A real-world pharmacovigilance study of drug-induced QT interval prolongation:analysis of spontaneous reports submitted to FAERS

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Abstract

Objective: To identify the most commonly reported drugs associated with QT interval prolongation in the FDA Adverse Event Reporting System (FAERS) and evaluate their risk for QT interval prolongation. Methods: We employed the preferred term (PT) "electrocardiogram QT prolonged" from the Medical Dictionary for Regulatory Activities (MedDRA) 26.0 to identify adverse drug events (ADEs) of QT interval prolongation in the FAERS database from the period 2004-2022. Reporting odds ratio (ROR) was performed to quantify the signals of ADEs. Results: We listed the top 40 drugs that caused QT interval prolongation. The 3 drugs with the highest number of cases were quetiapine (1151 cases, ROR 7.62), olanzapine (754 cases, ROR 7.92), and citalopram (720 cases, ROR 13.63). The two most frequently reported first-level Anatomical Therapeutic Chemical (ATC) groups were the drugs for nervous system (n=19, 47.50%) and antiinfectives for systemic use (n=7, 17.50%). More females (7,536, 51.24%) than males (5,158, 35.07%) were involved. 3720 patients (25.29%) suffered serious clinical outcomes resulting in deaths or life-threatening conditions. Most drugs caused QT interval prolongation had early failure types according to the assessment of the Weibull's shape parameter (WSP) analysis. Conclusions: Our study offered a list of drugs that frequently caused QT interval prolongation based on the FAERS system, along with a description of some risk profiles for QT interval prolongation brought on by these drugs. When prescribing these drugs in clinical practice, we should closely monitor the occurrence of ADE for QT interval prolongation. Keywords: QT interval prolongation, pharmacovigilance, FAERS, data mining

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