

# Short Terms Safety of Chinese Origin Covid-19 Vaccine in Cardiac Patients

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## ABSTRACT

**Objective:** To find out short terms safety of Chinese origin Covid-19 vaccines in cardiac patients. To identify frequency of major and minor cardiovascular events in Covid-19 vaccinated cardiac patients.

**Methodology:** It was a cross sectional study conducted in Qazi Hussain Ahmad Medical Complex Nowshera and Kuwait Teaching Hospital Peshawar, Pakistan from February 2021 to April 2021 on a sample of 325 cardiac patients irrespective of their gender. Cardiac patients who received 2 doses of sinopharm vaccine were included in our study. The clinical characteristics of patients included age, gender, comorbidities like diabetes and hypertension and those patients who have undergone any cardiac procedures i.e post CABG and post PCI. The data was analyzed with SPSS version

**Results:** Total 325 known cardiac patients who received 2 doses of sinopharm vaccine were enrolled in the study, among them 198 were male and 127 were female. Participants age range was 56.48±5.9 years and among them mean age of male was 56.59±6.55 years and of female was 57.64±4.27 years. Among the participants 76(23.3%) were hypertensive out of which 44(22.2%) were male. Total number of diabetics were 98(30.15%) among which 59(29.79%) were male. Post CABG patients were 56(17.23%) in number, and among these 34(17.17%) were male. Among them 176(54.15%) were post PCI and among these 102(51.51%) were male. Out of total 325 participants the frequency of major adverse cardiovascular events was 4(1.2%) which include major cardiovascular events, death of any cause, urgent repeat revascularization, MI (not revascularized) an ischemic stroke were 1.2%, 0.91%, 0.31%, 0.92%, 0% respectively. Frequency of minor adverse cardiovascular events in cardiac patients after sinopharm vaccination was 4(1.2%) out of total 325 participants, which include minor cardiovascular events(9.85%), atrial fibrillations(0.92%), complete heart block(0%), increase in angina functional class(2.46%), increase in NYHA functional class(2.53%), and palpitations(3.69%).

**Conclusion:** Chinese origin covid-19 vaccine (sinopharm) is safe in cardiac patients and has minor side effects and rare major side effects in cardiac patients.

**Keywords:** Sinopharm vaccine, Cardiac patients, Corona virus

## INTRODUCTION

It is believed that the novel beta corona virus have been developed from bats in March 2019 in China city (Wuhan). Crossing the species barrier, it entered human beings with furtherance of infection through human to human transmission. It was reported to WHO on 21st December, 2019 and WHO proclaimed it as pandemic on 11, March 2020 in Pakistan. On February 26, 2020 the city of Karachi reported first case of corona[1]. Corona virus is caused by SARS Cov-2 which is transmitted through respiratory droplets and each infected person can spread the infection to 2.2 other people. Presentation of Covid ranges from no or mild symptoms such as cough, fever and fatigue to severe pneumonia and multiorgan failure.

Symptoms usually develop within 2 days to 2 weeks after exposure to the virus [2].

Although it was believed that SARS-Co-2 is primarily respiratory tract infection. It is now acknowledged that infection and its clinical affects are systemic including cardiovascular system of adults and children. Acute myocardial injury, arrhythmias, vasculitis and endothelial dysfunction thrombosis, myocardial fibrosis and myocarditis are some of the acute and chronic cardiac complications of variable severity which resulted from SARS covid 2 infection. [3].

The ongoing corona pandemic caused by Covid -19 has enveloped the entire world with serious impacts on almost every aspect of human life. The rapid upsurge in active Covid-19 cases produced a major health care crisis due to lack of alertness to confront a sudden pandemic specially in developing nations. At time of onset there was no effective medication available because of multifarious spectrum of the disease, so to find out solution for this morbid disease, trials on older drugs were made. As there was no definitive therapy there was rapid rise in cases so in order to bring a halt to further progression of the disease effective vaccine was the only solution against this deadly virus[4].

For over a year, scientists across the world have faced multiple challenges to overcome the disease. So different researches were carried out for Covid-19 treatment which included retasking existing drugs along with discovery of new vaccines and drugs. Currently in various countries about 13 Covid-19 vaccines are approved for emergency use. As sinopharm vaccine is widely used during our study period. Therefore, analysis from adverse events reported was performed on these vaccines[5]. Sinopharm vaccine is an inactivated vaccine that has 2 doses administered 2 to 3 weeks apart [6].

Every vaccine has certain side effects or complications associated with it. Local ones like redness, pain and swelling or systemic ones like nausea, myalgias, headache, fever and chills are expected with almost every vaccine. However it was suggested that certain serious side effects including clotting disorders, myocardial infarction and heart blocks were reported after administration of Covid-19 vaccines[7].

**Objectives:** To find out short terms safety of Chinese origin Covid-19 vaccines in cardiac patients.

To identify frequency of major and minor cardiovascular events in Covid-19 vaccinated cardiac patients.

