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Patient Characteristics, Disease Symptoms, and Treatment Patterns of Patients With Ulcerative Colitis and Crohn's Disease From the United States: Results From a Retrospective, Longitudinal Cohort Study

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Background

- Both ulcerative colitis (UC) and Crohn's disease (CD) are inflammatory bowel diseases with high burden of disease, including high rates of fatigue, disability, and health-related quality-of-life impairment[1]
- Treatment goals for both UC and CD have evolved from symptom control to prevention of disease progression and disability, and achieving disease clearance[2,3]
- Treatment options for moderate to severe UC and CD include conventional therapy (CT; 5-aminosalicylates [not recommended in CD], immunomodulators, corticosteroids) and advanced therapy (AT; biologic treatments and novel oral small molecules)[4,5]
- Although AT initiation in eligible patients can improve treatment outcomes, data show limited AT utilization in clinical practice[6,7]
- Real-world evidence is needed to elucidate patient journeys and clarify AT underuse in patients with UC and CD

Aim

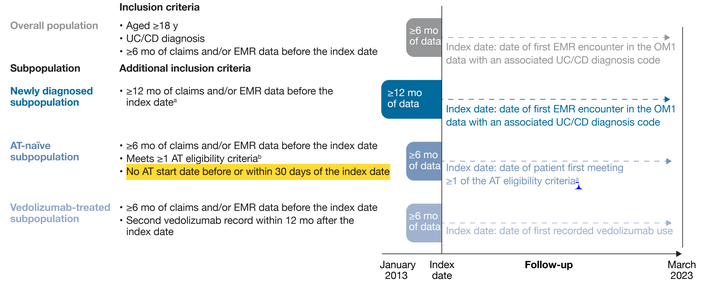
- To describe the patient characteristics and treatment patterns in a cohort of patients with UC and CD
- To describe disease symptoms over time in vedolizumab-treated patients from a real-world setting

Methods

Patient populations

- This was a retrospective, longitudinal cohort study in patients with UC and CD in the US who were included in the OM1 UC and CD PremiOM datasets from January 2013 to March 2023 (**Figure 1**)
  - The datasets were derived from deterministically linked, deidentified, individual-level healthcare claims and electronic medical record (EMR) data, enriched with variables extracted from unstructured clinical notes using natural language processing or technology-assisted manual content abstraction
- Patients aged ≥18 years who had a UC or CD diagnosis and had ≥6 months of claims and/or EMR data before the first EMR encounter in the OM1 dataset with an associated UC or CD diagnosis code were included in the overall cohort (**Figure 1**)
- Patients could be included in ≥1 of newly diagnosed, AT-naïve, and/or vedolizumab-treated subpopulations if they met additional criteria for inclusion into the specific subpopulation (**Figure 1**)

Figure 1. Study design



AT, advanced therapy; CD, Crohn's disease; EMR, electronic medical record; UC, ulcerative colitis.
[a]Patients with UC or CD diagnosis before the first EMR encounter date were excluded. [b]AT eligibility criteria[4,5,8] include steroid dependency and/or disease relapse and/or disease severity (severe disease for UC or moderate to severe disease for CD). Steroid dependency was defined as steroid (systemic steroids or budesonide) treatment for ≥3 months OR disease flare date ≤3 months after the date of stopping steroid treatment. Disease relapse was defined as increased corticosteroid dose (≥1 record for corticosteroids with a dose above the corticosteroid at initial corticosteroid start date within 3 months of initial corticosteroid start date) OR one of the following: hospital-based flare (hospitalization (admittance or discharge) with UC diagnosis or UC-related surgery), laboratory results-based flare (fecal calprotectin identified as abnormal [flagged as abnormal, outside reference range, or >250 µg/g] in patients with fecal calprotectin identified as normal or not measured in the previous 3 months), or clinician-reported flare (report of a relapse or flare in a clinical note). Severe UC was defined as endoscopic Mayo subscale score of 3/severe endoscopic disease activity (presence of ulcers) OR any of the following: physician global impression of severe disease, modified Mayo score of 7-9, or Truelove Wits definition (≥6 bowel movements per day AND blood in stool AND ≥1 marker of systemic toxicity [heart rate >90 beats per minute, temperature >37.8°C, hemoglobin <10.5 g/dL, or erythrocyte sedimentation rate >30]). Moderate to severe CD was defined as CD activity index ≥220 OR physician global impression of moderate to severe or severe disease OR stricture, fistula, or perianal disease.

