

ADVERSE EVENTS FOLLOWED BY COVID-19 VACCINATION AMONGST HEALTHCARE PROVIDERS

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ABSTRACT

Background: Effective mass vaccination appears to be the only way out of COVID-19 Pandemic. Unlike every other vaccine, adverse events with COVID-19 vaccine are common. Sinopharm made two vaccines which got approval by a prestigious medical journal. The Journal for American Medical Association (JAMA) recently published the clinical trial results for two Sinopharm inoculates-code named WIV004 and HB02. After two month of peer review the jabs were considered potent, safe and effective to curb the mortality related to COVID-19¹. WHO Strategic Advisory Group Experts (SAGE) re-evaluated the quality, safety and efficacy of both vaccines and recommended its use for people aged 18 and above.

Objective: To obtain a frequency of adverse outcomes following COVID-19 vaccine administration

Methods: We designed a single page online Performa containing most common adverse events as expected from a viral vaccine. For adverse events not mentioned in the Performa the participant could select an option 'Other', to document their experienced adverse event.

Results: Out of 101 participants 54 (52.4%) experienced adverse events. Most of the adverse events were mild except one participant who had anaphylactic reaction. Six participants had COVID-19 infection within fourteen days of first dose, confirmed either through PCR or HRCT. One participant had COVID-19 infection after thirty-seven days of 2nd dose of vaccine confirmed through PCR.

Conclusion: Our data show that people vaccinated with Sinopharm Vaccine will have high odds to experience mild adverse events. Minor proportion of the population is at risk to develop anaphylactic reaction. The frequency to develop clinically significant COVID-19 disease decreases after second dose of vaccine.

Keywords: COVID-19, JAMA, SAGE, SARS-CoV-2, Sinopharm, Vero Cell, PCR, HRCT

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INTRODUCTION

Covid Disease (COVID-19) was officially declared by The World Health Organization (WHO) as a pandemic brought about by Novel Corona virus (nCoV) and was

under Public Health Emergency of International Concern (PHEIC) on January 30, 2020.¹ The high-risk people are of sickle cell disease, pregnant, obese, and others. However, medical care laborers are one of the most high-hazard bunches during this pandemic. During this pandemic, healthcare workers were at high risk of getting infected to COVID-19. Therefore, there was a great need for an effective vaccine to control COVID-19.²

COVID-19 vaccines were developed and injected to almost everyone around the globe. However, many side effects of vaccine have been reported in clinical

evaluation, such as injection site pain, fatigue, headache, and muscle pain. More serious side effects have also been reported, such as COVID-19 vaccine-associated immune thrombosis and thrombocytopenia. The most common side effect reported was pain at the site of injection followed by tiredness.³ At DHQ/Teaching Hospital, Gujranwala adverse events were reported more frequently among male and female medical staff. The objective of this study was to obtain a frequency of adverse outcomes following COVID-19 vaccine administration

METHODS

On 4th February 2021, 1st dose of Sinopharm Vaccine was injected at Divisional Headquarter, University Teaching Hospital Gujranwala. The SARS-CoV-2 Vaccine (Vero Cell) is an inactivated vaccine to fight against corona virus disease 2019. It produces artificial active immunity in the recipient. With the help of antigen presenting cells, the humoral immunity prepares antibodies to respond to an infection with live SARS-CoV-2. Sinopharm vaccines are adjuvanted (with aluminum hydroxide), that help immune system to boost its response.

After three months and five days of 1st vaccine dose a single pager online Performa was designed. Participants were given access to the Performa for a period of eighteen days from 09.05.2021 to 27.05.2021. To be eligible and to get enrolled for the study, the participant had to be an employee, student or a worker of DHQ Teaching Hospital Gujranwala. The Performa was designed as such that only one time response was accepted by the system.

The first dose of vaccine is 0.5 ml Fully liquid, inactivated, adjuvanted, preservative-free suspension injected intramuscularly in Deltoid muscle with a 23 × 1” (0.60 × 25) Needle. The second dose of vaccine is 0.5 ml fully liquid, inactivated, adjuvanted, preservative-free suspension injected intramuscularly in Deltoid muscle with a 23 × 1” (0.60 × 25) needle after 21 days of first vaccine dose. After administration of vaccine the participant was observed by a general physician for a time minimum of thirty minutes. The aim was to treat any adverse outcome that occurred within thirty minutes of vaccine administration.

The primary objective of the study was to obtain a quantitative relationship between adverse outcomes to the vaccine administration. The given outcomes in Performa included Myalgias, body aches, fatigue, fever, chills, dizziness, seizures, anaphylaxis, corona infection confirmed through PCR/HRCT within 14 days of 1st vaccine dose, corona infection confirmed through PCR/HRCT after 14 days of 1st vaccine dose, none and other. After online account verification, each participant

was given access to the Performa where they could select a single option or multiples options. If none of the content matched to the participant’s experience secondary option was given using which participant could submit his unique experience post vaccination.

