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Short communication

Thrombocytopenia including immune thrombocytopenia after receipt of mRNA COVID-19 vaccines reported to the Vaccine Adverse Event Reporting System (VAERS)

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ABSTRACT

Background: The objective of this study is to assess cases of thrombocytopenia, including immune thrombocytopenia (ITP), reported to the Vaccine Adverse Event Reporting System (VAERS) following vaccination with mRNA COVID-19 vaccines.
Methods: This case-series study analyzed VAERS reports of thrombocytopenia after vaccination with Pfizer-BioNTech COVID-19 Vaccine or Moderna COVID-19 Vaccine.
Results: Fifteen cases of thrombocytopenia were identified among 18,841,309 doses of Pfizer-BioNTech COVID-19 Vaccine and 13 cases among 16,260,102 doses of Moderna COVID-19 Vaccine. The reporting rate of thrombocytopenia was 0.80 per million doses for both vaccines. Based on an annual incidence rate of 3.3 ITP cases per 100,000 adults, the observed number of all thrombocytopenia cases, which includes ITP, following administration of mRNA COVID-19 vaccines is not greater than the number of ITP cases expected.
Conclusions: The number of thrombocytopenia cases reported to VAERS does not suggest a safety concern attributable to mRNA COVID-19 vaccines at this time.

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1. Introduction

FDA issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine on December 11, 2020 as a two dose series administered 21 days apart [1]. Shortly after, on December 18, 2020, an EUA was issued for the Moderna COVID-19 Vaccine for administration as two doses given one month apart [2]. Both vaccines use a lipid-nanoparticle encapsulated mRNA platform that encodes the SARS-CoV-2 viral spike (S) glycoprotein. Interim recommendations for use were published by the Advisory Committee on Immunization Practices [3]. Prior to the issuance of the EUA for these vaccines, FDA and CDC planned for monitoring of their safety utilizing passive and active surveillance, which included enhanced surveillance for adverse events of special interest such as thrombocytopenia [4]. In addition, the EUA for both vaccines required reporting of serious adverse events (irrespective of attribution to vaccination) to the Vaccine Adverse Event Reporting System (VAERS), the national spontaneous reporting (passive surveillance) system for monitoring vaccine safety [1,2]. Shortly after authorization, FDA received reports of immune thrombocytopenia (ITP) in close temporal proximity to COVID-19 vaccination to VAERS. ITP is characterized by a platelet count less than 100 $x10^9$/L and immune-mediated destruction of platelets or impaired megakaryocytopoiesis [5]. Given that ITP has been associated with measles-mumps-rubella (MMR) vaccine and natural measles and rubella infection [6], it was considered biologically plausible to consider an association with COVID vaccines since ITP has also been associated with SARS-CoV-2 infection [7]. Thrombocytopenia was rarely reported in the clinical trial experience for mRNA COVID-19 vaccines with no imbalances between the vaccinated and placebo groups [8,9]. This report assesses thrombocytopenia cases, which includes ITP, reported to VAERS after vaccination against COVID-19 disease with the Pfizer-BioNTech or Moderna COVID-19 Vaccine.

2. Materials and methods

VAERS was searched for reports from the time of authorization of the first mRNA COVID-19 vaccine to the data lock point of February 4, 2020 for the following Medical Dictionary for Regulatory

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