# Data mining and analysis for Nilotinib adverse event signals based on the Food and Drug Administration Adverse Event Reporting System database

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## Abstract

Background: Nilotinib is a leukemia drug that can treat imatinib tolerance. During the drug trial, some adverse reactions of nilotinib have been proposed, and some articles have mentioned that nilotinib may have cardiovascular-related ADR signals. However, there is no systematic and comprehensive analysis of the potential ADR of nilotinib. AIM: The purpose of this study is to use the FDA adverse event reporting system (FAERS) database to detect the potential adverse event signals of nilotinib. Method: Data from the first quarter of 2015 to the fourth quarter of 2022 were selected for analysis from in the FAERS database. Use the preferred term in the Management activity Medical Dictionary (version 24.0) to extract cases of adverse events. The reported odds ratio (ROR) and information component (IC) methods based on statistical shrinkage transformation were used for disproportional analysis. Results: There were 24,451 adverse events associated with nilotinib in 11,190,626 records.A total of 529 positive signals of adverse reactions were found in taking nilotinib. Peripheral arterial occlusive disease ( 〖ROR〗 _025=41.74 〖IC〗 _025=5.36), Arteriosclerosis( 〖ROR〗 _025=33.49 〖IC〗 _025=5.04), Intermittent claudication ( 〖ROR〗 _025=32.12 〖IC〗 _025=4.96), Splenitis ( 〖ROR〗 _025=29.18 〖IC〗 _025=4.79), Peripheral vascular disorder ( 〖ROR〗 _025=27.00 〖IC〗 _025=4.72), Peripheral artery stenosis ( 〖ROR〗 _025=26.95 〖IC〗 _025=4.96), Carotid artery stenosis ( 〖ROR〗 _025=22.94 〖IC〗 _025=4.48) had the strongest signal intensities. Conclusion: This study found that patients with leukemia taking nilotinib may have adverse reactions such as arteriovenous adverse reactions, myocardial infarction, splenitis, intermittent claudication and so on. KEYWORDS Disproportionate analysis, Nilotinib, FAERS database, pharmacovigilance study, CML

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