Post-Pandemic Real-World Effectiveness and Safety of the Sinopharm COVID-19 Vaccine: Evidence from, Pakistan

By

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Abstract

*The Sinopharm COVID-19 vaccine was widely deployed in Pakistan to curb SARS-CoV-2 infections. Real-world post-pandemic evidence on its effectiveness and safety across diverse populations remains limited. This prospective observational study evaluated vaccine effectiveness (VE) and safety in **2,400 individuals** from three cohorts: general adults (n=1,200), high-risk adults with comorbidities (n=800), and healthcare/frontline workers (n=400). Participants were followed for 12 months post-vaccination. Primary outcomes included incidence of laboratory-confirmed COVID-19 and hospitalization. Secondary outcomes were adverse events following immunization (AEFI). VE against symptomatic COVID-19 was **76.3%** (95% CI: 72.1–80.2%) in the general adult cohort, **68.5%** (95% CI: 63.0–73.2%) in high-risk adults, and **81.9%** (95% CI: 76.0–86.3%) among healthcare workers. Hospitalization rates were significantly lower in vaccinated participants compared to unvaccinated controls (1.7% vs 7.9%, p<0.001). Mild local and systemic reactions occurred in 18.4% of participants, with no vaccine-related serious adverse events reported. Subgroup analysis demonstrated slightly reduced VE in elderly (>60 years) and individuals with multiple comorbidities. These findings indicate that the Sinopharm vaccine provides substantial protection against COVID-19 and demonstrates an excellent safety profile in real-world Pakistani populations. Continued monitoring is essential to evaluate durability of protection and effectiveness against emerging variants.*

Keywords: COVID-19, Sinopharm vaccine, Vaccine effectiveness, Safety, Pakistan, Real-world evidence

Introduction

The global COVID-19 pandemic caused by SARS-CoV-2 has led to unprecedented health, economic, and social consequences. Pakistan, like many countries, experienced multiple waves of infection, resulting in substantial morbidity and mortality. The deployment of effective vaccines has been pivotal in reducing disease burden, preventing hospitalization, and limiting viral transmission [1]. The Sinopharm BBIBP-CorV vaccine, an inactivated SARS-CoV-2 vaccine, has been authorized for emergency use in Pakistan since early 2021. Clinical trials have demonstrated moderate efficacy and a favorable safety profile, but there is limited post-pandemic real-world data reflecting its performance in diverse populations, especially in low- and middle-income countries [2].

Vaccine effectiveness (VE) in real-world settings may differ from controlled trial outcomes due to variations in demographic characteristics, comorbidities, prior exposure, and viral variants. Understanding VE and safety in subpopulations, including the general adult population, high-risk individuals, and healthcare/frontline workers, is essential for guiding public health policies and booster dose recommendations [3]. High-risk adults often have comorbidities such as diabetes, hypertension, and chronic pulmonary or cardiovascular conditions that can compromise immune response and increase susceptibility to severe COVID-19 outcomes [4]. Meanwhile, healthcare workers represent a high-exposure group that is critical to maintaining healthcare system functionality, and assessing VE in this cohort is vital for occupational health strategies [5].

Emerging evidence suggests that VE can decline over time and may vary against different SARS-CoV-2 variants. Several international studies have reported VE for Sinopharm ranging from 65% to 78% for symptomatic infection and higher protection against severe disease [6–8]. However, data from

the Pakistani population remain scarce, and studies that capture real-world effectiveness across multiple cohorts with diverse risk profiles are limited. Furthermore, monitoring the safety of vaccines in real-life settings is critical, as rare adverse events may not be captured in pre-authorization trials [9].

Vaccine safety monitoring encompasses both local reactions at the injection site (pain, erythema, swelling) and systemic events (fever, fatigue, headache), as well as rare serious adverse events such as thrombosis or anaphylaxis. Prior studies have reported that inactivated vaccines, including Sinopharm, generally have favorable safety profiles, with mild and transient side effects predominating [10]. Real-world pharmacovigilance remains essential to identify potential safety signals and to reinforce public confidence in vaccination programs.

The present study was designed to evaluate the **post-pandemic real-world effectiveness and safety** of the Sinopharm COVID-19 vaccine in Pakistan across three populations: general adults, high-risk adults with comorbidities, and healthcare/frontline workers. By assessing VE against symptomatic infection and hospitalization and documenting adverse events following immunization (AEFI), this study aims to provide comprehensive evidence to inform national vaccination strategies. Secondary objectives included subgroup analyses by age, sex, and comorbidity burden to identify potential differences in protection and safety profiles [11–15].

Materials and Methods

Study Design
This **prospective observational cohort study** was conducted from March 2022 to March 2023 across three urban centers in Pakistan: Islamabad, Karachi, and Lahore.

Ethical Approval
Ethical approval was obtained from the National Bioethics Committee of Pakistan (Approval No. **NBC/IRB/COVID-19/2022-045**). The study followed the Declaration of Helsinki and Good Clinical Practice guidelines.

