

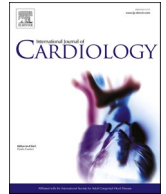


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Editorial

Myocarditis after RNA-based COVID-19 vaccines: Where do we stand?



Severe acute respiratory syndrome – Coronavirus 2 (SARS-CoV2) pandemics has been an unprecedented healthcare crisis, and has exacted a toll of millions of deaths worldwide since its inception in 2020. RNA-based vaccine against SARS-CoV2 were rapidly introduced in clinical practice by the end of 2020 and were shown to be effective in dramatically abating the incidence of infection and/or severe disease [1]. With widespread implementation of vaccination campaigns, pharmacovigilance data on RNA-based vaccine related side effects were able to prove

overall safety of the drug, with incidence of severe adverse events being initially reported as being around 1:10,000 [2]. Concerns about the potential of RNA-based vaccines to induce myocarditis have spread in the medical community, culminating in a recent report on United States passive report system describing 1626 cases of probable or confirmed myocarditis in 192,405,448 individuals having received 354,100,845 RNA-based SARS-CoV2, more commonly in adolescent males after the second vaccine dose [3]. The Authors conclude that the benefit of

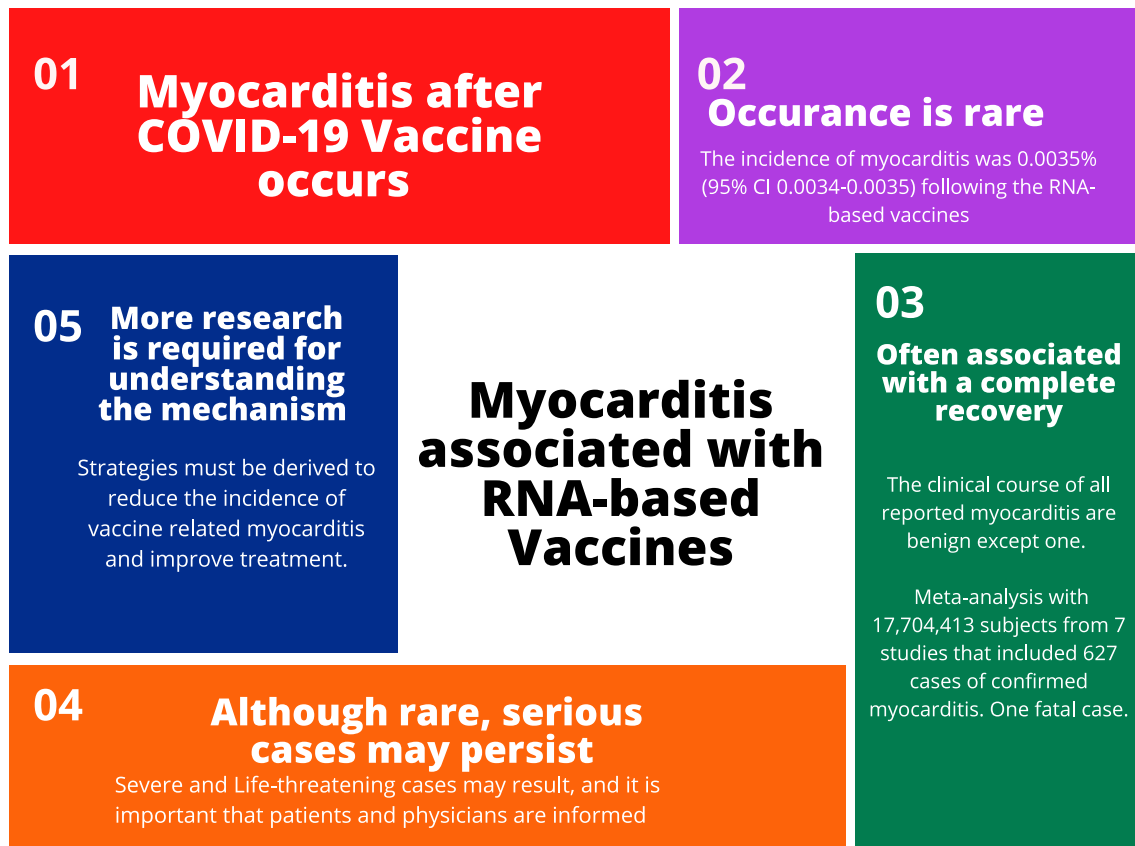


Fig. 1. Summary of the main findings and take-home message from the paper by Cordero et al. CI, confidence interval; COVID-19, coronavirus disease of 2019.

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vaccination should be weighted against the risk of myocarditis, especially among younger males.

In the present issue of the International Journal of Cardiology, Dr. Cordero and colleagues present a very well-conducted meta-analysis of studies reporting on the occurrence of myocarditis after a full vaccination course with RNA-based SARS-CoV2 vaccines [4]. Pooled incidence of myocarditis after vaccine was 0.0035% over the approximately two years of reporting, with only a single fatal case. Among the main limitations of the study are the intrinsic risk of under-reporting that spontaneous reporting system most of pharmacovigilance systems are subject to, and the lack of standardized diagnostic criteria for post-vaccine myocarditis. Myocarditis incidence after SARS-CoV2 vaccine appears to be higher than the cumulatively occurrence of 0.00024% that has previously been reported after vaccination against other viral pathogens [5], and somewhat in line with the background expected yearly myocarditis incidence, ranging between 15 and 20 cases per 100,000 [6].

These data are rather reassuring for what concerns the risk/benefit profile of the vaccine, given that the potential for the (rare) occurrence of myocarditis are preferable when weighted against the risks connected to SARS-CoV2 infection - which appear to be significant even with the less virulent variants currently circulating in the general population [7], and also in consideration that SARS-CoV2 infection itself was shown to be causing myocarditis in a significantly higher proportion of cases, i.e. 0.146% of infected individuals [8].

These data, however, also represent an important contribution and benchmark because they do support the association of the vaccination with myocarditis, and prompt an increased awareness for the recognition of vaccine-induced myocarditis. Indeed, even if rare, several thousands of cases are expected to occur per each million of vaccinated individuals. Furthermore, while most cases are reported to have favorable clinical course, not all are benign and critical and fatal cases have been reported [9,10]. Fig. 1 summarizes the main findings of the paper.

Declaration of Competing Interest

None

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