Adverse Drug Reactions Linked to the COVID-19 Vaccination: A Comprehensive Review

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Abstract - A class of RNA viruses known as coronaviruses is responsible for human respiratory tract infections and is linked to a number of respiratory illnesses, including as bronchitis, pneumonia, coughing, and the common cold. COVID-19 can cause a fever, cough, sore nose, exhaustion, asthma episodes, diarrhoea, kidney failure, and other symptoms. To overcome COVID-19, the various vaccines are manufactured by various countries, such as AstraZeneca, Moderna, CoronaVac, Covishield, Sputnik, etc. These vaccines may increase the immune response of people, and it is expected that this will protect us from viruses in the future. The efficacy of AZ122 is 70%, the efficacy of m-RNA is 94.55, the efficacy of Cova vaccines is 78%, the efficacy of Covishield is 70%, the efficacy of Coronavac is 50%, and the efficacy of sputniks is 96.6%. But these vaccinations may cause ADRs in human beings. ADR may be mild to severe like thrombosis, Myocarditis, pericarditis, and Gynaecological effects, such as those on pregnant women and the menstrual cycle, also affect pediatrics. In this study we found the various ADRs associated with COVID-19 vaccination.

Keywords: Corona Vaccine ADRs, COVID-19 Vaccines, COVID-19 Adverse drug reaction (ADR), ADRs linked to Coronavirus Vaccine

I. INTRODUCTION

"Corona" is the Latin word for "crown." It has a spherical form with a protein crown. The virus that can infect them is recognized by the proteins. Respiratory viruses like COVID-19, MERS (Middle East respiratory viruses), and SARS (Severe Acute Respiratory Syndrome) are included in the coronavirus. Human respiratory tract infections are caused by a class of RNA viruses known as coronaviruses. Numerous respiratory conditions, such as the common cold, cough, pneumonia, and bronchitis, are linked to the coronavirus [1]. SARS and MERS viruses are circulated in the human population [2]. There are many cases, especially in children, adults, and immune-compromised patients, where the human coronavirus can cause pneumonia and bronchitis [3]. The coronavirus gets its name from the way it looks under an electron microscope—it resembles a crown. It is an RNA virus that is enveloped and has a diameter of between 80 and 160 nm [4]. Figure 1 illustrates the 30 kb single-stranded positive sense RNA molecule that makes up the coronavirus genome, the biggest of any known RNA viruses. Humans can contract respiratory tract infections from the coronavirus group of viruses, which can cause anything from minor to fatal symptoms. [5, 6].

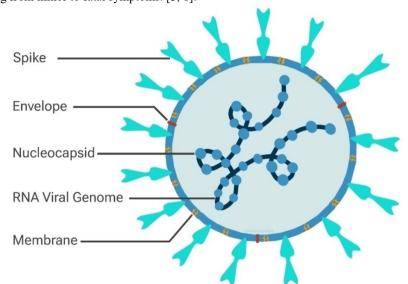


Figure 1: Structure of coronavirus

Severe Acute Respiratory Syndrome, one novel corona virus that causes the most difficult pandemic of the century is coronavirus disease 2019 (Covid-19), which is caused by coronavirus 2 (SARS-COV-2) [7]. In 2002, the coronavirus initially appeared in China's Guangdong Province. 8,098 persons contracted SARS-CoV between 2002 and 2004, which led to the SARS-related deaths. MERS-CoV infections arrived in Saudi Arabia in 2012 [8].

II. HISTORY OF COVID-19

In Wuhan, China, a novel coronavirus strain has the potential to cause serious respiratory illnesses in December 2019. The illness, COVID-19, or coronavirus disease 2019, and the virus, SARS-CoV-2, were designated by the WHO. Acute respiratory syndrome, fatality, and mild to moderate flu-like symptoms are among the clinical signs of COVID-19. Upon reviewing the COVID-19 case files, long-term lung, cardiovascular, and neurological consequences were also observed [9]. After seeing the COVID-19 case report, COVID-19 may cause 2.2 new infections with SARS and MERS [10]. In October 2020, SARS-CoV-2 had infected 4.3 million people, and the death rate of people worldwide was 1.15 million [11]. In January 2020, the first case of COVID-19 came from three towns in Kerala, among which were three Indian students who had returned from Wuhan. On March 23, the lockdown was announced, and in the rest of the country, the lockdown was announced on March 25. Around 90,000 cases were reported in the middle of September. In March 2021, the second wave of COVID-19 will come and be much more dangerous than the first. In a 24-hour period on April 30, 2021, there were 40,000 new instances. India started its immunization plan with indigenous (Covaxin) and AstraZeneca (Covishield) on January 16, 2021. Emergency use of the m-RNA vaccines Moderna and Sputnik is authorized.

