(EPH87) Safety of Interchanging from Reference Biologic to its Biosimilar: A Systematic Review and Meta-Analysis

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Background

Biosimilars are products that are highly similar to a reference biologic in terms of quality, safety, and efficacy profiles with minor differences in clinically inactive components and manufacturing processes. Safety remains an issue when interchanging patients from a reference biologic to a its biosimilar or from a biosimilar to another.

Objectives

In this systematic review and meta-analysis, we aim to assess if the rate of adverse events is impacted by switching from the reference product to its biosimilar using data from randomized controlled trials.

Methods

We searched MEDLINE, and Cochrane Central from inception to January 2022. Randomized clinical trials reporting on adverse drug reactions from interchanging/switching between reference-to-reference biologic and reference-to-biosimilar biologic were included. Record screening, data extraction, and risk of bias assessment were performed in duplicate. Random effect models were used when pooling crude numbers of study outcome.

Results

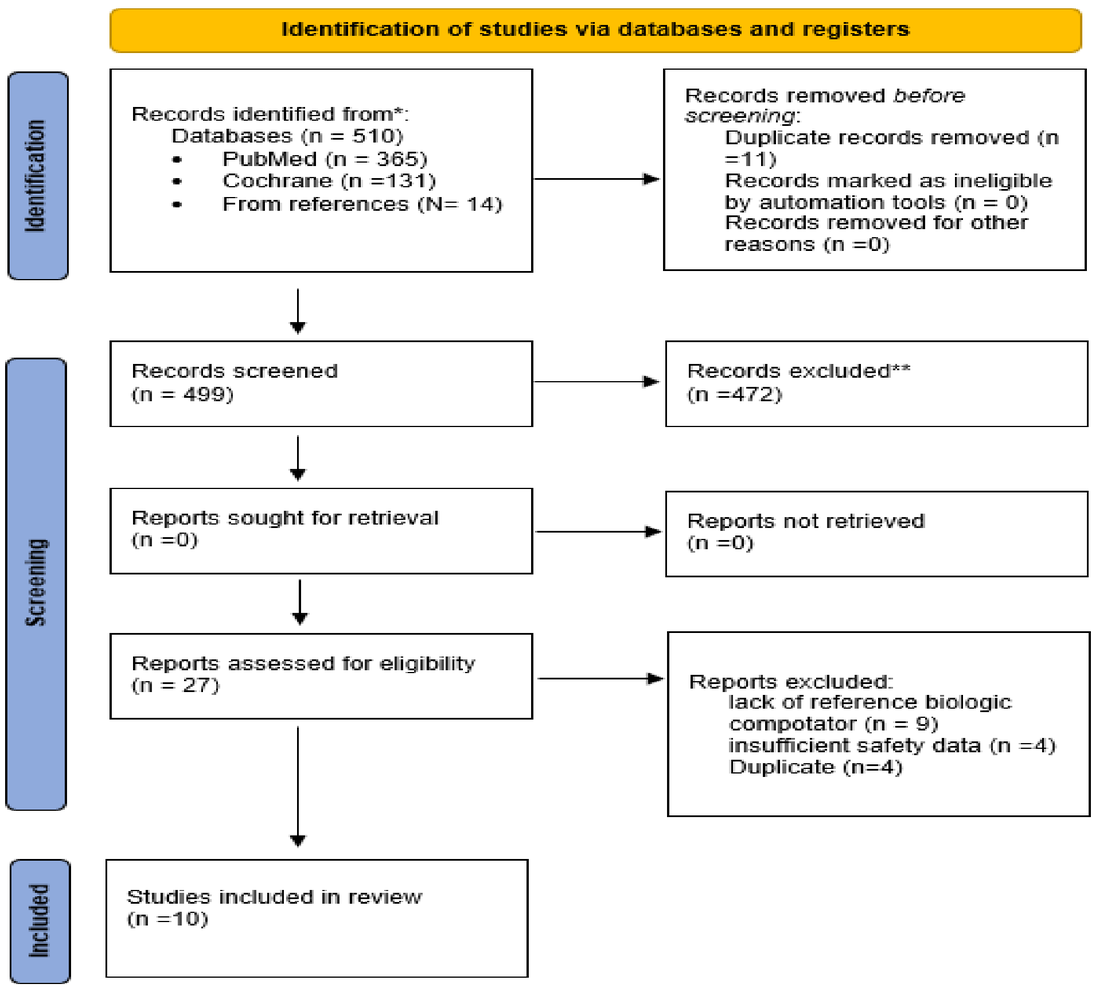


Figure 1. Study Selection

Figure 2. Total adverse events in reference-reference arm versus reference-biosimilar arm

