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Adverse events, including cardiac involvement, after vaccination for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been reported. We sought to evaluate trends of hospital encounters for vaccine recipients before and after vaccination. We analyzed patients who received the coronavirus disease 2019 (COVID-19) vaccine in the MedStar Health system (11 hospitals in Washington, District of Columbia and Maryland) from December 2020 through August 2021. We then compared hospital encounters (emergency department visits) of patients 60 days before a vaccine dose and 30 days after a vaccine dose, along with encounters related to the SARS-CoV-2 infection itself. The cohort included 5,217 patients who were vaccinated against COVID-19. Our analysis revealed a total of 6,751 emergency department visits, and we divided this total into 3 cohorts: fully vaccinated (n = 1,779), in vaccination window (n = 1,420), and before vaccination (n = 3,552). We found no significant association between vaccination and rate of presentation for acute coronary syndrome, pericarditis, myocarditis, heart failure, conduction abnormality, or noncardiac conditions. Further, encounters for complications related to SARS-CoV-2 infection decreased significantly from those before vaccination (5.4%) to those in vaccination window (4.2%) to those who were fully vaccinated (1.6%). These findings were consistent when all vaccinated encounters were combined into 1 cohort (fully vaccinated + in vaccination window). In conclusion, our analysis suggests that there is no significant association of COVID-19 vaccination with the rate of hospital encounters for cardiac disease, including acute coronary syndrome, pericarditis, myocarditis, congestive heart failure, and conduction abnormality. Further, administration of the vaccine resulted in a significant decrease in hospital encounters for SARS-CoV-2 infections and associated complications. © 2022 Published by Elsevier Inc. (Am J Cardiol 2022;170:105–111)
“in vaccination window.” The final diagnosis and inclusion in our analysis as the primary end point was based on the hospital-stay International Classification of Diseases, Tenth Revision (ICD-10) codes from our EMR system. In our EMR system, this ICD-10 code is identified as “active encounter”.

Baseline characteristics were collected for all patients. The rate of hospital encounter during the 60 days before vaccination was compared with the 30 days after vaccination. ICD-10 diagnosis rates were reported on a per hospital encounter basis rather than a per patient basis. Vaccination status at each visit was categorized as before vaccination, in vaccination window, or fully vaccinated. Before vaccination was defined as the encounter occurring before receiving any vaccine dose. In vaccination window was defined as the encounter having occurred after 1 dose but before the second dose of the Pfizer (New York, New York)-BioNTech or Moderna vaccine. Fully vaccinated was defined as the encounter having occurred after the single dose Ad26.COV2.S vaccine (Janssen/Johnson and Johnson). These cohorts were compared individually, and then further analysis was performed with the in vaccination window and fully vaccinated cohorts being combined. This study was conducted in accordance with the Declaration of Helsinki and was approved by our institutional review board.

Descriptive statistics such as frequencies, means, and standard deviations were used to describe the study population. A t test or analysis of variance was used to compare mean values of normally distributed data. 2-tailed Fisher’s exact test or chi-square test was used to compare categoric variables. Statistical significance was considered to be a p value <0.05. All analyses were done in SAS 9.4 (SAS Institute, Cary, North Carolina). One author (B.C.C.) has full access to all the data in the study and takes full responsibility for its integrity and the data analysis.

### Results

The cohort included 5,217 patients who received the COVID-19 vaccine, with 3,146 receiving the Pfizer-BioNTech vaccine, 1,682 receiving the Moderna vaccine, and 389 receiving the Ad26.COV2.S vaccine (Janssen/Johnson and Johnson). Our analysis revealed a total of 6,751 emergency department visits, and we divided this total into 3 cohorts: fully vaccinated (26.35%), in vaccination window (21.03%), and before vaccination (52.61%). Baseline characteristics are displayed in Table 1. In this cohort of vaccinated patients, the mean age was 58.23 ± 17.84 years, and the majority were women. The majority received the Pfizer-BioNTech vaccine (60.3%), with the remaining patients receiving the Moderna vaccine (32.2%) or the Johnson and Johnson vaccine (7.5%).