Symptoms

Some people have mild symptoms, and some have no symptoms of the coronavirus. The mild symptoms include fever, cough, runny nose, fatigue, asthma attack, respiratory disease and pharyngitis in some cases. And some other symptoms are diarrhea, nausea, vomiting, kidney failure, etc. The severe illness may cause respiratory illness. These symptoms vary from person to person, and few kinds of viruses will be fatal [12].

COVID -19 Vaccines

A vaccine may be defined as a complex of biological products that contain multiple antigens, living organisms, supplements, and preservatives that help to improve a disease. It also improves the immunity of the body against the disease [13]. The WHO defines vaccines as biological agents that trigger an immune response against a specific pathogen. Vaccines are considered safe, but not any other medicine; any other medicine may cause harmful adverse reactions [14]. On June 19, 2021, 78 vaccines were developed in different outgoing trials, of which 12 vaccines were approved by the USFDA, WHO, and European medical agencies [15]. The virus may cause numerous infectious diseases and spread widely throughout the population. Researchers may have discovered that the COVID-19 vaccination boosts people's immune responses, and they anticipated that this would shield us against infections going forward [16].

Table 1: Various Vaccines Introduced by Manufacturer

(1) AZD1222 (Adenovirus vector)					
Manufacturer	Oxford/AstraZeneca/serum institute of India				
Origin	United Kingdom, Sweden				
1 st Authorization	December 2020				
Efficacy	70%				
No. of Trials	16 trials in 12 countries				
(2) m-RNA1273 (m-RNA based vaccine)					
Manufacturer	Moderna, NIAD				
Origin	United state				
1 st Authorization	January 2020				
Efficacy	94.5%				
No. of Trials	5 trials in 1 country				
	(3) Covaxin (Inactivated)				
Manufacturer	Bharat Biotech				
Origin	India				
1 st Authorization	January 2021				
Efficacy	78%				

No. of Trials	5 trials in 1 country			
(4) Covishield(Adenovirus vaccine)				
Manufacturer	Serum institute of India			
Origin	India			
1 st Authorization	January 2021			
Efficacy	70%			
No. of Trials	2 trials in 1 country			
(5) Coronavac (Inactivated vaccine)				
Manufacturer	Sinovac			
Origin	China			
1 st Authorization	September 2021			
Efficacy	50%			
No. of Trials	11 trials in 5 countries			
(6) Sputnik-v (Adenovirus vector)				
Manufacturer	Gamaleya			
Origin	Russia			
1 st Authorization	August 2020			
Efficacy	91.6%			
No. of Trials	3 trials in 1 countries			

AZD1222 (Adenovirus vector), m-RNA 1273 (m-RNA-based), COVAXIN (inactivated), COVISHIELD (Adenovirus vaccine), CORONOVAC (inactivated vaccine), and sputnik (adenovirus vaccine) are manufactured by different manufacturers, as shown in Table 1 [17]. The vaccine's efficacy and safety were tested in different trials in different countries. Phase 1 trials have shown that the vaccines are well tolerated. The efficacy of AZD1222 is 70%, the efficacy of Moderna vaccine is 94.5%, the efficacy of Covovax is 78%, the efficacy of Covishield is 70%, the efficacy of Coronavac is 50%, and the efficacy of Sputnik vaccine is 91.6% [18, 19].

