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Case Report

Delayed Fatal Pulmonary Hemorrhage Following Covid-19 Vaccination: Case Report, Batch Analysis, And Proposed Autopsy Checklist

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Abstract

COVID-19 vaccines have been previously associated with pulmonary hemorrhage, typically observed shortly after vaccination. We present a healthy, 47-year-old Caucasian male that died unexpectedly from acute pulmonary hemorrhage 555 days after completing the BNT162b2 (Pfizer) COVID-19 vaccination primary series. Before death, he exhibited symptoms of a mild respiratory infection. Despite a healthy medical history and no medication use, the patient's condition rapidly deteriorated and he experienced severe respiratory distress, followed by cardiopulmonary arrest with evidence of profuse pulmonary bleeding. Autopsy findings revealed massive lung congestion without embolism, normal heart size, and moderate coronary atherosclerosis without myocardial infarction. Despite these findings, the medical examiner determined the cause of death was attributed to atherosclerotic and hypertensive cardiovascular disease, without considering the recent pulmonary hemorrhage and unremarkable medical history. The autopsy failed to investigate potential contributions from the COVID-19 vaccine, such as the presence of the Spike protein, vaccine mRNA, or related antibodies. A batch analysis revealed the BNT162b2 vaccine batch this patient received is among the top 2.8% for number of reported deaths out of all Pfizer COVID-19 vaccine batches and is associated with fatal cardiovascular adverse events including cardiac arrest. The evidence suggests that this man died of a cardiopulmonary arrest most likely as a result of acute pulmonary hemorrhage, with the COVID-19 vaccine potentially playing a role in the development of cardiopulmonary pathology and hemorrhage. We propose autopsy protocols for deceased individuals that have received one or more COVID-19 vaccines to help improve diagnostic accuracy in future cases.

Keywords: ***COVID-19 vaccination; Death; Autopsy; Pulmonary hemorrhage; Case report.***

Introduction

COVID-19 vaccines were developed and approved for emergency use in less than a year after COVID-19 was declared a pandemic [1]. As of February 17th, 2024, over 5 billion people (67% of the world population) has been vaccinated with a complete primary series of a COVID-19 vaccine [2]. Through January 26th, 2024, there have been 1,626,370 adverse event reports, including 214,248 hospitalizations, 37,100 deaths, 21,431 heart attacks, and 9,116 thrombocytopenia cases associated with COVID-19 vaccines in the Vaccine Adverse Events Reporting System (VAERS) [3]. Many other major Western pharmacovigilance databases report record levels of adverse events associated with COVID-19 vaccines, such as Australia's Database of Adverse Event Notifications (DAEN) [4].

Some batches of the BNT162b2 (Pfizer) vaccine have been shown to exhibit abnormally high numbers of suspected adverse events (SAEs), while others are associated with low numbers of SAEs, as demonstrated by multiple studies conducted worldwide [5-7]. One possible explanation for this variability could be differences in manufacturing processes, specifically the transition from 'Process 1' to 'Process 2' for scaling production after clinical trials [8]. 'Process 2' batches, which were shown to have lower mRNA integrity due to changes in the DNA template, purification phase, and lipid nanoparticle manufacturing, may have resulted in increased batch-to-batch variability, potentially impacting the safety profile of certain lots [8]. Pulmonary hemorrhage has been reported as a serious adverse event shortly following COVID-19 vaccination with BNT162b2 (Pfizer) and mRNA-1273 (Moderna) [9-11]. However, pulmonary hemorrhage as a potential long-term complication post-COVID-19 vaccination has not been previously documented. Here, we report an autopsy case of a 47-year-old male that died unexpectedly from pulmonary hemorrhage over one year after primary COVID-19 vaccination with BNT162b2 and perform an investigation into the BNT162b2 batch he received. Moreover, we propose autopsy recommendations for individuals that have received one or more COVID-19 vaccines to better ascertain the cause of death.

