Evaluating Inadequate Therapy Response in Ulcerative Colitis Adult Patients: A Retrospective Analysis of German Health Claims Data on Advanced Therapy Initiation

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INTRODUCTION

Ulcerative colitis (UC) is a chronic inflammatory bowel disease of the colon and rectum, leading to significant morbidity and reduced quality of life[1]. In Germany, about 160,000 individuals are affected[2], with a standardized prevalence of 5.3 per 1,000 in 2019[3]. Despite the availability of advanced therapies, treatment outcomes may remain suboptimal, with many patients requiring frequent dose adjustments and therapy switches[4].

High treatment failure rates among patients with active UC[5] indicate a need to identify patients for whom a new advanced therapy may improve clinical prognosis.

OBJECTIVE

This study aimed to identify and quantify the prevalent and incident UC patient population in Germany, as well as patients who show inadequate response to their first advanced therapy using real-world German claims data.

METHODS

Database and study design:

- Research database of anonymized health claims 'German Analysis Database for Evaluation and Health Services Research' (DADB)[6]
  - Data from 15 German statutory health insurances (SHI), from ~4.1 million patients, representative of German population.
- Study time period from 1-Jan-2015 to 31-Dec-2022.

Patient selection:

Table 1: Population selection criteria	2021*
1) Persons in the DADB database (≥18y)	2,426,311
2) Diagnosis M2Q K51.X (ICD-10-GM)	12,767
3) Full health insurance coverage calendar year prior to year of UC diagnosis	12,406
4) At least one prescription of UC therapy after UC index diagnosis	8,799
5) No diagnosis of Crohn's disease and other specific diseases within 365 days preceding index treatment date = UC treated study population	7,077
6) Pre-observation period of at least 12 months before index treatment date	7,044
7) Index treatment agent can be determined (multiple prescriptions on index date excluded)	6,859
8) Patients with first advanced treatment	347

M2Q K51.X, *a confirmed outpatient or inpatient secondary UC diagnosis in at least two quarters or as one inpatient primary diagnosis*; UC, ulcerative colitis.

* 2021 was selected as a reference year to illustrate the population selection.

Analysis:

- Data analysis tools: Microsoft SQL Server, R, Excel
- Extrapolation to German SHI population
- Prevalence and incidence of UC and UC-treated population
- Indicators of inadequate response were observed for 12 months following prescription of advanced therapy):**

Table 2: indicators of inadequate response	
1.	Prolonged use of CS
2.	Augmentation
3.	Discontinuation
4.	UC-related hospitalization
5.	Therapy switch
6.	Dose escalation
7.	UC-related surgery
8.	Prescription of anti-diarrheal medication

CS, corticosteroids; UC, ulcerative colitis

** For a more detailed definition for the indicators of inadequate response, see the QR code linking to our publication.

Read our publication submission (preprint) scanning the QR code below

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RESULTS

Prevalence and incidence of ulcerative colitis in Germany

Adult UC prevalence increased slightly from 0.45% (95% CI, 0.44% to 0.46%) to 0.53% (95% CI, 0.52% to 0.54%), while the prevalence of UC-treated patients rose from 0.31% (95% CI, 0.30% to 0.32%) to 0.39% (95% CI, 0.38% to 0.39%). Incidence rates for total UC and UC-treated patients remained steady at around 0.04% and 0.025%, respectively.

However, incidence estimates were slightly lower in 2022 (total UC incidence: 0.034%, 95% CI: 0.032% to 0.037%) compared to 2017 and 2018 (Figure 1A). In 2021, adult UC prevalence increased with age, peaking in the 60-64 age group. Gender differences showed higher prevalence among younger females, while males had higher prevalence in middle and older age groups (Figure 1B).
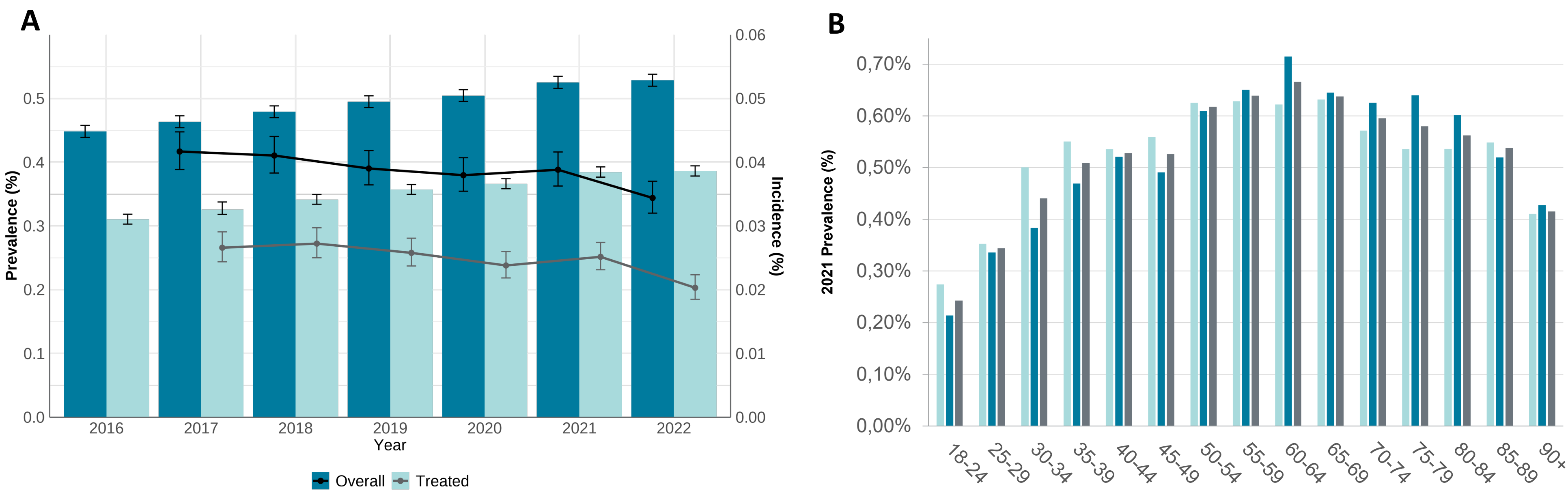

