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Comparison of the Onset and End of Specific and Major Side Effects in Iranian Teenage Participants Vaccinated With COVID-19 Vaccine: Sinopharm and Soberana

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Abstract

Background: Clinical trials were conducted on children on side effects after vaccination. We tried to assess the frequency and onset of the main symptoms in children who were vaccinated. We aimed to evaluate early and delayed adverse effects after coronavirus disease 2019 (COVID-19) vaccine among Iranian pediatrics and adolescents in a national survey.

Methods: This cross-sectional study included people <18 years who received the Soberana (PastoCoVac) and Sinopharm vaccines since 2021. The basic information was gender, age, type of vaccine, and reaction after vaccination besides the main events that occurred for them. The required data were collected via a predetermined checklist by trained interviewers through phone calls by their parents or legal guardians. The independent t test and Fisher exact test were used. P values less than 0.05 were considered significant.

Results: A total of 11,042 participants (age range, 10-18 years) consisting of 5374 boys (47.8%) and 5768 girls (52.2%) were studied and 88.1% of the children (n = 9727) were vaccinated by Sinopharm and 11.9% (n = 1315) by Soberana. The data of kidney-related side effects had delayed improvement of side effects after the Sinopharm compared with the Soberana vaccines (P = 0.012). Cardiovascular and hematological side effects showed early-onset (P = 0.006) and delayed improvement of side effects (P = 0.002) after the Soberana vaccine compared with the Sinopharm vaccine. Neurological side effects showed delayed improvement of side effects after the Soberana vaccine compared with the Sinopharm vaccine (P = 0.027). Joint-related side effects showed early-onset (P = 0.004) and delayed improvement of side effects (P = 0.023) after the Soberana vaccine compared with the Sinopharm vaccine. Respiratory side effects showed delayed improvement of side effects after the Soberana vaccine compared with the Sinopharm vaccine (P = 0.013), and dermatological side effects showed early-onset (P = 0.050) and delayed improvement of side effects (P = 0.035) after the Soberana vaccine compared with the Sinopharm vaccine. There was not any statistically significant difference regarding gastrointestinal side effects between the 2 vaccines (P > 0.05).

Conclusion: The cardiovascular and hematological, joint-related (non-neurologic musculoskeletal) and dermatological side effects after the Soberana vaccine appear earlier and end later compared with the Sinopharm vaccine. Improvement of renal side effects in the Sinopharm vaccine group and improvement of neurological and respiratory side effects in the Soberana vaccine group occurred with delay compared with other vaccines.

Keywords: Vaccination, COVID-19, Safety, Children; Pediatric, Adolescent, Adverse Effect, Early, Delayed, Sinopharm, Soberana

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↑What is "already known" in this topic:
Vaccination is the only safe way to prevent mortality from COVID-19, although each vaccine has its own efficacy and side effects. Most of clinical trials on this subject were conducted on adults and a few have been done on children.

→What this article adds:
Based on our study conducted on Iranian teenage participants, improvement of renal side effects in the Sinopharm vaccine group and improvement of neurological and respiratory side effects in the Soberana vaccine group occurred with a delay compared with other vaccines. There were no differences in the onset and duration of the side effects.

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Introduction

The coronavirus disease 2019 (COVID-19) pandemic rapidly is involving about all countries worldwide (1-3). All variants showed different consequences, including kidney, liver, lung, heart failures, and so on, as well as various symptoms like severe acute respiratory syndrome (4), and the Middle East Respiratory Syndrome (5-8). To treat COVID-19, various drug therapies and vaccines were tested to reduce the main risk of mortality due to the disease (9-12). In this regard, pediatrics is susceptible to COVID-19 with different manifestations (13). Most of the patients with COVID-19 are asymptomatic or have mild symptoms (13-15). It is generally accepted that vaccination is the only safe way to prevent mortality from COVID-19, although each vaccine has its own efficacy and side effects (16-18). Most of clinical trials on this subject were conducted on adults and a few have been done on children (19-22). In this study, we tried to assess the possible side effects of vaccination in children.

