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Original Research Article

## Investigating the possible neurological side effects follow the COVID-19 vaccine

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### ABSTRACT

**Background:** With the widespread of COVID-19 vaccination around the world, there are many case reports which referred to the neurological complications following vaccination. However, due to the lack of more information about this, especially in our country Iran, the aim of this study was to investigate the possible neurological side effects of the COVID-19 vaccine in patients.

**Methods:** This cross-sectional study was conducted on 1046 people injecting various types of COVID-19 vaccines, including Sinopharm, AstraZeneca, Sputnik V, CovIran-Barekat, Covaxin, SpikoGen, and PastoCovac plus, who were registered in the health system due to vaccine complications. These people were evaluated in terms of the overall incidence rate of neurological complications, types of neurological complications, and the relationship between the occurrence of neurological complications and the type of vaccine.

**Results:** Of all patients, 589 (56.3%) were female and 457 (43.7%) were male, and most of them were from the age group of 60 years and older (43.8%). 247 people (23.6%) had neurological complications that most of them related to the headache (16.6%).

**Conclusions:** The results of this study showed that the neurological side effects associated with the covid-19 vaccination were in mild level and most of them were seen in AstraZeneca vaccine and so, in line with the recommendation of the European medicines agency, the injection of this vaccine should be done with caution.

**Keywords:** COVID 19, Vaccine, Neurological side effects

### INTRODUCTION

In December 2019, doctors at a hospital located in the Chinese city of Wuhan noticed unusual cases of patients with pneumonia. Subsequent investigations showed that the origin of this disease was from the seafood, poultry and live animal market located in the city of Wuhan, located in Hubei province in central China.<sup>1</sup> After widespread speculation about the causative agent of this disease, the Chinese center for disease control and prevention (CDC) finally confirmed the report published by the Wall Street

Journal and on January 9, 2020, the causative agent of this disease was a new coronavirus called nCoV-2019 announced.<sup>2</sup>

The 2SARS-CoV virus replicates efficiently in the upper respiratory tract. It is believed that the novel coronavirus 2019 is transmitted through droplets, close contact, aerosol and fecal-oral transmission, and patients can transmit the virus to other people during the incubation period.<sup>3</sup> Research for a vaccine has begun in a number of countries, including China, Germany, and the United States. The measures taken in the past in order to prepare a vaccine

against coronavirus diseases such as acute respiratory syndrome and Middle East respiratory syndrome, had increased the information about the structure and function of coronaviruses.<sup>4-6</sup> This information helped scientists to design and produce multiple and innovative vaccines to deal with COVID-19 at a higher speed than usual.<sup>7</sup> Until January 2021, 69 proposed vaccines entered the clinical trial stage, including 43 vaccines in phases 1 and 2 and 26 vaccines in phases 2 and 3. In phase 3, several proposed vaccines were reported to be 95% effective in preventing the spread of COVID-19. As of April 2021, 17 vaccines have received approval for injection and general use from at least one country. These vaccines include 2 RNA vaccines, Pfizer's COVID-19 vaccine and Moderna's COVID-19 vaccine, 8 inactivated corona virus vaccines, Kovaxin, Koviran Barkat, QazVac, Minhai-Kangtai, QazVac, WIBP-CorV and BBIBP-Kroi. 6 viral vector vaccines are Sputnik V, Sputnik Light, Johnson & Johnson, Convidecia and Oxford-Astrazenka and 2 peptide vaccines EpiVacCorona and RBD-Dimer.<sup>8</sup> Many countries have given priority to receive the vaccine to high-risk population groups such as the elderly and vulnerable people such as medical staff. According to official statistics, until December 12, 2022, more than 13 billion doses of vaccine have been injected into people around the world.<sup>9</sup> Vaccination for the covid-19 disease in Iran started on 21 February 2019 with the approval and import of the Sputnik 5 vaccine from Russia. The purchase of Oxford-Astrazenka vaccine under the title of Swedish vaccine was announced on 17 February 2019. The first Iranian COVID-19 vaccine that reached the clinical trial stage was developed by Barkat Pharmaceutical Group and Shafa Daru Company under the name "Kovu Iran Barkat". According to the information published by the World Health Organization, this vaccine is made with inactivated virus technology. On May 5, 1400 Barkat vaccine passed clinical phase 3.<sup>10</sup> The side effects of the vaccine are completely normal and this indicates the proper functioning of the vaccine; But not all vaccine recipients show side effects. Short and mild side effects include sensitivity to touch, swelling or redness of the injection area, headache or muscle pain, joint pain, fever, chills, nausea or vomiting, swelling of the axillary glands or neck on the injection side.<sup>11</sup>

