Review

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Review

A Landscape on Disorders Following Different COVID-19 Vaccination: A Systematic Review of Iranian Case Reports

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Abstract: Vaccination against SARS-CoV-2 has significantly contributed to the recent pandemic control. COVID-19 vaccines are available with different platforms and the primary clinical trials results presented acceptable safety profile of the approved vaccines. Nevertheless, the long-term assessment of the adverse events or rare conditions need to be investigated. The present systematic review, aimed at classification of Iranian case reports following COVID-19 immunization. To achieve this goal, the related published case reports were explored via PubMed, Web of Science and Google scholar according to PRISMA guideline and available up to 14th Dec, 2022. Out of 437 explored studies, the relevant data were fully investigated which totally led to 40 studies including 64 case reports with a new onset of a problem. The cases were then classified according to the various items such as the type of adverse event manifestations and COVID-19 vaccine. The reported COVID-19 vaccines in the studied cases included Sinopharm, AstraZeneca, and COVAXIN. The results showed that the adverse events presented in 8 different categories from which cutaneous problems accounted as the most prevalent manifestations (43.7%) in which rare diseases were also screened such as Steven-Johnson syndrome, Morphea and Toxic Epidermal Necrolysis. Notably, almost 60% of the cases had no comorbidities. Moreover, the obtained data revealed nearly half of the incidences occurred after the first dose of injection and the mean duration of improvement after the symptom onset was 18.72±24.69 days. 73% of all the cases were either significantly improved or fully recovered. Although the advantages of COVID-19 vaccination is undoubtedly significant, the high risk individuals including those with a history of serious disease or comorbidities immunodeficiency conditions should be vaccinated with the utmost caution.

Keywords: COVID-19; vaccination; adverse event; case report; Iran

Introduction

COVID-19 as the most recent global pandemic typically presents as lower respiratory tract infection which may lead to severe symptoms (1, 2). Fortunately, vaccination against COVID-19 was explored at the right time and led to fast outcomes through different platforms and hopefully pandemic control (3, 4). Nevertheless, booster shots are still recommended as the immunity wanes over the time and new variants are capable to escape from immune system (5, 6).

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From another point of view, the quick procedure of vaccine development could possibly have lately unsolicited events beside the immunity protection. Many studies have shown SARS-CoV-2 manifestations through which the virus affect body in various presentations even in a late episode (7, 8). As the number of vaccinated individuals grows up, the knowledge of possible and probable vaccine impact develops through case reports and long-term safety studies (9, 10).

Although the exact mechanism through which the vaccine components can manipulate human body is not clear yet, the cumulative and comparative data would bring sufficient data especially by the follow-up outcomes.

Comparison of advantages and disadvantages of COVID-19 vaccines has shown that it is still recommended. It has been assumed that there will be more in cardiovascular diseases due to spike proteins encoded in vaccines (11, 12). Furthermore, there is a possible threat of unknown organ hurt caused by the immunization which is still hidden.

In the present study, analysis of documented case reports of Iranian individuals who developed any new disorders following administration of either COVID-19 vaccines was aimed.

Methodology

The present study was conducted according to preferred reporting items for systematic reviews and **meta**-analyses (PRISMA) guideline (13).

Three databases, PubMed, Web of Science and Google scholar, were explored and all the relevant data available up to 14th Dec, 2022 were collected. The relevant data were targeted with terms of: “COVID-19 vaccine”, “SARS-CoV-2”, “case reports”, “adverse events” and “Iran”.

In order to exclude the irrelevant data, titles and abstracts were initially screened. At the next step, the full text of the articles were evaluated regarding the eligibility of inclusion in the study. The data including the case reports after COVID-19 disease were also removed. Moreover, only the new onsets were considered which means the cases who had a history of the exactly same disorder were not considered (Figure 1). The following data were extracted according to a valid datasheet including: age, gender, vaccine type, date of injection, date of disorder appearance, duration of the symptoms, type of the developed disorder, medical history of the case, hospitalization, response to the treatment, follow-up and outcomes.

