Discontinuation and Effectiveness of Originator and Biosimilar TNFi in Patients with Rheumatoid Arthritis: Real World Data from a Rheumatoid Arthritis Registry in Canada

Mohammad Movahedi, Angela Cesta, Xiuying LI, Claire Bombardier

Background: In recent years, biosimilars, highly similar copies of originator biologics, have been available in clinical practice to patients with Rheumatoid Arthritis (RA) in Canada. The Ontario government is expected to implement a policy mandating a switch from originator biologics to biosimilars. We may be able to anticipate the outcomes of implementing such a policy by analyzing the existing data for patients already using biosimilars in Ontario.

Objectives: We aimed to describe discontinuation and disease activity in patients starting an originator or biosimilar TNFi, using real-world data from the Ontario Best Practices Research Initiative (OBRI), Canada.

Methods: Patients with active RA enrolled in the OBRI and initiating an originator or biosimilar TNFi between 1st Jan 2015 and 30st March 2022 were included. We investigated time to discontinuation by using Kaplan-Meier (KM) survival curves in the two groups. Due to a small number of biosimilar users, curves were not statistically compared. Using clinical disease activity index (CDAI), disease status was also described for patients with available data at 12 months after treatment.

Results: A total of 494 patients started an originator TNFi (n=401) or biosimilar TNFi (n=93) with mean (SD) disease duration of 12.0 (9.4) and 9.7 (9.3) years, respectively. In the originator group, 81.5% were female and mean age (SD) was 57.2 (11.9) years. In the biosimilar group, 82.8% were female and mean (SD) age was 59.2 (11.5) years. The originator group was less likely to have prior biologic use (31.9%) compared to the biosimilar group (58.1%). The mean (SD) baseline CDAI was lower in the originator group [17.2 (11.6)] compared to the biosimilar group [22.6 (13.7)].

Over a mean follow-up of 25.9 months, discontinuation was reported in 154 (38.4%) and 21 (22.6%) originator and biosimilar groups, respectively. The mean survival (standard error) in originator group was 49.5 (1.85) months and 56.1 (4.70) months in biosimilar group. The retention rate (95% Confidence Interval) at 12 months was 74.8% (70.1%-78.9%) in the originator group and 84.6% (74.4%-91.0%) in the biosimilar group (Table 1). At 12 months after treatment initiation, disease activity was similar in the two groups (mean of CDAI: 14.0 vs.13.0).

Conclusion: In this real-world data descriptive study, we found that the proprtion of patients who remained on their medication in the biosimilar group was numerically higher than the originator TNFi. We also found that disease activity after 12 months after initiation was numerically similar in both groups. Next steps include, comparing discontinuation and disease activity between the two groups using a statistical regression analysis adjusting for potential confounders.

Table 1. Survival rate over 2 years of follow-up by treatment group

	TNFi Biosimilar N=93	**Originator TNFi N=401**
Number of discontinuation	21	154
Probability of survival		
6 month (%, (95%CI))	92.9 (84.9-96.8)	88.4 (84.7-91.2)
12 months (%, (95%CI))	84.6 (74.4-91.0)	74.8 (70.1-78.9)
18 months (%, (95%CI))	77.8 (65.9-85.9)	69.8 (64.7-74.2)
24 months (%, (95%CI))	70.9 (57.5-80.8)	65.9 (60.7-70.6)

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