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Review Article

Life-Threatening COVID-19 Vaccine-Related Side Effects: Are They Noteworthy?

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Abstract

The development of COVID-19 vaccines with high efficacy has given people hope to overcome the pandemic. However, the increasing number of reports of side effects could affect the number of people who are adherent to vaccination. In most cases, pain, fever, and fatigue have been reported, which is the normal side effect of many vaccines. More serious side effects have also been reported, such as Guillain-Barre syndrome, thrombotic thrombocytopenia, anaphylaxis, and death. Although these side effects seem to be lethal, they are rare, and vaccination is the most efficient strategy to overcome this disease.

Keywords: COVID-19; Mortality; Morbidity; Side Effect; SARS-CoV-2; Vaccine

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Introduction

Coronavirus disease 2019 (COVID-19) is a viral disease caused by SARS-CoV-2 and has led to an ongoing pandemic (1, 2). After the pandemic announcement by the World Health Organization (WHO) on January 30th (3), the majority of countries in the world started to implement lockdowns so that they could reduce the spread of the virus (4, 5). It has been demonstrated that this policy could be effective in reducing viral spread (6). However, these strategies could not be used for a long period since the lockdown policy has exhausted people and hurt the economy (7, 8). Although non-pharmaceutical interventions, such

as lockdown, social distancing, enforcing mask usage, and hand sanitization were effective to some extent in controlling the disease progression (9), the most favorable way to decrease mortality and morbidity caused by COVID-19 might be achieved by medical biotechnology (10). Vaccines are the products of medical biotechnology, which have been widely used for many purposes and have shown a promising effect against epidemic diseases (11). Since the beginning of the pandemic, researchers have started to develop different vaccines with different technologies, including inactivated vaccines, new mRNA vaccines, and non-replicating viral vectors (12). Among these vaccines, 50 vaccines have got emergency use permission from WHO up to the end of 2022, including Pfizer/BioNTech and Moderna, which are mRNA vaccines, Janssen, Oxford/AstraZeneca, and Covishield that are non-replicating viral vectors, and Sinovac and Sinopharm made up of inactivated virus. However, only three vaccines, including Pfizer-BioNTech, Moderna, and Novavax, have received emergency authorization from U.S. Food and Drug Administration (FDA) (13).

Studies have shown that mRNA vaccines, such as Pfizer/BioNTech and Moderna, have demonstrated efficacy rates exceeding 90% in preventing COVID-19, particularly in severe cases (14). Although scientists estimate that at least 70% of the population needs to be vaccinated to achieve herd immunity against COVID-19, it is still in a state of ambiguity (15). In addition, emerging variants of the virus have raised concerns about vaccine effectiveness, necessitating ongoing research into booster doses and vaccine modifications to enhance immunity against these variants (16). During the vaccination, some reports of side effects were determined and reported by the health authorities. In most cases, pain, fever, and fatigue have been reported, which is the normal side effect of many vaccines. However, these signs usually disappear after 24 hours (17). Iatrogenic side effects like shoulder injury related to vaccine administration (SIRVA), as the result of needle deep penetration, are an injection site adverse reaction (18). More serious side effects, such as myocarditis and pericarditis, have been reported primarily in young males following mRNA vaccination, though these cases are rare and typically mild (19). Additionally, thrombosis with thrombocytopenia syndrome (TTS) has been associated with adenovirus-based vaccines like Oxford/AstraZeneca and Janssen, with a higher incidence observed in younger women (20). Guillain-Barré syndrome (GBS) has also been reported as a rare side effect of mRNA vaccines, though the causal relationship remains under investigation (21). The increasing concern and misinformation about the vaccine's side effects could decrease the number of people adherent to vaccination. For instance, the development of autism spectrum disorder (ASD) after vaccination is a kind of hesitancy (22-24). A thorough examination of multiple studies can provide comfort to individuals who harbor concerns about receiving the COVID-19 vaccine injection. So, this study aims to review the serious side effects of available vaccines against COVID-19, incorporating the latest evidence to provide a balanced perspective on their safety and efficacy.

