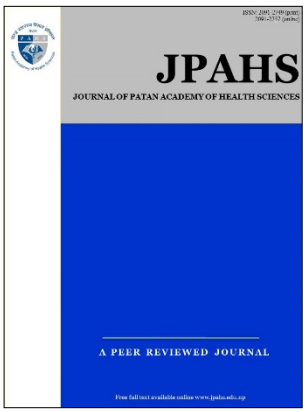

ISSN: 2091-2749 (Print)
2091-2757 (Online)

Adverse events following Immunization with Sinopharm (Vero Cell) inactivated COVID-19 vaccine

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Submitted
25 Jul 2021

Accepted
17 Aug 2021

How to cite this article
Sushant Aryal, Ranjan Prasad Devbhandari, Ashis Shrestha, Piyush Rajbhandari, Tripti Shakya, Shreyashi Tuladhar, et al. Adverse events following Sinopharm (Vero Cell), the inactivated COVID-19. Journal of Patan Academy of Health Sciences. 2021Aug;8(2):18-24.

https://doi.org/10.3126/jpahs.v8i2.31099

Abstract

Introduction: Various types of COVID-19 vaccines are being used globally to control the current pandemic. Post-licensure surveillance of vaccines is essential to ensure safety. This study aimed to determine Adverse Events Following Immunization (AEFIs) of Sinopharm (Vero Cell), the inactivated COVID-19 vaccine from China.

Method: This is a cross-sectional observational study conducted at Patan hospital, Patan Academy of Health Sciences (PAHS). Sinopharm (Vero Cell) COVID-19 vaccine recipients between April and May were contacted through a phone call after 72 h of vaccination to record the AEFIs. Pattern and distribution of AEFIs were analyzed. Ethical approval was taken from PAHS IRC.

Result: A total of 6142 individuals got the first dose of the vaccine and out of them we were able to contact 4574 through phone calls. Of the 4574, only 941 were included for the follow-up phone call after the second dose of the vaccine. A total of 1336 AEFIs were reported in 868(19%) first dose vaccine recipients while 147 AFEIs were reported in 105(11.2%) second dose vaccine recipients. The frequently reported AEFIs were pain at the injection site, lethargy, headache, muscle ache, and fever. All the AEFIs were mild to moderate in severity. Most of the AEFIs started within 24 h and resolved within 72 h.

Conclusion: The Sinopharm (Vero Cell) COVID-19 vaccine was found to have mild to moderate AEFIs in our study cohort and no case of severe AEFI was identified.

Keywords: AEFI, inactivated COVID-19 vaccine, Sinopharm (Vero Cell) vaccine

Introduction

Coronavirus has infected 188,128,952 people and claimed 4,059,339 lives worldwide as of 16 July 2021.[1] Non-pharmacological intervention along with immunization is essential to control the pandemic.[2-4] So far, 20 vaccines have been approved for use in different countries and more than 23.5 % of the world population is fully vaccinated.[5,6] As the countries are rolling out vaccines, much concern has been on their adverse reaction.[7-10] Sinopharm (Vero Cell) is an Inactivated COVID-19 vaccine developed by China National Biotec Group, Beijing Institute of Biological Products Co., Ltd. (BIBP). It is a two-dose vaccine that is also approved for use in nearly 56 countries including Nepal.[11-13]In Nepal, the vaccine was rolled out in the second phase of vaccination and was offered to the 18 to 59 y age category from April 7, 2021.[14, 15] So far 792,992 people have received one dose of this vaccine whereas 648,134 has received both doses.[16] Pre-marketing studies have found an acceptable safety profile of the Sinopharm vaccine; however, most of the adverse reactions are revealed when the vaccine is administered to a larger population post-licensure.[17-22] Furthermore, post-licensure data of the Sinopharm vaccine is limited.[23] We aimed to assess and report adverse events following immunization (AEFIs) of the Sinopharm vaccine after the first and the second doses. This will not only help in the early detection of any adverse events but also help in establishing safety and maintaining public trust for future phases of vaccination.