- Patients were followed until the earliest of the end of study (March 2023) or end of available patient data
- Data on demographic and clinical characteristics, clinical outcomes (including disease symptoms and disease activity), and treatment patterns were collected
  - In treatment pattern analysis, combination (CT and AT) therapy was defined using an overlap period of ≥30 days

Statistical analysis

- Descriptive analyses were performed, with continuous variables summarized as mean±SD and categorical variables summarized as n (%)
- Analyses were performed using SAS version 9.4 or higher (Cary, NC, USA)

Results

Study population

- The overall population included 14,480 patients with UC and 14,934 patients with CD; the newly diagnosed subpopulation included 7209 patients with UC and 6097 patients with CD; the AT-naïve population included 4790 patients with UC and 5340 patients with CD; and the vedolizumab-treated population included 889 patients with UC and 927 patients with CD
- Baseline demographics and clinical characteristics of patients with UC and CD are shown in **Table 1** and **Table 2**, respectively

Table 1. Clinical characteristics of patients with UC

	Overall (N=14,480)	Newly Diagnosed (n=7209)	AT Naïve (n=4790)	Vedolizumab Treated (n=899)
Age, mean±SD, y	53.2±16.8	53.9±17.2	53.2±17.3	46.8±17.1
Sex, n (%)				
Female	8401 (58.0)	4250 (59.0)	2764 (57.7)	472 (52.5)
Male	6079 (42.0)	2959 (41.0)	2026 (42.3)	427 (47.5)
Race, n (%)				
White	8092 (55.9)	3594 (49.9)	2430 (50.7)	405 (45.1)
Black	681 (4.7)	297 (4.1)	212 (4.4)	28 (3.1)
Asian	236 (1.6)	115 (1.6)	65 (1.4)	11 (1.2)
Other	977 (6.7)	568 (7.9)	395 (8.2)	98 (10.9)
Unknown	4494 (31.0)	2635 (36.6)	1688 (35.2)	357 (39.7)
BMI, mean±SD, kg/m²	28.2±6.4	28.2±6.5	28.2±6.7	27.1±6.0
CCI, mean±SD	1.3±2.0	1.6±2.3	1.7±2.4	1.1±1.7
Disease extent, n (%)				
Proctitis	886 (6.1)	610 (8.5)	352 (7.3)	88 (9.8)
Left-sided colitis	401 (2.8)	269 (3.7)	228 (4.8)	76 (8.5)
Pancolitis	786 (5.4)	516 (7.2)	365 (7.6)	170 (18.9)
Unknown	12,407 (85.7)	5814 (80.6)	3845 (80.3)	565 (62.8)
Disease activity, n (%)				
Remission/no disease activity	105 (0.7)	49 (0.7)	64 (1.3)	40 (4.4)
Mild	120 (0.8)	77 (1.1)	59 (1.2)	13 (1.4)
Mild to moderate	26 (0.2)	17 (0.2)	16 (0.3)	8 (0.9)
Moderate	98 (0.7)	69 (1.0)	38 (0.8)	44 (4.9)
Moderate to severe	31 (0.2)	23 (0.3)	21 (0.4)	35 (3.9)
Severe	87 (0.6)	46 (0.6)	230 (4.8)	35 (3.9)
Unknown	14,013 (96.8)	6928 (96.1)	4362 (91.1)	724 (80.5)

AT, advanced therapy; BMI, body mass index; CCI, Charlson Comorbidity Index; UC, ulcerative colitis.

