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Comparison of side effects of the dose-1 of AstraZeneca and Sinopharm vaccines in patients with multiple sclerosis in Kermanshah, Iran (2021)

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Keywords
SARS-CoV-2; Multiple Sclerosis; Vaccination; COVID-19 Vaccines; AstraZeneca; Sinopharm

Abstract

Background: Coronavirus 2019 (COVID-19) vaccination is recommended for people with multiple sclerosis (MS). This study evaluated the side effects of Sinopharm and AstraZeneca vaccines in MS patients.

Methods: In this cross-sectional study among MS patients in Kermanshah province, Iran, who received Sinopharm or AstraZeneca vaccine, sampling was performed through convenience sampling according to the nationwide MS registry of Iran (NMSRI). Demographic and clinical information of the participants and data on the side effects of vaccines were collected by telephone after the first dose. The data were analyzed in SPSS software.

Results: 264 vaccinated MS patients (217 with Sinopharm and 47 with AstraZeneca) were studied. In the Sinopharm and AstraZeneca groups, respectively, 58.5% and 73.3% of patients had side effects that were not significantly different between the 2 groups ($P = 0.064$). In the AstraZeneca group, the severity of side effects and prevalence of taking painkillers were significantly higher ($P < 0.050$) and the interval between vaccination and side effects onset was significantly shorter ($P = 0.013$).

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The most commonly experienced side effects in the Sinopharm group were fatigue (29.0%), myalgia (24.9%), fever (24.0%), and headache (21.7%), and in the AstraZeneca group were fever (59.6%), chills (51.1%), myalgia (40.4%), and fatigue (34.0%). Logistic regression by controlling for confounding variables showed that considering some factors as confounding factors did not show a significant difference between the 2 vaccines in the experience of side effects (P = 0.104).

Conclusion: The AstraZeneca vaccine caused more severe side effects in MS patients than the Sinopharm vaccine. Most of the side effects were moderate in severity and transient.

Introduction

The current coronavirus 2019 (COVID-19) epidemic first emerged in Wuhan, China, and spread rapidly around the world, causing millions of people to contract the disease and die.[1] As of May 1, 2021, there have been 152661445 cases of COVID-19 and 3202256 deaths due to COVID-19 in the world.[2] In addition to increasing immunity, vaccines can prevent serious diseases, and health crises.[3] With the announcement of the epidemic by the World Health Organization (WHO), worldwide efforts for the COVID-19 vaccine began.[4]

The ChAdOx1 nCoV-19 vaccine (AstraZeneca-Oxford), which is one of the COVID-19 adenovirus carrier vaccines, was studied by researchers and the results showed that this vaccine has the desired safety profile,[3] and thus, on February 15, 2021, this vaccine was approved for emergency use.[5] As of May 16, 2021, the AstraZeneca vaccine has been approved by 101 countries and distributed in 139 countries. The effectiveness of the AstraZeneca vaccine is 70.4%.[2] The BBIBP-CorV vaccine (Sinopharm COVID-19) is a vaccine of inactivated COVID-19 virus that was in the third phase of testing in late December 2020.[6] Sinopharm claimed in December that its first vaccine was 79% effective in preventing the symptoms of COVID-19 based on transient phase III data.[7] Studies have shown that the efficacy of the Sinopharm vaccine is 50.4%.[8]

Multiple sclerosis (MS) is an autoimmune disease and a neurodegenerative disorder that causes significant disability in young and middle-aged people.[9,10] MS patients are themselves at higher risk for COVID-19, and the use of disease modifying therapies (DMT) can increase this risk.[11,12] While vaccination is recommended for people with MS,[13] there is uncertainty about how COVID-19 vaccines interact with MS and DMT treatments.[14] There is also the fact that MS patients are not included in clinical trials evaluating the safety of vaccines,[15] so it seems necessary to evaluate the effects of vaccination on MS patients.

Several COVID-19 vaccines are currently available in various countries, including Iran. In Kermanshah (a western province of Iran), the injection of Sinopharm and AstraZeneca vaccines was conducted on MS patients as of May 2021. In this study, Sinopharm and AstraZeneca vaccines were compared in terms of their side effects in MS patients in Kermanshah.