Another side effect that has recently received attention is Vaccine Induced Prothrombic Immune Thrombocytopenia (VIPIT), which if it occurs in the brain is called Cerebral Venous Thromboembolism (CVST). This complication is very similar to the complication that occurs after the injection of HIT (Heparin induced Thrombocytopenia) in the body. In this complication, the platelets are damaged, and with the decrease in their number, bleeding and clot formation occur. Symptoms that can indicate VIPIT are: shortness of breath, chest pain, leg swelling, abdominal pain, neurological symptoms such as severe and persistent headache or blurred vision, and petechiae around the injection site. These complications occurred mostly in women under 60 years of age and within 5 to 28 days after receiving the vaccine. The prevalence of this complication

is reported to be 1 in 250,000, which is very small compared to the complication of blood clots following the use of contraceptives (one in a thousand) or CVST caused by corona (8 times more than corona vaccination).<sup>12</sup> So far, no study has been conducted on the neurological side effects of the COVID-19 vaccine in the northwestern region of the country, which was the aim of this study.

## METHODS

### Study design and participants

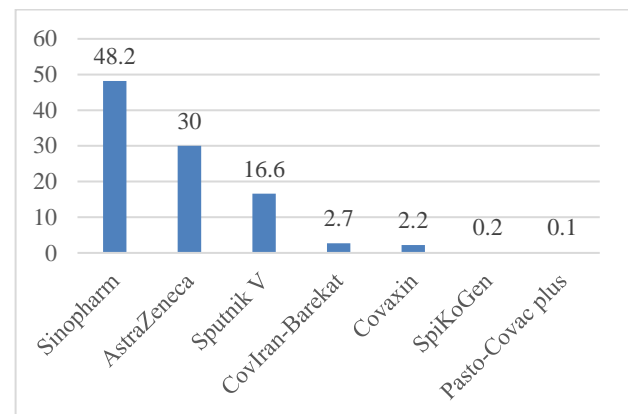
The current study was a cross-sectional study that was conducted on a number of 1046 people who suffered from various complications following the injection of the COVID-19 vaccine. The required information includes sex, age, year of vaccination, month of vaccination, region of residence, type of vaccine, time of vaccination, occurrence or non-occurrence of neurological complications caused by vaccination, type of neurological complications, and the interval between vaccination and the occurrence of complications. It was extracted from the patient registration system.

### Statistical analysis

After collecting information for all patients, data analysis was done in SPSS software version 25. Quantitative variables were presented as mean and standard deviation, and qualitative variables were presented as frequency and percentage. In order to determine the risk of neurological complications according to the type of vaccine, logistic regression analysis was used. A significance level of 0.05 was considered.