## METHODOLOGY

It was a cross sectional study conducted in Qazi Hussain Ahmad Medical Complex, Nowshera and Kuwait Teaching Hospital, Peshawar Pakistan from February 2021 to April 2021 on a sample of 325 cardiac patients irrespective of their gender. It was approximately 3 months study which included data collection, analysis and report writing. The sample size was calculated through open epi software and data was analyzed using SPSS version 22. Our study included cardiac patients who received 2 doses of sinopharm vaccine. The data was collected on a self structured questionnaire. The clinical characteristics of patients included age, gender, comorbidities like diabetes and hypertension and those

patients who have undergone any cardiac procedures i.e post CABG and post

PCI .Cardiac patients with active covid 19 infection and those with known chronic kidney disease was not included in our study and those participants who don't give consent was also excluded from our study.Permission from institution where study was done was obtained to carry out the study and verbal consent was taken from all the participants and data of all participants was kept confidential on a password protected computer.

**RESULTS**

Total 325 known cardiac patients who received 2 doses of sinopharm vaccine were included in the study, among them 198 were male and 127 were female.

Participants age range was 56.48±5.9 years and among them mean age of male was 56.59±6.55 years and of female was 57.64±4.27 years. Among the participants 76(23.3%) were hypertensive out of which 44(22.2%) were male and 29(22.9%) were female. Total number of diabetics were 98(30.15%) among which 59(29.79%) were male and 36(28.3%) were female. Total 36(11.07%) participants were both diabetic and hypertensive and out of these 29(14.64%) were male and 15(11.8%) were female. Post CABG patients were 56(17.23%) in number, and among these 34(17.17%) were male and 22(17.32%) were female.176(54.15%) were post PCI and among these 102(51.51%) were male and 74(58.26%) were female. The baseline demographics and clinical characteristic of patient's data for these participants were illustrated in table 1.

Table 1: Baseline demographic and clinical characteristic of patients

Title	Variables	Total (n=325)	Male (n=198)	Female (n=127)
Untitled	Mean Age (years)	56.48 ± 5.9	56.59 ± 6.55	57.64 ± 4.27
Untitled	Weight (Kg)	77.63 ± 8.7	83.46 ± 8.6	72.32 ± 7.4
Untitled	Hypertension	76 (23.3%)	44 (22.2%)	29 (22.9%)
Untitled	Diabetes	98(30.15%)	59 (29.79%)	36 (28.3%)
Untitled	Diabetes and Hypertension	36 (11.07%)	29 (14.64%)	15(11.8%)
Untitled	CABG	56(17.23%)	34 (17.17%)	22(17.32%)
Untitled	PCI	176 (54.15%)	102 (51.51%)	74(58.26%)

Out of total 325 participants the frequency of major adverse cardiovascular events was 4(1.2%).frequency of deaths due to any cause was 3(0.91%).frequency of people who need urgent repeat revascularization was 1(0.31%).Frequency of participants who get myocardial infarction (not vascularized) was 3 (0.92%).None of the participants got ischemic stroke (frequency=0) after sinopharm vaccination. table2

Table 2: Major Adverse Cardiovascular Events in COVID vaccinated cardiac patients (n=325)

Title	Events	Frequency	Percentage
Untitled	Major Adverse Cardiovascular Events	4	1.2%
Untitled	Death of any Cause	3	0.91%
Untitled	Urgent repeat Revascularization	1	0.31%
Untitled	Myocardial infarction (Not Revascularized)	3	0.92%
Untitled	Ischemic Stroke	0	0%

Table 3: Minor Adverse Cardiovascular Events in COVID vaccinated cardiac patients (n=325)

Title	Complications	Frequency	Percentage
Untitled	Minor Adverse Cardiovascular Events	32	9.85%
Untitled	Atrial Fibrillations	3	0.92%
Untitled	Complete Heart Block	0	0%
Untitled	Increase in angina functional class	8	2.46%
Untitled	Increase in NYHA functional class	18	5.53%
Untitled	Palpitations	12	3.69%

Frequency of minor adverse cardiovascular events in cardiac patients after sinopharm vaccination was 4(1.2%) out of total 325

participants. Frequency of patients with atrial fibrillation was 3(0.92%).Frequency of patients who reported with increase in angina

functional class was 8(2.46%) and with increase in NYHA functional class was 18 (2.53%) after sinopharm vaccination. Palpitations was most frequently reported in post vaccination patients with frequency of 12 (3.68%).table 3

**DISCUSSION**

SARS-CoV-2 was declared as pandemic by WHO in China on March 11,2020. As an emergency response to this outbreak , all European countries implemented physical distancing and use of face mask as an important measures against COVID-19 and its associated death toll, especially in older population[8].Different strategies including social restrictions,contact tracing and testing were adopted globally to limit the interpersonal spread of COVID 19. The outcome was major physical, psychological, and economic distress suffering of most countries' citizens. Thus, a safe and effective COVID-19 vaccine is the most effective alternative to manage this pandemic[9]. Several countries around the world has started vaccinating their citizens [10]. Vaccines are considered the best strategy for overcoming the COVID-19 pandemic [11].Nevertheless, people still have doubts about the safety and efficacy of these vaccines, including the longevity of protection against COVID-19, as several cases of reinfection and adverse effects have been reported following COVID vaccination [12]

As no vaccine is without adverse effects [13].So the purpose of our research is to find out effects of covid vaccines in cardiac patients.For this we studied literature from google scholar and PubMed regarding effects of Chinese origin sinopharm vaccine specifically on cardiac patients .

