

COVID vaccination and myocarditis, Is it real?

Authors:

Ayman S. Abd-Elsalam¹, Dr. Azeza Gum S. S.², Ahmed H.M. Lameen Almnifi³, Ahmed G. Elsayed³,
Laila M. Elgendy⁴

¹ Anesthesia and Surgical Intensive Care Department, Faculty of Medicine, Tobruk University, Libya.

² Omar Al-Mukhtar University, Faculty of Medical Technology, Department of Lab. Medicine, Box 919, Al-Bayda, Libya

³ Internal Medicine Department, Faculty of Medicine, Tobruk University, Libya.

³ Pathology Department, Tobruk Medical Center, Libya.

⁴ Biochemistry Department, Tobruk Medical Center, Libya.

Corresponding Author:

Ayman S. Abd-Elsalam

Article Received: 15-November-2023

Revised: 05-December-2023

Accepted: 25-December-2023

ABSTRACT:

Introduction: SARS-CoV-2 first emerged during the coronavirus pandemic in Wuhan, China. The period from outbreak to aftermath was December 21, 2019, with the first case associated with a seafood market. The most common symptoms are fever, cough, and shortness of breath. COVID-19 has also been associated with cardiovascular involvement. Myocarditis is an inflammatory disease of the heart that can occur as a result of infection, exposure to toxic substances, and activation of the immune system. Many pharmaceutical companies and academic institutions from around the world are working together to develop a vaccine for the new coronavirus infection. **Aim of the Study:** Study the prevalence of myocarditis in healthy subjects after COVID vaccination due to an increase in the number of cases. **Materials and Methods:** This was a retrospective study on the prevalence of myocarditis after COVID-19 vaccination in the city of Tobruk. The study included medical records of all patients treated for myocarditis in the Coronary Care Unit (CCU) and Intensive Care Unit (ICU) of Tobruk Medical Center, including gender and age group from 17 to 64 years. samples were collected. From January 1, 2020 to December 31, 2021, the total number of cases was 63. All necessary basic information and data were obtained from medical documents. Excel was used for data collection and descriptive analysis. **Results:** Our study included 63 patients. Of these, 51 (81%) were male and 12 (19%) were female. The male to female ratio in this study was 1.6:1. The ages of patients tested in this study ranged from 17 to 64 years, with a mean of 49 years. The highest age group observed to have a higher incidence of myocarditis after COVID-19 vaccination was 20-29 years (34.9%). According to the data, all patients (63 patients, 100%) experienced palpitations, 52 patients (82.5%) experienced mild fatigue, and 46 patients (73%) experienced shortness of breath. All patients had received the Pfizer-BioNTech COVID vaccination (mRNA vaccine). There were 56 patients (89%) after the second dose compared to 7 patients (11%) after the first dose. Echocardiograms of all these patients showed no regional wall abnormalities and preserved left ventricular ejection fraction (LVEF) in all patients. All patients recovered within 6 days of onset. **Conclusion:** Cardiac symptoms in the form of myocarditis occur after COVID-19 vaccination and require further investigation to determine the actual mechanism and appropriate treatment.

Keywords: COVID-19; Vaccination; Myocarditis.

INTRODUCTION:

The 2019 novel CoV is currently referred to as severe acute respiratory syndrome coronavirus-2 (SARSCoV-2) by the International Committee on Taxonomy of Viruses and belongs to the Beta CoV genus [1]. SARS-CoV-2 first emerged during the coronavirus pandemic in Wuhan, China: from origins to consequences, on December 21, 2019, the first case was linked to a seafood market [2]. Although SARS-CoV-2 appears to

have a lower mortality rate than SARS-CoV and MERS-CoV, it is much faster and more widely transmitted in comparison, causing a global health and financial crisis [3]. After successful infection of the human host, further horizontal transmission of SARS-CoV-2 occurs primarily through person-to-person contact, direct contact via respiratory droplets, or touching contaminated surfaces. It occurs through indirect contact [4]. The most common symptoms are fever, cough, and