Treatment patterns

- In the overall population, CT was used more widely than AT for both the UC (**Figure 2**) and CD (**Figure 3**) cohorts at baseline
  - The most common CT types in the overall populations were 5-aminosalicylates (5-ASAs) for UC and steroids for CD
  - Although the clinical guidelines recommend against 5-ASA use in CD,[4] 5-ASA treatment at baseline was reported in 14.1% of the overall CD cohort
  - A notable proportion of vedolizumab-treated patients were receiving combination therapy with steroids at baseline
- In both UC and CD, less than half of AT-naïve patients initiated AT during the study (UC, 1543/4790 [32.2%]; CD, 2369/5340 [44.4%])
- Average time from meeting AT eligibility criteria to AT initiation among AT-naïve patients who initiated AT treatment exceeded 2 years in both UC and CD (mean±SD: UC, 755.6±767.7 days; CD, 760.7±775.9 days)

Outcomes over time in vedolizumab-treated patients

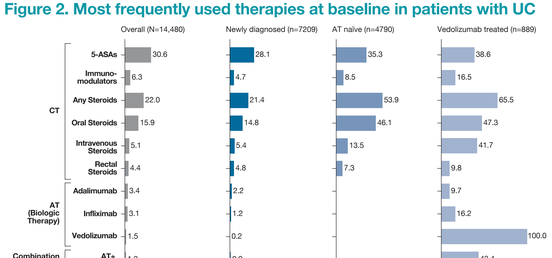
- In vedolizumab-treated patients, the proportions of patients reporting fatigue, diarrhea, and weight loss numerically decreased from baseline during the follow-up in both patients with UC and CD (**Figure 4**)
  - During the follow-up, stool frequency numerically decreased from baseline in vedolizumab-treated patients with UC and remained similar in patients with CD (**Figure 5**)

Table 2. Clinical characteristics of patients with CD

	Overall (N=14,934)	Newly Diagnosed (n=6097)	AT Naïve (n=5340)	Vedolizumab Treated (n=927)
Age, mean±SD, y	49.5±16.7	49.6±17.0	50.2±17.1	48.1±17.1
Sex, n (%)				
Female	9212 (61.7)	3738 (61.3)	3244 (60.7)	570 (61.5)
Male	5722 (38.3)	2359 (38.7)	2096 (39.3)	357 (38.5)
Race, n (%)				
White	8701 (58.3)	3110 (51.0)	2726 (51.0)	530 (57.2)
Black	902 (6.0)	315 (5.2)	316 (5.9)	35 (3.8)
Asian	149 (1.0)	67 (1.1)	40 (0.7)	8 (0.9)
Other	809 (5.4)	385 (6.3)	365 (6.8)	49 (5.3)
Unknown	4373 (29.3)	2220 (36.4)	1893 (35.4)	305 (32.9)
BMI mean±SD, kg/m²	28.0±6.8	28.1±6.7	28.1±6.9	26.8±6.6
CCI, mean±SD	1.2±1.8	1.2±1.9	1.4±2.1	1.4±1.9
Disease extent, n (%)				
Gastroduodenal	96 (0.6)	70 (1.1)	79 (1.5)	14 (1.5)
Ileum	1092 (7.3)	614 (10.1)	673 (12.6)	144 (15.5)
Colon	1373 (9.2)	732 (12.0)	648 (12.1)	108 (11.7)
Ileocolon	606 (4.1)	303 (5.0)	364 (6.8)	85 (9.2)
Gastroduodenal + colon	25 (0.2)	11 (0.6)	16 (0.3)	<5
Gastroduodenal + ileocolon	10 (0.1)	<5	7 (0.1)	<5
Unknown	11,732 (78.6)	4363 (71.6)	3553 (66.5)	571 (61.6)
Disease activity, n (%)				
Remission/no disease activity	77 (0.5)	39 (0.6)	55 (1.0)	28 (3.0)
Mild	106 (0.7)	74 (1.2)	35 (0.7)	10 (1.1)
Mild to moderate	7 (0.0)	6 (0.1)	11 (0.2)	5 (0.5)
Moderate	46 (0.3)	32 (0.5)	26 (0.5)	25 (2.7)
Moderate to severe	19 (0.1)	6 (0.1)	12 (0.2)	11 (1.2)
Severe	51 (0.3)	21 (0.3)	74 (1.4)	26 (2.8)
Unknown	14,628 (98.0)	5919 (97.1)	5127 (96.0)	822 (88.7)

