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## Acute Myocarditis Following COVID-19 mRNA Vaccination in Adults Aged 18 Years or Older

Vaccination is an essential component of the public health strategy to end the COVID-19 pandemic.[1-3] Recently, there have been reports of acute myocarditis following COVID-19 mRNA vaccine administration.[4-6] We evaluated acute myocarditis incidence and clinical outcomes among adults following mRNA vaccination in an integrated health care system in the US.

**Methods** | We included Kaiser Permanente Southern California (KPSC) members aged 18 years or older who received at least 1 dose of the BNT162b2 (Pfizer) or mRNA-1273 (Moderna) mRNA vaccine between December 14, 2020, and July 20, 2021. Potential cases of postvaccine myocarditis were identified based on reports from clinicians to the KPSC Regional Immunization Practice Committee and by identifying hospitalization within 10 days of vaccine administration with a discharge diagnosis of myocarditis. All cases were independently adjudicated by at least 2 cardiologists. We calculated incidence rates and 95% confidence intervals (CIs) of myocarditis using vaccine administration as the denominator and compared it with the incidence of myocarditis in unexposed individuals between December 14, 2020, and July 20, 2021; and with vaccinated individuals during a 10-day period 1 year prior to vaccination. Incidence rate ratios (IRRs) and 95% CIs were calculated using STATA statistical software (version 14, Stata Corp). We described the characteristics and outcomes of acute myocarditis cases. A 2-sided $P < .05$ was used to define statistical significance. This study was approved by the institutional review board of KPSC with a waiver of informed consent because of the observational nature of the study in the course of standard care.

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**Results** | Of 2 392 924 KPSC members who received at least 1 dose of COVID-19 mRNA vaccines, 50.2% received mRNA-1273 and 50.0% BNT162b2. In this cohort, 54.0% were women, 31.2% White, 6.7% Black, 37.8% Hispanic, and 14.3% were Asian individuals. Median age was 49 years (IQR, 34-64 years), 35.7% were younger than 40 years, and 93.5% completed 2 doses of vaccines. In the unexposed group of 1 577 741 individuals, median (IQR) age was 39 (28-53) years, 53.7% were younger than 40 years, 49.1% women, 29.7% White, 8.8% Black, 39.2% Hispanic, and 6.6% were Asian individuals.

There were 15 cases of confirmed myocarditis in the vaccinated group (2 after the first dose and 13 after the second), for an observed incidence of 0.8 cases per 1 million first doses and 5.8 cases per 1 million second doses over a 10-day observation window (**Table 1**). All were men, with a median (IQR) age of 25 (20-32) years. Among unexposed individuals, there were 75 cases of myocarditis during the study period, with 39 (52%) men and median (IQR) age of 52 (32-59) years. The IRR for myocarditis was 0.38 (95% CI, 0.05-1.40) for the first dose and 2.7 (95% CI, 1.4-4.8) for the second dose. Sensitivity analyses using vaccinated individuals as their own controls showed similar findings (Table 1).

Of the patients with myocarditis postvaccination, none had prior cardiac disease (**Table 2**). Eight patients received BNT162b2 and 7 received mRNA-1273. All were hospitalized and tested negative for SARS-CoV-2 by polymerase chain reaction on admission. Fourteen (93%) reported chest pain between 1 to 5 days after vaccination. Symptoms resolved with conservative management in all cases; no patients required intensive care unit admission or readmission after discharge.

**Table 1. Incidence Rates and Rate Ratios of Myocarditis in Vaccinated Individuals Compared With Control Groups**

| Variable | Myocarditis cases, No. | No. of at-risk individuals | Follow-up time, person-days | Incidence over a 10-d observation period per 1 million individuals (95% CI) | Incidence rate ratio (95% CI) | *P* value |
|---|---|---|---|---|---|---|
| Compared with individuals who did not receive the COVID-19 mRNA vaccine | | | | | | |
| Unexposed[a] | 75[b] | 1 577 741 | 343 947 538 | 2.2 (1.7-2.7) | | |
| 0-10 d After dose 1 | 2 | 2 392 924 | 23 929 240 | 0.8 (0.2-3.3) | 0.38 (0.05-1.40) | .15 |
| 0-10 d After dose 2 | 13 | 2 236 851 | 22 368 510 | 5.8 (3.4-10) | 2.7 (1.4-4.8) | .004 |
| Compared to the same cohort during a 10-d period 1 y prior to vaccination[c] | | | | | | |
| During a 10-d observation period 1 y prior to dose 1 | 2 | 2 392 924 | 23 929 240 | 0.8 (0.2-3.3) | | |
| 0-10 d After dose 1 | 2 | 2 392 924 | 23 929 240 | 0.8 (0.2-3.3) | 1.0 (0.1-13.8) | >.99 |
| During a 10-d observation period 1 y prior to dose 2 | 4 | 2 236 851 | 22 368 510 | 1.8 (0.7-4.8) | | |
| 0-10 d After dose 2 | 13 | 2 236 851 | 22 368 510 | 5.8 (3.4-10) | 3.3 (1.0-13.7) | .03 |

Abbreviation: KPSC, Kaiser Permanente Southern California.

