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Short communication

Myocarditis following COVID-19 mRNA vaccination

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ABSTRACT

Background: Clinical trials of the BNT162b2 vaccine, revealed efficacy and safety. We report six cases of myocarditis, which occurred shortly after BNT162b2 vaccination.
Methods: Patients were identified upon presentation to the emergency department with symptoms of chest pain/discomfort. In all study patients, we excluded past and current COVID-19. Routine clinical and laboratory investigations for common etiologies of myocarditis were performed. Laboratory tests also included troponin and C-reactive protein levels. The diagnosis of myocarditis was established after cardiac MRI.
Findings: Five patients presented after the second and one after the first dose of the vaccine. All patients were males with a median age of 23 years. Myocarditis was diagnosed in all patients, there was no evidence of COVID-19 infection. Laboratory assays excluded concomitant infection; autoimmune disorder was considered unlikely. All patients responded to the BNT162b2 vaccine. The clinical course was mild in all six patients.
Interpretation: Our report of myocarditis after BNT162b2 vaccination may be possibly considered as an adverse reaction following immunization. We believe our information should be interpreted with caution and further surveillance is warranted.

1. Introduction

1.1. Background

On December 2020 the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech mRNA vaccine (BNT162b2) for prevention of COVID-19 disease. The vaccine's EUA relied on data which were obtained from several clinical trials [1,2]. The results of these trials revealed that the vaccine's efficacy is 95% and its safety profile is good and similar to that of other vaccines [1–3]. Systemic reactions to the vaccine, which were usually mild and transient, were reported more commonly among the younger population and more often after the second dose [1,2].

In Israel, the nationwide rollout of the 2-dose BNT162b2 vaccination program started in December 2020. More than 4 million people have received two doses of the vaccine, by the time of writing. These include persons 16 years old and older. In this report, we inform on the unforeseen occurrence of myocarditis in five male persons shortly after they received two doses of the BNT162b2 vaccine and in one male person 16 days after he received the first dose of the BNT162b2 vaccine. We suspect that these adverse events were related to the vaccine.

1.2. Patients and Clinical, laboratory and imaging Assessments

In a three-week interval (January 30th through February 20th 2021, six men were hospitalized with suspected myocarditis, all shortly after the vaccination. The COVID-19 status of the six

Abbreviations: BNT162b2, Pfizer-BioNTech mRNA Vaccine; CMR, Cardiac Magnetic Resonance Imaging; Covid-19, SARS-COV-2; CT, Computerized Tomography; EUA, Emergency Use Authorization; FDA, Food and Drug Administration; RT-PCR, Reverse Transcription-Polymerase Chain Reaction.

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