shortness of breath, but occasionally gastrointestinal symptoms such as diarrhea may also occur [5]. COVID-19 is also associated with cardiovascular involvement [6]. The gene sequence of SARS-CoV-2 was published on January 11, 2020, and since then, many pharmaceutical companies and academic institutions from different countries have been working together to develop his COVID-19 vaccine. Fortunately, some candidates passed the clinical trial evaluation and progressed to phase 3 [7]. Myocarditis is an inflammatory disease of the heart that can occur as a result of infection, contact with toxic substances, or activation of the immune system [8] and is classified as secondary by the 1996 World Health Organization classification. It is one of the cardiomyopathy [9]. Myocarditis has a wide range of clinical manifestations and courses, and most cases resolve spontaneously. It is also a relatively common cause of sudden cardiac death (SCD) in young people (6%–10% in autopsy-based series) [10]. Viral infections are a common cause of acute myocarditis and are usually associated with typical symptoms of inflammatory infiltrate and cardiomyocyte damage, unrelated to ischemia and without overt

vascular disease [11]. Immune eosinophilic myocarditis associated with antiviral vaccines is rare in healthy volunteers, but has been previously reported in healthy adults with smallpox and seasonal influenza vaccines [12].

Due to the increasing number of cases, we are investigating the prevalence of myocarditis in healthy subjects after vaccination against the new coronavirus.

Patients and Methods:

This study was a retrospective study on the prevalence of myocarditis after COVID-19 vaccination in the city of Tobruk. The study included medical records of all patients treated for myocarditis in the Coronary Care Unit (CCU) and Intensive Care Unit (ICU) of Tobruk Medical Center, including gender and age group from 17 to 64 years. samples were collected. From January 1, 2020 to December 31, 2021, the total number of cases was 63. All necessary basic information and data were obtained from medical documents. Excel was used for data collection and descriptive analysis.

RESULTS:

This study was conducted on 63 patients. As shown in (Figure 1), 51 (81%) of these were male and 12 (19%) were female. The male to female ratio in this study was 1.6:1.

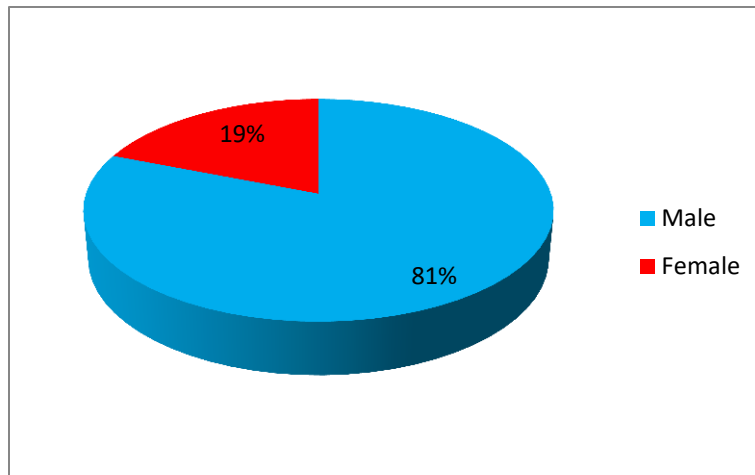


Figure (1): The overall prevalence of Myocarditis after COVID vaccination in males and female

Patients in this study ranged in age from 17 to 64 years, with a mean of 49 years. The prevalence between age groups is shown in Table 1. The highest observed age group for myocarditis following COVID-19 vaccination was found to be those aged 20 to 49 years. 29 (34.9%), followed by 30-39 (27%) and 40-49 (14.3%). The final number of patients with myocarditis (4.8%) were in the younger age group, ranging from 10 to 19 years.

Group of Age (By Years)	Male	Female	Total Number and Percentage (%)
10-19	3	-	3 (4.8%)

20-29	18	4	<u>22 (34.9%)</u>
30-39	14	3	17 (27%)
40-49	8	1	9 (14.3%)
50-59	6	2	8 (12.7%)
60-69	2	2	4 (6.3%)
Total	51	12	63 (100%)

Table (1): Prevalence of myocarditis according to patient age and gender after COVID-19 vaccination

The main complaint of patients with myocarditis after vaccination with the new coronavirus was evaluated. According to the data, all patients (63 patients, 100%) experienced palpitations, 52 patients (82.5%) experienced mild fatigue, and 46 patients (73%) experienced difficulty breathing (figure 2).

