Evaluation of Sinopharm and Sinovac COVID-19 Vaccination Adverse Effects among the Population of Karachi: A survey based study.

ABSTRACT:

Introduction: Vaccines function through a variety of methods to provide disease protection; nevertheless, the process of establishing immunity can create side effects.

Objectives: The purpose of this research was to determine the acute side effects of two COVID–19 immunizations that are commonly used in the Karachi population.

Materials and Methods: Between August and September of 2021, a cross-sectional analytical survey was carried out. The 291 immunization recipients were asked to complete a survey concerning the vaccine's side effects. The Chi-Square test was used to compare the post-vaccination side effects of categorization groups. A p-value of ≤ 0.05 was statistically significant.

Results: Among post-vaccination side effects, fever was reported by 32.3% of the participants, followed by fatigue, redness at the injection site and gastrointestinal disturbances. The results show association of minor adverse effect with Gender and history of COVID infection.

Conclusion: In conclusion, vaccines are a potent weapon for controlling the COVID-19 pandemic, with high efficacy and low adverse reactions. The most common side effects of the Sinopharm and Sinovac vaccination was found to be fever, and there was a linear association between the presentations of most of the adverse effects and the history of Covid-19 infection.

Keywords: Sinopharm, Sinovac, Adverse Effects, COVID-19, Vaccination

INTRODUCTION:

In December 2019, COVID-19 virus first appeared in Wuhan, China, and has since spread to over 213 countries and regions, wreaking havoc on human health. The pandemic has resulted in the large number of deaths, along with the global economic downturn (1). As of June 29, 2021, more than 181 million SARS-CoV-2 infections had been documented, with approximately 4 million deaths from COVID-19 (2).

Despite the massive economic collapse and increase in mortality owing to viral burden, the WHO has been unable to confirm an antiviral therapeutic treatment that is effective against COVID-19. However, some particular drugs have been allowed for COVID-19, but antiviral development takes time. As a result, drug repurposing allows for a more rapid course of treatment. Because of their previously known applications, drug repurposing may be pledging for treating and lowering disease symptoms(3).

Due to a lack of appropriate treatment and the fear of outbreak, damage to economic and social life will almost probably endure until effective vaccines are widely given to the world's population (4). Since the pandemic has progressed rapidly, new measures for maintaining clinical preventative therapies, such as immunization, are required to avoid overburdening health systems and their inevitable collapse (5, 6).

According to data issued by the World Health Organization on November 12, 2020, 212 vaccines were being tested, which included inactivated or attenuated vaccines, traditional vaccines, genetically engineered recombinant adenovirus vector vaccines, ribonucleic acid (RNA) vaccines, recombinant viral vector vaccines, and deoxyribonucleic acid (DNA) vaccines (7).

The first COVID-19 vaccinations were approved for emergency use in the United States in December 2020 (8). Vaccination doses have been given out in the billions around the world (9). Still, some people are concerned about the safety of the COVID-19 vaccine and its potential side effects (10). Since the discovery of the COVID-19 genome, commendable efforts have resulted in the creation of over 300 vaccination projects. According to current studies, 40 vaccines are

presently in the clinical evaluation phase, with more than ten of these vaccinations in phase III trials trials, three of which have managed to pass phase III trial evaluations (11).

Safety concerns have been made regarding the vaccines since they have been utilized. The most common side effects following COVID-19 vaccination are a local reaction at the injection site, followed by non-specific systemic symptoms such headache, fatigue, myalgia, and fever. These symptoms may appear soon after vaccination and disappear quickly (12). Symptoms, on the other hand, can vary depending on the severity of the disease, age, gender, and the existence of comorbidity. Therefore, awareness of side effects may reduce COVID-19 vaccine refusal as the side effects are mild and guide future planning and development of public health studies.

The ultimate goal of this research was to look into the short-term side effects of COVID-19 vaccines in the Karachi population.

