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ORIGINAL ARTICLE

Common Local and Systemic Side Effects of Sinovac Covid-19 Vaccine Among Children and Adult Participants

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ABSTRACT

Objective: Vaccination is one of the primary measures for halting the COVID-19 outbreak. Although there are several vaccines in use around the globe, little is known about the Sinovac vaccine's efficacy and side effects. Therefore, the purpose of this study was to investigate the reported side effects of the Sinovac vaccine in children and adult participants.

Methodology: This was a multi-centered, cross-sectional study that was performed, using a non-probability sampling method. The study's duration was about eight months, from March 1, 2022, to October 31, 2022 after taking approval. The study included 450 participants, including 225 children and 225 adults, who had either received the first or second dose of the Sinovac vaccination. Age, weight, height, and duration of diabetes and hypertension were documented as means and standard deviations. Frequencies and percentages were documented for demographic features. A chi-square test was used to determine the association between local and systemic side effects among children and adult participants.

Results: The study findings showed that out of 450 participants, One hundred forty (62.2%) male participants and 85(37.8%) female participants were under the age of 18, and 163(72.4%) male participants and 62(27.6%) female participants were above the age of 18 years, with a significant difference observed among them (p=0.021). Following the first dose of the Sinovac vaccine, fever was the most frequently reported side effect in 123(54.7%) children and 81(36.0%) adult participants, with a substantial association noticed among them (p<0.001). Similarly, following the 2nd dose of the Sinovac vaccine, fever was the commonly reported side effect in 94(41.8%) children and 61(27.1%) adult participants, with a substantial association noticed among them (p=0.001).

Conclusion: This study concluded that the most frequently reported side effect was fever in both children and adult participants following receiving the first and second doses of Sinovac vaccines. Moreover, pain and swelling at the injection site were the only local side effects observed. Additionally, the observed side effects were more pronounced after the first dose as compared to the second dose.

Keywords: Sinovac vaccine, fever, pain, swelling injection site.

INTRODUCTION

Coronavirus 2 (SARS-CoV-2) first identified at the end of 2019. It had a quick global spread and a high mortality and morbidity rate. Consequently, in March 2020, the World Health Organization declared SARS-CoV-2 a global pandemic [1]. Clinical symptoms of SARS-CoV-2 infections can range widely, from minor or asymptomatic infections to acute, life-threatening multiple organ and respiratory illnesses [2]. Due to the high rates of transmission and the emergence of novel SARS-CoV-2 variants, it is now difficult to control the current pandemic [3]. Even though governments and organizations all over the world have taken several steps to stop the pandemic's spread, the only option for eradicating the risk of infection is the development of a vaccine [4].

Several COVID-19 vaccines were developed to combat the pandemic, including those from AstraZeneca, Sinopharm, Sinovac, Sputnik V, Janssen (Johnson & Johnson's), and Pfizer-BioNTech [5]. Each type of immunization has distinct benefits and drawbacks in terms of efficacy, immunogenicity, and efficiency, while the efficiency of these vaccines in preventing COVID-19 infection differs [6].

One of the most frequently used vaccinations in many nations even now is the Sinovac vaccine, a Chinese inactivated virus vaccine. 83.5% and 95%, respectively, of the Sinovac and Pfizer vaccinations were efficacious [7,8]. The Sinovac vaccine has one of the most extensive coverage rates of any other vaccination, and an investigation of potential side effects has been performed to increase its efficacy. According to various clinical studies of the COVID-19 vaccine, a high temperature or allergic responses, like itchiness and inflammatory processes, were among the less severe reactions brought on by COVID-19 vaccines [9.10]. In contrast, swelling and pain at the injection site were among the most frequently observed side effects, and they typically resolved within 48 hours after vaccination [9,10]. The most frequent side effect linked to practically all COVID-19 vaccinations was pain at the injection site. Other modest side effects of the Sinovac vaccine included weakness, aches in the muscles, and diarrhea, which only persisted for two days. Contrary to other COVID-19 vaccines, CoronaVac/Sinovac recipients experienced fewer fever episodes. The Sinovac vaccine was recommended for people 18 years of age and older [10].

