Article published online: 2025-09-11

Clinicians' Perceptions and Adoption of Oncology Biosimilars in India: Results from a National Survey

Anita Ramesh[1]

[1] Department of Medical Oncology, Saveetha Medical College and Hospital, Chennai, Tamil Nadu, India

Ind J Med Paediatr Oncol

Address for correspondence Anita Ramesh, MBBS, DCH, DNB, MNAMS, MD, MSc, DM, PhD, Department of Medical Oncology, Saveetha Medical College and Hospital, Saveetha University, Thandalam, Chennai 602105, Tamil Nadu, India (e-mail: info.anitar@gmail.com).

Abstract

Biosimilars enhanced access to advanced therapies by providing cost-effective alternatives to reference biologics. However, their adoption in clinical practice remains limited due to concerns regarding efficacy, safety, and data reliability. This survey aimed to assess Indian clinicians' perspectives on biosimilars and identify factors influencing their adoption. A questionnaire-based online survey was conducted from July to August 2024. Fifty-two medical, radiation, and surgical oncologists across India provided a complete response. Questionnaires addressed prescription patterns, confidence in biosimilars, and clinical decision-making criteria. Descriptive statistics were performed. Among 52 respondents, 34.6% of clinicians prescribed biosimilars to >60% of patients, while 17.3% prescribed to <20%. Safety (27.1%), efficacy (35.6%), and pharmacokinetics (21.2%) were key determinants for biosimilar adoption; 76.9% of clinicians rejected biosimilars with biomolecular deviation; 65.4% of clinicians opposed data extrapolation without clinical trial evidence; and 76.9% lacked confidence in biosimilars before peer-reviewed publication. Clinicians stressed the importance of rigorous statistical analysis in biosimilar trials, with 46.2% hesitant without intention-to-treat/per-protocol analyses, 69.2% concerned about deviations beyond 80% to 125% margins, and 63.5% accepted efficacy differences within ± 20% of the noninferiority range. Clinicians' concerns and limited evidence hinder biosimilar adoption, despite their potential to improve access. Larger trials, transparent reporting, and real-world evidence may improve confidence.

Keywords

- biosimilars
- clinical practice
- survey
- oncology
- adoption

Introduction

Biosimilars are biologics that exhibit strong similarity to existing Food and Drug Administration (FDA)-approved reference drugs while offering a significantly more cost-effective alternative, making them particularly beneficial for resource-limited countries like India. The Biologics Price Competition and Innovation Act of 2010 introduced a simplified regulatory process to expedite their approval while ensuring they meet therapeutic standards.[1] India is emerging as a key player in the development and use of biosimilars, with several biosimilars already approved and in use for various cancer therapies.[2] However, the adoption rate has been relatively slow, mainly due to concerns about their safety and efficacy. Even after receiving regulatory approval, many clinicians are cautious about routinely incorporating biosimilars into clinical practice, particularly in oncology.[1,3]

Biosimilar development aims to demonstrate high similarity in structure, biological activity, efficacy, safety, and immunogenicity with the reference biologic. This allows the biosimilar to rely on the existing safety and efficacy data

DOI https://doi.org/10.1055/s-0045-1811566.
ISSN 0971-5851.

Thieme Medical and Scientific Publishers Pvt. Ltd., A-12, 2nd Floor, Sector 2, Noida-201301 UP, India

from the reference biologic, avoiding redundant clinical trials. Demonstrating biosimilarity involves comprehensive comparability studies. The extrapolation of biosimilar data across multiple indications continues to be a topic of ongoing discussion and scrutiny. While regulatory agencies allow extrapolation based on comprehensive comparability studies, concerns persist regarding its validity (including quality, nonclinical, and clinical data).[4] Literature suggests that although this approach is scientifically justified in many cases, it may not be universally applicable, particularly for complex biologics with multiple mechanisms of action. This study aimed to investigate the factors influencing biosimilar adoption among Indian clinicians and assess clinicians' prescription patterns, confidence in biosimilars, and decision-making criteria when considering biosimilars for cancer treatment.