Materials and Methods

Study design and research community: This original article was the result of a cross-sectional study performed between May and August 2021. Using convenience sampling method, the participants were selected from the MS registry system.[16] The study population included all MS patients in Kermanshah province who had received at least 1 dose of the Sinopharm or AstraZeneca vaccine. The inclusion criteria were a definitive diagnosis of MS, an age of higher than 18 years, and at least 1 injection of Sinopharm or AstraZeneca vaccine. The exclusion criteria included unwillingness to participation in the study and lack of response to phone calls.

Data collection tools and methods: The data collection tool was a researcher-made form designed to collect demographic and clinical information, and information on infection with COVID-19 before vaccination and vaccine side effects. The form consisted of 3 parts. The first part was related to patients' demographic and clinical information including gender, age, marital status, age at diagnosis, type of MS, and current MS medication. The second part included questions on COVID-19 infection before vaccination, and the MS medication they were taking at the time of infection. For the diagnosis of COVID-19, 3 conditions were considered: either the person himself tested positive, or he did not get tested, but the doctor told him it was COVID-19, or there was a family infection and at least one family member tested positive. The third part of the questionnaire included questions related to the side effects of dose-1 of the vaccines. Patients were contacted by telephone, and the necessary information was collected.

Ethical considerations: The present study was approved by the ethics committee of Kermanshah University of Medical Sciences with the code

IR.KUMS.MED.REC.1400.087. Patients' consent for cooperation in the study was obtained after providing them with clear explanations on the preservation of their information, and assuring them that the data obtained would remain confidential and would be used for research purposes only. Each participant was assigned a code that was used in all forms.

The collected data was entered into SPSS software (version 25, IBM Corp., Armonk, NY, USA), and data analysis was performed according to the project objectives. Descriptive statistics such as mean, frequency, percentage, and graph were used. After checking the normality of the data using Kolmogorov-Smirnov test, the Mann-Whitney test was used to compare the mean ranks of the abnormal variables, and chi-square test and Fisher's exact test were used to examine the relationship between qualitative variables. In examining the experience of side effects, multiple logistic regression analysis was used to control potential confounding factors.

Results

In total, 264 MS patients were evaluated after dose-1 of the COVID-19 vaccine, of which 217 (82.2%) and 47 (17.8%) received the Sinopharm and AstraZeneca vaccine, respectively.

Moreover, 206 (78.0%) participants were women and 58 (22.0%) were men. The mean ± standard deviation (SD) of age and disease duration in the Sinopharm group were 41.89 ± 11.20 years (range: 21-79 years) and 9.37 ± 6.90 years (range: 0-36 years), respectively. These values were, respectively, 37.82 ± 9.40 years (range: 20-60 years) and 9.02 ± 4.60 years (range: 2-23 years) in the AstraZeneca group. In the Sinopharm and AstraZeneca group, 73.3% and 78.6% of MS patients had relapsing-remitting MS (RRMS), respectively. Before vaccination, 58 patients (27.0%) in the Sinopharm group and 11 patients (24.4%) in the AstraZeneca group were infected with COVID-19 (Table 1).

Furthermore, 58.5% of the subjects in the Sinopharm group and 73.3% of patients in the AstraZeneca group had side effects that were not significant (P = 0.064).

In the Sinopharm group, more than 30% of people had low-severity side effects, but in the AstraZeneca group, only 8% of people had low-severity side effects, and 92% of people experienced moderate to severe side effects. The severity of the side effects was significantly higher in the AstraZeneca group compared to the Sinopharm group (P < 0.001).

The mean ± SD time of side effects initiation was 12.61 ± 20.90 hours after vaccination in the Sinopharm vaccine group and 11.88 ± 8.90 hours after vaccination in the AstraZeneca vaccine group. A significantly shorter interval between vaccination and onset of side effects was observed in the AstraZeneca group compared to the Sinopharm group (P = 0.013).

Although the side effects in the AstraZeneca group (14.75 ± 13.00 hours) had an average shorter duration than the Sinopharm group (44.58 ± 78.00 hours), this difference was not significant (P = 0.826).

In AstraZeneca recipients, the prevalence of taking painkillers after vaccination was significantly higher than in Sinopharm recipients (P = 0.018). The most common side effects in the Sinopharm group were fatigue (29.0%), myalgia (24.9%), fever (24.0%), and headache (21.7%), and in the AstraZeneca group were fever (59.6%), chills (51.1%), myalgia (40.4%), and fatigue (34.0%).

