CHARACTERISTICS, MEDICATION, AND HEALTHCARE UTILIZATION OF CROHN'S DISEASE PATIENTS STRATIFIED BY SHORT-CDAI STATUS: DESCRIPTIVE RESULTS FROM THE IBD PLEXUS AND IQVIA LINKED DATASET

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BACKGROUND

- Crohn's disease (CD) is a life-long chronic inflammatory disorder of the gastrointestinal tract[1]
- Although clinical guidelines recommend treatment with biologic agents for patients with inadequate response to conventional therapy, treatment failure rates with biologics are high during both the induction and maintenance periods[2,3]
- A better understanding of the characteristics, treatment patterns, and healthcare resource utilization (HCRU) of patients who do not achieve remission is crucial to allow identification of these patients and early intervention
- Current real-world studies of the characteristics, treatment patterns, and HCRU of patients with CD rarely include disease severity measures due to limited available longitudinal databases with robust clinical and long-term administrative claims data

OBJECTIVE

- To describe a cohort of CD patients stratified by disease severity at enrollment in the unique Crohn's & Colitis Foundation (CCF) and IQVIA claims–linked dataset and describe their baseline demographics, clinical characteristics, medication use, and HCRU

METHODS

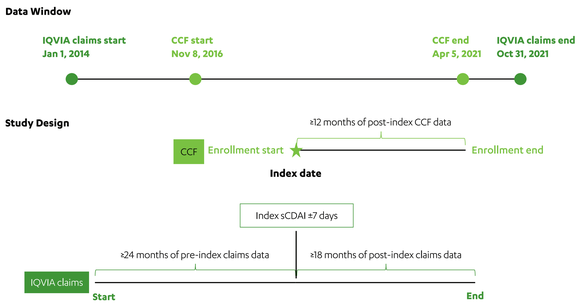
Study Design

- This retrospective analysis used data from the CCF Study of a Prospective Adult Research Cohort (SPARC) IBD and IBD Qorus® databases linked with IQVIA Longitudinal Prescription Data (LRx) and Medical Claims Data (Dx; Research Triangle Park, NC) from January 1, 2014 through October 31, 2021 (**Figure 1**)
  - The CCF SPARC and Qorus® databases are structured electronic registries containing clinical and patient-reported outcomes data from patients diagnosed with inflammatory bowel disease (IBD) in the United States, collected via questionnaires
  - The IQVIA LRx is based on retail pharmacy data, capturing co-prescribing as well as new, switch, and repeat prescriptions
  - The IQVIA Dx consists of pre-adjudicated claims collected from payers or healthcare providers that are based on diagnostic codes
- Index date was defined as enrollment in CCF

Study Population

- Adult patients (≥18 years old) who had a diagnosis of CD, ≥24 months of IQVIA data prior the index date, and ≥12 months of CCF and ≥18 months of IQVIA data after the index date were included in the analysis
- CD patients were stratified into 3 disease activity cohorts based on index (±7 days) short Crohn's Disease Activity Index (sCDAI) scores
  - Remitters (R): sCDAI <150
  - Non-remitters and non-moderate–severe (nRnMS): sCDAI = 150 to 219
  - Moderate–severe (MS): sCDAI ≥220

Figure 1. Study Design



Measures

- Baseline demographic and clinical characteristics were collected from CCF at the index date
- Prior medication use was collected during the 6-month period prior to the index date and categorized into mutually exclusive groups based on a hierarchical index as follows: 1) biologics; 2) immunosuppressants (IMS); 3) 5-aminosalicylates (5-ASA); 4) other supportive care (ie, antibiotics, corticosteroids [CS], or opioids); and 5) no current therapy
- History of HCRU was collected during the 24-month period prior to the index date and included emergency room (ER) visits, hospitalization, CD-related surgery, and office visits (due to the limited number of surgeries, the history of past surgery was not restricted to 24 months)

Data Analyses

- Descriptive analyses were performed
- The R cohort was separately compared with the nRnMS and MS cohorts
- Statistical comparisons between continuous variables were conducted using Wilcoxon Rank Sum tests; categorical variables were compared using Fisher's exact tests

RESULTS

Demographic and Disease Characteristics

- A total of 1756 patients were included in the analysis; 1027, 361, and 368 were in the R, nRnMS, and MS disease activity cohorts, respectively (**Table 1**)
- Mean age was approximately 43 years across cohorts
- Time since CD diagnosis was >10 years in 54.5%, 52.9%, and 58.4% of the R, nRnMS, and MS cohorts, respectively

Table 1. Baseline Demographic and Disease Characteristics[a,b]