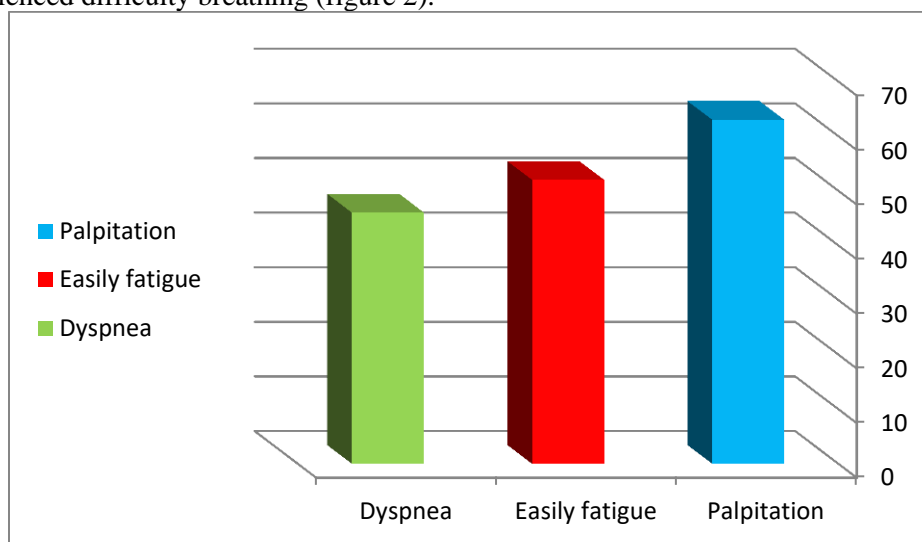


Figure (2): The main complains of Myocarditis after COVID vaccination patients

All patients had COVID vaccination of Pfizer-BioNTech (mRNA Vaccine). 56 patients (89%) after second dose while 7 patients (11%) after first dose as shown in (figure 3).

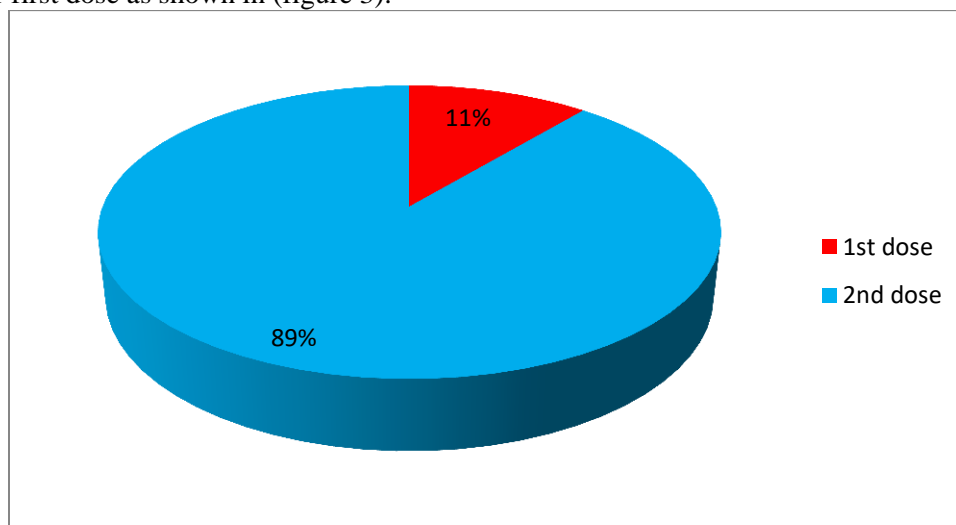


Figure (3): The prevalence of Myocarditis after COVID vaccination patients who had Pfizer-BioNTech (mRNA Vaccine) first dose and second dose

Echocardiograms showed preserved left ventricular ejection fraction (LVEF) in all these patients. The exact LVEF values reported were a mean LVEF of 58% and a range of 51% to 65%. No local wall abnormalities occurred in all patients. All patients recovered within 6 days of onset.