• Oxford-AstraZeneca (AZD1222 (Adenovirus vector)

A recombinant adenovirus vaccine is what the AstraZeneca/Oxfords vaccine is. The s-glycoprotein is the basis for its synthesis. The chimpanzee adenovirus used in the AstraZeneca/Oxfords vaccination is given in modest amounts via genetic material derived from the SARS-CoV-2 virus, which produces COVID-19. Spike protein is a type of protein that can be produced by the body's genetic material. The SARASCOV-2 virus has the spike protein on its surface. Our body protects itself from the virus when the immune system recognizes the spike protein. AstraZeneca/Oxford was given approval by the UK regulatory body in December 2020 for use by the Medicines and Health Products and Regulation Agency (MHRA) in an emergency. Originally intended to be a single dose of the COVID-19 vaccine, a booster dose was recommended since certain individuals may not have a robust enough immune response to the antigens [20There was an 80% chance of a serious infection and a 43% chance of needing hospital care following the first dose of this vaccination. This vaccination should be administered in two complete doses, separated by a period of four to twelve weeks. Following vaccination with both doses, the vaccine's efficacy is assessed. The vaccination provides 70% protection against COVID-19 infection and antigens [21].

• Moderna Vaccine (m-RNA 1273) (m-RNA based vaccine)

M-RNA-1273 is the modified mRNA vaccine. It works by delivering the mRNA into the body; the cells may produce a virus called the spike protein [22]. This vaccine may increase the immunity of the body and help the body fight against bacteria. The vaccination is administered in two doses to maximize immunological response [23]. Each dose volume should be 0.5 mL, and that should be given via the IM route. This vaccine will show 94.1% efficacy [24].

• Covaxin Vaccine (Inactivated)

Covaxin is manufactured by Bharat Biotech. It may be an inactivated virus and induce ALGEL-IMDG, which will increase the immune response [25]. The vaccine is tested on animals in phase 1, which is called preclinical trials, and in phase 2, the vaccine is tested on humans, which is called clinical trials. The higher dose of vaccine may produce a better immune response as compared to the low dose of vaccine [26].

• Covishield Vaccine (Adenovirus vaccine)

The full-length glycoprotein of SARS-CoV-2 is present in the adenovirus vector ChAdOxl, which is used in the Covishield vaccination. It shows the spike protein's codon-optimized coding sequence. After the patients received one dose of the Covishield vaccination against SARS-CoV-2, their protein levels increased and peaked

on day 28. Elderly individuals tolerate this vaccination better than younger ones, and it has comparable immunogenicity across all age categories [27]. In January 2021, the Drug Controller General of India approved the Covishield vaccination. The trials of this vaccine had been conducted in South Africa, the UK, and Brazil. This vaccine spikes a specific T cell, which was produced on day 14, and their immunoglobulin response by day 28. Due to this vaccine, after the vaccine's first dose, the antibodies were detected at roughly 86%–91%, and after the second dose, they were 100% [28].

• CoronaVac Vaccine (Inactivates vaccine)

The CoronaVac vaccine is also called the sinovacCOVID-19 vaccine. The CoronaVac vaccine is an inactivated vaccine that is produced from Vero cells, and it is approved for emergency use in China [29]. In January 2021, it was added to the World Health Organization's list of emergency uses. The data that is genuinely collected from the trials of CoronaVac vaccines is safe, effective, and immunogenic in children, adults, and older patients. This vaccine is used in various countries, such as Asia, South Africa, America, and Europe. In July 2021, the CoronaVac vaccine was widely used in the world to fight COVID [30].

• Sputnik V Vaccine (Gamaleya)

Russia's Gamaleya Research Institute created the COVID-19 vaccination known as the Sputnik vaccine. For the first vaccination, they employ human adenovirus vector 26, and for the second, they use human adenovirus vector 5. The Sputnik vaccination has a 91.6% success rate against COVID-19. Despite this, individuals with weakened immune systems and the elderly may find it less effective. However, the Sputnik vaccine's clinical trial revealed that it is prohibited in specific circumstances. For instance, it is not licensed for use in individuals under the age of 18, and it should not be administered during pregnancy or lactation. Anaphylaxis, or a severe allergic reaction, is one of the vaccine's negative effects, and receiving it again is not recommended [31].

