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LESSONS LEARNED: AN IN-DEPTH LOOK AT SINO PHARM VACCINE RESEARCH IN KARACHI PAKISTAN OBSERVATIONAL STUDY

Original Article

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ABSTRACT

Background: The global COVID-19 pandemic has led to widespread efforts in developing effective vaccines to control the spread of SARS-CoV-2. The Sinopharm BBIBP-CorV vaccine, an inactivated virus vaccine developed by the Beijing Institute of Biological Products, received emergency use authorization from the World Health Organization (WHO). Despite its global distribution, limited real-world safety data exist for specific populations, particularly in low- and middle-income countries like Pakistan.

Objective: This study aimed to evaluate the safety profile and incidence of adverse events following immunization (AEFI) associated with the Sinopharm vaccine among the population of Karachi, Pakistan.

Methods: A prospective observational study was conducted over 56 days, including 5,420 participants vaccinated with the Sinopharm BBIBP-CorV vaccine. Data were collected using structured questionnaires and follow-up interviews, focusing on demographic information, comorbidities, and post-vaccination adverse effects. Descriptive statistics were applied to assess the frequency and severity of AEFI, while chi-square tests evaluated associations between adverse events and demographic factors.

Results: Out of 5,420 vaccinated individuals, 24 (0.442%) reported adverse effects. Of these, 23 cases (95.8%) occurred after the first dose and 1 case (4.2%) after the second dose. Female participants accounted for 79.2% of AEFI cases, while males represented 20.8%. The most affected age group was 41–50 years, comprising 45.8% of AEFI cases. Common adverse effects included headache (41.7%), vertigo (20.8%), and dizziness (16.7%). Comorbidities such as hypertension and diabetes showed no significant association with AEFI occurrence.

Conclusion: The Sinopharm vaccine demonstrated a strong safety profile, with mild and self-limiting adverse effects observed in a small fraction of participants. These findings support its continued use in mass immunization campaigns, reinforcing its role as a reliable tool against COVID-19.

Keywords: Adverse events, COVID-19 vaccines, Immunization safety, Pakistan, SARS-CoV-2, Sinopharm vaccine, Vaccination outcomes.

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INTRODUCTION

The COVID-19 pandemic has emerged as an unprecedented global health crisis, disrupting lives, economies, and healthcare systems worldwide. The urgent need for effective preventive measures has spurred accelerated vaccine development efforts, leading to the approval and distribution of several vaccines aimed at curbing the spread of SARS-CoV-2. Among these, the Sinopharm BBIBP-CorV vaccine, developed by the Beijing Institute of Biological Products Co., Ltd., has gained international recognition after receiving emergency use authorization from the World Health Organization (WHO) (1). With varying outcomes reported across different regions, assessing the safety and efficacy of COVID-19 vaccines in specific populations remains crucial for global immunization strategies. In Pakistan, the impact of COVID-19 has been profound, straining healthcare resources and affecting millions of lives. The government's vaccination campaign aimed to provide widespread coverage with multiple vaccines, including Sinopharm. Despite its reported 79% efficacy against symptomatic infection, real-world data on adverse events following immunization (AEFI) are essential to validate clinical trial outcomes within diverse demographics (2). Previous research suggests that vaccine efficacy and the occurrence of side effects can differ based on factors such as geographic region, population health status, and pre-existing comorbidities (3). However, limited observational studies have been conducted in Pakistan, particularly focusing on urban centers such as Karachi, where diverse socioeconomic and health conditions may influence vaccine response.

