Abstract

Background: Despite the global use of trastuzumab biosimilars, concerns remain regarding their efficacy and safety. In particular, when used concurrently with pertuzumab, trastuzumab biosimilars lack extensive real-world data and safety information. Additionally, as cancer drug expenditures continue to rise worldwide, cost savings from biosimilars have become increasingly important.

Objective: This study aims to assess the safety, efficacy, and cost-effectiveness of trastuzumab originators and their biosimilars in real-world clinical settings, focusing on a large patient population.

Methods: The analysis included 31,661 HER2-positive breast cancer patients from the Medical Data Vision (MDV) database in Japan. Additionally, adverse event reports for the trastuzumab originator and its biosimilars were obtained for 58,799 patients from the WHO's VigiBase, the global adverse event reporting database.

Results: No significant differences were observed in heart failure hospitalizations, liver dysfunction, or infusion reaction rates in both the MDV database and WHO's VigiBase. In the MDV database, the addition of pertuzumab did not significantly influence the incidences of adverse events, and the use of biosimilars significantly reduced medical costs, with no significant difference in breast cancer recurrence rates.

Conclusions: By analyzing two large and diverse datasets from multiple perspectives, we obtained reliable results that the trastuzumab originator and its biosimilars have similar safety profiles. The concurrent use of pertuzumab was also found to be safe. The use of biosimilars can lead to cost savings. These findings provide crucial insights for the evaluation and adoption of biosimilars in clinical practice.

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