The prevalence of myalgia, fever, and chills was significantly higher in the AstraZeneca group than in the Sinopharm group (P < 0.050), but hot flashes was observed only in the Sinopharm group in 7.8% of people which was significantly more than the AstraZeneca group (P = 0.049) (Table 2 and Figure 1).

To control potential confounding factors, multiple logistic regression was used. The variables of gender, age, education, duration of disease, type of MS, prior infection with COVID-19, MS medicine, and type of vaccine were not considered as confounding variables in experiencing side effects after vaccination (Table 3).

Among patients who were infected with COVID-19 before vaccination, 36 (62.1%) in the Sinopharm group and 10 (90.9%) in the AstraZeneca group experienced side effects. Sinopharm and AstraZeneca groups did not show any significant difference in side effects between those who had COVID-19 before vaccination and those who did not (P > 0.050).

In both Sinopharm and AstraZeneca groups, more than 85.0% of patients who had COVID-19 before vaccination experienced mild to moderate-severity side effects. There was no significant difference in the severity of side effects between those who experienced COVID-19 before dose-1 and those who did not in either group (P > 0.050) (Table 4).

Table 1. Demographic and clinical information of patients with multiple sclerosis (MS) vaccinated with Sinopharm or AstraZeneca vaccines

Variable	Sinopharm	AstraZeneca	P
Age [median (IQR)]	4000 (15)	3800 (12.5)	0.043**
Total	214	45	
Duration of disease [median (IQR)]	800 (10)	800 (7)	0.583**
Total	212	43	
Gender [n (%)]			0.899*
Female	169 (77.9)	37 (78.7)	
Male	48 (22.1)	10 (21.3)	
Total	217 (100)	47 (100)	
Marital status [n (%)]			0.189*
Single	57 (26.5)	15 (36.6)	
Married	158 (73.5)	26 (63.4)	
Total	215 (100)	41 (100)	
Education [n (%)]			0.139*
Primary or middle	54 (25.0)	5 (12.5)	
Diploma	69 (32.2)	18 (45.0)	
College level	91 (42.6)	17 (42.5)	
Total	214 (100)	40 (100)	
Type of MS [n (%)]			0.509*
RR	157 (73.7)	33 (78.6)	
PP	22 (10.3)	1 (2.4)	
SP	25 (11.7)	6 (14.3)	
RP	9 (4.2)	2 (4.8)	
Total	213 (100)	42 (100)	
Prior infection with COVID-19 [n (%)]			0.726*
Yes	58 (27.0)	11 (24.4)	
No	157 (73.0)	34 (75.6)	
Total	215 (100)	45 (100)	
MS medicine [n (%)]			0.106*
Oral therapy	58 (28.3)	9 (20.0)	
Fingolimod	33 (16.1)	6 (13.3)	
Triflunomide	4 (2.0)	0 (0)	
Dimethylfumarate	21 (10.2)	3 (6.7)	
Injectable therapy	67 (32.7)	20 (44.1)	
Interferon beta-1a	33 (16.1)	11 (24.4)	
Interferon beta-1b	25 (12.2)	6 (13.3)	
Glatiramer acetate	9 (4.4)	3 (6.7)	
Infusion therapy	44 (21.5)	13 (28.9)	
Rituximab	42 (20.5)	12 (26.7)	
Ocrelizumab	2 (1.0)	1 (2.2)	
Other	36 (17.6)	3 (6.6)	
Total	205 (100)	45 (100)	
Vaccine	217 (82.2)	47 (17.8)	

*Chi-square, **Mann-Whitney

IQR: Interquartile range; MS: Multiple sclerosis; RR-MS: Relapsing-remitting-MS; PP: Primary progressive-MS; SP-MS: Secondary progressive-MS; RP-MS: Relapsing- progressive-MS; COVID-19: Coronavirus 2019

In the AstraZeneca group, there were no major events after vaccination, but in the Sinopharm group, a 46-year-old man who had MS for 14 years developed severe symptoms of COVID-19 two days after the dose-1 vaccination. The COVID-19 test was positive for him. He was hospitalized for a week following the worsening of his symptoms and was then released. This person received dose-2 52 days after dose-1, and had no side effects after dose-2.