Case Presentation

A 47-year-old Caucasian male, weighing 173 pounds, was healthy in adult life, had no chronic illnesses and took no medications. He had a normal physical exam and routine laboratories on September 15th, 2020. This was the last time h/e was examined by a doctor. He

had no suspected or documented episodes of COVID-19 illness. On July 1st, 2021, he completed a COVID-19 vaccination primary series with two doses of BNT162b2. With each COVID-19 vaccine administration, he had an injection site reaction, malaise, weakness, and felt sufficiently ill that he could not work the next day. After recovery from the primary series, his only health encounter was a dental appointment where his blood pressure was found to be 134/87. Four days before his death, on January 3rd, 2023, there was a fire drill at work and the elevators where stopped, so he had to go up 10 flights of stairs after which he remarked to a colleague that he was out of breath. The next day, both the patient and his wife were infected with a mild viral upper respiratory tract infection, and this was nearly resolved on the day of death. He awoke on the day of death with hoarseness. Throughout the day, his symptoms worsened. Around 12:30, the hoarseness became severe, and he could barely talk. The patient appeared to have fallen asleep around 14:50 on the floor and made some unusual snoring and gurgling sounds. His family noticed he was unresponsive and turning blue, so they called 911 for emergency medical assistance. The paramedic records indicate the estimated time of cardiac arrest was 15:00, the dispatch call was at 15:11, and the unit was on scene at 15:22. The paramedics indicated “patient was bleeding profusely out of his mouth.” He received chest compressions and bag/valve ventilation throughout the resuscitation. The paramedics noted multiple times that profuse bleeding clogged up tubes, required suctioning and worked to prevent prompt airway access. The initial cardiac rhythm was ventricular fibrillation for which there were six defibrillation attempts at 360 J. He underwent successful endotracheal intubation on the second attempt at 15:45 and had intravenous lines placed. He received three doses of epinephrine 1:10, amiodarone 300 mg, 150 mg, normal saline 1000 ml, and tranexamic acid 1000 mg was given in an attempt to stop the hemorrhage. The patient remained unresponsive to these measures and was transported to the hospital where he was declared dead at 16:08 on January 7th, 2023, which was 555 days after the last COVID-19 vaccination.

Gross examination revealed evidence of oral expectoration of blood during cardiac arrest and massively congested lungs with blood (**Figure 1**). An autopsy was performed by the County Medical Examiner with the major findings of: 1) dark red, purple lungs with marked amounts of blood and frothy fluid, right lung weight: 1552 g, left lung weight: 1333 g (normal: ~250 g – 300g per lung [12]), no pulmonary embolism, 2) heart weight was normal: 474 g (normal: < 500 g [13]) and myocardial tissue was normal, 3) coronary arteries estimated visually without detailed sectioning: left main normal, left anterior descending 90%, left circumflex 90%, right coronary 60%, stenoses without thrombus or occlusion, 4) moderate atherosclerosis in the aorta and basilar arteries to the neck, 5) there were multiple small faint contusions on the arms and legs. Pertinent negatives: no gastrointestinal or cerebral hemorrhage, no myocardial infarction, toxicology was negative, tests for COVID-19 and upper respiratory pathogens were negative. The medical examiner concluded that the patient died from atherosclerotic and hypertensive cardiovascular disease. However, the patient had no recorded history of hypertension and the pulmonary hemorrhage was not cited as the major cause of death or as a contributing factor by the medical examiner in the report or on the death certificate. There were no tests performed for the detection of COVID-19 vaccine mRNA or its encoded Spike protein.