Results

The initial search yielded 437 studies. After duplication removal, 250 papers were investigated regarding the titles and abstracts from which 128 articles were excluded according to the eligibility of the criteria including the case reports which had the same medical history or those with insufficient data. Eventually 40 manuscripts met the criteria of the systematic review.

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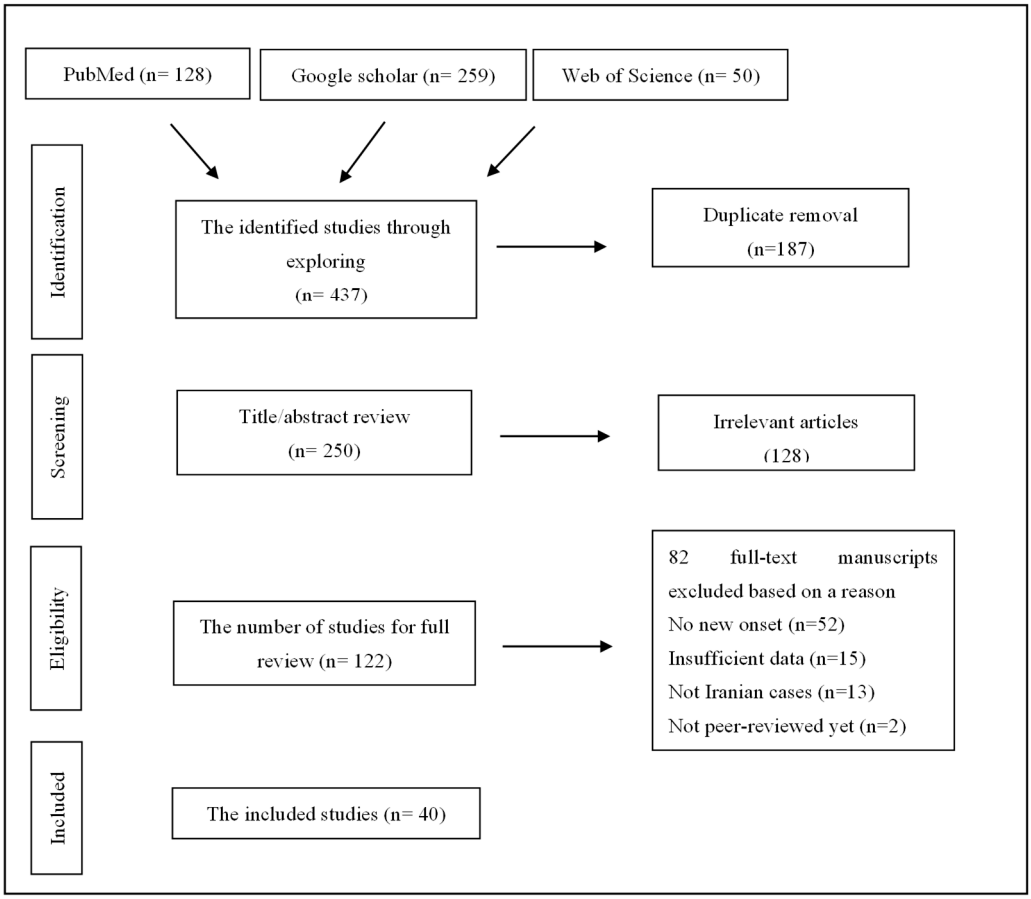

Figure 1. The review flowchart based on PRISMA.

A total of 64 cases including 31 females and 33 males with a mean age of 47.67±17.69 and a range of 18 to 91 were investigated from whom 60% had no remarkable medical history. The previous history of COVID-19 was rare among the cases and all the COVID-19 PCR tests were negative at the time of manifestation (Table 1).

The reported COVID-19 vaccines in the studied cases included Sinopharm (n=36), AstraZeneca (n=22), Sputnik (n=5) and Bharat (n=1).

The mean duration between the vaccination and any appeared event was 9.3±9.11 days. Of 64 cases, 52 ones experienced a type of manifestation post-first dose, 10 post-second dose and only 2 after the booster shot.