Table 2 summarizes the hospital encounters during the 60 days before receiving the vaccine (before vaccination) compared with the 30 days after vaccination (fully vaccinated). In the 30 days after vaccination, there was a significantly increased rate of hospital encounters for cerebrovascular events. However, this increased rate of cerebrovascular event presentations was only seen in the subset of fully vaccinated patients; it was seen less in the in vaccination window group. In addition, this trend was not seen when the 2 vaccination

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**Table 1**

| Demographics | Overall (N = 5,217) | Pfizer (N = 3,146) | Moderna (N = 1,682) | Johnson & Johnson (N = 389) | p-Value |
|--------------|-------------------|--------------------|---------------------|-----------------------------|---------|
| Age ± SD (years) | 58.23±17.84 | 57.75±17.89 | 59.90±17.75 | 55.31±17.19 | <0.001 |
| Male | 36.2% | 33.9% | 36.9% | 50.9% | <0.001 |
| Ethnicity | | | | | |
| White | 37.0% | 34.1% | 43.4% | 33.2% | <0.001 |
| Black | 54.2% | 56.1% | 49.5% | 59.5% | <0.001 |
| Asian | 1.9% | 2.2% | 1.7% | 1.0% | 0.201 |
| Multi-ethnicity | 0.5% | 0.5% | 0.4% | 0.5% | 0.941 |
| Native American | 0.1% | 0.1% | 0.2% | 0.0% | 0.680 |
| Other | 6.0% | 6.8% | 4.7% | 5.5% | 0.010 |

SD = standard deviation.

**Table 2**

| Cardiovascular                | Overall (N = 6,751) | Fully Vaccinated (N = 1,779) | In Vaccination Window (N = 1,420) | Before Vaccination (N = 3,552) | p-Value |
|------------------------------|---------------------|-------------------------------|-----------------------------------|---------------------------------|---------|
| Coronary artery disease*     | 12.9%               | 14.1%                         | 12.4%                             | 12.6%                           | 0.247   |
| Congestive heart failure     | 12.2%               | 13.0%                         | 10.8%                             | 12.4%                           | 0.170   |
| Conduction abnormalities     | 12.7%               | 13.8%                         | 12.9%                             | 12.1%                           | 0.201   |
| Valvular heart disease       | 3.9%                | 4.6%                          | 3.5%                              | 3.80%                           | 0.52    |
| Pericarditis                 | 0.52%               | 0.62%                         | 0.42%                             | 0.51%                           | 0.738   |
| Myocarditis                  | 0.04%               | 0.11%                         | 0.00%                             | 0.03%                           | 0.256   |

(continued)
cohorts were combined. There was also a significantly increased rate of hospital encounters for “musculoskeletal disease” and “hyperlipidemia.” These findings are difficult to draw conclusions from and may be due to chance.

As expected, the rates of encounters for “respiratory infection” were significantly decreased after full vaccination. More importantly, we found no significant association between vaccination and rate of presentations for coronary artery disease (including acute coronary syndrome), pericarditis, myocarditis, heart failure, or conduction abnormality. Further, there was no difference when it came to gastrointestinal disorders, hematologic disorders, genitourinary disorders, and multiple other diagnoses.

Table 3 summarizes hospital encounters specifically related to COVID-19 and the direct administration of the vaccines themselves. An ICD-10 diagnosis of “vaccine reaction” was reported in 2.4% of hospital encounters in the in vaccination window cohort and in 2.1% of encounters for the fully vaccinated cohort. Specifically, the rate of allergic reactions in fully vaccinated patients was 0.4%,
and an encounter for an adverse reaction to the vaccines was 0.2%. More importantly, encounters for complications related to SARS-CoV-2 infection decreased significantly from those before vaccination (5.4%) to those who were fully vaccinated (1.6%). Furthermore, presentations for acute respiratory failure due to COVID-19 decreased significantly from 0.5% in the before vaccination cohort to 0.1% in the fully vaccinated cohort.