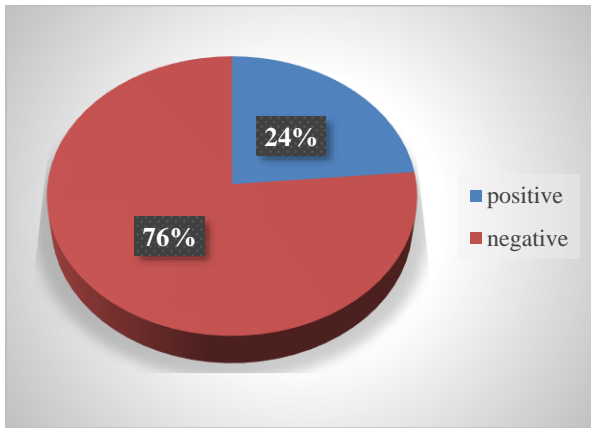
## RESULTS

Vaccine was administered in 29 cases (2.8%) in 2019, in 965 cases (92.3%) in 2010, and in 52 cases (5%) in 2011. In most cases, the vaccine was administered in the spring months (55.2% of all cases). 589 people (56.3 percent) were female and 457 people (43.7 percent) were male.

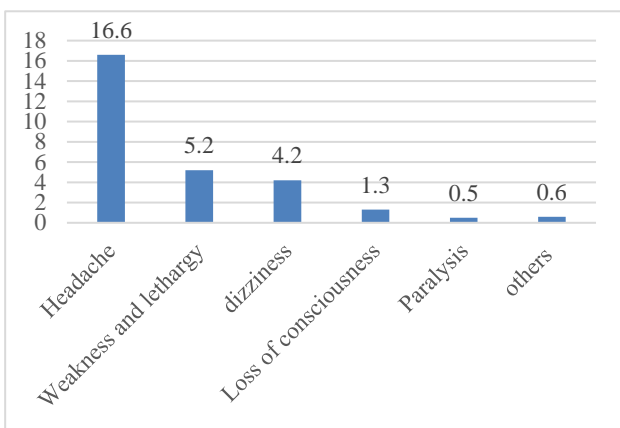


**Figure 1: Frequency of the examined people based on the type of injectable vaccine.**

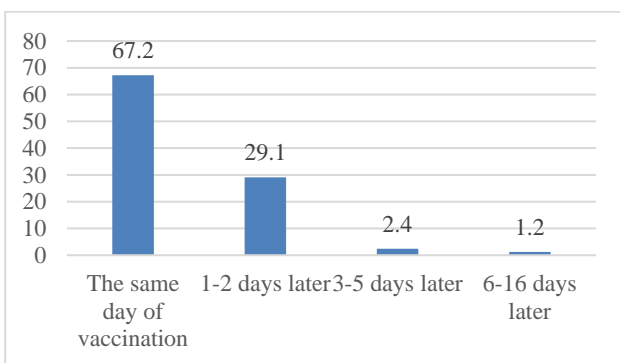
Most of the people injecting the vaccine belonged to the age group of 60 years and older (458 cases, 43.8 percent). The residence of most of the people injecting the vaccine was in rural areas (571 people, 54.6%).



**Figure 2: Frequency of the examined people based on the incidence of neurological complications caused by vaccine injection.**



**Figure 3: Frequency of the examined people based on the type of neurological complication.**



**Figure 4: Frequency of the interval between the injection of the vaccine and the occurrence of complications.**

The type of vaccine in 504 cases (48.2%) was Sinopharm made in China and 314 cases (30%) was AstraZeneca

made in the UK-Sweden (Figure 1). 469 people (44.8%) received the vaccine for the first time, 163 people (15.6%) for the second time, and 51 people (4.9%) for the third time. The vaccination schedule was not recorded for 363 people (34.7%). A total of 247 people (23.6 percent) of the vaccine recipients had neurological complications (Figure 2). The types of neurological complications seen included headache in 174 people (16.6 percent) and weakness and lethargy in 54 (5.2%) people (Figure 3). In 247 people who had a neurological presentation, the interval between the injection of the vaccine and the occurrence of complications in 166 people (67.2%) was on the same day of injection and 72 people (29.1%) was 1 to 2 days after the injection (Figure 4).