FIGURE 1: Adult prevalence and incidence of UC (overall UC population and UC-treated population) in the German SHI population by year. Prevalence is indicated by the bar plots and incidence is indicated by the line plots [A], and UC prevalence by age and gender group in the German SHI population, 2021 [B].

Inadequate response to the first advanced therapy

In 2021, 71.2% of patients starting their first advanced UC treatment showed at least one indicator of inadequate response (overall average: 78.8%). Additionally, 48.9% exhibited a multifactorial inadequate response with ≥2 indicators (overall average: 55.3%), and 25.7% had ≥3 indicators (overall average: 31.4%) (Figure 2A).

From 2016 to 2021, the most common signs of inadequate response were prolonged corticosteroid use (46.2%), augmentation with conventional therapies (43.9%), and therapy discontinuation (38.8%) (Figure 2B).
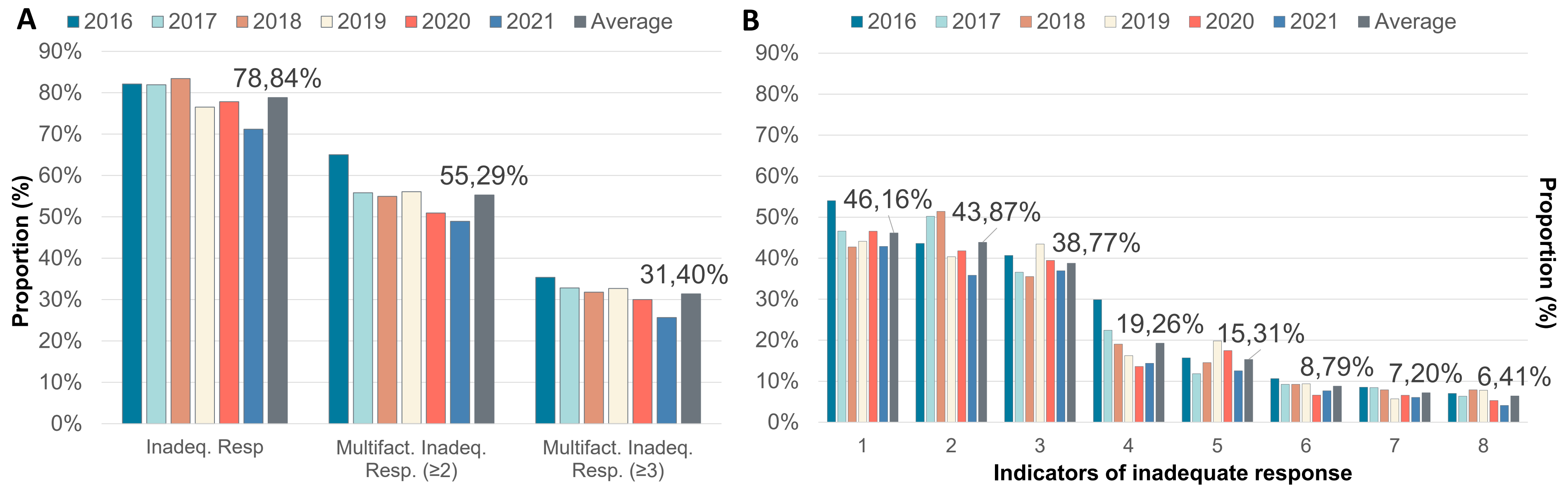

FIGURE 2: Proportion of patients showing inadequate response to first advanced treatment based on presence of ≥1, ≥2, or ≥3 indicators (multifactorial inadequate response) [A], and proportion of patients showing individual indicators of inadequate response [B]. Patients excluded due to incomplete follow-up time (< 12 months): N=4 (2016), 16 (2017), 6 (2018), 17 (2019), 19 (2020), 13 (2021). CS, corticosteroids; Rx, prescription; UC, ulcerative colitis. The numbers on the x-axis correspond to the indicators stipulated in Table 2.

CONCLUSIONS

- Our study provides current data on the epidemiology of UC in Germany (2015-2022) and inadequate therapeutic response among patients on their first advanced treatment in the current treatment landscape.
- Understanding patterns of inadequate response to UC advanced therapy may help identify patients who could benefit from a change in therapy to improve long-term outcomes.

References

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