# Rates of Disease-Related Hospitalization and Colectomy in Real-World Patients with Ulcerative Colitis on Anti-TNF Agents: Evidence from a Systematic Review

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Abstract ID#: 121009

## Background

Ulcerative colitis (UC) is a chronic idiopathic inflammatory bowel disease (IBD) of the colon that causes continuous mucosal inflammation starting in the rectum and extending to the more proximal colon, with variable extents.

Anti-TNF agents (ATAs) are generally the first-line biological therapy in UC patients who have failed treatment with corticosteroids and/or immunomodulators.

Despite the compelling evidence on efficacy and safety of ATAs from clinical and real-world studies, there is lack of evidence on the patients with non-response/loss of response with ATAs who undergo either treatment switch or colectomy/surgery.

## Objective

We assessed the rates of UC-related hospitalization and colectomy among patients on ATAs in real-world UC patients.

## Methodology

A systematic literature review was conducted using comprehensive searches in Embase and Medline databases to identify real-world studies published in English during 2005–January 2022.

Studies were included if conducted in biological-naïve UC patients who initiated ATAs in first-line biological therapy, had ≥50 patients, and published as full manuscripts.

Exclusion criteria were mixed population, <50 patients, conference abstracts and non-English articles.

## Results

Of the 2593 records retrieved from literature, 29 were included providing 27 unique studies. Illustrated the inclusion of the studies in PRISMA flow chart (Fig. 1). [1-9]

Included studies were from Europe (n=15), Korea (n=5), Canada (n=3), US, and Japan (n=2 each). The study design was retrospective (n=19) and prospective observational (n=7).

The follow-up duration ranged from 10 weeks to 5.8 years. Baseline characteristics were presented in Table 1.

UC-related hospitalization was reported in 7 studies, with 7–32% of patients being hospitalized in these studies (Fig. 2).[4, 5, 6, 9]

All studies reported UC-related colectomy, with rates of colectomy/surgery varied between 0% and 42% of patients.

Colectomy rates by individual ATA were 1–42% (infliximab), 0–8% (adalimumab), and 1–8% (golimumab). Four studies comparing infliximab and adalimumab showed no significant difference in colectomy rates (Fig. 3).[1-9]

## Conclusion

This review revealed that a considerable proportion of biologics-naïve UC patients in real-world clinical practice undergo colectomy/surgery while on/after treatment with ATAs, whereas data on UC-related hospitalization is limited in literature.

## Conflict of interest

Gautam R, Gutta D, Prasanna R, Rai MK are employees of EVERSANA India.