RESULTS

Total 101 responses were documented. Among total, 22(21.8%) experienced Myalgias, 34 (33.7%) experienced fatigue, 28 (27.7%) experienced body aches, 8 (7.9 %) experienced body aches, 2 (2%) experienced chills, 8 (7.9%) experienced dizziness, 1 (1%) experienced anaphylactic reaction, 6 (5.9 %) had corona infection within 14 days of administration of first dose of vaccine confirmed through PCR or HRCT, 1 (1%) participant experienced hypotension, 1 (1 %) had sore throat, 1 (1%) had sore throat, 1 (1 %) participant had nausea, 1 (1 %) participant had COVID-19 infection after 37 days of 2nd dose of vaccine confirmed through PCR/HRCT . There were 48 (47.5 %) participants who did not experience any adverse event.

DISCUSSION

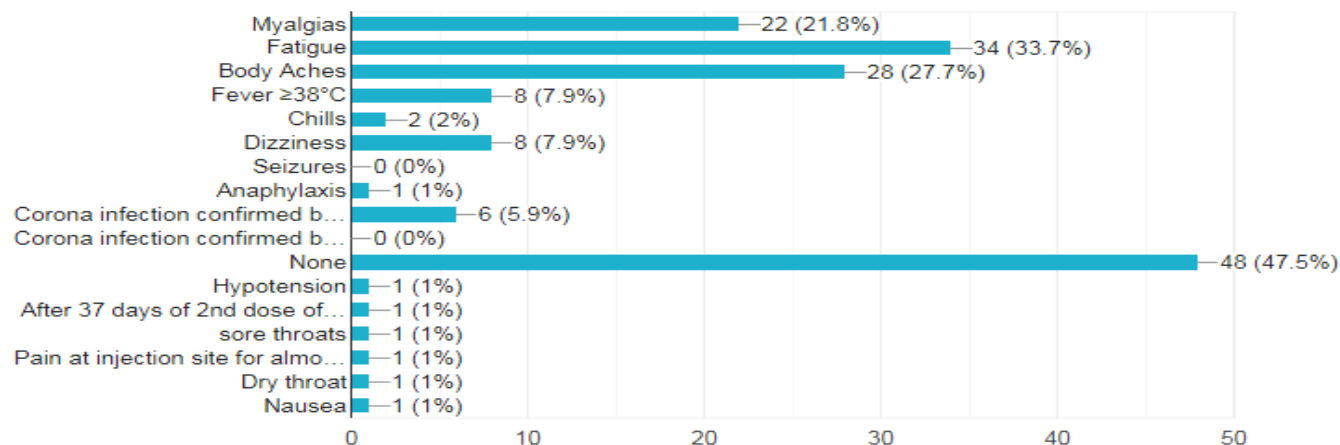
Adverse events following COVID vaccines are very common, especially after the second dose. The pathophysiology is not clear thus requires a separate study.² Not much is known about the adverse events related to Chinese COVID vaccine due to time and resource constraints. Multiple multi-national and multi centric clinical trials and surveys are under way whose results are still awaited.

According to a survey done by Pfizer and BioNTech the efficacy of two American vaccines BNT 162B2 and Moderna are 100% and 94%.^{3,4} Most of the adverse events observed with the two vaccines were mild. With BNT 162B2 vaccine the frequency of Fatigue, headache and Myalgias were 29%, 25% and 17% with the first dose and 48%, 40% and 37% with the second dose. Joint pains, chills and fever were more common with the second dose on the first day following vaccination.^{5,6} Severe adverse events such as anaphylactic reactions occurred at a rate 05 events per one million doses.^{7,9} Ninety percent of these reactions occurred within one minute of vaccine administration. 80% of anaphylactic reactions were observed in persons who already had history of allergy.^{7,8}

With the help of a large multi-country Phase 3 trial, it has been demonstrated that after 14 days of the second dose, administered 21 days apart, the Sinopharm vaccine has an efficacy of 79% against symptomatic SARS-CoV-2 infection and hospitalization. Safety data is not clear for persons above 60 years of age (due to the small number of participants in clinical trials). Currently no data is

available to demonstrate the safety profile of the vaccine in older adults as compared to younger age groups.^{9, 10}

101 responses



The frequency of fatigue, body aches and myalgias in our study group were observed to be 38%, 28% and 22%. These symptoms occurred either after first dose of vaccine or second dose of vaccine. One anaphylactic reaction was notified out of 101 participants within one minute of vaccine administration. There was no previous history of allergy in the patient who experienced anaphylactic reaction.

CONCLUSION

Most of healthcare workers vaccinated with Sinopharm Vaccine had mild adverse events. Minor proportion of the population is at risk to develop anaphylactic reaction

ETHICAL REVIEW BOARD APPROVAL

The study was approved from Institutional Review Board of Gujranwala Medical College-DHQ / Teaching Hospital Gujranwala via reference No. admn/377/GMC dated May 8, 2021

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AUTHOR'S CONTRIBUTION

AH: Questionnaire design, data collection, data analysis and drafting

AM: Study design, concept and data interpretation