Prescribing Patterns of Novel Oral Therapies for Ulcerative Colitis in a Large Integrated Delivery Network

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BACKGROUND

Inflammatory bowel disease (IBD) is a chronic and relapsing inflammatory disease which include ulcerative colitis (UC) and Crohn's disease (CD). Although the etiology of IBD remains unclear, knowledge of inflammatory processes has facilitated therapeutic development in recent years. These have resulted in improved health outcomes and a decreased need for surgery.[1] However, there remains a need for oral agents beyond aminosalicylates, steroids, and thiopurines. Recently, Janus kinase (JAK) inhibitors such as upadacitinib and tofacitinib and sphingosine 1-phosphate (S1P) receptor modulators such as ozanimod and etrasimod have been approved in the United States for the treatment of UC. [2,3,4,5]

Limited real-world evidence is available regarding prescribing patterns and rates of discontinuation in these therapies. Although JAK inhibitors are approved for use after failure of one or more anti-TNFα agents in the United States, studies from a US claims database and real-world cohort in the United Kingdom have shown that there might be effectiveness in those who are biologic-naïve.[6,7]

On the other hand, there are currently no guidelines available incorporating the use of S1P receptor modulators.[8] Results from the Phase 3 trials indicate efficacy in both biologic-naïve and biologic-experienced patients with UC, therefore, clinicians' choice on placement within the treatment algorithm with S1P receptor modulators can vary widely.

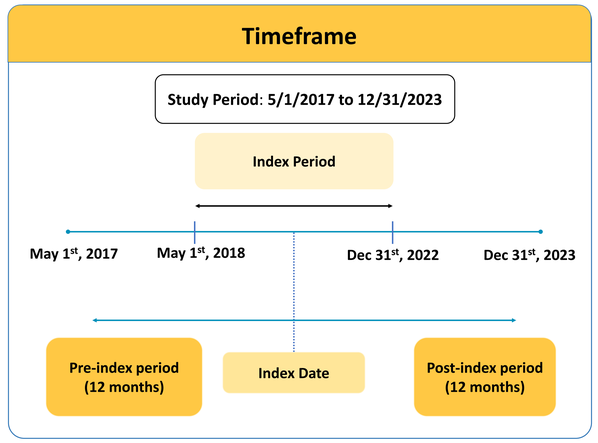
OBJECTIVE

The objective of this study is to identify prescribing patterns and time to discontinuation of novel small molecule oral therapies in patients with UC.

METHODS

Study Design:

- Retrospective review of electronic health records
- Pre- and post-index periods were limited to 1 year before and after the index date



- Index date is defined as the date of the first order for eligible medications
- Discontinuation is defined as ≥90-day gap in prescription orders (inclusive of refills)

Inclusion Criteria:

- Age ≥18 years
- Diagnosed with UC identified using ICD-10 codes K51.XX
- Prescribed a novel oral small molecule therapy (upadacitinib, tofacitinib, or ozanimod) between 5/1/2018 and 12/31/2022

Exclusion Criteria:

- Patients with >1 indication for included novel oral therapies

Data Analysis:

- Baseline characteristics are summarized using descriptive statistics and prescribing patterns visualized using a Sankey plot
- A survival curve was constructed using unadjusted Kaplan-Meier estimates

RESULTS

Table 1. Patient demographics

Baseline Characteristics	Number of Patients (n=71)
Age, mean (SD)	38 (12.7)
Female (n, %)	34 (47.8)
Race (n, %)	
White	50 (70.4)
Black or African American	9 (12.7)
Asian	4 (5.6)
Other/Unknown	8 (11.2)
Ethnicity (n, %)	
Hispanic or Latino	8 (11.2)
Not Hispanic or Latino	62 (87.3)
Unknown	1 (1.4)
Insurance type (n, %)	
Commercial	64 (90.1)
Medicare	4 (5.6)
Medicaid	1 (1.4)
Other	2 (2.8)
Medication (n, %)	
Tofacitinib	50 (70.4)
Upadacitinib	16 (22.5)
Ozanimod	5 (7.0)
Discontinuation before 1-year (n, %)	23 (32.4)

Figure 1. Prescribing patterns before initiation and after discontinuation of novel oral small molecule therapies

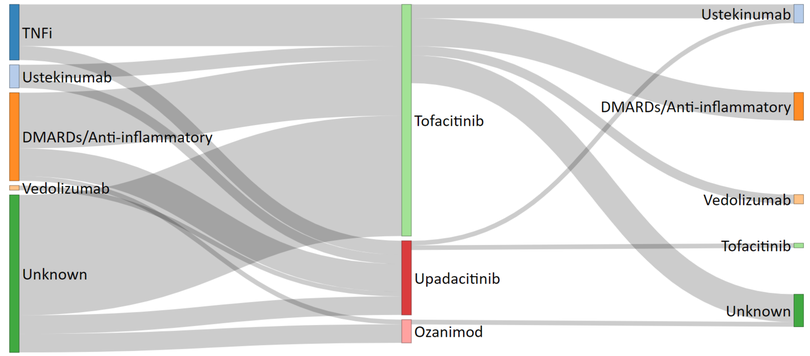
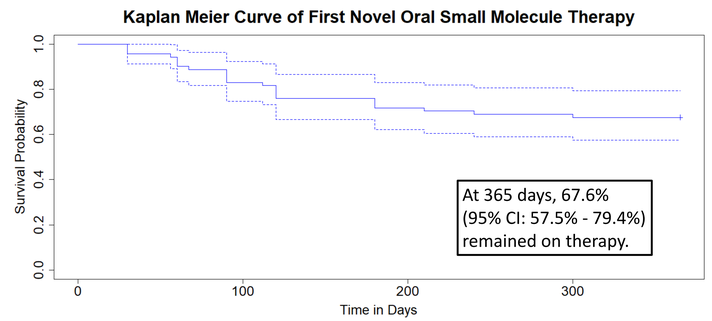


Figure 2. Time to discontinuation of first prescribed novel oral small molecule therapy



LIMITATIONS

- Order level data was obtained from the EHR for this analysis; therefore, patients may not have been using therapies as prescribed
- Reasons for discontinuation were not documented in discrete fields
- A limited timeframe used in the pre- and post-index period led to large amounts of missing data in treatment history and therapy switches

DISCUSSION/CONCLUSION

- Most patients did not discontinue their oral therapy before 1 year, consistent with other real-world effectiveness and persistence studies on upadacitinib and tofacitinib[6,9]
- Prescribing patterns show approximately 25% of the included patients having used biologics prior to transitioning to tofacitinib and upadacitinib, however, this may be underestimated in the data set due to the limitations stated above
- Large amounts of missing treatment history in the pre-index period can signal that there continues to be an unmet need for new therapies for patients who are in remission or non-responders and/or unable to tolerate biologics
- Future studies should elicit greater insight into real world effectiveness and safety to help guide optimal positioning of new UC therapies in different populations

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DISCLOSURES

All authors are investigators of studies sponsored by Sanofi-Aventis and Pfizer but not in connection with this study.

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