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# Evaluation of the side effects of Sinopharm and PastoCovac COVID-19 vaccines in children aged 5-12 years in Iran

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***Abstract***

***Background:*** Vaccination of children against COVID-19 in Iran was conducted for children 5-12 years on July 22, 2021, with PastoCovac and Sinopharm. This study aimed to evaluate the side effects following the administration of vaccines in children.

***Methods:*** This descriptive-analytical study was performed on 394 children aged 5-12 years who were referred to health centers in Bojnurd, Iran, and received PastoCoVac or Sinopharm COVID-19 vaccines from March to July 2022. After receiving the first dose of the vaccine, in health centers, the children's parents filled out sections of a COVID-19 vaccine questionnaire that included sociodemographic and clinical characteristics of children. After that, other sections of the questionnaire related to side effects following vaccination were filled out by parents of children at different time intervals after receiving the first or second dose of vaccines.

***Results:*** Our results showed that the incidence of vaccine side effects in children aged 5-12 years varies between 24%-37%, depending on the type and dose of vaccine. The most common side effects after getting the first and second doses of vaccines were injection site pain and swelling, fever, fatigue, and myalgia. No serious side effects were reported, and almost all side effects were resolved within a few days without special treatment.

***Conclusion:*** It can be concluded that the incidence of side effects following COVID-19 vaccination in children aged 5-12 years varies depending on the type and dose of the vaccine. However, no serious side effects were reported, and most were resolved within a few days without special treatment. These findings suggest that the vaccination of children against COVID-19 is generally safe and well-tolerated.

***Key Words:*** Children, COVID-19, Fever, Fatigue, Injections, Myalgia, Side effect, Vaccination.

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## 1- INTRODUCTION

Before the introduction of an effective vaccine against SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2), nationwide quarantines and face mask-wearing were the only ways to control the COVID-19 pandemic (1). However, fear, stress, depression, closure, limitation of businesses, deprivation of social services, etc., were challenges and problems of nationwide quarantines during the COVID-19 pandemic (2).

The first COVID-19 vaccine receiving emergency authorization from the FDA (Food and Drug Administration) and the EMA (European Medicines Agency) on December 11, 2020, was an mRNA–based vaccine named the Pfizer–BioNTech vaccine (3). Since then, AstraZeneca ChAdOx1, Moderna, Johnson & Johnson, and Sinopharm, were other COVID-19 vaccines which received WHO (World Health Organization) emergency use listing (4).

COVID-19 vaccination began in Iran in February 2021, first targeting healthcare workers and the highest-risk population using the Sputnik V COVID-19 vaccine (5). Since then, the nationwide COVID-19 vaccination program for all individuals aged ≥12 years has followed with three imported vaccines, Vazzevria, Sinopharm, and Covaxin, and four domestically developed vaccines, COVIran Barekat, PastoCoVac, Razi Cov Pars, and Noora vaccine (6, 7). Iran has administered over 150 million doses of COVID-19 vaccines (8).

Although it is well known that people of any age can be infected with COVID-19 (9, 10), there are misconceptions that children do not develop severe diseases and do not need intensive care unit treatment (11). Vaccination of children against COVID-19 helps prevent hospitalization and death and reduces the spread and transmission of COVID-19 and its social and economic issues (12, 13). The Iranian government conducted a nationwide COVID-19 vaccination program for children 5-12 years on July 22, 2021, with PastoCovac and Sinopharm (14). Previous studies have reported that the most common side effects of PastoCovac and Sinopharm are mild to moderate and self-limiting; however, most volunteers participating in these studies were over 18 years old or 12-18 years old (15, 16, 17, 18).

Moreover, providing adequate knowledge on the side effects of children's COVID-19 vaccinations can help lower apprehension about this type of vaccine and increase COVID-19 vaccine desire, acceptance, and coverage among children (19, 20). Therefore, in the present study, we aimed to identify the side effects reported by the children's parents among children aged 5-12 years who were vaccinated with COVID-19 vaccines, PastoCovac, and Sinopharm in North Khorasan, Iran.

## 2- MATERIALS AND METHODS

### 2-1. Study design and participants

This descriptive-analytical study evaluated the side effects of the COVID-19 vaccine on 5–12-year-old children referred to rural and urban health centers in Bojnurd, Iran, and received COVID-19 vaccines, including PastoCoVac and Sinopharm from March to July 2022. Subjects were selected by stratified sampling and cluster multistage sample design from five rural and four urban health centers. The sample size was calculated using an online Raosoft sample size calculator with a 95% confidence interval, 50% proportion of the population, and 3% margin of error (16).