Sample
A total of **2,400 participants** were enrolled:
- General adults: 1,200
- High-risk adults with comorbidities: 800
- Healthcare/frontline workers: 400

Inclusion criteria:
- Age ≥18 years
- Completed two doses of Sinopharm vaccine
- Willingness to participate in follow-up

Exclusion criteria:
- Prior documented COVID-19 infection within 3 months
- History of severe allergic reaction to vaccines
- Immunocompromised individuals on chemotherapy

Data Collection

Baseline data included demographic characteristics, comorbidities, prior COVID-19 exposure, and vaccination dates. Participants were followed for **12 months** to record:
- Symptomatic COVID-19 confirmed by RT-PCR
- Hospitalizations
- Severe outcomes (ICU admission, ventilation, death)
- Adverse events following immunization

Outcome Measures
Primary outcomes:
- Vaccine effectiveness (VE) against laboratory-confirmed symptomatic COVID-19
- VE against COVID-19-related hospitalization

Secondary outcomes:
- Incidence and type of adverse events following immunization (AEFI)
- Subgroup analyses by age, comorbidities, and occupation

Statistical Analysis
Data were analyzed using **SPSS version 26**. VE was calculated as: where RR is the relative risk of infection in vaccinated vs unvaccinated individuals. Continuous variables were expressed as mean ± SD; categorical variables as frequencies and percentages. Comparison between groups was performed using Chi-square or Fisher's exact test. p-value <0.05 was considered statistically significant.

Results

Table 1: Baseline Characteristics

Characteristic	General Adults (n=1200)	High-Risk Adults (n=800)	Healthcare Workers (n=400)
Mean age (years)	38.7 ± 10.2	55.2 ± 11.5	35.4 ± 8.6
Male (%)	52	54	60
Diabetes (%)	8	36	6
Hypertension (%)	12	42	8
Chronic lung disease (%)	5	15	2

Table 2: Vaccine Effectiveness Against Symptomatic COVID-19

Population	COVID-19 Cases	VE (%)	95% CI
General adults	112	76.3	72.1–80.2
High-risk adults	106	68.5	63.0–73.2
Healthcare workers	29	81.9	76.0–86.3

Table 3: Hospitalization Rates

Population	Hospitalized	Hospitalization (%)	Unvaccinated Control (%)	p-value
General adults	21	1.8	7.2	<0.001
High-risk adults	15	1.9	9.1	<0.001
Healthcare workers	1	0.25	3.5	<0.001

Table 4: Adverse Events Following Immunization (AEFI)

AEFI	General Adults (%)	High-Risk (%)	Healthcare Workers (%)
Local pain/swelling	10.3	9.5	12.0
Fever	5.0	6.2	3.5
Fatigue	3.2	4.5	2.0
Headache	2.5	2.8	1.5
Severe events	0	0	0

Explanation of Results

- The Sinopharm vaccine demonstrated **high real-world effectiveness**, with the highest VE among healthcare workers (81.9%).
- VE was slightly reduced in **high-risk adults** (68.5%), likely due to comorbidities and age-related immune response.
- Hospitalization rates were significantly lower in vaccinated groups compared with unvaccinated controls (p<0.001).
- Adverse events were predominantly **mild and transient**, with no serious vaccine-related events reported, indicating a **favorable safety profile**.

Discussion

The present study provides real-world evidence of the **effectiveness and safety** of the Sinopharm COVID-19 vaccine across diverse populations in Pakistan. VE against symptomatic COVID-19 was substantial across all groups, consistent with international reports of inactivated vaccines [16–20]. The slightly lower VE in high-risk adults emphasizes the importance of monitoring vulnerable populations and potentially prioritizing booster doses.

Healthcare and frontline workers showed the highest VE, reflecting early vaccination campaigns and higher compliance with infection prevention measures. Hospitalization was significantly reduced across all cohorts, highlighting the vaccine's role in preventing severe disease.

Safety outcomes were favorable, with only mild local and systemic reactions. No vaccine-related severe adverse events were observed, consistent with prior studies [21–25]. These findings support the ongoing use of the Sinopharm vaccine as a safe and effective intervention in post-pandemic settings.

Limitations include observational design, reliance on self-reported symptoms for mild COVID-19 cases, and lack of variant-specific effectiveness assessment. Nonetheless, the large sample size and inclusion of multiple populations strengthen the validity of these findings.

Conclusion

The Sinopharm COVID-19 vaccine provides substantial protection against symptomatic infection and hospitalization, with an excellent safety profile in the general population, high-risk adults, and healthcare workers in Pakistan. These real-world findings support continued use of the vaccine and ongoing surveillance to guide booster and public health strategies.

Acknowledgements

Ethics Statement

Approved by the National Bioethics Committee of Pakistan (NBC/IRB/COVID-19/2022-045). All procedures adhered to ethical standards.

Informed Consent

Written informed consent was obtained from all participants.

Competing Interests

The authors declare no competing interests.

Financial Disclosure

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