Hematologic and cardiovascular side effects

Cardiovascular involvements

Cardiomyopathies, myocarditis, and pericarditis have been reported mostly in young adults (25, 26). It has been demonstrated that 4.8 instances per 1 million of myocarditis were linked to COVID-19 mRNA vaccinations, according to the CDC report (27). According to studies, there were 20 occurrences of vaccine-related myocarditis among the 2,000,287 people (76.5% of whom received more than one dosage) who received the Pfizer-BioNTech (52.6% of all), Moderna (44.1% of all), and Janssen-Johnson & Johnson (3.1% of all) vaccines (26). Recent data from 2023 indicate that the risk of myocarditis remains higher in adolescents and young adults, particularly males aged 12–29 years, following mRNA vaccination, though the overall risk remains low (28). Numerous negative consequences have been recorded as a result of the widespread use of the four vaccinations, notably ChAdOx1 and Ad26.COV2.S, BNT162b2, and mRNA-1273.2. Cardiovascular complications, including myocarditis, immune thrombocytopenia (ITP), and cerebral sinus venous thrombosis (CVST), are among the most severe. All of these unfavorable incidents jeopardize

the health of vaccine recipients and have an impact on how vaccines are administered (29). Myocarditis cases following mRNA vaccines are typically mild, with most patients recovering fully with conservative treatment (30). However, emerging evidence suggests that the risk of myocarditis may be slightly higher with the Moderna vaccine compared to Pfizer-BioNTech, particularly in younger age groups (31). After receiving the second dosage of the mRNA-based COVID-19 vaccine, two fully healthy people (Pfizer-BioNTech and Moderna) displayed signs of myocarditis, including increased pressure and chest discomfort, respiratory distress, and elevated cardiac and inflammatory indicators (32). studies have emphasized the importance of early recognition and management of post-vaccination myocarditis, as delayed diagnosis can lead to complications such as arrhythmias or heart failure (33). Vascular involvements, from vessels to capillaries, are another aspect of this group's side effects. Capillary leak syndrome (CLS) is a rare but life-threatening adverse effect of the Oxford-Astrazenka COVID-19 Vaccine (34).

Case reports have highlighted the need for vigilance in diagnosing CLS, as it can mimic other conditions, such as sepsis or anaphylaxis (35). In addition, some studies have reported the association between ANCA-associated vasculitis (AAV) and COVID-19 infection and its vaccination (36-39). A 2023 systematic review identified 47 cases of AAV following COVID-19 vaccination, with most cases occurring after mRNA vaccines (40). The pathogenesis is thought to involve molecular mimicry or immune dysregulation triggered by the vaccine. While the majority of cases responded well to immunosuppressive therapy, early diagnosis, and treatment are critical to prevent long-term organ damage (40). Thrombotic complications, such as thrombosis with thrombocytopenia syndrome (TTS), have been predominantly linked to adenovirus-based vaccines like Oxford-AstraZeneca and Janssen. A 2023 meta-analysis reported an incidence of 8.1 cases of TTS per million doses of adenovirus vaccines, with a higher risk observed in women under 60 years of age (41). Emerging evidence suggests that the risk of TTS may be lower with second-generation adenovirus vaccines, which are currently under development (42).

Thrombosis and Thrombocytopenia

There have been several case reports of uncommon adverse reactions, including thrombotic thrombocytopenia occurring after receiving an adenovirus vector vaccination (43). Due to thrombocytopenia and vascular adverse effects, some countries banned vaccine usage (44). To infer that vaccination causes a specific condition, reliable and verified evidence is required. One such autoimmune disease, vaccine-induced thrombosis, and thrombocytopenia, often known as 'thrombosis thrombocytopenia syndrome (TTS),' now has convincing evidence. It is estimated that between 1 in 100,000 and 1 in 1,000,000, previously healthy people developed this syndrome 1–3 weeks after initial vaccination with either the ChAdOx1 nCov-19 AstraZeneca (AZ) adenoviral vector vaccine or the Ad26.COV2.S Johnson & Johnson (JJ) adenoviral vector vaccine. This syndrome is characterized by thrombosis (often involving the cerebral cortical or splanchnic venous systems), thrombocytopenia (often severe), systemic activation of coagulation (elevated concentrations of D-dimer and reduced concentrations of fibrinogen), and the presence of antibodies of platelet factor IV (PF4) (45). The unique and unusual clinical and serological characteristics of this disease, along with preliminary findings implicating the virus in antigen production, provide credence to the idea that vaccination and the autoimmune response are linked (46). When it develops after vaccination, Immune thrombocytopenic purpura (ITP), also known as idiopathic thrombocytopenic purpura or immune thrombocytopenia, is an exclusion diagnosis with no distinguishing symptoms. There is no particular test that verifies the diagnosis. Thus, physicians depend on the lack of differentiating characteristics of other diseases to make the diagnosis. One in every seven patients who were first diagnosed with ITP was eventually given a different diagnosis. A robust response to ITP-directed treatments is possibly the most accurate inclusive 'diagnostic' test (47, 48). Another issue is distinguishing de novo ITP from aggravation of undetected, pre-existing ITP, which necessitates knowledge of pre-vaccination platelet counts, which are seldom accessible for people who do not require regular medical treatment. Platelet counts can be as low as 30,000 to 50,000 platelets per microliter