#### 2-1-1. Inclusion and exclusion criteria

Inclusion criteria were having no COVID-19 infection or any other infections at the time of receiving the COVID-19 vaccine, being between 5 to 12 years of age,

without any prior COVID-19 vaccination, and completing both doses of COVID-19 vaccine with PastoCoVac or Sinopharm. Exclusion criteria were having an incomplete questionnaire, a COVID-19 positive test or any other infections during the study period, and/or incomplete COVID-19 vaccination.

### 2-2. Instrument

The 5-12 year olds' COVID-19 vaccine questionnaire to be filled out by parents was designed according to the WHO and Iran's Health Ministry literature review and guidelines on the expected side effects after children's COVID-19 vaccination. The questionnaire was validated by a group of clinical faculty members of North Khorasan University of medical sciences who were experienced in research and survey development.

The questionnaire was designed in three sections. The first section consisted of an introductory part about the study's purpose, the parents' contact details, a part of which related to voluntary informed consent. The second section included sociodemographic and clinical data on children and COVID-19-related information items. Finally, the last section was a list of possible local and systemic side effects post-first and -second doses of COVID-19 vaccines (Sinopharm or PastoCoVac). At the end of the questionnaire, an open section was also provided that allows parents to report any unlisted symptoms experienced by their children.

### 2-3. Data collection

After receiving the first dose of the vaccine, the children's parents were asked to fill out the first and second sections of the questionnaire in health centers. After that, the third section of the questionnaire related to side effects following vaccination was filled out by the parents to report any side effects. They were interviewed through telephone calls or face to face in case of the presence of parents in health centers. Before receiving the second dose in health centers, the side effects of the first dose of the COVID-19 vaccine 72 hours after injection were also recorded. The side effects of the second dose were collected through telephone calls to parents 72 hours and two weeks after the injection vaccine.

### 2-4. Data analysis

GraphPad Prism software version 5.0 (GraphPad Software, USA) was used to carry out descriptive statistics of the participants for the sociodemographic variables and COVID-19-related anamnesis. Chi-square test was used to test the significance of the difference between the demographics and other variables of interest (comorbid conditions, previous history of COVID-19 infection, etc.) against adverse effects. It was also performed to assess the difference between the adverse effects based on the type of vaccine and doses. Data were expressed in terms of their type, frequency, percentage, mean, and standard deviation. P values less than 0.05 were considered statistically significant.

## 3- RESULTS

From March 11 until July 6, 2022, 394 COVID-19-vaccinated children aged 5 to 12 years participated in the present study. The mean age of the subjects was 9.20 ± 2.07 (95% CI, 9-10), and 212 (53.80%) were boys. **Table 1** presents the demographic and clinical characteristics of the participants.

From among 394 children, 260 (65.99%) were vaccinated by Sinopharm and 134 (34.01%) by PastoCoVac. One hundred and forty-one participants (35.69%) after the first dose and one hundred thirteen (28.60%) after the second dose of vaccination suffered post-vaccination side effects, which shows a statistically significant difference (P=0.038).

**Table-1:** Demographic and clinical characteristics of the study subjects

| Variable | | N (%)/ Mean |
|---|---|---|
| Age | | 9.20 ± 2.07 |
| Body Mass Index | | 17.03 ± 3.09 |
| Ethnicity | Persians | 130 (32.99) |
| | Khorasani Turks | 67 (17.00) |
| | Khorasani Kurds | 124 (31.47) |
| | Turkomen | 64 (16.24) |
| | Tat | 9 (2.28) |
| | History of exposure to COVID-19 | 66 (16.75) |
| Habitation | City | 256 (64.97) |
| | Village | 138 (35.03) |
| | Comorbidities | 12 (3.04) |
| | Chronic kidney disease | 3 (25) |
| | Autoimmune disease | 5 (41.67) |
| | Respiratory diseases | 3 (25) |
| | Blood disorder | 1 (8.33) |
| Parents' Education Level | Elementary school | 227 (57.61) |
| | High school | 72 (18.27) |
| | College/University | 95 (24.12) |
| History of COVID-19 in parents or household members | Hospitalization | 38 (9.64) |
| | Death | 13 (3.3) |
| | Post-COVID-19 vaccination side effects in parents or household members | 17 (5.78) |

According to parents' reports, 69.3% of children who developed side effects post-first dose of vaccination and 75.9% of those who developed post-second dose, had experienced the symptoms around 12 hours after vaccine injection. The side effects duration after the first dose lasted ≤24 hours for 52.4% of children and >24-48≥ hours for 38.5% of them, while this duration for the second dose lasted ≤24 hours for 36.6% of children and >24-48≥ hours for 47.5% of them.