Method

A cross-sectional study was conducted between April 2021 and May 2021 at Patan Hospital, Patan Academy of Health Sciences (PAHS), Lalitpur, Nepal. This is a tertiary care hospital of Nepal and was one of the vaccination sites allocated by the Government of Nepal (GoN) covering the population of the Lalitpur district. Vero Cell (Sinopharm) vaccine was provided by GoN as a part of the national immunization program against COVID-19. The population for vaccination during this period was defined by GoN which included people aged between 18-59 y and excluded pregnant ladies and lactating mothers. The notice was given by GoN and vaccination within those categories was voluntary. Upon arrival to the vaccination site, clients were verified for the specified age category and then screened for any exclusion criteria (pregnant and lactating) and contraindication (anaphylaxis to any vaccination in past). Vaccines were given by trained nurses and following vaccination, the recepients were observed for 30 min to see any immediate AEFI. The second dose vaccine was announced by GoN after 4 w of the first dose, the clients had an opportunity to take a vaccine from PAHS as well as other sites designated for vaccination.

To document AEFIs following the first dose of the Sinopharm (Vero Cell) vaccine, a daily list of clients registered for the vaccine was extracted from the electronic record available in the record section of the hospital. Electronic record forms contained, name, age, sex, and phone number of vaccine recipients. To assess for the AEFIs after the second dose, we calculated sample size with an average rate of occurrence of clinically significant AEFI from the first dose of vaccination, keeping a margin of error as 5% and the dropout rate for a telephone survey of 20%. The clients were listed chronologically as per their arrival to get the first vaccine and were randomly allocated by the formula: (N=Total number of clients for first vaccine/Total sample required). A random start number was selected and every N number of clients were called if they did not respond to the call or did not give consent or if they have not taken the vaccine, subsequent client after that in the serial number was called. The total sample for the second dose vaccine was 930 and the random start number selected was '4' and therefore firstly 4th person on the list was selected and then every 4th person registered during the first dose was called. Those clients who did not receive a phone call but called back were also included.

Vaccine recipients were contacted by the investigators through phone calls after 72 h of the first and second doses of the vaccine. During the phone call, the introduction of the investigator and the purpose of the call were

explained and then the information on AEFIs was recorded in the proforma. All clients were called individually and were taken consent for the study. Those individuals who were not reachable through phone calls, not giving consent, and those not taken a second dose were excluded. Percentages and frequencies were used for data such as gender, age, incidence, type, outcomes of AEFIs, and the Chi square test was used to test statistical significance and the p-value of 0.05 was considered significant.

Result

The total number of individuals who received the first dose of vaccine was 6142 and only 4574(74.5%) who were reachable through phone calls were enrolled in the study. Among 4574, 2585(56.5%) were male, and in 1989(43.5%) were female. The mean age was 37.36±11.69 y (range 18-59 y), Table 1.

Out of the 4574 recipients, 868(19%) individuals reported AEFI after the first dose of the vaccine. Of the 868 individuals, 450(51.8%) were female and 418(48.2%) were male. The Chi-square test showed a statistically significant difference in the percentage of AEFIs seen between males and females (p=0.00). The AEFI was more frequently reported in 18-27 and 38-47 age groups, Table 2. The difference in the percentage of AEFIs seen among age groups was not significant (p=0.228). Of the 4574, the positive history of COVID-19 (PCR positive before vaccination) was found in 405(8.9%) individuals, Table 1.