- The primary objective was to determine the prevalence of vaccination adverse effects.
- The secondary objectives was to examine the demographic and previous covid infection associations with the side effects of the COVID-19 vaccine.

MATERIALS AND METHODS:

This is a cross-sectional web-based survey. Residents of Karachi, Pakistan, who were at least 18 years old were the study's target population. A questionnaire was created using MS Forms. The link was subsequently distributed to Karachi locals via various social media groups.

The survey started on June, 2021, and finished on August, 2021. The sample size was determined using the following equation: $\mathbf{n} = (z)^2\, \mathbf{p}\, (\, 1 - \mathbf{p}\,) \,/\, d^2$ presuming a 50% intended outcome (Sinopharm Vaccines general knowledge and awareness) with a margin of error of 0.5% and a confidence level of 95% (13). The estimated sample size is 285 people. During this time, 291 people were recruited for the study using the convenience sampling technique. The participants completed the questionnaire individually in an estimated average duration of 5 - 10 minutes. In every case, research ethical guidelines were met by providing the necessary information.

Residents of Karachi were included in this study as participants. If the individuals met one of the exclusion criteria, the collected answers were removed from the final sample (being underage,

not vaccinated or living out of Karachi, Pakistan). Participation was completely voluntary and there was no monetary compensation.

The questionnaire is divided into three sections: the first is for personal information (age, gender, place of residence, and employment status); the seco(13)nd is about application and type of COVID vaccination; and the third is for vaccination related adverse effects

Data Management:

To ensure accuracy, the data was placed into an Excel spreadsheet and quality-checked by a researcher. Each survey response will be totally anonymous, and the questionnaire must clearly prohibit participants' identities from being revealed. All data was accessible only to the management team. Following that, the data will be cleaned and sent to SPSS for statistical analysis.

Statistical Analysis:

IBM SPSS (version 23.0) was used to perform statistical analysis on the data. Continuous variables' descriptive statistics were provided as mean and standard deviation, whereas categorical data, frequencies, and percentages were used.

The Chi-Square test was used to evaluate post-vaccination side effects among categorical categories, such as gender, comorbidities, and history of COVID-19 infection. A statistically significant p-value of 0.05 was used.

RESULTS:

There were 291 participants in this survey, all of which had been vaccinated against the COVID-19 virus. The average age of study participants was 29.3 8.9 years, with a range of 18 to 50 years. There were 86 males (29.6%) and 205 females (70.4%) in the group. Around 27.1% of the subjects had been tested positive for COVID-19 infection within last 6 month, while 72.9% had never tested positive for COVID-19 infection. Table-I summarizes the baseline characteristics of study participants.

Table I: Baseline characteristics of study participants (n=291)

		Frequency	**Percentage**

Age in years (mean ± SD)	**29.3 ± 8.9**		
Gender	**Male** **Female**	**86** **205**	**29.6%** **70.4%**
History of Covid-19	**Yes** **No**	**79** **212**	**27.1%** **72.9%**

Age is presented as a mean and standard deviation, whereas other variables are listed in frequency and percentage.

The most common post-vaccination side effect was Fever, which were reported by 32.3 percent of subjects, followed by Fatigue by 26.8%. Following immunization, 24.1 percent of individuals experienced headache, while 23% reported redness, and swelling at the injection site. Furthermore, 20.9 percent of individuals experienced GI disturbance, while 20.1 percent and 18.2 percent of participants reported loss of smell/taste, flu-like symptoms, and cough, respectively.

Table-II shows comparisons of post-vaccination acute adverse effects by gender and history of COVID-19 infection at the time of vaccination.

