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Case Report

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Successful Vaccination of Patients with History of Severe Anaphylactic Reaction with Pfizer-Biotech COVID-19 Vaccine

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Case Presentation

A history of severe anaphylactic reaction to a vaccine components is a contraindication for all currently approved COVID-19 vaccinations [1,2]. We report a successful vaccination of two patients with a history of severe anaphylactic reaction with Pfizer-BioNTech COVID-19 Vaccine. During December 14 to 23, 2020, after administration of a reported 1 893 360 first doses of Pfizer-BioNTech COVID-19 vaccine, CDC identified 21 case reports, corresponding to an estimated rate of 11.1 cases per million doses administered. No deaths from anaphylaxis were reported [3].

Anaphylaxis is a rare risk of drug administration, including vaccines. Anaphylaxis has a good prognosis when diagnosed and treated promptly and correctly [4]. A typical history is of severe allergic reactions to several classes of drugs, for example, penicillin, laxatives, injected corticosteroids, or antacids, all containing polyethylene glycol (PEG) [4]. Symptoms are of rapid onset, usually within minutes, and typically result in severe generalised pruritus, urticaria, angioedema, hypotension, or difficulty in breathing. Reactions are more severe with higher doses and with higher-molecular-weight PEGs.

The two patients ; a female in her 40's and male in his 50's years of age. The female patient had a documented history of severe, life threatening anaphylactic allergic reaction to insect bites with previous intensive care admission and four allergic reactions to different seasonal influenzas vaccine and food items and medications including penicillin, seafood and preserve food items which has been also confirmed in allergy skin test. The male patient had a similar history of severe, life threatening anaphylactic allergic reaction to various medications including aspirin, penicillin, seasonal influenzas vaccine and history of recurrent mastocytosis; he was asymptomatic at the time of the vaccination.

Both patients expressed their interest in getting vaccinated and were counselled about the risk and benefit. Both were pretreated with prednisone 40 mg, diphenhydramine 25 mg and famotidine 20 mg given 6 hours and 1 hour prior to the first dose. The female patient had no immediate anaphylactic reactions after 3 hours observations. She experienced palpitation and heat waves at 26 hours (day 2) and 56 hours (Day 3) from the vaccination time, she was treated successfully with prednisone 40 mg, diphenhydramine 25 mg. The 2nd dose was uneventful. At 12 days post the second dose the patient had Anti-SARS-CoV-2 Spike level of 250 U/mL (> 0.8 level is in keeping with positive Anti-SARS-CoV-2 Spike level). The second male patient had similar protocol for both vaccination doses without any symptoms of any allergic reaction. His Anti-SARS-CoV-2 Spike level of 120 U/mL 10 days after 2nd dose.

These two cases illustrate the feasibility of administering Pfizer-BioNTech COVID-19 Vaccine in a subject with a history of severe anaphylactic reaction to PEG with the use of the above protocol. With the increase of COVID-19 cases worldwide and increasing risk of infection in general population, more novel approaches to vaccinate as many of the population is critical. The current 2 cases certainly cannot be used as a basis to make recommendations rather to increase the awareness of the feasibility of such approach in history of severe and life-threatening anaphylactic reaction to PEG who were excluded from all current COVID-19 vaccinations trials. Patient education, acceptance of the potential risk, premedication and close monitoring with administration of prophylactic medications immediately at the onset of symptoms is critical to prevent the symptoms from progressing and requiring epinephrine or hospital admission. Close accessibility to medical care within few minutes in case of rebound allergic reaction is an important aspect of the final decision regarding vaccinating a patient with such history. Most biphasic responses which can

occur up to 20% of anaphylactic cases can occur during the first 8 hours, but it might be delayed up to 72 hours [5].

With the excellent antibodies' response in this case, the administration of cortisone did not hinder the Anti-SARS-CoV-2 Spike response to the vaccine. Lastly, Anaphylaxis-type reactions occur in approximately 1 in 1000 of the general population, and this number will translate into millions of people around the globe [6]. Further studies are needed to evaluate COVID-19 vaccination in patients with a history of severe anaphylactic reaction as mass vaccination is the main way to control the current pandemic.

Declaration of interest:

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