Tables 4 and 5 summarize our secondary analysis in which we combined the fully vaccinated and in vaccination window cohorts and compared them with the visits before vaccination. In Table 4, the diagnoses were similar in the 2 cohorts. Further, the previous differences of cerebrovascular events and musculoskeletal disorders are no longer seen, whereas hyperlipidemia and respiratory infections continued to differ between the 2 cohorts. Table 5 summarizes hospital encounters specifically related to COVID-19 based on vaccination status overall. Once again, findings were similar in this analysis with the 3 cohorts in Table 3.

Discussion

The results of our primary analysis from our large cohort suggests that there is no significant association of COVID-19 vaccination with the rate of hospital encounters for

| Table 3 |
| --- |
| Hospital encounters related to vaccine and COVID-19 based on vaccination status |
| | Overall (N = 6,751) | Fully Vaccinated (N = 1,779) | In Vaccination Window (N = 1,420) | Before Vaccination (N = 3,552) |
| Vaccine reaction | 1.1% | 2.1% | 2.4% | 0.0% | <0.001 |
| Allergic reaction | 0.1% | 0.4% | 0.3% | 0.0% | <0.001 |
| Adverse reaction | 0.1% | 0.2% | 0.3% | 0.0% | 0.011 |
| COVID-19 complication | 4.1% | 1.6% | 4.2% | 5.4% | <0.001 |
| SARS-CoV-2 infection | 4.1% | 1.6% | 4.2% | 5.4% | <0.001 |
| Acute respiratory failure | 0.3% | 0.1% | 0.2% | 0.5% | 0.035 |
| History of COVID-19 | 2.2% | 2.0% | 2.1% | 2.3% | 0.818 |
| COVID-19 exposure | 24.2% | 25.1% | 23.5% | 24.0% | 0.540 |

Boldface type denotes statistical significance. COVID-19 = coronavirus disease 2019; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

| Table 4 |
| --- |
| Hospital encounters based on vaccination status overall |
| | Overall (N = 6,751) | Vaccinated (N = 3,199) | Before Vaccination (N = 3,552) | p-Value |
| Coronary artery disease* | 12.9% | 13.3% | 12.6% | 0.352 |
| Congestive heart failure | 12.2% | 12.0% | 12.4% | 0.684 |
| Conduction abnormalities | 12.7% | 13.4% | 12.1% | 0.108 |
| Valvular heart disease | 3.9% | 3.8% | 3.80% | 0.668 |
| Pericarditis | 0.52% | 0.53% | 0.51% | 0.888 |
| Myocarditis | 0.04% | 0.06% | 0.03% | 0.504 |
| Hypertension without complications | 42.6% | 43.6% | 41.8% | 0.124 |
| Hypertension with complications | 12.9% | 12.7% | 13.1% | 0.577 |
| Hypotension | 3.5% | 3.6% | 3.4% | 0.580 |
| Peripheral vascular disease | 6.8% | 6.7% | 7.0% | 0.630 |
| Hyperlipidemia | 27.1% | 28.7% | 25.7% | 0.006 |
| Neurologic | | | | |
| Cerebrovascular event | 3.5% | 3.8% | 3.2% | 0.250 |
| Neurological disorder | 13.3% | 12.5% | 13.9% | 0.083 |
| Peripheral neuropathy | 8.2% | 8.1% | 8.4% | 0.692 |
| Pulmonary | | | | |
| Pulmonary embolism | 0.8% | 0.7% | 0.8% | 0.542 |
| Chronic lung disease | 21.7% | 21.9% | 21.5% | 0.667 |
| Pulmonary hypertension | 2.7% | 2.7% | 2.8% | 0.743 |
| Respiratory infection | 7.1% | 5.5% | 8.5% | <0.001 |
| Gastrointestinal | | | | |
| Obesity | 9.2% | 8.9% | 9.4% | 0.507 |
| Metabolic disorder | 4.8% | 4.7% | 4.9% | 0.732 |
| Malnutrition | 2.5% | 2.4% | 2.6% | 0.580 |
| Upper GI disorders | 10.8% | 10.6% | 11.0% | 0.584 |
| Lower GI disorders | 0.8% | 0.8% | 0.9% | 0.496 |
| Liver/gallbladder disease | 4.4% | 4.4% | 4.4% | 0.975 |

(continued)
cardiac disease, including acute coronary syndrome, pericarditis, myocarditis, congestive heart failure, and conduction abnormality. Second, there was no difference when it came to gastrointestinal disorders, hematologic disorders, genitourinary disorders, and multiple other diagnoses. Finally, the administration of the vaccines resulted in a significant decrease in hospital encounters for respiratory infections, SARS-CoV-2 infections, and COVID-19-related complications.

