

Research Article

COVID-19 Vaccine Effectiveness in Preventing SARS-CoV-2 Infection and Antibody Response Among Health Care Workers in Base Hospital Wathupitiwala, Sri Lanka

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Abstract

Background: Real-time data on COVID-19 vaccines among Healthcare Workers (HCWs) in low-income settings are crucial to the ongoing global vaccination programs. This study aimed to determine the Vaccine Effectiveness (VE) in reducing the risk of symptomatic COVID-19 infection, hospitalization, mortality and the dynamics of post-vaccination antibody titres in Sri Lankan health care workers

Methodology: This longitudinal cohort study was conducted at Base Hospital Wathupitiwala from January 31st to October 31st, 2021. Blood samples were collected four weeks after the first COVISHIELD dose, one month after the first and second doses and seven months after the first dose. Healthcare workers were monitored for 8 months for symptomatic disease.

Results: Antibody titres in vaccinated groups were significantly higher compared to the unvaccinated counterparts during the study period. The increase in antibody levels after the second dose of COVISHIELD/ChAdOx1 nCoV-19 vaccination, compared to the first dose, was notably high, while a significant decline in antibody levels was observed after a 7-month period. Only mild to moderate vaccine-induced adverse reactions were reported following the first dose of COVISHIELD/ChAdOx1 nCoV-19, with no adverse reactions other than site-specific local reactions reported for the subsequent dose. Overall, the adjusted vaccine effectiveness of COVISHIELD against symptomatic infection was 68% (95% CI: 25%, 87%) and for Sinopharm, it was 58% (95% CI: -4%, 80%). The adjusted vaccine effectiveness with two doses of COVISHIELD was higher among males, younger age groups and individuals with a BMI lower than 25.

Conclusion: The results have important clinical implications, supporting the rationale for full vaccination with both doses, possibly with boosters, especially for high-risk populations like healthcare workers.

Keywords: Vaccine Effectiveness; Prospective Cohort; COVID-19 Vaccines; Health Care Workers; Neutralizing Antibody

Introduction

In March 2020, the World Health Organization (WHO) declared the rapidly spreading novel coronavirus outbreak a pandemic [1]. As of December 2024, the virus has resulted in over six hundred million cases and over seven million deaths globally. It continues to advance as new variants of concern emerge. Consequently, several vaccines have been expedited across various platforms, including RNA vaccines, inactivated vaccines, protein subunit vaccines and non-replicating viral vaccines [1,2]. All

vaccines demonstrated high efficacy in preventing severe disease and mortality during controlled clinical trials [1].

Vaccine effectiveness and immune response vary widely among different vaccines, according to post-immunization data [1,2]. Vaccine distribution has been inequitable globally [3]. High-income countries have largely used mRNA vaccines or AZD1222, while many lower/middle-income countries have relied on inactivated vaccines like Sinovac and Sinopharm (BBIBP-CorV) [3]. These disparities have significantly impacted the transmission dynamics of highly transmissible and virulent SARS-CoV-2 variants [4]. In response to these variants, high-income countries have ramped up vaccination programs with booster doses, while many low-income countries have lagged due to cost and accessibility issues. Most real-world vaccine data come from high- and middle-income countries, with limited studies from low-income regions [5-7]. Additionally, these studies address COVID-19 vaccine safety, a major concern contributing to vaccine hesitancy.

Sri Lanka, with a population of 22.16 million, experienced three major COVID-19 waves from January 2020 to May 2022[8,9]. The first case, a 44-year-old woman from Hubei, China, was confirmed on January 27, 2020. Initially, the virus spread slowly, mainly among returnees and their contacts. The second wave began in October 2020, with outbreaks in Minuwangoda and Divulapitiya clothing factories and the navy. This soon spread to the Colombo region. The third wave in mid-2021 saw cases spike from over 1,000 per day in April to nearly 6,000 daily between August and September, driven by the Delta variant [8,9].