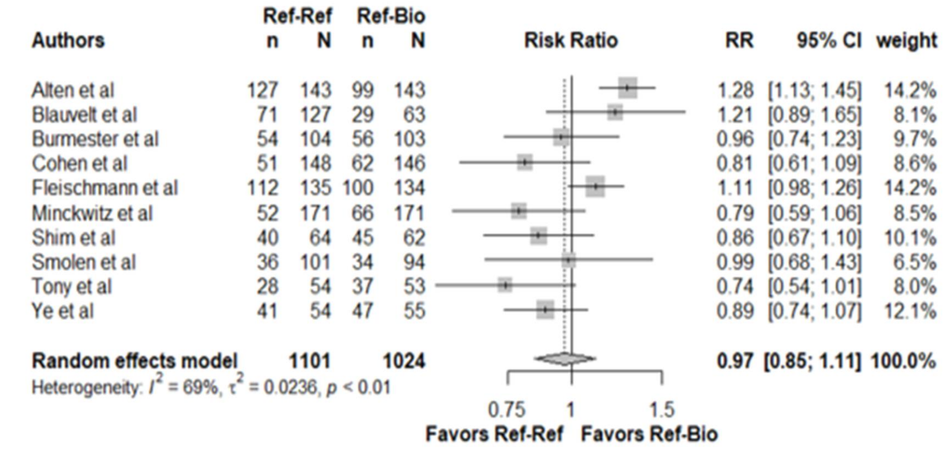


Figure 3. Total number of serious adverse events in reference-reference arm versus reference-biosimilar arm

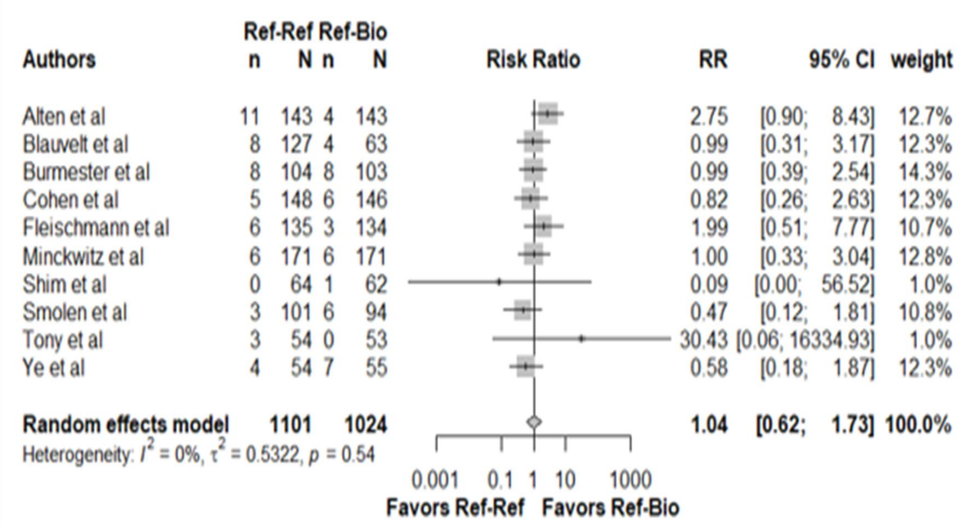
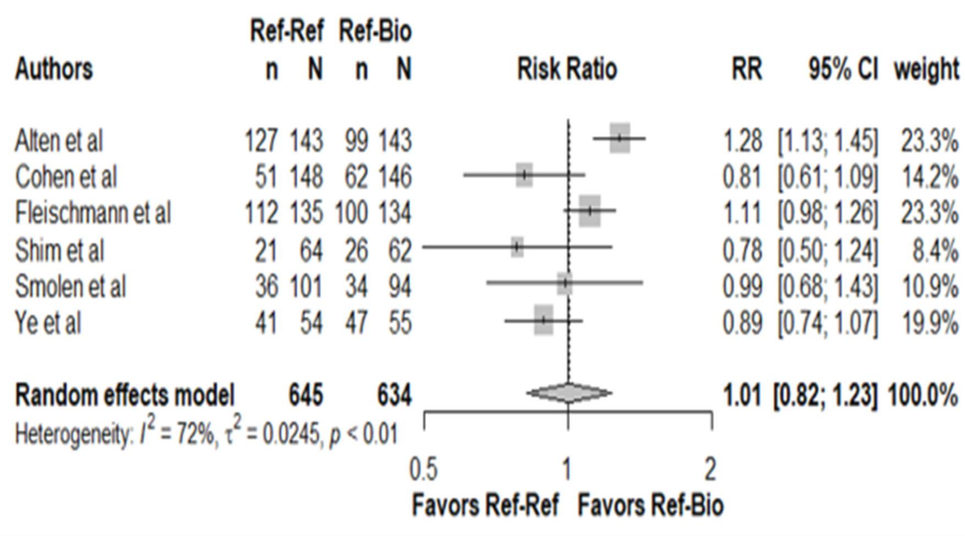


Figure 4. Total number of emergent adverse events in reference-reference arm versus reference-biosimilar arm



CI: Confidence Interval; RR: relative Risk; Ref: Reference product; Bio: biosimilar product

Conclusion

Given the similar safety profile when switching between reference to reference or reference to a biosimilar, the use of any of these modalities appears to be acceptable. However, the current data is limited by the number of trials included, and the type of patients/products studied.