COVID-19 vaccine triggered different manifestations from which cutaneous disorders were spotted as the most frequent one accounting for 43.7% (n=28) followed by neurologic problems in 25% of the cases (n=16). Other unsolicited events included blood/vessel involvement (n=6), cardiovascular involvement (n=5), ocular disorders (n=4), liver disorder/failure (n=2), graft rejection (n=2) and one metabolic disorder (Figure 2). The mean duration of improvement after the symptom onset was 18.72±24.69 days.

Cutaneous involvement presented in various forms such as alopecia, lichen planus, rash, dermatitis and stromal keratitis. Notably, the dermal manifestation occurred equally on both men and women among whom only one person had a history of COVID-19. The other interesting finding is that rare diseases were also screened such as Steven-Johnson syndrome, Morphea and Toxic Epidermal Necrolysis (TEN).

In addition to type of disorders, we also evaluated the recovery time as well. To achieve that, the provided data were categorized to 6 outcomes as resolved, significant improvement, partial improvement, under treatment, not-treated and expired. Based on the outcome statement of the manuscripts, of 64 incidences, 13 were resolved, 33 were significantly improved and 10 were partially

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improved. 4 cases were under treatment, one remained untreated and 2 cases expired. Three studies did not mention the outcome. Therefore, 73% of all the cases were either significantly improved or fully recovered from the incidence.

According to the available statements, 20 cases were hospitalized and 22 ones were recommended to be followed-up in the schedule varying from 14 days to six months.

Table 1. The categorized adverse events manifestations following COVID-19 vaccines in Iran.

Case no.	Type of disorder	Age	Gender	Comorbidity	Covid-19 test/history	Vaccine type	Time of incidence	Ref.
Cutaneous involvement								
1	Extensive rash and edema	77	Female	Hypertension	Negative	AstraZeneca	2 days after the 1st dose	(14)
2	Radiation Recall Dermatitis	50	Female	History of breast cancer and radical mastectomy	Not stated	Sinopharm	1week after the 2nd dose	(15)
3	Erythemato-violaceous and sclerotic lesions	70	Female	-	Negative	AstraZeneca	2 days after the 1st dose	(16)
4	Panniculitis	40	Female	-	Not stated	Sputnik	13 days after the 1st dose	(17)
5	Alopecia areata	23	Female	-	Not stated	AstraZeneca	1 week after the 1st dose	(18)
6		74	Male	Fatty liver	Not stated	Sinopharm	2 days after the 2nd dose	(19)
7		37	Male	-	Not stated	Sinopharm	6 days after the both doses	(19)
8	Herpes simplex	63	Female	Rheumatoid arthritis	Not stated	Sinopharm	7 days after the 2nd dose	(20)
9	Toxic Epidermal Necrolysis (TEN)	76	Male	Atorvastatin 10 mg/day taken for several years	Not stated	Sinopharm	1 day after vaccination	(21)
10		71	Male	-	Not stated	Sinopharm	10 days after the 1st dose	(19)
11	Pemphigus vulgaris (PV)	76	Female	Diabetes mellitus, hyperlipidemia, and ischemic heart disease	Not stated	Sinopharm	1 month after the 2nd dose	(22)
12		30	Female	-	Not stated	Sinopharm	16 days after 1st dose	(19)
13	New-onset lichen planus (LP)	52	Female	-	Positive	Sinopharm	1 week after the 2nd dose	(23)
14		45	Female	Hypertension	Not stated	Sinopharm	14 days after the 1st dose	(19)
15		40	Male	-	Not stated	Sinopharm	10 days after the both	(19)
16		45	Male	-	Not stated	Sinopharm	7 days after the both	(19)
17		45	Male	-	Not stated	AstraZeneca	7 days after the 1st dose	(19)
18		49	Female	-	Not stated	Sinopharm	10days after the 1st dose	(19)
19	Psoriasis exacerbation	50	Male	Arthritis	Not stated	Sinopharm	4 days after the first dose, 6 days after the 2nd dose	(19)
20	Bullous pemphigoid	85	Female	-	Not stated	Sinopharm	20days after the 1st dose	(19)
21		91	Male	-	Not stated	Sinopharm	19 days after the 1st dose	(19)
22	Cutaneous vasculitis	45	Male	-	Not stated	Sinopharm	2 days after the 1st dose	(19)
23	Pytriasis rosea	26	Male	Hypertension, diabetes mellitus	Not stated	Sinopharm	14 days after the booster	(19)
24	Herpes zoster	60	Female	-	Not stated	Sinopharm	6 days after the 1st dose	(19)
25	Urticaria and erythema multiform	31	Male	-	Not stated	Sinopharm	11 days after the 2nd dose	(19)
26		32	Female	-	Not stated	AstraZeneca	20 days after the 1st	(19)
27	Morphea	35	Female	Hyperlipidemia, diabetes	Not stated	AstraZeneca	10 days after the 1st	(19)