Sri Lanka began COVID-19 vaccinations for health care and frontline workers with the AZD1222/Covishield vaccine on January 30, 2021 (two doses, three months apart) [10]. Health care workers were prioritized due to their high risk of infection and potential transmission to vulnerable patients [11]. Owing to supply shortages, Sri Lanka later received Sinopharm/BBIBP-CoV vaccines starting May 10, 2021 (two doses, four weeks apart). This provided a chance to evaluate vaccine effectiveness and post-vaccine surveillance among health care workers. Although data on antibody and T cell responses are available, comprehensive information on immunity duration and real-world effectiveness is still lacking.

This study aimed to assess COVID-19 vaccination effectiveness in preventing symptomatic infection, hospitalization and death among partially and fully vaccinated healthcare workers over an 8-month follow-up. Secondly, this analysis examined post-vaccination antibody levels based on vaccination status and socio-demographic factors. Thirdly, this study also sought to determine the nature and type of adverse reactions caused by COVID-19 vaccines.

Material and Methods

The national vaccination program began on January 30, 2021, with COVISHIELD and added Sinopharm on May 10, 2021. The longitudinal cohort study at Base Hospital Wathupitiwala ran from January 31 to October 31, 2021, starting after the first dose of the COVISHIELD vaccine. Both vaccines were available to all healthcare workers at the hospital.

Study Population

The institution has 600 beds and 818 Healthcare Workers (HCWs). Forty vaccinated HCWs and forty-three unvaccinated controls were selected. The sample size was based on COVID-19 seroprevalence and dropout rates [12,13]. Exclusions included prior COVID-19, ineligibility for vaccination or inability to follow up. Study goals and voluntary participation were communicated to all participants. Participants completed a baseline questionnaire on demographics, vaccination, side effects and work/community interactions.

Exposure Definition

An individual was considered exposed after one vaccine dose. The control cohort's vaccination status changed over time. Participants were Partially Vaccinated (PV) two weeks post-first dose and Fully Vaccinated (FV) two weeks post-second dose.

Serological Assessment

Four weeks after administering the COVISHIELD vaccine, 3 ml of venous blood was collected from both cohorts by trained medical staff using plain tubes. The samples were labelled with unique identifiers, centrifuged at 3500 RPM for 10 minutes to separate serum, transported to Teaching Hospital Anuradhapura under national biosafety regulations and stored in a -20°C freezer until testing. Serum samples were obtained one month after the first dose, following the second dose and seven months after the initial dose.

The virology laboratory at Teaching Hospital Anuradhapura conducted serum analysis using the quantitative SARS-CoV-2 S1/S2 IgG LIAISON® test (DiaSorin, Italy) via a fully automated Chemiluminescence assay as per the manufacturer's instructions. This test has been calibrated and validated at the hospital's clinical virology laboratory. Daily quality control included processing one positive and one negative kit control. The assay measures SARS-CoV-2 S1/S2 IgG antibody concentrations within a detection range of 3.8-400 AU/ml, categorizing results as negative (<12 AU/ml), equivocal (12-15 AU/ml) or positive (>15 AU/ml) (Fig. 1).

Clinical Follow-up of Participants

Both groups were monitored for 8 months by the principal investigator, with weekly checks for COVID-19 symptoms, vaccination status updates and potential exposures. Respiratory specimens for RT-PCR testing of SARS-CoV-2 were collected from symptomatic participants as part of the hospital's post-exposure surveillance at Base Hospital Wathupitiwala. Nasopharyngeal swabs were taken by medical staff and RT-PCR tests were performed at Maharagama's reference laboratory or Rapid Antigen tests at Base Hospital Wathupitiwala.