## References

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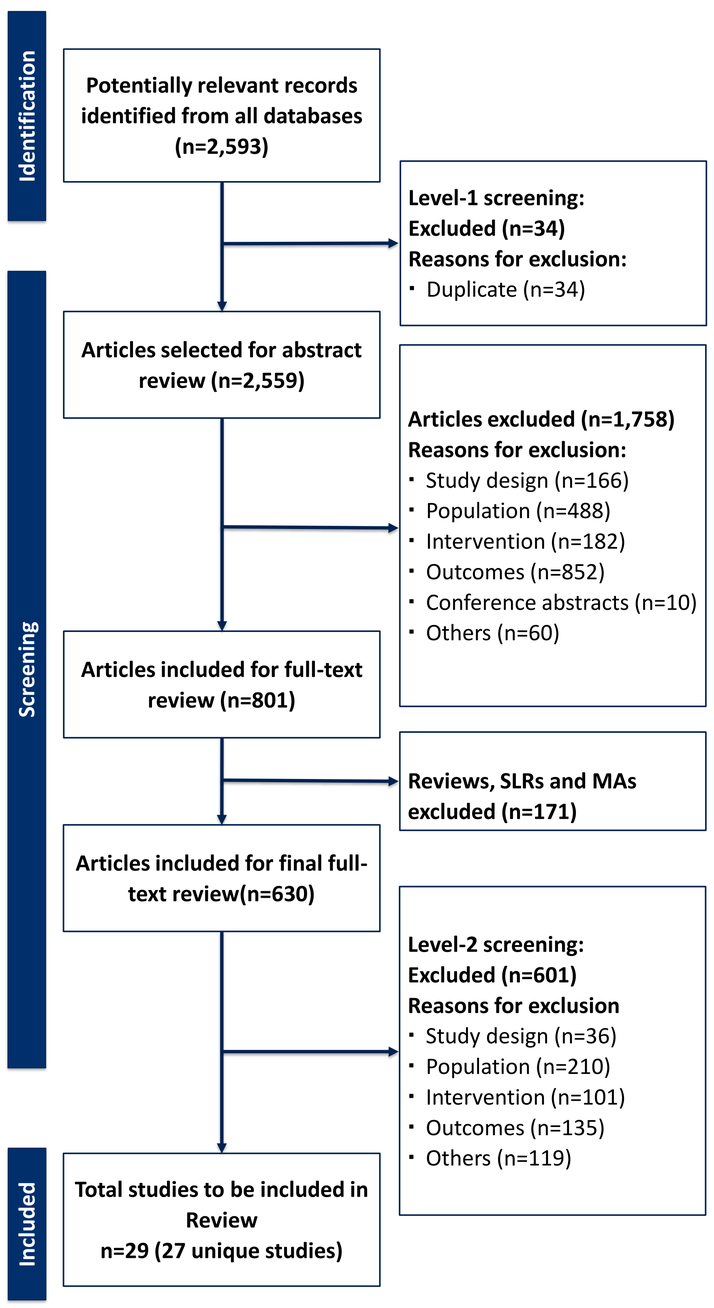
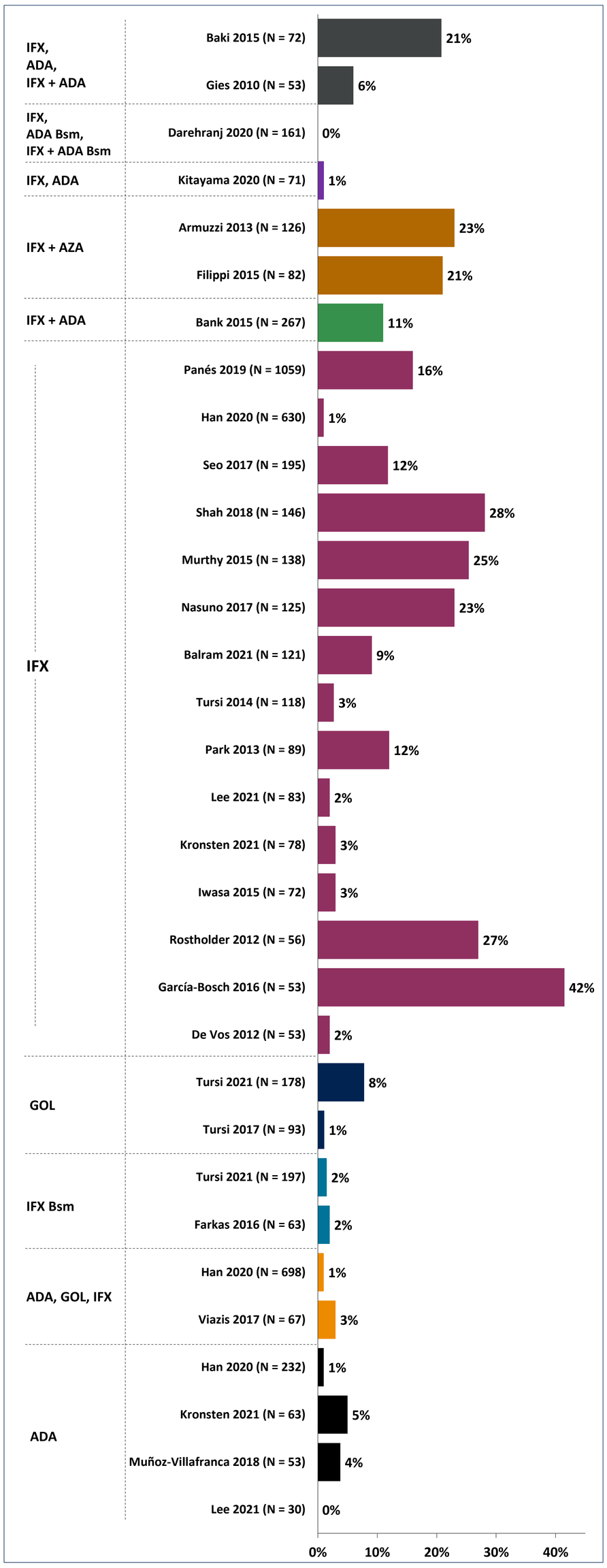
## Table. 1 Baseline characteristics

