RESEARCH ARTICLE

Short term side effects of inactivated COVID-19 vaccines among Pakistani population: a survey-based cross-sectional study

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Abstract

Objective: To assess the short-term adverse effects of two inactivated coronavirus disease-2019 vaccines, and the demographic factors associated with such events.

Method: The cross-sectional study was conducted in Karachi from August to October 2021 after approval from the ethics review board of Dow University of Health Sciences, Karachi, and comprised adults of either gender who had received at least one dose of either Sinopharm or CoronaVac vaccine. Data was collected using online and printed survey forms. The questionnaire investigated the symptoms experienced by the participants after the administration of the vaccine dose. Data was analysed using SPSS 22.

Results: Of the 1000 survey forms filled, 896 were analysed; 505(56.4%) women and 391(43.6%) men were included in the study. Most of the participants were aged 18-30 years 644(71.9%). Overall, 581(64.8%) subjects had received Sinopharm vaccine, and 315(35.2%) received CoronaVac. The incidence of side effects after the first and second dose respectively was 63.3% (368 out of 581) and 55.2% (239 out of 433) for Sinopharm and 65.4% (206 out of 315) and 61.4% (89 out of 145) for CoronaVac. The factors associated with a higher risk of side effects were female gender and young age ($p<0.05$).

Conclusion: Most of the reported symptoms were minor in nature, like pain at the injection site, and women and those of young age reported such symptoms more than men and the elderly.

Key Words: COVID-19 vaccine, Side effects, Sinopharm, CoronaVac, SARS-CoV-2.

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Introduction

Coronavirus disease-2019 (COVID-19), caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), was declared a pandemic by the World Health Organisation (WHO) on March 2020.[1] Global statistics updated on April 10, 2023, confirmed 685 million cases and more than 6 million deaths worldwide.[2] Public health measures, like social distancing, hand washing, wearing masks, testing of suspected individuals and isolation, proved to be insufficient in completely stopping viral transmission. This hinted towards the dire need for vaccination.[3]

Several vaccines against COVID-19 were approved by the WHO for their safe and effective use. These included Pfizer–BioNTech, Oxford–AstraZeneca, Moderna, Johnson & Johnson, Sinopharm Beijing Institute of Biological Products (BBIBP), CoronaVac, Covovax and Novavax.[3] Pakistan began its campaign to vaccinate the population against the virus on February 3, 2021, with Sinopharm and CoronaVac vaccines which utilise an inactivated whole virus to stimulate the body's immune response.[4,5] As healthcare professionals, the elderly, and individuals with comorbidities were among the highest risk groups for COVID-19 infection and its related complications, they were given priority for vaccination.[6] The total adult population i.e., 18 years or above, of Pakistan in 2019 was approximately 113.4 million[7] and as of November 2022, around 132 million people of 12 years or older were fully vaccinated in Pakistan.[8]

However, the development of vaccines is not enough. Several factors need to be addressed when aiming for the implementation of a mass vaccination programme, and among them, people's acceptance of vaccinations is crucial for adequate vaccine coverage in a population. The rapid development of vaccines, although a big achievement of science, caused anxiety in the general public owing to concerns over the safety profile, which led to vaccine hesitancy.[9] To assess the people's willingness to get vaccinated, several investigations were conducted[10] and a decreasing trend was observed worldwide. Major concerns related to vaccine acceptance were risks of side effects, effectiveness of vaccine and fast development.[10] An online survey conducted to evaluate

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reasons for vaccine hesitancy in Pakistani population showed the risks of known or unknown side effects as the most common concern.[11]

The current study was planned to assess the prevalence of short-term side effects of two inactivated SARS-CoV-2 vaccines in the general population, and to find the relationship of these side effects with demographic factors.

Subjects and Methods

The cross-sectional study was conducted in Karachi from August to October 2021 after approval from the ethics review board of Dow University of Health Sciences (DUHS), Karachi. A questionnaire, designed in English and Urdu languages, was made available online and in printed form. The online forms were circulated using social media platforms, while the printed forms were circulated at Civil Hospital Karachi (CHK) and Khaliqdina Hall vaccinations centres. Data was collected by assigned individuals who had full command over English and Urdu/Sindhi languages and were responsible for surveying the designated centres and interviewing the vaccinated individuals in their local language (Urdu/Sindhi). In addition, pilot surveys were conducted with 25 subjects before the commencement of data collection to ascertain comprehensibility of the questionnaire. Informed consent was obtained from each participant and no incentives were given to the participants. The questionnaire was self-designed and structured following El-Shitany et al.[12] The questionnaire comprised two sections. The first section was to establish the demographic details (age, gender) and information about any previous infection with SARS-CoV-2. The second section included details regarding the COVID-19 vaccine, such as the type of vaccine the participants had received (Sinopharm BBIBP or CoronaVac), the number of doses, and the side effects that were experienced following vaccination. The most common side effects identified in clinical studies[13-15] were included in the questionnaire. If the participants experienced any side effect other than the ones mentioned, they were required to report those as well.