Materials and Methods

A cross-sectional survey was conducted online over 2 months, from July to August 2024, to assess clinicians' perspectives on biosimilars and their adoption in oncology practice. The survey was designed based on insights from published literature on biosimilars and data regarding their availability in clinical practice. Questions were tailored and validated to address key aspects, such as familiarity with biosimilars, factors influencing prescription decisions, and perceived barriers to their use. The participants were recruited through professional networks, institutional contacts, and oncology-specific forums across India. The survey was conducted from July to August 2024. The survey questionnaire (►**Supplementary Table S1** [available in the online version only]) was distributed to practicing oncologists, including specialists in radiation, medical, and surgical oncology via professional network and email. A purposive sampling strategy was employed, targeting practicing oncologists relevant to the study's scope.

Descriptive statistics, primarily frequency counts and percentages, were used to analyze clinicians' responses and describe their prescribing patterns and attitudes toward biosimilars.

Ethical approval and informed consent were not required under the Common Rule, as this is a survey study and de-identified data were used.[5]

Results

A total of 76 oncologists were approached, of whom 52 responded, yielding a response rate of 68.4%. The final sample comprised 46 medical oncologists, 5 radiation oncologists, and 1 surgical oncologist. A summary table of key survey items and response distributions is given in ►**Supplementary Table S2** (available in the online version only). Significant variability in biosimilar adoption was observed among respondents. Notably, 34.6% ($n = 18$) of respondents reported that more than 60% of their patients received biosimilars, and 17.3% ($n = 9$) of clinicians indicated that biosimilars were prescribed to less than 20% of their patients. About 23% ($n = 12$) of clinicians prescribed biosimilars to 20% to 40% of their patients, while 25% ($n = 13$) prescribed them to 40% to 60% of their patients. Clinicians showed significant reluctance to consider biosimilars over innovator biologics. About 75% of respondents preferred not to use biosimilars and rather opted for biologics, while only 9.6% were open to adopting biosimilars and 15.4% were unsure.

Several clinical factors were found to influence the adoption of biosimilars in clinical practice among the clinicians who participated in this survey. A significant proportion of respondents (35.6%) identified similar efficacy as the most important factor, followed by similar safety (27.1%) and similar pharmacokinetic (PK) parameters (21.2%), similar to their reference standard. Only 16.1% of clinicians considered data from studies across all indications as a priority while prescribing biosimilars. Additionally, 45.3% of clinicians reported requiring a comprehensive evaluation across multiple efficacy endpoints before considering biosimilar use. Among individual parameters, 16.3% considered overall survival (OS), while 12.8% chose safety. Additional key factors included an overall response rate (ORR) of 9.3%, progression-free survival (PFS) of 8.1%, and PK parameters at 8.1% (►**Fig. 1**).

The presence of structural differences in biosimilars, such as oxidation or glycosylation issues, contributed to increased resistance among clinicians. A significant proportion of respondents (76.9%) rejected biosimilars with biomolecular deviations—defined as primary structural differences from the reference biologic—while only 13.5% were willing to proceed with their use. A majority of respondents (65.4%) opposed the extrapolation of biosimilar data across indications without supporting clinical trial data. 26.9% supported extrapolation, and 7.7% were unsure. Before peer-reviewed publication, the majority of clinicians (76.9%) lacked confidence in prescribing biosimilars, while 17.3% expressed comfort and 5.7% remained uncertain (►**Fig. 2**).

