

Ventricular fibrillation and ventricular tachycardia post-SARS-CoV-2-targeted mRNA/viral vector vaccination



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The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-targeted messenger RNA (mRNA)/viral vector vaccines have been effective in preventing severe infection requiring hospitalization with COVID-19.¹ Multiple studies and postmarketing surveillance have reported on the safety profile of SARS-CoV-2-targeted mRNA/viral vector vaccines with only a few rare documented adverse outcomes.² While minor side effects like fatigue, muscle pain, headache, chills, redness/swelling at the injection site, joint pain, fever, and rare anaphylactic reactions have been reported, the data on the incidence of ventricular cardiac rhythm abnormalities post-SARS-CoV-2-targeted mRNA/viral vector vaccination are limited.³ A study using the Vaccine Adverse Event Reporting System (VAERS) reported the incidence of atrial fibrillation of around 5 per million SARS-CoV-2-targeted mRNA/viral vector vaccine doses administered.⁴ The current study aimed at reporting the incidence of ventricular fibrillation (VF) and ventricular tachycardia (VT) post-SARS-CoV-2-targeted mRNA/viral vector vaccination as reported in the VAERS database.

VAERS a passive reporting system database co-managed by the Centers for Disease Control and Prevention and the U.S. Food and Drug Administration. It has been used to identify potential adverse events related to vaccines approved in the United States early. VAERS is not designed to establish causation between the adverse event and vaccine but is helps establish unusual occurrences of adverse events among individuals postvaccination.

KEYWORDS Ventricular fibrillation; Ventricular tachycardia; Adverse effect; Vaccine; SARS-CoV-2 (Heart Rhythm 0² 2023;4:826–828)

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Events of VF and VT from VAERS database was extracted as of last update on May 26, 2023, and were reported as absolute numbers. Further, event rates were reported overall, reporting as new onset VF and VT, stratified by sex, VF and VT occurring <7 or ≥7 days since vaccination, following first and second dose, and among <40 and ≥40 years of age. Individual subgroups were further stratified based on the type of SARS-CoV-2-targeted mRNA vaccine such as Moderna and Pfizer/BioNTech and the viral vector vaccine as Johnson Johnson's. The total dose of SARS-CoV-2-targeted mRNA/viral vector vaccination administered was obtained from the Centers for Disease Control and Prevention website. The current study was deemed exempt from institutional ethical board approval, as no identifiable patient data were used in the present analysis.

In the United States, a total of 516 VF/VT (167 VF and 349 VT) events were reported as an adverse event post-SARS-CoV-2-targeted mRNA/viral vector vaccination from the beginning of the vaccination until May 2023 (Table 1). Close to 676,728,000 SARS-CoV-2-targeted mRNA/viral vector vaccines were administered during this period, resulting in incidence of VF/VT reported as adverse events post-SARS-CoV-2-targeted mRNA vaccination of 0.76 per 1 million vaccinations. Of the total administered SARS-CoV-2-targeted mRNA/viral vector vaccines, ~ 401,685,000 were manufactured by Pfizer/BioNTech, making the incidence of reported VF/VT specific to Pfizer/BioNTech to be 0.75 per 1 million vaccinations. The incidence of reported VF/VT specific to the Moderna vaccine was 1 per 1 million vaccinations. Only 3 VF and 8 VT events were reported as new onset postvaccination. The absolute numbers of VF and VT reported were higher in males compared with females (121 VF and 204 VT vs 45 VF and 145 VT). Further, the absolute number of VF and VT occurring were higher ≥7 days since vaccination and

KEY FINDINGS

- In the U.S. a total of 516 ventricular fibrillation/ventricular tachycardia (VF/VT) (167 VF and 349 VT) events were reported as an adverse event post severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-targeted messenger RNA (mRNA)/viral vector vaccination from the beginning of the vaccination until May 2023.
- The incidence of VF/VT reported as adverse events post-SARS-CoV-2-targeted mRNA vaccination was 0.76 per 1 million vaccination.
- The absolute number of VF and VT occurring were higher ≥ 7 days since vaccination and after the second dose.