A total of 1336 AEFIs were reported by 868 individuals. Of 1336, 110 AEFIs were reported by 78(9%) individuals with a history of COVID-19. The Chi-square test showed no association between the history of COVID-19 and the occurrence of AEFIs (p=0.879). Out of 1336 AEFIs, 505(37.8%) were local and 831(62.20%) were systemic. Thirty-four different types of AEFIs were reported, of which the most frequently reported local AEFIs by 868 were pain at the injection site (10.7%), swelling (0.2%), and heaviness in the arm (0.2%) while most common systemic AEFIs were lethargy (3.9%), headache (2.9%) and muscle ache (2.5%), Table 3. AEFIs reported were either mild or moderate in severity. Among the candidates with AEFIs after the first dose of vaccine, the onset of first symptoms for 821(94.6%) was within 24 h, for 35(4%) was between 24-48 h, and for 12(1.4%) was between 48–72-h. Similarly, resolution of all symptoms for 406(46.8%) was within 48 h, for 345(39.7%) between 48-72 h. In 117(13.5%), symptoms persisted beyond 72 h. Of the 868 who developed AEFIs, 233(26.8%) of them took non-steroidal anti-inflammatory drugs for symptomatic relief. The hospital visit was done by 3(0.3%) while 6(0.7%) of them took leave from work.

Among the 4574 recipients, 941 were randomly selected for the follow-up phone call after the second dose of the vaccine. Among the 941(20.5%) vaccine recipients who were selected for assessing AEFIs after the second dose of the vaccine, 451(47.9%) were male and 490(52.1%) were female. The mean age was 39.23 ±11.80 (range 18-59 y) and 46(4.9%) had a positive history of COVID -19, Table 1. Out of 941 selected for assessing AEFIs after the second dose AEFIs were reported by 105(11.2%) among which 40(38.1%) were male and 65(61.9 %) were female. The Chi-square test showed a statistically significant higher incidence of AEFIs in females than in males (p=0.002), Table 2. The AEFI was more frequently reported in 38-47 age groups (26%), Table 2. No statistically significant difference in the percentage of AEFIs was seen among age groups(p=0.334). After the second dose of the vaccine, a total of 147 AEFIs were reported and there were 20 different AEFIs. Of 147 AEFIs, 64(43.5%) were local and 83(56.5%) were systemic. The common local AEFIs reported by 105 were pain at injection (6.7%) and the common systemic reaction was Lethargy (1.9%), headache (1.6%), and muscle ache (1.3%), Table 3. All the AEFIs were mild to moderate in severity.

Out of 941 selected for assessing AEFIs after the second dose, 46(4.9 %) had a history of COVID-19 (PCR positive), Table 1. There were 8 AEFIs reported in 4(8.7%) individuals with a history of COVID-19. The Chi-square test showed no statistically significant association

of history of COVID-19 and AEFIs (p=0.586). Among the 105 who reported AEFIs after the second dose of the vaccine, the onset of first symptoms for 102(97.1%) was within 24 h, for 3(2.9%) was between 24-48 h. Resolution of all symptoms for 41(39%) was within 48 h, for 43(41%) between 48-72 h. In 21(20%), symptoms persisted beyond 72 h. Nonsteroidal anti-inflammatory drugs were taken by 31(29.5%) for symptomatic relief.

Table 1. Characteristics of the recipients of the first (N= 4574) and the second dose (N=941) of the Sinopharm (Vero cell) COVID-19 vaccine

Characteristic		First dose, N(%)	Second dose, N(%)
Gender "*'	Male	2585(56.5)	451(47.9)
	Female	1989(43.5)	490(52.1)
Age (y)#	18-27	1228(26.8)	213(22.6)
	28-37	1111(24.3)	188(20.0)
	38-47	1129(24.7)	265(28.2)
	>47	1106(24.2)	275(29.2)
History of COVID-19		405(8.9)	46(4.9)

*p = 0.00001, # p= 0.00038

Table 2. Distribution of AEFIs following the first and second dose of Sinopharm (Vero cell) COVID-19 vaccine