This apprehension extends to the design of clinical trials, with many clinicians emphasizing the importance of intention-to-treat (ITT) and per-protocol (PP) analyses. Most of the respondents (46.2%) were reluctant to consider a biosimilar study without ITT and PP analyses for clinical use. Additionally, 21.2% felt biosimilars could still be considered with modified intention-to-treat (mITT) without ITT and PP, and 32.6% were uncertain. About 69.2% of clinicians believed that deviations beyond the standard 80% to 125% margin would affect their clinical use of biosimilars. Only 21.2% disagreed, and 9.6% were uncertain. When asked about the impact of confidence intervals (CIs) at 90%, with efficacy parameters within $\pm 20\%$ of the predefined noninferiority range, a majority (63.5%) of clinicians responded positively. However, 21.1% were concerned and would refrain from adoption, while 15.4% remained uncertain (►**Fig. 2**).

Discussion

The results of this study underline the rigorous decision-making process regarding the adoption of biosimilars in oncology practice. While biosimilars hold the potential to

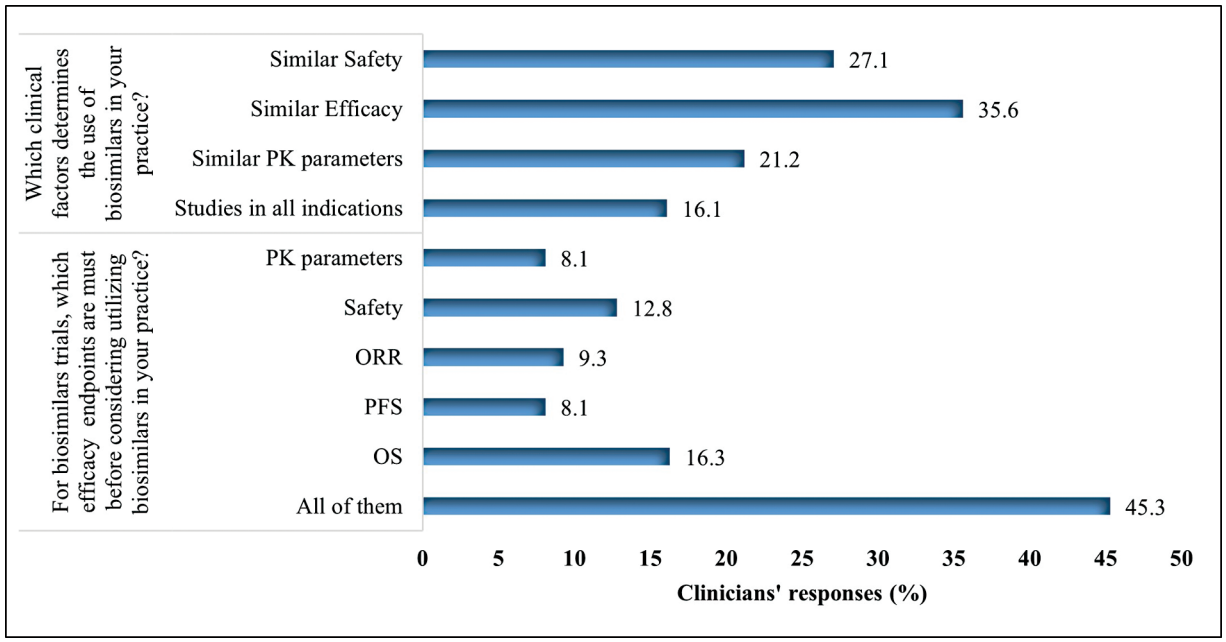

Fig. 1 Key factor considerations for integrating biosimilars into clinical practice.

reduce treatment costs and increase access to critical therapies,[1,3,6] the findings of this survey study indicate that clinicians remain cautious in their use due to concerns about clinical data consistency and the potential for differences in efficacy and safety. These findings are consistent with previous studies conducted in the United States and Europe demonstrating clinicians' prudence in biosimilar use,[7,8] especially when switching patients from bio-originator to biosimilar.[7] Furthermore, the clinicians rely on clinical studies and publications for evidence, as reported in previous studies.[9,10] A high proportion of clinicians reported requiring comprehensive safety and efficacy data across