To date, there have been several case reports and case series documenting myocarditis following vaccination with an mRNA COVID-19 vaccine.5,7,8 In addition, a recent population-level investigation of the Pfizer-BioNTech vaccine found significantly increased risk of myocarditis after vaccination. However, the same study also noted that the risk of myocarditis and other serious adverse cardiovascular events from SARS-CoV-2 infection was significantly higher than from vaccination.9 Our large-scale analysis of post-vaccination hospital presentations failed to show any significantly increased incidence of myocarditis. One possible explanation for this discrepancy is that our study examined a population receiving a mixture of the 3 vaccines available to the United States market. It is likely that these 3 vaccines have different risk profiles and are associated with different adverse events. In addition, a recent large-scale study demonstrates that the complication rates of the

| Table 4 (Continued) | Overall (N = 6,751) | Vaccinated (N = 3,199) | Before Vaccination (N = 3,552) | p-Value |
|---------------------|---------------------|------------------------|-------------------------------|---------|
| Pancreatic disease  | 1.6%                | 1.6%                   | 1.5%                          | 0.880   |
| GI bleed            | 2.1%                | 1.8%                   | 2.3%                          | 0.177   |
| Hematological       |                     |                        |                               |         |
| Anemia              | 1.1%                | 1.1%                   | 1.0%                          | 0.746   |
| Coagulopathy        | 2.8%                | 2.8%                   | 2.8%                          | 0.879   |
| White blood cell disorder | 5.8% | 5.5% | 6.0% | 0.443 |
| Genitourinary       |                     |                        |                               |         |
| Renal disease       | 19.1%               | 19.0%                  | 19.1%                         | 0.885   |
| Electrolyte abnormalities | 17.2% | 16.8% | 17.5% | 0.490 |
| Urinary disorders   | 5.7%                | 5.5%                   | 5.9%                          | 0.439   |
| Urologic disorders  | 4.1%                | 4.1%                   | 4.0%                          | 0.789   |
| Gynecological disorders | 2.9% | 3.0% | 2.8% | 0.758 |
| Pregnancy           | 0.8%                | 1.0%                   | 0.6%                          | 0.104   |
| Other               |                     |                        |                               |         |
| Musculoskeletal disorders | 32.5% | 33.7% | 31.5% | 0.055 |
| Diabetes            | 24.9%               | 24.7%                  | 25.1%                         | 0.732   |
| Trauma              | 15.5%               | 15.9%                  | 15.9%                         | 0.360   |
| Substance abuse     | 12.0%               | 10.5%                  | 13.4%                         | <0.001  |
| Infection           | 11.0%               | 10.2%                  | 11.7%                         | 0.045   |
| Psychiatric disorders | 10.0% | 9.1% | 10.9% | 0.014 |
| Thyroid disease     | 8.4%                | 8.8%                   | 8.1%                          | 0.279   |
| Malignancy          | 6.6%                | 7.0%                   | 6.3%                          | 0.214   |
| Eyes, ears, nose and throat disorders | 6.5% | 6.5% | 6.5% | 0.919 |
| Toxins              | 5.4%                | 6.5%                   | 4.3%                          | <0.001  |
| Skin disorders      | 4.5%                | 4.7%                   | 4.3%                          | 0.416   |
| Autoimmune disorders | 1.3% | 1.4% | 1.2% | 0.356 |
| Allergic reaction   | 1.4%                | 1.9%                   | 0.9%                          | <0.001  |

Boldface type denotes statistical significance. GI = gastrointestinal; SD = standard deviation.

* Includes acute coronary syndrome.