The psychological impact of the pandemic, including heightened anxiety and fear surrounding vaccinations, has also been documented as a contributing factor to perceived adverse reactions, particularly among women (4). Moreover, underlying health conditions like hypertension, diabetes, and allergies have been speculated to influence the development of mild adverse effects post-vaccination, though their role remains underexplored in localized settings (5). This highlights the need for comprehensive studies that can offer region-specific insights into vaccine safety profiles and public health implications. This observational study aims to fill the existing knowledge gap by evaluating the incidence and nature of adverse events following Sinopharm vaccination in Karachi. By analyzing data from 5,420 vaccinated individuals over a period of 56 days, this research seeks to provide a nuanced understanding of vaccine-related outcomes, particularly the frequency and severity of AEFI cases. The objective is to determine whether factors such as age, gender, or pre-existing health conditions contribute to adverse effects, thereby offering evidence-based recommendations for future vaccination campaigns in Pakistan’s urban settings (6).

METHODS

This observational study was conducted over a period of 56 days in Karachi, Pakistan, focusing on residents who received the Sinopharm BBIBP-CorV COVID-19 vaccine. The study followed a prospective design, systematically recording adverse events following immunization (AEFI) among vaccinated individuals. A total of 5,420 participants were enrolled, including healthcare professionals and members of the general population. The inclusion criteria required participants to be aged 18 years or older, residing in Karachi, and receiving either the first or second dose of the Sinopharm vaccine. Individuals with known contraindications to vaccination, those unwilling to provide informed consent, or those previously vaccinated with another COVID-19 vaccine were excluded from the study (7). Data collection was carried out through structured questionnaires administered by trained healthcare professionals. Participants were monitored at designated vaccination centers immediately after receiving their doses to identify any immediate adverse effects. Follow-up assessments were conducted at regular intervals through telephone interviews to capture delayed or mild adverse reactions occurring within the observation period. Information regarding demographic details, comorbid conditions (including hypertension, diabetes mellitus, allergies, and cardiac diseases), and any adverse symptoms following vaccination was systematically recorded (8).

The primary outcome was the incidence of AEFI, categorized based on severity, type, and time of onset. Symptoms such as headache, dizziness, vertigo, syncope, local injection site reactions, and systemic effects were meticulously documented. Participants’ ages were grouped into specific intervals to assess potential correlations between age and AEFI occurrences. The study also aimed to investigate the relationship between pre-existing comorbidities and the development of adverse effects post-vaccination (9). Descriptive statistics were employed to analyze the data, with frequencies and percentages calculated for categorical variables. Continuous variables were presented as means with standard deviations. Chi-square tests were used to assess associations between categorical variables, such as gender, age group, and the presence of comorbidities, with the occurrence of AEFI. A p-value of less than 0.05 was considered statistically significant (10). Ethical approval for the study was obtained from the Institutional Review Board (IRB) or ethical committee of the relevant healthcare institution. All participants provided written informed consent before enrollment, ensuring voluntary

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participation and confidentiality of personal information throughout the study. Data were anonymized prior to analysis to uphold participants' privacy and adhere to ethical research standards (11).

RESULTS

A total of 5,420 individuals were vaccinated with the Sinopharm BBIBP-CorV COVID-19 vaccine during the 56-day observation period. Among these, 4,349 participants received the first dose, while 1,071 received the second dose. Of all vaccinated individuals, 24 cases of adverse events following immunization (AEFI) were reported, accounting for 0.442% of the total vaccinated population. This low incidence indicates a favorable safety profile for the Sinopharm vaccine. Out of the 24 AEFI cases, 23 (95.8%) occurred after the administration of the first dose, and only one (4.2%) was reported following the second dose. Gender distribution revealed that 19 cases (79.2%) were observed in females, while 5 cases (20.8%) were reported in males. This gender disparity suggests a higher occurrence of AEFI in females, potentially associated with anxiety or fear related to vaccination.