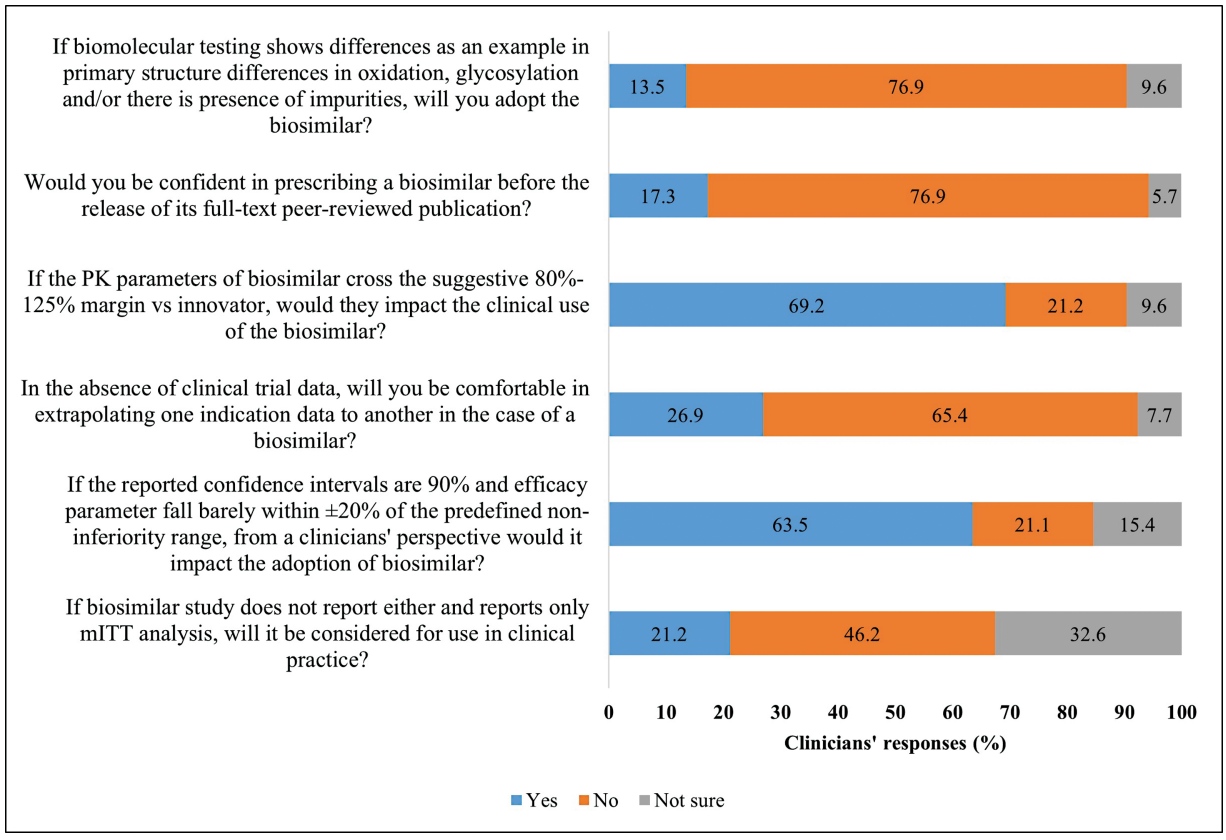

Fig. 2 Key factors influencing the adoption of biosimilars.

