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Смерть после вакцинации от COVID-19: клинический случай

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АННОТАЦИЯ

Для снижения смертности и заболеваемости от инфекционных заболеваний, особенно в условиях пандемии COVID-19, необходимы вакцины. Для борьбы с пандемией во всём мире были разработаны различные типы вакцин. Однако в отношении всех типов вакцин от COVID-19 регистрировались поствакцинальные осложнения, включая анафилаксию, которая часто возникает у ранее страдавших аллергическими реакциями. В Индии лица, получившие вакцину, остаются под наблюдением в медицинском учреждении в течение 30 минут, поскольку неблагоприятные реакции развиваются в течение нескольких минут или часов после её введения.

В статье представлен случай 23-летней женщины, скончавшейся через 24 часа после введения рекомбинантной вакцины ChAdOx1 nCoV-19 (COVISHIELD). Во время наблюдения в медицинском учреждении у пациентки не было никаких симптомов после вакцинации, а также аллергических реакций в анамнезе. Женщина была доставлена мёртвой в больницу при Медицинском колледже им. М.С. Рамайя, вскрытие показало отёк лёгких. В посмертном образце крови обнаружены антитела к COVID-19, маркеры воспаления, сывороточный IgE и признаки коагуляции. Причиной смерти была названа аллергическая реакция замедленного типа на вакцину COVISHIELD.

Вакцины нового поколения могут вызывать фатальные аллергические реакции иногда позже, чем предусмотрено протоколом, и даже при отсутствии кожных реакций.

Ключевые слова: вакцина; COVID-19; побочные реакции; смерть; клинический случай.

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Death following COVID-19 vaccination: A case report

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ABSTRACT

Vaccines are necessary to reduce the mortality and morbidity of infectious diseases. It has played a vital role in the ongoing coronavirus disease 2019 (COVID-19) pandemic. Different types of vaccines have been developed to combat the pandemic. Adverse events following immunization including anaphylaxis have been reported for all types of COVID-19 vaccine. Anaphylaxis is common in a person who has a history of allergic reactions. Adverse reactions develop within minutes or a few hours after vaccination. Thus, in India, vaccine recipients are made to stay in the medical facility for 30 min for observation.

Herein, we report the case of a 23-year-old woman who succumbed after 24 hours of taking COVISHIELD ChAdOx1 nCoV-19 Corona Virus Vaccine (recombinant). She did not have any symptoms after vaccination during her observation at the medical facility and did not have a history of allergic reactions. She was brought dead to M.S. Ramaiah Hospital, and the autopsy revealed pulmonary edema. Antibodies to COVID-19, inflammatory markers, serum IgE, and coagulation indicators in the postmortem blood sample were high. The cause of death was attributed to a delayed allergic reaction to COVISHIELD vaccine. Newer vaccines can cause fatal allergic reaction, sometimes later than expected, even when cutaneous reactions may not be present.

Keywords: vaccine; COVID-19; adverse reactions; death; case report.

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接种COVID-19疫苗后的死亡：临床病例

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简评

降低传染病的死亡率和发病率需要疫苗。这一点在COVID-19大流行中尤为重要。世界各地已开发出不同类型的疫苗来应对大流行。然而，所有COVID-19疫苗类型都有接种后并发症的报道。其中一种并发症是过敏性休克。过敏性休克通常发生在曾经有过过敏反应的人身上。在印度，接种疫苗的人要在医疗机构接受30分钟的监督，因为在接种疫苗后几分钟到几小时内就会出现不良反应。

本文介绍一名23岁女性的案例。她在接种重组ChAdOx1nCoV-19疫苗（COVISHIELD）24小时后去世了。在医疗机构随访期间，患者没有出现接种后症状。过去也未出现过敏反应。这名妇女被送到M.S.Ramaiah医学院附属医院（M.S.RamaiahMedicalCollege）时已经去世了。尸检显示了肺水肿。尸检血样显示了有COVID-19抗体、炎症标记物、血清IgE和血凝迹象。死因是对COVISHIELD疫苗的迟发型过敏反应。新一代疫苗可能会引起致命的过敏反应，有时比方案规定的时间更晚。即使没有皮肤反应，疫苗也可能引起致命的过敏反应。

