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Polyserositis (pericarditis and bilateral pleural effusion) after COVID-19 mRNA vaccine

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Abstract

The coronavirus disease 2019 (COVID-19) pandemic has been responsible for more than 5.5 million deaths worldwide. Vaccination is the most effective method of preventing this type of disease. The efficacy and safety of COVID-19 vaccines authorized in the European Union have been assessed in clinical trials that recruited many participants. As the number of vaccinated people increases, infrequent adverse effects are expected. We would like to report a case of polyserositis (pericarditis, and bilateral pleural effusion) observed a few days after administering the Pfizer BioNTech COVID-19 mRNA vaccine (Comirnaty®) in a 65-year-old man with no cardiovascular, metabolic or autoimmune disorders in his history. The incidence of myocarditis and pericarditis after COVID-19 mRNA vaccines is very low (combined reports from the USA and EU suggest the incidence of 1.02 × 10^{-5} and 7.61 × 10^{-6} respectively). Therefore, it is vital to inform people volunteering for vaccination to be aware of such symptoms as chest pain, breathlessness, or irregular forceful heartbeat. Moreover, the presence of these symptoms should alert healthcare professionals to the potential risk of pericarditis associated with the administration of the COVID-19 vaccine.

Key words: pericarditis, pleural effusion, polyserositis, COVID-19, Comirnaty®, COVID-19 mRNA vaccine

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Introduction

The coronavirus disease 2019 (COVID-19) pandemic, responsible for more than 5.5 million deaths worldwide, has emerged as the most dangerous infectious disease of the 21st century [1]. The most effective method of preventing this type of disease is vaccination. To date, four COVID-19 vaccines have been authorized for use in the European Union (EU) [2]. All of them utilize modern genetic technologies to achieve effective immunization [3–6]. The efficacy and safety of vaccines have been assessed in clinical trials recruiting large numbers of participants [7–10]. The trials confirmed high effectiveness in preventing COVID-19 (66.9% to 95%, depending on the vaccine) and a low incidence of serious adverse events [7–10]. As the number of vaccinated people increases, we can expect cases of infrequent undesirable side effects that occur after vaccination. The report we present describes such an uncommon case of polyserositis (pericarditis and bilateral pleural effusion) observed a few days after administering the Pfizer BioNTech COVID-19 mRNA vaccine (Comirnaty®).

Case description

A 65-year-old man with no cardiovascular, metabolic or autoimmune disorders in his his-

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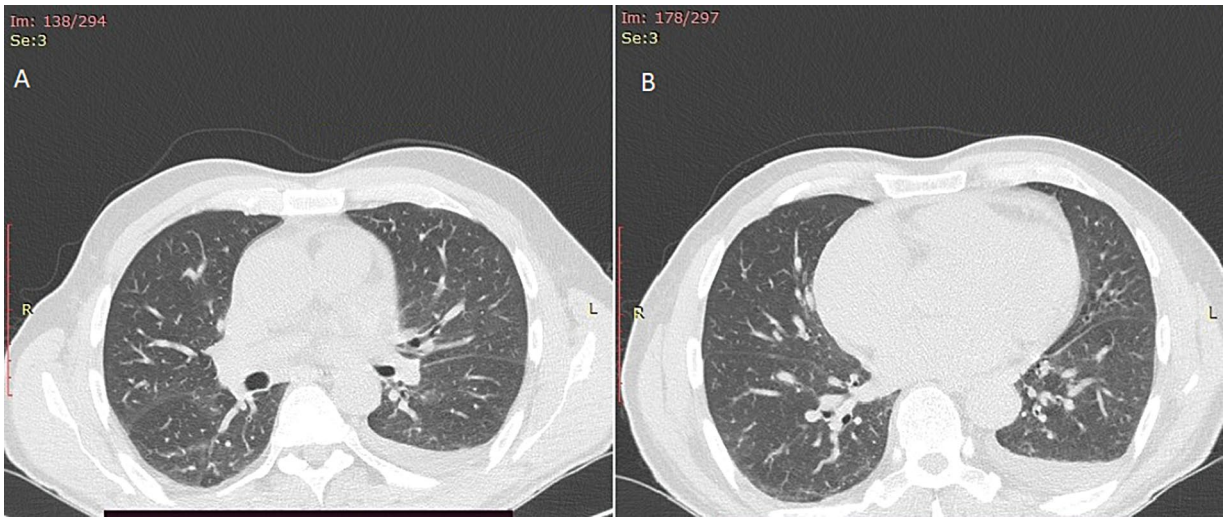