Discussion

In the present study, we investigated the side effects of COVID-19 vaccines after dose-1 in MS patients. The results of our study showed that, in the Sinopharm group, 58.5% of patients experienced side effects including fatigue, myalgia, fever, headache, etc.

Table 2. Side effects of Sinopharm and AstraZeneca vaccine after injection of the first dose of the vaccine in patients with multiple sclerosis (MS)

Variable	Sinopharm (Dose-1)	AstraZeneca (Dose-1)	P
Interval between injection and the onset of side effects (hours) [median (IQR)]	550 (9.5)	1200 (5.5)	0.013*
Duration of side effects (hours) [median (IQR)]	16 (44.0)	1475 (-)	0.826*
Existence of side effects [n (%)]			
Yes	127 (58.5)	33 (73.3)	0.064**
No	90 (41.5)	12 (26.7)	
The severity of side effects [n (%)]			
Mild	107 (31.2)	10 (8.0)	
Moderate	212 (61.8)	106 (84.8)	< 0.001**
Severe	24 (7.0)	9 (7.2)	
Taking painkillers after injection [n (%)]			
Yes	78 (41.7)	26 (61.9)	0.018**
No	109 (58.3)	16 (38.1)	
Side effects [n (%)]			
Fatigue	63 (29.0)	16 (34.0)	0.496**
Myalgia	54 (24.9)	19 (40.4)	0.031**
Fever	52 (24.0)	28 (59.6)	< 0.001**
Headache	47 (21.7)	10 (21.3)	0.954**
Restlessness	27 (12.4)	8 (17.0)	0.401**
Chills	24 (11.1)	24 (51.1)	< 0.001**
Anorexia	20 (9.2)	6 (12.8)	0.427***
Loss of consciousness	19 (8.8)	2 (4.2)	0.387***
Shortness of breath	18 (8.2)	5 (10.6)	0.574***
Hot flashes	17 (7.8)	0 (0)	0.049***
Cough	9 (4.1)	1 (2.1)	1.000***
Vomit	7 (3.2)	3 (6.3)	0.390***
Vertigo	6 (2.8)	3 (6.3)	0.203***
Low blood pressure	5 (2.3)	2 (4.2)	0.612***
Diarrhea	5 (2.3)	1 (2.1)	1.000***
Joint pain	4 (1.8)	2 (4.2)	0.290***
Wheezing	2 (0.9)	0 (0)	1.000***
Shock	2 (0.9)	0 (0)	1.000***
Skin urticaria	1 (0.5)	1 (2.1)	0.325***
Exacerbation of MS symptoms	0 (0)	1 (2.1)	0.178***
Heart beat	0 (0)	1 (2.1)	0.178***
Feeling very thirsty	0 (0)	1 (2.1)	0.178***

*Mann-Whitney, **Chi-square, ***Fisher's exact
IQR: Interquartile range; MS: Multiple sclerosis

In the AstraZeneca group, 73.3% of side effects included fever, chills, myalgia, and fatigue, etc. Side effects were significantly more severe in the AstraZeneca group than in the Sinopharm group.

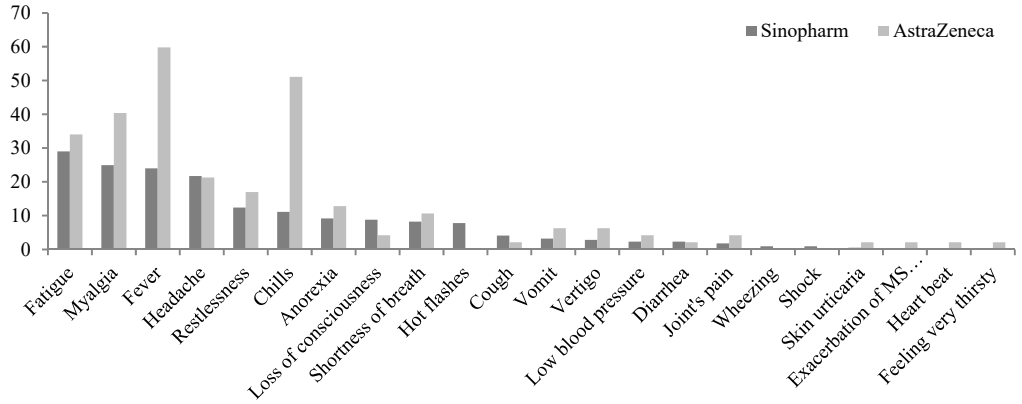

Figure 1. The most common side effects of Sinopharm and AstraZeneca vaccines after the first dose