Methods

This cross-sectional study included all children (through census method) who were referred to one of the designated vaccination centers for people <18 years and received Soberana (PastoCoVac) and Sinopharm vaccines since 2021. The Soberana vaccine (PastoCovac) has been developed in collaboration with the Pasteur Institute of Iran.

The inclusion criteria were having no COVID-19 infection at the time of interview, age between 1 to 18 years, and receiving at least the first dose of the vaccine.

The exclusion criteria were having COVID-19 infection or any other infections at the time of interview and not being vaccinated with the COVID-19 vaccine.

At the beginning of the project and through the coordination with the deputy of the treatment committee of the Tehran province's COVID-19 committee, among the designated centers for the vaccination of children against COVID-19, five centers are located in the 5 districts of Tehran (north, south, east, west and the city center), will be selected. Then, with the help of the vice president of treatment and with the assistance of the appropriate facilities, the fundamental data of the individuals—including their gender, age, level of education, kind of vaccine, and phone number—is gathered.

The basic information was gender, age, type of vaccine, and reaction after vaccination, besides the main events that occurred for participants. The required data were collected via a predetermined checklist by trained interviewers through the phone call by their parents or legal guardians.

The outcomes we studied in this article are as follows:

General side effects: fever, shivering, lethargy, tiredness, dizziness, body pain, and pain at the injection site (more than 24 hours).

Statistical Analysis

The data were analyzed by SPSS Version 21. Descriptive statistics for variables were expressed in terms of type, frequency, percentage (such as those with first and second dose vaccination; those who received Sinopharm or Soberana/PastoCoVac vaccine), and mean and standard deviation (such as age, weight, height, and COVID-19 history duration). To compare quantitative variables, an independent t test and to compare the frequency of outcomes, the Fisher exact test (such as comparison of cardiovascular and hematological side effects between Sinopharm and PastoCoVac groups) was used. Moreover, *P* values less than 0.05 were considered significant.

Results

In this study, 11,042 participants (10-18 years old) consisting of 5374 boys (47.8%) and 5768 girls (52.2%) were assessed. Additionally, 88.1% of the children (n = 9727) were vaccinated by Sinopharm and 11.9% (n = 1315) by Soberana (PastoCoVac). Regarding vaccination dose, 80.5% (n = 8890) received their second dose. Some important clinical data are presented in Table 1.

The time to onset and end of specific and major side effects in the first dose vaccinated patients is of great importance for specialists, thus, we presented the data of kidney-related side effects showing delayed improvement of side effects after the Sinopharm vaccine compared with

Table 1. Quantitative demographic characteristics of the participants

Variable	Value	Sinopharm group	Soberana group
Age, mean± SD, year	14.55±1.830	14.62±1.836	14.06±1.714
Weight, mean± SD	57.05±15.614	57.66±15.949	54.07±13.446
Height, mean± SD, centimeter	162.62±14.497	163.21±14.544	159.93±13.976
Covid-19 history duration , mean± SD, day	11.88±8.789	11.97±8.754	11.26±9.013
Vaccine first dose, N (%)	2152 (19.5)	1404 (65.6)	736 (34.4)
Vaccine second dose, N (%)	8890 (80.5)	8276 (93.5)	579 (6.5)
Sinopharm vaccine, N (%)	9727 (88.1)	-	-
Soberana (PastoCoVac) vaccine, N (%)	1315 (11.9)	-	-

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Table 2. Onset and ending times after developing kidney-related side effects following COVID-19 vaccination

