The Use of Risankizumab-rzaa for Crohn's Disease in Home Infusion Patients

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Background

Crohn's disease is a chronic and progressive disease that causes inflammation in the gastrointestinal tract, affecting any part of the tract from the mouth to the anus. According to the National Institutes of Health, it is estimated that more than half a million people live with Crohn's disease in the United States. Traditional therapies including immunosuppressants and biologics have demonstrated varying degrees of effectiveness but are also often associated with adverse effects affecting the quality of life for the patients.[1]

The 2022 FDA approval of risankizumab-rzaa for Crohn's Disease offers a targeted treatment approach for adults with moderately to severely active Crohn's disease. This third approved indication for risankizumab-rzaa is supported by safety and efficacy data from two induction and one maintenance clinical trials evaluating risankizumab-rzaa in moderately to severely active Crohn's disease, ADVANCE, MOTIVATE and FORTIFY.[2-5] While the use of risankizumab-rzaa provides a new hope for improved patient outcomes, its real-world efficacy and safety profile in the context of home infusion has not been thoroughly investigated.

Purpose

The primary objective of this study was to assess the usage of risankizumab-rzaa for Crohn's disease in home infusion patients with a specific focus on identifying and analyzing adverse drug reactions (ADRs) reported by participants. This research sought to provide evidence-based insights into the clinical utility of risankizumab-rzaa in a home infusion environment that can inform treatment decisions and enhance patient care for Crohn's disease management. The secondary objective of this research study was to assess patient tolerability of risankizumab-rzaa.

Methods

This study was a retrospective, multi-center, chart review for a period of 12 months. Patients aged 18 or older with a confirmed diagnosis of Crohn's disease were included. Baseline demographics and ADRs were reviewed. Patients were also categorized as naïve to injectable biologic therapy vs non-naïve to biologic injectable therapy for Crohn's disease.

Disclosures

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Edna Truong; Maria Giannakos: Nothing to disclose.

Table 1:

Patient Demographics	
Gender (n = 727)	
Male	318 (43.7%)
Female	409 (56.3%)
Age Range (years) (n = 727)	
18-24	94 (12.9%)
25-34	148 (20.4%)
35-44	168 (23.1%)
45-54	138 (19%)
55-64	111 (15.3%)
≥ 65	68 (9.3%)
Switched to risankizumab from other biologic therapies (n = 727)	
Yes (Switched)	567 (78%)
No (Naive)	160 (22%)
Induction dose completion (n = 727)	
1 dose	18 (2.5%)
2 doses	20 (2.8%)
Completed (3 doses)	688 (94.7%)
Adverse drug reactions (ADRs) (n = 727)	
Yes	57 (7.8%)
No	670 (92.2%)
ADR and induction completion (n = 57)	
Complete	43 (75.4%)
Incomplete	14 (24.6%)

Figure 1:

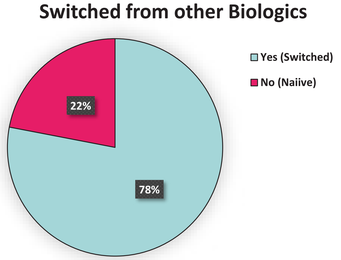
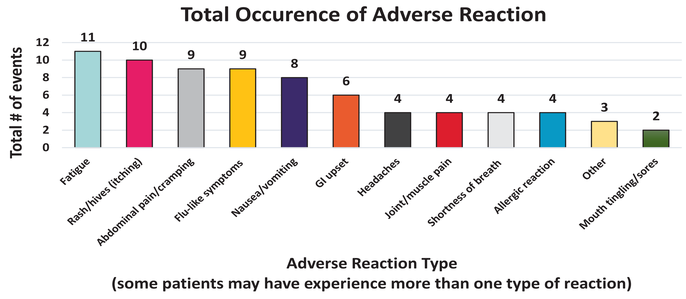


Figure 2:



Results

A total of 727 patients met the inclusion criteria and were evaluated for this retrospective analysis. As shown in *Table 1*, 318 (43.7%) male and 409 (56.3%) female were included with an average age of 43 (18-88 years). 567 (78%) patients had received another biologic injectable previously for their indication of Crohn's before switching to risankizumab *(Figure 1)*.

Induction doses consisted of risankizumab 600 mg administered by intravenous infusion over a period of at least one hour at Week 0, Week 4, and Week 8. 688 patients (94.7%) completed all 3 doses, and 38 patients (5.3%) did not for various reasons. Of the 38 patients that did not complete the induction doses, 14 patients (1.9%) had stopped due to adverse events. This data was similar to results from the ADVANCE and MOTIVATE clinical trials with approximately 2% of patients having adverse events leading to discontinuation of drug.

Approximately 7% (n = 57) of patients experienced ADRs, of which 4 patients required the use of an anaphylaxis kit contents, specifically diphenhydramine (PO/IV) or hydration bolus. Use of epinephrine was not required. Common ADRs were in line with product labeling and included fatigue, rash/hives, abdominal pain/cramping, flu-like symptoms, nausea/vomiting, GI upset, headaches, joint/muscle pain, shortness of breath, etc. *(Figure 2)*.

Discussion

This study showed a significant proportion of patients had prior exposure to other biologic therapies. The high completion rate of induction doses, with 94.7% (n= 668) of patients receiving all three doses, suggests high tolerability of risankizumab. The study reports that 7% (n = 57) of patients experienced ADRs and only 1.9% (n = 14) of patients discontinued treatment due to ADRs, emphasizing the overall tolerability of risankizumab.

Conclusion

In conclusion, this study contributes to the limited data available on risankizumab in the home infusion setting. The high completion rate of induction doses and low discontinuation rate due to ADRs indicate that risankizumab is generally well-tolerated, in a diverse patient population of patients with moderate-to-severe Crohn's disease.

References

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