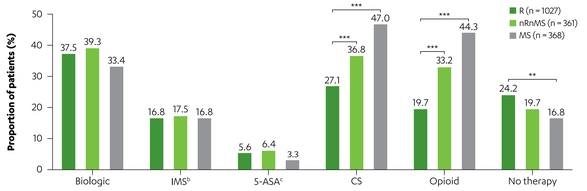
Characteristic	R (n = 1027)	nRnMS (n = 361)	MS (n = 368)
Female sex, n (%)	545 (53.1)	230 (63.7)***	250 (67.9)***
Age, years, mean (SD)	42.9 (15.2)	43.2 (15.2)	43.1 (13.9)
Age at first diagnosis, years, n (%)			
≤11	60 (5.8)	25 (6.9)	25 (6.8)
12-17	161 (15.7)	50 (13.9)	50 (13.6)
18-39	557 (54.2)	206 (57.1)	210 (57.1)
≥40	202 (19.7)	66 (18.3)	63 (17.1)
Unknown/missing	47 (4.6)	14 (3.9)	20 (5.4)
Race, n (%)			
Black or African American	79 (7.7)	43 (11.9)	29 (7.9)
Asian	69 (6.7)	24 (6.6)	22 (6.0)
Unknown/missing/other	103 (10.0)	37 (10.2)	42 (11.4)
White	776 (75.6)	257 (71.2)	275 (74.7)
Ethnicity, n (%)			
Hispanic or Latino	11 (1.1)	3 (0.8)	6 (1.6)
Not Hispanic or Latino	894 (87.0)	311 (86.1)	318 (86.4)
Unknown/missing	122 (11.9)	47 (13.0)	44 (12.0)
Smoking within the last 3 months			
Yes	32 (3.1)	15 (4.2)	31 (8.4)***
No	302 (29.4)	107 (29.6)	106 (28.8)
Unknown/missing	693 (67.5)	239 (66.2)	231 (62.8)
Time since diagnosis, years, mean (SD)	14.4 (10.9)	14.7 (11.1)	15.8 (11.9)*
sCDAI at enrollment, mean (SD)	96.2 (28.1)	182 (20.3)***	302 (77.7)***
Abdominal pain	0.3 (0.5)	1.0 (0.7)***	1.7 (0.9)***
Stool frequency	2.6 (1.4)	4.4 (2.4)***	8.1 (4.6)***
General well-being	0.1 (0.3)	0.9 (0.5)***	1.7 (0.9)***
CD phenotype, n (%)			
Both stricturing and penetrating	105 (10.2)	36 (10.0)	42 (11.4)
Non-stricturing and non-penetrating	371 (36.1)	124 (34.3)	115 (31.3)
Penetrating and non-stricturing	129 (12.6)	47 (13.0)	47 (12.8)
Stricturing and non-penetrating	218 (21.2)	77 (21.3)	92 (25.0)
Unknown/missing	204 (19.9)	77 (21.3)	72 (19.6)

SD, standard deviation.
[a]Percentages may not add up to 100% due to missing/unknown values for some variables.
*[b]P value thresholds: *P <0.05 vs R; ***P <0.001 vs R.*

Medication Utilization

- The use of biologics was similar among cohorts (37.5%, 39.3%, and 33.4% of patients in R, nRnMS, and MS cohorts, respectively; **Figure 2**)
- The use of CS and opioids was high across cohorts, with significantly greater use observed in patients with more active disease

Figure 2. Medication Use During the 6-month Pre-index Period[a]

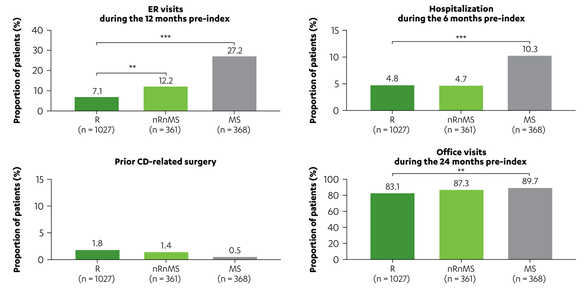


*[a]P value thresholds: **P <0.01; ***P <0.001.*
[b]IMS users who had never used a biologic.
[c]5-ASA users who had used neither a biologic nor an IMS.

Healthcare Resource Utilization

- ER visits and hospitalization were highest in the MS cohort (**Figure 3**)
- Overall, 24 patients had ≥1 prior CD-related surgery, with 14 patients having multiple surgeries; prior CD-related surgery was lowest in the MS cohort
- Office visits were similar among cohorts

Figure 3. HCRU During the Pre-index Period[a]



*[a]P value thresholds: **P <0.01; ***P <0.001.*

CONCLUSIONS

- This study utilized a unique longitudinal dataset linked to administrative claims data to describe the characteristics of 3 cohorts of patients with CD classified by sCDAI disease activity thresholds
- CD patients who were not in remission generally had more severe disease features, and greater medication and HCRU than those in remission
- Future research evaluating relationships between disease characteristics, treatment patterns, and poor outcomes during follow-up are warranted

References

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Disclosures

MS, FY, and MM are employees of Janssen Global Services, LLC. KL is an employee of Janssen Business Technology Commercial Data Sciences. YZ was an employee of Janssen Business Technology Commercial Data Sciences at the time of the study.

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