

Moderna COVID-19 Vaccine Recipients Suffers Myocarditis

The spread of the [severe acute respiratory syndrome coronavirus 2](#) (SARS-CoV-2) caused the coronavirus disease 2019 (COVID-19) pandemic and caused health, social and economic crises. To tackle this, vaccination and non-pharmaceutical interventions (NPIs) were considered essential to contain the virus and reduce casualties, which have crossed five million worldwide as of now.



Vaccine adverse effects, especially blood clots and [myocarditis](#), have been given extensive media coverage, contributing to the negative sentiment against vaccines. A new preprint reports on the incidence of myocarditis in a large population of over 150 million who received two doses of the first vaccine to receive emergency use authorization (EUA) against the virus.

Introduction

The first two vaccines to receive EUA were developed on the [messenger ribonucleic acid](#) (mRNA) platform. Both the Pfizer/BioNTech and Moderna vaccines contain mRNA bits that encode the viral spike antigen. On injection, these cause the spike to be produced inside the host cells, inducing an immune reaction that creates antibodies and cells primed to recognize and eliminate the spike-bearing pathogen.

Both vaccines ([Pfizer and Moderna](#)) have passed phase 3 trials, involving 15,000 and 22,000 individuals above the age of 18 and 16 years, respectively, without any serious adverse effects being reported, and 94% efficacy against symptomatic COVID-19. Following their administration to millions of people worldwide, continuing surveillance has provided a source of safety data to help identify rare complications that may occur only after the vaccine is distributed in much larger numbers than in the clinical trials.

Given that this is the first reported use of any mRNA vaccine, the need for such monitoring becomes still more important. Despite the overall safety of these vaccines, repeated reports of myocarditis have come up, triggering several investigations into a possible causal association with the [vaccines](#).

For instance, Israel reported <150 cases among five million vaccine recipients; the US military reported 23 among 2.8 million doses. In both cases, young adult males were affected for the most part.

Myocarditis had not been reported in the [clinical trials](#), possibly because of the observed rarity of this complication.

The current study, reviews the global incidence of myocarditis and myopericarditis among [Moderna vaccine](#) recipients, beginning December 18, 2020, using only the Moderna safety database.

Study Shows?

The study period included over 275 million administered doses of the vaccine, during which over 1,400 were cases of myocarditis or [myopericarditis](#) – about 0.4% of total reported cases. Almost 80% were reported by a healthcare professional, with 1.5% having a fatal outcome.

Almost one in five cases were reported to be recovered, and 1% had recovered but had sequelae. About a quarter was still recovering; just over the same proportion had not recovered. The remaining quarter had not been reported for the outcome.

The majority of these cases were from the USA and Europe, the median age being 27 years. About 78% were males, and 61% were between 18-29 years old. Over half occurred after the [second dose](#). A quarter was after the first dose. Mostly, the symptoms set in at six days from the vaccination dose.

The median time to symptom onset was three days, and the symptoms lasted for a median of 5 days.

The rate of reported cases was 0.95 cases per 100,000 [vaccine recipients](#) overall, vs. the observed reporting rate of 1.56 cases and 0.37 cases per 100,000 vaccine recipients for males and females, respectively. In people aged 18-24 years, it stood at almost 4 per 100,000, while for males in this age group, the rate was doubled to 7.4 cases per 100,000.

The baseline incidence in the [US military](#) was 0.45 times that in the whole cohort overall. When stratified by age, the rate was much higher in males aged 18-24 years at 3.49 per 100,000, compared to a 5% increase above baseline in males below 18 years. In those males who were 25-39 years, the rate was 23% above the baseline rate.

While considerably less in females, the incidence was highest in the 18-24-year age group at 0.89 cases per 100,000 recipients. The rate for females in the US military in the same age group was only 20% of the baseline, while for those aged 18-24 years, it was 73%.

If the analysis was confined to cases occurring within seven days of [vaccination](#), the rate was typically higher after the second dose, especially in males below the age of 39 years, and most particularly in the 18-24-year age group, with a reported incidence of 5 cases per 100,000.

What are the Implications?

The study shows a low but significant rate of myocarditis among vaccine recipients, at less than 1 per 100,000 recipients. As younger males get vaccinated, the reported rates have gone up, with the highest observed rates being among males below 39 years, especially after the second vaccine dose.

The [post-vaccination](#) myocarditis incidence was the highest, at 7.4 cases per 100,000 recipients, which was 3.5-fold the baseline rate for this group. Most of these reports came from regulatory authorities.

Despite the rarity of this event, myocarditis is known to complicate [smallpox vaccination](#) using a live attenuated virus vaccine, with a rate similar to the highest incidence in this study, at 7.8 per 100,000 over 30 days post-vaccination. This is 3.6-fold higher than the baseline rate.

Myocarditis is due to both [infections](#) and non-infectious causes. SARS-CoV-2 infection can also cause myocarditis, with a calculated incidence of 15.7 times higher than the rate among those without the infection. Again, males are at higher risk, while children below the age of 16 and adults aged 50 years or more are at the highest risk.

Another study reports 450 cases of myocarditis during [SARS-CoV-2 infection](#) per million males aged 12-17 years, which is six times higher than that following vaccination.

Meanwhile, another population-based study came up with an incidence of 0.08 and 0.58 cases per 100,000 after the first and second doses – considered a rare event. Every myocarditis case was in hospitalized males with a median age of 25 years and resolved without specialized treatment.

The [US Food and Drug Administration](#) (FDA) reported recently on this condition, using the FDA Biologics and Effectiveness Safety (BEST) monitoring system. While the rates were low overall, they also reported the highest dose among males aged 18-25 years. This was confirmed by other groups, such as the COVID-19 Vaccine Safety Technical (VaST) Work Group in October 2021, and the Centers for Disease Control and Prevention (CDC) ACIP meeting, and the COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS).

While some studies indicate comparable rates of myocarditis after either mRNA vaccine, another shows almost 10 cases more per million doses of [Moderna vs. Pfizer](#). However, the data in this study was limited. It should never be forgotten that even though myocarditis occurs after vaccination in rare cases, the vast majority of such cases are self-limiting and mild, compared to the much greater risk of this condition with COVID-19 that is prevented by the vaccines.

The CDC [COVID-19](#) Response Team reported that in about four months, males aged 18-24 years would develop 45 to 56 cases of myocarditis per million second vaccine doses, the vaccines could potentially reduce hospitalizations by 530, intensive care unit admissions by ~130, COVID-19 cases by 12,000 and prevent three deaths.

This follow-up monitoring report from Moderna defends the use of the vaccine to control the [pandemic](#).

Source:

<https://www.news-medical.net/news/20211116/Myocarditis-among-Moderna-COVID-19-vaccine-recipients.aspx>