STUDI LAPORAN KASUS REAKSI YANG MERUGIKAN PASCA VAKSINASI COVID-19: *NARRATIVE REVIEW*

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CASE REPORT STUDIES OF ADVERSE EFFECTS POST COVID-19 VACCINATION: A NARRATIVE REVIEW

ABSTRACT

The accelerated Covid-19 vaccines' emergency use authorization raises many questions regarding the safety and effectiveness of the vaccine due to the short duration of the pre-marketing clinical trial phase. In terms of vaccine safety, longer studies are needed, especially to see if there are long-term effects or unusual effects that were not detected during pre-marketing clinical trials. This study aims to summarize and assess the adverse reactions that occur after the administration of the Covid-19 vaccine that has obtained approval for emergency use. The search for case reports was carried out in the PubMed database with the keyword "case report on post covid-19 vaccination". Screening for duplication and assessment of each study was also carried out. The case findings obtained were then grouped based on patient demographics, type of vaccine, post-vaccination effects, medical interventions, and end results. There were 118 case reports of adverse effects after the Covid-19 vaccination. The most widely used type of vaccine was mRNA vaccine (76 cases; 64.41%) and the least was inactivated virus vaccine (3 cases; 2.54%). The most reported cases were those affecting the cardiovascular/circulatory/lymphatic system (42 cases; 35.59%) and the least were those affecting the respiratory system (1 case; 0.85%). A total of 89 cases were resolved (89 cases; 75.42%), 4 cases (3.39%) with disability and 2 cases (1.69%) of death were reported. The medical interventions used were mostly inflammatory response-related interventions.

Keywords: adverse effect, case report, Covid-19, pharmacovigilance, post-vaccination, narrative review, vaccine safety

INTRODUCTION

Covid-19 is an infectious disease that first appeared at the end of 2019 in Wuhan, China, caused by a new virus which was later named Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) (Sheneer *et al.,* 2020). Until June 3, 2022, the number of confirmed positive cases of Covid-19 in the world was 528,816,317 cases with a death toll of 6,294,969 (WHO 2022). The emergence of variants of concern from the SARS CoV-2 virus such as alpha, beta, gamma, delta, epsilon, and omicron cause the transmission of Covid-19 disease to be very fast so that appropriate steps are needed to control this disease (CDC 2022).

As of May 31, 2022, a total of 11,947,644,522 doses of the Covid-19 vaccine have been administered worldwide (WHO 2022). These vaccines are used based on the emergency use authorization (EUA) policy that causes the clinical trial period for stages 1, 2, and 3 to be shortened and/or combined while still reporting the results of the interim study. This causes many questions in the community regarding the effectiveness and safety of vaccines that are produced in only a short time, which is about one year. The short duration of pre-marketing clinical trials (stages 1, 2, and 3) also led to the possibility that other effects after the Covid-19 vaccination could not be detected, such as long-term and unexpected effects. Therefore, a systematic study is needed on the long-term effects of the Covid-19 vaccination, especially in conditions beyond clinical trials, where the vaccine has been given to various groups of people with different demographic backgrounds, such as age, comorbidity, and pregnancy/breastfeeding. Thus, this study intended to assess individual case reports in terms of its adverse effects, demographics, medical interventions, and end results. This study also summarizes its possible mechanism of actions of the adverse effects. The findings are expected to serve as a form of initial information to healthcare workers as well as preliminary evidence to conduct more detailed studies.

METHODS

Study Selection

The study articles selected in this study were case reports of adverse effects of post-Covid-19 vaccination in real world setting. The search of articles was carried out for articles that was published until January 6, 2022.

Inclusion criteria: case report or case series of adverse reactions after the administration of the Covid-19 vaccine that has received approval for emergency use, either the 1st dose or more (case series will be divided into individual cases), indexed in PubMed, available in English, and is available in full-text form. Demographics of patients in the study can come from all ages and conditions, such as pregnant or lactating women or having comorbidities. The outcome seen is the effect on each individual after the Covid-19 vaccination.

Exclusion criteria: Articles in the form of a review and meta-analysis, no Covid-19 vaccine administered to patients.

Data Extraction

From each article, the following data were collected: adverse effects, type of vaccine, patient demographics, including age, gender, ethnicity, and comorbidities, medical intervention, and end result of the adverse effects.

Data Analysis

The data were analyzed descriptively by grouping based on the type of vaccine, the organ system involved, and the end results. The grouping of adverse effects by organ system referred to the International Classification of Disease-10 (ICD-10), 2019 edition. Screening for duplication was done by one researcher (main author) whereas the assessment was done by two researchers (all authors). First, the main author assessed each article by its title and abstract, and extracted its main data (type of adverse effects) and then discussed it further with the co-author to decide its inclusion in the study.

RESULT AND DISCUSSION

Articles Search Results

The search for articles on PubMed until January 6, 2022, with the keyword "case reports post-covid-19 vaccination" resulted in 111 journal articles. After screening for duplication and eligibility, 78 articles were included. Several articles reported more than 1 case, bringing the total reported cases to 118 individual cases from which the data were collected (Figure 1).

