

TREATMENT EFFICACY TO RISANKIZUMAB IN CROHN'S DISEASE PATIENTS WITH AND WITHOUT PRIOR USTEKINUMAB EXPOSURE

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1. BACKGROUND AND IMPORTANCE

Risankizumab (anti-IL23) and **Ustekinumab** (anti IL-12/23) are approved treatments for active **Crohn's Disease** (CD). Given the increasing use of sequential biologic therapies in CD, evaluating the role of Risankizumab (RZB) after Ustekinumab (USK) is **clinically relevant**.

2. AIM AND OBJECTIVES

Describe baseline characteristics and assess the **efficacy** of RZB in patients with active CD, including both anti-IL23-naïve individuals and those previously treated with USK, in real-world clinical practice at a tertiary hospital.

3. MATERIALS AND METHODS

- Population: all CD patients treated with RZB.
- Period: November 2023-September 2025.
- Collected variables: age, sex, previous treatments.

Efficacy was evaluated in patients completing **≥24 weeks of treatment** by comparing median **Stool Frequency** (SF) and **Faecal Calprotectin** (FC) levels **before and after** RZB using descriptive and comparative statistics.

Data were obtained from electronic medical records and hospital prescription software.

4. RESULTS

- **50 patients** (52% female).
- Median age **53 years** (21-73).
- Prior biologic therapies: 49 anti-TNF α , 18 Ustekinumab, 8 Vedolizumab, 5 Upadacitinib.
- Median SF/day before and after RZB: 4 (Interquartile range [IQR] 2-6) vs 3 (IQR 1-6).

- Median FC/day before and after RZB: **629 μ g/g** (IQR 276-2000) vs **323 μ g/g** (IQR 83-1890).

A trend toward FC reduction in anti-IL-23 naïve patients was observed (**not statically significant, $p > 0.05$**).

- One-year persistence: 91.7% (33/36 evaluable)

- 6 patients discontinued after a median of 51 weeks (IQR 24-59): inadequate clinical-biochemical response (5/6) or adverse events (1/6). 3 had prior Ustekinumab.

No significance difference in discontinuation rates was observed anti-IL23-naïve vs prior-Ustekinumab groups (9.4% vs 16.7%, $p = 0.446$).

- Treatment intensification was required in 22% overall (10/50 every 4 weeks; 1/50 every 6 weeks): 39% (7/18) prior-Ustekinumab vs 12.5% (4/32) anti-IL23-naïve.

It was **significantly higher** previously exposed patients (Relative risk 3.11; 95% confidence interval 1.08-8.95; $p = 0.031$).

3. CONCLUSION AND RELEVANCE

Prior Ustekinumab exposure was associated with **poorer response** to Risankizumab, requiring more frequent dose intensification. Further studies are needed to confirm these findings and clarify whether the number of previous treatment lines influences therapeutic outcomes.