Statistically significant differences were not seen in terms of the occurrence of serious neurological complications (limb paralysis, limb numbness, Bell's palsy, and the possibility of stroke) in people receiving different vaccines, but there was a difference in terms of the incidence of headache, dizziness, loss of consciousness and weakness and lethargy. There was significant (Table 1). In general, the relative risk of neurological complications in people who received Sputnik vaccines (OR=2.357 and  $p<0.001$ ), AstraZeneca (OR=1.455 and  $p=0.032$ ), and Bharat (OR=4.105 and  $p=0.001$ ) was significantly more than people who received Sinopharm vaccine. The relative risk of headache in people who received Sputnik (OR=2.052 and  $p=0.001$ ) and AstraZeneca (OR=1.691 and  $p=0.007$ ) vaccines was significantly higher than people who received Sinopharm vaccine. had received the relative risk of weakness and lethargy in people who received Sputnik (OR=3.506 and  $p<0.001$ ) and Bharat (OR=5.684 and  $p=0.004$ ) vaccines was significantly higher than those who received had received Sinopharm vaccine. The relative risk of vertigo was significantly higher in people who had received Sputnik (OR=2.703 and  $p=0.007$ ) and Bharat (OR=12.533 and  $p<0.001$ ) vaccines. He was one of the people who received the Sinopharm vaccine. The relative risk of loss of consciousness in the people who received the Barkat vaccine (OR=7.440 and  $p=0.005$ ) was significantly higher than the people who received the Sinopharm vaccine. were (Table 2).

## DISCUSSION

The most common neurological complication after vaccination against COVID-19 in the present study was headache, which was seen in 16.6% of all samples in recipients of all Sinopharm, Sputnik V, AstraZeneca, CovIran-Baraket, and Cpvaxin (Bharat) vaccines. In the study conducted by Finsterer, headache was the most common neurological complication after receiving the COVID-19 vaccines, which was consistent with the present findings.<sup>10</sup> In a multinational multicenter study, Göbel et al. introduced 2349 people who experienced headache after the vaccination of COVID-19 and introduced it as one of the common side effects after the injection of various vaccines of COVID-19.

**Table 1: Neurological complications observed in patients by type of vaccine.**

Complication, N (%)	Sinopharm	Sputnik V	Astra-Zeneca	CovIran-Baraket	Covaxin	Spico-Gen	Pastocovac plus	P value
<b>Headache</b>	No 440 (87.3)	134 (77.0)	252 (80.3)	25 (89.3)	18 (78.3)	2 (100)	1 (100)	0.016
	Yes 64 (12.7)	40 (23.0)	62 (19.7)	3 (10.7)	5 (21.7)	0 (0.0)	0 (0.0)	
<b>Weakness and lethargy</b>	No 486 (96.4)	154 (88.5)	302 (96.2)	28 (100)	19 (82.6)	2 (100)	1 (100)	0.001
	Yes 18 (3.6)	20 (11.5)	12 (3.8)	0 (0.0)	4 (17.4)	0 (0.0)	0 (0.0)	
<b>dizziness</b>	No 487 (96.6)	159 (91.4)	309 (98.4)	28 (100)	16 (69.6)	2 (100)	1 (100)	0.001
	Yes 17 (3.4)	15 (8.6)	5 (1.6)	0 (0.0)	7 (30.4)	0 (0.0)	0 (0.0)	
<b>Decreased consciousness</b>	No 496 (98.4)	173 (99.4)	312 (99.4)	25 (89.3)	23 (100)	2 (100)	1 (100)	0.033
	Yes 8 (1.6)	1 (0.6)	2 (0.6)	3 (10.7)	0 (0.0)	0 (0.0)	0 (0.0)	
<b>Paralysis</b>	No 503 (99.8)	174 (100)	311 (99)	27 (96.4)	23 (100)	2 (100)	1 (100)	0.105
	Yes 1 (0.2)	0 (0.0)	3 (1.0)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	
<b>Body numbness</b>	No 503 (100)	174 (100)	313 (100)	28 (100)	23 (100)	2 (100)	1 (100)	1.0
	Yes 1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
<b>Fainting</b>	No 502 (99.8)	174 (100)	313 (99.7)	28 (100)	23 (100)	2 (100)	1 (100)	1.0
	Yes 1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
<b>Bell's palsy</b>	No 504 (100)	173 (99.4)	314 (100)	28 (100)	23 (100)	2 (100)	1 (100)	0.218
	Yes 0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
<b>Chance of stroke</b>	No 504 (100)	174 (100)	313 (99.7)	28 (100)	23 (100)	2 (100)	1 (100)	0.518
	Yes 0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	