Data on type of Covid-19 vaccine, the affected organ system, and the end results of adverse effects reported in the selected cases is presented in Table 1.

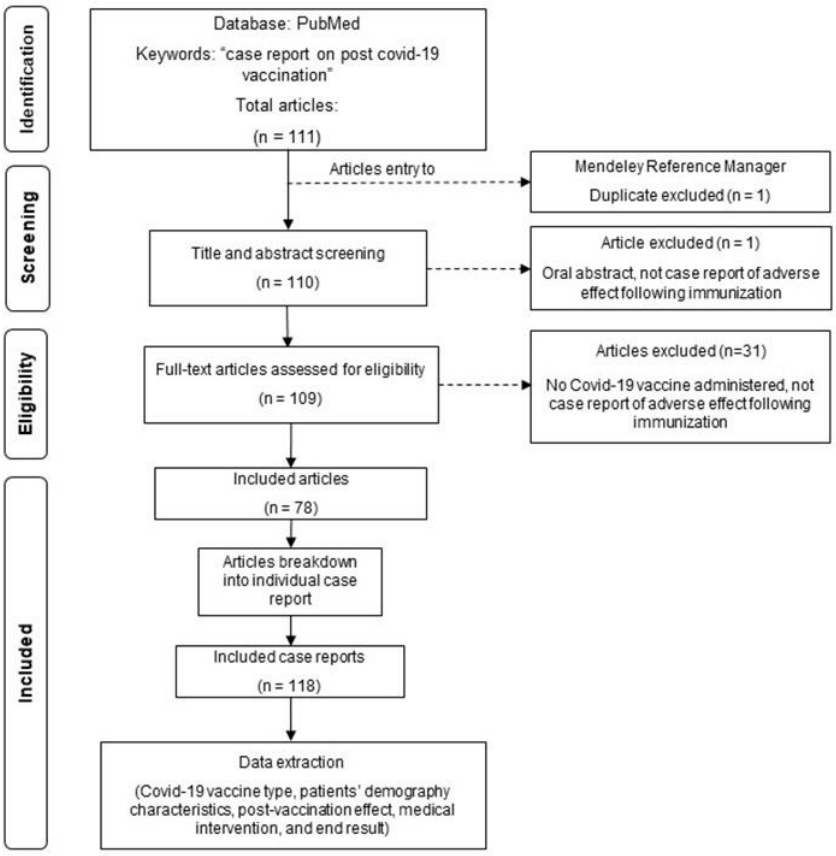

Figure 1. Flow diagram of study selection

Table 1. Data on vaccine type, organ systems involved, and end results of adverse effects reported in the selected cases

Parameter	**Number of cases, *n***	**Percentage (%)**
Total	118	
Vaccine type		
mRNA	76	64.41
Viral vector	31	26.27
Inactivated virus	3	2.54
Not stated	8	6.78
Organ system involved		
Cardiovascular/Circulatory/Lymphatic System	42	35.59
Nervous System	22	18.64
Integumentary System and Immune System	16	13.56
Genitourinary System	16	13.56
Visual Sensory System	10	8.47
Musculoskeletal System	8	6.78
Endocrine System	3	2.54
Respiratory System	1	0.85
End result		
Resolved	89	75.42
Ongoing	15	12.71
Disability	4	3.39
Death	2	1.69
Not stated	8	6.78

Table 2. Patients' demographics reported in the selected cases

Parameter	CV	NRV	INT/IMU	GENU	VS	MS	END	RES	Total, *n* (%)
Age (years)									
Period of youth (14-25)	5	1	-	1	1	1	-	-	9 (7.63)
Young age (26-44)	14	4	6	5	5	3	1	-	38 (32.20)
Middle age (45-60)	7	7	6	2	-	-	1	-	23 (19.49)
Elderly age (61-75)	11	9	2	4	2	1	1	1	31 (26.27)
Senile age (76-90)	5	1	1	4	2	3	-	-	16 (13.56)
Long-livers (>90)	-	-	1	-	-	-	-	-	1 (0.85)
Total	42	22	16	16	10	8	3	1	118 (100)
Gender									
Male	20	10	6	11	6	2	1	1	57 (48.31)
Female	22	12	10	5	4	6	2	-	61 (51.69)
Total	42	22	16	16	10	8	3	1	118 (100)
Ethnicity									
Caucasian/White	9	5	-	13	2	2	1	-	32 (27.12)
Asian	3	1	-	1	-	-	-	-	5 (4.24)
Taiwanese	1	-	-	-	-	-	-	-	1 (0.85)
Jordanian	1	-	-	-	-	-	-	-	1 (0.85)
Black South African	-	1	-	-	-	-	-	-	1 (0.85)
Ethiopian	-	-	-	1	-	-	-	-	1 (0.85)
Indian	-	-	-	-	1	1	-	-	2 (1.69)
Hispanic	-	-	-	-	-	1	-	-	1 (0.85)
Not stated	28	15	16	1	7	4	2	1	74 (62.71)
Total	42	22	16	16	10	8	3	1	118 (100)