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28	Steven-Johnson syndrome	63	Female	Mild plaque-type psoriasis type II diabetes mellitus	Not stated	Sinopharm	24h after vaccination	(24)
Neurologic involvement								
29	Facial Paresis	34	Female	Migraine attacks (under treatment)	Not stated	Sputnik V	1 day after the 1st dose	(25)
30	Encephalopathy	27	male	-	Not stated	AstraZeneca	8 days after the 1st dose	(26)
31		56	Female	-	Negative	AstraZeneca	2 days after the 1st dose	(14)
32	Transverse myelitis	31	Female	-	Negative	AstraZeneca	3 weeks after the 1st dose	(27)
33	Acute vestibular neuritis	51	Male	-	Negative	AstraZeneca	11 days after the 1st dose	(28)
34	Bell's palsy	27	Female	-	Negative	Sputnik V	3-5 days after the 1st dose	(29)
35		58	Male	Controlled diabetes mellitus	Not stated	Sputnik	10 days after the 1st dose	(29)
36	Thalamic hemi-chorea	72	Male	History of laparoscopic cholecystectomy	Negative	AstraZeneca	9 days after the 1st dose	(30)
37	Guillain-Barre syndrome	60	Male	Controlled hypertension and hypothyroidism	Negative	Sinopharm	20 days after the booster	(31)
38		46	Male	-	Negative	AstraZeneca	3 days after the 2nd dose	(32)
39		36	Male	-	Negative	Sinopharm	5 days after the 1st dose	(32)
40		32	Male	-	Negative	Sinopharm	14 days after the 1st dose	(32)
41		68	female	-	Negative	AstraZeneca	4 days post the 2nd	(33)
42	Aseptic meningitis	26	Female	-	Negative	AstraZeneca	A few hours the 1st dose	(34)
43	extensive myelitis	71	Male	Diabetes mellitus, hypertension and Ischemic Heart Disease	Not stated	Sinopharm	5 days after the 1st dose	(35)
44	Acute disseminated encephalomyelitis	37	Male	-	Negative	Sinopharm	few days to one month after the 1st dose	(36)
Vessel/Blood involvement								
45	Thrombotic thrombocytopenia	70	Female	Diabetes mellitus type 2, hypertension, and coronary artery disease	Not stated	AstraZeneca	1day after the 1st dose	(14)
46	Vasculitis	55	Female	controlled sarcoidosis	Not stated	Sinopharm	3 days after the 1st dose	(37)
47	Cerebral venous sinus thrombosis	55	Female	Hypertension/ a surgery history of hysterectomy 10 years ago	Negative	AstraZeneca	After the 1st dose	(38)
48	Acquired thrombotic thrombocytopenic purpura (aTTP)	22	Female	-	Negative	AstraZeneca	3 weeks after the 1st dose	(39)
49	Purpuric dermatosis &lymphocytic vasculopathy	53	Female	History of treated breast cancer	Not stated	Sinopharm	9 days after the 1st dose	(40)
50		50	Male	-	Not stated	Sinopharm	2 months after vaccination	(40)
Cardiac involvement								
51	Myocarditis	29	Male	-	Negative	Sputnik V	2days after the 2nd dose	(41)
52		26	Male	-	Negative	AstraZeneca	4 days after the 2nd dose	(42)
53		32	Female	-	Negative	AstraZeneca	3 days after the 1st dose	(43)
54	Atrioventricular block	65	Male	-	Not stated	Sinopharm	A few days after vaccination	(44)
55	Long QT interval and syncope	70	Male	Hypertension (HTN) and diabetes mellitus under medical treatment	Negative	AstraZeneca	3days after the 1st	(45)
Ocular involvement								

