A data analysis of Alprostadil in the FDA Adverse Event Reporting System (FAERS) database

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July 10, 2023

Abstract

Background: In clinical experience, the adverse events of alprostadil are widely acknowledged; However, there remain adverse reactions that go unnoticed. Methods: In order to evaluate the imbalance of adverse events associated with alprostadil in real-world data, four algorithms (ROR, PRR, BCPNN, and EBGM) were utilized as metrics to identify signals of adverse events linked to alprostadil. Results: In this study, a total of 13,703,053 reported cases were collected from the FAERS database during the study period (from the third quarter of 2014 to the second quarter of 2023). 2393 case reports were analyzed after the exclusion of duplicates and identified using four algorithms. Among these cases, 725 AEs were identified, of which 119 were found to be ADRs related to alprostadil as the primary suspect drug. The observed adverse effects of alprostadil, including hypokalemia and pain, were discovered. Additionally, other noted adverse effects were identified, indicating a condition that is not mentioned in the package insert. Conclusion: This study has discovered previously unknown indicators of adverse drug reactions linked to alprostadil, offering valuable understanding into the correlation between adverse drug reactions and the usage of alprostadil. The results emphasize the potential negative effects arising from alprostadil usage, as well as the potential harm resulting from incorrect administration operation, ultimately enhancing patient safety throughout alprostadil treatment.

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