while still staying asymptomatic, and transitory decreases following illness and immunization are frequent (49-51). Thrombotic thrombocytopenic purpura (TPT) was common in children who received a live attenuated (weakened) measles vaccination. The highest drop in platelet counts neared 100,000 platelets per microliter on average. In the context of Mumps–Measles-Rubella (MMR) vaccination, alive, albeit attenuated, a virus is responsible for the development of ITP. To ascribe the current study's findings to cases of de novo ITP, one would have to assume that both mRNA-based vaccinations against SARS-CoV-2 and their viral protein payloads changed a host protein or caused significant immunological disruption (52). Even exposing 30,000–70,000 recipients to these two vaccinations as part of the preliminary studies was inadequate to detect an ITP risk. This highlights the need for ongoing surveillance, as evidenced by the current study, which estimates 1.13 extra cases per 100,000 initial doses of ChAdOx1 (44). There is no convincing evidence of a link between ITP and the initial dosage of the ChAdOx1 vaccines. The various obstacles involved with ITP and the limited number of incident ITP episodes recorded make estimating the 'actual effect' difficult (44).

Despite these risks, the benefits of COVID-19 vaccination far outweigh the potential adverse effects, particularly given the high morbidity and mortality rates associated with the disease itself (53).

Thrombosis with thrombocytopenia Syndrome (TTS)

The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) recommended a stop in the administration of the Johnson & Johnson vaccine on April 13 (42). In the latest update, the U.S. FDA has restricted the Janssen COVID-19 Vaccine's authorized use to people over the age of 18 for whom other COVID-19 vaccines are not available or clinically appropriate, as well as to people over the age of 18 who choose to receive the Janssen COVID-19 Vaccine because they would not otherwise receive a COVID-19 vaccine (54). This was in response to reports of comparable occurrences in people who received the Oxford–AstraZeneca vaccination outside of the United States. Following the Moderna mRNA vaccination, a single instance of what looks to be the same condition has recently been described; nevertheless, the risk appears to be much smaller for the two mRNA vaccines (55). The danger of death from COVID-19 illness was considered to outweigh the relatively low risk of TTS by a large margin. According to the CDC assessment, the revised incidence for the JJ vaccination was two per million, based on a total of 15 cases recorded after 7.98 million doses were delivered. According to the most recent data from the United Kingdom, the AstraZeneca vaccine has a 20.3 per million dosage incidence in people aged 18 to 49 (56). The dangers of COVID-19 illness greatly exceed the possibility of extremely uncommon side effects like TTS associated with the highly effective SARS-CoV-2 vaccinations. So far, there is no evidence of an elevated risk of TTS in patients with blood disorders and pre-existing thrombosis or autoimmune risk factors. The single-dose JJ vaccination may be especially appealing for use in patients before the start of chemotherapy or other immunosuppressive treatments.

Following the AZ vaccination, a condition characterized by venous or arterial thrombosis, particularly at atypical locations, was initially observed. The vaccination is widely used in the United Kingdom, Europe, and Canada (57). The biggest and most current dataset, consisting of 220 definite and 50 probable cases from the United Kingdom, revealed a median age of 48 with no gender skew. Severe thrombocytopenia and cerebral bleeding were related to the greatest death rate. Many of the patients were extremely ill when they were identified, and up to one-third of those first reported perished (41). TTS has been documented in individuals who received the AZ vaccination and the JJ vaccine. Both vaccines use recombinant adenoviral vectors expressing the SARS-CoV-2 spike protein immunogen (chimp for AZ and human for JJ). In June 2021, a report detailing a full-blown TTS condition in a single patient who received the Moderna mRNA vaccination was released (56, 58). Patients with thrombocytopenia (TTS) display clinical and laboratory characteristics comparable to rare occurrences of Heparin-Induced Thrombocytopenia (HIT) -like autoimmune thrombosis in the absence of heparin. Researchers discovered that circulating

PF4-reactive antibodies are capable of activating platelets without the need for heparan. In vitro, intravenous immunoglobulin (IVIG) or monoclonal antibodies targeting the Fc receptor might prevent these antibodies from activating platelets. These antibodies are comparable to those previously identified in individuals not receiving heparins after surgery, certain medicines, or infections (59, 60). Emerging evidence suggests that second-generation adenovirus vaccines, currently under development, may have a reduced risk of TTS, offering a safer alternative for populations at higher risk (61). Ongoing surveillance and research are critical to better understand the pathophysiology, risk factors, and optimal management of TTS, as well as to improve vaccine safety profiles (62).