		AEFIs 1st dose			AEFIs 2nd dose		
		Yes	No	p value	Yes	No	p value
Gender	Male	418(16.2)	2167(83.8)	0.000	40(8.2)	450(91.8)	0.002
	Female	450(22.6)	1539(77.4)		65(14.4)	386(85.6)	
Age (y)	18-27	226(18.4)	1002(81.6)	0.228	22(10.3)	191(89.7)	0.334
	28-37	225(20.3)	886(79.7)		25(13.3)	162(86.7)	
	38-47	226(20.0)	903(80.0)		34(12.8)	231(87.2)	
	>47	191(17.3)	(915(82.7)		24(8.7)	251(91.3)	

AEFIs: Adverse events following immunization

Table 3. Incidence of AEFI following 1st and 2nd dose of Sinopharm (Vero cell) COVID-19 vaccine

Incidence	First dose	Second dose
Very common (≥1/10)	Pain at the injection site	NONE
Common (≥1/10)	Lethargy, Headache, Muscle ache, Fever, Dizziness	Pain at the injection site, Lethargy, Headache, Muscle ache
Uncommon (≥1/1000 to <1/100	Running nose, Cough, Joint pain, Nausea, Chills, Sore throat, diarrhea, Swelling, Sweating, Rigor, Heaviness in the arm, Vomiting, Loss of appetite, Pruritus, Fainting	Fever, Dizziness, Joint pain, Nausea, Chills, Cough, Diarrhoea, Sore throat, Sweating, Rigor, Vomiting, Pruritus, Fainting, Shortness of breath, Chest tightness, Redness
Rare (≥1/10 000 to <1/1 000)	Rashes, Shortness of breath, Abdominal pain, Chest tightness, Redness, Palpitation, Facial muscle twitching, Nasal blockage, Dry mouth, Polydipsia, Irritation, Decrease sleep, Loss of taste	NONE

Table 4. Occurrence of AEFIs in the recipients of first dose and second dose of Sinopharm (Vero cell) COVID-19 vaccine

Characteristic	N(%)
Nothing happened in both doses	739(78.5)
AEFI severity same in both doses	21(2.2)
More severe in 1st dose	13(1.4)
More severe in 2nd dose	20 (2.1)
AEFI in 1st dose only	97 (10.3)
AEFI in 2nd dose only	51(5.4)

Among the 941 vaccine recipient who were selected for assessing AEFIs after the second dose 739(78.5%) reported no AEFIs in both the first and second doses, 97(10.3%) reported AEFIs only in the first dose and 51(5.4%) reported AEFIs only in the second dose, Table 4.

Discussion

Adverse events following immunization were more common after taking the first dose vaccine compared to the second dose. In this study among the 4574 recipients of Sinopharm (Vero Cell) 868(19%) reported AEFIs in the first dose while out of 941, 105(11.2%) taking the second dose reported AEFI. There were no major adverse events reported in both doses of vaccine which is consistent with a report by a strategic advisory group of experts (SAGE), WHO.[24]A previous study conducted at PAHS after the first dose of ChAdOx1 nCoV19 (COVISHIELD) among 3991 vaccine recipients, reported incidence of AEFIs to be 85.04%. The common AEFIs in that study was, pain at the injection site in 2196(55%), fever in 1481(37.1%), myalgia in 1201(30.1%), lethargy in 1102(27.6%), and headache in 1051(26.3%). In addition, one severe minor and two serious AEFIs were also documented.[25]Compared to the AEFIs after ChAdOx1 nCoV19 (COVISHIELD) in that study, the incidence of occurrence of the total, as well as each of the AEFIs, was found to be lower and no severe AEFIs were encountered after the (Vero Cell) vaccine in our study.