For this we collected data through self-structured questionnaire in different hospitals of Nowshera and Peshawar in cardiac patients who received two doses of chinese origin Sinopharm vaccine to look for the major and minor adverse events after vaccination (sinopharm vaccine) in a time period of 3 months' duration. Our sample size was 325 including both male and female genders who were known cardiac patients. The mean age of our participants was 56.48 ±5.9years and average weight was 77.63±8.7kg.Out of 325 ,76 were hypertensive ,98 were diabetic, and 36 had both diabetes and hypertension,56 were post CABG and 176 were post PCI. Frequency of major adverse cardiovascular events was 4(1.2%) and frequency of people dying due to any cause was 03(0.91%).

Only 1(0.31%) patient need urgent repeat revascularization after vaccination. Frequency of patients who reported MI (not vascularized) was 03(0.92%).literature was reviewed on MI after Chinese sinopharm vaccination not a much cases were reported hence the ratio of myocardial infarction is much less with this Chinese origin vaccine. Ischemic stroke was not reported in any patient. No literature review is available in pub med on ischemic stroke after sinopharm vaccination but there were some researches on google scholar in which patient had ischemic stroke post mRNA based covid vaccines but no DATA WAS available specifically on ischemic stroke post sinopharm vaccination. However, literature is present showing other neurological complications post sinopharm vaccination one of research shows in a trial with the Chinese vaccine i.e Sinovac and Sinopharm , Out of which total 68% of participants reported post-vaccination headache and 60% had post vaccination induced myalgias[14]. Beside major some patient experienced minor adverse cardiovascular events frequency of which was 32(9.85). The frequency of Increase in NYHA functional class, palpitations, increase in angina functional class and atrial fibrillation was reported in 18,12,8 and 3 respectively. While none of patient presented with complete heart block. however, a study was conducted in which 80 yr. male post CABG 18 year back presented with heart block after first dose of sinopharm and temporary pacemaker was placed during hospital stay [15].

Hence adverse events reported after sinopharm were mild

and less frequent as compared to other covid vaccines. a study was published in Singapore general regarding cardiac effects of different covid 19 vaccines. According to their reports there were no studies reporting cardiac manifestations following sinopharm vaccine [16]. Hence sinopharm is the vaccine which is safest with most minor side effects .Regarding safety of sinopharm vaccine an article was published in New York Times which stated that On May 7, the World Health Organization announced an efficacy estimate of 78.1percent [17].A study was conducted in Pakistan (Islamabad)on Covid-19 vaccines safety. As per their efficacy, Sputnik V, Sinopharm, and Cansino have shown, 91.6%, 79.34%, and 90% effectiveness, respectively. All the vaccines resulted in milder side effects like headache, fever, and pain on injection sites. No adverse cardiac events were reported in cardiac patients[18]Another study was done on side effects of sinopharm vaccines in Rawalpindi Pakistan among health care workers in holy family hospital according to results .Not even a single participant experienced any serious adverse event[19].We study literature on effects of chinese origin vaccines but local studies are deficient and not much data is available .Our study differs from other local studies as not a single study is done on safety of these vaccines specifically in cardiac patients.However some of intenational studies done on safety of sinopharm also declared it as safest among all Chinese origin vaccines. Like A cross-sectional study was conducted among inhabitants of Jordan who received any COVID-19 vaccines, the vaccines received by the participants included Sinopharm, Pfizer- BioNTech, and AstraZeneca.Among them AstraZeneca vaccines resulted in most abundant and severe side effects among the participants , while “no symptoms” were reported by those who received Sinopharm vaccine [20]. A study was conducted in Iraq and Jordan on effects of Sinopharm, Pfizer-BioNTech, and AstraZeneca . Overall, recipients of AstraZeneca and Pfizer reported more local and systemic reactions than those who received Sinopharm vaccine.

The percentage of participants who did not report any signs and symptoms were 40% for those who received Sinopharm vaccine, 25.71% for Pfizer vaccine, and 18.39% for AstraZeneca vaccine. Hence sinopharm is more safe as compare to other Chinese vaccines [21]

**Limitations:** There are certain limitations to this study which should be taken into account.First the results of this study can't be generalized as this study is conducted in onecity.secondly due to small sample size the results were no quite accurate and questionares were not equally distributed among male and female participants.So more studies with bigger sample size and different cities data needs to be published in future to know about safety of sinopharm vaccines in cardiacpatients.

## CONCLUSION

Hence our study concluded that sinopharm vaccine is safe for cardiac patients and these patients should be encouraged to be vaccinated against this deadly virus .

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