Remarks:
CV = Cardiovascular/Circulatory/Lymphatic System; NRV = Nervous System; INT/IMU = Integumentary/Immune System; GENU = Genitourinary System; VS = Visual Sensory System; MS = Musculoskeletal System; END = Endocrine System; RES = Respiratory System

Table 3. Vaccine type and end result vs organ system involved reported in the selected cases

Parameter	CV	NRV	INT/IMU	GENU	VS	MS	END	RES	Total
Vaccine type									
mRNA	30	6	12	16	6	5	1	-	76
Viral vector	7	13	3	-	4	2	1	1	31
Inactivated virus	-	1	1	-	-	-	1	-	3
Not stated	5	2	-	-	-	1	-	-	8
Total	42	22	16	16	10	8	3	1	118
End result									
Resolved	33	17	16	11	3	5	3	1	89
Ongoing	8	2	-	2	2	1	-	-	15
Disability	-	3	-	-	-	1	-	-	4
Death	1	-	-	-	-	1	-	-	2
Not stated	-	-	-	3	5	-	-	-	8
Total	42	22	16	16	10	8	3	1	118

Remarks:
CV = Cardiovascular/Circulatory/Lymphatic System; NRV = Nervous System; INT/IMU = Integumentary/Immune System; GENU = Genitourinary System; VS = Visual Sensory System; MS = Musculoskeletal System; END = Endocrine System; RES = Respiratory System

Table 2 shows patients' demographics. Most cases stated specifically the age of the patient, but 3 cases only stated: "a middle aged-woman" (Chen *et al.,* 2021, Elboraey and Essa 2021, Jeeyavudeen, 2021). Most reported cases affected young age (26-44 years old) group (32.20%). In terms of ethnicity, the majority of cases does not state patient's ethnicity (62.71%), followed by Caucasian (27.12%). Table 3 shows a matrix of relationships between manifestations of adverse effects in organ systems and their end result as well as vaccine type.

Table 4. Adverse effects post-Covid-19 vaccination in various organ systems reported in the selected cases

No.	Adverse effects	Number of cases, *n*	Percentage (%)	Medical intervention					Time to resolve
				Inflammatory response-related					
				NSAIDs	IVIG	Plasmapheresis /plasma exchange	High dose steroid	Others	
A	**Cardiovascular/Circulatory/Lymphatic System**								
1	Pericarditis, myocarditis, perimyocarditis	7	16.67	√				Paracetamol, colchicine, beta-blocker, ACE-i, diuretic	2 days–3 weeks
2	Cardiac conduction disturbance	2	4.76					Permanent pacemaker insertion	1 day
3	Myocardial infarction	3	7.14					Drug-eluting stent insertion (everolimus, zotarolimus), noncompliant balloon insertion, antiplatelet, heparin	2 days–1 week
4	Tachycardia† (1 case)	2	4.76					Ringer's lactate, lorazepam, paracetamol, metoprolol	2 days
5	Cardiogenic shock	1	2.38				√	Norepinephrine, dobutamine, ACE-i	6 days
6	Takotsubo syndrome	1	2.38					Heparin, furosemide, losartan	8 days
7	Immune thrombocytopenia (ITP)	7	16.67		√	√	√	Platelet transfusion, mycophenolate mofetil, thrombopoietin receptor agonist (romiplostim, eltrombopag), apixaban, tranexamic acid, osmotic agent (mannitol)	3 days–1 month
8	Multisystem Inflammatory Syndrome in Adult (MIS-A)	1	2.38				√	Antibiotics, vasopressor	More than 5 days
9	Deep vein thrombosis (DVT)	1	2.38					Heparin, rivaroxaban	2 weeks
10	Pulmonary embolism	2	4.76					Apixaban	Not stated
11	Fatal thromboembolism‡ (1 case)	1	2.38				√	Heparin, anti-hypertensive, oral double anti-coagulants (dabigatran, rivaroxaban), dabigatran antagonist, craniectomy	
12	Splenic infarction	1	2.38					Heparin, apixaban	1 week
13	Bilateral thalamic stroke† (1 case)	1	2.38					Clopidogrel, aspirin as antiplatelet, heparin	