| Characteristic | |
|---|---|
| **Study related (No. of studies):** | |
| **Treatments assessed:**<br>Infliximab originator<br>Adalimumab<br>Golimumab<br>Infliximab biosimilar<br>ATAs as group | <br>18<br>6<br>2<br>2<br>5 |
| **Patient related:** | |
| Age (median, range) | 26-45 years |
| Gender ratio (%, range) | Male: 46-64 |
| Disease duration (median, range) | 3-8 years |
| **Concomitant medications (%, range):**<br>Steroids<br>Immunomodulators<br>5-ASA | <br>42-89<br>13-78<br>31-97 |

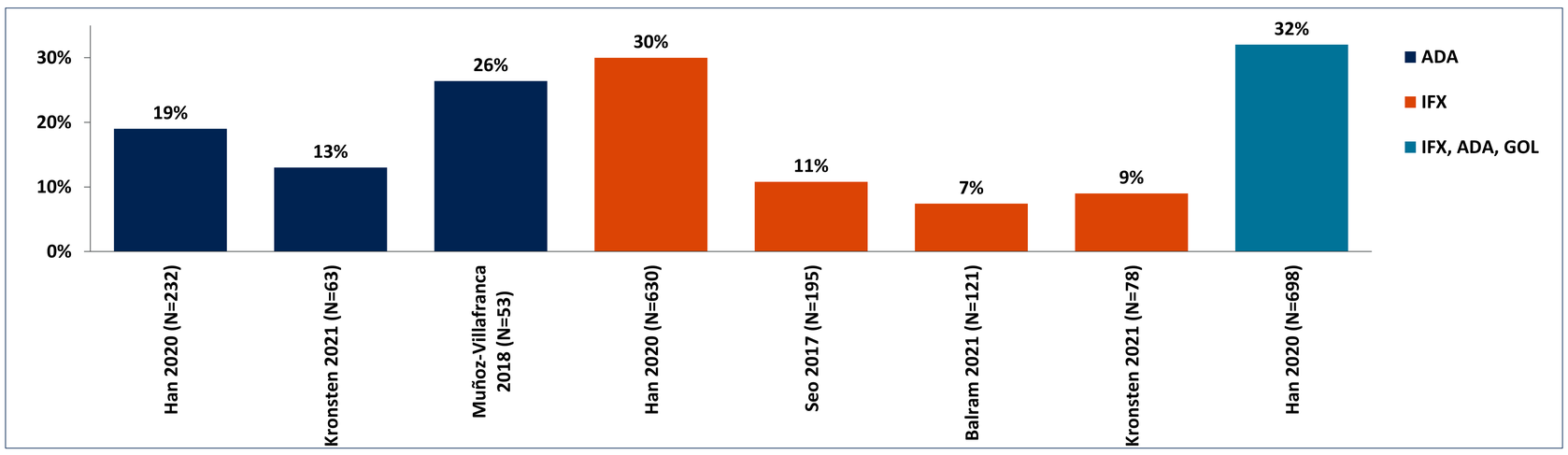
## Fig.1 PRISMA flow chart




## Fig. 3 Percent of patients requiring UC-related Surgery/Colectomy during the study




## Fig. 2 Percent of patients requiring UC-related Hospitalization




## Abbreviations

5-ASA – 5-Amino Salicylic acid; ADA – Adalimumab; ADA Bsm – Adalimumab Biosimilar; AZA – Azathioprine; GOL – Golimumab; IFX – Infliximab; IFX Bsm – Infliximab Biosimilar.