Poster ID: 00024-PS

Medicarte
gestión farmacoterapéutica avanzada

SPiN 2025
8TH CONGRESS OF THE SKIN INFLAMMATION & PSORIASIS INTERNATIONAL NETWORK
2-4 JULY 2025
PARIS - FRANCE

Absolute risk of therapeutic failure or adverse drug reactions associated with Guselkumab or Risankizumab

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Background: Over the last decade, there has been a therapeutic revolution in treatment options for plaque psoriasis. Anti-IL23 has demonstrated favorable safety and efficacy in individual clinical studies in adults with moderate to severe plaque psoriasis.

Objective: To estimate the absolute risk of therapeutic failure (TF) or adverse drug reactions (ADR) associated with Guselkumab or Risankizumab in patients diagnosed with plaque psoriasis.

Methods: A retrospective, observational, multicenter pharmacovigilance study was conducted in patients diagnosed with plaque psoriasis who were treated with Guselkumab or Risankizumab. Data were collected from patients between 2020 and 2024. The events of interest were TF or ADR. For the time-to-event analysis, the starting point was the date of medication initiation, and the endpoint was the treatment termination date recorded in the pharmacovigilance program. The Hazard Ratio for TF or ADR was calculated using Kaplan-Meier survival analysis, and the incidence rate (IR).

Results: A total of 492 patients were included, of whom 61.55% (n=303) were treated with Guselkumab. The IRs of ADRs were 3.1 and 2.9 per 1,000 person-months for Guselkumab and Risankizumab, respectively, while the IRs of TFs were 2.2 and 1.1 per 1,000 person-months.

In the Kaplan-Meier analysis, the probability of not experiencing an ADR at 19 months with Risankizumab was 0.952 (95% CI: 0.901–1), and at 41 months with Guselkumab was 0.832 (95% CI: 0.702–0.987. No ADRs led to medication withdrawal.

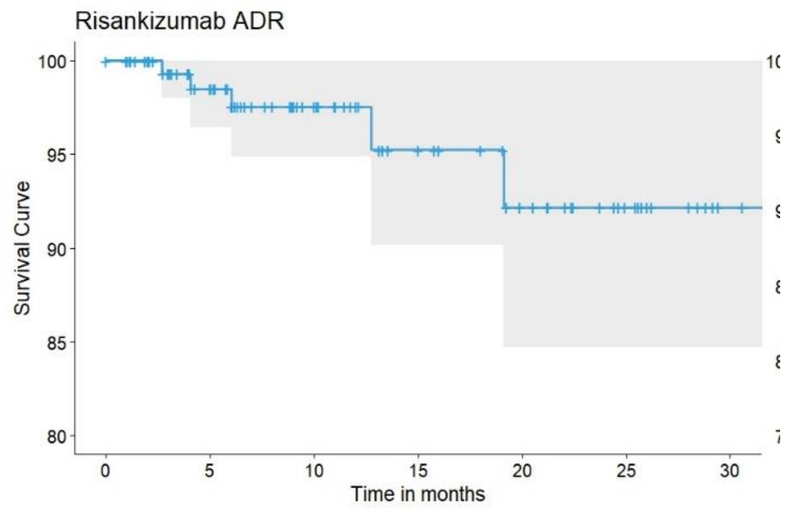
Conclusion: Guselkumab and Risankizumab have demonstrated acceptable safety and efficacy profiles for plaque psoriasis in a real-world setting, with low incidence rates of therapeutic failures and adverse drug reactions.

Keywords: *Adverse drug reactions (ADR), Therapeutic failure (TF), Ixekizumab, Secukinumab*

Table 1. Summary of Effectiveness and Safety of Guselkumab and Risankizumab

	Risankizumab (No. of people)	Guselkumab (No. of people)
Number of people with Therapeutic Failure	2	8
Number of people with Adverse Drug Reactions	5	11
Total	189	303

Figure 1. Kaplan-Meier Survival Curves for Therapeutic Failure and Adverse Reactions: Guselkumab VS Risankizumab



References

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Disclosure: *The authors declare that there is no conflict of interest*