关键词： 疫苗；COVID-19；不良反应；死亡；临床案例。

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INTRODUCTION

In India, a total of 42,957,477 people tested positive for coronavirus disease 2019 (COVID-19), and 514,878 succumbed to the pandemic until 4th March 2022 [1]. Effective immunization and achieving herd immunity are vital in controlling the pandemic. Several vaccines against COVID-19 are available in the Indian market. COVISHIELD ChAdOx1 nCoV-19 Corona Virus Vaccine (recombinant) and COVAXIN (whole virion inactivated coronavirus (SARS-CoV-2) vaccine) are widely used by government and private establishments. Adverse reactions to vaccines are commonly reported; however, most are not immunologically mediated. Immunologically mediated reactions include IgE-mediated and T-cell-mediated reactions and other immunologic mechanisms that occur following allergen exposure. These responses, particularly severe anaphylaxis, rarely occur [2].

A total of 1,785,247,566 doses of COVID-19 vaccines were administered until 5th March 2022 . Of these, 966,947,498 were first doses, 798,971,227 were second doses, and 19,328,841 were precaution doses [3].

Adverse events following immunization (AEFI) were recorded after 0.004% of the total 1,230,000,000 COVID-19 jabs till November 30, 2021. Of the 49,819 reported adverse events, 47,691 were minor, 163 were severe, and 1,965 were serious cases (December 8, 2021) [4]. Moreover, 488 deaths were linked to post-vaccination complications between 16th January 2021 to 7th June 2021, according to government data accessed by CNN-News18 [5]. Herein, we report one such death that was associated with the administration of COVISHIELD ChAdOx1 nCoV-19 Corona Virus Vaccine (recombinant).

CASE REPORT

A 23-year-old woman took her first dose of the COVISHIELD vaccine on July 4, 2021. She was the sole occupant of a room in a guest accommodation for ladies in Bangalore City. On the same day, she experienced fever and myalgia. She spent that night at her friend's place and returned to her room the next day at around 6.00 a.m. on July 5, 2021. While she was at her friend's place, no symptoms related to hypersensitivity to the vaccine were noted. She did not have a history of episodes of hypersensitivity to any substance. As she was still febrile, she informed her colleagues that she would not be coming to the office, and she rested in her room. She called her parents living far away in another city at around 9:30 a.m. and told them that she was too tired and was not well. She did not answer the door when her maid came around 10.30 a.m. Her parents had called her friends to check on her, and she did not answer anyone's calls. Later that afternoon at around 3.00 p.m., her friends broke her room's door, and she was found in a gasping state. An ambulance was called for, and she was transported to M. S. Ramaiah Hospital where she was declared brought dead at 5.00 p.m. on July 5, 2021. A medicolegal case was registered, and the body was subjected to autopsy because the cause of death was unknown.

Further information from the police and relatives revealed that the deceased had suffered from mild COVID-19 during the first week of April 2021. A police inquest was conducted, and later, her body was subjected to a forensic autopsy at M.S. Ramaiah Medical College Hospital on July 7, 2021. Before the autopsy, nasal and nasopharyngeal swabs were collected and tested for SARS-CoV-2 using reverse-transcription polymerase chain reaction (RT-PCR) test.

On examination, she was moderately built and nourished. Eyes were closed, and pupils were dilated and fixed. Conjunctival congestion (Figure 1) and marked cyanosis of nail beds (Figure 2) were noted. White fine froth was present over both nostrils (Figure 3). Postmortem staining was noted over the back and fixed. Rigor mortis was appreciated all over. An intramuscular injection mark was present over the outer aspect of her left arm over the deltoid region (Figure 4). The cut section revealed no abnormality. No external injuries on the body were noted.