Table 5
Hospital encounters related to vaccine and COVID-19 based on vaccination status overall Hospital encounters based on vaccination status for vaccine administration and COVID-19-related events

| Overall (N = 6,751) | Vaccinated (N = 3,199) | Before Vaccination (N = 3,552) | p-Value |
|---------------------|------------------------|-------------------------------|---------|
| Vaccine reaction    | 1.1%                   | 2.1%                          | 0.0%    | <0.001 |
| Allergic reaction   | 0.1%                   | 0.2%                          | 0.0%    | 0.010  |
| Adverse reaction    | 0.1%                   | 0.3%                          | 0.0%    | 0.003  |
| COVID-19 complication | 4.1%                 | 2.7%                          | 5.4%    | <0.001 |
| SARS-CoV-2 infection | 4.1%                 | 2.7%                          | 5.4%    | <0.001 |
| Acute respiratory failure | 0.3% | 0.1% | 0.5% | 0.014 |
| History of COVID-19 | 2.3%                   | 2.1%                          | 2.3%    | 0.541  |
| COVID-19 exposure   | 24.2%                  | 24.4%                         | 24.0%   | 0.747  |

Boldface type denotes statistical significance. COVID-19 = coronavirus Disease 2019; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
vaccines are less than the complication rates of having the SARS-CoV-2 infection. Our findings are promising and ensure the safety of the vaccines.

Second, there was no evidence of worsening thrombosis, pulmonary embolism, or other thrombotic events in the vaccinated arm compared with other groups. Early on, during the COVID-19 vaccine development, there were reports of thromboembolic events thought to be related to the vaccines. However, this was not seen in our large cohort, and this initial possible relation is unlikely. Further, the Food and Drug Administration issued a temporary hold on the administration of the Ad26.COV2.S vaccine (Janssen/Johnson and Johnson) due to a feared complication of cerebral venous sinus thrombosis. However, this specific diagnosis was not seen in our observation.

Lastly, our analysis further highlights the effectiveness of the COVID-19 vaccines overall. In our large cohort, we demonstrate that the incidence of SARS-CoV-2 infections decreased dramatically in both the in vaccination group and the fully vaccinated group. Also, the rate of serious infections highlighted by “acute respiratory failure” also decreased dramatically for those who received partial or full vaccination. Ongoing efforts to roll out the COVID-19 vaccines are imperative to help fight this deadly infection.

There are limitations to our study. First, the analysis is retrospective and relies on ICD-10 codes to identify the patient population. ICD-10 categories were determined by 3 authors, but variability may exist. Also, the analysis only accounts for hospital encounters (emergency department visits) and does not designate hospitalizations. Further, it misses cases/encounters in outside care settings as well as inaccurate EMR vaccination information. In addition, our findings do not prove causation; however, the short span between vaccinations and hospital encounter/diagnosis in the study hospitals lends support to a possible relation. Finally, our data captured patients in the mid-Atlantic region of the United States; our findings may not represent the broader United States outcome data.

In conclusion, our analysis suggests that there is no significant association of COVID-19 vaccination with the rate of hospital encounters for cardiac disease, including acute coronary syndrome, pericarditis, myocarditis, congestive heart failure, and conduction abnormality. Further, administration of the vaccines resulted in a significant decrease in hospital encounters for respiratory infections, SARS-CoV-2 infections, and COVID-19 complications.

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Disclosures

Toby Rogers reports being a proctor and consultant for Medtronic and Edwards Lifesciences; serving on the advisory board of Medtronic; and holding equity interest; Transmural Systems Inc., outside the scope of the submitted work.

Ron Waksman reports serving on the advisory boards of Abbott Vascular, Boston Scientific, Medtronic, Philips IGT, and Pi-Cardia Ltd.; being a consultant for Abbott Vascular, Biotronik, Boston Scientific, Cordis, Medtronic, Philips IGT, Pi-Cardia Ltd., Swiss Interventional Systems/SIS Medical AG, Transmural Systems Inc., and Venus Med-Tech; receiving grant support from AstraZeneca, Biotronik, Boston Scientific, Chiesi, Medtronic, and Philips IGT; serving on the speakers bureau of AstraZeneca; and being an investor in Med Alliance and Transmural Systems Inc. outside the scope of the submitted work.

All other authors have no conflicts of interest to declare.

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