No.	Adverse effects	Number of cases, *n*	Percentage (%)	Medical intervention					Time to resolve
				Inflammatory response-related					
				NSAIDs	IVIG	Plasmapheresis /plasma exchange	High dose steroid	Others	
14	Kikuchi-Fujimoto Disease (KFD) or necrotizing histiocytic lymphadenitis	2	4.76	√					21 days and 23 days
15	Lymphadenopathy† (6 cases)	10	23.81	√				No treatment	1 week–30 days
Total		42	100						
B	**Nervous System**								
1	Neuromyelitis optica	2	9.1			√	√		5 days
2	Encephalopathy	1	4.5				√	Patient initially did not respond to ceftriaxone and acyclovir for 5 days	8 days
3	Guillain-Barré syndrome† (1 case) § (1 case)	7	31.8		√	√			10 days–3 months
4	Neuralgic amyotrophy (with leg paralysis) § (1 case)	1	4.5				√		
5	Acute transverse myelitis	2	9.1			√	√		5 days and 8 days
6	Metastatic malignant melanoma	1	4.5					Mass resection	2 weeks
7	New onset glioblastoma† (1 case)	1	4.5					Definitive therapy (not stated specifically)	
8	Chronic inflammatory demyelinating polyneuropathy (CIDP)	1	4.5		√				Not stated
9	Longitudinal extensive transverse myelitis (LETM)	1	4.5				√	Enoxaparin	1 week
10	Encephalomyelitis	1	4.5				√		50 days
11	Encephalopathy with non-colvulsive focal status epilepticus	2	9.1					Lorazepam, fosphenytoin, levetiracetam	6 days and 8 days
12	New onset refractory status epilepticus (NORSE)	1	4.5			√	√	Patient initially did not respond to antiepileptics	3 weeks
13	Miller-Fisher syndrome (MFS) and Guillain-Barré syndrome (GBS) (MFS-GBS overlap syndrome) § (1 case)	1	4.5		√				
Total		22	100						
C	**Integumentary System and Immune System**								
1	Henoch-Schonlein vasculitis, IgA vasculitis	3	18.75				√	Paracetamol, deflazacort	7 days–several months
2	Stevens-Johnson	1	6.25				√	Triamcinolone	Not stated

No.	Adverse effects	Number of cases, *n*	Percentage (%)	Medical intervention					Time to resolve
				Inflammatory response-related				Others	
				NSAIDs	IVIG	Plasmapheresis /plasma exchange	High dose steroid		
	syndrome (SJS)							mouthwash	
3	Toxic epidermal necrolysis (TEN)	1	6.25					IV fluid replacement, antibiotics, etanercept	22 days
4	Reactivation of BCG vaccination scars	2	12.5					No treatment required	2 weeks
5	Palms and soles itchiness	1	6.25					Antihistamine	5 days
6	Herpes zoster infection	3	18.75					Analgesic, systemic antiviral, antiviral eyedrops	Not stated
7	Anaphylactic reactions (biphasic anaphylaxis, pseudo-anaphylaxis)	4	25				√	Diphenhydramine, epinephrine, salbutamol, ipratropium	4–7 days
8	Breast implant seroma	1	6.25	√				Fine needle aspiration	10 days
Total		16	100						
D	**Genitourinary System**								
1	IgA nephropathy[n] (2 cases)	4	25				√	ACE-i	1.5 months and 5 months
2	IgA nephropathy with acute interstitial nephritis[†] (1 case)	1	6.25				√		
3	Atypical anti-glomerular basement membrane (anti-GBM) nephritis[†] (1 case)	1	6.25				√	Mycophenolate mofetil, cyclophosphamide	
4	Minimal change disease (MCD)	2	12.5				√	Rituximab, furosemide, amlodipine	2 weeks and 2 months
5	MCD with acute tubular necrosis (ATN)	1	6.25				√		1 month
6	NELL-1-associated membranous nephropathy	1	6.25					ACE-i	2 months
7	Myeloperoxidase-antineutrophilic cytoplasmic antibody (MPO-ANCA)-associated vasculitis	1	6.25				√	Rituximab	1 months
8	Primary focal segmental glomerulosclerosis (FSGS)	1	6.25				√	Tacrolimus	3.5 months
9	Phospholipase A2 receptor (PLA2R)-associated membranous nephropathy[n] (1 case)	2	12.5					Tacrolimus, obinutuzumab	1 month
10	Anti-neutrophil	1	6.25				√	Cyclophosphamide	33 days

No.	Adverse effects	Number of cases, *n*	Percentage (%)	Medical intervention				Others	Time to resolve
				Inflammatory response-related					
				NSAIDs	IVIG	Plasmapheresis /plasma exchange	High dose steroid		
	cytoplasmic antibody (ANCA)-associated vasculitis (AAV)								
11	MCD with nephrotic syndrome and acute kidney injury (AKI)	1	6.25				√	Ramipril, furosemide	9 weeks
Total		16	100						
E	**Visual Sensory System**								
1	Corneal transplant rejection	3	30				√	Steroid eye drops	1, 3, and 4 weeks
2	Branch retinal artery occlusion[n] (1 case)	1	10					Aspirin as antiplatelet, simvastatin	
3	Combined arterial and venous occlusion [n] (1 case)	1	10					Intravitreal anti-VEGF	
4	Venous stasis retinopathy[†] (1 case)	1	10					Treatment is not stated	
5	Non-arteritic anterior ischemic optic neuropathy (NAION) [n] (1 case)	1	10					Treatment is not stated	
6	Cotton-wool spot (as a sign of nerve fiber layer infarction) [n] (1 case)	1	10					Treatment is not stated	
7	Bilateral acute macular neuroretinopathy (AMN) [n] (1 case)	1	10					Treatment is not stated	
8	Bilateral paracentral acute middle maculopathy (PAMM) dan acute macular neuroretinopathy (AMN) [†] (1 case)	1	10					Treatment is not stated	
Total		10	100						
F	**Musculoskeletal System**								
1	Fatal rhabdomyolysis[‡] (1 case)	1	12.5				√	Bicarbonate-rich intravenous fluids, antibiotics, hemodialysis	
2	Complex regional pain syndrome (CRPS)[†] (1 case)	1	12.5				√	Tramadol, topical capsaicin, amitriptyline. Patient decided to switch to Ayurveda	
3	Shoulder injury related to vaccine administration (SIRVA)[§] (1 case)	1	12.5	√			√	Vitamin D, physical therapy	
4	Mild shoulder discomfort, quadrilateral space region inflammation, and edema	3	37.5					No treatment required	2 days, 5 days, and 1 month