88 (34.3%) of the PastoCoVac recipients reported side effects following the first dose and 32 (23.9%) after the second dose. Out of the Sinopharm vaccine recipients, ninety-five (36.5%) had side effects after the first dose and seventy-eight (30%) after the second dose. We compared the percentage of side effects after the first and second doses according to the type of COVID-19 vaccine. We found a significant difference between Sinopharm and PastoCovac after the first dose ($P<0.001$) but not after the second dose. In other words, the side effects after the first dose were more common among recipients of the Sinopharm vaccine than among recipients of the PastoCovac vaccine, with an odds ratio of 3.32 (95% confidence interval [CI], 2.15-5.14).

The most frequent adverse effects after both the first and second doses of the Sinopharm vaccine were injection site pain and swelling (1st dose: 24.6%, second dose: 15.8%), fever (1st dose: 13.8%, second dose: 8.0%), and fatigue (1st dose: 3.8%, second dose: 4.2%). Injection site pain and swelling (1st dose: 23.1%, second dose: 18.6%), fever (1st dose: 11.9%, second dose: 8.2%), and myalgia (1st dose: 6.7%, second dose: 3.0% as well as fatigue: second dose: 3.0%) were the major adverse effects post-first and -

second dose of the PastoCoVac vaccine. Transient akathisia after the first dose and constant crying and transient akathisia after the second dose of the PastoCoVac vaccine have been reported as rare side effects. One of the subjects who received the second dose of Sinopharm revealed a bruise at the vaccine injection site. **Figure 1** presents the percentage of side effects reported based on the type of vaccines and their doses.