Table 1 Ventricular tachycardia and ventricular fibrillation post COVID-19 vaccination as reported in the Vaccine Adverse Event Reporting System

	Ventricular tachycardia	Ventricular fibrillation
All ventricular arrhythmias		
Total events	349	167
Johnson & Johnson	12 (3.44)	19 (11.38)
Moderna	207 (59.31)	82 (49.10)
Pfizer/BioNTech	213 (61.03)	89 (53.29)
New onset ventricular arrhythmia		
Total events	8	3
Johnson & Johnson	—	2 (66.67)
Moderna	4 (50)	—
Pfizer/BioNTech	6 (75)	1 (33.33)
Male		
Total events	204	121
Johnson & Johnson	5 (2.45)	17 (14.05)
Moderna	130 (63.73)	60 (49.59)
Pfizer/BioNTech	109 (58.33)	61 (50.41)
Female		
Total events	145	45
Johnson & Johnson	7 (4.83)	2 (4.44)
Moderna	77 (53.10)	22 (48.89)
Pfizer/BioNTech	94 (64.83)	26 (57.78)
<7 d for ventricular arrhythmia onset since vaccination		
Total events	134	71
Johnson & Johnson	4 (2.99)	4 (5.63)
Moderna	82 (61.19)	28 (39.44)
Pfizer/BioNTech	65 (61.19)	39 (54.93)

(Continued)

Table 1 (Continued)

	Ventricular tachycardia	Ventricular fibrillation
≥ 7 d for ventricular arrhythmia onset since vaccination		
Total events	213	94
Johnson & Johnson	8 (3.76)	15 (15.96)
Moderna	125 (58.69)	54 (57.45)
Pfizer/BioNTech	146 (68.54)	48 (51.06)
Following first dose		
Total events	141	74
Johnson & Johnson	12 (8.51)	12 (16.22)
Moderna	63 (44.68)	27 (36.49)
Pfizer/BioNTech	69 (48.94)	35 (47.30)
Following second or following doses		
Total events	234	85
Johnson & Johnson	—	1 (1.18)
Moderna	125 (53.42)	46 (54.12)
Pfizer/BioNTech	125 (53.42)	41 (48.24)
Age <40 y		
Total events	56	21
Johnson & Johnson	3 (5.36)	1 (4.76)
Moderna	21 (37.50)	10 (47.62)
Pfizer/BioNTech	42 (75.00)	11 (52.38)
Age ≥ 40 y		
Total events	293	146
Johnson & Johnson	9 (3.07)	18 (12.33)
Moderna	186 (63.48)	72 (49.32)
Pfizer/BioNTech	171 (58.36)	78 (53.42)

Values are n or n (%).

after the second dose. The number of VF/VT events were more among individuals ≥ 40 years of age. Finally, of the 167 VF events reported, 88 had death as the outcome, and of the 349 VT events reported, 74 had death as the outcome.

Overall, the incidence of VF/VT reported as an adverse event post-SARS-CoV-2-targeted mRNA/viral vector vaccination was low. To provide context, as of May 2023, 270,227,000 people, or 81% of the U.S. population, had received at least the first dose SARS-CoV-2-targeted mRNA/viral vector vaccination, and 230,637,000 people, or 70% of the population, were considered completely vaccinated. A study using the English National Immunization Database of COVID-19 vaccination linked to national data for mortality, hospital admissions, and SARS-CoV-2 infection, reported among 38,615,491 vaccinated individuals, 86,754 (0.2%) had cardiac arrhythmia 1 to 28 days postvaccination. Of the cardiac arrhythmias, only 2676 were VF or VT

after either the first or second dose.⁵ The results further reinforce the results obtained from our study related to the low incidence of VF/VT post-SARS-CoV-2-targeted mRNA/viral vector vaccination. Interestingly, the study also reported an increased risk of VF at 22 to 28 days (late) following a second dose of the ChAdOx1 vaccine (the Oxford–AstraZeneca viral vector vaccine, a World Health Organization approved COVID-19 vaccine not used in the United States) (incidence rate ratio 1.35, 95% CI 1.05–1.74) compared with all VF recorded during the study period with the ChAdOx1 vaccine, which was similar to the results obtained from our study, with higher VF/VT ≥ 7 days since vaccination.⁵

The current study is best interpreted in the context of several limitations. First, as mentioned previously, the VAERS database is not designed to establish causation. Second, the VAERS database does not provide information on the total number of vaccines administered, and the presentation of subgroups as incidence rates was not possible. The VAERS database is a passive reporting system, and under/overreporting is a possibility. Finally, because an individual could have received 2 different manufactured brands of vaccines, the overall and subgroup percentages can add up to be over 100%.

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