The sample size was calculated using OpenEpi calculator with 95% confidence level and 5% limit of error.[16] Those included were inhabitants of Karachi aged above 18 years of age who had received at least one dose of either Sinopharm or CoronaVac vaccine. Individuals who did not receive any shot of either of the vaccines, those aged below 18 years, pregnant females, and incomplete or duplicate survey forms were excluded.

Data was analysed using SPSS 22. Descriptive statistics were employed for demographic characteristics and were presented as frequencies and percentages. Chi-square test, Fisher's exact test and likelihood ratio were used to analyse the association between side effects and gender, age and past COVID-19 infection. P<0.05 was considered significant.

Results

Of the 1000 survey forms filled, 896 were analysed; 505(56.4%) women and 391(43.6%) men were included in the study. Most of the participants were aged 18-30 years 644(71.9%), and 148(16.5%) participants had been previously infected with COVID-19. Overall, 581(64.8%) subjects had received first dose of Sinopharm vaccine, and 433(74.5%) of them had also received their second dose. The corresponding numbers for CoronaVac were 315(35.2%) and 145(46.0%) (Table 1).

Table-1: Demographic characteristics.

Characteristics	Frequency (n and %) Total Participants (n= 896)		
Gender			
Female	505 (56.4%)		
Male	391 (43.6%)		
Age (years)			
18-30	44 (71.9%)		
31-40	53 (5.9%)		
41-50	78 (8.7%)		
51-60	72 (8.0%)		
> 60	49 (5.5%)		
Previous COVID-19 infection			
Infected	148 (16.5%)		
Not infected	748 (83.5%)		
Type of COVID-19 vaccine administered		**1st dose**	**2nd dose**
Sinopharm BBIBP	581 (64.8%)	581 (100%)	433 (74.5%)
CoronaVac	315 (35.2%)	315 (100%)	145 (46.0%)

COVID-19: Coronavirus disease-2019, BBIBP: Beijing Institute of Biological Products

The most frequently reported side effects after first dose of Sinopharm vaccine were injection site pain 299(51.5%), fatigue 105(18.1%) and muscle ache 71(12.2%). The most common side effects after first dose of CoronaVac were same; injection site pain 166(52.7%), fatigue 54(17.1%) and muscle ache 40(12.7%). The reported side effects after the second dose of both the vaccines were similar to the first dose (Table 2).

After the first dose of Sinopharm vaccine, younger age and female gender were significantly associated with reported side effects, and the status remained unchanged after the second dose (p<0.05) History of COVID-19 infection had no significant association with the reported side effects after the first dose of Sinopharm (p>0.05), but after the second dose, a significantly higher (p=0.034)

Table-2: Reported side effects after first and second doses of Sinopharm and CoronaVac vaccines.

