

Characterization of Thrombosis After Vaccination: Analysis of The United States Vaccine Adverse Event Reporting System

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Abstract

Abstract: Background: Vaccines are considered one of the milestones of modern medicine that promoted health and curbed morbidity and mortality. However, with the rapid development and approval of different vaccines, various thrombotic events have been reported. Yet, a comprehensive analysis of vaccine-associated stroke and other thrombotic events is not well-characterized. Methods: We utilized the vaccine adverse event reporting system (VAERS) database from 1990-2021 to examine the association between vaccines and thrombotic events. We analyzed the data by sex and age, and vaccine type, and COVID-19 vaccine manufacturer. Disproportionality signal analysis was conducted by measuring reporting odds ratio (ROR) with a 95% confidence interval (CI). Results: Out of over 1.3 million adverse events reported in VAERS, more than 6000 were strokes between 1990-2021. Most strokes (70%) COVID-19 vaccines accounted for over 80% of all vaccine-related strokes with ROR (CI 95%) of 13.3 (CI 12.4-14.3, $p < 0.0001$). Among COVID-19 vaccines, Pfizer/Biotech was associated with 46%, Moderna with 40%, and Janssen with 12% of strokes. Finally, our data revealed that prothrombotic diseases of various vascular territories were reported the most among patients who have received COVID-19 vaccines with ROR (CI 95%) of 19.32 (CI 18.17-20.54; $p < 0.0001$). Among these thrombotic events myocardial infarction, pulmonary embolism, and deep vein thrombosis were the most predominant. Conclusion: Our data suggest a link between COVID-19 vaccines and thrombotic events, especially strokes. This retrospective study highlights the urgent need for further longitudinal studies to examine the safety of vaccines in patients with high risk for thrombosis.

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