Treatment journey among patients with moderate ulcerative colitis in the United States: TARGET-IBD

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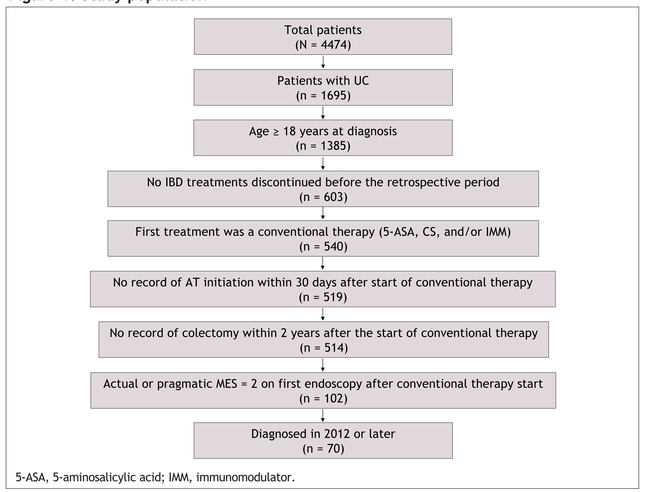
Introduction

- Patients with moderate ulcerative colitis (UC) have a high prevalence of corticosteroid (CS) use despite guidelines and known adverse effects[1-3]
- The purpose of this project was to assess treatment patterns and associations of patient characteristics with the initiation of advanced therapy (AT) among patients with moderate UC

Methods

- TARGET-IBD (ClinicalTrials.gov identifier, NCT03251118) is a noninterventional, longitudinal cohort study of patients receiving care for inflammatory bowel disease (IBD) at 34 US academic or community gastroenterology sites
- Patients from TARGET-IBD were included if they met the following inclusion criteria:
  - Adults with UC diagnosed in 2012 or later (post biologic (bio) therapy launch)
  - Receiving conventional therapy as a first treatment
  - No AT initiation (bio/Janus kinase inhibitor [JAKi]) within 30 days of starting conventional therapy
  - Mayo Endoscopic Score (MES) = 2. When unavailable, a "pragmatic" MES definition was used based on presence/severity of inflammation and ulcerations/erosions
- A Sankey diagram of the first 5 treatments from start of conventional therapy was generated
- Fine and Gray sub-distribution hazard regression models were used to estimate hazard ratios (HRs) and 95% confidence intervals (CIs) for AT initiation

Figure 1. Study population

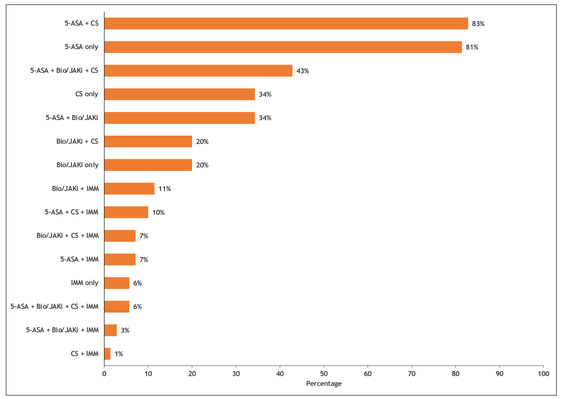


5-ASA, 5-aminosalicylic acid; IMM, immunomodulator.

Results

- Of 1695 patients with UC, 70 met the inclusion criteria (**Figure 1**)
- Overall, patients were a median of 36 years old, male (51%), non-Hispanic White (73%), and had a median body mass index of 25.9 kg/m^2. The majority of patients were privately insured (79%) and were receiving care at academic sites (66%)
- Conventional therapies were the most prevalent combination, with over 80% of patients receiving CS at some point during treatment (**Figure 2**)
- A Sankey diagram of treatment journeys depicted high cycling between combinations of 5-ASA, IMM, and CS after initial treatment (**Figure 3**)
- In the multivariable model (**Figure 4**), the likelihood of starting AT was significantly lower for Hispanic or non-White patients compared with non-Hispanic White patients (HR, 0.26; 95% CI, 0.09-0.77), and lower for patients aged 40-64 years at diagnosis compared with those aged 18-39 years (HR, 0.49; 95% CI, 0.23-1.06), and higher for those treated at academic sites compared with community sites (HR, 1.80; 95% CI, 0.92-3.53)
- The likelihood of starting AT was higher for patients with extensive disease compared with patients with proctitis, although this was not statistically significant (HR, 1.19; 95% CI, 0.54-2.63) (**Figure 4**)

Figure 2. Treatment combinations among patients with moderate UC



Note: Totals exceed 100 as patients could have multiple lines of therapy.