Regardless ofendorsements by concerned authorities and the apparently protection conferred by immunizations, concerns about vaccination safety persist. Vaccine hesitation is on the rise in many regions of the world despite the fact that vaccines are readily available and have both short- and long-term negative effects. Because of worries about the safety and potential side effects of a COVID-19 vaccine, large-scale sueveys and systematic reviews had projected substantial vaccine reluctance [11,12]. According to a study conducted in seven European nations, approximately 55% of those who expressed vaccine hesitation mentioned concern over adverse reactions as their primary motivation.[13]. Due to concerns about vaccine side effects, parents were reluctant to consent to their children receiving the COVID-19 vaccination [14]. According to other studies, if the fear of adverse effects is reduced, the general public will be more receptive to vaccinations [15]. A study conducted in China further confirmed that the general public continues to be seriously concerned about the side effects, particularly those related to inactivated vaccinations [16]. Recent surveys aimed at different demographics cohorts have revealed enduring vaccine reluctant. Almost ten percent of the population in Thailand was hesitant to obtain the vaccine or did not acquire it, despite the ratio being on the decline [17]. According to cross-sectional study in Saudi Arabia, anxiety of side effects was shown to be the primary motivator underlying vaccine hesitation [18]. In contrast, in Italy, 25% of youngsters stated their reluctance to receive the COVID-19 vaccine, and 31.5% of parents were reluctant to vaccinate their children [19].

Despite the widespread usage of the Sinovac COVID-19 vaccine in a number of countries there is a dearth of published evidence that supports any negative impacts. Therefore, the goal of this study was to find out whether participants who were both children and adults had ever had any of the negative effects associated with the Sinovac vaccine.

METHODOLOGY

This was a multi-centered, cross-sectional study that was performed, using a non-probability sampling method. The study's duration was about eight months, from March 1, 2022, to October 31, 2022. The ethical approval was taken from the Ethical Review Committee. The study included 450 participants, including 225 children and 225 adults, who had either received the first or second dose of the Sinovac vaccination. Participants who had previously acquired a COVID-19 immunization, had never received one, or had received a different vaccine instead of Sinovac, were excluded from the study.

Each participant was given a brief summary of the study's objectives before being questioned for their informed permission. A self-structured questionnaire was used to gather participant data. Gender, age, concurrent medical conditions, Sinovac vaccination with both dosages, prior exposure to COVID-19 infection, and the frequency of any local and systemic adverse effects after administering the first and additional doses of the vaccine were among the participant's demographic details. After either the first or second dose, the COVID-19 vaccine's side effects were also evaluated. Fever, chills, headache, breathing problems, vomiting, abdominal discomfort, painful joints, lymphadenopathy, sore throat, tension, and exhaustion are considered to be systemic adverse effects. Local side effects of the injection could include pain, burning, redness, and swelling. The extent of participant gratification was also documented.

The data was analyzed using SPSS version 22. A categorical data such as gender, coexisting illnesses, the previous exposure to COVID-19 infection, and post-vaccination side effects were presented as frequencies and percentages. While continuous data, for example, age, height, weight, and the duration of comorbidities, were reported as means and standard deviations. A chi-square test was used to determine the association between local and systemic side effects among children and adult participants. A p value of <0.05 was considered as statistically significant.

RESULTS

A total of 450recipients who were completely vaccinated with the Sinovac vaccine were studied. One hundred forty (62.2%) male participants and 85(37.8%) female participants were under the age of 18, and 163(72.4%) male participants and 62(27.6%) female participants were above the age of 18 years, with a significant difference observed among them (p=0.021). There were 141(62.7%) children and 159(70.7%) adults who exhibited hypertension, and 84(37.3%) youngstersand 66(29.3%) adults did not have hypertension, with an insignificant association among them (p =0.072). The mean age of the children was 17.93±1.99 years, and the mean age of the adult participants was 48.24±13.63 years, with a significant association among them (p<0.001). The mean weight of the children was 61.54±11.89 kg and that of adult participants was 71.62±14.88 kg, with a significant association among them (p<0.001). The mean height of the children were 5.48±0.73 feet, and adult participants was 5.13±0.64 feet, with a substantial relationship among them (p<0.001). The mean duration of hypertension was 2.66±1.28 years in children and 5.30±4.34 years in adult participants, with a substantial relationship among them (p=0.013). The mean duration of diabetes was 1.50±0.50 years in childrenand 8.19±3.05 years in adult participants, with a substantial association among them (p<0.001). Out of 450 participants, only 61(27.1%) in childrenand 142(63.1%) in adults had diabetes, with a significant association among them (p<0.001). More than a half 141(62.7%) children and 142(63.1%) in adults had hypertension, with an insignificant association among them (p=0.072). Additionally, only 7(3.1%) children and 6(2.7%) adult participants had past exposure to the COVID-19 infection, with an insignificant difference noticed among them (p=0.778), as presented in Table I.