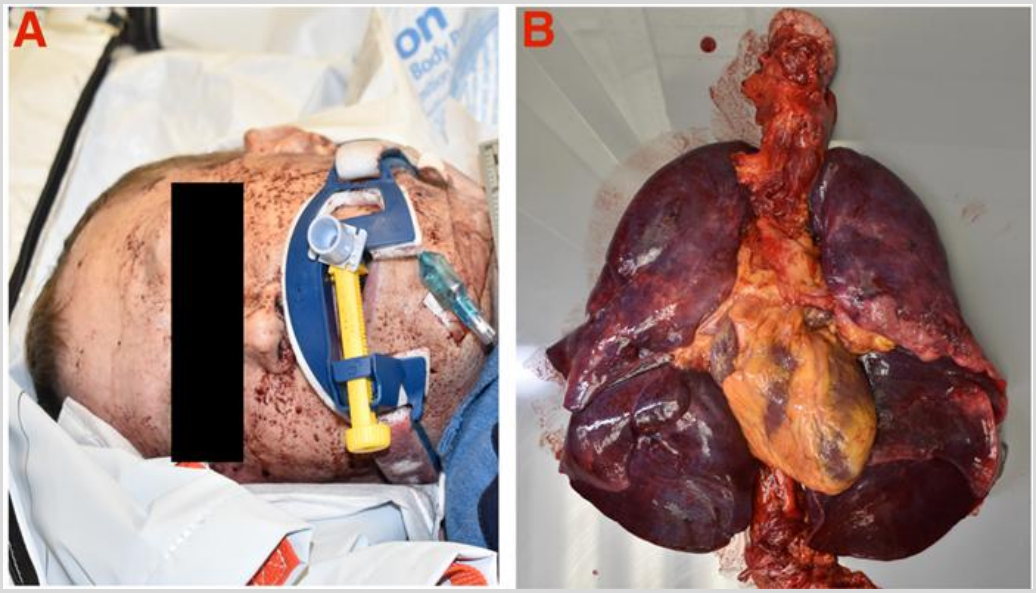

Figure 1: (A) Visible external manifestations from pulmonary hemorrhage: The image illustrates significant oral expectoration of blood, indicative of upper respiratory tract hemorrhage occurring during cardiac arrest. The visual details capture the extent of bleeding from the respiratory tract, emphasizing the severity of the hemorrhagic event that correlates with the patient's symptoms of severe hoarseness and the subsequent discovery during emergency response. (B) Gross pathology of the lungs: This panel shows extensive congestion with widespread infiltration of blood. The weight of the lungs (right lung: 1552 g, left lung: 1333 g), markedly higher than normal ranges (normal: ~250 g [12]), corroborates the diagnosis of massive pulmonary hemorrhage. This finding is critical as it suggests a rapid and significant hemorrhagic process, which likely contributed to the cardiopulmonary arrest.

Discussion

Because the autopsy failed to investigate the presence of COVID-19 vaccine-specific components, we conducted a thorough analysis of the specific COVID-19 vaccine batch administered to this individual using a digital resource known as "How Bad is My Batch?" [14]. This tool aggregates data from VAERS [3], methodically organizing it to present all adverse events associated with specific vaccine batches. This approach allows for a detailed and systematic examination of the batch in question, providing a comprehensive view of any potential adverse effects reported. The patient received two doses of a BNT162b2 mRNA COVID-19 vaccine, which both belonged to the batch EW0175. A review of batch information indicates there were 29 reports of death from his batch through February 2, 2024,

however, this case had not yet been reported to VAERS. Batch EW0175 is among the top 2.8% for number of reported deaths out of all Pfizer COVID-19 vaccine batches listed in VAERS (ranked 131 out of 4,730). Analysis of batch EW0175 indicated the lethality of injection (number of deaths among total EW0175 adverse event reports) was 1.69%. Among reported serious adverse events in this batch, there were 14 respiratory failure, 11 thrombosis, 7 myocarditis, 6 pericarditis, 5 cardiac arrest, 5 myocardial infarction, and 4 pulmonary embolism reports (**Figure 2**).

Without proper post-mortem investigation into specific COVID-19 vaccine components residing in blood and tissues, it is difficult to confidently determine the cause of death in COVID-19 vaccinated subjects that present anomalous symptoms, as in our case. To ensure a comprehensive understanding of the potential impact of COVID-19 vaccines on adverse fatal outcomes, it is critical to conduct specific tests during postmortem procedures [15]. Thus, we propose an autopsy checklist for deceased individuals that have received one or more COVID-19 vaccines to help improve diagnostic accuracy in future cases (**Table 1**). The checklist indicates the vital need to test for the presence of Spike protein and vaccine-derived mRNA within tissue samples. Additionally, a detailed antibody profile should be established, including tests for antibodies against platelet factor 4 (anti-PF-4), the SARS-CoV-2 Spike protein, the nucleocapsid component of the virus, antinuclear antibodies (ANA), and anti-neutrophil cytoplasmic antibodies (ANCA). Alongside these tests, an assessment of inflammation specific to various organs is necessary. These combined diagnostic efforts can reveal how the vaccine may contribute to unexpected fatal events [15,16], especially since most autopsies performed following COVID-19 vaccination don't include them [17]. This checklist is intended to complement existing autopsy pathology standards by incorporating additional tests relevant to suspected vaccine-related cases.