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56	Paracentral acute middle maculopathy	38	Male	-	Negative	Sinopharm	2 weeks after vaccination	(46)
57	Herpetic endotheliitis and stromal keratitis	30	Female	Hypothyroidism	Not stated	Sinopharm	2weeks after vaccination	(47)
58	Intracranial hypertension and papilledema	32	Male	-	Not stated	Sputnik V	3 days after the 1st dose	(48)
59	Acute macular neuroretinopathy	18	Female	-	Negative	Sinopharm	5 days after the 1st dose	(49)
Liver involvement								
60	Fulminant hepatitis	35	Male	Controlled psychological problems	Not stated	AstraZeneca	8 days after the 1st dose	(50)
61	Acute liver failure	34	Male	-	Not stated	AstraZeneca	2 days after the 1st dose	(51)
Thyroid disorder								
62	Subacute thyroiditis	34	Female	-	Negative	COVAXIN	11 days after the 1st dose	(52)
Graft rejection								
63	Corneal Graft Rejection	36	Female	Penetrating keratoplasty (PKP) secondary to herpes simplex keratitis (HSK)	Not stated	Sinopharm	7 days after the 1st dose	(53)
64		54	Female		Not stated	Sinopharm		

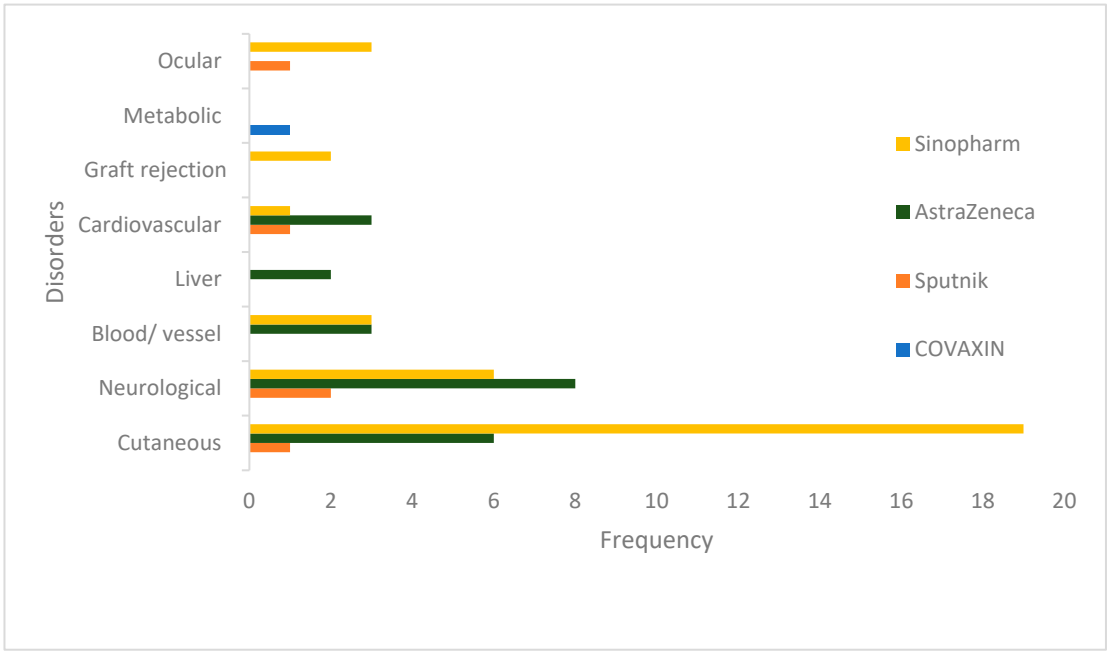

Figure 2. COVID-19 vaccines and their potential association with disorders in case reports.

