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ORIGINAL RESEARCH

Occurrence of Myopericarditis Following COVID-19 Vaccination Among Adults in the Eastern Region, Saudi Arabia: A Multicenter Study

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Background: Evidence supporting the possible causal association of myopericarditis with the coronavirus disease (COVID-19) vaccine has mainly come from case reports. Epidemiological evidence indicating an increased relative risk for myopericarditis after COVID-19 vaccination is lacking. Therefore, this study aimed to identify and assess all confirmed COVID-19 vaccine- related cases of myopericarditis presenting to major cardiac centers in the Eastern Region of Saudi Arabia, before and after the introduction of the COVID-19 vaccine.

Methods: According to case definition, the hospital's information system database detected all confirmed cases at two main cardiac centers.

Results: Of the 18 confirmed myocarditis and myopericarditis cases detected after the administration of COVID-19 vaccines, three were possibly related to COVID-19 immunization. The first case was of myopericarditis following a third dose of mRNA-1273. The second case was myocarditis, which occurred seven days after the first dose of AstraZeneca. The third case was myocarditis, which occurred 12 days after the third dose of BNT162b2. A cardiologist carefully evaluated the cases using recognized protocols and case definitions to demonstrate a direct relationship with vaccination consequences rather than coincidence.

Conclusion: We found no difference in the occurrence of myocarditis and myopericarditis after the COVID-19 vaccine compared with the background rate during a similar period (P = 0.9783). The incidences of myocarditis and myopericarditis following immunization were low. The advantages of the COVID-19 vaccination outweigh the risk of myopericarditis.

Keywords: Myocarditis, Myopericarditis, COVID-19 vaccine, Saudi Arabia

Introduction

Despite stringent control measures and restrictions, the rapid spread of the COVID-19 pandemic has had a significant effect on the healthcare systems worldwide. It has been estimated that 18.2 million people have died worldwide because of the COVID-19 pandemic.[1] Vaccination has substantially reduced COVID-19 morbidity and mortality worldwide.[2] Mathematical models have shown that vaccination has resulted in a 63% reduction in total deaths globally.[1] Most nations have mandated vaccination against COVID-19 for people aged > 12 years. Four COVID- 19 vaccines are widely used: whole viruses, protein subunits, viral vectors, and nucleic acids. GB0009895292 (AstraZeneca), BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and NVX-CoV2373 (Novavax) vaccines are used worldwide. However, the rapid rollout of COVID- 19 vaccination has been followed by many suspected adverse events reported worldwide.[3] Many people may have experienced reactions to the COVID-19 vaccine due to the widespread mass immunization still occurring in most of the world.[4] Several medical conditions have been reported in the treatment of various COVID-19

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vaccines. Concern has been raised about rare cases of thrombosis, Guillain-Barré syndrome, and capillary leak syndrome linked to receiving the adenoviral vector vaccine.[5] Acute myocardial infarction, immunological thrombocytopenia, disseminated intravascular coagulation, and pulmonary embolism are potential adverse events of interest that the FDA declared in July 2021 as a result of Pfizer vaccination based on data from medical claims.[6] Several studies have reported definite incidences of myocarditis and pericarditis following SARS-CoV-2 mRNA vaccination, mostly in young males after the second vaccine dose.[7] Myocarditis and pericarditis, together known as myopericarditis, are inflammations of the myocardium and pericardial sac with non-ischemic myocyte damage.[8]

