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Real-World Ustekinumab Experience in Ileum-Dominant versus Colonic Crohn's Disease <sup>1</sup>Division of Gastroenterology & Hepatology, Department of Internal Medicine, UC Davis School of Medicine, University of California Davis, Sacramento, CA <sup>2</sup>Division of Biostatistics, Department of Public Health Science, UC Davis School of Medicine, University of California Davis, Sacramento, CA

## Introduction

- Crohn's disease (CD) presents with diverse phenotypes.
- Literature suggests that ileal or ileocolonic CD behaves differently than colonic CD.
- It remains unclear how different CD phenotypes affect response to therapy.

# Aim

• To compare the performance of ustekinumab in ileum-dominant and colonic CD.

# **Design/Sample**

- A single center, IRB-approved, retrospective review of adult CD patients on ustekinumab.
- Patients were stratified by ileal involvement: ileum-dominant (ileal and ileocolonic) and colonic
- Data was collected on disease duration, disease behavior, prior biologic therapy, concomitant immunomodulator, CD-related surgeries and hospitalizations, serum c-reactive protein (CRP), and endoscopic ulcers.
- Primary outcome was absence of ulcers on follow-up colonoscopy. The secondary outcomes included CRP, calprotectin, surgery, and hospitalization.

## Results

Table 1: Baseline Disease Characteristics of Patients with Ileum-Dominant and Colonic CD		
	lleum-Dominant CD (n=84)	Colonic CD (n=27)
Age at diagnosis, n, mean years		
+/- SD	84, 27.7 +/- 13.8	27, 37.6 +/- 17.00
Female gender, n, %	42, 50.0%	17, 63.0%
Tobacco use	16, 19.1%	2, 7.4%
Median Disease duration, years		
(25 <sup>th</sup> , 75 <sup>th</sup> )	10.8, (5.4, 20.1)	5.2 (2.1, 16.0)
Disease Behavior		
<b>B1, n, %</b>	25, 29.8%	13, 48.2%
B2, B3, or B2/B3, n, %	59, 70.2%	14, 51.9%
Perianal Disease, n, %	20, 23.8%	11, 40.7%
Prior anti-TNF use, n, %	76, 90.5%	21, 77.8%
0, n, %	8, 9.5%	6, 22.2%
1, n, %	18, 23.7%	12, 57.1%
2, n, %	50, 65.8%	4, 19.1%
3, n, %	8, 10.5%	2, 9.5%
4, n, %	0,0%	3, 14.3%
Prior anti-integrin use	18, 21.4%	10, 37.0%
History of prior Crohn's related		
surgery, n, %	43, 51.2%	12, 44.4%
Concomitant therapy (steroids or thiopurine/MTX), n, %		
	34, 40.5%	9, 33.3%

## **Key Findings**

- 84 patients with ileum-dominant CD and 27 patients with colonic CD were treated with ustekinumab.
- The median time to follow-up endoscopy was 13 months.
- Follow-up colonoscopy after ustekinumab therapy was ulcer-free in 45% of ileumdominant CD and 76% of colonic CD (p=0.02).
- Of patients with ulcers on endoscopy prior to starting ustekinumab, 24% of ileumdominant CD and 67% of colonic CD were ulcer-free (p=0.01) on follow-up colonoscopy.
- There were similar rates of hospitalizations and surgery and no significant differences in mean calprotectin and CRP between the two groups on follow-up after ustekinumab therapy.

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# Analysis

Chi-square tests (or Fisher's exact test) and two-sample t-tests (or Wilcoxon's rank sum test) were used to compare categorical and numeric variables between groups, respectively; analyses were performed using R Computing Software versions 3.6.1

## Summary

- This updated real-world experience of ustekinumab demonstrates higher rates of endoscopic healing among colonic CD when compared to ileumdominant CD.
- There were no significant differences in secondary outcomes between the two groups with therapy.
- Disease location may predict endoscopic healing by ustekinumab in CD.
- Further studies are necessary to expand our understanding of different CD phenotypes and their responsiveness to ustekinumab.