Following the first dose of the Sinovac vaccine, fever was the most frequently reported side effect in 123(54.7%) children and 81(36.0%) adult participants, with a substantial association noticed among them (p<0.001). Additionally, burning at the injection site was found in 72(32.0%) children and 48(21.3%) adult participants, with a significant association found among them (p=0.011). Moreover, other side effects such as redness at the site of injection, lymphadenopathy, rashes, flu, fatigue, joint pain, chills, sore throat, diarrhea and chest pain in children and adult participants were significantly associated, (p<0.05). On the other hand, flu, fatigue, sore throat, diarrhea, and chest pain were the least reported side effects in children and adult participants, with a substantial relationship observed among them (p <0.05), as presented in Table II.

Similarly, following the 2nd dose of the Sinovac vaccine, fever was the commonly reported side effect in 94(41.8%) children and 61(27.1%) adult participants, with a substantial association noticed among them (p=0.001). Additionally, injection site pain was observed in 91(40.4%) children and 42(18.7%) adult participants, with a significant association found among them (p<0.001). Moreover, other side effects such as burning, swelling, and redness at the site of injection, redness at the site of injection, chills, headaches, nausea, anxiety, joint pain, muscular pain, cough, sore throat, and diarrhea in children and adult participants were significantly associated, (p<0.05). On the other hand, lymphadenopathy, rashes, flu, fatigue, shortness of breath, and chest pain were insignificantly associated among children and adult participants (p>0.05), as presented in Table III.

The satisfaction level with the Sinovac vaccine showed that the 89(39.6%) children,106(35.3%) and 65(28.9%) adult participants were satisfied, and 79(35.1%) children, and 54(24.0%) adult participants were very satisfied with their vaccinations, while 5(2.2%) children reported low levels of satisfaction, with a substantial association seen among them (p<0.001), as presented in Table IV.

Table 1: Demographic details of participants vaccinated by Sinovac vaccine (n=450).

Variable		18 years or less n(%)	More than 18 years n(%)	p-value
Age (years)		17.93±1.99	48.24±13.63	<0.001
Weight (kg)		61.54±11.89	71.62±14.88	<0.001
Height (feet)		5.48±0.73	5.13±0.64	<0.001
Hypertension Duration (years)		2.66±1.28	5.30±4.34	0.013
Diabetes Mellitus Duration (years)		1.50±0.50	8.19±3.05	<0.001
Gender	Male	140(62.2%)	163(72.4%)	0.021
	Female	85(37.8%)	62(27.6%)	
Hypertension	Yes	141(62.7%)	159(70.7%)	0.072
	No	84(37.3%)	66(29.3%)	
Diabetes Mellitus	Yes	61(27.1%)	142(63.1%)	<0.001
	No	164(72.9%)	83(36.9%)	
Previous COVID 19 exposure	Yes	7(3.1%)	6(2.7%)	0.778
	No	218(96.9%)	219(97.3%)	

Table 2: The association between the prevalence of side effects after receiving the 1st dose of the Sinovacvaccine among children and adult participants.