**Table 2: The results of the logistic regression model to determine the relative risk of neurological complications in the examined COVID-19 vaccines.**

Type of vaccine	Risk ratio and significance level	Any type of complication	Headache	Weakness and lethargy	dizziness	Decreased consciousness	Serious complication
<b>Sinopharm</b>	Reference	Reference	Reference	Reference	Reference	Reference	Reference
<b>Sputnik V</b>	OR	2.357	2.052	3.506	2.703	0.358	0.965
	P value	0.001	0.001	0.001	0.007	0.335	0.976
<b>AstraZeneca</b>	OR	1.455	1.691	1.073	0.464	0.397	3.253
	P value	0.032	0.007	0.853	0.135	0.245	0.097
<b>CovIran-Baraket</b>	OR	1.493	0.825	0.001	0.001	7.440	6.185
	P value	0.375	0.758	0.998	0.998	0.005	0.120
<b>Covaxin</b>	OR	4.105	1.910	5.684	12.533	0.001	0.001
	P value	0.001	0.216	0.004	0.001	0.998	0.998
<b>SpicoGen</b>	OR	0.001	0.001	0.001	0.001	0.001	0.001
	P value	0.999	0.999	0.999	0.999	0.999	0.999
<b>Pastocovac plus</b>	OR	0.001	0.001	0.001	0.001	0.001	0.001
	P value	0.999	0.999	0.999	0.999	0.999	0.999

It was consistent with the findings of the present study.<sup>11</sup>The comparison of vaccines in terms of the incidence of headache in the present study showed that the types of vaccines were significantly different in terms of the incidence of headache, so that the relative risk of headache after the injection of Sputnik and AstraZeneca vaccines was significantly higher than that of Sinopharm vaccine. Such a comparison between different vaccines was not seen in other studies, but in the study of Ramasamy et al and Samimagham et al headache was reported as the most common side effect of AstraZeneca and Sputnik vaccines, respectively, which were consistent with the findings of the present study.<sup>12-13</sup> It is worth

mentioning that in the present study, headache occurred in more than 70% of the cases on the same day of the vaccine injection and in the remaining 30%, it occurred 1-2 days after the injection. In Göbel et al study, headache occurred on average 18 hours after the injection of the COVID-19 vaccine, and in another study, it was stated that the headache in most cases starts after a few hours after the injection. It was consistent with the findings of the present study.<sup>14</sup> Feeling weak and lethargic and dizziness were other common side effects after headache in the present study population, which were seen among recipients of all types of vaccines. In other studies, these symptoms have been reported as common side effects after the injection of

COVID-19 vaccines, which mostly did not require special treatment and were cured by themselves.<sup>12,15</sup>

In the current study, decreased level of consciousness was another neurological side effect related to the injection of the COVID-19 vaccine, which was observed in a total of 1.3% of people receiving Sinopharm, Sputnik, AstraZeneca, and Barkat vaccines. The comparison of vaccines showed that the risk of this complication after the injection of Barkat vaccine was higher than other vaccines. No study was found that specifically examined the neurological complications after the Barkat vaccine, but in a case report study, Fallahi et al introduced a patient who probably developed encephalopathy with symptoms such as decreased level of consciousness after the Barkat vaccine injection. Was. There are also cases of decreased level of consciousness after AstraZeneca vaccine injection.<sup>16,17</sup> In general, the incidence of serious complications after the injection of the Covid-19 vaccine was rare in the subjects examined in this study. In line with the present study, other studies have also reported rare occurrence of serious complications following vaccination with anti-COVID-19 vaccines.<sup>11,12,18,19</sup>