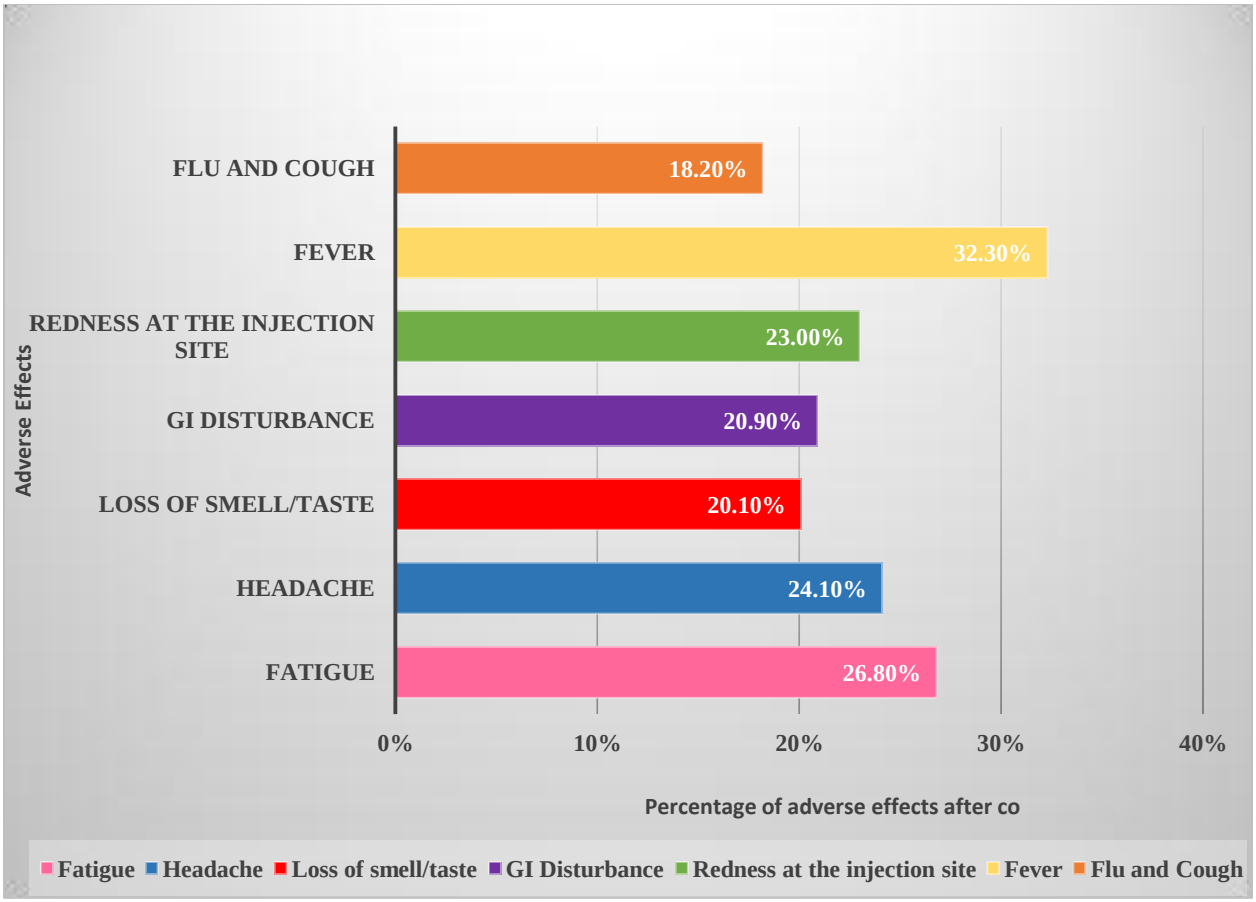

Figure 1: Distribution of post-vaccination acute side effects

Fever, fatigue, redness at the injection site, and gastrointestinal symptoms were all linked to gender. Females were more likely to have fever and redness at the injection site after immunization, whereas males were more likely to have Fatigue and GI disturbances as mentioned in Table II.

Fever ($p = <0.001$), loss of smell/taste ($p = <0.001$), fatigue ($p = <0.001$), and flu-like symptoms ($p =< 0.001$) were observed to be more common in those with a previous history of COVID-19 infection post-vaccination whereas headache, redness at the injection site and GI disturbances less commonly found in participants with a previous history of COVID-19 infection as concise in Table II.