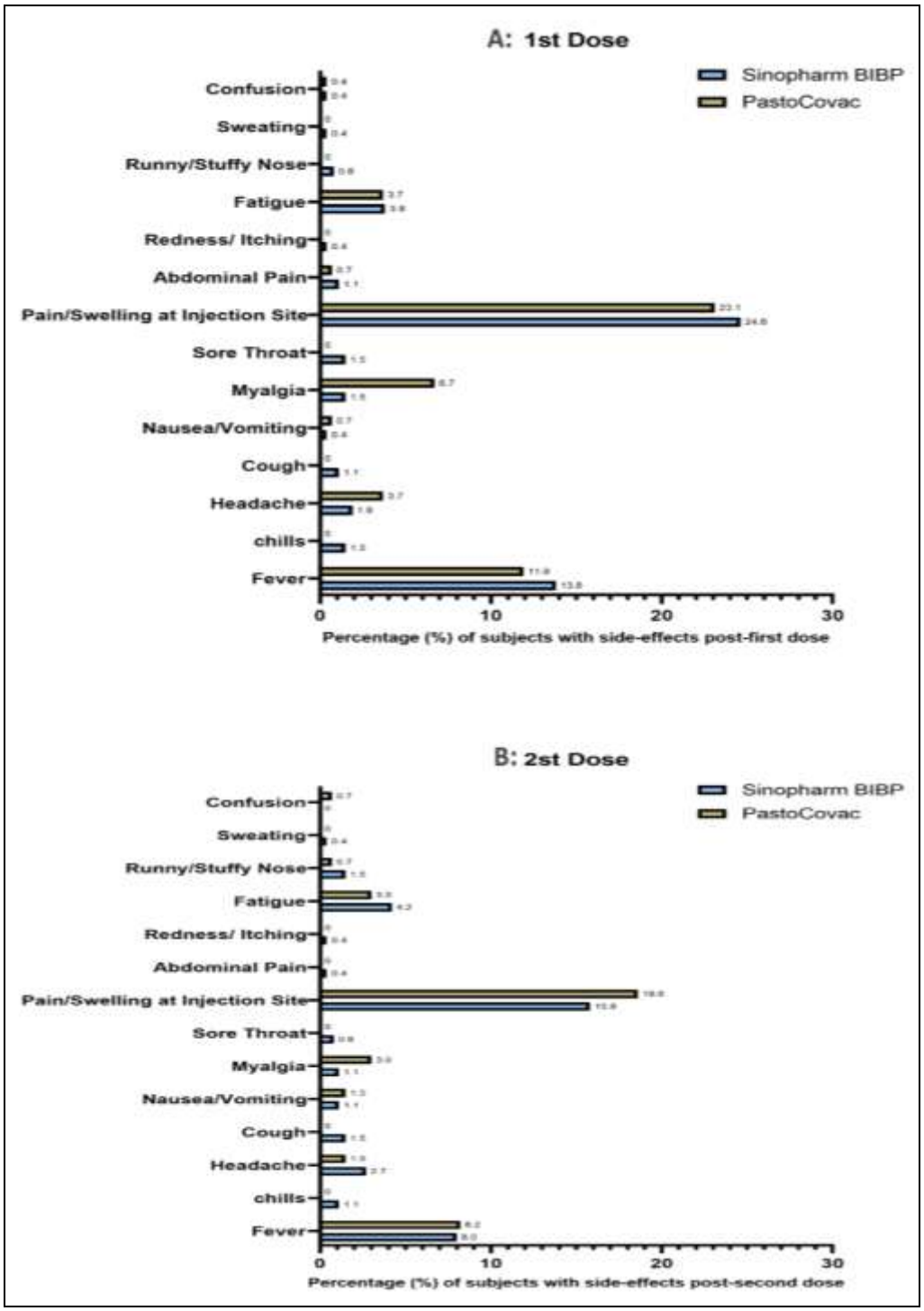


**Fig. 1:** Frequency of side effects reported after administration of PastoCoVac and Sinopharm BIBP

Chi-square test was also used to analyze the association between the demographic characteristics of the subjects and the side effects induced by post-first and -second doses of COVID-19 vaccines. We did not find any association between the demographic characteristics of the subjects and the percentage of side effects reported. However, in the age group of 5-7 years, Persian girls with a history of exposure to COVID-19 revealed a higher percentage of side effects than others. The results of the correlational analysis are shown in **Table 2**.

**Table-2:** Association between the demographic factors and the side effects after receiving the COVID-19 vaccines

| Factors | | Total (n) | First Dose | | Second Dose | |
|---|---|---|---|---|---|---|
| | | | Percentage of side effect | P-value | Percentage of side effect | P-value |
| Age (years) | 5-7 | 90 | 43.3% | 0.234 | 34.0% | 0.151 |
| | 8-10 | 189 | 33.3% | | 24.0% | |
| | 10-12 | 115 | 33.9% | | 31.8% | |
| Gender | Boy | 212 | 33.5% | 0.343 | 29.2% | 0.822 |
| | Girls | 182 | 38.4% | | 27.9% | |
| Ethnicity | Khorasani Turks | 67 | 25.4% | 0.314 | 18.2% | 0.236 |
| | Khorasani Kurds | 124 | 37.1% | | 32.0% | |
| | Turkoman | 64 | 39.0% | | 28.6% | |
| | Tat | 9 | 22% | | 22.2% | |
| | Persians | 130 | 39.2% | | 31.2% | |
| History of exposure to COVID-19 | Yes | 66 | 40.9% | 0.398 | 33.3% | 0.371 |
| | No | 328 | 34.7% | | 27.6% | |
| Comorbidities | Yes | 13 | 23.1% | 0.752 | 15.4% | 0.735 |
| | No | 381 | 36.2% | | 26.3% | |

12.9% of subjects after the first dose and 11.2% after the second dose received medication to relieve side effects following vaccination—none of those who received the vaccine needed to be visited by a physician or required hospitalization.

## 4- DISCUSSION

The success of the children's COVID-19 vaccination program is highly related to parents' acceptance. One of the most important factors for vaccine refusal or hesitancy is worrisome news of vaccine side effects in children. Advisedly, the safety of COVID-19 vaccines should be investigated in every country or region based on sociodemographic characteristics and types of vaccines used.

In the present study, two types of COVID-19 vaccines, PastoCovac and Sinopharm, were used for children 5-12 years. PastoCovac, or Soberana 02, is a conjugate vaccine that couples the SARS-CoV-2 spike protein's receptor-binding domain to tetanus toxoid (21). The recommended dosage of PastoCovac is two doses with an interval of 4 weeks (21). Sinopharm is an inactivated vaccine that comprises a dead copy of virulent SARS-CoV-2 strains plus aluminum hydroxide (15). The shot requires two doses at a recommended interval of four weeks (15).

The present study aimed to determine the side effects following the administration of

PastoCovac and Sinopharm vaccines in individuals aged 5-12 years.

The current study demonstrated that the prevalence of side effects in children aged 5-12 years varies between 24%-37%, depending on the type and dose of vaccine. The most common side effects after getting the first and second doses of vaccines were injection site pain and swelling, fever, fatigue, and myalgia. No serious side effects were reported and they were almost resolved within a few days without special treatment.

