	Inflammation	Inflammation	Dysplasia	Inflammation	Inflammation	Inflammation
Initial tofacitinib dose, mg	10	10	20	20	20	20
Dose change, mg	n/a	n/a	n/a	n/a	n/a	10
Current smoking	No	No	No	No	Yes	No
Number of prior biologics	3	1	0	4	2	5
Number of prior anti-TNFs	2	0	0	3	1	1
Prior vedolizumab	No	Yes	No	Yes	Yes	Yes
Current antibiotics	No	Yes	Yes	No	No	Yes
Current oral prednisone or budesonide	Yes	No	No	No	No	Yes
Current immunomodulator	No	No	No	No	No	No
BMI, kg/m^2	23.4	22.7	17.6	27.9	29.3	24.6
BMs per 24 hours	5	12	4	12	6	12
Nocturnal BMs	No	Yes	No	Yes	Yes	Yes
Rectal bleeding	No	No	No	Yes	No	No
Urgency	No	Yes	No	Yes	No	No
Fistula	No	No	No	No	No	No
CRP, mg/L	13.5	n/a	2.2	4.0	3.5	3.1
Fecal calprotectin, ug/g	n/a	134.9	482.1	n/a	54.9	262.0
Albumin, g/dL	3.9	3.3	4.5	4.6	4.4	3.6
Pre-tofacitinib pouchoscopy impression	Ulcers in pouch	Mild erythema, congestion, and ulcers in pouch	Mild erythema and friability in J pouch	Mayo 3 cuffitis	Mayo 3 cuffitis	Erythema in j-pouch, superficial ulcers along anastomosis and blind limb, neo-TI strictures

Outcomes	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Clinical response at follow-up	Yes	No	No	No	No	No
Post-tofacitinib pouchoscopy impression	Ulcers in pouch	Normal pouch	n/a	Mayo 3 cuffitis	n/a	n/a
Endoscopic response	No	Yes	n/a	No	n/a	n/a
Days to discontinuation	2103	294	83	134	131	38
Reason for discontinuation	Patient self-discontinued out of safety concerns	Adverse events	Ineffective	Ineffective	Ineffective	Adverse events
Oral antibiotics or steroids at follow-up	No	No	Yes	Yes	No	Yes
Δ BMs per 24 hours (post-pre) at follow-up	-2	-4	+4	-4	0	0
Resolution of nocturnal BMs	n/a	Yes	n/a	No	No	No
Resolution of rectal bleeding	n/a	n/a	n/a	Yes	n/a	n/a
Resolution of urgency	n/a	No	n/a	No	n/a	n/a
Δ CRP (post-pre), mg/L	-6	n/a	+0.2	-0.9	-1.1	n/a
Δ Fecal calprotectin (post-pre), ug/g	n/a	n/a	n/a	n/a	-10.9	n/a
IBD hospitalization during follow-up	Yes	Yes	No	No	No	No
Surgery during follow-up	No	No	No	No	No	No
Adverse event during follow-up	n/a	C. difficile, pneumonia, and candida esophagitis	n/a	Cytomegalovirus cuffitis	Intersphincteric abscess	Dizziness, headaches, fatigue