Table II: Comparison of post-vaccination acute side effects with gender and history of COVID-19 infection						
Post Vaccination Side effects	**Gender**			**Covid-19 Infection**		
	Male (n = 86)	**Female (n = 205)**	**p- value**	**Yes (n = 79)**	**No (n = 212)**	**p- value**
1. Fatigue						
Yes	**31**	**47**		**59**	**19**	**<0.001**
No	**55**	**158**	**0.020**	**20**	**193**	
2. Headache						
Yes	**16**	**54**		**28**	**42**	
No	**70**	**151**	**0.177**	**51**	**170**	**0.008**
3. Loss of Smell and Taste						
Yes	**20**	**40**		**44**	**16**	
No	**66**	**165**	**0.475**	**35**	**196**	**<0.001**
4. GI Disturbance						
Yes	**25**	**36**		**46**	**15**	
No	**61**	**169**	**0.039**	**33**	**197**	**<0.001**
5. Redness at the injection site						
Yes	**13**	**54**		**27**	**40**	
No	**73**	**151**	**0.047**	**52**	**172**	**0.012**
6. Fever						
Yes	**19**	**75**		**43**	**51**	
No	**67**	**129**	**0.019**	**36**	**161**	**<0.001**

7. Flu and Cough						
Yes	**18**	**34**		**41**	**12**	
No	**68**	**170**	**0.405**	**38**	**200**	**<0.001**

*Variables were listed in frequency, chi square test was applied to the categorical variable and p-*value < 0.05

DISCUSSION:

To fight the dreadful effects of the COVID-19 pandemic on humanity, it is critical to provide safe and efficient COVID-19 immunizations and predict the pandemic's adverse effects in the communities(14). The current study's findings imply that vaccine side effects are prevalent and vary per vaccine, but that the two regularly used vaccinations in Pakistan are Sino-pharm and Sinovac, that have minimal observed negative effects.

In our study, the percentage of participants who reported side effects was marginally higher in females (36.5%) than males (36%), who had Sinopharm and Sinovac immunisation. Similarly, a study in China found that females (55%) had higher chances of adverse effects than males (45%) in a two-phased randomised clinical trial on Sinopharm vaccine(15). Previous COVID-19 vaccine research have found that females experience higher side effects after vaccination than males in different settings (16, 17)

In current survey, the Sino-pharm and Sinovac vaccines were well tolerated by all age groups (18-50 years), with no serious side effects. In the same way, Xia et al. found that no serious adverse responses were recorded after 4 weeks of vaccination in people aged 18 to 59, and that the vaccination was well-tolerated and safe in all dosages(15).

The most prevalent post-vaccination adverse effect was Fever, which was reported by 32.3% of those surveyed, followed by fatigue, which were reported by 26.8 percent. Headache and redness at the injection site was reported by 24.1 percent and 23% of those surveyed, respectively. In China, a comparable vaccination called Sino-pharm was tested, and it showed no signs of fatigue, headache, or muscle aching, but it did show 14.3% localised pain and 2.4 percent fever. There were no major adverse reactions, and the side effects were minor and self-limiting (18)**.** In another

study, conducted at State Islamic University, Syarif Hidayatullah Jakarta, Indonesia, reported that injection site pain, fatigue, headache, drowsiness, chills, and hunger were the most common side effects of the Sinovac Biotech COVID-19 vaccination. All of the symptoms were minimal, and they went away within a week without causing any further issues(19).

The disparities in adverse effects could be related to differences in situations and populations. Vaccination studies are only being commenced in a few countries, including Europe, the United States, Australia, and China, therefore further research in other settings and with diverse age groups is needed. In a clinical experiment done in the United Kingdom with AstraZeneca, 70 percent of participants complained fatigue, 68 percent reported headache, 60 percent reported muscle discomfort, and 51 percent reported feeling feverish (20).