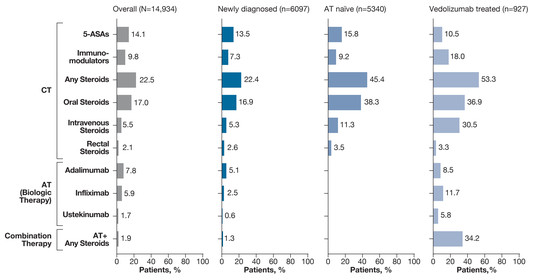
AT, advanced therapy; BMI, body mass index; CCI, Charlson Comorbidity Index; CD, Crohn's disease.

Figure 2. Most frequently used therapies at baseline in patients with UC



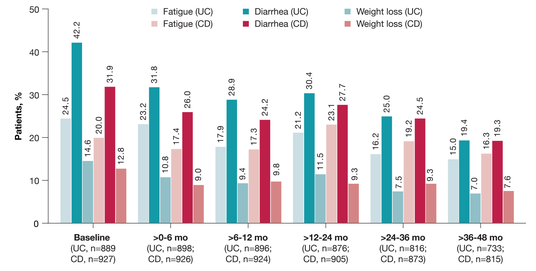
Only the 10 therapies most frequently used in the overall cohort at baseline are shown.
5-ASA, 5-aminosalicylate; AT, advanced therapy; CT, conventional therapy; UC, ulcerative colitis.

Figure 3. Most frequently used therapies at baseline in patients with CD



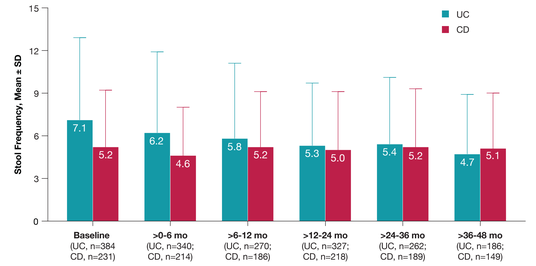
Only the 10 therapies most frequently used in the overall cohort at baseline are shown.
5-ASA, 5-aminosalicylate; AT, advanced therapy; CD, Crohn's disease; CT, conventional therapy; UC, ulcerative colitis.

Figure 4. Disease symptoms over time in vedolizumab-treated patients with UC and CD



CD, Crohn's disease; UC, ulcerative colitis.

Figure 5. Stool frequency over time in vedolizumab-treated patients with UC and CD



CD, Crohn's disease; UC, ulcerative colitis.

Conclusions

- **These real-world data provide additional insights into the patient journeys of patients with UC and CD**
- **Close to one-third of patients in both the UC and CD cohorts were eligible for but not treated with AT, potentially indicating undertreatment. This is further highlighted by the finding that fewer half of patients in the UC and CD cohorts eligible for but not treated with AT initiated AT during the study, with an average time to AT initiation in those who did initiate AT treatment exceeding 2 years**
- **Clinical outcome conclusions and the feasibility for future research to estimate proportions of patients achieving remission are limited due to a lack of systematic coding of disease activity and symptoms in real-world clinical practice**
- **In vedolizumab-treated patients, numerical decreases over time were observed in the proportions of patients with UC and CD reporting fatigue, diarrhea, and weight loss; furthermore, a numerical decrease in stool frequency over time was observed in vedolizumab-treated patients with UC**

References

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Disclosures

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