



Using Therapeutic Equivalence to Provide Safety and Efficacy

Hesham Soliman*

Department of Pharmaceutical Care, University of Banha, Banha, Egypt

DESCRIPTION

Therapeutic equivalence is a fundamental concept in healthcare that plays a pivotal role in ensuring that patients receive safe, effective, and affordable treatment options. It refers to the comparison of pharmaceutical products or medical interventions to determine whether they are clinically interchangeable in terms of efficacy and safety. The pursuit of therapeutic equivalence is grounded in the principles of evidence-based medicine and regulatory standards, aiming to provide healthcare professionals and patients with a range of choices while maintaining consistent and predictable outcomes.

Therapeutic equivalence serves as the cornerstone of modern healthcare systems by addressing various critical aspects. Ensuring that interchangeable treatments have similar therapeutic effects and safety profiles is paramount for patient well-being. Patients should be confident that switching between generic and brand-name medications will not compromise their health. Generics and biosimilar, which are therapeutic equivalents of brand-name drugs, offer significant cost savings to individuals and healthcare systems. By promoting the use of these alternatives, therapeutic equivalence contributes to making healthcare more accessible and affordable. A broad range of therapeutic equivalents provides healthcare providers and patients with options, ensuring that a suitable treatment is available even if specific products are in short supply.

Demonstrating therapeutic equivalence allows pharmaceutical companies to focus resources on developing new treatments rather than replicating existing ones. This fosters innovation and advances in medical science. Regulatory agencies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), play a crucial role in establishing standards for therapeutic equivalence. These standards ensure that products entering the market meet rigorous criteria for safety, efficacy, and quality. The process of establishing therapeutic equivalence involves comprehensive evaluations encompassing several key dimensions. For generic medications, bioequivalence studies compare the pharmacokinetics (absorption, distribution, metabolism, and elimination) of the generic product

to the brand-name product. If the generic version demonstrates similar blood concentration profiles, it is considered bioequivalent.

In the case of biologic medications, which are complex molecules, biosimilar are evaluated for similarity to the reference biologic. This involves a stepwise approach, including analytical, non-clinical, and clinical studies, to establish that the biosimilar behaves similarly to the reference biologic in terms of safety and efficacy. Clinical trials play a central role in demonstrating therapeutic equivalence. These trials involve comparing the efficacy and safety of the test product (generic, biosimilar, or alternative treatment) with the reference product in a controlled setting.

Continuous monitoring of adverse events and side effects is crucial for ensuring ongoing therapeutic equivalence. If unexpected safety concerns arise, regulatory agencies can take appropriate actions to protect patients. Regulatory agencies around the world play a critical role in establishing and maintaining therapeutic equivalence. They set rigorous standards and guidelines that manufacturers must adhere to when seeking approval for generic drugs or biosimilar. Some of the important regulatory bodies include:

The FDA employs the Abbreviated New Drug Application (ANDA) pathway for generic drugs, ensuring that generic versions are therapeutically equivalent to their brand-name counterparts.

The EMA provides guidelines for the development and approval of biosimilar in the European Union. These guidelines outline the requirements for demonstrating bio similarity through comparative quality, non-clinical, and clinical data. The World Health Organization (WHO) offers guidelines and supports the development of Similar Bio Therapeutic Products (SBPs), a concept similar to bio similar, to make essential biologic treatments more accessible in low-resource settings. While therapeutic equivalence is generally embraced, challenges and controversies exist there are concerns about switching patients from a reference product to a biosimilar or from one generic to another. Healthcare providers and patients need clear guidelines to navigate such transitions safely.

Correspondence to: Hesham Soliman, Department of Pharmaceutical Care, University of Banha, Banha, Egypt, E-mail: solimanhesham@dw.34.eg

Received: 26-Jul-2023, Manuscript No. JBB-23-22743; **Editor assigned:** 28-Jul-2023, PreQC No. JBB-23-22743 (PQ); **Reviewed:** 11-Aug-2023, QC No. JBB-23-22743; **Revised:** 21-Aug-2023, Manuscript No. JBB-23-22743 (R); **Published:** 28-Aug-2023, DOI: 10.35248/0975-0851.23.15.535

Citation: Soliman H (2023) Using Therapeutic Equivalence to Provide Safe and Effective. J Bioequiv Availab. 15:535.

Copyright: © 2023 Soliman H. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Achieving regulatory designation as an interchangeable product implies that a product can be substituted without consulting the prescribing healthcare provider. Demonstrating interchangeability requires additional data beyond bio similarity or bioequivalence. The evaluation of biosimilar is more complex than that of small-molecule generics due to the intricate nature of biologic molecules. Ensuring similarity in such cases demands sophisticated analytical methods and extensive clinical trials.

Some patients and healthcare providers may still have reservations about the effectiveness and safety of therapeutic equivalents, particularly when it comes to biosimilar. The field of therapeutic equivalence continues to evolve, driven by advancements in science, technology, and healthcare policy, as the understanding of individual variability in drug response grows, therapeutic equivalence assessments may incorporate personalized factors to ensure optimal outcomes. Empowering patients with accurate information about therapeutic equivalence,

including the rationale for switching between products, is essential to foster trust and cooperation. Regulatory agencies worldwide are working toward harmonizing standards for demonstrating therapeutic equivalence, enabling smoother global access to safe and effective treatments. Beyond biosimilar, researchers are exploring "bio betters"-modified biologics that offer enhanced efficacy, safety, or convenience compared to existing products.

In conclusion, therapeutic equivalence is a vital cornerstone of modern healthcare that ensures patients have access to safe, effective, and affordable treatment options. Through rigorous regulatory oversight, scientific evaluation, and ongoing monitoring, healthcare systems can maintain high standards of care while containing costs and fostering innovation. As the healthcare landscape evolves, therapeutic equivalence will continue to adapt to new challenges and opportunities, ultimately benefiting patients and society at large.