Figure 1. Computed tomography of the chest: **A.** Trace amount of fluid in the pericardium (apex area) and small areas of densities in the left lung, in the dorsal parts, and the vicinity of the fluid; **B.** A small amount of fluid in the left pleura

tory received his first dose of Pfizer BioNTech COVID-19 mRNA vaccine on 28 April 2021. On the sixth day after vaccination, he came to the hospital's emergency room due to a pain in his chest — in the area of the sternum and epigastrium, which intensified with deep breathing and changing body position. Acute coronay syndrome (ACS) was excluded [high-sensitivity troponin T (hs-TnT) = = 5 ng/L; reference range: 0–15 ng/L]. The echocardiography revealed no segmental abnormalities of contractility, left ventricular ejection fraction of 60% and visible distinction between the parietal and visceral layers. The patient was discharged home. On the seventh day after vaccination, he returned to the emergency room due to pain in the chest and epigastrium, with a fever of up to 38.6 degrees Celsius. Additional laboratory examinations revealed interleukin 6 (IL-6) = 165,00 pg/ /mL (reference range: 0.0–7.0) and hs-TnT = 10 ng/ /L. Once again, after excluding ACS, the patient was discharged home. On the nineteenth day after vaccination, a chest X-ray was performed, revealing a straightening of the cardiac waistline and enlargement of the cardiac silhouette. The patient was admitted to the hospital's cardiology ward. COVID-19 antigen test, carried out on admission, was negative. On the twentieth day after vaccination, echocardiography revealed separation of pericardial layer up to 10 mm (honeycomb-like structure), with no signs of compression of the right atrium and right ventricle. There was a small amount of fluid in the left pleural cavity. The contractility of the left ventricular wall was normal. On the same day, a computed tomography (CT) of the chest was performed, which showed no signs of pulmonary embolism, a significant amount of fluid in the pericardial sac with thickness up to 25 mm, atelectasis densities from pressure and fluid in the pleural cavities up to 15 mm on the right side and up to 30 mm on the left side. The standard treatment of pericarditis was started, which included colchicine (0.5 mg daily) and ibuprofen (3 × 400 mg daily). On the 29th day after vaccination, a control echocardiographic examination was performed, revealing a moderate amount of fluid with fibrin in the left pleura, while the pericardium was free of fluid. On the 33rd day after vaccination, a transthoracic ultrasound examination revealed the absence of fluid in the right pleura and the presence of fluid in the left pleura up to 26–30 mm. On the 39th day after vaccination, the patient was admitted to the pulmonology ward.

The transthoracic ultrasound examination revealed the decreased volume of the fluid in the left pleural cavity (up to 7 mm of fluid in the left diaphragmatic-costal recess). During hospitalization, the thoracentesis was abandoned due to the small amount of fluid. CT of the chest (Figure 1) showed free fluid in the left pleural cavity dorsally approximately 10–12 mm. There were small areas of densities in the left lung, especially at the base and in the dorsal parts, in the vicinity of the fluid. There was a suspicion of diffuse small ill-defined areas of ground-glass opacity and thickening of interlobular septa in both lungs, predominantly peripherally. The patient was discharged home