The variable clinical symptoms, etiologies, and consequences of myopericarditis include acute heart failure, chronic dilated cardiomyopathy, and sudden death.[9] Chest pain, dyspnea, and palpitations are nonspecific symptoms of myocarditis that may mimic those of other common diseases including coronary artery disease. Common viral infections are the leading causes of myocarditis. However, specific forms of myocarditis may result from other pathogens, drugs, vaccine-associated toxic or hypersensitivity reactions, giant cell myocarditis, and autoimmune diseases.[10,11] An earlier study has suggested the occurrence of myocarditis and pericarditis following live viral vaccination.[12] Myocarditis and pericarditis have been linked to smallpox and influenza vaccines.[12,13] For years, post-licensure safety surveillance has been associated with hypersensitivity myopericarditis as a drug/vaccine-induced cardiac adverse event.[8] Following the launch of the COVID-19 immunization program, myocarditis and pericarditis have been reported as adverse reactions to the mRNA vaccine in several countries.[14–18] Evidence supporting the possible causal association of myopericarditis with the COVID-19 vaccine comes mainly from case reports.[8] Epidemiological evidence indicating an increased relative risk for myopericarditis after COVID-19 vaccination is lacking. According to previous reports, a variant of myocarditis linked to COVID-19 vaccination resembles hypersensitive myocarditis, that is, a possible polyethylene glycol-induced immune response that is IgE-mediated.[19,20] In this regard, polyethylene glycol has been encountered in mRNA-based COVID-19 vaccines, both in BNT162b2 produced by Pfizer-BioNTech and mRNA-1273 produced by Moderna.[21] There is still a lack of knowledge regarding the probable processes underlying the adverse cardiac effects of mRNA-based vaccination. Most myocarditis cases develop 2–6 weeks after viral infection or injury, and most pericarditis cases develop within 1–6 weeks. Because of the proper temporal link, events that occur within these intervals following vaccination are more likely to be vaccine-induced.[8] According to data provided by the Saudi Ministry of Health, 20,906,174 (or 60.1%) of the population in Saudi Arabia had received at least one dose of the COVID-19 vaccine, and 11,374,999 (32.0%) were fully vaccinated by August 2021.[22] Vaccines approved in Saudi Arabia include Pfizer-BioNTech, Moderna, Oxford-AstraZeneca, and Janssen vaccines. This study aimed to identify and assess all confirmed COVID-19 vaccine-related myocarditis and pericarditis cases that presented to a primary cardiac center. This study also compared the occurrence of myopericarditis following COVID-19 vaccination against a background rate similar to that before the launch of the COVID-19 vaccine.

Materials and Methods

This study was approved by the Ethics Review Board of Prince Sultan Military College (IRB Number IRB-2023-BMT -31). This study was conducted in accordance with the principles of the Declaration of Helsinki. Informed consent was obtained from each participant on the opening page of the online questionnaire. Informed consent was obtained from the study participants prior to study commencement. This study was a retrospective analysis of all patients who presented with myocarditis, pericarditis, and myopericarditis between January 1, 2018, and December 31, 2022, at two main cardiac centers of King Fahad Military Medical Complex, Dhahran, and the King Fahad Hospital of the University, Al-Khobar. The hospital's information system database used the codes "myocarditis", 'pericarditis', and "myopericarditis" myopericarditis to identify patients. Electronic medical record systems were used to gather clinical data such as cardiac symptoms, supportive diagnostic testing, physical examination findings, laboratory results, and demographic characteristics. Electrocardiograms (ECG), echocardiograms, and cardiac magnetic resonance (CMR) images were used to evaluate all patients. A senior cardiologist assessed diagnostic certainty. All included cases were level 1 of certainty according to the Brighton Collaboration Myocarditis/Pericarditis case definition.[8] All patients reported after December 2020 had their medical records examined to determine their COVID-19 vaccination history, including the

type and number of doses received before presentation. Troponin I values of > 20 ng/L were considered indicative of high troponin levels.

Results

The administered vaccine dosages were 113,861, 28,895, and 66,606 µg for BNT162b2, mRNA- 1273, and GB0009895292, respectively. Seven confirmed myocarditis cases and 11 myopericarditis cases were detected after the Introduction of COVID-19 vaccines (Table 1). Pericarditis was not detected alone. The mean age of the 16 men (88.9%) males was 35.7 years. Of the 18 cases, only three male cases were possibly related to the COVID-19 vaccine. The first was myopericarditis, which occurred two days after the third dose of mRNA-1273 (Moderna). The second case was myocarditis, which occurred seven days after the first dose of AstraZeneca. The third case was myocarditis, which occurred 12 days after the third dose of BNT162b2 (Pfizer). We found no difference in myocarditis and myopericarditis after the COVID-19 vaccine when compared with the background rate of a similar period (odds ratio = 1.0091; P = 0.9783). Of the 36 patients detected throughout the study period, 27 (75%) were males of an average age of approximately 33 years. (Table 2). Men had the higher infection rates than women as represented by 61.1% and 88.9% of the total infections before and after vaccination, respectively. The average age of the infected men after the vaccination period was 33.11 years and that of women was 46.5 years.