[a] Members of the KPSC integrated health system who did not receive the COVID-19 mRNA vaccine between December 14, 2020, and July 20, 2021.

[b] Number of myocarditis cases between December 14, 2020, and July 20, 2021; 24 cases were in individuals aged 18 to 40 years.

[c] Using vaccinated individuals as their own controls. Myocarditis cases were identified during a 10-day period. For the vaccinated group, the 10-day postvaccination period was measured from the day of vaccination until day 10 after vaccination. For control, a 10-day period began 365 days prior to their vaccination date and ended 355 days prior to their vaccination date.

Table 2. Case Description and Clinical Course[a]

| Patient No. | Demographics[b] | Days to chest pain onset | ECG | Troponin I peak, ng/mL | Evaluation of CAD | LVEF on echo, % | LOS, d |
|---|---|---|---|---|---|---|---|
| 1 | 18-25 y, White man | 7 | Diffuse ST elevation | 8.10 | No CT evidence of CAD | 55-60 | 3 |
| 2 | 18-25 y, White man | 5 | Inferolateral T wave inversion | 8.87[c] | No CT evidence of CAD | 55-60 | 2 |
| 3 | 18-25 y, White man | 5 | Sinus tachycardia, no ischemic changes | 1.59[c] | No CT evidence of CAD | 60-65 | 3 |
| 4 | 26-40 y, White man | 3 | No ischemic changes | 2.50 | Normal coronaries on cardiac catheterization | 60-65 | 3 |
| 5 | 26-40 y, Hispanic man | 3 | Diffuse ST elevation | 1.53[c] | Normal coronaries on cardiac catheterization | 55-60 | 1 |
| 6 | 26-40 y, White man | 3 | Diffuse ST elevation | 17.12[c] | Normal coronaries on cardiac catheterization | 45, Global hypokinesis | 3 |
| 7 | 18-25 y, White man | 4 | Diffuse ST elevation | 5.00 | No cardiac catheterization or CT performed | 60-65 | 2 |
| 8 | 18-25 y, Hispanic man | 2 | Diffuse ST elevation | 11.79 | No CT evidence of CAD, MRI with myopericarditis | 50-55 | 3 |
| 9 | 18-25 y, White man | 3 | No ischemic changes | 7.37 | No CT evidence of CAD | 55-50 | 5 |
| 10 | 26-40 y, Hispanic man | 1 | No ischemic changes | 2.98 | Normal coronaries on cardiac catheterization | 60-65 | 3 |
| 11 | 26-40 y, man, unknown ethnicity | 3 | Diffuse ST elevation | 32.30 | No CT evidence of CAD | 55-60 | 3 |
| 12 | 26-40 y, White man | 1 | Diffuse ST elevation | 6.28 | No cardiac catheterization or CT performed | 55-60 | 1 |
| 13 | 18-25 y, Hispanic man | 3 | Diffuse ST elevation | 16.9 | No cardiac catheterization or CT performed | 30-35, Global hypokinesis[d] | 3 |
| 14 | 18-25 y, White man | 1 | Diffuse ST elevation | 15.9[c] | No cardiac catheterization or CT performed | 50-55 | 3 |
| 15 | 26-40 y, Asian man | 2 | Diffuse ST elevation | 0.49[c] | No CT evidence of CAD | 50-55 | 3 |

Abbreviations: CAD, coronary artery disease; CT, computed tomography; ECG, electrocardiogram; Echo, echocardiogram; LOS, length of stay; LVEF, left ventricular ejection fraction; MRI, magnetic resonance imaging.

[a] To confirm myocarditis, the following criteria were used (1) symptoms consistent with myocarditis, (2) elevated troponin I level, (3) no evidence of obstructive coronary artery disease, and (4) no other identifiable cause.

[b] Self-reported race and ethnicity from the electronic health record. To protect patient privacy, patient age was designated as either 18 to 25 or 26 to 40 years.

[c] High-sensitivity troponin I values were converted from pg/mL to ng/mL (99th upper reference limit: 0.02 ng/mL).

[d] LVEF recovered on a follow-up echocardiogram.

**Discussion** | In this population-based cohort study of 2 392 924 individuals who received at least 1 dose of COVID-19 mRNA vaccines, acute myocarditis was rare, at an incidence of 5.8 cases per 1 million individuals after the second dose (1 case per 172 414 fully vaccinated individuals). The signal of increased myocarditis in young men warrants further investigation.

This vaccinated cohort is unique in its racial and ethnic diversity and in receiving care at community hospitals with treatment reflective of real-world practice. Limitations of this study include the observational design; short follow-up time; absence of myocardial biopsy for definitive diagnosis; lack of uniform testing of all cases; possible more extensive workup of chest pain in vaccinated individuals during the immediate postvaccination period; and possible underdiagnosis of subclinical cases. No relationship between COVID-19 mRNA vaccination and postvaccination myocarditis can be established given the observational nature of this study.