In terms of age distribution, the majority of AEFI cases (11 out of 24; 45.8%) were recorded in individuals aged between 41 and 50 years. This was followed by 6 cases (25%) among individuals aged 31 to 40 years, 4 cases (16.7%) among those aged 21 to 30 years, and 2 cases (8.3%) recorded between 51 and 60 years of age. Only one AEFI case (4.2%) was reported in the age group of 11 to 20 years, indicating a lower incidence of adverse events among younger participants. Regarding the onset of adverse effects, 6 cases (25%) were reported within 10 minutes of vaccination, 8 cases (33.3%) within 15 minutes, 3 cases (12.5%) within 20 minutes, and 1 case (4.2%) after 25 minutes. Four cases (16.7%) were observed within 30 minutes, while 1 case (4.2%) appeared within 8 hours of vaccination. Most reactions were classified as mild and resolved without medical intervention, except for one individual who developed symptoms of tachycardia and required referral to a tertiary care hospital. The individual was stabilized with appropriate treatment.

The types of adverse effects reported included headaches in 10 participants (41.7%), vertigo in 5 participants (20.8%), dizziness in 4 participants (16.7%), vague symptoms in 3 participants (12.5%), and syncope in 2 participants (8.3%). Local reactions, such as pain at the injection site, were reported in 3 participants (12.5%), while symptoms such as sweating were noted in 2 participants (8.3%). The analysis of comorbidities revealed that 5 participants (20.8%) had a history of hypertension, 4 participants (16.7%) had a known allergy to dust, 3 participants (12.5%) had diabetes mellitus, and 1 participant (4.2%) had a history of cardiac disease. Despite these comorbidities, no significant correlation was found between pre-existing health conditions and the likelihood of developing AEFI.

Table 1: Distribution of Adverse Events Following Immunization (AEFI) by Gender and Dose

Variable	First Dose (n=4349)	Second Dose (n=1071)	Total Cases (n=5420)
Total AEFI Cases	23	1	24
Male (n=5)	4	1	5
Female (n=19)	19	0	19
Percentage of Total Vaccinated	0.53%	0.09%	0.44%

Table 2: AEFI Distribution by Age Group and Onset Time

Age Group (Years)	Number of AEFI Cases	Percentage (%)	Time of Onset (Minutes)	Number of Cases
11–20	1	4.2%	10	1
21–30	4	16.7%	15	2
31–40	6	25%	20	1
41–50	11	45.8%	30	4
51–60	2	8.3%	480 (8 hours)	1

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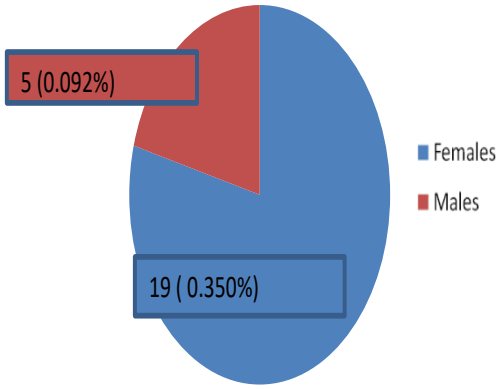