The ADRs Linked to the COVID-19 Vaccine

An adverse drug reaction may be defined as an unwanted reaction that occurs at the normal dose of the drug. These are the undesirable actions that our body does not want [32]. The ADR of the vaccines is the minor or acute reaction, which includes fatigue, redness, swelling, joint pain, injection pain, fever, etc. The FDA and CDC developed the Surveillance programme to track unfavorable events following immunization [33, 34]. The public and health care providers can submit the ADR report to the manufacturers. The ADRs are as below

• Thrombosis

According to recent reports, within 28 days of vaccination, the AstraZeneca vaccine (AZD1222) may result in rare episodes of blood coagulation in the brain. As a result, they follow numerous national vaccination policies. In the UK, Canada, and Germany, AstraZeneca was restricted to persons over 40, 55, and 60 years old [35, 36]. Consequently, on April 13, 2021, the CDC and FDA suggested ending the AstraZeneca vaccine's administration in the United States [37]. Severe headache may be the sign of CVT (cerebral venous sinusitis), which can occur after getting the vaccine [38, 39]. CVT can happen when the veins in the brain get blocked and affect younger adults more than women than men. It is important to find out the CVT in vaccinated people [40]. The person who receives the AstraZeneca vaccine, which can develop antibodies to a protein called PF4 [41]. These antibodies cause clotting by sticking to platelets and activating them, which may lead to low platelet levels and increase blood clotting. This condition may be called disseminated intravascular coagulation (excessive bleeding and organ damage) [42]. The researcher must be sure about this reaction, but in a study on animals, they saw that vaccine components might end up in the blood and cause immune responses and clotting [43].

• Guillian-Barre Syndrome

GBS is a disorder where the immune system of our body targets nerves, resulting in weakness, problems with senses, and occasionally even paralysis [44]. Some patients get vaccinated with mRNA vaccine, which helps the body fight against the virus by making copies of the virus called spike proteins. In some cases, the immune system can act on the protective covering of nerves, which may cause GBS [45]. The two cases of Guillian-Barre syndrome were seen after receiving the COVID-19 vaccine, but it is rare. It causes weakness in the limbs [46]. There is no strong proof that the COVID-19 vaccine shows GBS. But COVID-19 is more dangerous than GBS in adults.

• Transverse Myelitis

An uncommon disease called transverse myelitis attacks the spinal cord. It generally occurs in people whose ages range from 35 to 40 years. Myelitis may cause inflammation in the spinal cord, and this inflammation may lead to symptoms like weakness, numbness, and, at times, paralysis. Scientists found that certain proteins called interleukins, especially interleukin 17 and 6, play an important role in causing Transverse Myelitis [47]. This protein damages the cells in the spinal cord. There are extremely few instances of transverse myelitis associated

with the AstraZeneca vaccine. Scientists Mushtaq et al., 2022 found that the vaccine activates the immune response and may cause inflammation in the spinal cord.

• Myocarditis and Pericarditis

This ailment is characterized by inflammation of the heart muscle, and it usually manifests following immunization against COVID-19. According to some research, myocardial infarctions do occur occasionally following immunization, particularly with the COVID-19 vaccine's second dosage. Teenagers and young adults are the target audience for these few instances, and indications of myocardial infarction can include damage to the heart's tissue and chest pain [48]. Over 10,000 cases of cardiac events were documented in the USA following the COVID-19 immunization, according to the CDC. However, following COVID-19 vaccination, older patients may experience pericarditis inflammation [49].

• Glomerular Disease

The kidney disease may be shown after the COVID-19 vaccine, which may cause glomerular disease after vaccination, and the pathogens behind the COVID-19 vaccine, which cause glomerular disease, are not clearly understood. Some reports show that it can cause hematuria (blood in urine) after receiving the vaccine [50].

• Allergic Reaction & Anaphylaxis

Anaphylaxis and some allergic responses are possible side effects of the COVID-19 mRNA vaccination. According to earlier data, there are 2.5 cases of m-RNA vaccinations and 11.1 cases of BNT16b2 vaccines per million [51]. At the injection locations, these vaccinations result in delayed local reactions. Polyethylene glycol is a hydrophilic polymer of ethylene oxide found in the m-RNA vaccine family. Trometamol is an excipient in the Moderna vaccine, while polysorbate and surfactant which are typically found in foods and cosmetics are present in AstraZeneca [52]. An allergy may result in a cell-mediated hypersensitivity reaction, which is typically brought on by T-cell and macrophage overstimulation [53].