Lungs were congested and edematous, and the cut section exuded blood mixed with froth. Tracheal dissection showed copious amounts of froth and mucus but no signs of aspiration (Figure 5). The heart was intact and weighed 239 g. The coronary arteries were patent. The liver, kidneys, and spleen were intact and congested. The stomach was empty, congested with mucosa, and grossly hemorrhagic. A faint, fruity smell of alcohol was present. The uterus was normal in size, and its cavity was empty. The scalp and skull were intact. On opening the skull, the meninges were intact and congested. Sulci and gyri were flattened, and the brain was edematous. The cut section of the brain showed numerous petechial hemorrhages in the white matter.

Blood and viscera were sent for chemical analysis to the state forensic science laboratory. The heart, lungs, liver, kidneys, spleen, and brain were subjected to histopathological examination. The blood samples in relevant containers were sent for serum creatine kinase, CK- MB IgE, D-dimer, troponin I, prothrombin time, activated partial thromboplastin time, C-reactive protein, interleukin-6, and COVID-19 antibodies.

Histopathological examination revealed edema and congestion in the brain, lungs (Figure 6), and liver. The kidneys were congested and showed acute tubular necrosis. The heart was unremarkable. RT-PCR for SARS-CoV-2 tested negative. Color tests and gas chromatography methods revealed the presence of ethyl alcohol in the stomach, liver, and blood. It was quantified to 118 mg/100 mL of blood. Blood reports are shown in Table 1.

On perusal of brief facts of the case, autopsy findings, laboratory investigations, and chemical analysis report, the death was attributed to a delayed allergic reaction to a COVID-19 vaccine.

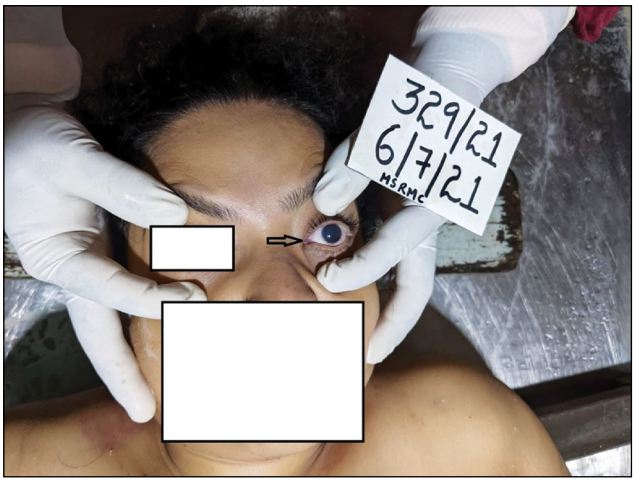

Fig. 1. Conjunctival congestion.

Fig. 2. Cyanosis of nail beds.

Fig. 3. Froth over both nostrils.

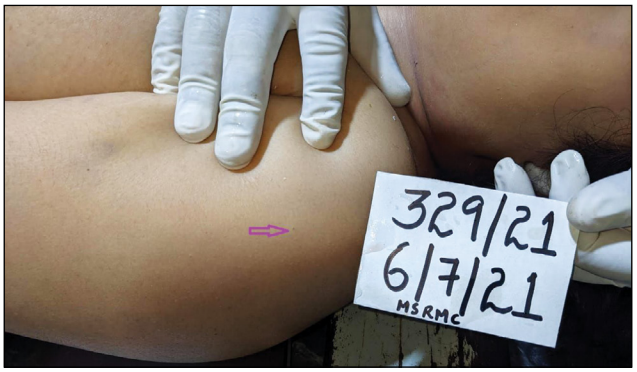

Fig. 4. Intra muscular injection mark present over the outer aspect of left arm.

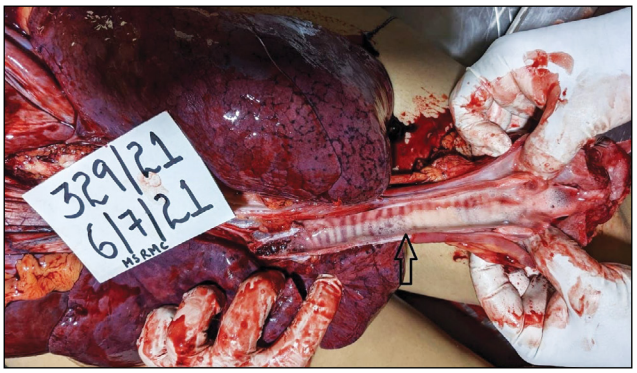

Fig. 5. Froth and mucus in trachea.

