Study provides more reassuring data on rare heart condition after COVID vaccination

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A study published by *The BMJ* today provides more reassuring data on the risk of heart inflammation (myocarditis or myopericarditis) after mRNA vaccination against the COVID-19 virus.

It confirms previous reports of an increased risk after vaccination with BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) but shows that the absolute number of cases was low, even in younger age groups, providing further evidence to support the overall safety of mRNA vaccines for COVID-19.

Myocarditis (inflammation of the heart muscle) and myopericarditis (inflammation of the outer lining of the heart) are rare but serious conditions, usually triggered by a viral, bacterial or fungal infection.

Recent reports and studies have indicated an increased risk of heart inflammation after mRNA vaccination, particularly after the second dose. But as yet, no study has investigated the association using information from a complete population.

To address this, researchers in Denmark used national healthcare data to look for links between mRNA vaccination and a hospital diagnosis of myocarditis or pericarditis, increased blood troponin levels (a measure of myocardial damage), and a hospital stay lasting more than 24 hours.

Their analyses included nearly 5 million Danish residents aged 12 years or older who received either the Pfizer-BioNTech or Moderna vaccine.

Participants were monitored from 1 October 2020 to 5 October 2021 and a range of potentially influential factors were taken into account, such as age, sex, vaccine priority group, and underlying health conditions.

During follow-up, 269 participants developed myocarditis or myopericarditis, of whom 108 (40%) were 12-39 years old and 196 (73%) were male.

Overall, the results show a strong association between vaccination with

Moderna and myocarditis or myopericarditis, while vaccination with Pfizer-BioNTech was only associated with an increased rate of myocarditis or myopericarditis among women.

The rate of myocarditis or myopericarditis was higher for Moderna vaccination than for Pfizer-BioNTech vaccination. Nevertheless, the absolute number of events after either vaccine was low, and cases were predominantly mild.

For example, of 3,482,295 individuals vaccinated with Pfizer-BioNTech, 48 developed myocarditis or myopericarditis within 28 days of vaccination (an absolute rate of 1.4 per 100,000) compared with unvaccinated individuals.

Among women, the absolute rate was 1.3 per 100,000 and in men it was 1.5 per 100,000. Among 12-39 year olds, the absolute rate was 1.6 per 100,000, and in the youngest age group (12-17 year olds) it was only 1 per 100,000 within 28 days of receiving the Pfizer-BioNTech vaccine.

Of 498,814 individuals vaccinated with Moderna, 21 developed myocarditis or myopericarditis within 28 days of vaccination (an absolute rate of 4.2 per 100,000) compared with unvaccinated individuals.

Among women, the absolute rate was 2 per 100,000 and in men it was 6.3 per 100,000. Among 12-39 year olds, the absolute rate was 5.7 per 100,000 within 28 days of receiving the Moderna vaccine.

Both vaccines were also associated with around a 50% reduced risk of cardiac arrest or death (the most severe manifestations of myocarditis or myopericarditis) compared with unvaccinated individuals.

In contrast, there was a 14-fold increased risk of cardiac arrest or death

28 days after a positive COVID-19 test compared with uninfected individuals.

This is an observational study, so can't establish cause, and the researchers point to some potential sources of bias, such as increased public awareness of potential side effects of vaccines, that may have affected the results.

However, they say this was a well designed study based on high quality healthcare data for a complete population, and results were largely unchanged after additional analyses, suggesting that they withstand scrutiny.

As such, the researchers conclude that mRNA vaccination with Moderna and Pfizer-BioNTech is associated with an increased risk of myocarditis or myopericarditis in the Danish population, but the absolute rate after either vaccine was low, even in younger age groups.

The benefits of vaccination should be taken into account when interpreting these findings, they add, and larger multinational studies are needed to further investigate the risks of myocarditis or myopericarditis after vaccination within smaller groups.

More information: SARS-CoV-2 vaccination and myocarditis or myopericarditis: population based cohort study, *BMJ* (2021). DOI: 10.1136/ bmj-2021-068665

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