Discussion

Massive vaccination campaigns have been launched Since December 2020, applying mRNA vaccines and also the viral vector-based vaccine as well as inactivated viral-based and recombinant protein vaccines. By the end of January 2023, more than 5 billion individuals were fully vaccinated (54). Thus, there is an increasing rate of reports over the adverse events associated with the administrated vaccines in real world. General symptoms which have been normally screened includes weakness, fever/chills, body pain, headache and local injection-site reactions. These symptoms are usually transient and do not normally need to be treated with specific medicine care.

Herein, we discussed 64 cases who experienced unsolicited events after vaccinating against COVID-19. The applied vaccines included viral-vector and inactivated virus-based vaccines. We tried to select the case reports with new onset of the symptoms in whom the pre-existing comorbidity was not as same as the triggered adverse events. Various disorders were captured induced by different vaccines suggesting that the type of a specific regimen is not the only factor in outcomes. Moreover,

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there is not enough clues to support the triggered manifestations and their association with the applied vaccine. However, the healthy individuals who did not have any remarkable medical history and experienced serious events suggest that this potency of COVID-19 vaccine must be considered.

The common adverse events of AstraZeneca vaccine were pain at the injection site, fever, lethargy, muscle pain and headache which were mostly screened after the first dose of vaccine (55). Moreover, irritability, nausea, myalgia, and chills some hours after vaccination with AZD1222 were reported in Nepal (56). In addition to common adverse events, severe disorders were captured as postural drop in blood pressure, abdominal cramps, syncope and urticaria (57).Fever/chills, general discomfort, headache arthralgia, myalgia, asthenia, tenderness were among the common side effects following Sputnik V COVID-19 Vaccine which seemed to be more frequents after the second dose (58, 59). In this review, we found that AstraZeneca mostly led to neurological incidences including encephalopathy (14), acute vestibular neuritis (28) and Guillain-Barre syndrome (32). Although the safe administration of vaccines is a crucial factor many unusual events following AstraZeneca vaccine have been reported. The Concern about neurological abnormalities regarding COVID-19 vaccines firstly rose in 2020 when some cases of Guillain-Barré syndrome and transverse myelitis were screened post-Oxford/AstraZeneca vaccine (60, 61). Furthermore, in the investigated cases in this review, AstraZeneca has been the only cause of liver disorder in forms of Fulminant hepatitis (50) and acute liver failure which led to death in both cases (51). Liver injury following COVID-19 vaccination is also investigated in a systematic review on individuals who got to Moderna (mRNA)–1273, Pfizer-BioNTech BNT162b2 mRNA or ChAdOx1 nCoV-19 vaccine. Nevertheless in those cases, pre-existing comorbidities was common as 69.6% such as liver disease. The mortality rate due to live disorders was reported 4.3% (62).

According to conducted studies in China, inactivated viral-based vaccines led to adverse events including injection site pain, lethargy and muscle pain 15.6% after the first and 14.6% after the second dose among the healthcare workers. The most common is pain at the injection site, followed by fatigue, muscle pain, and headache (63, 64). Furthermore, two serious events as multiple sclerosis and emesis were also recorded with hospitalization requirement (65, 66).

In the present review, Sinopharm vaccine resulted in corneal graft rejection in to cases a week after the first dose of injection (53).In a study by Shah AP et al., four cases with a history of keratoplasty developed rejection after being vaccinated with mRNA-1273 (67). This incidence has also been reported after adenovirus vector (AZD1222) and mRNA (BNT162) vaccines (68).

A systematic review also showed that Cornea rejection was the most reported organ rejection after vaccination against COVID-19, followed by kidney and liver rejections (69).