Post-vaccination fatigue (83.3%), headache (100%), localised soreness(100%), muscle discomfort (58.3%), and fever (66.7%) were discovered in another trial conducted in the United States with BioNTech-Pfizer. These findings suggest that the Sino-pharm and Sinovac vaccine has low negative effects. As a result, when compared to other available vaccinations, the inactivated Sino-pharm and Sinoavac vaccine in the current study reveals a considerably higher safety profile. However, these comparisons should be made with caution because some studies have a small sample size (21), while others have reported some serious adverse effects (22, 23). The majority of vaccines have a few adverse effects, which are frequently similar to coronavirus symptoms. According to the literature, Sino-pharm and Sinovac vaccines have a very low rate of side effects.

The latest survey mentioned that all of the immunization-related adverse effects mentioned were minimal and were handled with paracetamol tablets, which wore off after 1–2 days. Fever was the most commonly reported adverse effect after vaccination, followed by myalgia. There were no cases of severe or serious adverse effects among vaccination recipients (14, 24).

Comparable to our study, another prevalent adverse effect was local injection site symptom, which followed the same pattern as the clinical trial on BNT162b2 mRNA Covid-19 vaccine. 14 In a randomised, cross-sectional research, 88.04% of patients reported local pain, which was higher than other local site side effects (11).

There is a scarcity of information about the side effects of the Covid-19 vaccine. The Astra-Zeneca experiment was halted twice, according to the media (20). Multiple sclerosis and amyotrophic lateral sclerosis have been mentioned as adverse effects, but no further information is available (20). The Sinovac study has been halted twice in Brazil. However, Sino-pharm has no major negative effects that have been mentioned in the literature (25)**.**

There is significant scepticism about the Covid-19 vaccination among the wider population, which is a barrier to the vaccine's development of herd immunity.15 However, the vaccine's mild adverse effects, as documented in this study, will assist to alleviate people's fears about the vaccine. To lower the likelihood of a negative outcome, a vaccine that reduces the number of cases should be broadly accepted at the population level (14).

Researchers from all over the world have invested their efforts into developing a successful vaccine, and phase III clinical trials have yielded overwhelmingly positive results in terms of safety and effectiveness.

Despite this, the approved vaccines will face obstacles, as the general public will be suspicious of vaccines' widespread acceptance due to their novelty. According to published studies, 82 percent of a county's population must be vaccinated in order to build herd immunity; yet, scientists recognise that, based on early data, there is widespread vaccine apprehension. The lack of major side effects observed in this study will aid in reducing vaccine apprehension. In preliminary research, many countries around the world, including France, Russia, and Poland, have shown a significant degree of vaccine apprehension (26).

STRENGHT OF THE STUDY:

To the best of our knowledge, this is the first comparative study of Sinopharm and Sinovac vaccines in Pakistan based on post-vaccination side effects. Because the most common side effects were non-life threatening, the results of this study can help convince people, thereby addressing vaccine hesitancy and conspiracy beliefs.

And also the outcome of this research will assist researchers, health professionals, and the general public in receiving safe Sino-pharm and Sinovac immunizations with minimal adverse effects in the Pakistani population.

LIMITATION OF THE STUDY:

It has a very small sample size. It's difficult to predict the COVID – 19 vaccines' long-term adverse impact profile based on such a small sample size. Furthermore, because these findings were based solely on individuals who were inoculated with Sinopharm vaccine, no comparisons to other vaccines are possible.

CONCLUSION:

It is concluded that the vaccines sinopharm and sinovac are shown to be safe and well-tolerated, with just minor side responses. It is possible to suffer some side effects, which are common signs when the body is creating defences. These side effects may make it difficult to carry out daily chores, but they usually pass within a few days. Fever, fatigue, redness at the injection site, and GI issues are the most frequent post-vaccination adverse effects.

Serious side effects, including long-term health concerns, are exceedingly unlikely following any immunisation, including COVID-19.

Ethical Approval:

The Departmental review board committee approved the study protocol.

Consent

Before taking part in the study, all of the participants gave their written consent to be included.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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