Data Analysis

Data were extracted from baseline and follow-up questionnaires, the vaccine registry and infection control logs into Excel, then analysed in SPSS version 20. Continuous variables were reported as means (SEM) and categorical variables as proportions. Descriptive analysis identified socio-demographic characteristics of vaccinated and unvaccinated HCWs. Chi-square and Fisher's exact tests were used for categorical variables, with significance set at $p < 0.05$. Antibody levels were reported as Geometric Mean Concentrations (GMC) with 95% CI, stratified by socio-demographic factors. Vaccination status was treated as time-varying. Vaccine effectiveness was assessed by comparing disease risk between vaccinated and unvaccinated individuals. The impact of two vaccine doses on hospital admissions for lab-confirmed SARS-CoV-2 or clinical COVID-19 was evaluated. Multivariate Cox regression models analysed adjusted hazard progression, with $p < 0.05$ as significant.

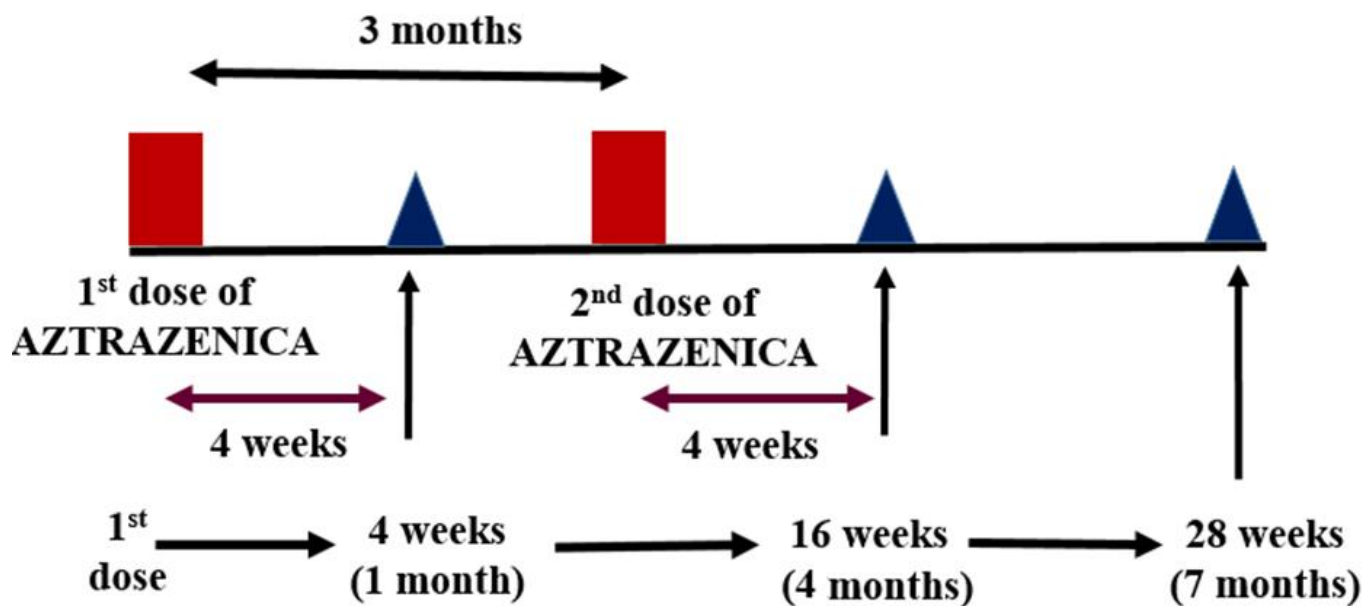


Figure 1: Diagram showing COVISHIELD vaccination doses and timing of antibody tests for study participants.

Ethical Statement

The ethics and review committee at Sri Lanka Medical Association, Colombo (ERC20-013) granted ethical clearance for the study.

Results

The study included 83 health care workers at Base Hospital Wathupitiwala, with at least one COVID-19 RT-PCR test ($n=68$) from January 31 to October 31, 2021. The median age was 41 years (IQR, 38-48 years) and most participants were female ($n=61$, 73.5%). Table 1 details participants' demographic information. No significant demographic differences were found between vaccinated and control groups.