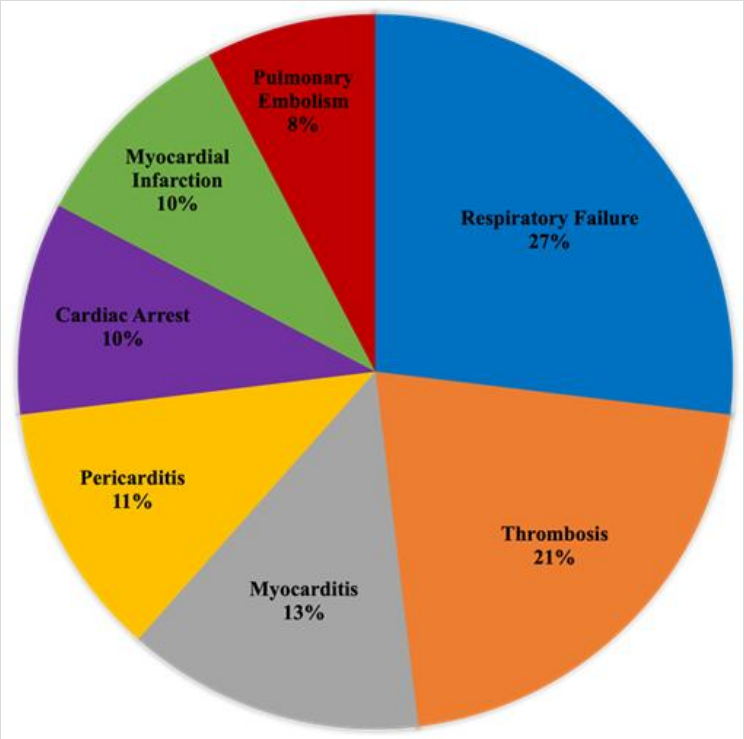

Figure 2: Proportion of common serious adverse events linked to COVID-19 vaccine batch EW0175 as reported in the Vaccine Adverse Events Reporting System (VAERS).

Table 1: Autopsy checklist for evaluating deaths post COVID-19 vaccination.

No.	Task	Yes	No	Comments
1.	Obtain most recent medical history, including any comorbidities, allergies, medication use, and any previous infections (especially COVID-19).			
2.	Obtain COVID-19 vaccination history, including date of administration, vaccine brand/batch, and any experienced symptoms.			
3.	Perform a blood test for hemoglobin and platelets, antibodies to SARS-CoV-2 Spike protein and nucleocapsid, anti-PF-4 antibodies, ANA, and ANCA.			
4.	Perform gross examination and sectioning of the affected organ, noting any visible pathology.			
5.	Perform histopathological staining of affected tissue samples for inflammation ($CD4^+$ and $CD8^+$ T cells) and Spike protein. Then, observe histological imaging for remarkable findings.			
6.	Perform RT-qPCR test of the affected tissue for vaccine mRNA.			

Abbreviations: anti-PF-4: anti-platelet factor 4. ANA: antinuclear antibodies. ANCA: antineutrophil cytoplasmic antibodies. RT-qPCR: reverse transcription-quantitative polymerase chain reaction.

Cause of death is always a matter of expert analysis and cases like this deserve a second opinion. A standard methodology applied to post-mortem investigations is differential diagnosis [18]. Despite having coronary atherosclerosis, this patient's vessels were patent and there was no myocardial infarction. The left ventricle was not hypertrophied nor dilated, so longstanding hypertension or heart failure can be excluded. Primary gastrointestinal and cerebral hemorrhage was excluded. The patient appeared to have died from acute pulmonary hemorrhage a few days after a viral infection. Primary pulmonary hemorrhage can occur in auto-immune

syndromes including Goodpasture's syndrome [19] and Wegener's granulomatosis [20]. The hemorrhage was rapid and quickly made the patient hypoxemic, thus creating a secondary cardiac arrest given extensive coronary disease. The reports of copious blood coming from the patient requiring suctioning and tranexamic acid are distinctly unusual for a primary cardiac arrest. Importantly, the coronary disease does not appear to be the primary cause of death but there is no plaque rupture reported, nor evidence of myocardial infarction. Multiple ecchymoses and a lack of response to tranexamic acid suggests impaired coagulation from a variety of sources including thrombocytopenia. It is reasonable to conclude that primary pulmonary hemorrhage or secondary hemorrhage from acute pulmonary edema in a perfectly healthy man after a viral respiratory illness is quite anomalous. Von Ranke *et al* summarized the range of upper respiratory infections that can result in diffuse alveolar hemorrhage, which include influenza A (H1N1), dengue, leptospirosis, malaria, and Staphylococcus aureus infection [21]. None of these diseases fits the presentation or time course of this patient's mild 3-day viral illness. He had no travel history, fever, or productive cough. His upper respiratory pathogen panel was negative. Ischemic heart disease could have played a role in the downward spiral as the cardiac arrest ensued but could not account for the gross pulmonary hemorrhage which was the fatal event as reviewed by an expert cardiologist (PM).