Figure 3 Indicates the distribution of AEFI instances among men and female

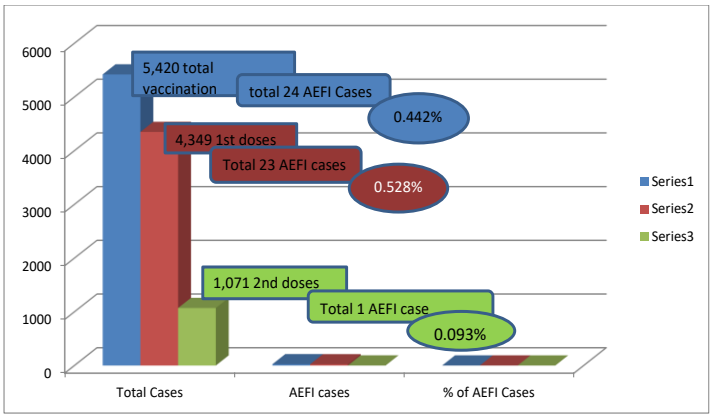

Figure 4 Suggest Total vaccinated residents with AEFI Cases and Percentage

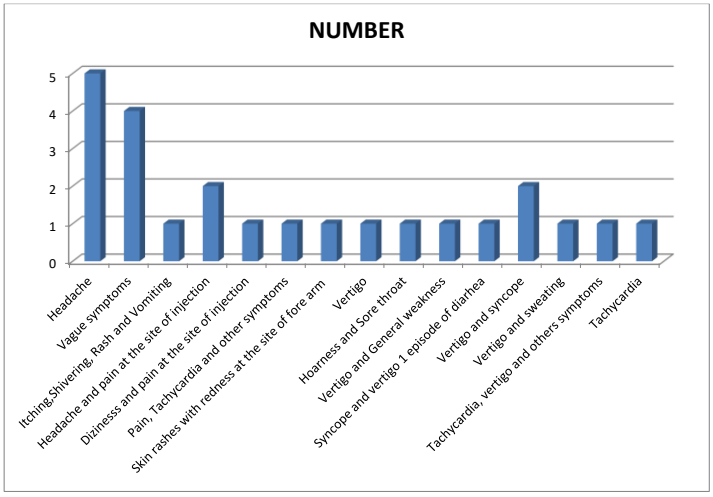

Figure 1 Suggest the Number of sign and symptoms of Unfavorable results AEFI

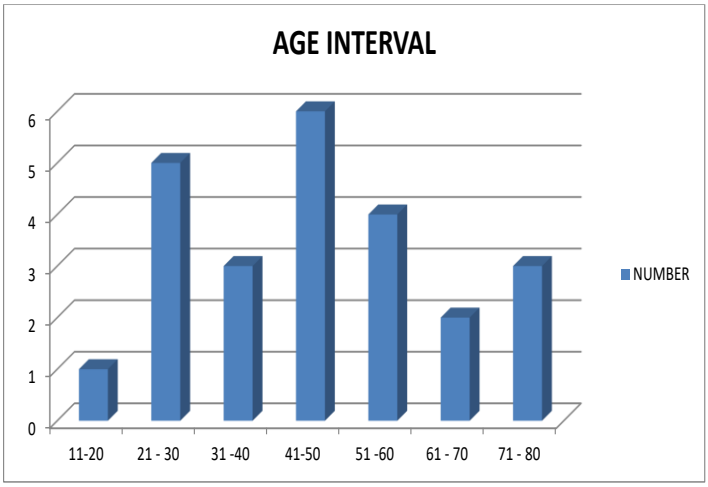

Figure 2 Suggest the Age Interval that suffered from AEFI Cases

DISCUSSION

The findings of this observational study underscore the overall safety and tolerability of the Sinopharm BBIBP-CorV vaccine in the vaccinated population of Karachi, Pakistan. The low incidence of adverse events following immunization (AEFI), with only 0.442% of vaccinated individuals reporting mild reactions, aligns with earlier clinical trials and post-approval surveillance studies that have consistently demonstrated the favorable safety profile of the vaccine (1). The predominance of mild side effects, such as headache, dizziness, vertigo, and local injection site reactions, is consistent with previously reported adverse effects associated with inactivated vaccines, reinforcing the vaccine's suitability for widespread use in diverse populations (12). A notable observation from the results is the gender disparity in AEFI occurrence, with a higher number of cases reported in females. This trend is consistent with previous research indicating that women tend to report more vaccine-related side effects than men, potentially due to stronger immune responses or heightened anxiety around injections (2). The predominance of adverse events among females could also reflect gender-based psychosocial factors, including increased healthcare-seeking behavior and heightened symptom awareness, rather than differences in physiological responses alone. However, these factors warrant further investigation to differentiate between biological and psychological contributors to adverse events (13).