Among the serious complications seen in the patients of the present study, limb paralysis was the most common case, which was seen in 5 people (0.5% of the total studied population). In similar studies, the occurrence of different variants of Guillain-Barré syndrome, which are associated with paralysis of different body parts, has been suggested as one of the most common serious neurological complications following the injection of COVID-19 vaccines, which was almost consistent with the findings of the present study.<sup>10,20</sup> In addition to limb paralysis, other serious complications seen in this study include limb numbness in 2 people (0.2 percent), Bell's palsy in 1 person (0.1 percent), and the possibility of stroke in 1 person (0.1 percent). In line with the present study, in some other studies, there have been reports of the occurrence of these complications after vaccination against COVID-19, which also emphasized the rarity of these complications.<sup>21,22</sup>

It is worth noting that more than half (55.6%) of the serious complications observed in the present study occurred among AstraZeneca vaccine recipients (3 of 5 cases of limb paralysis, 1 of 2 cases of limb numbness, and 1 of 1 case with possible stroke). This finding of the present study is very similar to the results of the study of Sriwastava et al in their study, 55% of the neurological complications caused by the COVID-19 vaccination were related to the AstraZeneca vaccine. Similarly, Finsterer also stated in his study that although serious complications are rare after COVID-19 vaccination, the occurrence of serious complications such as limb paralysis or stroke after vaccination with AstraZeneca was more reported, which was consistent with the present finding. 10). It was because of such observations that the World Health Organization (WHO) and the European Medicines Agency (EMA)

officially listed Guillain-Barré syndrome as a very rare side effect of the AstraZeneca vaccine.<sup>23</sup>

Although the cause-effect relationship between the occurrence of neurological complications and vaccines has not yet been conclusively proven, each vaccine has components including an antigen, a delivery system, and an adjuvant, which side effects after the vaccine can be caused by each of them. From these components and several pathogenic mechanisms have been described to determine how vaccines are associated with neurological complications. For example, mechanisms such as molecular mimicry, abnormal immune reactions, and neurotoxicity have been attributed to these complications.<sup>24-25</sup> Overall, according to the results of the present study and similar studies, it seems that the neurological complications associated with the COVID-19 vaccines are often non-serious and the occurrence of dangerous complications is generally rare. In this regard, large recent epidemiological evidences have shown that the risk of serious complications such as stroke following the covid-19 vaccination is much lower than the serious complications related to the COVID-19 infection itself. While the association between vaccines and prothrombotic states is being studied, it is important to remember that these side effects are rare and far less common than CVST and ischemic stroke related to the COVID-19 infection itself, as reported by a recent large epidemiological study has shown that.<sup>26</sup>

### **Limitations**

A limitation of the present study is that the number of people injecting SpikoGen and Pasto-Covac plus vaccines was very small, therefore, based on the results of the present study, it is not possible to comment on the neurological side effects of these vaccines. Another limitation of the current study was that we could not collect possible risk factors involved in the occurrence of neurological complications in people and examine their impact on the occurrence of these complications.

### **CONCLUSION**

The results of the present study primarily showed that the neurological side effects associated with the COVID-19 vaccination often include non-serious and mild cases such as headache, weakness and lethargy, and dizziness, and the occurrence of dangerous neurological complications following vaccination with approved vaccines. It is rare in the country as a whole. However, since most of the serious neurological complications occurred after vaccination with AstraZeneca, it seems that in line with the recommendation of the European Medicines Agency, the injection of this vaccine should be done with caution.

### **Recommendations**

It is recommended that health care professionals, especially those directly involved in the management of

persons undergoing vaccination against COVID-19, be aware of the common neurologic complications associated with COVID-19 vaccines. This may be helpful in the timely diagnosis and management of these complications, and in the end, it will lead to more people's satisfaction and make them more likely to get vaccinated. It is also suggested to conduct studies in the future to determine the risk factors of neurological complications in the recipients of the COVID-19 vaccine. suggested high and with the least possible complications.

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