Case Report

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Anaphylaxis for COVID-19 Pfizer-BioNTech mRNA vaccination in a person with previous allergy to the vaccine: a case report

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ABSTRACT

Protection from COVID-19 infection has been a major challenge and priority to protect the health and life of people around the globe. In clinical trials, vaccination has shown to protect people from severe COVID-19 infection and reduce both morbidity and mortality. At the time of writing this article, mRNA-based vaccines were being used as new form of vaccination against the COVID-19 infection. As this is a new method of vaccination, full information about managing cases with allergy to the vaccine was not clearly available. So, any form of allergic response was considered contraindication for the future doses of the mRNA based COVID-19 vaccines. A 35 years old female received 2nd dose COVID-19 mRNA vaccine as per vaccination plan in a healthcare center. She developed features of allergic reaction and anaphylaxis including urticarial rash, intense itching of whole body, tightness in the chest, hypotension, reduced central pulse volume, decreased level of consciousness and grunting. Immediate anaphylaxis diagnosis with level 1 certainty of Brighton Anaphylaxis scoring and management with Epinephrin, Hydrocortisone and IV fluids was undertaken. Patient was stabilized and transferred to secondary care for further management. The use of mRNA vaccines for COVID-19 had initial uncertainties about allergic reactions, severity of allergic reactions, the patients for future allergic reaction and dealing with these patients about future vaccine doses. We presented a case with history of previous immediate mild rash to 1st COVID-19 mRNS vaccine dose and subsequent anaphylaxis following 2nd dose of the same mRNS vaccine.

Keywords: COVID-19 infection, Pfizer-BioNTech mRNS vaccine, Anaphylaxis, Severe acute respiratory syndrome coronavirus-2

INTRODUCTION

By 10th March 2021, 380,000 Coronavirus disease 2019 (COVID-19) vaccine doses have been administered under COVID-19 National vaccination program in Qatar. After the initial reports of anaphylaxis to the COVID-19 vaccine in December 2021, by the directive of ministry of public health (MOPH), the vaccine was administered in the centers which have the facility of managing anaphylaxis like health centers and hospitals. But due to the need for whole population vaccination, vaccination campaign was set up in bigger halls/grounds as well with trained staff who can manage anaphylaxis.

COVID-19 pandemic is caused by the virus severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).² COVID vaccine was given emergency approval by food and drug administration (FDA), US, in December 2020.³ These are the new mRNS type vaccines which elicit antigenicity for the spike proteins over the COVID-19 coronavirus. These have shown an amazingly high level of efficiency of 95% in preventing symptomatic laboratory confirmed COVID-19 infection in persons without evidence of previous SARS-CoV-2 infection, two weeks after the 2nd dose.⁴ These have also shown to reduce transmission of COVID-19 infection from vaccinated people to unvaccinated people.⁵

Anaphylaxis as an adverse effects immunisation (AEFI) is uncommon, occurring at a rate of less than 1 per million doses for most vaccines. However, within the first days of initiating mass vaccination with the Pfizer BioNTech COVID-19 vaccine BNT162b2, there were reports of 2 and 6 anaphylaxis events in the United Kingdom and United States respectively. There were cases of anaphylaxis reported on CDC website and also in its mortality morbidity weekly reporting (MMWR).

We would like to report a case of anaphylaxis in a person after Pfizer mRNS COVID-19 vaccination.

CASE REPORT

A 35 years old female received second dose of Pfizer BioNTech vaccine and developed urticaria rash in the right forearm immediately after the vaccination. She was transferred to the emergency treatment area of the health center straightaway. Within 10 minutes she developed

intense pruritis of the whole body including the scalp. She had a blood pressure of 135/75 mmHg and pulse of 88/min regular. At this point she received promethazine 25 mg intramuscular and hydrocortisone 100 mg Intramuscular and was started on 100% oxygen.

She developed tightness in the sternal area within further 5 minutes and on assessment, only had feeble central pulse and blood pressure dropped to 95/65 mmHg, so adrenalin 0.5 ml intramuscular was given and Intravenous line was placed and started normal saline. Meanwhile ambulance was arranged to prevent further delay in her care. Patient's blood pressure raised to 140/70, pulse rate 76/minute and oxygen saturation at 100% on 15L oxygen. The management has been in accordance with the guidelines for anaphylaxis management.⁸

Patient was transferred to the secondary care hospital for further management via the ambulance after she was stable.

