



SERIOUS ADVERSE REACTIONS AFTER COVID-19 VACCINATION- A CASE SERIES

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ABSTRACT India has so far given Jabs of 73,82,07,378 Coronavirus disease 19 (COVID-19) vaccines approved by the regulatory authorities in India till 12th September 2021. The vaccine provide protection against the development of severe disease, as a result of an immune response to the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) virus. In our centre we have given two vaccines to the beneficiaries namely Covishield and Covaxin. The hypersensitivity reactions to vaccine includes a spectrum of events ranging from local rash to severe life-threatening anaphylactic reaction. In our centre, the vaccination programme was started from 25 January 2021 and is ongoing. Till 12 September 2021 total 25000 doses of Covishield vaccine were given. Here we report 03 cases of serious adverse reactions following immunization after the first dose of Covishield. There was no death due to serious adverse reactions after vaccination at our centre. The present case series highlighted the careful monitoring of the beneficiaries after the vaccination.

KEYWORDS : COVID 19, Vaccination, Anaphylaxis, Covishield

INTRODUCTION

In the beginning of December 2019, a major pandemic of pneumonia began in Wuhan City of Hubei Province, China. As per World Health Organisation (WHO), the causative agent of this pandemic, a novel coronavirus, was named Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), while the disease caused by it was termed as Coronavirus disease 19 (COVID-19). [1] Preventive measures, such as social distancing, masks, and hand washing to prevent the spread of SARS-CoV-2, are essential, but not adequate. [2] As a result, there has been a global urgency for vaccine development. India approved two vaccines (Covishield and Covaxin) in January 2021 under Emergency Use Approval (EUA). These vaccines were used only after phase II trials. [3] Minor allergic reactions are known to occur after vaccination such as itching, rash, giddiness or fever. However, there are very few cases reported having post vaccine anaphylactic reactions. [4] Hence, it is important that physicians are cognisant of an unusual adverse event of COVID-19 vaccine. We report a case series of 03 beneficiaries who developed anaphylactic reaction after the first dose of Covishield.

Case - 1

A 50-year old gentleman with a prior history of allergic bronchial asthma was given the first dose of Covishield vaccine at our centre. Patient started having a headache within 5 minutes of vaccination. His immediate vitals were pulse rate 74 per minute, regular, blood pressure 110/70 mmHg in left arm supine position, saturation 98% on room air, without any adventitious sounds in chest. After 10 minutes, he complained of dizziness which was followed by altered sensorium. He was made recumbent, and kept on continuous non-invasive vital monitoring. Vitals checked again revealed pulse rate 38 per minute regular, Blood pressure was 60 mmHg systolic, with bilateral diffuse wheeze on chest auscultation, Saturation on room air was 98%. ECG was suggestive of sinus bradycardia. Patient received Injection adrenaline 0.5mg (1:1000) intramuscularly immediately along with 500ml bolus of intravenous 0.9% normal saline. He also received intravenous hydrocortisone 200 mg and Chlorpheniramine 10 mg single dose. After 5

minutes, his pulse rate was 84 per minute, regular, Blood pressure was 116/72 mm Hg. Auscultatory findings revealed clear lung fields and normal heart sounds. His giddiness subsided and he became conscious and oriented. He was observed for further two hours and then discharged in a hemodynamically stable state with advice to visit a local physician in case of development of any new symptom.

Case - 2

A 76-year-old male, with a prior history of ischemic heart disease status post coronary bypass, on antiplatelet (Aspirin), no history of previous allergies, received the first dose of covishield vaccine. Within 15 minutes of vaccine administration, he complained of an urticarial rash associated with intense itching over the right upper limb and earlobe. Over the next 10 minutes, the rash gradually progressed to bilateral upper limbs, chest, back and face. He was hemodynamically stable with normal oxygen saturation (99% on room air). Chest auscultation revealed bilateral rhonchi over lung fields with normal heart sounds. Patient was immediately kept on continuous non-invasive vital monitoring. Patient received intravenous chlorpheniramine 10 mg and hydrocortisone 200 mg single dose along with salbutamol nebulization. ECG showed T wave inversion in chest leads V1 and V2 [Figure 1].



Figure-1 ECG showing T wave inversion in lead V1 and V2 and urticarial rash over chest & upper limb

He improved over the next 10 minutes without any new symptoms. Auscultation revealed clear lung fields bilaterally. Repeat ECG showed similar changes. The rash and itching gradually decreased over the next one hour and the patient was discharged in a hemodynamically stable state with advice to visit a local physician in case of development of any new symptom.