Table 1 Clinical Characteristics of Cases with Myocarditis/Myopericarditis Following COVID-19 Vaccination in Dammam

Case No	Age	Gender	ECHO	MRI	Tro pon in	Diagnosis	Dose and Type	Days after vaccine
1	23	M	Abnormal	–	H	Myoperi	3rd - mRNA-1273	2
2	49	M	Abnormal	Normal	H	Myocard	1st - GB0009895292	7
3	48	M	Abnormal	-	H	Myocard	3rd - BNT162b2	12
4	56	F	Normal	-	H	Myocard	2nd - BNT162b2	203
5	35	M	Normal	-	H	Myoperi	2nd - GB0009895292	> 15
6	20	M	Abnormal	-	H	Myoperi	3rd - mRNA-1273	> 15
7	39	M	Abnormal	Normal	-	Myocard	3rd - BNT162b2	> 15
8	46	M	Abnormal	Abnormal	-	Myocard	3rd - BNT162b2	> 15
9	37	M	Abnormal	-	H	Myocard	/	> 15
10	20	M	Abnormal	-	H	Myoperi	3rd - BNT162b2	> 15
11	21	M	Abnormal	Abnormal	H	Myoperi	3rd - BNT162b2	> 15
12	48	M	Abnormal	-	H	Myoperi	2nd - BNT162b2	> 15
13	55	M	Abnormal	-	H	Myoperi	3rd - BNT162b2	> 15
14	17	M	Abnormal	-	N	Myoperi	2nd - Moderna	> 15
15	29	M	Abnormal	Abnormal	N	Myoperi	2nd - BNT162b2	> 15
16	23	M	Abnormal	-	H	Myocard	3rd - BNT162b2	> 15
17	40	M	Abnormal	Abnormal	H	Myoperi	3rd - mRNA-1273	> 15
18	37	F	Abnormal	-	H	Myoperi	3rd - BNT162b2	> 15

Abbreviations: H, high; N, normal; -, not performed; Myocard, myocarditis; Myoperi, myopericarditis.

Table 2 Myocarditis/Myopericarditis Cases After COVID-19 Vaccine as Compared to the Background Rate by Age and Gender

	Before vaccination	After Vaccination
Male	11 (61.4%)	16 (88.9%)
Female	7 (38.6%)	2 (11.1)
Average male age ± SD	36.73 ± 15.58	33.11 ± 12.48
Average Female age ± SD	45.57 ± 13.24	46.5 ± 13.43
Myocarditis	10	7
Myo/pericarditis	8	11
Total	18	18
Total population	301,542	304,284
Odds ratio	1.0091	
95% CI	0.5250–1.9395	
P-value	0.9783	

Discussion

Three of the 18 myocarditis and myopericarditis cases were likely related to the COVID-19 vaccines. The first case occurred two days after the third dose of mRNA-1273 (Moderna). The second case occurred seven days after the first dose of AstraZeneca. The final dose was administered 12 days after the third dose of BNT162b2 (Pfizer). These myopericarditis cases were carefully observed, and cases were looked into and examined by a consultant cardiologist according to established standards.[8] This is because of the dispute over whether these cases were a direct result of immunization, rather than coincidental events that had been ongoing. The remaining cases were mostly of viral origin and not linked to any vaccine. Many studies have reported confirmed occurrences of myocarditis and pericarditis following SARS-CoV-2 mRNA vaccination, mostly in young males.[23–28] Myocarditis cases following the BNT162b2 COVID-19 vaccine have been recorded earlier, mostly in young men, following the second vaccine dosage.[29] Myocarditis cases following immunization with Pfizer/BioNTech and Moderna mRNA vaccines have been reported on several occasions.[30–32] Two cases reported in this study occurred following the third dose of the mRNA vaccine (mRNA-1273 and BNT162b2). It has been reported that the second dose of mRNA COVID-19 vaccination had the highest risk among young males, with 4.6 cases per 100 000, compared to 0.4 cases per 100000 among females of the same age.[30] Twenty cases of myocarditis were documented among 2,000,287 individuals who received at least one dose of a COVID-19 vaccine; 11 of these cases occurred after receiving the mRNA-1273 vaccine, while the other nine included the BNT162b2 vaccines.[32] The mean patient age of the detected cases was 35 years. The older adults reported fewer incidents. There have been 23 cases of myopericarditis among young males with a median age of 25 years within four days following an m-RNA COVID-19 vaccine in the United States, mainly following the second dose.[30] We also detected a male case of myocarditis that occurred seven days after the first dose of GB0009895292 (AstraZeneca). However, mRNA vaccines have been the cause for the majority of recorded occurrences of post-vaccination myocarditis. However, new reports of myocarditis after adenovirus vector immunization have also been reported.[33–35] The estimated current risk is 0.88 cases per 100,000 BNT162b2 vaccinated individuals. A previous study reported an overall risk of 2.7 cases of myocarditis per100000BNT162b2 vaccinated people.[36] Moreover, the clinical presentation was mild in all the cases. In another study, 1.5 and 2.7 possible cases of myocarditis and pericarditis, respectively, per 100,000 administered Pfizer-BioNTech, were reported.[37] Similarly, out of the 100,000 Moderna doses provided, there have been 2.2 and 2.9 cases of possible myocarditis and pericarditis, respectively.[37] Another study that linked myocarditis to COVID-19 mRNA vaccinations, especially in younger males within a few days following the second immunization, has estimated an