Among patients with moderate UC, treatment patterns show high levels of cycling between various combinations of 5-aminosalicylic acid, immunomodulators, and corticosteroids

Figure 3. Treatment journey of patients with moderate UC

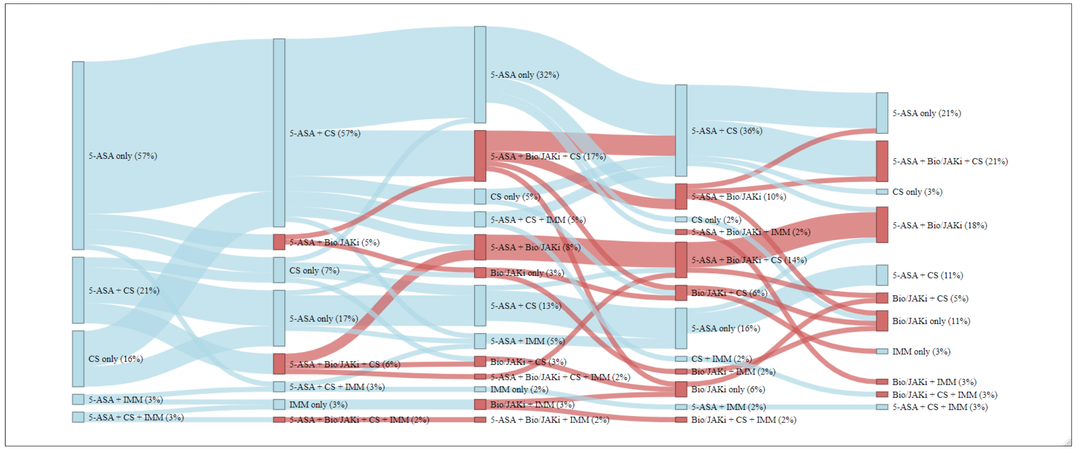
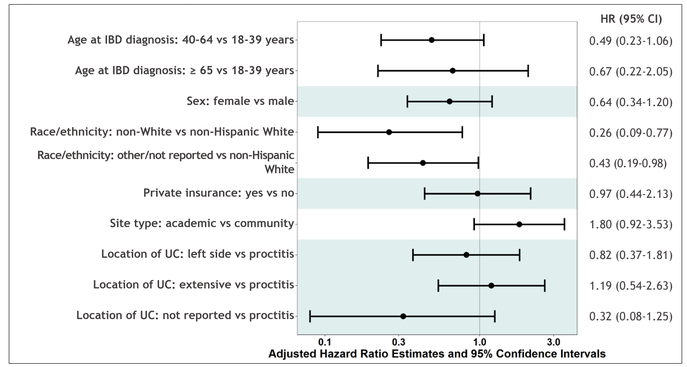


Figure 4. Association of patient and disease characteristics with AT initiation



Limitations

- The sample size is limited due to the treatment and endoscopy requirements in this analysis. Examining treatment patterns of patients with moderate UC in a larger cohort over a longer period of time would provide a more comprehensive understanding in this understudied patient population

Conclusions

- Treatment patterns show high cycling between various combinations of 5-ASA, IMM, and CS
- Even patients with extensive disease did not have a significantly greater likelihood of initiating an AT
- These treatment patterns and associations help to characterize patients with moderate UC, an often-overlooked population, but also emphasize healthcare disparities that require attention

References

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Acknowledgments

- The authors would like to acknowledge the patients and families who made this study possible, and the investigators and research staff associated with TARGET-IBD. TARGET-IBD is a study sponsored by Target RWE, headquartered in Durham, NC, USA
- TARGET-IBD is supported in part by funding from Bristol Myers Squibb. All authors contributed to and approved the presentation
- Editorial support was provided by Parexel, funded by Bristol Myers Squibb

Declaration of interests

ELB served as a consultant for Target RWE. MR served on advisory boards or as a consultant for AbbVie, Afrasigma, Allergan, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly, Genentech, Gilead, Janssen, Miraca Labs, Pfizer, Prometheus, Salix, Seres, Takeda, TARGET PharmaSolutions, and UCB. SS and HAA are employees and/or shareholders of Bristol Myers Squibb. DG, HLM, and JMC are employees of Target RWE. ML has nothing to declare. MCD served as a consultant for Arena, AbbVie, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, Pfizer, Prometheus Labs, Prometheus Biosciences and Takeda, and is a shareholder for Trellus Health. DTR has received grant support from Takeda, and has served as a consultant for AbbVie, Altrubio, Bellatrix Pharmaceuticals, Boehringer Ingelheim Ltd., Bristol Myers Squibb, Syneos, Dizal Pharmaceuticals, Galapagos, Ichnos Sciences S.A., InDex Pharmaceuticals, Iterative Health, Janssen Pharmaceuticals, Lilly, Pfizer, Prometheus Biosciences, Reistone, and Takeda.

Presented at the American College of Gastroenterology (ACG) 2023 Annual Scientific Meeting; October 20-25, 2023; Vancouver, BC, Canada

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