Case-3

A 30-year-old female, married, pre-morbidly healthy, without any prior allergies, received her first dose of covishield at our vaccine centre. She complained of giddiness, chest tightness, nausea, and development of urticarial rash [Figure 2] associated with itching over the left forearm within 15 minutes of vaccine administration. Her vitals recorded were a pulse rate of 72 per minute, regular, blood pressure 126/70 mmHg, and 99% saturation on room air. Auscultatory findings revealed clear lung fields, and normal heart sounds. Patient was immediately made supine and kept on continuous non-invasive vital monitoring. In a couple of minutes, her symptoms worsened with one episode of vomiting, colicky abdominal pain, bradycardia with a regular pulse rate of 50 per minute, BP 124/72 mm hg in right arm with clear lung fields and normal heart sounds. Patient was conscious and oriented. Abdomen was soft and non-tender on palpation. Patient received intravenous chlorpheniramine 10 mg and hydrocortisone 200 mg, ondansetron 4 mg single dose, and started on rapid infusion of intravenous fluid with 0.9% normal saline. Symptoms gradually subsided over the next 10 minutes with normalization of heart rate to 72 per minute. Rash over the forearm gradually faded and disappeared after 45 minutes of vaccination and the patient was discharged in a hemodynamically stable condition.



Figure 2- Urticarial rash over left forearm

DISCUSSION:

Covishield vaccine was approved for public vaccination in January 2021 under EUA. This vaccine is developed by Serum institute of India along with Oxford vaccine group and AstraZeneca. This is a recombinant (ChAdOxInCoV-19 coronavirus vaccine), replication deficient, chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein developed in genetically modified embryonic kidney (HEK). [5,6] Minimal side effects of vaccination like skin rash, itching, giddiness, headache, fever can be managed by antihistamines and anti-pyretic. However, severe anaphylactic reaction requires management of airway, circulation, emergency drugs like intramuscular or intravenous adrenaline along with antihistamines and steroids. Anaphylactic reaction generally manifests with cutaneous, respiratory, cardiovascular and / or gastrointestinal tract symptoms. These reactions can be mild or severe. It can halt, progress or regress at different pace. If unattended, it can be fatal within minutes. However, there is no definite order in which symptoms of anaphylaxis will occur. Post vaccine monitoring at our centre detected three cases of anaphylactic reactions after the first dose of covishield vaccine. Anaphylaxis can be potentially life threatening and requires immediate treatment. [7] In our cases, beneficiaries started developing symptoms within 15 minutes of vaccination. Amongst our three cases, one had a history of bronchial asthma, albeit, he was not on regular inhaled bronchodilators. One patient developed anaphylactic shock requiring intramuscular Adrenaline, while other developed a moderate reaction. All the cases met the Brighton Collaboration case definition criteria for anaphylaxis. [4] There are very few case reports of anaphylactic reactions after COVID 19 vaccination in India. [8] Based on post vaccine monitoring at our centre, we observed that anaphylaxis after the first dose of covishield vaccine appears to be a rare event 0.012% (3 in 25,000). The incidence rate of anaphylaxis in India is one per million doses of either covishield or Covaxin.[9] However the data available from one study from US for Pfizer-BioNTech and Moderna vaccine shows anaphylaxis rate of 0.027% and 0.023% respectively.[10] Until now, there is no data on the safety of the second

dose of vaccine after an allergic reaction to the first dose.[11] None of the three beneficiaries at our centre received second dose of COVID 19 Vaccine as per Government Of India guidelines.[3] Delayed reaction to Covid 19 vaccine can appear 48 hours after the first vaccine dose. In contrast to immediate hypersensitivity reactions (e.g., anaphylaxis and urticaria) that present within 4 hours of vaccine administration, these delayed localized hypersensitivity reactions are not a contraindication to subsequent vaccination. [3,12] Till date no data is available regarding vaccine efficacy in patients who develop hypersensitivity reactions. Mortality from COVID-19 in populations of increased risk from severe illness is substantial and treatment options are limited. [13] Widespread vaccination against COVID-19 will play a major role in control of pandemic and will help in reducing morbidity and mortality. However, screening for contraindications and precautions before administering COVID 19 vaccine should be done. Moreover, vaccination centres should have the necessary equipment, protocols and trained staff members for management of adverse events and anaphylaxis. It is necessary to implement a post vaccination observation period, including a facility to transport the patient to an advanced centre for higher medical care. It is important to remember that benefits of COVID-19 vaccine far outweigh the risk of anaphylaxis, which is highly reversible and treatable.

Declaration Of Patient Consent

The authors certify that they have obtained all appropriate patient consent forms. Patients understands that their name and initials will not be published and due efforts will be made to conceal their identity.

Financial Support And Sponsorship

Nil.

Conflicts Of Interest

There are no conflicts of interests.

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