DISCUSSION:

The introduction of various vaccines against coronavirus disease 2019 (COVID-19) has significantly reduced the morbidity and mortality associated with COVID-19 worldwide, and all approved vaccines against COVID-19 disease has been eliminated. Vaccines have been shown to offer benefits that outweigh potential risks. Different age groups are predominant among them [13,14]. Recent reports have raised concerns about myocarditis associated with various types of COVID-19 vaccines. However, data regarding the characteristics and impact of myocarditis in these patients are limited [15]. The benefits of vaccination in older adults during the pandemic have been clearly recognized, as mortality rates from COVID-19 have increased significantly in people aged 70 years and older, especially those with underlying health conditions. In contrast, symptomatic disease associated with SARS-CoV-2 and severe disease requiring hospitalization, life-saving treatment, and death are relatively rare in children and adolescents, and vaccination is not recommended in these age groups. is not an option. He was hesitant about vaccinations and had limited concentration. group. This is further exacerbated by the fact that a predominantly asymptomatic or predominantly mild upper respiratory tract infection develops and resolves within a few days. Although the number of serious illnesses leading to death is low in children, it is more common in young people who are already suffering from serious life-threatening illnesses [16]. Our study included 63 patients. Of these, 51 (81%) were male and 12 (19%) were female. The male to female ratio in this study was 1.6:1. The ages of patients tested in this study ranged from 17 to 64 years, with a mean of 49 years. The highest age group observed to have a higher incidence of myocarditis after COVID-19 vaccination was 20-29 years (34.9%). Data showed that all patients (63 patients, 100%) experienced palpitations, 52 patients (82.5%) experienced mild fatigue, and 46 patients (73%) experienced shortness of breath. did. All patients had received the Pfizer-BioNTech COVID vaccination (mRNA vaccine). There were 56 patients (89%) after the second dose compared to 7 patients (11%) after the first dose. Echocardiograms of all these patients showed no regional wall abnormalities and preserved left

ventricular ejection fraction (LVEF) in all patients. All patients recovered within 6 days of onset.

In Australia, as of 11 July 2021, the Department of Health's Therapeutic Goods Administration (TGA) had reported 288 adverse events after 3.7 million mRNA COVID-19 vaccinations, including contains 50 reports of suspected myocarditis or pericarditis. Obtained from the Pfizer vaccine [17].

In the UK, as of July 7, 2021, approximately 19.7 million first doses of the Pfizer/BioNTech vaccine, approximately 11.6 million second doses had been administered, and first doses of the Moderna COVID-19 vaccine had been administered. Approximately 1.1 million doses have been administered. [18]. As part of its official 'yellow card' report, the UK Medicines and Healthcare products Regulatory Agency (Health and Social Care Agency) lists the incidence of suspected myocarditis and pericarditis following vaccination with the Pfizer/BioNTech vaccine. I mentioned it. (81 cases of myocarditis, 63 cases of pericarditis). The incidence for Moderna (9 myocarditis, 9 pericarditis, 1 endocarditis) was 5.0 cases per million doses administered. Interestingly, myocarditis occurred (69 cases) after administration of the AstraZeneca COVID-19 vaccine (an adenovirus vector, not an mRNA vaccine) after 24.7 million first doses and 22.3 million second doses. There were also reports of pericarditis (107 cases) (incidence 1 case) (3.7 per million doses).

At the end of May 2021, the European Medicines Agency announced that Pfizer had approximately 160 million doses of its COVID-19 vaccine, Moderna had 19 million doses, AstraZeneca had 40 million doses, and Janssen had 2 million doses. It was announced that there was. It is recommended that he receive one dose of the vaccine [19]. His EudraVigilance adverse event data for these dose exposures reported myocarditis following the Pfizer (122), Moderna (16), and AstraZeneca (38) vaccines. Post-vaccination pericarditis has also been reported with Pfizer (126 cases), Moderna (18 cases), AstraZeneca (47 cases), and Janssen's COVID-19 vaccine (1 case).