Variable			Vaccine type		Total	*P* value
			Soberana	Sinopharm		
Renal side effects (onset time)	The same day of injection	Frequency	1	3	4	0.853
		Percent	0.1%	0.0%	0.0%	
	The day after injection	Frequency	1	2	3	
		Percent	0.1%	0.0%	0.0%	
	During three days after injection	Frequency	1	5	6	
		Percent	0.1%	0.1%	0.1%	
	During one week after injection	Frequency	1	5	6	
		Percent	0.1%	0.1%	0.1%	
	During two weeks after injection	Frequency	0	1	1	
		Percent	0.0%	0.0%	0.0%	
	Three weeks after injection	Frequency	0	2	2	
		Percent	0.0%	0.0%	0.0%	
Renal side effects (ending time)	The same day of injection	Frequency	0	1	1	0.012
		Percent	0.0%	0.0%	0.0%	
	The day after injection	Frequency	0	2	2	
		Percent	0.0%	0.0%	0.0%	
	During three days after injection	Frequency	1	4	5	
		Percent	0.1%	0.0%	0.0%	
	During one week after injection	Frequency	2	0	2	
		Percent	0.2%	0.0%	0.0%	
	During two weeks after injection	Frequency	0	6	6	
		Percent	0.0%	0.1%	0.1%	
	Three weeks after injection	Frequency	1	5	6	
		Percent	0.1%	0.1%	0.1%	

Table 3. Onset and ending times after developing cardiovascular and hematological side effects following COVID-19 vaccination

Variable			Vaccine type		Total	*P* value
			Soberana	Sinopharm		
Cardiovascular and hematological side effects (onset time)	The same day of injection	Frequency	3	5	8	0.002
		Percent	0.2%	0.1%	0.1%	
	The day after injection	Frequency	2	4	6	
		Percent	0.2%	0.0%	0.1%	
	During one week after injection	Frequency	1	0	1	
		Percent	0.1%	0.0%	0.0%	
	During two weeks after injection	Frequency	1	1	2	
		Percent	0.1%	0.0%	0.0%	
	During three days after injection	Frequency	0	6	6	
		Percent	0.0%	0.1%	0.1%	
Cardiovascular and hematological side effects (ending time)	The same day of injection	Frequency	0	3	3	0.006
		Percent	0.0%	0.0%	0.0%	
	The day after injection	Frequency	2	2	4	
		Percent	0.2%	0.0%	0.0%	
	During three days after injection	Frequency	1	2	3	
		Percent	0.1%	0.0%	0.0%	
	During one week after injection	Frequency	0	2	2	
		Percent	0.0%	0.0%	0.0%	
	During two weeks after injection	Frequency	2	1	3	
		Percent	0.2%	0.0%	0.0%	
	Three weeks after injection	Frequency	2	5	7	
		Percent	0.2%	0.1%	0.1%	

the Soberana vaccine ($P = 0.012$) (Table 2). Cardiovascular and hematological side effects showed early-onset ($P = 0.006$) and delayed improvement of side effects ($P = 0.002$) after the Soberana vaccine compared with the Sinopharm vaccine (Table 3). Neurological side effects showed delayed improvement of side effects after the Soberana vaccine compared with the Sinopharm vaccine ($P = 0.027$) (Table 4). Joint-related side effects showed early-onset ($P = 0.004$) and delayed improvement of side effects ($P = 0.023$) after the Soberana vaccine compared with the Sinopharm vaccine (Table 5). Respiratory side effects showed delayed improvement of side effects after the Soberana vaccine compared with the Sinopharm vaccine ($P = 0.013$) (Table 6). Gastrointestinal side effects showed no difference (Table 7), and dermatological side effects showed early-onset ($P = 0.050$) and delayed improvement of side effects ($P = 0.035$) after the Soberana vaccine compared with the Sinopharm vaccine (Table 8).

Also, fever, shivering, lethargy, tiredness, dizziness, body pain, and pain at the injection site (more than 24 hours) were among general side effects questioned. Edema, angioedema, redness, wheal (urticaria), itching, rash, tenderness, bruise, abscess, hematoma, and eczema were among dermatological side effects that were asked based on the checklist. Nausea, vomiting, diarrhea, constipation, abdominal pain, dyspepsia, appetite loss, gastrointestinal bleeding, and liver dysfunction were among gastrointestinal side effects in the checklist. Dyspnea, chest pain, palpitation, cough, sputum, sore throat, rhinorrhea, nose congestion, nose itching, and throat itching were among the

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Table 4. Onset and ending times after developing neurological side effects following COVID-19 vaccination

