VANDERBILT HEALTH | Specialty Pharmacy

Risankizumab Dose Escalation in Patients with Crohn's Disease

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BACKGROUND

- Patients who do not achieve optimal response at standard dosing of biologic therapies or lose response over time often benefit from escalated doses of biologic therapies to manage moderate to severe Crohn's disease (CD).
- Currently, no data exists on dose escalating risankizumab, an interleukin-23 inhibitor recently approved for the treatment of moderate to severe CD.

PURPOSE

This cohort study aimed to describe patient characteristics, insurance access, and response to therapy in patients prescribed risankizumab more frequently than the FDA-approved subcutaneous (SQ) maintenance dosing of 180mg or 360mg every 8 weeks.

METHODS

Setting	Vanderbilt Inflammatory Bowel Disease Clinic- large academic medical center in the Southeastern United States serving approximately 10,000 patients
Design	Retrospective single-center cohort study
Sample	Patients with CD initiated on and received at least one escalated dose of risankizumab between June 2022 and July 2023 with follow-up evaluation before 10/03/2023
Data Source	Electronic Heath Record - Epic

211
Patients initiated on risankizumab

12
Patients with at least 2 doses of escalated dosing by 10/03/2023

Key Findings

- **Heavily treatment-experienced** patients with previous dose escalations and severe CD may require risankizumab dose escalation
- **Additional insurance authorization** is commonly **required** for escalated doses
- Most patients **improved or remained stable** on the escalated dosing, showing promise for risankizumab dose escalation outcomes
- As of 12/12/2023, there have been 50 additional referrals for escalated dosing at the study site

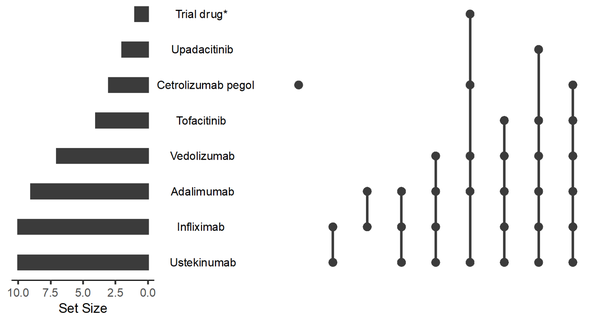
RESULTS

Table 1. Cohort Characteristics

ID	Gender	Age (yrs)	BMI (kg/m²)	Prior Surgical Intervention	Advanced Therapies Tried (#)	Previously Escalated Medications (#)	Years Since Diagnosis	Dosing Frequency	Reason for Escalation	Response to Therapy
1	Female	22	23.5	Yes	2	0	15	Q4W	High fecal cal, pouch inflammation	No
2	Female	24	21.1	No	5	3	15	Q6W	Persistent symptoms	Improved
3	Male	30	21	Yes	6	3	6	Q6W	Persistent symptoms	Improved
4	Male	30	25.1	No	2	1	7	Q4W	Persistent symptoms	Improved
5	Female	36	22.1	No	6	1	17	Q6W	Inflammation on endoscopy	Stable
6	Female	38	34.9	Yes	4	1	27	Q4W	Flare requiring hospitalization	No
7	Female	45	24.7	No	3	2	13	Q6W	Persistent symptoms	No
8	Female	51	25.3	No	1	1	17	Q6W	Moderate colitis on pathology	Improved
9	Female	52	30.1	No	2	2	3	Q4W	Inflammation on endoscopy	Improved
10	Male	52	26.7	Yes	4	1	18	Q4W	High fecal cal, pouch inflammation	Stable
11	Female	64	29.2	Yes	6	2	11	Q6W	Inflammation on endoscopy	Stable
12	Male	69	20.9	Yes	4	2	48	Q6W	Inflammation on CTE, symptoms	Improved

Abbreviations: yrs: years; BMI: body mass index, Q6W, every 6 weeks; Q4W, every 4 weeks; CTE, computed tomography enterography; cal, calprotectin

Figure 1. Previous Medication Upset Plot



- Infliximab, adalimumab, and ustekinumab were commonly tried and failed prior to dose escalation
- Patients had tried and failed a median of 4 (IQR 2-5) advanced therapies
- *Pizzicato Trial

Figure 2. Dose Escalation Timing

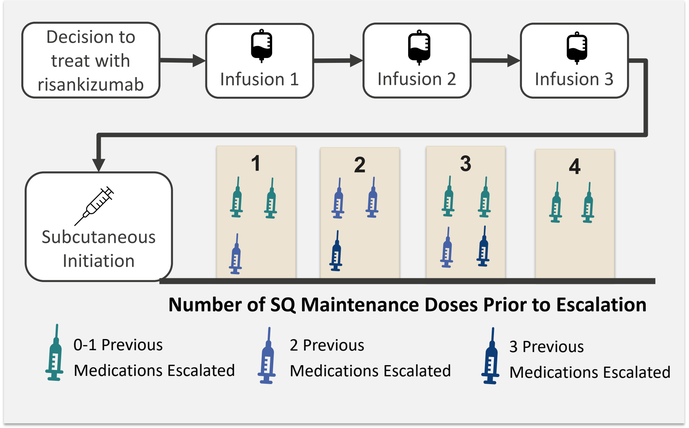


Figure 3. Medication Access Pathway

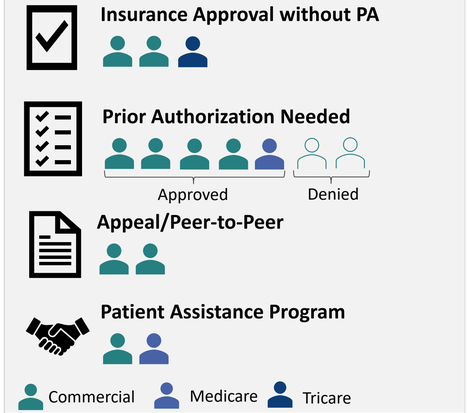
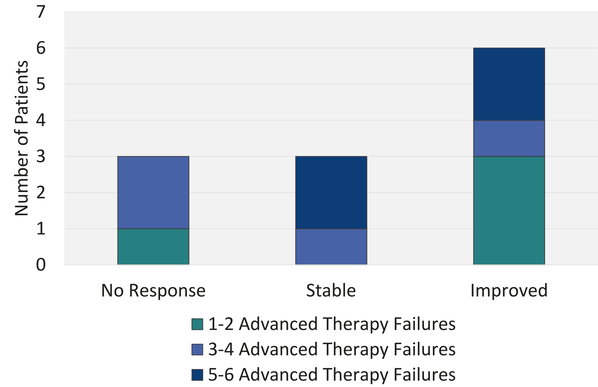


Figure 4. Response to Therapy (n=12)



- Median follow-up from escalation was 88 days (IQR 71-103)

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