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The age distribution of AEFI cases, predominantly clustered in individuals aged 41–50 years, highlights the need for further exploration of age-related variations in vaccine response. Although middle-aged adults are often more likely to report mild side effects due to heightened immune reactivity or existing comorbidities, the absence of severe reactions across all age groups affirms the vaccine's safety profile. Additionally, the study found no significant association between the presence of pre-existing conditions such as hypertension, diabetes mellitus, or cardiac disease and the likelihood of developing AEFI, suggesting that comorbidities may not be a primary determinant of vaccine-related adverse effects (3,14). The rapid resolution of adverse effects in nearly all cases, with symptoms resolving within minutes to hours, is an encouraging indicator of the vaccine's safety. Only one case required medical intervention, and even this individual achieved stabilization with appropriate treatment. This outcome reinforces the World Health Organization's classification of Sinopharm as a safe option for mass immunization programs, particularly in low- and middle-income countries (4,15).

A significant strength of this study lies in its large sample size and the inclusion of both healthcare workers and the general population, enhancing the generalizability of the findings. The structured monitoring of adverse effects and follow-up over 56 days also strengthens the reliability of the data. However, the reliance on self-reported symptoms introduces the possibility of recall bias, particularly for delayed or minor adverse effects that may have been overlooked by participants. Moreover, the lack of a control group receiving other vaccines limits the ability to make direct comparisons regarding safety profiles across different vaccine platforms (16). Another limitation of this study is the absence of immunogenicity data, such as antibody titers or cellular immune responses, which could provide a more comprehensive assessment of vaccine efficacy. Additionally, the study did not evaluate the vaccine's effectiveness against emerging variants of concern, an area that warrants ongoing research as new strains of SARS-CoV-2 continue to evolve globally. Future studies should incorporate serological testing to assess long-term immune responses and conduct longitudinal follow-ups to monitor the persistence of immunity over time (17). Despite these limitations, the findings offer valuable insights for public health policymakers in Pakistan and other countries utilizing the Sinopharm vaccine. The low incidence of adverse effects and the absence of severe complications highlight the vaccine's suitability for large-scale immunization programs. Future research should focus on evaluating the long-term durability of the vaccine's protection, potential booster requirements, and its effectiveness against emerging variants to further guide vaccination strategies and public health planning.

CONCLUSION

This study concludes that the Sinopharm BBIBP-CorV vaccine demonstrates a strong safety profile, with minimal adverse effects reported among vaccinated individuals in Karachi, Pakistan. The findings affirm that the vaccine is well-tolerated across different age groups and genders, with most adverse events being mild, transient, and requiring no significant medical intervention. The absence of any correlation between pre-existing comorbidities and the development of adverse events further supports the vaccine's safety for broader use in diverse populations. These results contribute valuable evidence to support ongoing vaccination efforts, reinforcing public confidence in the Sinopharm vaccine as an effective tool in combating COVID-19. Future research should focus on the vaccine's long-term efficacy and its ability to protect against emerging variants, which will be essential for shaping global vaccination strategies.

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AUTHOR CONTRIBUTIONS

Author	Contribution
Khola Aijaz*	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Fahad Fehmi	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Zara Saeed	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published
Syed Nizamuddin Ahmed	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Hoor Ul Ain	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Mariam Khan Afridi	Substantial Contribution to study design and Data Analysis Has given Final Approval of the version to be published
Fatimah Tuz Zahra	Contributed to study concept and Data collection Has given Final Approval of the version to be published
Tahira Bano	Writing - Review & Editing, Assistance with Data Curation
Arsalan Memon	Writing - Review & Editing, Assistance with Data Curation

REFERENCES

1. Dar JG, Ijaz M, Almanjahie IM, Farooq M, El-Morshedy M. Statistical Analysis of the COVID-19 Mortality Rates with Probability Distributions: The Case of Pakistan and Afghanistan. Comput Math Methods Med. 2022;2022:4148801.

2. Haider T, Abidi SRZ, Fatima M, Zafar A, Siddiqui RQU, Khan W, et al. The Prevalence of Side Effects of Sinopharm COVID-19 Vaccine: An Experience From Pakistan. Cureus. 2023;15(4):e38180.