No.	Adverse effects	Number of cases, *n*	Percentage (%)	Medical intervention				Others	Time to resolve
				Inflammatory response-related					
				NSAIDs	IVIG	Plasmapheresis /plasma exchange	High dose steroid		
	in deltoid muscle								
5	Severe polyarthralgia with severe functional impairment	1	12.5					No treatment required	9 days
6	Thrombotic thrombocytopenic purpura	1	12.5			√	√	Red blood cell and platelet transfusion, rituximab	10 days
Total		8	100						
G	**Endocrine System**								
1	Subacute thyroiditis	1	33,3				√	Propranolol	7 weeks
2	Pheochromocytoma multisystem crisis	1	33,3					Mass resection and adrenalectomy	2 months
3	Thyrotoxicosis (subacute destructive thyroiditis)	1	33,3	√					8 weeks
Total		3	100						
H	**Respiratory System**								
1	Acute eosinophilic pneumonia	1	100				√	Nebulization with salbutamol and ipratropium. Patient initially did not respond to antibiotics for 2 days.	5 days
Total		1	100						

Remarks:
† Ongoing
§ Disability
‡ Death
[n] End result is not stated

Adverse Effects Affecting the Cardiovascular/Circulatory/Lymphatic System

As shown in Table 4, there were 15 types of effects on the cardiovascular/circulatory/lymphatic systems with a total of 42 cases, of which 33 cases were resolved, 8 cases were ongoing, and 1 case was death, as shown in Table 3.

The resolved cases were 7 cases of pericarditis/myocarditis/perimyocarditis, both rapid onset (within 1-10 days after vaccination) as reported by Ashaari *et al.* (2021), Nagasaka *et al.* (2021), Khogali and Abdelrahman (2021), Williams *et al.* (2021), McCullough *et al.* (2021), Tailor *et al.* (2021) and late onset, which occurred 3 months after vaccination as reported by Gautam *et al*. (2021); 2 cases of cardiac conduction disturbance (Elhassan *et al.,* 2021); 3 cases of myocardial infarction (Sung *et al.,* 2021, Maadarani *et al.,* 2021); 1 case of tachycardia (Tate *et al.,* 2021); 1 case of cardiogenic shock revealing myocarditis (Mimouni *et al.,* 2021); 1 case of Takotsubo syndrome (Fearon *et al.,* 2021); 7 cases of ITP of both new cases as reported by Idogun *et al.* (2021), Lin *et al.* (2021), Nutalapati *et al.* (2021), Bennet *et al.* (2021), Helms *et al.* (2021) and relapse cases as reported by Ali *et al.* (2022) and Qasim *et al.* (2021); 1 case of MIS-A (Al Bishawi *et al.,* 2021); 1 case of DVT (Bhan *et al.,* 2021); 2 cases of pulmonary embolism(Ifeanyi *et al.,* 2021); 1 case of splenic infarction (Anderson *et al.,* 2021); 2 cases of KFD (Tan *et al.,* 2021); and 4 cases of lymphadenopathy (Tan *et al.,* 2021, Hiller *et al.,* 2021).

The ongoing cases were 1 case of tachycardia in the form of postural orthostatic tachycardia syndrome (POTS) as reported by Reddy *et al.* (2021), where the patient still felt symptoms when the case was published and controlled by wearing compression socks and increasing sodium intake; 1 case of bilateral thalamic stroke as reported by Giovane and Campbell (2021), where left extremity weakness was still present when the report was published; and 6 cases of lymphadenopathy in the form of new onset lymphadenopathy found during FDG-PET/CT examination in cancer or tumor patients (Weeks *et al.,* 2021, Shah *et al.,* 2021).

A case of fatal thromboembolism was reported in which patient developed symptoms 1 day after receiving viral vector vaccine (Oxford-AstraZeneca) (Mauriello *et al.,* 2021). The patient had a history of thrombocytopenia in 2016 and a clinical history of allergy to penicillin. The autoptic examination result suggested thrombocytopenia related to myelodysplasia but no anti-PF4 antibodies was found which usually appeared in other cases of immune thrombotic thrombocytopenia related to Oxford-AstraZeneca viral vector vaccine, such were reported by Lin *et al.* (2021).