Variable	Sinopharm Vaccine		CoronaVac Vaccine	
	First Dose (n=581)	Second Dose (n=433)	First Dose (n=315)	Second Dose (n=145)
No side effects	213 (36.7%)	194 (44.8%)	109 (34.6%)	56 (38.6%)
Pain at injection site	299 (51.5%)	185 (42.7%)	166 (52.7%)	62 (42.8%)
Swelling at injection site	10 (1.7%)	14 (3.2%)	13 (4.1%)	6 (4.1%)
Itching at injection site	5 (0.9%)	8 (1.8%)	4 (1.3%)	4 (2.8%)
Headache	40 (6.9%)	27 (6.2%)	36 (11.4%)	10 (6.9%)
Dizziness	40 (6.9%)	23 (5.3%)	24 (7.6%)	11 (7.6%)
Fever	47 (8.1%)	25 (5.8%)	26 (8.3%)	10 (6.9%)
Fatigue	105 (18.1%)	50 (11.5%)	54 (17.1%)	21 (14.5%)
Nausea	11 (1.9%)	5 (1.2%)	11 (3.5%)	7 (4.8%)
Vomiting	0 (0.0%)	3 (0.7%)	3 (1.0%)	3 (2.1%)
Loss of appetite	4 (0.7%)	4 (0.9%)	7 (2.2%)	3 (2.1%)
Diarrhoea	9 (1.5%)	9 (2.1%)	1 (0.3%)	2 (1.4%)
Constipation	3 (0.5%)	1 (0.2%)	1 (0.3%)	0 (0.0%)
Joint pain	23 (4.0%)	14 (3.2%)	11 (3.5%)	7 (4.8%)
Muscle ache	71 (12.2%)	45 (10.4%)	40 (12.7%)	16 (11.0%)
Cough	4 (0.7%)	5 (1.2%)	4 (1.3%)	0 (0.0%)
Runny nose	11 (1.9%)	12 (2.8%)	8 (2.5%)	3 (2.1%)
Difficulty breathing	3 (0.5%)	2 (0.5%)	4 (1.3%)	1 (0.7%)
Difficulty swallowing	1 (0.2%)	0 (0.0%)	2 (0.6%)	0 (0.0%)
Hypersensitivity reaction	2 (0.3%)	3 (0.7%)	1 (0.3%)	1 (0.7%)
Others	9 (1.5%)	7 (1.6%)	6 (1.9%)	3 (2.1%)

number of previously infected individuals reported nausea compared to the non-infected group (Table 3).

After the first dose of CoronaVac, gender and age showed significant association with reported side effects ($p<0.05$), but the differences were non-significant after the second dose ($p>0.05$). Individuals with history of past COVID-19 infection reported fatigue significantly more after receiving first dose of CoronaVac ($p=0.041$) as compared to individuals with no COVID-19 history. (Table 4).

Discussion

The study included two of the earliest vaccines that were administered in Pakistan, and assessed their side effects after the first and second doses as well as their relationship with various demographic parameters. Sinopharm is an inactivated SARS-CoV-2 vaccine with an efficacy reaching 79%.[17] In phase I and II trials, it was revealed that the vaccine is safe with mild to moderate adverse reactions in a small percentage of vaccine recipients.[13] The current study observed that post-vaccination side effects were more prevalent after the first dose of Sinopharm vaccine, as a higher proportion of participants were asymptomatic after the second dose compared to the first dose (44.8% vs 36.7%). This finding is in contrast to a study in which participants reported more side effects after the second dose of Sinopharm vaccine.[18] The contradictory findings may be attributed to the lower percentage of participants who had received

Table-3: Reported side effects after first and second doses of Sinopharm vaccine and correlation with gender.

	First Dose				Second Dose			
	Male (n = 228)	Female (n = 353)	Chi square value	Sig	Male (n = 172)	Female (n = 261)	Chi square value	Sig
No side effects	101 (44.3%)	112 (31.7%)	9.426	0.002	95 (55.2%)	99 (37.9%)	12.549	0.000
Pain at injection site	90 (39.5%)	209 (59.2%)	21.595	0.000	54 (31.4%)	131 (50.2%)	14.968	0.000
Swelling at injection site	1 (0.4%)	9 (2.5%)	-	0.098*	4 (2.3%)	10 (3.8%)	0.751	0.386
Itching at injection site	0 (0.0%)	5 (1.4%)	-	0.162*	3 (1.7%)	5 (1.9%)	-	1.000*
Headache	13 (5.7%)	27 (7.6%)	0.819	0.365	11 (6.4%)	16 (6.1%)	0.012	0.911
Dizziness	12 (5.3%)	28 (7.9%)	1.539	0.215	9 (5.2%)	14 (5.4%)	0.004	0.952
Fever	23 (10.1%)	24 (6.8%)	2.015	0.156	6 (3.5%)	19 (7.3%)	2.739	0.098
Fatigue	38 (16.7%)	67 (19.0%)	0.501	0.479	15 (8.7%)	35 (13.4%)	2.232	0.135
Nausea	3 (1.3%)	8 (2.3%)	-	0.541*	3 (1.7%)	2 (0.8%)	-	0.389*
Vomiting	0 (0.0%)	0 (0.0%)	-	-	1 (0.6%)	2 (0.8%)	-	1.000*
Loss of appetite	2 (0.9%)	2 (0.6%)	-	0.647*	2 (1.2%)	2 (0.8%)	-	0.651*
Diarrhoea	4 (1.8%)	5 (1.4%)	-	0.743*	1 (0.6%)	8 3.1(%)	-	0.094*
Constipation	1 (0.4%)	2 (0.6%)	-	1.000*	0 (0.0%)	1 (0.4%)	-	1.000*
Joint pain	14 (6.1%)	9 (2.5%)	4.698	0.030	5 (2.9%)	9 (3.4%)	0.097	0.755
Muscle ache	28 (12.3%)	43 (12.2%)	0.001	0.972	17 (9.9%)	28 (10.7%)	0.079	0.778
Cough	1 (0.4%)	3 (0.8%)	-	1.000*	1 (0.6%)	4 (1.5%)	-	0.652*
Runny nose	4 (1.8%)	7 (2.0%)	-	1.000*	4 (2.3%)	8 (3.1%)	-	0.770*
Difficulty breathing	2 (0.9%)	1 (0.3%)	-	0.564*	1 (0.6%)	1 (0.4%)	-	1.000*
Difficulty swallowing	0 (0.0%)	1 (0.3%)	-	1.000*	0 (0.0%)	0 (0.0%)	- -	