Hemorrhagic and Other Thromboembolic events

Hemorrhagic and thromboembolic events are associated with the first dose of the Oxford-Astrazenka COVID-19 Vaccine. According to a Scottish national population-based analysis, among individuals who received their first doses of COVID-19 vaccines, the occurrence of ITP was reported at a rate of 1.13 per 100,000 vaccinations for those who received the Oxford-Astrazenka vaccine. Within 30 days of receiving their first dose of Vaxzevria, individuals under the age of 65 had a greater likelihood of experiencing blood thrombotic episodes, according to a study involving a large population in England. Nonetheless, this increased risk was not observed with the BNT162b2 mRNA vaccine (47). A Denmark retrospective cohort study found no statistically significant differences in the risk of thromboembolic events between those who received the BNT162b2 vaccine and those who did not. (63). In relation to the Pfizer-BioNTech COVID-19 mRNA vaccine (BNT162b2), instances of blood clotting or hemorrhage in the brain or leg were reported. (64, 65). Other Serious thromboembolic events, such as Myocardial Infarction (MI) (66, 67), pulmonary thromboembolism (PTE) (68, 69), and Deep Vein Thrombosis (DVT) (65, 70) Have also been reported after COVID-19 vaccines. Notably, a meta-analysis estimated the overall incidence of thromboembolic events following vaccination to be approximately 0.8 per 100,000 doses, with adenovirus vector-based vaccines showing a slightly higher risk compared to mRNA vaccines (71). This finding underscores the importance of balancing risks and benefits when considering vaccination, especially in high-risk populations. Furthermore, vaccine-induced immune thrombotic thrombocytopenia (VITT), primarily linked to adenovirus vector-based vaccines like Oxford-AstraZeneca and Janssen, represents another critical concern. VITT is characterized by thrombosis with concomitant thrombocytopenia and occurs at an estimated rate of 1 in 100,000 recipients (72). Early recognition and appropriate management of VITT are essential to mitigate its severity and improve outcomes. Despite these reports, the absolute risk of thromboembolic events following vaccination remains exceedingly low compared to the substantial risk posed by severe COVID-19 infection itself.

Neurologic side effects

Guillain-Barré syndrome (GBS)

Infections and vaccinations have been proposed to play a role in the development of GBS. Vaccine safety beliefs can have a significant influence on limiting vaccination coverage (73, 74). GBS can be caused by a variety of factors, including infections, and is more common in men and those over the age of 50. Cases may develop as a result of immunization (75). The FDA has announced changes to the Johnson & Johnson (Janssen) COVID-19 vaccine recipient and immunization provider information sheets. Following immunization, there has been an increase in the risk of GBS (76). On July 9th, the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) published a statement proposing the inclusion of a warning to enhance awareness of GBS following vaccination. By June 27, 2021, the EU/EEA had reported 227 instances of Vaxzevria to the EMA, and about 51.4 million doses have been administered to patients in Europe (77). In Canada, there have been 25 occurrences of GBS following the COVID-19 vaccination, with 25 cases occurring among those who got COVISHIELD/AstraZeneca vaccinations (0.91 reports per 100,000 doses administered). According to current Canadian statistics from the Public Health Agency of Canada, there have been 48 instances of GBS as a result of the vaccine (78). Consequently, the Europe-

an Medicines Agency (EMA) classified GBS as a very rare adverse effect of the COVID-19 Vaccine Janssen and mandated the inclusion of a warning in product materials to inform healthcare professionals and patients (79). Further studies support these observations. For instance, a large-scale cohort study conducted in the United Kingdom identified an incidence rate of 1.4 cases of GBS per million doses of the Oxford-AstraZeneca vaccine, reinforcing its association with this neurologic condition (80). In contrast, mRNA-based vaccines such as Pfizer-BioNTech (BNT162b2) and Moderna (mRNA-1273) have shown no significant increase in GBS risk compared to background rates (81). Despite these findings, it is crucial to note that the absolute risk of GBS following vaccination remains exceedingly low compared to the risks posed by severe COVID-19 infection itself. Ongoing surveillance and research are essential to better understand the mechanisms underlying this rare adverse event and ensure the continued safety of global vaccination efforts.

Bell's palsy

Bell's palsy, a kind of acute facial nerve paralysis, has been mentioned as an adverse event in the package information for some vaccines (82-84). Bell's palsy, a type of sudden facial nerve paralysis, is mentioned as an unwanted occurrence listed in the product details of vaccines created using innovative mRNA technology. Although, to date, there hasn't been definitive evidence linking COVID-19 vaccination and facial paralysis, some studies have suggested a possible link, where decreased IgG positivity and reactivation of dormant virus being the proposed mechanisms.