incidence of roughly 4.8 cases per 1 million.[33] Generally, the risk of acute myocarditis and pericarditis after COVID-19 vaccination is low. There is still a lack of knowledge regarding the probable processes underlying the adverse cardiac effects of mRNA-based vaccination. Although several theories have been proposed in recent studies, there is still a lack of conclusive evidence for a particular mechanism of myocarditis following mRNA immunization, and further research is required to establish this. Several theories have been proposed, such as a generalized innate inflammatory response or a molecular mimicry mechanism between the viral spike protein and an unidentified cardiac marker.[38]

The immune response to mRNA may not be suppressed in genetically predisposed individuals, which may activate abnormal innate and acquired immune responses.[38,39] COVID-19 vaccines contain nucleoside-modified mRNA. Vaccine genes may be recognized as antigens by the immune system, thereby generating inflammatory cascades and immunological pathways that may aid in the development of myocarditis. Other proposed pathways include abnormally triggering apoptosis, which causes inflammation of the heart and pericardium, and generates cytokine production through anti-idiotypic cross-reactive antibodies in the myocardium. Myocarditis may be linked to COVID-19 mRNA vaccinations, especially in younger males. Most (88.9%) of the detected myopericarditis cases were in male patients, which is in agreement with previous reports.[33–35] However, it remains unclear why men have been seen to experience this condition more frequently. It is worth mentioning here that infections with COVID-19 are also anticipated to cause 11 instances of myocarditis per 100,000 infections, whereas mRNA immunization is estimated to cause 2.7 cases per 100,000 people.[40] The incidence of myocarditis following immunization was low. The incidence of myocarditis and pericarditis among a population aged ≤ 12 years is 1.2/100,000 and 2.8/100,000 per year, respectively.[41] A meta-analysis of morbidity showed a low incidence rate of myocarditis (0.000011) in subjects who received the mRNA COVID-19 vaccine.[26] Consequently, COVID- 19 immunization has been recommended by all national and international health agencies, because its advantages outweigh the risk of myopericarditis. Evidence of a potential causal link between COVID-19 vaccination and myopericarditis has come from case reports. There are insufficient epidemiological data to suggest that COVID-19 vaccination increases the relative risk of myopericarditis. This multicenter study included a comparison of all cases of myopericarditis after the introduction of the COVID-19 vaccine with the background occurrence before the vaccine era. The incidences of myocarditis and myopericarditis following immunization were low. The limitations of our study include the fact that we overlooked some instances of myopericarditis and that temporal association does not prove causality, even though the proximity of the onset of myopericarditis to immunization may imply a potential link.

Conclusion

The risk of myopericarditis associated with COVID-19 vaccination was low. There was no difference in the occurrence of myopericarditis following COVID-19 vaccination compared with the background rate of a comparable period. Undoubtedly, the benefits of the COVID-19 vaccination exceed the risk of myopericarditis. Thus, COVID-19 vaccination continues to be recommended by all national and international health authorities.

Data Sharing Statement

Data supporting the findings of this study are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

The study was approved by the Ethics Committee of Prince Sultan Military College of Health Sciences Ethics Review Board (IRB Number IRB-2023-BMT-31). Informed consent was obtained from the study participants prior to study commencement.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests in this work.

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