Variable		18 or less than 18 years n(%)	More than 18 years n(%)	p-value
Pain at the site of injection	Yes	79(35.1%)	68(30.2%)	0.269
	No	146(64.9%)	157(69.8%)	
Swelling at the site of injection	Yes	71(31.6%)	68(30.2%)	0.760
	No	154(68.4%)	157(69.8%)	
Redness at the site of injection	Yes	46(20.4%)	24(10.7%)	0.004
	No	179(79.6%)	201(89.3%)	
Lymphadenopathy	Yes	10(4.4%)	30(13.3%)	0.001
	No	215(95.6%)	195(86.7%)	
Fever (temperature >37.8 ˚C)	Yes	123(54.7%)	81(36.0%)	<0.001
	No	102(45.3%)	144(64.0%)	
Headache	Yes	28(12.4%)	30(13.3%)	0.778
	No	197(87.6%)	195(86.7%)	
Nausea	Yes	21(9.3%)	18(8.0%)	0.615
	No	204(90.7%)	207(92.0%)	
Rashes	Yes	49(21.8%)	30(13.3%)	0.019
	No	176(78.2%)	195(86.7%)	
Burning at injection site	Yes	72(32.0%)	48(21.3%)	0.011
	No	153(68.0%)	177(78.7%)	
Flu	Yes	39(17.3%)	18(8.0%)	0.003
	No	186(82.7%)	207(92.0%)	
Anxiety	Yes	35(15.6%)	30(13.3%)	0.503
	No	190(84.4%)	195(86.7%)	
Muscle pain (Myalgia)	Yes	39(17.3%)	30(13.3%)	0.239
	No	186(82.7%)	195(86.7%)	
Fatigue	Yes	60(26.7%)	18(8.0%)	<0.001
	No	165(73.3%)	207(92.0%	
Joint pain	Yes	52(23.1%)	24(10.7%)	<0.001
	No	173(76.9%)	201(89.3%)	
Chills	Yes	65(28.9%)	36(16.0%)	0.001
	No	160(71.1%)	189(84.0%)	
Cough	Yes	23(10.2%)	30(13.3%)	0.306
	No	202(89.8%)	195(86.7%)	
Swelling of glands	Yes	41(18.2%)	30(13.3%)	0.155
	No	184(81.8%)	195(86.7%)	
Sore throat	Yes	53(23.6%)	18(8.0%)	<0.001
	No	172(76.4%)	207(92.0%)	
Shortness of breath	Yes	35(15.6%)	30(13.3%)	0.503
	No	190(84.4%)	195(86.7%)	
Diarrhea	Yes	27(12.0%)	12(5.3%)	0.012
	No	198(88.0%)	213(94.7%)	
Chest Pain	Yes	32(14.2%)	18(8.0%)	0.036
	No	193(85.8%)	207(92.0%)	

Table 3: The association between the prevalence of side effects after receiving the 2nd dose of the Sinovacvaccine among children and adult participants.

Variable		18 years or less n(%)	More than 18 years n(%)	p-value
Pain at the site of injection	Yes	91(40.4%)	42(18.7%)	<0.001
	No	134(59.6%)	183(81.3%)	
Swelling at the site of injection	Yes	70(31.1%)	48(21.3%)	0.018
	No	155(68.9%)	177(78.7%)	
Redness at the site of injection	Yes	10(4.4%)	24(10.7%)	0.013
	No	215(95.6%)	201(89.3%)	
Lymphadenopathy	Yes	31(13.8%)	30(13.3%)	0.890
	No	194(86.2%)	195(86.7%)	
Fever (temperature >37.8 ˚C)	Yes	94(41.8%)	61(27.1%)	0.001
	No	131(58.2%)	164(72.9%)	
Headache	Yes	43(19.1%)	18(8.0%)	0.001
	No	182(80.9%)	207(92.0%)	
Nausea	Yes	12(5.3%)	0(0.0%)	<0.001
	No	213(94.7%)	225(100.0%)	
Rashes	Yes	44(19.6%)	42(18.7%)	0.810
	No	181(80.4%)	183(81.3%)	
Burning at injection site	Yes	65(28.9%)	30(13.3%)	<0.001
	No	160(71.1%)	195(86.7%)	
Flu	Yes	29(12.9%)	24(10.7%)	0.465
	No	196(87.1%)	201(89.3%)	
Anxiety	Yes	31(13.8%)	12(5.3%)	0.002
	No	194(86.2%)	213(94.7%)	
Muscle pain (Myalgia)	Yes	61(27.1%)	30(13.3%)	<0.001
	No	164(72.9%)	195(86.7%)	
Fatigue	Yes	44(19.6%)	36(16.0%)	0.324
	No	181(80.4%)	189(84.0%)	
Joint pain	Yes	56(24.9%)	24(10.7%)	<0.001
	No	169(75.1%)	201(89.3%)	
Chills	Yes	63(28.0%)	26(11.6%)	<0.001
	No	162(72.0%)	199(88.4%)	
Cough	Yes	21(9.3%)	6(2.7%)	0.003
	No	204(90.7%)	219(97.3%)	
Swelling of glands	Yes	41(18.2%)	42(18.7%)	0.903
	No	184(81.8%)	183(81.3%)	
Sore throat	Yes	38(16.9%)	6(2.7%)	<0.001
	No	187(83.1%)	219(97.3%)	
Shortness of breath	Yes	40(17.8%)	42(18.7%)	0.807