Table 1: Person characteristics.

Characteristics	Results
Age (years)	35
Sex	Female
Previous allergies	Shrimps, Latex, COVID-19 Pfizer-BioNTech mRNS vaccine
Previous anaphylaxis episode	None
Onset of symptoms	Within 10 minutes of administration
Symptoms and signs	Generalized pruritis, urticarial rash on the right forearm, hypotension, reduced central pulse volume, decreased level of consciousness, tachypnoea, chest recession and grunting
Treatment setting	Emergency area of the primary care health center
Epinephrine received	0.5 ml intramuscular to left outer thigh
Brighton level of severity of anaphylaxis	Level 1 diagnostic certainty
Outcome or disposition	Vital signs back to normal after hydrocortisone 100 mg IM, adrenaline 0.5 mg IM, IV fluids and admitted to secondary care hospital. Her medical records show that the patient had recovered by the time she reached emergency department, she was observed for few hours and was discharged. The patient did not seek medical attention during the following week according to her electronic medical records.
Comorbidities	None
Current medication	None

Criteria used for diagnosis of anaphylaxis

Brighton collaboration case definition criteria for anaphylaxis was used in defining the level of anaphylaxis. According to this criterion, the sudden onset of symptoms/signs and rapid progression of symptoms/signs should be associated with major / minor criteria depending on level of certainty. Our case qualifies for level 1 certainty because it has above symptoms/signs of sudden onset and rapid progression with involvement of skin, respiratory and cardiovascular systems.

DISCUSSION

In the current climate where widespread uptake of vaccines against COVID-19 is a key global intervention

to control the pandemic, it is essential that vaccination proceeds safely and with as few barriers as possible. Both the public and healthcare workers need reassurance that the vaccines are safe.

In our reported case, the patient presented within 10 minutes of giving vaccination and needed hospitalization. The patient also needed epinephrine 0.5 ml intramuscular at health center and after initially stabilizing the patient's needed hospitalization to secondary care. patient was observed for few hours and was discharged from the hospital. The patient did not need hospital admission, intubation, or ICU admission.

In its MMWR, the authors found that 86% of patients had anaphylaxis symptoms within 30 mins of vaccination,

81% had history of allergy or allergic reactions, 90% were women.⁷

COVID-19 has been a major threat to those vulnerable and vaccination has shown in studies to protect from the severe form of the infection. This has come at the risk of adverse events including allergic reactions. A CDC study found the rate of anaphylaxis after all vaccines is 1.31 per one million vaccine doses given. 10 The monitoring of allergic reactions including anaphylaxis has been through vaccine adverse events reporting system (VAERS) in the US which found that between 14th December 2020 through 18th January 2021, the anaphylaxis reporting rate of 4.7/million Pfizer-BioNTech vaccine while the anaphylaxis rate according to MMWR is 11.1/million doses administered.^{7,11} MOPH Qatar also has adverse events reporting mechanism by patients through its website. Given the context of morbidity and mortality from COVID-19 infection, the benefits of vaccination outweigh the risk of anaphylaxis which can be treated safely if prompt and appropriate action taken.

Due to the risk of anaphylaxis, we believe the decision by the MOPH to vaccinate the people in the facilities having trained staff to manage is appropriate.

Any history of allergy to the COVID-19 vaccine (as reported in this case) should be considered contraindication. The outcome in our case of anaphylaxis could have been fatal if had not been attended immediately. This has also been considered a contraindication in manufacturer's vaccine fact sheet and the local MOPH guideline document.

Limitations

We have only one case report of anaphylaxis in our center but do not know the prevalence of anaphylaxis in the local population. We also could not find this on MOPH website though there is robust monitoring system in place with reporting of medication adverse events or allergies within the PHCC. More research is needed in establishing the prevalence of anaphylaxis from COVID-19 mRNS Pfizer vaccine in the local population to definitely establish the risk and justify the benefit of vaccine. If the prevalence found to be high in some subset of people, then alternative vaccine may be offered to them.

CONCLUSION

The health center which is part of primary health care corporation (PHCC) gives the right to the patient to complaint under its feedback and complaint management policy through telephone by calling 107, online through PHCC website and in person by filling a complaint form at customer service desk.

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