

The rate of vaccine-induced heart inflammation in children



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The Pfizer-BioNTech and Moderna mRNA vaccines have demonstrated great efficacy in reducing transmission, hospitalization risk, and the chance of death from coronavirus disease 2019 (COVID-19). However, there have been early reports of adverse events from the vaccines amongst teens and young adults, namely myocarditis occurring in young men in Israel and the USA. In August 2021, the Federal Drug Administration identified a potential 1:5,000 risk of myocarditis developing in teenaged males. The CDC also reported an approximately 95% hospitalization rate for myocarditis-related adverse vaccine events.



Study: SARS-CoV-2 mRNA Vaccination-Associated Myocarditis in Children Ages 12-17: A Stratified National Database Analysis. Image Credit: anyaivanova/Shutterstock

In a paper recently uploaded to the preprint server medRxiv*, a risk-benefit analysis was undertaken utilizing data collected from the vaccine adverse event

reporting system (VAERS) relating to adolescents having received an mRNA vaccine before June 18th 2021. The findings suggested that an alternative vaccination schedule may be most appropriate for males in this age group.

A preprint version of the study is available on the medRxiv* server while the article undergoes peer review.

What proportion of children receiving the vaccine experienced myocarditis?

The group searched the VAERS database for symptoms including "myocarditis," "pericarditis," "myopericarditis," or "chest pain," with the requirement that laboratory data were available with the individual's troponin levels. In total, 257 reports fitting the criteria were gathered, 25 of which were regarding females, and all but one had received the Pfizer-BioNTech vaccine.

Following the second dose of the vaccine, the group found a 162.2 per million incidence rate of cardiac adverse events in boys aged 12-15, around three times higher than estimated by the CDC. In boys aged 16-17, the group also found a higher rate than estimated by the CDC by around 40%, 94 individuals per million vaccinations. The rate of adverse events was also higher than estimated by the CDC amongst girls, 13 and 13.4 per million in those aged 12-15 or 16-17, respectively.

In individuals having received only one dose of the vaccine, adverse event rates were much lower in all groups, 12 and 8.2 per million in boys aged 12-15 and 16-17, respectively. The rate was similarly reduced in girls, with no risk of adverse events in those aged 12-15 and only 2 per million in 16-17-year-olds. The group found that 15% of adverse events occurred following the first dose of the vaccine, with the majority after the second. Most adverse events occurred two days after vaccination, with 91.5% occurring within five days.

Risk-benefit analysis

To compare the rates of vaccine-induced adverse events to the rate of hospitalization that could have been avoided by vaccination, the group obtained COVID-19 hospitalization records for individuals in the same age group, also considering comorbidities that were found to increase the probability of

hospitalization 4.7 fold, with 70% of hospitalized children bearing at least one. As around 20% of children are obese in the USA and almost 10% have asthma, in addition to the wide range of other related conditions any child may bear, such as diabetes, the group estimate that around 33% of children in the 12-17-year-old age group suffer from at least one COVID-19 comorbidity.

An otherwise healthy adolescent bears an approximate risk of 44.4 in 1 million hospitalized due to COVID-19 within the next 120 days. In teens with at least one comorbidity, the rate spikes to 210.5 per million, or 294.7 per million in periods of intense severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission.

Therefore, the risk of cardiac adverse events following the second dose of the mRNA vaccine could be around 3.7 times more likely than hospitalization due to COVID-19 in healthy 12-15-year-old boys during periods when the pandemic is better under control 2.1 times in 16-17-year-olds. The group found that this trend remains even when SARS-CoV-2 transmission rates are high, with vaccination being riskier than hospitalization from COVID-19. However, for those with at least one COVID-19 comorbidity, receiving the vaccine was safer than the risk of being hospitalized during periods of high transmission, but not when COVID-19 hospitalization rates were low.

When COVID-19 hospitalization numbers are adjusted for those that attended hospital for another purpose and were incidentally infected with COVID-19, estimated to be around 40% of cases, the risk of hospitalization for COVID-19 drops notably in otherwise healthy individuals to around a 7.1, 26.7, and 37.3 per million during times of low, medium, or high transmission, respectively. In this case, however, as those with comorbidities are more likely to be hospitalized by COVID-19, the risk of vaccine-induced injury is lower than that of hospitalization in times of high transmission for 12-15-year-old boys and both moderate and high periods of disease transmission amongst 16-17-year-olds.

The long-term health effect of the mRNA vaccines on teenage boys is unknown. Few clinical trials have been conducted due to the early observation of adverse events. The group suggests that vaccination of this age group could be done on a case-by-case basis, allowing the risks and benefits to be weighed for each individual. Countries such as Germany and Norway have avoided recommending vaccinating children altogether; while the UK is considering distributing just one

dose of the vaccine to these individuals, the vast majority of serious adverse events occurring after the second dose.

*Important notice

medRxiv publishes preliminary scientific reports that are not peer-reviewed and, therefore, should not be regarded as conclusive, guide clinical practice/health-related behavior, or treated as established information.

Journal reference:

- Høeg, T. et al. (2021) "SARS-CoV-2 mRNA Vaccination-Associated Myocarditis in Children Ages 12-17: A Stratified National Database Analysis". *medRxiv*. doi: 10.1101/2021.08.30.21262866.
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