	No	185(82.2%)	183(81.3%)	
Diarrhea	Yes	35(15.6%)	6(2.7%)	<0.001
	No	190(84.4%)	219(97.3%)	
Chest Pain	Yes	32(14.2%)	24(10.7%)	0.253
	No	193(85.8%)	201(89.3%)	

Table 4: The overall satisfaction level of vaccine among children and adult participants.

Variable		18 years or less n(%)	More than 18 years n(%)	p-value
Overall subject level of Satisfaction for vaccine	Very Satisfied	79(35.1%)	54(24.0%)	<0.001
	Satisfied	89(39.6%)	65(28.9%)	
	Unknown	52(23.1%)	62(27.6%)	
	Dissatisfied	5(2.2%)	44(19.6%)	

DISCUSSION

Millions of people have continued to be influenced by the coronavirus, which has claimed many of lives and devastated financial systems all over the world. The most important step in putting a halt to this epidemic is mass vaccination to build immunity among people, and numerous vaccines are being employed worldwide to immunize the populace. Regardless of the COVID-19 vaccines' widespread acceptance and the defensive shield they clearly provide, concerns about vaccination safety and worry about their potential adverse effects have persisted throughout immunization campaigns. The purpose of this cross-sectional study is to determine the frequency of side effects in Pakistan's general population following the Sinovac COVID-19 vaccine.

Riad et al. studied 780 Turkish medical professionals who had just received the CoronaVac vaccine in a countrywide cross-sectional study. The side effects that appeared locally and systemically were identified four weeks after vaccination. Of them, 62.5% of the 780 subjects experienced at least one side effect. Pain at the injection site was the most common local adverse effect (41.5%), whereas fatigue (23.6%), headaches (18.7%), muscle aches (11.2%), and joint pain (4.9%) were the most common general side effects. Significantly more female medical professionals (67.9%) than male medical professionals (51.4%) experienced local and overall side effects. Younger people, prior exposure to infection, and poor health status (concurrent diseases and regular drug use) were also associated with a higher incidence of CoronaVac adverse effects [21]. These findings were not in accordance with the present study and indicated that the most commonly reported systemic side effect was fever in both children and adults following the first dose as well as the second dose, whereas, a significant difference was observed between side effects in younger age groups, and the existence of coexisting illnesses.

Similarly, another study indicated that among individuals after receiving the first dose, 350 (43.8%), and those after receiving the second dose, 262 (32.8%), fever was the most frequently reported side effect. Additionally, after both doses, reports of pain and swelling at the injection site predominated. However, modest frequencies of tiredness, aches and pains in the muscles, a headache, and joint pain were common. In terms of gender, there were 534 more male recipients of the vaccinations (66.8%) than female recipients (266, 33.3%) [22].The present study was consistent with the above-mentioned study and showed that fever was the most frequently reported side effect in 123(54.7%) children, and 81(36.0%) adults after getting the first dose. Moreover, it was also observed that fever was the common side effect following the second dose in 94(41.8%) children, and 61(27.1%) adults. Additionally, swelling, and pain at the injection site were also predominantly reported after both doses in children and adult participants.