Characteristics		Vaccinated Cohort	Control Cohort	P-value
		n (%)	n (%)	
Gender	Male	11 (27.5%)	11 (25.6%)	0.843
	Female	29 (72.5%)	32 (74.4%)	
Age (Years)	mean (SD)	43.78 ± 7.24	41.72 ± 7.32	
Age groups	18-30 years	2 (5%)	3 (7%)	0.203
	31-40 years	15 (37.5%)	20 (46.5%)	
	41-50 years	16 (17.2%)	14 (32.6%)	
	51-60 years	8 (20%)	6 (13.9%)	
BMI	mean (SD)	23.74 ± 3.94	24.3 ± 4.16	0.534
Comorbidity*	No	28 (70%)	32 (74.4%)	0.653
	Yes	12 (30%)	11 (25.6%)	
Smoking	No	37 (92.5%)	39 (90.7%)	0.768
	Yes	3 (7.5%)	4 (9.3%)	
Alcohol consumption	No	34 (85%)	38 (88.4%)	0.651
	Yes	6 (15%)	5 (11.6%)	

Differences between groups were assessed using the Pearson's χ^2 test ($p < 0.05$)
x-At least one chronic disease (Diabetes, Liver cell disease, Hypertension, Dyslipidemia, Kidney disease, Malignancy, Immuno-suppressive condition, any other), BMI: Body Mass Index. SD: Standard Deviation, n: Number

Table 1: General and socio-demographic characteristics of participants.

A total of 26 (31.3%) patients tested positive at least once for the SARS-CoV-2 virus. Unvaccinated individuals and those in lower age groups showed a higher incidence of infection with COVID-19 compared to vaccinated individuals (Table 2).

Characteristics	Variables	SARS-CoV-2 Infection Status		
		Positive	Negative	<i>p-value</i>
Type of vaccine	Unvaccinated	9	6	0.008
	Vaccinated	17	51	
Age (Years)	21 - 40	14	18	0.053
	41 - 60	12	39	
Gender	Male	8	14	0.552
	Female	18	43	
BMI	16 - 24.9	14	36	0.421
	≤ 25.0	12	21	
Smoking	No	23	53	0.492
	Yes	3	4	
Alcohol	No	22	50	0.699
	Yes	4	7	

Differences between groups were assessed using the Pearson's χ^2 test ($p < 0.05$), BMI: Body Mass Index

Table 2: Participants demographic characteristics according to SARS-CoV-2 infection status.

Baseline serology levels were not assessed for all health care workers, as the study commenced immediately following the administration of the first dose of COVISHIELD/ChAdOx1 nCoV-19 vaccination. Antibody levels were detected in 37 healthcare workers (92.5%) four weeks after receiving the first dose of COVISHIELD/ChAdOx1 nCoV-19. This figure reached 100%

following the second dose and remained constant up to seven months post-vaccination. One participant from the control cohort exhibited a high titre of antibodies for SARS-CoV-2 based on serology testing, despite denying any history of symptomatic SARS-CoV-2 infection. Additionally, another healthcare worker from the controlled cohort was lost to follow-up during the study. Table 3 presents the geometric mean of antibody titres in the two groups over time following COVISHIELD/ChAdOx1 nCoV-19 vaccination.

Stage of test	Vaccinated Group		Unvaccinated Group		p-value
	Assay (U/ml) ^x Geometric mean	95% CI	Assay (U/ml) ^x Geometric mean	95% CI	
First antibody titre (4 weeks after 1 st dose)	51.43	38.54 - 67.07	4.28	3.86 - 4.89	< 0.001
Second antibody titre (4 months after 1 st dose)	158.01	125.89 - 194.77	5.75	4.38 - 7.93	< 0.001
Third antibody titre (7 months after 1 st dose)	108.50	78.837 - 139.71	6.67	4.66 - 10.38	< 0.001

^xSARS-CoV-2 S1/S2 IgG antibody concentration assay: detection range is from 3.8-400 AU/ml. It discriminates negative (<12 AU/ml), equivocal (12-15 AU/ml) and positive (>15 AU/ml). CI: Confidence Interval, P: p<0.05 were significant

Table 3: Antibody response in healthcare workers after receiving the COVISHIELD/ChAdOx1 nCoV-19 vaccine.