Public Health Agency of Canada (PHAC), Health Canada has administered more than 41.5 million doses of COVID-19 vaccine as of July 9, 2021, and recorded 163 cases of "myocarditis/pericarditis" did. Cases were listed (mean age 39 years, range 15–86 years) [20]. According to Pfizer-BioNTech, there have been 111 cases, Moderna has had 40 cases, and AstraZeneca has had 11 cases. One of them was from an unspecified vaccine. This corresponds to an incidence of 3.9 cases per million doses administered. After vaccination, the time to onset of symptoms ranged from 5 hours to 92

days. There were 52 women (mean age 49 years, range 15-86 years) and 59 men (mean age 38 years, range 15-82 years). Interestingly, 67 cases occurred after the first vaccination and 26 after the second vaccination. Additionally, dose numbers were not provided in 18 cases. Detailed reporting of cases, clinical management and outcomes regarding the association or causal relationship between myocarditis/pericarditis and mRNA vaccines is ongoing as further data become available.

As of mid-June 2021, the U.S. Centers for Disease Control and Prevention (CDC) estimated that 1,226 cases of myocardial inflammation have been reported after 296 million mRNA vaccinations (Pfizer or Moderna, December 2020). From June 29th to June 11th, 2021 [37]., an incidence of 4.1 people per million doses administered. The median age of these cases was 26 years (range, 12-94 years), and first symptoms appeared a median of 3 days later (range, 0-179 years), meaning that more than half of the patients were in their third year of life. It was less than It is important to note that they were 30 years old, more than two-thirds were male, and more than 75% had received the second dose of an mRNA vaccine [21, 22].

As a result, CDC physicians and cardiologists tested 484 patients under the age of 30, including 323 from Dallas and Lake Louise to define acute myocarditis, acute pericarditis, or pericarditis. It met the criteria. I was completely satisfied [22]. The mean age of these subjects was 19 years (range 12-29 years), mean onset of symptoms was 2 days (range 0-40 days), and 92% experienced symptoms within 7 days. Of note, 96% of these individuals were immediately hospitalized. Most patients were treated with a mild clinical course, which subsequently resolved upon discharge. There were no fatalities.

CONCLUSION:

In conclusion, Cardiac symptoms in the form of myocarditis have occurred after COVID-19 vaccination, and further research is required to determine the actual mechanism and appropriate treatment.

REFERENCES:

1. Lai CC, Shih TP, Ko WC, Tang HJ, Hsueh PR. Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) and coronavirus disease-2019 (COVID-19): The epidemic and the challenges. *Int J Antimicrob Agents*. 2020; 55 (3), 105924.
2. Bogoch II, Watts A, Thomas-Bachli A, Huber C, Kraemer MUG, Khan K. Pneumonia of unknown aetiology in Wuhan, China: potential for international spread via commercial air travel. *J Travel Med*. 2020; 27 (2).
3. Meo SA, Alhowikan AM, Al-Khlaiwi T, et al. Novel coronavirus 2019-nCoV: prevalence, biological and clinical characteristics comparison with SARS-CoV and MERS-CoV. *Eur Rev Med Pharmacol Sci*. 2020; 24 (4), 2012-9.
4. Doremalen NV, Morris DH, Holbrook MG, et al. Aerosol and surface stability of HCoV-19 (SARS-CoV-2) compared to SARS-CoV-1. *N Engl J Med*. 2020; 382 (16), 1564-7.
5. Ye ZW, Yuan S, Yuen KS, Fung SY, Chan CP, Jin DY. Zoonotic origins of human coronaviruses. *Int J Biol Sci*. 2020; 16 (10), 1686-97.
6. Wang D, Hu B, Hu C, et al. Clinical characteristics of 138 hospitalized patients with 2019 Novel Coronavirus-Infected Pneumonia in Wuhan, China. *JAMA*. 2020; 323 (11), 1061-9.
7. Zhang N, Li C, Hu Y, et al. Current development of COVID-19 diagnostics, vaccines and therapeutics. *Microbes Infect*. 2020; 22 (6-7), 231-5.
8. Caforio AL, Pankuweit S, Arbustini E, Basso C, Gimeno-Blanes J, Felix SB, Fu M, Heli T, Heymans S, Jahns R, et al; European Society of Cardiology Working Group on Myocardial and Pericardial Diseases. Current state of knowledge on aetiology, diagnosis,