A cross-sectional study using an online survey was conducted to gather information on COVID-19 vaccination adverse effects among the general population. The majority of subjects (62.2%) were under 20 years old, female (74.9%), and had no prior COVID-19 infection. More frequently, Sinovac (38.7%), Sinopharm (30.4%), and Moderna (18.4%) were administered. Pain at the injection site (82%), myalgia (55%), headaches (46%), fatigue/illness (45%), and fever (41%) were the most frequently reported adverse effects. The first dosage of the vaccine was associated with a higher likelihood of side effects than the second dose. Comorbidities and prior COVID-19 infection were shown to be independent (p = 0.707) of the prevalence of adverse effects [23]. This conclusion was equivalent to another study performed in Saudi Arabia; conversely, UK research by Cristina et al. presenteda low incidence of injection site pain [24,25].Likewise, these findings were similar to those of the present study and revealed that side effects were more pronounced in children than in adult participants. Moreover, side effects were more likely to be observed following the first dose as compared to the second dose. Furthermore, previous exposure to COVID-19 infection (p=0.778), and the presence of hypertension (p=0.072) were not significantly associated with the prevalence of side effects.

Interestingly, Riad et al.'s study revealed a lower incidence for both fatigue and headache side effects, with fatigue occurring in 23.6% and headache in 18.7% of the individuals [21]. These findings were partially similar to the present study results and revealed that fatigue and headache were observed in 60(26.7%)and 28(12.4%) children, respectively, after receiving the first dose, while after getting the second dose, fatigue and headache were observed in and 44(19.6%) and 43(19.1%) children, respectively. On the other hand, fatigue and headaches were observed at a lower frequency in adult participants.

Similar findings were found in another study, which reported that the percentage of negative effects increased after the second dose was administered in comparison to the first [23]. Cytokines may have a role in the strong immunological response to the second dose by inducing an inflammatory reaction in the muscles, vascular system, and other structures. Even days after the vaccination, the immune response may still result in flu-like symptoms [26]. This result was in line with a prior study by Menni et al., which similarly revealed a higher incidence of negative effects following the second dose. This might be brought on by a rise in immunogenicity brought on by vaccination, resulting in increased reactogenicity [25]. Choi and Cheong showed that comorbidities had no discernible influence on the frequency of adverse events [27]. As far as the present study is concerned, participants who received the first dose of the vaccine experienced side effects that were more pronounced than those who received the second dose, both in children and adults. Additionally, whereas hypertension had no statistically significant relationship to side effects (p=0.072), diabetes had a significant impact on reported side effects following Sinovac immunization (p<0.001).

Likewise, one of the studies reported that the youngsters, particularly those participants under the age of 30, also demonstrated a higher prevalence of vaccination side effects. The cause could be a strong immunological response in youth that becomes weaker with age [23]. This finding was consistent with those of Saeed et al.'s study [28], which revealed that younger adults were more susceptible to the adverse effects of immunization. The transitory rise of inflammatory cytokines and the vaccinations' reactogenicity are known to be connected, suggesting that the vaccines' reactiveness decreases with age [29]. These findings corroborated the present study findings and indicated that the children under 18 years of age showed a higher incidence of reported side effects, thereby indicating that the inflammatory response declined with ageing.

The study had some drawbacks. The small sample size substantially restricts our cross-sectional analysis. The individuals

were also asked to recall earlier negative impacts, which might have caused recall bias. Furthermore, there may be reporting bias in our study as a result of the use of self-reported data. Long-term side effects, which need to be examined further in future trials, were not addressed in this article.

CONCLUSION

This study concluded that the most frequently reported side effect was fever in both children and adult participants following the first and second doses ofSinovac vaccines. Moreover, pain and swelling at the injection site were the only local side effects observed. Additionally, the observed side effects were more pronounced after the first dose as compared to the second dose. More extensive research on the safety of vaccines is needed to increase public trust in the vaccination campaign. By dispelling beliefs that have persisted in immunization drives and empowering the populace with knowledge about what to expect after immunization, this study will contribute to raising immunization rates in our nation.

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