Antibiotics and antibiotic-associated diarrhea: a real-world disproportionality study of the FDA Adverse Event Reporting System from 2004 to 2022

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Abstract

Aims: Our study aimed to assess the risk signals of antibiotic-associated diarrhea (AAD) caused by various antibiotics using real-world data and provide references for safe clinical applications. Methods: We analyzed data extracted from the FDA Adverse Event Reporting System (FAERS) database, covering the period from the first quarter of 2004 to the third quarter of 2022. We computed the odds ratio (ROR) for each antibiotic or antibiotic class to compare the signal difference. Furthermore, we also examined the differences in the onset times and outcomes of AAD caused by various antibiotics. Results: A total of 5,397 reports met the inclusion requirements. Almost all antibiotics, except tobramycin and minocycline (ROR 0.98 and 0.42, respectively), showed a significant correlation with AAD. The analysis of the correlation between different classes of antibiotics and AAD revealed that lincomycins (ROR 29.19), third-generation cephalosporins (ROR 15.96), and first/second generation cephalosporins (ROR 15.29) ranked the top three. The ROR values for antibiotics from the same class of antibiotics also varied greatly, with the ROR values for third-generation cephalosporins ranging from 9.97 to 58.59. There were also differences in ROR values between β-lactamase inhibitors and their corresponding β-lactamase drugs, such as amoxicillin-clavulanate (ROR = 13.31) and amoxicillin (ROR = 6.50). 91.35% antibiotics have an onset time of less than four weeks. Conclusions: There is a significant correlation between almost all antibiotics and AAD, particularly lincomycins and β-lactam antibiotics, as well as a different correlation within the same class. These findings offer valuable evidence for selecting antibiotics appropriately.

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