Table 3. Results of multiple logistic regression by control for potential confounding factors for experiencing side effects after vaccination

Variable	B	SE	Wald	df	P	Exp (B)
Gender	-0.054	0.321	0.026	1	0.872	0.948
Age	-0.009	0.015	0.359	1	0.549	0.991
Education	0.113	0.126	0.794	1	0.373	1.119
Duration of disease	0	0.024	0.001	1	0.978	0.999
Type of MS	-0.031	0.172	0.033	1	0.856	0.969
Prior infection with COVID-19	0.444	0.318	1.950	1	0.163	1.560
MS medicine	-0.046	0.030	2.352	1	0.125	0.955
Type of vaccine	0.632	0.389	2.638	1	0.104	1.882
Constant	-0.045	0.952	0.002	1	0.962	0.956

SE: Standard error; df: Degree of freedom; MS: Multiple sclerosis; COVID-19: Coronavirus 2019

A review article about the effects of 3 vaccines (Sinopharm, Sputnik V, and AstraZeneca) on the general population from January 1, 2020, to May 1, 2021, showed that all 3 vaccines created immunity to the disease and all 3 Vaccines were 100% effective in preventing severe COVID-19.[17] A study by Almufty et al. In Iraq,[18] which studied the side effects of Sinopharm, AstraZeneca-Oxford, and Pfizer-BioNTech vaccines among the general public, found that 84.0% of the participants were symptomatic after vaccination. In the AstraZeneca group the most commonly experienced side effects included fever (68.4%), fatigue (64.9%), myalgia (54.2%), and injection site reaction (54.2%), and in the Sinopharm group, injection site reaction (54.5%), fatigue (40.9%), myalgia (36.3%), and headache (33.3%). In this study, the most commonly experienced side effects of Sinopharm and AstraZeneca were similar to that in our study. Moreover, the researchers of the mentioned study observed that the side effects had mild to moderate severity in 83.7% of individuals and the severity of the side effects was significantly higher in the AstraZeneca group. Similarly, our study showed that more than 90.0% of people had mild to moderate side effects, and the severity of the side effects was significantly higher in AstraZeneca group.

Menni et al. evaluated the efficacy and safety of Pfizer and AstraZeneca vaccines at 590,655 vaccine doses in the UK community.[19] They found that systemic side effects occurred in 33.7% of individuals and local side effects were reported in 58.7% of individuals after dose-1 of AstraZeneca.[19] The most commonly experienced side effects in the AstraZeneca group were headache (22.8%), fatigue (21.1%), chills and shiver (14.7%), arthralgia (11.5%), and fever (8.2%). Furthermore, the prevalence of systemic side effects in people who had experienced COVID-19 before vaccination was 1.6 times higher than in those who had not. The results of the abovementioned studies are similar to the results of our study which showed that in patients with a history of COVID-19 in both groups, both the number and severity of side effects were higher, although this difference was not statistically significant in our study.

Jayadevan et al conducted an online survey among 5,396 people in India from January to February 2021.[20] Their findings showed that 65.9% of their participants reported to have experienced at least 1 post-vaccination side effect, and the most commonly experienced side effects included fatigue (45%), myalgia (44%), fever (34%), and headache (28%).

Table 4. Comparison of side effects between patients who had Coronavirus 2019 (COVID-19) before the vaccination and those who did not

Variable	Sinopharm (Dose-1)		AstraZeneca (Dose-1)	
	Infected	Uninfected	Infected	Uninfected
Existence of side effects				
Yes	36 (62.1)	90 (57.3)	10 (90.9)	23 (67.6)
No	22 (37.9)	67 (42.7)	1 (9.1)	11 (32.4)
P	0.531*		0.240*	
The severity of side effects				
Mild and moderate	112 (94.9)	207 (92.0)	37 (88.1)	79 (95.2)
Severe	6 (5.1)	18 (8.0)	5 (11.9)	4 (4.8)
P	0.315*		0.162**	