Most of the resolved cases affecting cardiovascular/circulatory/lymphatic system were treated with NSAIDs, such as aspirin, indomethacin, and ibuprofen. Some cases of ITP required IVIG, plasmapheresis, and/or high dose steroid. The hypothesis of the mechanism of pericarditis, myocarditis, and perimyocarditis could be the reactivity of the immune system to systemic components of the vaccine (Ashaari *et al.,* 2021). The mechanism of DVT might be that the vaccine component binds to pattern recognition receptors (PRR) in the endosome and cytosol which causes a pro-inflammatory cascade reaction and coagulopathy (Bhan *et al.,* 2021). The mechanism of splenic infarction is not clearly known, but the patient in this report was known to have atherosclerotic plaques in the superior mesenteric artery, celiac axis, and aorta, so it might be possible that the vaccine component (viral vector) interacts with the existing plaques (Anderson *et al.* 2021). While it is not clear how the Covid-19 vaccine caused Takotsubo syndrome, in the influenza vaccine, it was reported a possible association between the influenza vaccine and this syndrome, where the influenza vaccine induces a systemic inflammatory reaction that leads to increased levels of catecholamines and myocardial sensitivity to catecholamines (Fearon *et al.* 2021).

Adverse Effects Affecting the Nervous System

As shown in Table 4, 13 types of effects were found to be related to the nervous systems, with a total of 22 cases. Of this number, 17 cases were resolved, 2 cases were ongoing, and 3 cases ended up with disabilities, as shown in Table 3.

The resolved cases were 2 cases of neuromyelitis optica (Badrawi *et al.,* 2021, Chen *et al.,* 2021); 1

case of encephalopathy (Al-Mashdali *et al.,* 2021); 5 cases of Guillain-Barré syndrome (GBS) (Razok *et al.,* 2021, Oo *et al.,* 2021, Kanabar and Wilkinson, 2021, Jain *et al.,* 2021); 2 cases of acute transverse myelitis (Hsiao *et al*., 2021, Khan *et al*., 2022); 1 case of metastatic malignant melanoma in the frontal lobe (Einstein *et al*., 2021); 1 case of CIDP (Oo *et al.,* 2021); 1 case of LETM (Tan *et al.,* 2021); 1 case of acute disseminated encephalomyelitis (Vogrig *et al.,* 2021); 2 cases of encephalopathy with non-convulsive focal status epilepticus (Liu *et al.,* 2021); and 1 case of NORSE (Aladdin and Shirah, 2021).

The ongoing cases were 1 case of GBS that had been treated with IVIG but the patient was still being treated for rehabilitation and other health problems (Oo *et al.,* 2021); and 1 case of new onset glioblastoma that was still being treated with definitive treatment at the time of publication (Einstein *et al*., 2021).

There were 3 cases that ended with disabilities, 1 case of GBS as reported by Oo *et al.* (2021), characterized by worsening of bulbar function that required a ventilator, rendering the patient being classified into a functional disability scale 5 based on the GBS Disability Scale (Leonhard *et al.,* 2019); 1 case of neuralgic amyotrophy with leg paralysis as reported by Kim *et al.* (2021), where muscle strength was reduced to 0.5 (normal: 5); and 1 case of MFS-GBS overlap syndrome as reported by Dang and Bryson (2021) with a result of functional disability scale 3 based on the GBS Disability Scale(Leonhard *et al.,* 2019).

Most cases affecting nervous system were treated with IVIG, plasmapheresis, or high-dose steroid. This suggest an immune-mediated mechanism, either through formation of auto-antibodies that cause myelin damage (Oo *et al.,* 2021), immune-mediated inflammatory response that might attack the lumbosacral plexus (Kim *et al.,* 2021), molecular mimicry in vaccine components (which can be viral vectors) with self-antigens (Hsiao *et al*., 2021, Tan *et al*., 2021), genetic factor (Vogrig *et al.,* 2021), or possibly direct entry of viral vector vaccine to cerebral neuronal pathway, leading to an inflammatory reaction that eventually causes neuronal hyperexcitation and seizures (Aladdin and Shirah, 2021).

Adverse Effects Affecting the Integumentary System and the Immune System

As shown in Table 4, there were 8 types of effects on the integumentary system and immune system with a total of 16 cases. All cases were resolved, as shown in Table 3. They were 3 cases of Henoch-Schonlein vasculitis or IgA vasculitis (Naitlho *et al.,* 2021, Grossman *et al,* 2021, Sirufo *et al.,* 2021); 1 case of SJS (Elboraey and Essa, 2021); 1 case of TEN (Bakir *et al.,* 2021); 2 cases of reactivation of BCG vaccination scar (Mohamed *et al.,* 2021); 1 case of palms and soles itchiness (AL-Ansari *et al*., 2021); 3 cases of Herpes zoster infection (Muhie *et al.,* 2021, Thimmanagari *et al*., 2021); 4 cases of anaphylactic reaction (Abi Zeid Daou *et al.,* 2021, Lim *et al.,* 2021), and 1 case of breast implant seroma (Kayser *et al,.* 2021). Most cases affecting the integumentary and immune system were resolved by high-dose steroid therapy.

