Data-mining for adverse drug reaction signals of macitentan based on real-world data: pharmacovigilance study of the FAERS database

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Abstract

Background: The purpose of pharmacovigilance is the timely detection and identification of harmful drug-related reactions in the clinical application of drugs to reduce the risk of their clinical use. Macitentan has been on the market for close to 10 years, during which time several clinical studies have reported adverse events associated with macitentan outside of the drug description and uploaded them into the U.S. Food and Drug Administration's (FDA) Adverse Event Reporting System.Aim: This study aimed to promote the safe use of macitentan by mining and analyzing the adverse event signals of macitentan in the FAERS database.Method: The proportionate disequilibrium method was used to mine and analyze the FAERS database for macitentan-related adverse events. Preferred Terms of ADR reports were categorized by System Organ Class (SOC) based on the Medical Dictionary for Regulatory Activities. Results: A total of 32,607 macitentan adverse events were retrieved, and after exclusion by the methodology developed in this study, a total of 253 positive signals for AEs were obtained, and it was found that macitentan may have potential new adverse reactions such as blood potassium decreased(ROR [95% CI]= 3.51[3.10-3.98]), respiratory failure(ROR [95% CI]=4.06[3.77-4.39]), epistaxis(ROR [95% CI]=2.50[2.29-2.73]), and other potential adverse reactions in addition to the adverse reactions that have already been reported in the specification.Conclusion: Clinical attention is recommended for the new adverse drug reactions to macitentan detected in this study.

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