• Effect on Pediatric

The European Commission recommends the COVID-19 vaccine for youth aged 12 to 17 in order to avoid sickness. Additionally, booster shots have been advised for the same age group in a few other nations. The European Medicines Agency (EMA) has approved the m-RNA vaccine, BNT162b2, and Moderna vaccine for children aged 6 to 11. Additionally, the FDA approved the Moderna vaccine, and children under the age of five are also administered m-RNA [54]. Certain adverse reactions (ADRs) such as edema, local pain, injection site redness, weakness, headache, chills, fever, nausea, joint pain, muscle soreness, and mucocutaneous side effects that could disrupt the mucosal membrane can occur when children receive this vaccination [55, 56].

III. MAJOR ADRS OF VACCINE ON VARIOUS ORGANS OF HUMAN BODY

• ADR of Vaccine in Diabetic Patients

The acute respiratory syndrome (SARS-CoV-2) infection that is the primary cause of coronavirus disease 2019 was initially documented by Zhun *et al.*, 2020 in Wuhan, China in December of that year. A global pandemic brought on by this pathogen resulted in 360,000 deaths and 6 million cases as of June 2020. An estimated 463 million individuals worldwide suffer from diabetes mellitus. As Figure 2 illustrates, diabetes mellitus is a significant risk factor for infection, and the risk rises with poor glycemic control. Though present data do not indicate that people with diabetes mellitus have a higher risk of getting SARS-CoV-2, glycated haemoglobin is generally greater than 9% and is associated with a 60% increase in the risk of severe bacterial pneumonia [57-59].

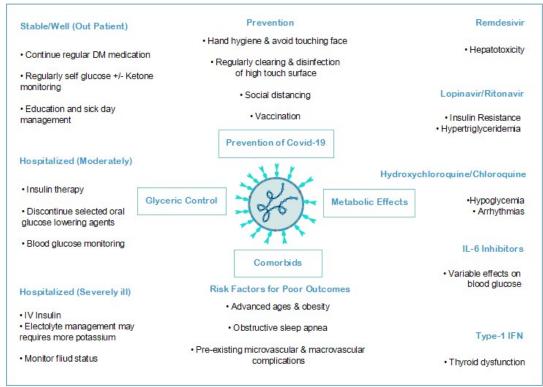


Figure 2: Interaction between Diabetes Mellitus & Coronavirus Disease. (Type-1 IFN- Interferon's, IL-6 inhibitors- Interleukins, DM-Diabetes Mellitus, and IV- Intravenous)

• Neurological Side Effects

We can study the various neurological side effect associated with COVID-19 vaccination. In this 48 articles were included and the conclusion was that there is no major severe neurological adverse reaction to any person [60]. We looked at it thoroughly, and we didn't agree with the notion that SARS-CoV-2 had no negative effects. Numerous infrequent, moderate, and mild neurological adverse effects have been documented [61]. Information from mRNA vaccination study clinical trials revealed that 7 cases out of 37,000 immunization recipients experience Bell's palsy. Guillian-Barre syndrome emerged during the Johnson & Johnson vaccine experiment based on DNA. The Food and Drug Administration's (VAERS) Adverse Event Reporting System states that as of March 2, 2021, 9442 reports of ADRs were filed. Table 2 lists the neurological adverse effects of SARS CoV-2, which include headache, facial nerve palsy, epilepsy, GBS (Guillian-Barre syndrome), ischemic stroke, and other side symptoms that some individuals have reported.

Table 2: Before the end of September 2021, neurological side effects from SARS-Cov-2 vaccinations. (Here AZV-AstraZeneca, JJ- Janssen Vaccine, GBS- Guillian-Barre syndrome and n= total number of incidents)[62-68]

Adverse Reaction	Incidence Count	Vaccine	Response
(Headache)	n = 3051	(AZV, Pfizer)	Complete
(Facial nerve Palsy)	n= 4	(AZV, Pfizer, Bharat Biotech)	Complete, Partial
(GBS)	n= 389	(AZV, Pfizer, JJ)	Complete, Partial
(Epilepsy)	n= 1	(Moderna)	Complete
(Ischemic Stroke)	n= 1	(AZV)	Partial