IgA vasculitis is possibly caused by the formation of an immune complex between the antigen in the vaccine and the antibodies already in existence in the human body (native antibodies), which triggers vasculitis, through the mechanism of the mannan-binding lectin pathway and alternative pathways in the complement system (Sirufo *et al*., 2021). Meanwhile, allergic reaction after the administration of the Covid-19 mRNA vaccine (Pfizer-BioNTech) might be due to the excipient in the vaccine, namely polyethylene glycol (PEG), used as a lipid stabilizer which wraps the mRNA that encodes the spike virus protein (US FDA 2022). PEG is known to have cross-reactivity with polysorbate, used as a stabilizer in many vaccines, including influenza vaccine (Song *et al.,* 2020). Based on this data, one might suggest patients previously exposed to polysorbate might have higher possibility of an allergic reaction. Indeed, one of the patients had received influenza vaccine in the same year as the Covid-19 vaccine (Abi Zeid Daou *et al.,* 2021).

Adverse Effects Affecting the Genitourinary System

There were 11 types of adverse effects related to genitourinary systems with a total 16 cases (Table 4). As further shown in Table 3, 11 were resolved, while 2 were ongoing cases. The remaining 3 cases

did not state the end result because there were no follow-up data, as shown in Table 3.

The resolved cases were 2 cases of new onset IgA nephropathy (Klomjit *et al.,* 2021); 1 case of MCD with ATN (Klomjit *et al.,* 2021); 1 case of NELL-1-associated membranous nephropathy (Klomjit *et al.,* 2021); 1 case of MPO-ANCA-associated vasculitis (Klomjit *et al.,* 2021); 1 case of relapse of MCD (Klomjit *et al.,* 2021); 1 case of relapse of FSGS (Klomjit *et al.,* 2021); 1 case of relapse of PLA2R-associated membranous nephropathy (Klomjit *et al.,* 2021); 1 case of new onset MCD (Thappy *et al.,* 2021); 1 case of AAV (Hakroush and Tampe, 2021); and 1 case of MCD with AKI (Hanna *et al.,* 2021).

The ongoing cases were 1 case of IgA nephropathy with acute interstitial nephritis (Klomjit *et al.,* 2021), for which the patient was given high-doses of steroid but failed to show improvement in the follow-up examination at the 3rd month; and 1 case of atypical anti-GBM nephritis that did not respond to prednisone and mycophenolate at follow-up examination of 1.5 month, and too early to know the response following cyclophosphamide regimen (Klomjit *et al.,* 2021).

Three cases without follow-up data were 1 case of new onset IgA nephropathy, 1 case of relapse of PLA2R-associated membranous nephropathy, and 1 case of relapse of IgA nephropathy (Klomjit *et al.,* 2021).

A possible mechanism of adverse effect on the genitourinary system might be the cross-reactivity of antibodies formed against the SARS-CoV-2 spike protein and nucleocapsid with self-human antigens, such as transglutaminase 3, extractable nuclear antigen, myelin basic protein, mitochondria, α-myosin, thyroid peroxidase, collagen, and claudin (Klomjit *et al.,* 2021). Due to its high immunogenicity and cross-reactivity, this vaccine might be able to activate the immune system non-specifically.

Adverse Effects Affecting the Visual Sensory System

As shown in Table 4, there were 8 types of effects on the visual sensory system with a total of 10 cases, of which 3 cases were resolved and 2 cases were ongoing, while the remaining 5 cases did not state the end result because there were no follow-up data, as shown in Table 3.

The resolved cases were 3 cases of corneal transplant rejection (Parmar *et al.,* 2021, Phylactou *et al.,* 2021). The ongoing cases were 1 case of venous stasis retinopathy (Girbardt *et al.,* 2021), which is marked by persistent symptoms (intraretinal hemorrhage) in 2 weeks follow-up and 1 case of bilateral PAMM and AMN (Vinzamuri *et al.,* 2021), which is marked by persistent symptoms in 3 weeks follow-up. Five cases without follow-up data were 1 case of branch retinal artery occlusion that was given aspirin (as antiplatelet) and simvastatin, 1 case of combined arterial and venous occlusion treated with intravitreal anti-vascular endothelial growth factor (anti-VEGF) in the left eye, 1 case of NAION, 1 case of cotton-wool spot, and 1 case of bilateral AMN (Girbardt *et al.,* 2021).

A possible mechanism of retinal transplant rejection after Covid-19 administration might be the activation of toll like receptors (TLRs) on the ocular surface which eventually led to rejection of the corneal graft via T helper 1 (Th1) cells (Ng *et al.* 2022). While occlusion of blood vessels in the retina might be caused by the same mechanism as the occurrence of vaccine-induced immune thrombotic thrombocytopenia/VITT (Ng *et al.* 2022), where vaccine administration induces the formation of anti-PF4 antibodies that will trigger blood clots. Meanwhile, AMN and PAMM might be caused by the presence of vasculitis in the deep capillary plexus triggered by vaccine administration (Vinzamuri *et al.,* 2021).

Adverse Effects Affecting the Musculoskeletal System

As shown in Table 4, there were 6 types of effects related to the musculoskeletal system, with a total of 8 cases. Of this number, 5 cases were resolved, 1 case was ongoing, 1 case ended up with disability and 1 case was death, as shown in Table 3.