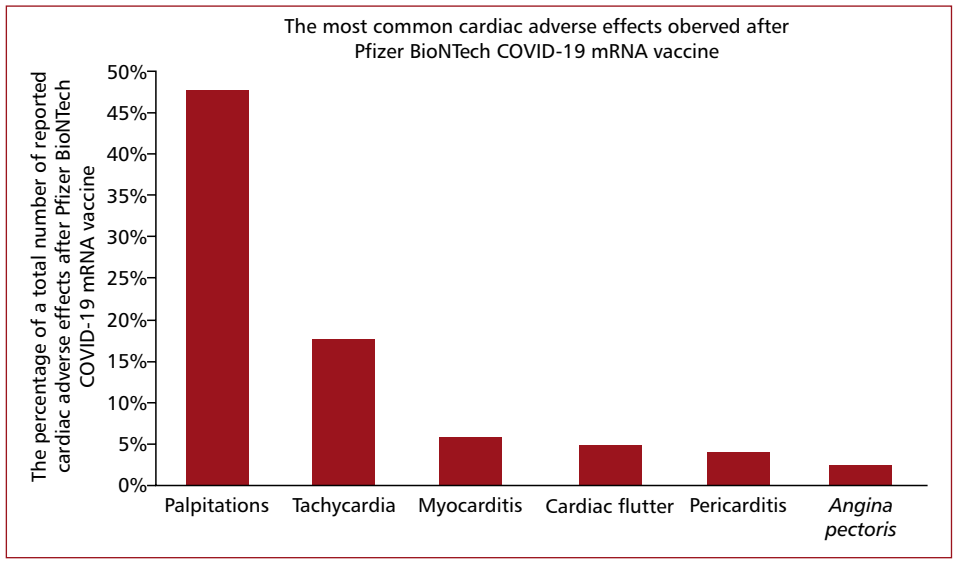

Figure 2. The most common cardiac adverse effects reported by patients receiving Pfizer BioNTech COVID-19 mRNA vaccine. Bars on the chart present the percentage of the total number of reported cardiac adverse effects (calculations based on [28])

with a recommendation to continue treatment with colchicine for up to 3 months. According to the regulations, the information about the adverse event was reported to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in Poland.

Discussion

Acute pericarditis is the most common pericardium disorder observed in clinical practice and the cause of 5% of emergency room admissions for chest pain [11]. The most important symptoms include chest pain, shortness of breath, and heart palpitations [12]. The diagnosis of pericarditis involves the identification of at least two out of the following criteria [12]:

- pericardial chest pain;
- pericardial friction rubs;
- new global ST elevation with PR depression;
- pericardial effusion (up to 60%).

The long-term prognosis of pericarditis is good with rare complications [12].

The patient's epidemiological background plays an essential role in the diagnostic process, as pericarditis can be caused by bacterial, fungal, parasitic or viral infection [12]. According to the CAPACITY-COVID registry, cardiac complications (including pericarditis) may also occur during the COVID-19 course; however, the incidence is low (0.03% for pericarditis) [13]. On the other hand, a growing number of clinical cases report pericarditis during SARS-CoV-2 infection, indicating that the actual incidence may be underdiagnosed [14–19].

Some vaccines (e.g., smallpox, influenza) were also associated with pericarditis [20]. Recent data indicate that mRNA COVID-19 vaccines (Comirnaty® and Spikevax®) may be linked to sporadic cases of myocarditis and pericarditis, usually occurring within several days after receiving the vaccine [21–27]. The analysis of the collection of United Kingdom (UK) spontaneous reports received between 9/12/20 and 19/01/22 for mRNA Pfizer/BioNTech vaccine results in the identification of 449 reported cases of pericarditis (0.28% of all reports) out of a total of 11,498 cardiac adverse effects (Figure 2) [28]. An extensive evaluation of Israeli data identified 21 cases of myocarditis and 27 of pericarditis in a cohort of > 800,000 vaccinated people; myocarditis was found to have the highest risk ratio [29]. The reports from Australia indicated that the incidence of myocarditis and pericarditis after the Pfizer mRNA COVID-19 vaccine might reach 13.5 per million doses [30]. This observation is consistent with the US Centers for Disease Control and Prevention data showing myocarditis/pericarditis rates as 12.6 per million doses in the age group 12–39 years [31].

