ISPOR Europe Virtual Conference, 30 November to 3 December 2021

USE OF REAL-WORLD EVIDENCE TO EVALUATE INFLIXIMAB BIOSIMILARS: A SCOPING REVIEW

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Background

- Infliximab biosimilars have been introduced in recent years as therapeutic alternatives to originator infliximab.
- These have been approved in Europe, the United States, and Canada for the treatment of chronic conditions such as rheumatoid arthritis and Crohn's disease.
- Real-world evidence (RWE) may provide valuable information about the long-term effectiveness and safety of infliximab biosimilars compared to originator infliximab outside of the clinical trial setting, and scoping reviews may guide research question development for future work in this area.

Objective

This study aimed to review the use of RWE to evaluate infliximab biosimilars for the treatment of inflammatory, rheumatic, and autoimmune diseases.

Methods

- A search strategy was implemented in MEDLINE and Embase in September 2020 using indexed terms and keywords related to biosimilars, originators, and observational study designs.
- Abstracts and full-text articles describing the evaluation of infliximab biosimilars using RWE were included.
- Outcomes of interest were:
  - Number (%) of studies comparing infliximab biosimilars and originator infliximab
  - Of these, number (%) describing clinical effectiveness, safety/tolerability (adverse events/discontinuations), biomarkers, and healthcare resource utilization (HRU).
  - Number (%) of studies evaluating switch from infliximab biosimilars to originator infliximab were also determined.

Disclosures and contact information

The authors of this study did not receiving any funding for this work. For any questions regarding this project, please contact: acheung@broadstreetheor.com

Results

- Of 1,739 abstracts identified from a search of the literature, 164 assessed infliximab biosimilars using RWE and were included.
- Across the 164 included studies, the most common countries and geographic regions studied were (Figure 1):
  - Spain (20, 12.2%)
  - Europe (19, 11.6%)
  - United Kingdom (17, 10.4%)
- There were no included studies from South America or Africa.
- 99 (60.4%) included studies reported at least one outcome following switch from originator infliximab to infliximab biosimilar.
- Among included studies, 66 (40.2%) compared infliximab biosimilars and originator infliximab.
- The most frequently reported outcomes in these studies were:
  - Safety/tolerability, including adverse events (AEs) & biosimilar discontinuation (47, 71.2%)
  - Clinical effectiveness (43, 65.2%)
  - Biomarker levels (31, 47.0%).
- HRU was infrequently reported among studies comparing infliximab biosimilars and originator infliximab (10, 15.2%).

Figure 1: Countries and geographic regions represented by ≥5 studies

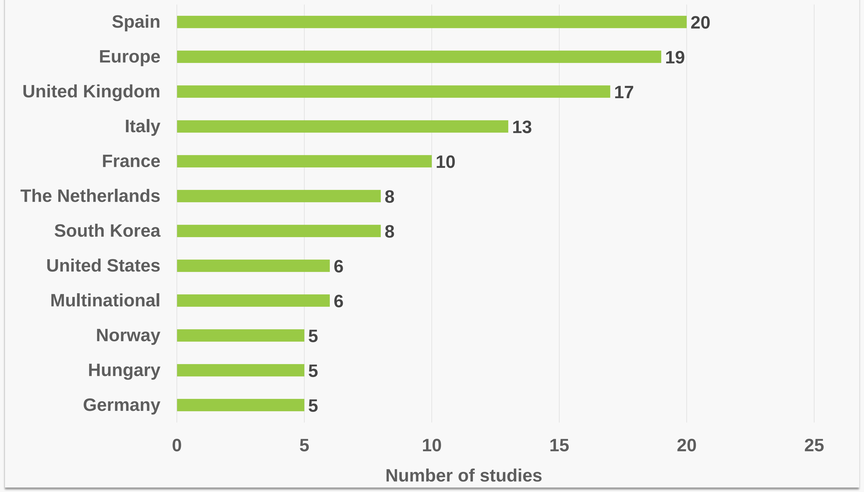
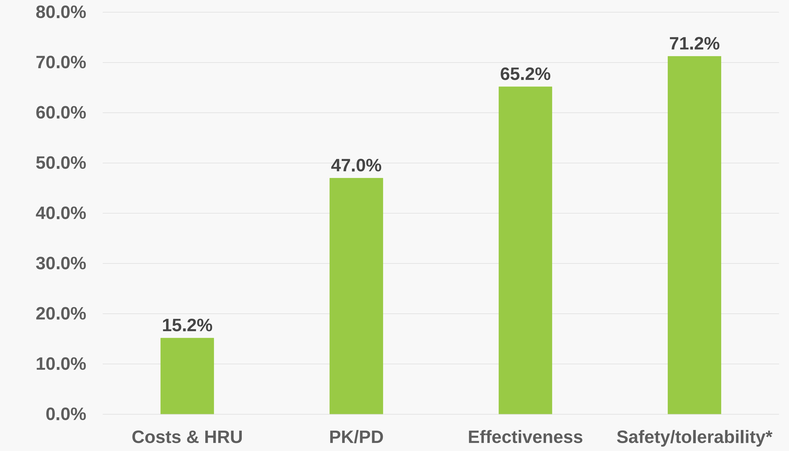


Figure 2: Frequency of outcomes reported by included studies comparing infliximab biosimilars with originator infliximab (n=66)



*Includes adverse events and discontinuation
Abbreviations: HRU, healthcare resource utilization; PD, pharmacodynamics; PK, pharmacokinetics

Conclusions

- This scoping review described the availability of research on infliximab biosimilars using RWE.
- Studies describing RWE for infliximab biosimilars were primarily based in Europe; comparatively fewer studies were identified in North America or Asia.
- It is currently unclear whether the variation between regions in availability of RWE on infliximab biosimilars contributes to a difference in their uptake.
- Despite the preliminary nature of this review, findings highlighted a paucity of RWE on HRU associated with infliximab biosimilars, regardless of region.
- An extension to this initial scoping review will be to synthesize and characterize the results of identified studies to assess the observed relationships between infliximab biosimilars and originators across the outcomes most commonly reported.
- Future work to characterize HRU/costs associated with infliximab biosimilars compared to originator infliximab may also be valuable, as well as studies in regions where there is currently little evidence on the effectiveness and safety of infliximab biosimilars.