(Sig: Significance), Chi-squared test and Fisher's exact test* were employed with a significance level set at $p < 0.05$.

Table-4: Reported side effects after first and second doses of CoronaVac vaccine and correlation with gender.

	First Dose				Second Dose			
	Male (n=163)	Female (n=152)	Chi square value	Sig	Male (n=80)	Female (n=65)	Chi square value	Sig
No side effects	67 (41.1%)	42 (27.6%)	6.309	0.012	36 (45.0%)	20 (30.8%)	3.064	0.080
Pain at injection site	71 (43.6%)	95 (62.5%)	11.321	0.001	30 (37.5%)	32 (49.2%)	2.016	0.156
Swelling at injection site	7 (4.3%)	6 (3.9%)	0.024	0.877	4 (5.0%)	2 (3.1%)	-	0.691*
Itching at injection site	3 (1.8%)	1 (0.7%)	2.255**	0.324**	1 (1.3%)	3 (4.6%)	-	0.326*
Headache	20 (12.3%)	16 (10.5%)	0.236	0.627	6 (7.5%)	4 (6.2%)	-	1.000*
Dizziness	12 (7.4%)	12 (7.9%)	0.032	0.859	8 (10.0%)	3 (4.6%)	-	0.346*
fever	15 (9.2%)	11 (7.2%)	0.401	0.526	7 (8.8%)	3 (4.6%)	-	0.512*
Fatigue	35 (21.5%)	19 (12.5%)	4.458	0.035	12 (15.0%)	9 (13.8%)	0.039	0.844
Nausea	8 (4.9%)	3 (2.0%)	2.009	0.156	6 (7.5%)	1 (1.5%)	-	0.132*
Vomiting	2 (1.2%)	1 (0.7%)	-	1.000*	3 (3.8%)	0 (0.0%)	-	0.253*
Loss of appetite	4 (2.5%)	3 (2.0%)	-	1.000*	3 (3.8%)	0 (0.0%)	-	0.253*
Diarrhoea	1 (0.6%)	0 (0.0%)	-	1.000*	1 (1.3%)	1 (1.5%)	-	1.000*
Constipation	1 (0.6%)	0 (0.0%)	-	1.000*	0 (0.0%)	0 (0.0%)	-	-
Joint pain	6 (3.7%)	5 (3.3%)	0.036	0.850	3 (3.8%)	4 (6.2%)	-	0.701*
Muscle ache	19 (11.7%)	21 (13.8%)	0.331	0.565	6 (7.5%)	10 (15.4%)	2.271	0.132
Cough	3 (1.8%)	1 (0.7%)	-	0.624*	0 (0.0%)	0 (0.0%)	-	-
Runny nose	3 (1.8%)	5 (3.3%)	-	0.489*	1 (1.3%)	2 (3.1%)	-	0.587*
Difficult breathing	2 (1.2%)	2 (1.3%)	-	1.000*	1 (1.3%)	0 (0.0%)	-	1.000*
Difficulty swallowing	2 (1.2%)	0 (0.0%)	-	0.499*	0 (0.0%)	0 (0.0%)	-	-
Hypersensitivity reaction	0 (0.0%)	1 (0.7%)	-	0.483*	0 (0.0%)	1 (1.5%)	-	0.448*

(Sig: Significance), Chi-squared test, Fisher's exact test* and Likelihood ratio** were employed with a significance level set at $p < 0.05$

the second dose in the current study.