Primary pulmonary hemorrhage can occur after mRNA COVID-19 vaccination [9-11]. The U.S. Food and Drug Administration Center for Biologics Evaluation and Research (CBER) regulatory window of concern for a novel genetic product, such as the BNT162b2 mRNA COVID-19 vaccine, is 5-15 years [22]. That means unusual serious adverse events such as fatal pulmonary hemorrhage should not only be reported to VAERS, but also be considered as being a consequence of the novel product even months to years after the last injection. The COVID-19 vaccine batch EW0175 that this patient received has been associated with cardiovascular, hematological, and respiratory adverse events and exhibits a high degree of lethality compared to most batches. The Spike protein produced from COVID-19 vaccine mRNA is known to cause bleeding, thrombosis and specific hemorrhagic-thrombotic syndromes including vaccine-induced thrombotic thrombocytopenia (VITT) which has been reported after the Pfizer vaccine [23-25]. The majority of VITT cases arising from vaccine induced anti-platelet factor-4 antibodies reported in the literature are caused by the adenoviral vector vaccines, however, "long VITT" has been reported where findings last for months after vaccine administration [26,27]. It is possible that any mild viral upper respiratory infection in a mRNA COVID-19 vaccinated patient could result in acute hemorrhage. The systemic circulation and extensive persistence (>4 months) of Spike protein from COVID-19 vaccination likely accelerated asymptomatic coronary atherosclerosis, pulmonary capillary disease, and alveolar inflammation as summarized by Parry *et al* [15]. Furthermore, COVID-19 vaccine-modified mRNA has been shown to persist in humans for up to 28 days [28]. The discovery of residual plasmid DNA, including spike-coding sequences and the SV40 promoter/enhancer, in BNT162b2 vaccine lots highlights a potential mechanism for genome integration, potentially enabling prolonged spike protein production in transfected cells [29]. Incorporating our proposed autopsy checklist would significantly improve diagnostic accuracy in this and similar cases reported following COVID-19 vaccination [16,17].

Conclusion

In conclusion, this man died of a cardiopulmonary arrest most likely as a result of acute pulmonary hemorrhage. The coronary artery disease was coincident but was not the primary cause of the cardiac arrest. Because the autopsy ruled out other possible causes of death and the received BNT162b2 vaccine batch is associated with fatal hematological, respiratory, and cardiovascular syndromes including cardiac arrest, prior COVID-19 vaccination is potentially either the direct cause or contributed to the causal pathway leading to death. COVID-19 vaccine-induced Spike protein may have caused acceleration of asymptomatic coronary atherosclerosis via direct vessel injury and inflammation. Our recommendation for a specialized autopsy approach can help improve the diagnosis of COVID-19 vaccine-induced pathologies in future cases. Healthcare providers are encouraged to be aware of and monitor for any long-term cardiopulmonary complications that may arise after COVID-19 vaccination.

List of abbreviations

VAERS: Vaccine Adverse Events Reporting System
SAEs: suspected adverse events
anti-PF-4: Against platelet factor 4
ANA: Antinuclear antibodies
ANCA: Anti-neutrophil cytoplasmic antibodies
CBER: U.S. Food and Drug Administration Center for Biologics Evaluation and Research
VITT: vaccine-induced thrombotic thrombocytopenia
RT-qPCR: reverse transcription-quantitative polymerase chain reaction

Declarations

Author Contributions:

Nicolas Hulscher and Peter A. McCullough: Conceptualization, Investigation, Data curation, Formal analysis, Methodology, Project administration, Visualization, Writing – original draft, Writing – review & editing, Validation.

Funding Statement

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Institutional Review Board statement

Approval by an institutional ethics committee is not required because informed consent was obtained from the next of kin and all data has been anonymized.

Informed consent statement

Written informed consent was obtained from the next of kin for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

Data availability statement

The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author.

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None.

Conflicts of Interest

The authors declare no conflict of interest.

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