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## Association of Nursing Home Characteristics With Staff and Resident COVID-19 Vaccination Coverage

Vaccines have been instrumental in reducing COVID-19 cases and related deaths among US nursing home residents.[1] However, low vaccination coverage among nursing home staff,[2] who may introduce COVID-19 into facilities, could contribute to future outbreaks, especially in the presence of more transmissible variants.[3,4] Maximizing vaccination coverage among nursing home staff and residents is critical because of the extreme vulnerability of this population to COVID-19, but little is known about which nursing homes have been successful at achieving high vaccination coverage.

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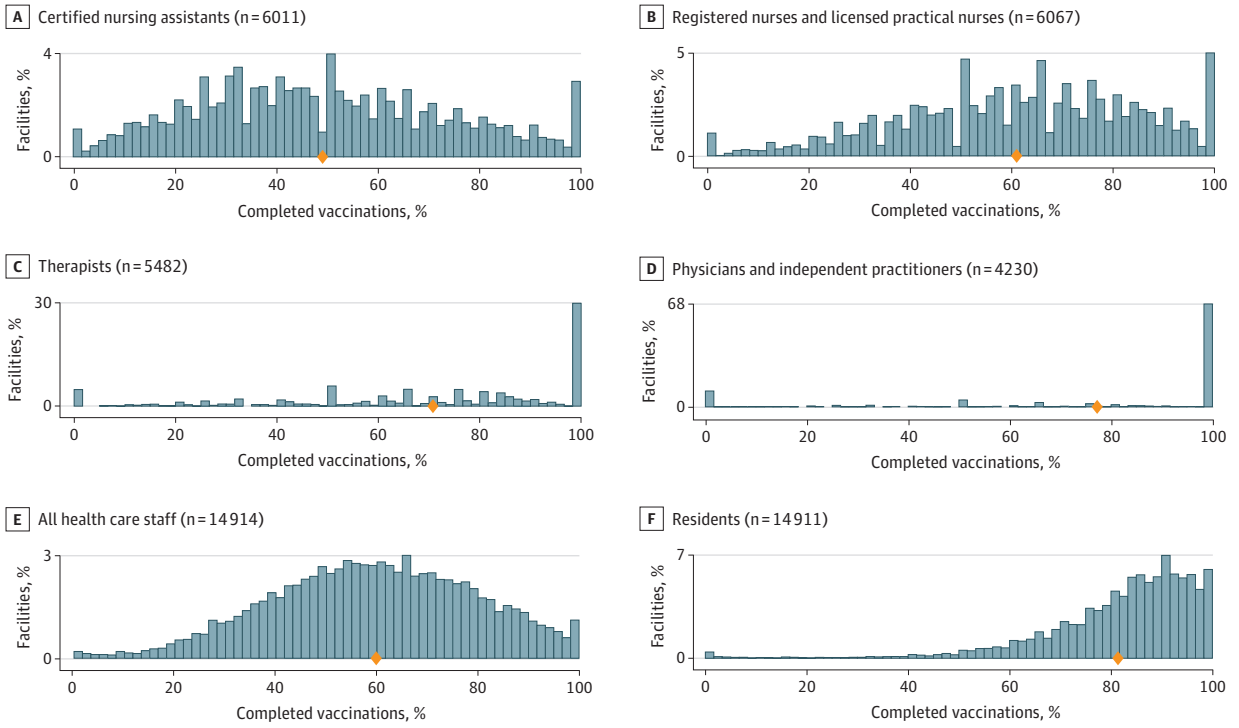
Supplemental content

**Methods** | We performed a cross-sectional analysis of federal National Healthcare Safety Network facility-level data through the week ending July 18, 2021, combined with other publicly available data sets (eMethods 1 in the Supplement). We examined the percentage of completed COVID-19 vaccinations among nursing home residents and different staff types at each facility, including all health care personnel eligible to work in the nursing home in the prior week, registered nurses and licensed practical nurses, certified nursing assistants (CNAs), therapists, and physicians and independent practitioners. Estimated means were weighted by the relevant population size (resident census and staff counts). Per Harvard University institutional policy, institutional review board approval and written informed consent were not required owing to use of publicly available data. This study was informed by the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines for cross-sectional studies.

We examined the association between weighted group vaccination coverage and facility characteristics using multivariate linear regressions. The regressions included state fixed effects to account for the state variation in vaccine availability and other policies. Facility characteristics of interest included ownership status, overall quality rating, demographic characteristics of residents and staff, percentage of direct care

Figure 1. Distribution of Completed Vaccination Coverage Among Nursing Home Residents and Staff




Orange diamonds denote weighted estimates of average vaccination coverages for each group. Weights are obtained from the corresponding number of staff members or residents within each facility reported in the National Healthcare Safety Network data.