The research conducted by Eric Wan and his colleagues and published in The Lancet Infectious Diseases revealed a generally higher likelihood of experiencing Bell's palsy after receiving CoronaVac (Sinovac Biotech), a vaccine employing an inactivated virus (85, 86). An increased incidence of Bell's palsy has been discovered following immunization with the Sinovac-CoronaVac COVID-19 vaccine, an inactivated viral vaccine. However, no strong proof of a link between COVID-19 immunization and facial paralysis has been found till now. However, research found an overall higher risk when compared to other vaccines (87, 88). Regulatory agencies have claimed that the reported frequency in vaccinated people was no greater than the predicted background rate, notwithstanding the numerical imbalance of Bell's palsy cases seen in trials of the two mRNA vaccines but not in those of other vaccine platforms. A deeper examination of these numbers, as well as an examination of raw real-world data from pharmacovigilance agencies, revealed that Bell's palsy occurred more often in the mRNA vaccination groups than would be anticipated in the general population (89-92). Researchers discovered that COVID-19 vaccinations did not enhance the risk of facial paralysis when compared to other viral vaccines. Patients who were vaccinated against the virus, on the other hand, had a higher chance of developing Bell's palsy, according to the researchers (93, 94).

A small case-control study from Israel revealed no link between SARS-CoV-2 vaccination and Bell's palsy. Notably, hospital admissions for facial nerve palsy were 29–112 percent higher in January and February 2020 and 2021 than in the preceding five years, although this was not judged significant (95). In Hong Kong, vaccinations for Bell's palsy and mRNA (BNT162b2; Fosun–BioNTech) and inactivated virus (CoronaVac) were tested. The authors discovered a significant rise in the age-standardized incidence of Bell's palsy during the immunization campaign using a volunteer surveillance reporting system and electronic health data. After controlling for confounding factors, the incidence difference with the same observation period in 2020 was 41.5 instances per 100,000 person-years for CoronaVac and 17.0 for BNT161b2 (87, 96). The nested case-control research included 298 individuals with clinically diagnosed Bell's palsy. One thousand one hundred eighty-one controls were randomly matched (4:1) to each case based on gender, age, date of hospitalization, and seasonality of the illness. CoronaVac and BNT162b2 were linked to a substantially higher risk of Bell's palsy, according to the findings. Because of the timing of vaccine distribution in Hong Kong, immunization was significantly lower in this population than in the Israeli research. Vaccines for Bell's palsy may have varied safety profiles in various age groups, and data obtained in Hong Kong during the early stages of immunization may have created selection bias. The prevalence of Bell's palsy varies considerably

with age, and the vaccination is likely to range from person to person (87, 97).

Aseptic meningitis

Aseptic meningitis is a rare but serious neurological complication following COVID-19 vaccination. Most patients with aseptic meningitis had received the Pfizer COVID-19 vaccine (BNT162b2). Symptoms, which included headache, fever, nausea, and neck stiffness, often appeared within a week of vaccination. The most common clinical symptom among patients was headache, and it has been suggested that patients with persistent or delayed headaches after COVID-19 vaccination should be evaluated for aseptic meningitis (98, 99). Saito and colleagues describe the first instance of aseptic meningitis following the first dose of the BNT162b2 mRNA COVID-19 vaccine administered intramuscularly. The 42-year-old woman had a history of migraine and was hospitalized one week after vaccination for severe headache and high fever (100). In other cases, female patients were hospitalized with similar symptoms but no significant medical history (101, 102). The majority of cases were women with a mean age of 20–45 years (98). Chan et al. studied two women with meningitis, the first with symptoms appearing 4 days after the second dose and the second 10 days after the first dose of BNT-162b2. Both patients had negative SARS-CoV-2 PCR tests on nasopharyngeal swabs during their admissions. Both women were treated with nonsteroidal anti-inflammatory drugs (NSAIDs) (101). Methylprednisolone, another drug used to control meningitis, has been used in some studies (100, 102, 103). Zavari et al. used this drug to treat a 26-year-old Iranian woman. The patient's initial symptoms (low-grade fever and headache) were observed only a few hours after the first dose of the AZD1222 vaccine. However, the patient's symptoms were very mild after the second dose and resolved spontaneously (103). In addition to women, aseptic meningitis is also considered a side effect of the COVID-19 vaccine in men (104, 105).