Dermal abnormalities have been the most frequent reported incidences after Sinopharm vaccine among which new-onset lichen planus (LP) was observed in 6 cases (23). Nevertheless, rare conditions were also screened such as Toxic Epidermal Necrolysis (21), Morphea (19) and Pemphigus vulgaris (22). Notably, of 28 skin disorders in the reported cases from Iran, 20 cases got Sinopharm vaccine. The other study from Iran evaluated the cutaneous reactions post-COVID-19 vaccination which presented that most of the individuals showed symptoms after injection of AstraZeneca, Sinopharm, Sputnik V, and COVAXIN vaccines (70).

Herpes zoster has been reported in case series and has also been documented in the Center of Disease Control following COVID-19 vaccines (VAERS). There are more than 1000 cases with mRNA vaccine-triggered herpes zoster in VAERS, mostly aged over 60 (71). We also found a reported case of Herpes Zoster in a 60-year-old healthy woman 6 days after the first dose of Sinopharm vaccine (19). It has been suggested that molecular mimicry between the human components and vaccine-induced proteins could lead to pathological autoantibodies generation and hence, autoimmunity accordingly (72).

Neurological disorders also counted a quarter of the investigated cases mostly with Guillain–Barré syndrome (32) and Bell's palsy caused (29) by AstraZeneca, Sinopharm and Sputnik vaccines. Although the most incidences were captured post-first dose, a 60-year-old man presented Guillain–Barré syndrome 20 days after the Sinopharm booster shot (73). The correlation between Bell's palsy and vaccinations has been introduced previously such as influenza H1N1 monovalent vaccine and

intranasal inactivated influenza vaccine (74, 75). Similar to other unknown mechanisms of vaccine induced problems, precise pattern of neurologic disorders is still under question. Some hypothetical thoughts though propose that autoimmune phenomenon as a result of host molecules mimicry with the vaccine antigen could activate auto-reactive T cells (76).

Blood/vessels involvement were also reported in 6 cases as vasculitis, thrombotic thrombocytopenia, Cerebral venous sinus thrombosis, acquired thrombotic and lymphocytic vasculopathy caused by Sinopharm and AstraZeneca (14, 38-40, 77). Notably, all the cases presented the manifestation after the first dose of vaccination. A review study showed that thrombotic complications occurred 5–25 days post-first dose of AstraZeneca vaccinated individuals in which the thrombosis site was mostly in cerebral veins (78). Although the exact mechanism of the events is not well understood, the pre-existing antibodies like heparin-PF4 antibody in the cases might give rise to the manifestations (79) . In addition, vasculitis precipitation has been also detected after other vaccines against hepatitis B virus (HBV), influenza virus and human papillomavirus (HPV) (80).

Although the discussed disorders have been screened post-vaccination, it is suggested that hot immune responses are strong potential cause of the events. It is to say that, anti-spike immune responses might be linked to post-vaccine syndromes as all the vaccines against COVID-19 encode the whole or a part of spike protein. In addition to spike protein, anti-idiotypic antibodies can bind to the ACE-2 receptor as well (81). Furthermore, the generated autoantibody stemming from molecular mimicry and independent immune-dysregulation may both contribute to a symptom onset (82).

Conclusions

The present review showed that various unsolicited adverse events have been captured as case reports in Iran. Interestingly, all the vaccine platforms could result in similar unsolicited events. Although, clinical trials provide safety data, the long-term evaluation of newly launched vaccines are essential to keep the public trust balanced.

COVID-19 has been the most recent mass vaccination program due to the broad range of infection world-wide. Thus, it is not far from view to face some rare disorders or late onset of a disease. Considering the advantage of the vaccination against SARS-CoV-2 which eventually led to the chaos management globally, the number of unsolicited AEs are not significant. However, the collective data from different populations would result in a better perspective for further vaccination program. The high risk individuals including those with a history of serious disease or comorbidities and those with immunodeficiency conditions should be vaccinated with the utmost caution.

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Conflicts of Interest: All the authors declare that they have no conflict of interest.

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