Variable			Vaccine type		Total	*P* value
			Soberana	Sinopharm		
Neurological side effects (onset time)	The same day of injection	Frequency	10	39	49	0.225
		Percent	0.8%	0.4%	0.4%	
	The day after injection	Frequency	3	20	23	
		Percent	0.2%	0.2%	0.2%	
	During three days after injection	Frequency	4	24	28	
		Percent	0.3%	0.2%	0.3%	
	During one week after injection	Frequency	5	17	22	
		Percent	0.4%	0.2%	0.2%	
	During two weeks after injection	Frequency	0	6	6	
		Percent	0.0%	0.1%	0.1%	
	Three weeks after injection	Frequency	2	6	8	
		Percent	0.2%	0.1%	0.1%	
Neurological side effects (ending time)	The same day of injection	Frequency	4	12	16	0.027
		Percent	0.3%	0.1%	0.1%	
	The day after injection	Frequency	3	12	15	
		Percent	0.2%	0.1%	0.1%	
	During three days after injection	Frequency	0	21	21	
		Percent	0.0%	0.2%	0.2%	
	During one week after injection	Frequency	4	20	24	
		Percent	0.3%	0.2%	0.2%	
	During two weeks after injection	Frequency	5	10	15	
		Percent	0.4%	0.1%	0.1%	
	Three weeks after injection	Frequency	5	24	29	
		Percent	0.4%	0.2%	0.3%	

Table 5. Onset and ending times after developing joint-related side effects following COVID-19 vaccination

Variable			Vaccine type		Total	*P* value
			Soberana	Sinopharm		
Joint-related side effects (onset time)	The same day of injection	Frequency	5	15	20	0.004
		Percent	0.4%	0.2%	0.2%	
	The day after injection	Frequency	1	16	17	
		Percent	0.1%	0.2%	0.2%	
	During three days after injection	Frequency	5	10	15	
		Percent	0.4%	0.1%	0.1%	
	During one week after injection	Frequency	5	10	15	
		Percent	0.4%	0.1%	0.1%	
	During two weeks after injection	Frequency	2	5	7	
		Percent	0.2%	0.1%	0.1%	
	Three weeks after injection	Frequency	1	6	7	
		Percent	1	2	3	
Joint-related side effects (ending time)	The same day of injection	Frequency	0.1%	0.0%	0.0%	0.023
		Percent	0.4%	0.2%	0.2%	
	The day after injection	Frequency	0	5	5	
		Percent	0.0%	0.1%	0.0%	
	During three days after injection	Frequency	2	14	16	
		Percent	0.2%	0.1%	0.1%	
	During one week after injection	Frequency	3	9	12	
		Percent	0.2%	0.1%	0.1%	
	During two weeks after injection	Frequency	6	11	17	
		Percent	0.5%	0.1%	0.2%	
	Three weeks after injection	Frequency	5	19	24	
		Percent	0.4%	0.2%	0.2%	

respiratory side effects questioned. Arthritis, arthralgia, joint swelling and redness, and muscle pain were among the joint-related (non-neurologic musculoskeletal) side effects in the checklist. Paresthesia, convulsion, blurred vision, headache, vertigo, insomnia, and ataxia were among neurological side effects questioned. Arrhythmia, thrombosis, pericarditis, myocardial infarction, anemia, thrombocytopenia, leukocytosis and leukopenia were among the cardiovascular and hematological side effects. Proteinuria, hematuria, and renal dysfunction were among renal side effects questioned items in the checklist.