During the study period, antibody titres in the vaccinated groups were significantly higher than those in the unvaccinated counterparts (Table 2). Antibody levels rose significantly after the second COVISHIELD/ChAdOx1 nCoV-19 dose compared to the first but decreased notably after 7 months (Table 2). Sinopharm/BBIBP-Cor V vaccine was made available to HCWs as an institutional policy. Consequently, 34 (79.07%) health care workers in the control group became partially or fully vaccinated using Sinopharm/BBIBP-Cor V (32), AstraZeneca (1) or Pfizer (1). However, 9 HCWs (20.93%) remained unvaccinated at the study's end. The changes in their serum IgG antibody levels are shown in Table 4.

Stage of Vaccination	Geometric Mean (U/ml) ^x	95% CI	p-value
Antibody level Before starting vaccination	4.28	3.86 - 4.89	
Antibody after 2 weeks of 1 st dose	6.36	4.24 - 10.86	0.049
Antibody after 2 weeks of 2 nd dose	43.03	24.68 - 70.59	0.034

CI: Confidence Interval; P-value<0.05 were significant

Table 4: Serum SARS-CoV-2 S1/S2 IgG antibody levels after two doses of Sinopharm/BBIBP-Cor V vaccine in healthcare workers.

Only mild to moderate adverse reactions were reported after the first dose of COVISHIELD/ChAdOx1 nCoV-19, with no reactions beyond local site effects after consecutive doses. High fever (62.5%) and arthralgia (67.5%) were common within 24 hours, alongside headache (15%) and nausea (10%). Adverse effects were more frequent in males and those aged 41-60 years.

Vaccine Effectiveness

Adjusted vaccine effectiveness of COVISHIELD against symptomatic infection was 68% (95% CI: 25%, 87%) and Sinopharm was 58% (95% CI: -4%, 80%). COVISHIELD showed higher effectiveness in males, younger individuals and those with a BMI under 25. Conversely, Sinopharm was more effective in older individuals and those with a BMI over 25 (Table 5).

Characteristics	Variables	COVISHIELD (95% CI)	Sinopharm (95% CI)
	Overall	68.4% (24.8 - 86.7)	54.7% (-3.9 - 80.2)
Age (Years)	21 - 40	76.9% (10.4 - 94.1)	47.6 (-90.2 - 85.6)
	41 - 60	52.0% (-74.1 - 86.8)	55.6% (-44.3 - 86.3)
Gender	Male	72.2% (-135.4 - 96.7)	58.3% (-235.7 - 94.8)
	Female	68.0% (17.8 - 87.5)	54.9% (-10.0 - 81.5)
BMI	16 - 24.9	74.0% (5.6 - 92.9)	48.1% (-78.0 - 84.9)
	≤ 25.0	55.0% (-40.8 - 85.6)	60.0% (-22.3 - 86.9)
CI: Confidence Interval; BMI: Body Mass Index			

Table 5: Estimated vaccine effectiveness of vaccines against SARS-CoV-2 infection in different population subgroups.

Discussion

In Sri Lanka, the COVISHIELD (Oxford-AstraZeneca) and Sinopharm vaccines were the first approved and imported to control COVID-19. This study evaluated the effectiveness of these vaccines among healthcare workers during the initial months of the vaccination campaign.