A search in Vaccine Adverse Event Reporting System (VAERS) database gives 1,580 cases of pericarditis reported by people vaccinated with one of the mRNA COVID-19 vaccines (Table 1) [32]. Considering the number of vaccine doses administered so far (more than 460 million mRNA

Table 1. Pericarditis reported after vaccination with Pfizer BioNTech or Moderna mRNA vaccine in sex and age groups in the United States of America (based on the data from Vaccine Adverse Event Reporting System [32])

Vaccine	Sex	Age	Number of pericarditis cases reported	Percentage [%]
Moderna	Female	18–29 years	58	3.27
	Female	30–39 years	35	1.98
	Female	40–49 years	50	2.82
	Female	50–59 years	48	2.71
	Female	60–64 years	29	1.64
	Female	65–79 years	49	2.77
	Female	80+ years	12	0.68
	Female	Unknown	3	0.17
		Total	284	16.03
	Male	6–17 years	1	0.06
	Male	18–29 years	127	7.17
	Male	30–39 years	57	3.22
	Male	40–49 years	52	2.93
	Male	50–59 years	49	2.77
	Male	60–64 years	22	1.24
	Male	65–79 years	51	2.88
	Male	80+ years	6	0.34
	Male	Unknown	7	0.40
	Male	Total	372	20.99
	Unknown	30–39 years	1	0.06
	Unknown	60–64 years	1	0.06
	Unknown	65–79 years	2	0.11
	Unknown	Unknown	9	0.51
		Total	13	0.73
	Total		669	37.75
Pfizer BioNTech	Female	< 6 months	1	0.06
	Female	6–17 years	20	1.13
	Female	18–29 years	49	2.77
	Female	30–39 years	71	4.01
	Female	40–49 years	77	4.35
	Female	50–59 years	68	3.84
	Female	60–64 years	39	2.20
	Female	65–79 years	52	2.93
	Female	80+ years	9	0.51
	Female	Unknown	18	1.02
		Total	404	22.80
	Male	3–5 years	1	0.06
	Male	6–17 years	136	7.67
	Male	18–29 years	210	11.85
	Male	30–39 years	111	6.26
	Male	40–49 years	57	3.22
	Male	50–59 years	65	3.67
	Male	60–64 years	20	1.13
	Male	65–79 years	63	3.56
	Male	80+ years	12	0.68
	Male	Unknown	16	0.90
		Total	691	39.00
	Unknown	6–17 years	1	0.06
	Unknown	65–79 years	2	0.11
	Unknown	Unknown	5	0.28
		Total	8	0.45
	Total		1,103	62.25
Total			1,772	100.00

vaccines in the US), these data confirm pericarditis as a very rare adverse effect [33]. It is worth noting that pericarditis after receiving the mRNA vaccine is more frequent in younger males. The situation in the EU population is similar (Table 2) [34]. It is consistent with clinical data showing a higher

Table 2. Pericarditis reported after vaccination with Pfizer BioNTech or Moderna mRNA vaccine in sex and age groups in the European Union (based on the data from EudraVigilance [34])

Vaccine	Sex	Age	Number of pericarditis cases reported	Percentage [%]
Moderna	Female	12–17 years	5	0.06
		18–64 years	489	5.72
		65–85 years	86	1.01
		Unknown	31	0.36
		Total	611	7.15
	Male	12–17 years	13	0.15
		18–64 years	713	8.34
		65–85 years	97	1.13
		85+ years	1	0.01
		Unknown	56	0.66
		Total	880	10.29
	Unknown	18–64 years	9	0.11
		65–85 years	2	0.02
		Unknown	2	0.02
		Total	13	0.15
	Total		1,504	17.59
Total			8,548	100.00
Pfizer BioNTech	Female	2 months–2 years	1	0.01
		12–17 years	119	1.39
		18–64 years	2,637	30.85
		65–85 years	249	2.91
		85+ years	28	0,33
		Unknown	190	2.22
		Total	3,224	37.72
	Male	3–11 years	4	0.05
		12–17 years	342	4.00
		18–64 years	2,790	32.64
		65–85 years	299	3.50
		85+ years	27	0.32
		Unknown	223	2.61
		Total	3,685	43.11
	Unknown	12–17 years	3	0.04
		18–64 years	60	0.70
		65–85 years	8	0.09
		85+ years	1	0.01
		Unknown	63	0.74
		Total	135	1.58
	Total		7,044	82.41

risk of pericarditis in men than women [35]. The reason for this difference is unknown; however, it was suggested that the testosterone effect might be involved [12].

