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Signal mining Study of Adverse Events of Vericiguat Based on FAERS Database

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SUMMARY. **Vericiguat was approved by the Food and Drug Administration (FDA) on January 19, 2021, for the treatment of chronic heart failure. Given its short time on the market, there is limited research regarding its adverse effects. Therefore, this study aimed to explore adverse drug events (ADEs) related to vericiguat in the FDA adverse event reporting system (FAERS) database and analyze its potential adverse reactions to provide a reference for safe clinical drug use. The reports on vericiguat in the FAERS database over two years from 2021 to 2022 were collected, and their signals were detected by disproportionality analysis. A total of 312 reports related to vericiguat were collected, with the majority being published in the United States. Twenty vericiguat-related ADE signals were retrieved, involving seven system organ classes (SOCs), mainly concentrated among "cardiac disorders (n = 5), general disorders and administration site conditions (n = 7), and investigations (n = 4)". Among them, 15 signals were not listed on the drug label, including "ejection fraction abnormal, blood creatinine increased, atrial fibrillation, oedema, and malaise". Our study identified several potential ADEs of vericiguat, several of which were not previously documented on the drug label, thus providing important information for clinicians when prescribing vericiguat and contributing towards improved patient safety.**

RESUMEN. Vericiguat fue aprobado por la Administración de Alimentos y Medicamentos (FDA) el 19 de enero de 2021 para el tratamiento de la insuficiencia cardíaca crónica. Dado su poco tiempo en el mercado, existe poca investigación sobre sus efectos adversos. Por lo tanto, este estudio tuvo como objetivo explorar los eventos adversos a medicamentos (ADE) relacionados con vericiguat en la base de datos del sistema de notificación de eventos adversos (FAERS) de la FDA y analizar sus posibles reacciones adversas para proporcionar una referencia para el uso clínico seguro de medicamentos. Se recopilaron los informes sobre vericiguat en la base de datos FAERS durante dos años, de 2021 a 2022, y sus señales se detectaron mediante análisis de desproporcionalidad. Se recogieron un total de 312 informes relacionados con el vericiguat, la mayoría publicados en Estados Unidos. Se recuperaron veinte señales de ADE relacionadas con vericiguat, que involucran siete clases de órganos y sistemas (SOC), concentradas principalmente entre "trastornos cardíacos (n = 5), trastornos generales y condiciones del lugar de administración (n = 7) e investigaciones (n = 4)". . Entre ellas, 15 señales no figuraban en la etiqueta del medicamento, incluidas "fracción de eyección anormal, aumento de creatinina en sangre, fibrilación auricular, edema y malestar". Nuestro estudio identificó varios EAM potenciales de vericiguat, varios de los cuales no estaban documentados previamente en la etiqueta del medicamento, proporcionando así información importante para los médicos al recetar vericiguat y contribuyendo a mejorar la seguridad del paciente.

KEY WORDS: adverse events, FDA adverse event reporting system, signal analysis, vericiguat.

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