Encephalitis

Encephalitis, an inflammation of the brain, is a rare but serious condition that can arise from various causes, including infections and autoimmune responses. Significant neurological complications have been reported following the administration of mRNA COVID-19 vaccines and in COVID-19-infected individuals. Despite this, there are few published accounts of encephalitis and acute disseminated encephalomyelitis linked to mRNA vaccinations. (106-108). Several publicly available databases show the incidence of post-vaccination encephalitis with ChAdOx1 nCoV-19 (AZD1222) (108). A case of acute disseminated encephalomyelitis (ADEM), a type of encephalitis, was observed in a 45-year-old man who received the ChAdOx1 nCoV-19 vaccine. The patient developed numbness in his hands approximately twelve days after receiving his first dose. Magnetic resonance imaging (MRI) showed large, poorly marginated T2-weighted hyperintensities in multiple parts of the brain and spinal cord. Treatment included high-dose intravenous methylprednisolone followed by oral prednisone, which resulted in significant improvement (109). In another study, a 56-year-old woman was evaluated with symptoms of generalized weakness centered in the lower extremities. These symptoms appeared 10 days after receiving the AstraZeneca vaccine, and her MRI showed multifocal white matter lesions characteristic of ADEM. The disease was controlled with pulse-dose steroids (110). The incidence of encephalitis was approximately equal in men and women, and in most studies, MRI played an important role in detecting abnormal brain signals associated with encephalitis. This was despite their COVID-19 PCR being negative in most cases (111-113).

Stroke

Recently, instances of coagulopathy have been linked to COVID-19 vaccination, namely the ChAdOx1 nCoV-19 vaccine. These have been characterized by thrombocytopenia, similar to that found in HIT, but without heparin and with antibodies to platelet factor 4. In one study of 23 individuals, 13 had cerebral venous thrombosis, and 5 had pulmonary emboli (59). Three instances of ischemic stroke in individuals who got the COVID-19 vaccine have been recorded (114). The illness was linked to major artery blockage, including carotid and middle cerebral arteries, and venous thrombosis affecting the portal and cerebral venous systems in all three patients.

This research emphasizes that immune-mediated coagulopathy can induce arterial thrombosis, including ischemic stroke, while venous thrombosis and, in particular, Cerebral venous sinus thrombosis (CVST) appear to be more common (115). During the present COVID-19 vaccination period, a high index of suspicion is necessary to detect thrombotic events following vaccination. However, it is crucial to recall that these adverse effects are uncommon and far less prevalent than both cerebral venous thrombosis and ischemic stroke associated with COVID-19 infection, as demonstrated by a recent large epidemiological research (116, 117).

Myelitis

The integrity of the blood-brain barrier was compromised in both COVID-19-infected and COVID-19-vaccinated individuals (118). Case reports of myelitis following COVID-19 vaccination, on the other hand, have been infrequent, and have mostly occurred following vaccination with the AstraZeneca/Oxford ChAdOx1 nCoV-19 vaccine, an adenovirus vector vaccine (21, 119). As of March 2, 2021, there were 9 instances of transverse myelitis in the Centers for Disease Control (CDC) Vaccine Adverse Event Reporting System (VAERS) database, according to Goss et al. (120). In 2024, a study was conducted in 159 patients with acute transient myelitis (ATM) who had received the first or second dose of the COVID-19 vaccine. The majority of participants were men with a mean age of 30–74 years. The highest incidence of ATM was seen after the first and second doses of the BNT162b2 vaccine, with symptoms occurring in most individuals 1–42 days after vaccination. Although the incidence of ATM still appears to be rare, this study showed that the incidence of ATM increased after COVID-19 vaccination (121).

Gastrointestinal side effects

Appendicitis

Instances of appendicitis have been documented following the administration of COVID-19 vaccines (122, 123). According to a study of mRNA vaccines safety surveillance from 6.2 million persons who received 11.8 million doses of an mRNA vaccine, incidence of events per 1 000 000 person-years for appendicitis 21 days for individuals after vaccine first or second dose was 1179 and 1345, respectively (124). Acute appendicitis (AA) is the most common cause of acute abdominal surgery worldwide, with an annual incidence of 1 per 10,000 and a lifetime risk of 7-8%. While obstruction due to follicular hyperplasia or fecaliths is the primary cause, rare cases are linked to parasitic infections (e.g., amebiasis, ascariasis) or tumors (125-127). Identified three AA cases following Pfizer-BioNTech vaccine, with a mean patient age of 48.6 ± 21.45 years and a slight female predominance. Two patients required laparoscopic appendectomy due to perforation, while one was treated outpatient with antibiotics and steroids (128-130). Other studies suggest a higher AA risk with Pfizer-BioNTech than Moderna, with symptoms appearing within 21 days post-vaccination (131, 132). Unlike classical AA, vaccine-induced AA shares similar clinical features but may involve unique mechanisms. SARS-CoV-2 vaccines enhance Th1 immune responses, producing cytokines like interferon-gamma and tumor necrosis factor-alpha, which are linked to autoimmune inflammation (123, 133). Despite these differences, outcomes for vaccine-induced AA remain favorable, with no reported deaths and full recovery in all cases (134).

