ScienceDirect

Clinical Immunology

Volume 259, February 2024, 109882

Autoimmune and auto-inflammatory adverse events after COVID-19 vaccination in the United States

Seong-Jang Kim [a b c 1], Taeho Greg Rhee [d e f 1], Sung Ryul Shim [g h]

Show more

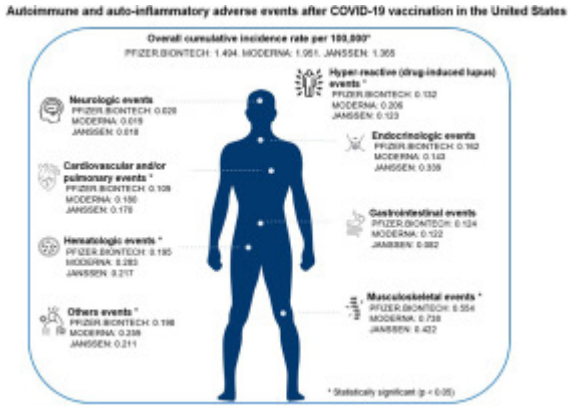
https://doi.org/10.1016/j.clim.2023.109882

Get rights and content

Abstract

We identified 3620 autoimmune-related adverse events among 223.2 million US residents using Vaccine Adverse Events Reporting System and the COVID-19 Data Tracker. This study is the first to quantify the cumulative incidence of autoimmune and auto-inflammatory adverse events after COVID-19 vaccination. We reported autoimmune and auto-inflammatory adverse events across 6 major classes of medical conditions and stratified by age, sex, and manufacturer.

Graphical abstract



Download : Download high-res image (201KB)

Download : Download full-size image

We identified 3,620 autoimmune-related adverse events among 223.2 million US residents using Vaccine Adverse Events Reporting System and the COVID-19 Data Tracker.

Introduction

The emergence of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) in December 2019 caused the novel coronavirus disease 2019 (COVID-19) pandemic and it is declared to be a global emergency by World Health Organization (WHO), which has negatively impacted globally [1]. Although accurate and rapid detection of SARS-CoV-2 infection is essential to reduce the spread of the virus, other many preventive approaches and non-pharmaceutical treatments have been used to decrease COVID-19 spread, including infection control, patient isolation, and social distancing.

Vaccination against COVID-19 is one of the most effective methods to prevent morbidity and mortality associated with SARS-CoV-2 infection. At present, >4.6 billion persons, about 59% of the world population, have received one or more doses [2]. A recent study showed that the effectiveness of COVID-19 vaccines in the general population aged≥16, the elderly, and healthcare workers was 86.1%,

83.8%, and 95.3%, respectively leading to the findings that COVID-19 vaccines are highly protective against SARS-CoV-2-related diseases [3].

Since December 2020, the three vaccines; BNT162b2 (Pfizer Inc./BioNTech SE, Mainz, Germany), mRNA-1273 (Moderna Therapeutic, Cambridge, Massachusetts, USA) and Ad26.COV2·S (Janssen Pharmaceuticals, Beerse, Belgium) have been widely used and could be evaluated using VAERS. [4]. The Centers for Disease Control and Prevention (CDC) expanded its passive surveillance system, Vaccine Adverse Event Reporting System (VAERS), to evaluate any potential vaccine-associated adverse events [5]. Although several studies have documented a temporal association between individual adverse events and COVID-19 vaccination [6,7], COVID-19 vaccine-related autoimmune and auto-inflammatory adverse events have not been fully explored.

Therefore, we aim to estimate the cumulative incidence (CIR) of autoimmune and autoinflammatory adverse reactions per 100,000 people fully vaccinated against COVID-19 in the United States. We reported autoimmune and auto-inflammatory adverse events across 6 major classes of medical conditions and stratified by age, sex, and manufacturer.

Section snippets

Methods

The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) reporting guidelines were followed in this study. This study was deemed exempt by the Institutional Review Boards at Konyang University and Yale School of Medicine, as we used publicly available, de-identified data.…

Results

There were 3620 autoimmune and autoinflammatory AEs identified in the VAERS database and 223,270,498 fully vaccinated individuals in the United States identified in the CDC Data Tracker. Since the COVID-19 vaccine was first approved in the United States

in December 2020, actual data were collected from December 2020 to September 2022. The reports of AEs by Pfizer-BioNTech, Moderna, and Janssen groups were 1921 (52.4%), 1515 (41.3%), and 233 (6.4%), respectively. Fully vaccinated people of…

Discussion

The world-wide vaccination efforts to protect the general population against COVID-19 were the most important step to curb the spreading the SARS-CoV-2. In the USA, FDA authorized vaccines have helped in significantly reducing the morbidity and mortality of the disease, hospitalization and prevented socioeconomic burden effects of SARS-CoV-2 [9].

In general, the most common COVID-19 vaccine-related autoimmune and autoinflammatory AEs are reported to be thrombocytopenia, myocarditis, GBS,…

Funding/Support

None.…

Informed consent

Written informed consent was not required for this study because this study based on the publicly available CDC database.…

Ethical statement

Institutional review board approval was not required because this study based on the publicly available CDC database.…

Declaration of Competing Interest

The authors of this manuscript declare no relationships with any interest related to the subject matter of the article.…

Recommended articles

References (14)

T. Dörner *et al.*
Novel paradigms in systemic lupus erythematosus
Lancet (2019)

C. Zheng *et al.*
Real-world effectiveness of COVID-19 vaccines: a literature review and meta-analysis
Int. J. Infect. Dis. (2022)

T.T. Shimabukuro *et al.*
Safety monitoring in the vaccine adverse event reporting system (VAERS)
Vaccine (2015)

Y. Rodríguez *et al.*
Autoinflammatory and autoimmune conditions at the crossroad of COVID-19
J. Autoimmun. (2020)

P. Vizcarra *et al.*
BNT162b2 mRNA COVID-19 vaccine Reactogenicity: the key role of immunity
Vaccine (2021)

S. Mallapaty *et al.*
How COVID vaccines shaped 2021 In eight powerful charts
Nature (2021)

U.S. Food & Drug Administration

Comirnaty and Pfizer-BioNTech COVID-19 vaccine

(2020)

There are more references available in the full text version of this article.

Cited by (0)

1 These authors contributed equally to this work.

View full text