Data from Israel: Myocarditis after COVID-19 vaccines remain rare, highest risk in young males

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A new study from Israel found that the risk of developing myocarditis among males ages 16 to 19 years was about 1 in 15,000 after a third dose of the Pfizer-BioNTech COVID-19 vaccine, and the cases were rare and mild, according to new research published today in *Circulation*.

Several previous studies and reports from public health agencies around the world including the U.S. Centers for Disease Control and Prevention have highlighted a possible connection and potentially increased risk of myocarditis after receiving an mRNA COVID-19 vaccine, generating considerable scientific, policy and public interest.

Typically thought to be triggered by a viral infection, myocarditis is the inflammation of the middle layer of the wall of the heart muscle, the myocardium. This condition is uncommon and may temporarily or permanently weaken the heart muscle and the heart's electrical system, which keeps the heart beating normally. An episode of myocarditis may resolve on its own or with treatment, or may result in lasting damage to the heart. In the general population not during a global pandemic, it is estimated that approximately 10 to 20 people per 100,000 are diagnosed with myocarditis each year, according to the American Heart Association's 2021 scientific statement on myocarditis.

Research detailing post-vaccination myocarditis in Israel after the first and second dose of the Pfizer-BioNTech COVID-19 vaccine were recently published by the country's Ministry of Health. The incidence rate of myocarditis was low, however, it was primarily in young males after a second COVID-19 vaccination, suggesting a potential relationship between the vaccine and myocarditis. The results raised concerns about the potential for increased myocarditis after a booster dose, therefore,

this new analysis was focused on the risk of myocarditis after a booster dose.

"It is important to understand the connections between this rare heart condition and COVID-19 vaccines, so we can monitor the prevalence of myocarditis and pay extra attention to those who are most at risk," said lead study author Dror Mevorach, M.D., a professor of medicine and head of Immunology-Rheumatology Institution at Hadassah Ein Karem Medical Center and chairman of the Israeli Ministry of Health Committee for Identifying Myocarditis as an Adverse Effect of mRNA Vaccines in Jerusalem, Israel.

From July 31, 2021, to November 5, 2021, nearly 4 million (3.94 million) adults in Israel received a booster dose of the Pfizer-BioNTech vaccine, about half (48.7%) of whom were males. Health data for all reported cases of myocarditis after receiving the Pfizer-BioNTech COVID-19 vaccine were evaluated. A cardiologist and a rheumatologist reviewed and classified the data based on the Brighton Collaboration Myocarditis Case Definition.

The analysis found that after a 30-day follow up:

- Fewer than 100 cases (91) of myocarditis were reported, including 35 cases that occurred within the first 30 days of receiving a COVID-19 booster (a 3rd dose) of the Pfizer-BioNTech COVID-19 vaccine.
- 28 cases of myocarditis were probable or confirmed, and 18 occurred within the first seven days after receiving the booster dose of the Pfizer-BioNTech vaccine.
- All 28 cases of myocarditis were clinically defined as mild, and individuals recovered within an average of 3.5 days in the hospital.
- Among all age groups, the risk rates of developing myocarditis

were nearly nine times higher in males than in females (1.42 vs. 0.16).
- Males ages 16-19 were at the highest risk, with 6 in 100,000 individuals developing myocarditis, followed by males ages 20-24 (5.21 cases per 100,000), 30-39 (1.81 cases per 100,000), and 25-29 (0.79 cases per 100,000).

The risk differences declined significantly between the second and third vaccine doses across both genders and across all age groups. Authors believe there are two potential explanations for the changes. "The first is that individuals who developed myocarditis after the second COVID-19 vaccine dose did not receive a third shot, which was a medical precaution in Israel. The second potential explanation is the interval of time between doses: first and second doses are administered approximately three weeks apart, however, the time between a second dose and a booster was about 20 to 24 weeks," added Mevorach.

Researchers believe further study is required to better explain what may predispose young males to develop myocarditis after a COVID-19 vaccine and the pathophysiological mechanisms involved.

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