multiple endpoints, including OS, PFS, ORR, and PK parameters. This aligns with global oncology standards, where robust clinical evidence plays a crucial role in treatment decisions.[1,11] The majority of the clinicians in this survey emphasized the importance of ITT and PP analyses. The JAMA Guide to Statistics and Methods (2014) emphasizes that both ITT and PP analyses should be conducted and reported in a noninferiority trial,[12] highlighting the need for rigorous statistical reporting to maintain clinician confidence in clinical decision-making for biosimilars. Reluctance to accept biosimilars without peer-reviewed data and concerns about PK margins highlight the need for transparent, peer-reviewed clinical trial reporting.[13] This aligns with prior research suggesting that lack of long-term data and uncertainty about equivalence with reference products contribute to limited biosimilar use.[4] The importance of PK data is particularly evident,[4] as the majority of clinicians indicated that deviations beyond the acceptable margin would impact their prescribing behavior. While there is openness to biosimilars with a 90% CI within $\pm 20\%$ of the noninferiority range, concerns, uncertainty, and skepticism toward the extrapolation of untested indications highlight the need for further validation, transparency, and robust clinical trial evidence. These findings mirror the concerns demonstrated by the United States and European providers in terms of extrapolated indications, referring to the approval of biosimilars for indications held by the innovator biologic that were not directly assessed in the clinical trial of the biosimilar.[7] Despite India ranking first in approval of numerous biosimilars ($n = 98$) compared with the United States ($n = 26$) and European Union (EU, $n = 61$) in 2019, there remain concerns over regulatory rigor, pharmacovigilance system, clinical data, statistical validity, testing criteria in India compared with the U.S. and EU markets, which may have driven the skepticism demonstrated by the Indian clinicians toward biosimilars.[14,15] In contrast to Europe and America, India's fragmented regulatory framework, limited RWE dissemination, and lack of structured academic training on biosimilars may contribute to clinicians' hesitancy and less consistent adoption patterns.[16] Therefore, it is paramount to foster various industry–academic collaboration, rigorous post-marketing surveillance, and strengthen regulatory infrastructure, specifically quality control and approval processes, to boost confidence in biosimilars among clinicians.[15,17] It is also crucial to generate real-world evidence (RWE) to reinforce biosimilar safety and efficacy,[18] which could help validate biosimilar use in diverse patient populations. Clinicians need access to transparent, peer-reviewed studies demonstrating the safety and efficacy of biosimilars for a successful integration of biosimilars into oncology treatment regimens.

Limitations

One key limitation of this study is its reliance on self-reported data, which may introduce bias, particularly in the subjective reporting of prescribing practices and perceptions of biosimilars.[2] Second, the study was conducted among Indian clinicians, which may limit the generalizability of the findings to other regions with different regulatory frameworks and healthcare infrastructures. Moreover, the use of an online distribution method may have introduced selection bias, despite the efforts to disseminate the survey to a wider oncology community. Therefore, the participants may not accurately represent the broad cross-section of oncologists. Additionally, while the study identifies a lack of peer-reviewed data and RWE as key concerns influencing biosimilar adoption, it did not include a direct question comparing clinicians' preference for biologics versus biosimilars, which would have provided stronger support for the findings. Future studies are warranted with a larger sample representing a wide spectrum of healthcare professionals, to gain deeper insights on the real-world adoption of oncology biosimilars.

Conclusion

This survey highlights the multifaceted challenges in the adoption of oncology biosimilars in India. While biosimilars hold the potential to offer lower treatment costs and expand treatment choices, the lack of comprehensive, peer-reviewed clinical data, especially on efficacy and safety, raises significant concerns about biosimilar use among Indian clinicians. Therefore, clinicians remain cautious toward the adoption of biosimilars and emphasize the importance of transparent trial reporting and long-term data to boost confidence in biosimilars. To further enhance adoption, the study suggests the need for larger multicenter trials and RWE, and increased collaboration among different stakeholders to successfully integrate biosimilars into oncology practice.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Authors' Contributions

The author confirm that they are the sole author of this manuscript. The author meet the criteria for authorship as outlined in the journal's guidelines and that the manuscript represents honest and original work.

Ethical Approval

Ethical approval is not required under the Common Rule, as this is a survey study and de-identified data were used.

Patients' Consent

Patient consent is not required.

Funding

None.

Conflict of Interest

None declared.

Acknowledgment

The author extends gratitude to all participating clinicians for their valuable contributions to this survey.