- management, and therapy of myocarditis: a position statement of the European Society of Cardiology working group on myocardial and pericardial diseases. *Eur Heart J*. 2013;34:2636–48.
9. Corrado D, Basso C, Thiene G. Sudden cardiac death in young people with apparently normal heart. *Cardiovasc Res*. 2001;50:399–408.
 10. Harmon KG, Drezner JA, Maleszewski JJ, Lopez-Anderson M, Owens D, Prutkin JM, Asif IM, Klossner D, Ackerman MJ. Pathogenesis of sudden cardiac death in national collegiate athletic association athletes. *Circ Arrhythm Electrophysiol*. 2014;7:198–204
 11. Piccirillo F, Watanabe M, Di Sciascio G. Diagnosis, treatment and predictors of prognosis of myocarditis. a narrative review. *Cardiovasc Pathol*. 2021 Jun 27:107362.
 12. Kuntz J, Crane B, Weinmann S, Naleway AL, Vaccine Safety Datalink Investigator Team. Myocarditis and pericarditis are rare following live viral vaccinations in adults. *Vaccine*. 2018;36(12):1524–7.
 13. Haas EJ, Angulo FJ, McLaughlin JM, Anis E, Singer SR, Khan F, Brooks N, Smaja M, Mircus G, Pan K, Southern J, Swerdlow DL, Jodar L, Levy Y, Alroy-Preis S. Impact and effectiveness of mRNA BNT162b2 vaccine against SARS-CoV-2 infections and COVID-19 cases, hospitalisations, and deaths following a nationwide vaccination campaign in Israel: an observational study using national surveillance data. *Lancet* 2021;397:1819–1829.
 14. Lv G, Yuan J, Xiong X, Li M. Mortality rate and characteristics of deaths following COVID-19 vaccination. *Front Med (Lausanne)* 2021;8:670370.
 15. Lopez Bernal J, Andrews N, Gower C, Robertson C, Stowe J, Tessier E, Simmons R, Cottrell S, Roberts R, O’Doherty M, Brown K, Cameron C, Stockton D, McMenamin J, Ramsay M. Effectiveness of the Pfizer-BioNTech and Oxford-AstraZeneca vaccines on covid-19 related symptoms, hospital admissions, and mortality in older adults in England: test negative case-control study. *BMJ* 2021;373:n1088.
 16. Tsaouri S, Makis A, Kosmeri C, Siomou E. Risk factors for severity in children with Coronavirus Disease 2019: a comprehensive literature review. *Pediatr Clin North Am*. 2021;68(1):321–38.
 17. Australian Federal Government, Department of Health, Therapeutic Goods Administration COVID-19 vaccine weekly safety report - 15-07-2021 [cited July 15, 2021].
 18. Medicines and Healthcare Products Regulatory Agency (MHRA). Coronavirus vaccine-weekly summary of Yellow Card reporting [Internet]. London (United Kingdom): Department of Health and Social Care; 2021 July 16 [cited July 20, 2021].
 19. European Medicines Agency Pharmacovigilance Risk Assessment Committee Summary June 7-10, 2021 [Cited July 20, 2021].

20. Public Health Agency of Canada. COVID-19 daily epidemiology update. Ottawa (ON): Government of Canada; 2021 May 12 [cited May 13, 2021].
21. Center for Disease Control. United States of America Department of Health and Human Services. COVID-19 Vaccine Safety Technical (VaST) Work Group Report, June 28, 2021 [Cited July 13, 2021].
22. Gargano JW, Wallace M, Hadler SC, Langley G, Su JR, Oster ME, et al. Use of mRNA COVID-19 vaccine after reports of myocarditis among vaccine recipients: Update from the advisory Committee on Immunization Practices - United States, June 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70(27):977–82.