• Gynecological Effects

SARS-CoV-2 affects pregnant women and causes serious illness; it raises the chance of admission to an intensive care unit, which leads to maternal death and serious negative pregnancy outcomes [69, 70]. As we know immune system is directly towards fetal tolerance which is why COVID-19 affects pregnancy [71]. The physiological stress occurs in pregnancy because this infection directly targets to respiratory and cardiovascular systems. Pregnancy difficulties arise from the induction of both acute and chronic placental insufficiency in the maternal placental surface due to infection with SARS-CoV-2 [72, 73]. Pregnancy-related COVID-19 immunization research was linked to a decreased risk of serious or severe illness during the pandemic. Reports typically state that the individual who received the vaccination had a lower risk of experiencing unfavorable pregnancy outcomes. Maternal-Fetal medicine, during the pregnancy, the COVID-19 vaccine is issued under guidance support [74-78].

Side Effects on The Cardiovascular System

Reported to occur more often in patients receiving the COVID-19 vaccination BNT162b2 (Pfizer-BioNTech), are side events related to the cardiovascular system. Palpitation and tachycardia are two prominent side effects of cardiovascular disease (CV), and in this study, we identified 30% and 44% of severe side effects following immunization by BNT162b2 (Pfizer-BioNTech) and Moderna, respectively. Table 3 illustrates the extremely low prevalence of myocarditis that follows Moderna vaccinations [79, 80].

Table 3: Some side effects related to cardiac system from COVID-19 vaccine. (Here n= total number of incidents)

Effects	BioNTech	Moderna
(Pericarditis)	n= 68	n = 13
(Myocarditis)	n= 462	n = 49
(Myocardial Infarction)	n= 310	n = 67
(Arrhythmia)	n= 254	n = 0
(Cardiogenic Shock)	n = 1	n = 0
(Thrombotic Events)	n= 13,893	n= 43
(Thrombocytopenia Events)	n = 1346	n= 28

Some specific adverse side effects from various vaccines on cardiovascular system 40% 35% 30% 25% 20% 15% 0% Moderna Pfizer Paicardia transfer and transfer an

Figure 3: The cardiac effect associated with m-RNA and Pfizer vaccine

The side effects of Moderna are more as compared to Pfizer-BioNTech as shown in Figure 3. The majority of the 444 CV events reported in review reports for the m-RNA-1273 (Moderna) vaccination were acquired after the vaccine's first and second doses. Stroke is the most prevalent adverse effect, occurring in 39.9% of cases; it is followed in each case by 15% of pulmonary embolism. 43 occurrences of thrombosis and 13 cases of

pericarditis were included in 19.1% of cases, but in the case of BNT162b2 (Pfizer-BioNTech), the patient's first symptoms appeared between 5.6 days after the immunization, necessitating a 7.8-day hospital stay. Following the study, 13 effects related to CRP levels were documented; five individuals had elevated Troponin T levels, and eight cases were recorded at Troponin I levels. Hypertension and cerebral bleeding occurred following the initial dosage. When treating steroid use, corticosteroids, prednisone, and methylprednisolone are the most commonly administered drugs. NSAIDs were primarily used in 7 cases, while IVIG was used in 10 [81].

IV. CONCLUSION

The COVID-19 vaccination has been linked to a number of adverse drug reactions (ADRs) that impact the various organ systems of humans. These mild to severe adverse drug reactions (ADRs) also happen soon after immunization or after a delay. ADRs that are most frequently experienced include headache, weariness, fever, edema, and pain. The COVID-19 vaccination has the potential to produce thrombocytopenia syndrome, which is typically linked to an adenovirus vector, as well as neurological problems including Gillian-Bare syndrome and cardiovascular diseases like myocarditis and pericarditis. The COVID-19 vaccination has been linked to a variety of adverse drug reactions (ADRs) that impact various organs; nonetheless, the vaccine's general safety and effectiveness are still known. To address ADRs, ensure vaccination safety and efficacy, and ultimately defeat the COVID-19 pandemic, regulatory bodies, public health authorities, and healthcare professionals are crucial. The immunization has the advantage of preventing COVID-19-related serious illness and mortality.

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