The resolved cases were 3 cases of mild shoulder discomfort, quadrilateral space region inflammation, and edema in deltoid muscle (Eisenberg *et al.,* 2021); 1 case of severe polyarthralgia with severe functional impairment

(Chan and Irimpen, 2021); and 1 case of thrombotic thrombocytopenic purpura (Chamarti *et al.,* 2021).

One ongoing case was CRPS (Raman, 2021), characterized by severe pain and weakness for 2 months in the left hand. The patient was able to perform daily activities independently but was not fully recovered and she chose to switch to Ayurvedic treatment. This incident was probably caused by an injection technique error (Raman, 2021).

One case of SIRVA ended up with disability (Rodrigues *et al.,* 2021), characterized by persistent pain in the right shoulder for 8 weeks, reduced range of motion, and inability to perform daily activities. This incident was probably caused by an injection technique error. The patient had received topical diclofenac cream; a combination of caffeine, carisoprodol, and diclofenac sodium; and ice packs for 5 days, but the symptoms persisted, the patient was then given oral prednisone, vitamin D supplements and physical therapy (Rodrigues *et al.,* 2021).

One case of fatal rhabdomyolysis was reported (Ajmeera, 2021). The patient was a woman in her 80s with clinical history of rheumatoid arthritis, hyperlipidemia, asthma and cerebrovascular accident. The patient had also been taking statins for years as one of her routine treatments. She experienced symptom onset 2 days after receiving the second dose of the mRNA-type Covid-19 vaccine and her condition continued to decline until she finally suffered cardiac arrest and died. Risk factors that may worsen the patient's condition are taking statins, autoimmune disease (rheumatoid arthritis) and a family history of autoimmune (in maternal grandmother) (Ajmeera, 2021).

Adverse Effects Affecting the Endocrine System

As shown in Table 4, there were 3 cases related to the endocrine system. All cases were resolved, as shown in Table 3. One case of subacute of subacute thyroiditis were resolved within 7 weeks with oral prednisone and oral propranolol (Soltanpoor and Norouzi, 2021). One case of pheochromocytoma multisystem crisis was resolved with mass resection and adrenalectomy (Haji *et al.,* 2021). The patient had experienced complications, but finally recovered after about 2 months (Haji *et al.,* 2021). One case of thyrotoxicosis was resolved within 8 weeks with NSAID administration (Jeeyavudeen *et al.,* 2021).

Adverse Effects Affecting the Respiratory System

As shown in Table 4, 1 case of acute eosinophilic pneumonia was reported (Miqdadi and Herrag, 2021). The patient was given amoxicillin/clavulanic acid for 2 days but there was no improvement, then high-dose corticosteroids (methylprednisolone), nebulization with salbutamol and ipratropium, and prophylactic antibiotics (third generation cephalosporins and quinolones) were given and he finally recovered within 5 days. The mechanism of pneumonia in this case might be due to an allergic reaction. This was indicated by the rapid onset, which was 5 hours after the administration of the viral vector Covid-19 vaccine (AstraZeneca) and the patient's good response to corticosteroid administration. One of the substances that might be an allergen contained in the vaccine formulation was polysorbate 80 (Cabanillas and Novak, 2021).

Strengths, Limitations, And Implication Of This Study

Strengths: This study extracts essential data in individual cases, such as patient demographics, type of vaccine, post-vaccination effects, medical interventions, and end results. This study also summarizes its possible mechanism of actions of the adverse effects.

Limitations: This study only includes case reports and case series, does not include higher studies so that the prevalence cannot be counted. The authors intended to elaborate/assess each case more detailed rather than knowing its prevalence and types of adverse effects which might be offered by the cross-sectional studies. This study only used one database (PubMed) and ignores grey literature which may contain data outside published literature. The authors assumed that all articles included in this study (which indexed in PubMed database) have undergone peer-review process that maintained its validity by one of three means: its respected journal stated that articles should conform with CARE case report guideline, it had its own modified checklist for case report articles, or

it encouraged its article to refer to CARE case report guideline. Furthermore, some cases did not mention its follow-up results.

Implications: Most cases were treated by inflammatory-related interventions which indicate the vaccines did affect/regulate the immune systems however its immunogenicity varies in larger group/real-world settings/conditions beyond clinical trials, so we suggest healthcare workers to inform participants/patients regarding its safety or adverse effects that might occurs and to strengthen pharmacovigilance systems.

CONCLUSION

A total of 118 case reports of adverse reactions after Covid-19 vaccination were found. The most widely used vaccine was mRNA (76 cases; 64.41%) and the least was inactivated virus (3 cases; 2.54%). The most reported cases were those affecting the cardiovascular/circulatory/lymphatic system (42 cases; 35.59%) and the least were those affecting the respiratory system (1 case; 0.85%). The majority of cases (89 case; 75.42%) could be resolved, 4 cases (3.39%) with disabilities and 2 cases (1.69%) of death were reported. Medical intervention used to treat adverse effects were mostly inflammatory response-related intervention.

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