*Chi-square, **Fisher's exact

In a study by Riad et al. among health care workers in the Czech Republic who received COVID-19 vaccine (Pfizer), the findings indicated that injection site pain (89.8%), fatigue (62.2%), headache (45.6%), muscle pain (37.1%), and chills (33.9%) were the most common side effects; in addition, the duration of side effects was mainly 1 day (45.1%) or 3 days (35.8%) after vaccination.[21]

Several studies have been performed on the side effects of COVID-19 vaccination in MS patients. In a study by Lotan et al. on 239 MS patients who received the BNT162b2 COVID-19 vaccine, a total of 136 patients (56.9%) reported vaccine side effects.[15] The most common side effect was injection site pain, which was reported by 111 patients (46.4%); followed by fatigue (38.1%), muscle pain (36.8%), headache (36.8%), Chills (29.7%), fever (15.9%) and dizziness (12.6%).

In the study by Allen-Philbey et al., the side effects of COVID-19 vaccines in MS patients were evaluated, and 29 patients received the AstraZeneca and 4 patients received BioNTech/Pfizer.[22] All patients except 2 (94%) had symptoms including sore arm (70%), flu-like symptoms (64%), fever (21%), fatigue (27%), and headache (21%), fever/chills (12%), joint pain/muscle pain (9%), nausea (9%), and swelling at injection site (6%). In their study, as in our study, for most patients the symptoms lasted less than 48 hours.

Sahraian et al. examined the side effects of the Sinopharm vaccine in 583 MS patients and found that 350 (60%) of the patients reported at least 1 side effect.[23] No serious side effects were reported and the most commonly experienced side effects included malaise (25%), fatigue (25%), generalized body pain (18%), fever (17%), and headache (9%). In addition, the average duration of side effects was 2 days, which was similar to the findings of our study.

The abovementioned studies conducted on the general public suggest that the side effects in MS patients in our study are similar to those observed in the general population and MS patients in other studies. However, for more accurate conclusions, more studies with larger sample sizes and longer follow-up times are needed.

One of the limitations of the present study was that a complete list of MS patients who had received the vaccine in Kermanshah province was not available. Moreover, some patients did not answer the phone. These two reasons made it impossible for us to have a larger sample size.

It is recommended that vaccinations for MS patients be recorded at specialized centers for these patients so that a more complete list of patients can be accessed.

Another limitation of the present study was that in order to conduct a correct evaluation without bias and distortion of the side effects, a randomized clinical trial design should be used, so that people with similar clinical conditions are assigned to the study groups and the number of people in the groups is balanced. Nevertheless, it was not possible to conduct the study in this way, and thus, a cross-sectional study was performed. Gathering information by phone and not using clinical examination or observation, and the possibility that the researcher and the patient are not blind can create information bias. In this study, data collection was performed by phone and it was not possible to examine the patients.

Conclusion

In the present study, we investigated the side effects of 2 vaccines after dose-1 in MS patients. The results of our study showed that 58.5% of people in the Sinopharm group and 73.3% of people in the AstraZeneca group experienced at least 1 side effect. The interval between vaccination and onset of side effects was significantly shorter in the AstraZeneca group. In the AstraZeneca group, the side effects were significantly more severe and the prevalence of taking painkillers after injection was significantly higher than that in the Sinopharm group. The most common side effects in the Sinopharm group were fatigue, myalgia, fever, and headache. In the AstraZeneca group, fever, chills, myalgia, and fatigue were the most common side effects. In the AstraZeneca group, the severity of side effects was significantly higher, the interval between vaccination and the onset of side effects was significantly shorter, and the prevalence of taking painkillers after vaccination was significantly higher than in the Sinopharm group. In both groups, the prevalence of side effects was higher in patients who had been infected with COVID-19 before vaccination, but this difference was not significant. In both groups, most of the side effects were mild and moderate in severity and were mostly transient. Chi-square test in univariate analysis showed that the type of vaccine has a significant effect on side effects, and some side effects occurred significantly more with AstraZeneca than Sinopharm, while the results of multiple logistic regression by controlling for confounding variables showed that the type of

vaccine has no significant effect on side effects. This shows that considering some important clinical and demographic factors as confounding factors showed no significant differences between the side effects of the 2 vaccines.

Conflict of Interests

The authors declare no conflict of interest in this study.

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