Acute liver injury

Only 0.6 percent of participants in the Pfizer/BioNTech BNT162b2 mRNA study had liver damage. There were 214 individuals with mild liver disease and just three with moderate to severe liver disease. This patient suffers from fatty liver disease. It is unknown whether this was a potential risk factor for hepatotoxicity in this case (135, 136). In another study Two weeks after receiving the Moderna mRNA-1273 vaccine, a woman had a petechial rash, thrombocytopenia, and significant elevations in her liver function tests. The unexpected test data could not be explained by any new medicines or her oral contraceptive. In general, the pathophysiology of ITP is not well known, particularly in the context of the recent COVID-19 vaccination (137).

Pancreatitis

Vaccine-induced pancreatitis is a rare adverse response to certain viral vaccinations, including MMR, Hepatitis A and B, and Human papillo-

mavirus (45, 138). Bizjak et al. (139) found key variables that point to a probable connection between COVID-19 immunization and pancreatitis. Pfizer statistics show one incidence of pancreatitis and one case of obstructive pancreatitis were detected during the Phase 2/3 clinical trial of the COVID-19 mRNA vaccine (140). According to a medical report, a 71-year-old woman presented herself at the hospital complaining of gastrointestinal pain. The report indicates that there was no previous record of gastrointestinal illness in the individual. However, following the administration of the first dose of the Pfizer/BioNTech COVID-19 mRNA vaccine, there was an observed elevation in serum pancreatic enzymes (141). 9 cases of acute pancreatitis (AP) were studied, most of which were associated with the Pfizer-BioNTech vaccine. Symptoms appeared on average 13.97 ± 28.82 days post-vaccination, with no surgical interventions required—all patients received medical treatment and recovered without fatalities. A unique case involved a pregnant woman at 31 weeks gestation who developed AP after the Pfizer-BioNTech vaccine, leading to spontaneous delivery (142).

Gynecological side effects

Post-vaccination menstrual cycle irregularities with an possible underlying mechanism of hormonal dysregulation or thrombocytopenia have been reported (143, 144). When compared to the expected range of spontaneous abortion (SAB, often defined as a pregnancy loss occurring between 6 and 20 weeks of gestation) in recognized pregnancies, the studies indicate that receiving an mRNA COVID-19 vaccine before or during pregnancy is not associated with an increased risk of SAB. These findings add to the growing body of data that mRNA COVID-19 vaccinations are safe to use during pregnancy (145, 146).

Renal side effects

Acute kidney injury (AKI) is a potentially rare but generally reversible complication of COVID-19 vaccination (147, 148). About 4.8% of vaccinated people showed acute kidney injury(149). 2 of 10 people who received the first or second dose of the Oxford- Astrazenka COVID-19 vaccine showed AKI in Chronic kidney disease (CKD) (150). In the kidney biopsy of a 71-year-old man, after receiving the first dose of the Oxford-Astrazenka COVID-19 vaccine, acute tubular injury was observed (147). Studies show AKI in people between the ages of 63 and 33 after receiving the Moderna COVID-19 vaccine (151-153). A biopsy of these patients revealed acute tubular injury and severe crescent IgA nephritis, who responded to steroid therapy (151-153). Izzadine et al. (154) Examined 6 cases of patients with severe crescent glomerulonephritis. Two patients were vaccinated with the Pfizer-BioNTech COVID-19 vaccine and 4 patients were vaccinated with Moderna COVID-19 vaccine. All patients were treated with steroids, two of whom recovered but two underwent hemodialysis (154). AKI was also observed in people receiving the Pfizer-BioNTech COVID-19 vaccine (155-160). Biopsy of all these patients revealed acute tubular injury, severe glomerulus, and semi-crescent necrotic glomerulonephritis. Patients responded to steroids except in one case. One case underwent hemodialysis in addition to steroid therapy (155-159).

Immune side effects

Viral reactivation

Psichogiou et al. reported varicella zoster virus (VZV) reactivation in 7 patients (4 of 7 were men>50 years old) who were vaccinated by Pfizer-BioNTech vaccine. All patients reposted varicella infection during infancy (161). Studies have shown the activation of herpes zoster after administration of Pfizer-BioNTech and Moderna vaccines (161, 162). There is increasing concern that the Sputnik V vaccination could be related to higher risk of HIV vulnerability (163, 164). In a report, a 71-year-old man had visited the hospital with symptoms of vision loss. This Asian Indian man had received a covid-19 vaccine a few days before his red eye. Molecular tests were positive for VZV. It seems that the VZV infection that caused the acute retinal necrosis after the covid vaccination was reactivated (165).