Discussion

There are a few studies to date with a high level of evidence on the efficacy and safety of the COVID-19 vaccine in the population under 21 years old. We therefore need further research on the efficacy and safety of the vaccination in various people from various geographic locations, as well as more comparative studies to learn more about the benefits of each type of vaccine. Although recent data support the COVID-19 vaccines' acceptable safety profiles in children and adolescents, some temporary major potentially fatal adverse events, like myocarditis and myopericarditis, have been recorded (21-23), thus, vaccination in children and adolescents aged 2 to 21 years

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Table 6. Onset and ending times after developing respiratory side effects following COVID-19 vaccination

Variable			Vaccine type		Total	*P* value
			Soberana	Sinopharm		
Respiratory side effects (onset time)	The same day of injection	Frequency	5	33	38	0.862
		Percent	0.4%	0.3%	0.3%	
	The day after injection	Frequency	3	17	20	
		Percent	0.2%	0.2%	0.2%	
	During three days after injection	Frequency	5	31	36	
		Percent	0.4%	0.3%	0.3%	
	During one week after injection	Frequency	3	20	23	
		Percent	0.2%	0.2%	0.2%	
	During two weeks after injection	Frequency	3	12	15	
		Percent	0.2%	0.1%	0.1%	
	Three weeks after injection	Frequency	0	9	9	
		Percent	0.0%	0.1%	0.1%	
Respiratory side effects (ending time)	The same day of injection	Frequency	0	10	10	0.013
		Percent	0.0%	0.1%	0.1%	
	The day after injection	Frequency	2	4	6	
		Percent	0.2%	0.0%	0.1%	
	During three days after injection	Frequency	3	21	24	
		Percent	0.2%	0.2%	0.2%	
	During one week after injection	Frequency	2	25	27	
		Percent	0.2%	0.3%	0.2%	
	During two weeks after injection	Frequency	8	15	23	
		Percent	0.6%	0.2%	0.2%	
	Three weeks after injection	Frequency	4	35	39	
		Percent	0.3%	0.4%	0.4%	

Table 7. Onset and ending time after developing gastrointestinal side effects following COVID-19 vaccination

Variable			Vaccine type		Total	*P* value
			Soberana	Sinopharm		
Gastrointestinal side effects (Onset time)	The same day of injection	Frequency	7	32	39	0.564
		Percent	0.5%	0.3%	0.4%	
	The day after injection	Frequency	2	24	26	
		Percent	0.2%	0.2%	0.2%	
	During three days after injection	Frequency	3	18	21	
		Percent	0.2%	0.2%	0.2%	
	During one week after injection	Frequency	3	10	13	
		Percent	0.2%	0.1%	0.1%	
	During two weeks after injection	Frequency	1	13	14	
		Percent	0.1%	0.1%	0.1%	
	Three weeks after injection	Frequency	0	8	8	
		Percent	0.0%	0.1%	0.1%	
Gastrointestinal side effects (ending time)	The same day of injection	Frequency	2	13	15	0.143
		Percent	0.2%	0.1%	0.1%	
	The day after injection	Frequency	2	7	9	
		Percent	0.2%	0.1%	0.1%	
	During three days after injection	Frequency	4	21	25	
		Percent	0.3%	0.2%	0.2%	
	During one week after injection	Frequency	1	18	19	
		Percent	0.1%	0.2%	0.2%	
	During two weeks after injection	Frequency	5	10	15	
		Percent	0.4%	0.1%	0.1%	
	Three weeks after injection	Frequency	2	29	31	
		Percent	0.2%	0.3%	0.3%	

is safe and also beneficial for aborting the pandemic (24, 25). Studies that evaluate risk-benefit concerns revealed favorable results of vaccinating children and adolescents, especially those with underlying diseases and immunosuppressed conditions (21, 23, 26, 27). An immune response of 90% to 100% has been reported in healthy pediatrics vaccine recipients that is higher and more durable than natural COVID-19 infection (28-30), and vaccination in 12 to 18-year-old participants has decreased the rate of hospitalization due to COVID-19 and its consequences among these age groups (31, 32). Children who received the COVID-19 vaccine most frequently experienced general side effects, including fatigue, body pain, erythema, and pain at the injection site, headache, myalgia, and fever, as well as some organ-specific side effects, particularly gastrointestinal, dermatological, and joint-related issues like nausea, emesis, and diarrhea, urticarial, exanthema, papulosquamous eruptions like pityriasis rosea, and joint pain (33-36).

