

# COMPARISON OF PATIENTS IN ROUTINE CLINICAL PRACTICE AND PATIENTS INCLUDED IN RANDOMIZED TRIALS OF DRUGS FOR INFLAMMATORY BOWEL DISEASE: DISEASE COURSE AND TREATMENT OUTCOMES

Jurij Hanžel<sup>a,b</sup>, Katja Krupenko<sup>b</sup>, Jonas Podnar<sup>b</sup>

<sup>a</sup>Department of Gastroenterology, University Medical Center Ljubljana, Ljubljana, Slovenia

<sup>b</sup>Faculty of medicine, University of Ljubljana, Ljubljana, Slovenia

**BACKGROUND:** New advanced drugs for the treatment of chronic inflammatory bowel disease (IBD) are being tested in randomized clinical trials. Previous Slovenian studies have shown that only one-third of IBD patients in everyday clinical practice are eligible for inclusion in randomized clinical trials. This calls into question the transferability of clinical trial results to clinical practice.

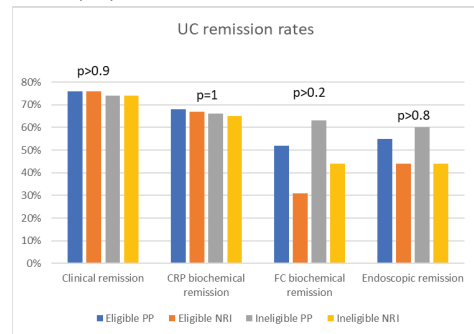
**AIM:** Determine differences between trial eligible and ineligible patients.

**METHODS:** The clinical study is retrospective and comparative. The sample consisted of adult patients who were treated at the chronic inflammatory bowel disease consortium in Ljubljana in 2022. We obtained data on demographic and clinical characteristics, target therapy replacement, surgeries, hospitalizations, glucocorticoid initiation, and deaths within one year after the consortium, as well as data on remission of different types one year after the council. We compared the data of patients suitable for inclusion with the data of those unsuitable.

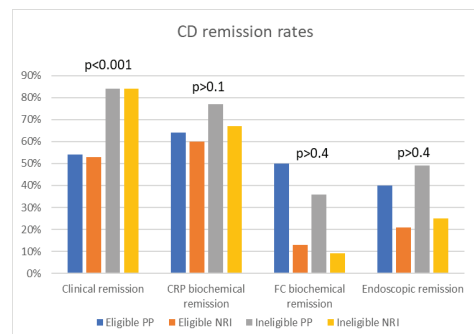
**RESULTS:** We analyzed data from 111 patients with ulcerative colitis (UC) and 142 patients with Crohn's disease (CD). No significant demographic or clinical differences were found. Analysis of treatment outcomes is shown in graphs 1 and 2, for UC and CD respectively.

Similar analysis was performed for disease course and is shown in graphs 3 and 4.

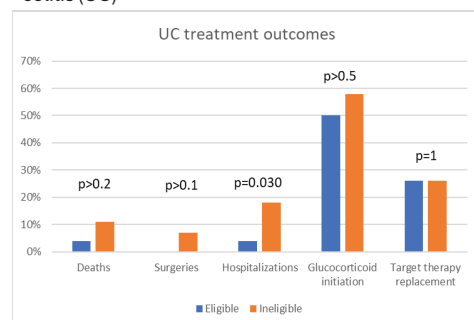
Graph 1: Comparison of remission rates in ulcerative colitis (UC)



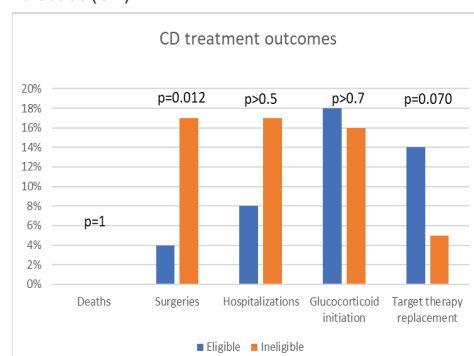
Graph 2: Comparison of remission rates in Crohn's disease (CD)



Graph 3: Comparison of outcomes in ulcerative colitis (UC)



Graph 4: Comparison of outcomes in Crohn's disease (CD)



**CONCLUSIONS:** Trial eligible and trial ineligible patients with IBD don't differ in clinical and demographic characteristics. Real world use of biologics does not show inferior efficacy, with only minor differences in safety between trial eligible and ineligible.