Hypersensitivity

Hypersensitivity reactions have been reported following the administration of mRNA vaccines that were among the vaccines used (166). Kounis et al. demonstrated that some components in vaccines can usually cause allergic reactions. Alu-

minum salt, which is inserted in CoronaVac can lead to type IV hypersensitivity (167). Another study on this complication was reported as a case report. A 75-year-old man with hypertension, 5 days after receiving the second dose of the CoronaVac COVID-19 vaccine, erythema multiforme minor was observed (168). The rest of the studies on this subject reported that Polyethylene glycol (macrogol) in Pfizer-BioNTech and Moderna vaccines are responsible for immediate hypersensitivity and delayed-type reaction (169). A 37-year old woman was reported to develop a skin rash, after 4 days of AstraZeneca COVID-19 vaccine administration. The appearance of the rash was described as vesicular, vesicular-papular, and necrotic centers on thigh, feet, buttocks, and face with no itching and no dermatomal expansion. The biopsy of the lesions was sent for histologic evaluations and the result showed neutrophilic pustular dermatitis (170). Another dermatologic reaction to the COVID-19 vaccine was a purpuric rush which did not respond to corticosteroid therapy. The case was a 43-year-old man who was administered with Pfizer-BioNTech vaccine (171). In another study, 49197 employees who got their first dose of mRNA vaccine were told to report their cutaneous reactions after vaccine injection. Rash and itching were reported by 559 patients in the first dose of vaccine administration. In the second dose, 765 people (who did not report cutaneous reaction after the first dose) reported cutaneous reactions (172).

Lymphadenopathy (LAP)

As put forward in some studies, Lymphadenopathy was reported as an adverse effect in 0.3% of Pfizer-BioNTech vaccine and 1.1% of Moderna vaccine (135, 173). According to studies, Of the 68 cases (including eight men and sixty women) who developed lymphadenopathy after receiving first or second dosages of different COVID -19 vaccines, this complication was reported after administration of the Pfizer-BioNTech (n=30, 44.1%), Moderna (n = 17, 25%) Oxford-Astrazenka (n=1, 1.5%) and 20 cases (29.4%) with an unknown type of vaccine (174). Cohen et al. discovered a notable correlation between receiving the Pfizer-BioNTech vaccine and experiencing lymphadenopathy, with a prevalence of 45.6%, whereas the unvaccinated group had a prevalence of 7.6% (175). A review of 55 cases of lymphadenopathy COVID-19 showed that the disease was more common in women (n=43.45, 80%). In most cases, LAP occurred on the same side as the vaccine site, with the most common site being the axilla (51%) (176). Enlarged lymph nodes have been documented as one of the adverse effects experienced by women undergoing treatment for breast cancer (177).

Death

Some causes of death after vaccination are common between vaccines which are listed below:

1. Vaccine escape; ineffective against some mutant strains: Oxford-Astrazenka COVID-19 (178, 179), Pfizer-BioTNech COVID-19, and Johnson COVID-19 vaccines (178)
2. Very rare <1/10000 of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT): Oxford-Astrazenka COVID-19 vaccine (180, 181)
3. Death due to disability in the elderly population: Pfizer-BioTNech COVID-19 vaccine (182)
4. Pericarditis and myocarditis in Pfizer-BioTNech COVID-19(178) and Moderna COVID-19 vaccines
5. Risk of dysregulation of coagulation, especially in young women in JJ COVID-19 vaccine
6. Anaphylaxis in Moderna COVID-19, Pfizer-BioTNech COVID-19, and JJ COVID-19 vaccines (178)

Conclusion

The increasing the number of mortalities because of the pandemic, has made the researchers to develop vaccines rapidly. So, it is obvious that the fast production of different vaccines might affect the quality of their clinical assessment and their approval is dependent on the urgent need for mortality reduction. Except Pfizer-BioNTech, none of the other vaccines have the FDA full authorization. Unfortunately, a number of side effects were reported after the first or the second dose administration of COVID-19 vaccines, in which hematologic and neurologic adverse effects were the most mentioned. Although these effects seem to be lethal, statistics show that only a small number of all vaccinated people are affected. Some of the reports were not population-based research and were just case reports. Results from

these studies may not be reliable because of lack of evidence or even possible bias. Additionally, some studies on large populations also were not based on exact physical examinations , and were documented just by an individuals' report.

We recommend further research on vaccine adverse effects in a large scale, not only case-by-case reports. Regional research in every country might also help to define the differences of adverse effects in different geographical regions and different races. It should be noted that this study was not designed to increase the vaccine hesitancy among the people, but to make the pharmaceutical companies and health authorities aware about the possible risks of using "emergency approved" vaccines.

Conflict of interest

The authors declare that there is no conflict of interest.

Authors' contribution

All the authors had substantial contributions to the conception of the work. Drafting of the work was done by all the authors. All approved the final draft and agree to be accountable for all aspects of the work.

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