A Scoping Review of the Real-World Evidence Related to the Safety and Effectiveness of Biosimilars in the Oncology Landscape

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INTRODUCTION

- Biosimilars are similar to biologics and have no clinically meaningful differences from their reference products.[1]
- Utilization of biosimilars can provide a cost-effective option for patients and healthcare providers, it is estimated that using biosimilar agents can lead to health care savings of about $44.2 billion over 10 years.[2]
- In a study conducted with 300 managed care and specialty pharmacy professionals, it was agreed that the strategies that are likely to help overcome barriers to biosimilar adoptions revolved around prescriber education and real-world evidence (RWE).[3]
- This research aims to summarize the RWE available and uncover gaps in the data to enhance the information discovered by clinical trials on the safety and effectiveness of oncology related biosimilars.

METHODS

- Included studies were observational, prospective or retrospective, and included patients aged 18 years or older treated with a biosimilar for an oncology indication.
- Literature was indexed from Medline (PubMed), EMBASE, Web of Science, and Google Scholar with simple terms, (biosimilar AND (real world OR observational OR post market) AND (safety OR effectiveness OR efficacy OR comparative) and filtered when applicable for observational studies, English language, and studies in humans when available.
- The body of included literature was analyzed based on geographic or regional distribution, drugs and comparators, data sources used, methodology or design, outcome measures and general results, and strengths and limitations noted by the authors of each study.
- Data were summarized based on overall trends, similarities, and differences across included studies.

RESULTS

Characteristic	Number of Studies (%)	Results
Objective	8 (22)	To assess safety outcomes only
	14 (37)	To assess efficacy outcomes only
	15 (41)	To assess safety and efficacy outcomes
Study Design	12 (33)	Prospective
	25 (67)	Retrospective
Data Source	30 (81)	Data from hospital charts or electronic medical records
	3 (8)	Claims database
	4 (11)	Registry database
Location	5 (14)	United States of America
	21 (57)	Europe
	9 (24)	Other
	2 (5)	Multiple
Primary Diagnosis	8 (22)	Solid tumor
	13 (35)	Hematological malignancy
	16 (43)	Included both solid tumors and hematological malignancies
Biosimilar Evaluated	12 (32)	Oncology agent
	25 (68)	Supportive therapy

Characteristic	Number of Studies (%)	Results
Biosimilar Treatment Group	29 (78)	Therapy naïve
	8 (22)	Therapy naïve and patients switching from brand reference product
Compared Outcomes to Brand Reference Product	19 (51)	Yes
	18 (49)	No
Outcomes Captures	31 (84)	Efficacy outcomes*
	28 (76)	Safety outcomes **
	7 (18)	Humanistic outcomes
Race/Ethnicity Data Captured	1 (3)	Yes
	36 (97)	No
Funding Source	14 (38)	Manufacturer
	20 (54)	Non-funded
	3 (8)	Other
Conclusion	18 (49)	Biosimilar product is non-inferior to brand reference product
	19 (51)	Other

* Examples of efficacy outcomes include: CD34 cell count, Hgb levels, response rate, and duration of response
** Examples of safety outcomes include: Any adverse events including serious adverse events

- Overall, 37 studies were included in this scoping review
- These studies were published between 2014 and 2022
- **Common strengths:** large sample size, broad patient population, and the utilization of propensity score matching
- **Common limitations:** Retrospective design of many studies, selection bias, and short follow-up time was not appropriate for evaluating long term safety outcomes

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CONCLUSIONS

- In conclusion, this scoping review characterizes observational research on the safety and effectiveness of biosimilars when used in oncology.
- Most studies were retrospective in nature and assessed both safety and efficacy outcomes.
- Most studies also evaluated supportive therapies such as epoetin alpha and G-CSF treatment.
- Almost all of the studies included did not capture evidence specific to racial or ethnic minorities.
- In general, most studies that compared biosimilar utilization with its brand reference product found that the biosimilar results were non-inferior to those of the reference biologic. Most studies that did not compare biosimilar results to a reference product found that biosimilar unitization was generally effective and well tolerated.

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