We found that the very common local reaction was pain at the injection site and uncommon were swelling and heaviness in the arm while the most common systemic reaction was lethargy, headache, muscle ache, fever, and dizziness, Table 3. These findings are consistent with the interim analysis of safety data conducted in China, Bahrain, Egypt, Jordan, and the United Arab Emirate which reported pain at the injection site, redness, swelling, induration, and itching as the frequently reported local reaction whereas very common systemic reactions were headache and common were fever, fatigue, myalgia, arthralgia, cough, dyspnea, nausea, diarrhea.[23,26,27] However, in our cohort, the headache was a common systemic event while arthralgia, cough, nausea, diarrhea, pruritus, and dyspnea were uncommon events. Moreover, heaviness in the arm was not recorded in their studies whereas; induration and itching were not reported in our study. Adverse events were seen more in female than in male in both dose of vaccination and was statistically significant. However, as two groups do not have equal distribution (Table 1), this cannot be concluded.

Similarly, post-licensure safety data from China have shown that the most frequently reported local reaction was induration at the injection site followed by redness, swelling, and rashes while the most frequently reported systemic AEFI was fever.[23,27] In our study, most of the AEFIs were mild to moderate in severity and got resolved within 72 h either spontaneously or following NSAIDs which is similar to the finding in the interim analysis of the pooled data and post-licensure study. [23,26,27] Interim analysis of the pooled data reported two serious adverse events (nausea and inflammatory demyelination syndrome / acute encephalomyelitis) and post-licensure study have reported cases of facial nerve palsy; however, we did not find such severe AEFIs in our study.[23,26,27]

Minor adverse events are seen in immunization which is not an allergic reaction but is because of the vaccine stimulating a protective immune response.[28] Major adverse events like anaphylaxis are very rare occurring in 1/mil doses for most of the vaccine.[29] We did not find any event of anaphylaxis in our study.

The Sinopharm vaccine is preferred not only because it is accessible but also easy to store and transport, as well as suitable for a developing country like Nepal with constrained resources. In addition, the efficacy of the Sinopharm vaccine meets the WHO requirement and has acceptable adverse reactions. [30] Studies in Peru have found the Sinopharm vaccine to be 50.4% effective in preventing COVID-19 and 94% effective at

preventing deaths.[31] Therefore, it is important to research on large scale to find out breakthrough infection and AEFIs of the Sinopharm vaccine. The limitation of the study was that the AEFIs information was collected through a one-time phone call and we did not do a follow-up phone call for those with AEFIs persisting beyond 72-h. Any events occurring after the 72-h phone call are also not captured in this study.

Conclusion

The current study identified that adverse event following immunization by Sinopharm (Vero Cell) COVID-19 vaccine in Nepal was mild to moderate in severity and most of the AEFIs resolved within 72-h. The most frequently reported AEFIs were pain at the injection site, lethargy, headache, muscle ache, and fever. No cases of severe AEFIs were identified. A slightly higher percentage of AEFIs were observed in females than in males and in the 38-47 y age group. No differences in the rate of occurrence or severity of AEFIs were observed in those with past SARS CoV-2 infection. Studies with a longer follow-up are required to evaluate the delayed AEFIs.

Acknowledgment

The authors are greatly thankful to Dr. Mayuri Gupta, Dr. Binnam Shakya, Dr. Ram Krishna Shrestha, Dr. Prabesh Pandey, and Dr. Archana Regmi for facilitating the data collection, Mr. Krishna Bahadur G.C. for assistance in data analysis.

Conflict of Interest

None

Funding

None

Author Contribution

Concept, design, planning: SA, SS, RD, AS, PR, TS, ST, RS, SM, RB, DM, RKJ; Literature review: SA, SS, RD, AS; Data collection/analysis: SA, RD, TS, ST, RS, SM, RB, DM, RKJ; Draft Manuscript: SA, SS, RD, AS, PR, TS, ST, RS, SM, RB, DM, RKJ: Revision of draft: SA, SS, RD, AS; Final manuscript: SA, SS, RD, AS, PR, TS, ST, RS, SM, RB, DM, RKJ; Accountability of the work: SA, SS, RD, AS, PR, TS, ST, RS, SM, RB, DM, RKJ.

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