Real-world Study of Antiresorptive-Related Osteonecrosis of Jaw Based on the US Food and Drug Administration Adverse Event Reporting System (FAERS) database

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Abstract

Objective To explore the risk signals of osteonecrosis of jaw induced by antiresorptive drugs and provide references for the clinical safety application. **Method** Based on the Food and Drug Administration Adverse Event Reporting System (FAERS) from January 2004 to June 2021, We chosen ‘Osteonecrosis of jaw’ as Preferred Terms (PT) and antiresorptive drugs. We used proportional reporting ratio (PRR), odds ratio (reporting odds ratio, ROR), Bayesian confidence propagation neural network (BCPNN) and multi-item Gamma-Poisson contraction (MGPS) algorithm to evaluate the association between drugs and adverse events. Results 27,065 reports related to osteonecrosis of the jaw in the FAERS dated from January 2004 to June 2021 . A total of 9 antiresorptive agents were included in the analysis. Affected patients tended to be older than 65 years. Most cases were reported from North America (39.82%) and Europe (36.15%) and were submitted by health-care professionals (81.44%). Pamidronate and clodronic acid showed a higher score than the other agents in every method. Zoledronic acid and denosumab were reported more than other agents.. Rate of hospitalization due to antiresorptive-related osteonecrosis of the jaw was from 7.66% to 28.78%; rate of fatality was from 0 to 12.78%. **Conclusion** All antiresorptive drugs may cause ONJ, and ONJ can be effectively prevented. Practitioners should consider the factors that may increase the likelihood of ONJ. The findings support a continued surveillance and risk factor identification studies.

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