Table. Results of Laboratory Investigation 1

Sl No.	Test	Result	Biological reference interval
1	Plasma D-dimer	**3.27**	0.0–0.5 µg/mL FEU
2	IgE	**281.0**	Up to 100 IU/mL
3	Serum CK–total	**> 48000**	34–145 U/L
4	Serum CKMB mass	**> 400**	0.00–2.88 ng/mL
5	Serum troponin I	**> 80.0**	0.0–0.10 ng/mL
6	Prothrombin time	**> 2 min**	11.64–15.64 s
7	aPTT	**> 2 min**	24–34 s
8	COVIPROTECT- anti-SARS-CoV-2 spike	**392.5**	Negative: <50 AU/mL Positive: > 50 AU/mL
9	Serum COVID-19 Ab	**REACTIVE (130)**	

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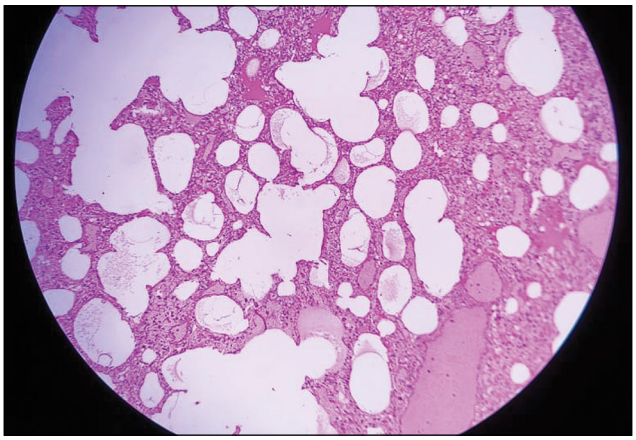

Fig. 6. Pulmonary oedema.

DISCUSSION

In view of the high mortality and infectivity of the SARS-CoV-2, various pharmaceutical have developed different types of vaccines in a short duration. Mild, moderate, and severe allergic reactions can occur immediately or within minutes or several hours later. The signs and symptoms of anaphylaxis stem from the effects of histamine and other substances on the target organs to include dermatologic (urticaria, flushing, and angioedema), respiratory (stridor, cough, wheeze, and shortness of breath), and gastrointestinal (nausea, emesis, abdominal pain, and diarrhea). Systemic vasodilatation and vascular leakage can also lead to hypotension (usually preceded by reflex tachycardia), which can lead to syncope and vascular collapse. Fatalities from anaphylaxis are caused by asphyxiation from the upper airway angioedema or severe bronchospasm or hypotension. These can occur in combination or alone [6].

In India, 235,000,000 doses COVISHIELD vaccine were administered between 16th January 2021 to 7th June 2021 In total, 26,200 cases of AEFI and 488 deaths linked to post-vaccination complications were reported according to government data accessed by CNN-News18. AEFI cases accounted for just approximately 0.01% of the total doses administered [5].

Following Pfizer-BioNTech COVID-19 vaccination in the United States between December 14, 2020, and December 23, 2020, 1,893,360 first vaccine doses were administered, and 21 people had anaphylactic features. No deaths from anaphylaxis were reported after receipt of Pfizer-BioNTech COVID-19 vaccine. Moreover, 17 (81%) of 21 patients with anaphylaxis had a documented history of allergies or allergic reactions, including to drugs or medical products, foods, and insect stings. In addition, 7 (33%) patients had experienced an episode of anaphylaxis in the past, including one after receipt of a rabies vaccine and another after receipt of an influenza A(H1N1) vaccine [7].