Sinopharm and Soberana (PastoCoVac) COVID-19 vaccines are generally safe and effective in children and adolescents. Mild, transient general complications were the most common side effects. Our previous study showed that breakthrough infection could occur after full

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Table 8. Start and finish time after developing dermatological side effects following COVID-19 vaccination

Variable			Vaccine type		Total	*P* value
			Soberana	Sinopharm		
Dermatological side effects (onset time)	The same day of injection	Frequency	6	25	31	0.050
		Percent	0.5%	0.3%	0.3%	
	The day after injection	Frequency	4	17	21	
		Percent	0.3%	0.2%	0.2%	
	During three days after injection	Frequency	6	17	23	
		Percent	0.5%	0.2%	0.2%	
	During one week after injection	Frequency	1	20	21	
		Percent	0.1%	0.2%	0.2%	
	During two weeks after injection	Frequency	1	6	7	
		Percent	0.1%	0.1%	0.1%	
	Three weeks after injection	Frequency	4	9	13	
		Percent	0.3%	0.1%	0.1%	
Skin side effects (ending time)	The same day of injection	Frequency	0	6	6	0.035
		Percent	0.0%	0.1%	0.1%	
	The day after injection	Frequency	1	9	10	
		Percent	0.1%	0.1%	0.1%	
	During three days after injection	Frequency	5	17	22	
		Percent	0.4%	0.2%	0.2%	
	During one week after injection	Frequency	7	16	23	
		Percent	0.5%	0.2%	0.2%	
	During two weeks after injection	Frequency	3	10	13	
		Percent	0.2%	0.1%	0.1%	
	Three weeks after injection	Frequency	5	22	27	
		Percent	0.4%	0.2%	0.2%	

vaccination in teenagers; however, the incidence is significantly reduced after vaccination.

More research is required to determine the type and degree of side effects as well as the effectiveness and safety of the COVID-19 vaccine in children as compared to adults. Additionally, it appears crucial to assess the benefits of each common vaccine in light of the negative consequences of COVID-19 viremia and any potential treatment-related or COVID-19-related side effects from a clinical and histopathology perspective (26, 37-47).

Limitations

Limitations in our study were the type of data collection in which the data may be missed due to the interval in COVID-19 development of the children and the lack of systematic registration system in medical centers for COIVD-19 data. The diagnosis of COVID-19 in patients is based on self-report and is not 100% reliable.

Conclusion

Compared to the Sinopharm vaccine, many negative effects following Soberana vaccination start earlier and last longer. The time to onset and end of side effects in patients who got vaccination with Sinopharm and Soberana are significantly different regarding the kidney-related, cardiovascular and hematological, neurological, respiratory, joint-related, dermatological and gastrointestinal side effects. As a result, compared to Sinopharm vaccine, the side effects of Soberana vaccine are related to the heart and hematology, joints (non-neurologic musculoskeletal), and dermatology. Improvement of renal side effects in the Sinopharm vaccine group and improvement of neurological and respiratory side effects in the Soberana vaccine group occurred with a delay compared with other vaccine. There were no differences in term of the time to onset and end of side effect.

Ethical Considerations

The research followed the Tenets of Declaration of Helsinki. This study was approved by ethic committee of Iran University of Medical Sciences (ethical code#IR.IUMS.REC.1400.936). Moreover, informed consents were obtained orally from all the patients.

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Authors' Contributions

N.T., N.N., S.S., and A.G. contributed to the study idea and design, M.F., S.S., T.R., and A.G. conducted database search, literature review, quality evaluation, data gathering, designing and drafting the proposal, R.V. conducted database search and followed up with the ethical committee for approval, statistics, and analysis. S.K. and A.J. contributed to the literature review, and drafting the manuscript, and the proposal preparation and edit. A.G. contributed to the supervision of the study. S.S., M.F., S.S., T.R., S.K., A.J., and A.G. conducted data gathering. All authors contributed to drafting the manuscript and revising the manuscript critically for importance intellectual content and read and approved the final version to be published and agreed to be accountable for all aspects of the work. All authors agreed on the order in which their names are listed in the manuscript.

Conflict of Interests

The authors declare that they have no competing interests.

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