The mechanism underlying the development of pericarditis after receiving an mRNA COVID-19 vaccine is currently unknown. The most interesting hypotheses include [36]:

- generation of a very high antibody response in some young people, resulting in symptoms similar to a multisystem inflammatory syndrome in children [observed in the course of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection]; more data on SARS-CoV-2 antibody tests is required to support it;
- induction of cross-reactive antibody-mediated cytokine expression in the myocardium, leading to the inflammation of the myocardium and pericardium;
- induction of a non-specific innate inflammatory response by the mRNA vaccine;
- a molecular mimicry mechanism between spike protein and an unknown cardiac protein;
- bystander or adjuvant effect of the RNA molecule present in the vaccine, leading to cytokine

Table 3. Incidence of pericarditis and myocarditis per dose of Pfizer BioNTech or Moderna mRNA vaccine in the United States of America (USA) and European Union (EU) (calculations based on VAERS, CDC COVID Data Tracker, EudraVigilance and European Centre for Disease Prevention and Control COVID-19 Vaccine Tracker [32–34, 37])

Parameter	USA		EU		Total
	Pfizer	Moderna	Pfizer	Moderna	
Number of myocarditis cases	1,706	876	8,406	2,858	13,846
Number of pericarditis cases	1,103	669	7,044	1,504	10,320
Number of administered doses	316,041,356	204,143,412	658,188,007	177,345,002	1,355,717,777
Myocarditis cases per dose	5.40×10^{-6}	4.29×10^{-6}	1.28×10^{-5}	1.61×10^{-5}	1.02×10^{-5}
Pericarditis cases per dose	3.49×10^{-6}	3.28×10^{-6}	1.07×10^{-5}	8.48×10^{-6}	7.61×10^{-6}

COVID-19 — coronavirus disease 2019

activation of pre-existing autoreactive immune cells.

According to the current reports from the United States of America (USA) and EU, the incidence of myocarditis and pericarditis after COVID-19 mRNA vaccines is very low (Table 3) [32–34, 37]. Nevertheless, the European Medical Agency safety committee has recommended adding these disorders as new side effects in the product information [21]. A recent paper from the Canadian team described solid guidance for health care providers concerning myocarditis and pericarditis after COVID-19 vaccination, including serum troponin measurement, tests for COVID-19 infection, routine additional lab work, a 12-lead electrocardiogram and echocardiography. Moreover, they recommended a deferral of the vaccine's second dose in case of suspected myocarditis/pericarditis after the first dose [38].

Polyserositis is defined as the inflammation with the effusion of different serous membranes simultaneously (most commonly pericardium and pleura) and can be associated with various diseases [39]. A recent paper described a case of polyserositis (a combination of pleural and pericardial effusion) in a 60-year-old woman with COVID-19 infection [40]. There was also a case of polyserositis observed after the 13-valent pneumococcal conjugate vaccine in series with the 23-valent pneumococcal polysaccharide vaccine administered to 75-year-old woman [41]. In our opinion, this term is appropriate for the description of our patient's state, as the CT of the chest has confirmed the fluid's presence in both the pericardium and pleura. Pleural effusion (predominantly small, left-sided and exudative) is frequently associated with idiopathic pericarditis [42]. Browsing the VAERS data, we have found 572 reported cases of pleural effusion in US inhabitants who received an mRNA COVID-19 vaccine. In 40 cases, both pleural effusion and pericarditis were reported; however, no cases of polyserositis were returned by the search indicating that the actual incidence of this adverse effect may be underestimated [32]. Searching the PubMed database, we did not find any case reports of pericarditis with concomitant pleural effusion and one case report of myocarditis with small bilateral pleural effusion [43].

Conclusion

The presented case is an interesting example of polyserositis (pericarditis and bilateral pleural effusion) developed shortly after receiving the mRNA COVID-19 vaccine. The patient's age is noteworthy, as most confirmed cases occurred in male adolescents or young adults. It seems clear that people getting vaccination should be informed about the shallow risk of pericarditis and that in case of such symptoms as chest pain, breathlessness, and irregular forceful heartbeat, they should immediately seek medical attention. Moreover, the presence of these symptoms should alert healthcare professionals to the potential risk of pericarditis associated with the administration of the COVID-19 vaccine.

Conflict of interest

None reported.

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None reported.

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