In total, 4,041,396 first doses of the Moderna COVID-19 vaccine were administered between December 21, 2020, and January 10, 2021, in the United States. Monitoring by the vaccine adverse event reporting system detected 10 cases of anaphylaxis (2.5 cases per million doses administered). In nine cases, the onset occurred within 15 min of vaccination. No anaphylaxis-related deaths were reported [8].

The most commonly identified risk factors for anaphylactic and nonanaphylactic reactions to SARS-CoV-2 mRNA vaccines were being female and previous history of atopy [2]. Sensitization to polyethylene glycol (PEG) is more common in women because of the relatively frequent exposure to PEG-containing products, such as cutaneous exposure to cosmetics or the use of medications such as contraceptive injections, and explains female predominance in the reported cases of vaccine-associated anaphylactic and nonanaphylactic reactions. Another possible explanation includes hormonal differences such as the role of estrogen, which may be an important factor in allergic immunological responses [9].

Some of the current non-mRNA-based COVID vaccines such as COVISHIELD contain Polysorbate-80. Polysorbates are derived from PEGs but tend to have lower molecular weights (e.g., polysorbate 80 has a molecular weight of 1310 Da) and thus may be much less likely to trigger an allergic reaction. Polysorbates were reported to induce anaphylaxis-like reactions in animal models (typically via an IgE-independent pathway); however, very few cases of clinical reactivity were reported in humans [10]. Polysorbate 80 is a ubiquitously used solubilizing agent that can cause severe nonimmunologic anaphylactoid reactions [11].

In this case, the 23-year-old female patient experienced fever and tiredness a few hours after COVID-19 vaccination; on the next day while alone in her room, she had difficulty breathing and was found gasping by her friends. No immediate allergic symptoms were noted, and she did not have any dermatological lesions. She did not have a prior history of allergy to any substance. To rule out active COVID-19, swabs were taken for RT-PCR for SARS-CoV2; simultaneously, postmortem blood samples were collected and analyzed for troponin I, CK-MB, coagulation indicators, and serum IgE.

The identification of cardiac-specific biomarkers may reflect the severity of COVID-19, and some studies of patients with COVID-19 reported that levels of specific myocardial biomarkers including creatine kinase- total, creatine kinase-MB, Cardiac troponin I were higher in patients treated in an intensive care unit (ICU) than in patients who did not require ICU care [12]. In this case, as the patient tested negative for COVID-19, the high levels of cardiac biomarkers are nonspecific and rule out COVID-19 as the cause of death. Further, antibodies to COVID-19 were detected in the postmortem blood sample. Coagulation indicators (D-dimer and prothrombin time) were also high, including serum IgE levels. High levels of coagulation indicators is a feature seen in a postmortem blood sample and is nonspecific in the present case in determining the cause of death.

Postmortem diagnosis of fatal allergic reactions usually requires suspicion gleaned from the circumstances of the

death because autopsy findings are often inconspicuous and challenging. Tests for specific IgE and mast cell tryptase might help determine whether anaphylaxis is the cause of death [13]. In the present case, the postmortem blood sample only revealed high IgE levels as there was no provision at our center to analyze blood samples for tryptase levels.

After considering the facts of the case, postmortem findings, and high IgE levels, delayed allergic reaction was ascertained as the cause of death. Polysorbate-80 could be the allergen in this case, which is an excipient in COVISHIELD ChAdOx1 nCoV-19 Corona Virus Vaccine (recombinant).

CONCLUSION

Deaths caused by severe allergic reactions to COVID-19 vaccines are rare. The onset may be delayed, and cutaneous reactions may not be present. Various vaccine components that can cause allergic reactions should be identified, and a larger study is necessary to understand their mechanism and further identify susceptible victims beforehand. Vaccine recipients should be advised to report to a medical facility when any untoward incident occurs after vaccination, even if there are no allergic symptoms during the observation period after vaccination.

ADDITIONAL INFORMATION

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Consent for publication. Written consent was obtained from the patient's legal representatives for publication of relevant medical information and all of accompanying images within the manuscript in "Russian Journal of Forensic Medicine".

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