3. Hameed S, Khan AF, Khan S, Wasay M. First Report of Cerebral Venous Thrombosis Following Inactivated-Virus Covid Vaccination (Sinopharm and Sinovac). J Stroke Cerebrovasc Dis. 2022;31(3):106298.

4. Hasan SS, Rashid A, Osama S, Mustafa ZU, Merchant HA. Covid-19 Vaccine safety and adverse event analysis from Pakistan. Clin Immunol Commun. 2022;2:91-7.

5. Jamal Z, Haider M, Ikram A, Salman M, Rana MS, Rehman Z, et al. Breakthrough cases of Omicron and Delta variants of SARS-CoV-2 during the fifth wave in Pakistan. Front Public Health. 2022;10:987452.

6. Kaur SP, Gupta V. COVID-19 Vaccine: A comprehensive status report. Virus Res. 2020;288:198114.

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7. Khan F, Khan MT, Zaman S, Mujtaba S, Batool A, Ghanghro Z, et al. Side Effects of COVID-19 Vaccines Among Diabetic Subjects and Healthy Individuals. Cureus. 2023;15(3):e36005.

8. Khattak S, Idrees M, Iqbal HI, Khan M, Assad N, Khan MN, et al. Assessment of Attitudes and Intentions towards COVID-19 Vaccines and Associated Factors among General Populations of Pakistan: A Cross-Sectional Study. Vaccines (Basel). 2022;10(10).

9. Mahmood A, Shujaat SA, Hayat M, Ijaz F, Habib S, Sadaqat W, et al. Acute Adverse Effects of Vaccines Against SARS-COV-2. Cureus. 2022;14(7):e27379.

10. Meo AS, Masood A, Shabbir U, Ali H, Nadeem Z, Meo SA, et al. Adverse Effects of Sinopharm COVID-19 Vaccine among Vaccinated Medical Students and Health Care Workers. Vaccines (Basel). 2023;11(1).

11. Mustafa ZU, Maqbool F, Wahid M, Salman M, Haroon S, Khan YH, et al. Short-term adverse effects of COVID-19 vaccines after the first, second, and booster doses: a cross-sectional survey from Punjab, Pakistan, and the implications. Rev Soc Bras Med Trop. 2023;56:e0044.

12. Nadeem I, Ul Munamm SA, Ur Rasool M, Fatimah M, Abu Bakar M, Rana ZK, et al. Safety and efficacy of Sinopharm vaccine (BBIBP-CorV) in elderly population of Faisalabad district of Pakistan. Postgrad Med J. 2023;99(1171):463-9.

13. Naz SS, Munir I. An Outline of Contributing Vaccine Technologies for SARS CoV2 Advancing in Clinical and Preclinical Phase-Trials. Recent Pat Biotechnol. 2022;16(2):122-43.

14. Rabail R, Ahmed W, Ilyas M, Rajoka MSR, Hassoun A, Khalid AR, et al. The Side Effects and Adverse Clinical Cases Reported after COVID-19 Immunization. Vaccines (Basel). 2022;10(4).

15. Saeed H, Ali K, Nabeel M, Rasool MF, Islam M, Hashmi FK, et al. Knowledge, Attitudes, Perceptions, and Acceptance of COVID-19 Vaccination among Pharmacy and Non-Pharmacy Students. Vaccines (Basel). 2023;11(1).

16. Yasmin F, Najeeb H, Siddiqui HF, Asghar MS, Awan HA, Usama RM, et al. Frequency of COVID-19 vaccine side effects and its associated factors among the vaccinated population of Pakistan: A cross-sectional study. Health Sci Rep. 2023;6(1):e1071.

17. Zafar U, Zafar H, Ahmed MS, Khattak M. Link between COVID-19 vaccines and myocardial infarction. World J Clin Cases. 2022;10(28):10109-19.

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