

SARS-CoV-2 mRNA Vaccine-related Myocarditis and Pericarditis: An Analysis of the Japanese Adverse Drug Event Report Database

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Abstract

Background: The association between severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccines and myocarditis/pericarditis in the Japanese population has not been systematically investigated. This study was aimed at clarifying the association between SARS-CoV-2 mRNA vaccines (BNT162b2 and mRNA-1273) and myocarditis/pericarditis as well as influencing factors by using the Japanese Adverse Drug Event Report database.

Methods: Reporting odds ratios (RORs) and 95 % confidence intervals (95 % CIs) for the association between the vaccines and myocarditis/pericarditis were calculated using data from the database (April 2004-December 2023). Age, sex, onset time, and outcomes in symptomatic patients were evaluated.

Results: The total number of reports was 880,999 (myocarditis: 1846; pericarditis: 761). The adverse events associated with the vaccines included myocarditis (919 cases) and pericarditis (321 cases), with the ROR [95 % CIs] being significant for both (myocarditis: 30.51 [27.82-33.45], pericarditis: 21.99 [19.03-25.40]). Furthermore, the ROR [95 % CIs] of BNT162b2 and mRNA-1273 were 15.64 [14.15-17.28] and 54.23 [48.13-61.10], respectively, for myocarditis, and 15.78 [13.52-18.42] and 27.03 [21.58-33.87], respectively, for pericarditis. Furthermore, most cases were ≤ 30 years or male. The period from vaccination to onset was ≤ 8 days, corresponding to early failure type based on analysis using the Weibull distribution. Outcomes were recovery or remission for most cases; however, they were severe or caused death in some cases.

Conclusion: In the Japanese population, SARS-CoV-2 mRNA vaccination was significantly associated with the onset of myocarditis/pericarditis. The influencing factors included age of ≤ 30 years and male. Furthermore, although most adverse events occurred early after vaccination, overall outcomes were good.

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Featured image: A hand holding an mRNA vaccine vial. (Spencer Davis / Unsplash)

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