References

1 Chen A, Dennison T, Palmer S, et al. Biosimilars in oncology practice: a multi-site health system examination of the use and perception of oncology biosimilars. J Hematol Oncol Pharm 2024;14(02):83–90. https://www.ncbi.nlm.nih.gov/nlmcatalog/?term=J+Hematol+Oncol+Pharm
2 Chopra R, Lopes G. Improving access to cancer treatments: the role of biosimilars. J Glob Oncol 2017;3(05):596–610
3 Joshi D, Khursheed R, Gupta S, et al. Biosimilars in oncology: latest trends and regulatory status. Pharmaceutics 2022;14(12):2721
4 Rasi G. Biosimilars in the EU - Information Guide for Healthcare Professionals;1–36. Accessed February 3, 2025 at: https://www.ema.europa.eu/en/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf
5 45 CFR Part 46–Protection of Human Subjects. Accessed April 23, 2025 at: https://www.ecfr.gov/current/title-45/part-46
6 Barbier L, Declerck P, Simoens S, Neven P, Vulto AG, Huys I. The arrival of biosimilar monoclonal antibodies in oncology: clinical studies for trastuzumab biosimilars. Br J Cancer 2019;121(03):199–210
7 Leonard E, Wascovich M, Oskouei S, Gurz P, Carpenter D. Factors affecting health care provider knowledge and acceptance of biosimilar medicines: a systematic review. J Manag Care Spec Pharm 2019;25(01):102–112
8 Peipert JD, Kaiser K, Kircher S, et al. Medical oncologists' knowledge and perspectives on the use of biosimilars in the United States. JCO Oncol Pract 2023;19(03):e457–e464
9 Foreman E, Patel H, Siderov J, Harchowal J, Bubalo J, Chan A. A survey of global biosimilar implementation practice conducted by the International Society of Oncology Pharmacy Practitioners. J Oncol Pharm Pract 2020;26(3 Suppl, Suppl): 22–32
10 Shin G, Kim BS, Kim DY, Bae S. Unveiling the biosimilar paradox of oncologists' perceptions and hesitations in South Korea: a web-based survey study. BioDrugs 2024;38(02):301–311
11 Giuliani R, Tabernero J, Cardoso F, McGregor KH, Vyas M, de Vries EGE. Knowledge and use of biosimilars in oncology: a survey by the European Society for Medical Oncology. ESMO Open 2019;4 (02):e000460
12 Detry MA, Lewis RJ. The intention-to-treat principle: how to assess the true effect of choosing a medical treatment. JAMA 2014;312(01):85–86
13 Monga A, Gagan , Jamwal P, Sharma S, Kaur A. Biosimilars: a critical review of development, regulatory landscape, and clinical implications. AAPS PharmSciTech 2025;26(01):46
14 Panda S, Singh PK, Mishra S, et al. Indian biosimilars and vaccines at crossroads - replicating the success of pharmagenerics. Vaccines (Basel) 2023;11(01):110
15 Musti K, Yarra SP, Munukutla KS, Kavala NR. Possible guidelines and regulatory issues on biosimilars in INDIA, USA, EU. World J Pharm Biotechnol 2023;10(01):51–56
16 Halimi V, Daci A, Ancevska Netkovska K, Suturkova L, Babar ZUD, Grozdanova A. Clinical and regulatory concerns of biosimilars: a review of literature. Int J Environ Res Public Health 2020;17(16): 5800
17 Kaur S, Yadav S, Sahu V, Sharma N, Shukla VK. Biosimilar Regulations: Current Framework and Future Prospects. Accessed July 7, 2025 at: https://www.eurekaselect.com/article/148549
18 Lasia. Increasing adoption of quality-assured biosimilars to address access challenges in low- and middle-income countries - GaBI Journal. May 7, 2024. Accessed February 25, 2025 at: https://gabi-journal.net/increasing-adoption-of-quality-assured-biosimilars-to-address-access-challenges-in-low-and-middle-income-countries.html