A study confirmed that the two doses of the COVISHIELD/ChAdOx1 nCoV-19 vaccine are moderately effective in real-world conditions (95% CI=24.8-86.7). The adjusted effectiveness was higher in males, younger individuals and those with a BMI under 25. These estimates are slightly lower compared to findings from efficacy trials and similar prospective studies involving healthcare personnel [14-16]. However, even among those infected, the vaccine demonstrated substantial protection against severe forms of infection. The hospitalization and mortality rates were zero in our study, which aligns with other research findings [16-18]. Nevertheless, our results are not robust enough to conclusively demonstrate vaccine effectiveness against different variants, single versus multiple doses or other demographic factors.

The Sinopharm vaccine shows moderate effectiveness after two doses, slightly less than the adenoviral vector vaccine (95%=54.7% (-3.9 - 80.2)), consistent with other real-world studies [17]. Notably, effectiveness was higher in older age groups and those with a BMI over 25. However, confirmation through double-blind placebo-controlled trials with more participants is needed. COVISHIELD provided good protection against reinfection for the fully vaccinated, with fewer and milder, delayed onset of breakthrough infections. This effect was not observed after partial immunization or in the Sinopharm group. Similar findings have been reported globally [17,19,20].

The efficacy of COVID-19 vaccines varies, correlating with levels of neutralizing antibodies (Nabs) they produce [21-23]. Studies suggest postimmunization antibody titres can estimate vaccine protection. Kristen, et al., found a strong correlation between antibody titres and vaccine efficacy across seven different platforms [24]. One month after the first dose of COVISHIELD, our study found a seropositivity rate of 92.5%, similar to Pfizer-BioNTech (99.5%) and Oxford-AstraZeneca (97.1%) [20,21,23]. This rate reached 100% one month after the second dose. Jeevandara, et al., reported a 94% rate across all age groups after two doses of AstraZeneca, indicating neutralizing antibodies. Immunity waned significantly six months post-vaccination, leading to more breakthrough infections and hospitalizations, reinforcing the need for a booster dose [19,20].

Few participants in our study were seropositive for SARS-CoV-2 antibodies at enrolment, consistent with previous general population surveys [25]. The Sinopharm vaccine did not achieve significant seropositivity levels after the first and second doses. However, this finding should be interpreted cautiously due to the small sample size. Jevandara, et al., reported that Sinopharm's seropositivity ranged from 38.1% to 68.3% across different age groups and antibody response was lower compared to COVISHIELD in Sri Lanka previously [20].

The adverse effects of vaccines vary among different population groups [26]. This study found both vaccines to be safe regarding local and systemic adverse events. Participants who received the COVISHIELD/ChAdOx1 nCoV-19 vaccine reported fewer instances of fever, arthralgia and headache, which diminished with subsequent doses. No severe adverse events, thrombotic events, neurological complications or deaths were observed during the study. These findings reassure healthcare providers and vaccine recipients about the safety and confidence of COVID-19 vaccines. Additionally, a study in Saudi Arabia reported side

effects for the Oxford-AstraZeneca and Pfizer-BioNTech vaccines at 60% and 68.5%, respectively [27]. In Sri Lanka, low incidence of adverse events was reported previously after the first dose of AstraZeneca in healthcare workers [28].

Our study has several limitations. The Health Workers (HWs) involved may have different COVID-19 exposure rates and sociodemographic traits, affecting generalizability to the broader Sri Lankan population. We only examined humoral immunity, not cellular-mediated immunity and a protective threshold against SARS-CoV-2 remains unclear. Also, our study is underpowered to evaluate secondary Vaccine Effectiveness (VE) objectives, such as VE by comorbidity or variant infection due to low number of participants. Additionally, many controlled arm participants changed their vaccination status over time, complicating the analysis.

Conclusion

Results are clinically significant, supporting the rationale for full vaccination with both doses, possibly including boosters, to address waning antibody responses, especially for high-risk groups like healthcare workers.

Conflict of Interest

The authors declare no conflict of interest.

Author Contributions

All authors have contributed equally to the final manuscript.

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