Our findings are largely supported by previous studies (14, 22). In line with the present study, Tavakoli et al. evaluated the safety of COVID-19 vaccination in Iranian children and adolescents. They reported that about 30% of vaccinated children with PastoCovac or Sinopharm developed side effects (14), and the most common side effects included: injection site pain, fever, fatigue, chills, and dizziness (14). Tavakoli et al. concluded that these vaccines are safe with no serious side effects in children (14). In a prospective cohort study, Thonginnetra and co-workers evaluated safety after the Sinopharm vaccine in adolescents aged 10-17 years in Thailand (23). 51% of adolescents reported side effects, and the results confirmed the vaccine's safety profile in this age group (23). The most common reactions experienced by participants were pain at the injection site, fatigue, myalgia, and headache (23). Han and colleagues indicated that the incidence of side effects following receiving an inactivated SARS-CoV-2 vaccine (CoronaVac) in children and adolescents aged 3-17 years old ranged from 18%-35% (24). They also reported that the most frequent post-vaccination event with CoronaVac was injection site pain, fever, and fatigue; and concluded that CoronaVac is well tolerated and safe (24).

Puga-Gómez et al. evaluated the safety of the Soberana02 in children 3-18 years old and did not report severe and serious vaccine-associated adverse events (25). 53% of children suffered at least one adverse event. Local pain and fever were reported as common post-vaccination adverse effects (25).

Tian et al. in a systematic review including multiple studies investigating the safety of COVID-19 vaccines (Pfizer–BioNTech, Sinopharm, Soberna 02, and Spikevax in adolescents and children population less than 18 years of age), reported that injection site pain, fever, headache, and fatigues are the most common adverse events (22). Also, several studies have confirmed that injection site pain, fever, fatigue, and headache are common adverse effects of Pfizer–BioNTech in children (26, 27, 28).

The incidence of post-COVID-19 vaccination adverse events in this investigation was relatively lower compared with other studies such as Puga-Gómez et al. (25) and Thonginnetra et al. (23). The reason might be related to differences in the age range of participants. Adverse reactions are more prevalent in teenagers than in young children (22, 24, 25).

Although we did not report severe post-vaccination reactions in children aged 5-12, some studies have recorded limited critical side effects, such as myocarditis, pericarditis, respiratory complication, and thrombosis (14, 29, 30, 31). This inconsistency can be explained by differences in the type of vaccines administered, sample size, and age range of participants.

Our results also revealed a significantly increased incidence of side effects after the first dose of vaccine compared with the second dose ($1^{st}$: 35.69% vs. $2^{nd}$: 28.60%, P=0.038). This finding agrees with Puga-Gómez's findings which showed that adverse events of the Soberana02 in 3-18-year-old children are more frequent after

the first dose than the second or third dose (25). Similarly, Thonginnetra et al. reported a higher incidence of side effects following the first dose of Sinopharm injection than the second dose (23). On the contrary, Ali et al. reported more side effects in adolescents after the second dose of the mRNA-1273 vaccine (Moderna) than the first dose (32). Blois et al. found some differences in reactogenicity between the first and second doses of the BNT162b2 mRNA COVID-19 vaccine in children 5-11 years old (33). Injection site reactions and systemic symptoms frequently happened after the first and second vaccination doses, respectively (33).

Consistent with earlier studies (14), we also found that the side effects were more common among recipients of the Sinopharm vaccine than recipients of the PastoCovac vaccine.

A smaller sample size may have affected the results of our trial in comparison to previous studies. Questionnaires about side effects were mainly filled out by calling the parents, and information accuracy might be doubtful. Therefore, recording all the side effects by health workers in the health centers would be better.

## 5- CONCLUSION

Based on the study's results, it can be concluded that the incidence of side effects following COVID-19 vaccination in children aged 5-12 years in Iran varies depending on the type and dose of the vaccine. However, no serious side effects were reported, and most were resolved within a few days without special treatment. These findings suggest that the vaccination of children against COVID-19 is generally safe and well-tolerated.

## 6- ETHICAL CONSIDERATIONS

The study was performed based on informed consent and was approved by the Ethics Committee of North Khorasan University of Medical Sciences, Bojnourd, Iran (Ethic approval Cod: IR.NKUMS.REC.1401.012). This study did involve human participants; therefore, consent was obtained consciously.

## 7- CONFLICT OF INTEREST

None.

## 8- ACKNOWLEDGMENT

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