According to the WHO, three clinical trials comprising 16,671 participants showed that injection site reactions, headache and fatigue were the most reported adverse events with Sinopharm.[19] Injection site reactions were reported in several studies.[13,20,21,22] In the current study, the most common side effects after the first and second dose were injection site pain (51.5% and 42.7%), fatigue (18.1% and 11.5%), and myalgia (12.2% and 10.4%). Consistent with these results, a study observed pain at the injection site and fatigue as the most reported adverse events post-vaccination.[18] A cross-sectional study conducted in Pakistan also had similar findings.[23] The current study revealed a higher proportion of participants with fatigue (18.1% after first dose and 11.5% after second dose) compared to that reported in phase I and II trials of the Sinopharm vaccine (1% and 3%).[13] This was in line with earlier findings.[18]

Females in the current study were more symptomatic following vaccination than males (68.3% of females had side effects compared to 55.7% of males after first dose and 62.1% females vs 44.8% males after second dose). These findings are consistent with earlier studies.[14] Gender difference has also been observed with other COVID-19 vaccines.[20,21,24,25] The current results showed that injection site pain occurred more frequently in females than males after both doses. This finding is consistent with a study in Islamabad.[26]

In a randomised controlled phase I trial, a lower proportion of participants above 60 years of age reported adverse events compared to participants aged 18-59 years (17% vs 42%), with injection site reactions being most common in participants aged below 60 years.[13] These findings were reaffirmed in the current study. This was also documented in a meta-analysis evaluating the safety profile of COVID-19 vaccines using clinical trials and post-authorisation studies.[27]

A cross-sectional study in Iraq showed that vaccine recipients who were previously infected with SARS-CoV-2 were more susceptible to post-vaccination adverse reactions.[21] This was also reported in a prospective study.[24] However, the current study found no such association. This inconsistency in results may be attributed to the small percentage of participants with a history of COVID-19 infection in the current study.

CoronaVac, another inactivated whole virus vaccine, was estimated to have varying efficacies of 50.7%, 65.3% and 83.5% in phase III trials conducted in Brazil, Indonesia and Turkey.[14,15] Phase III trials evaluating safety and effectiveness of CoronaVac showed injection site pain and fatigue as the most common side effects.[14,15] The

Food and Health Bureau (FHB) of Hong Kong in its evaluation report also demonstrated pain at injection site, headache and fatigue as "very common" adverse reactions.[28] Riad et al. and Zhang et al. also observed injection site pain as the most common adverse event in their studies among healthcare workers.[25,29] The current results are consistent with these findings. According to the FHB report, fever and dizziness were uncommon adverse reactions.[28] However, the incidence of these side effects was slightly higher in the current study.

There were more side effects after the first dose of CoronaVac compared to the second dose (34.6% vs 38.6% of participants remained asymptomatic after first and second dose). This was also observed in a Chinese study.[29] In the current study, the disparity in the prevalence of side effects with respect to gender and age of participants was consistent with literature.[25,29] In contrast to a study[25], however, the current study observed males experiencing fatigue more commonly than females.

The current study has a few limitations. It used a self-administered online survey that may have caused reporting bias.. Also, it did not provide the same set of conditions to the participants during the survey. However, online surveys are supposed to be cost-effective and are helpful in collecting responses from a wider population. The study targeted the population of a single city, and used convenience sampling for data collection. Therefore, there is susceptibility to bias and the results cannot be generalised to the broader population of the country. There may be an overestimation of the prevalence of side effects as some adverse events may not be a result of the vaccination. The medical status and drug history of the participants were not taken into account, which may have influenced the side effect profile of the participants. Additionally, the study only addressed the short-term side effects post-vaccination, while long-term effects were excluded. No measures were taken to grade the severity and to estimate duration of the reported symptoms either.

Country-wide studies with a broader scope are needed to validate the current findings.

Conclusion

The most commonly reported side effects after receiving Sinopharm and CoronaVac vaccines were injection site pain, fatigue and muscle ache. Participants experienced side effects more frequently after first dose than the second dose. Female gender and younger age were the risk factors associated with increased incidence of post-vaccination adverse reactions.

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