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SIDE EFFECTS FOLLOWING SINOPHARM COVID-19 VACCINATION IN SALAH AL-DIN / IRAQ: A COMMUNITY-BASED STUDY

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Abstract:

To this day, vaccination is the primary intervention to eliminate the expansion of COVID-19 and avoid its health consequences for humanity. This study was aimed to appreciate the adverse side effects of the Sinopharm COVID-19 vaccine. A cross-sectional study was conducted on 606 individuals attended the COVID-19 vaccine health center of Baiji Health Sector, Salah al-Din Governorate (Iraq), between January and December 2021. Males constituted about 59% compared to 41% of females of the study population. The study showed that 3.5% of the subjects were in the age group of less than 20 years old, while 65.5% of the total participants was in the age group of 20-40 years. The sequence of side effects for the study participants was as follows: pain at the injection site 40%, fever 30%, headache 20%, fatigue or lethargy 4%, redness or reaction at the injection site 3.5%, complaints of muscles pain 1%, gastrointestinal symptoms 1%, and mild allergic reactions 0.5%. Also, results demonstrated that 68% of individuals had side effects from the first dose, and these people were treated. Besides, no person who received the Sinopharm vaccine reported serious side effects or fatal complications during the study period, as the mortality rate for Sinopharm was 0%. Thus, it can be concluded that this vaccine is effective and safe for all age groups.

Keywords: COVID-19, Sinopharm vaccine, side effects.

INTRODUCTION

As it is known, COVID-19 infection is a highly contagious viral disease (SARS-CoV-2) that targets the respiratory system, induces acute pneumonia and sometimes complications up to multiple organ failure and life threatening [1-3]. The first case of this disease was recorded in an elderly person in 2019 from China. Then it fast expansion all over the world, so with the third month of 2020, this infection was declared a global pandemic [4,5]. The adverse effects of the COVID-19 pandemic have been very considerable in terms of social life, economic as well as public health [6]. Effective treatment against this infection remains a challenge globally, as many of the therapeutic drugs used against COVID-19, have been supportive rather than proven [7,8].Many practical studies worldwide have led to the development of successful vaccines for this highly contagious infection [9]. Vaccination has already proven to be the key strategy to combat this pandemic [10]. Sinopharm vaccine for COVID-19 is one of the inactivated vaccines that provides the body with dead copies of the COVID-19 virus, given intramuscularly in two doses, 14 or 21 days apart [11]. The purpose of this type of vaccine is to produce antibodies that make preparations the immune system for futurity virus aggression [12]. In general, the technology used to produce an inactivated virus vaccine is considered safe, as in some inactivated influenza vaccines, which have proven their efficiency and safety for a long time [13]. Therefore, this study came to estimate the safety of Sinopharm vaccine in a community of individuals in Salah El-Din Governorate during the follow-up of side effects after dosing.

METHODOLOGY

In this cross-sectional study, approximately 606 individuals vaccinated with Sinopharm COVID-19 in the health center designated for COVID-19 vaccine in Baiji Health Sector, Salah Al-Din Governorate (Iraq), were participated during the period between January and December 2021. Participants were of both gender and ranged in age from 18 to 72 years old. They had taken the vaccine (either one or two doses) at least a month before the study. The information questionnaire for each participant was filled out through a direct interview as well as through an online form. The questionnaire included study information such as demographic data of the participants (age and

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gender), comorbidities, if any, completion of vaccine doses, side effects that may have appeared on participants after dosing, and recovery from these symptoms. The incidence of these adverse proceedings was assessed and estimated to identify the most common symptoms that could be associated with this type of vaccine. Descriptive statistical analysis of the data was carried out using SPSS software (version 26). The results were expressed in the form of a number and a percentage. An appropriate non-parametric test was used to compare between age groups, and the P-value was set at less than 5 percent as a significant difference.

RESULTS AND DISCUSSION

Out of 606 participants vaccinated with Sinopharm, 59% of the study population was males, versus 41% females (Fig. 1).

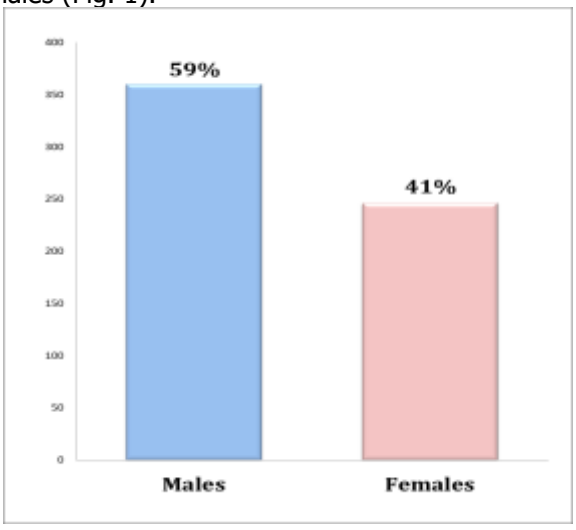

Figure 1: Distribution of participants by gender.

Table (1) shows the distribution of the age group of the study population, as it is clear that (3.5%) individuals were less than (21) years old, while the largest proportion of the vaccinated participating was from the age group 20-40 years old (65.5%). On the other hand, there were only 18 people (3%) in the group older than 60 year old.

Table 1: Distribution of study population by age group

Age categories	Frequency	Percentage %	P-value
< 20	21	3.5%	0.08
20 – 40	397	65.5%	0.38
41 – 60	170	28%	0.14
> 60	18	3%	0.10

According to the results of the study, the main complaints about the side effects of this vaccine were pain at the injection site (40%), followed by fever (30%) or high body temperature of more than 38 C of the total side effects, then headache (20%). In contrast, the minor complaints were of allergic localized reactions (0.5%) , then muscle pain as well as gastrointestinal symptoms that included nausea, vomiting, diarrhea or colic (1%) .

Table 2: The incidence of side effects following the vaccine among the participants

Side effects	Frequency	Percentage**%**
Pain at site of injection	242	40
Fever	181	30
Headache	120	20
Fatigue or Lethargy	25	4
Redness or reaction at site of injections	23	3.5
Muscles ache	6	1
Allergic reactions (localized)	3	0.5
GIT symptoms	6	1

The timing of complaints to the occurrence of these negative effects was in 450 (74%) of the total study population within the first 24 hours, while another 156 (26%) had complaints more than 24 hours after vaccination (Fig. 2).

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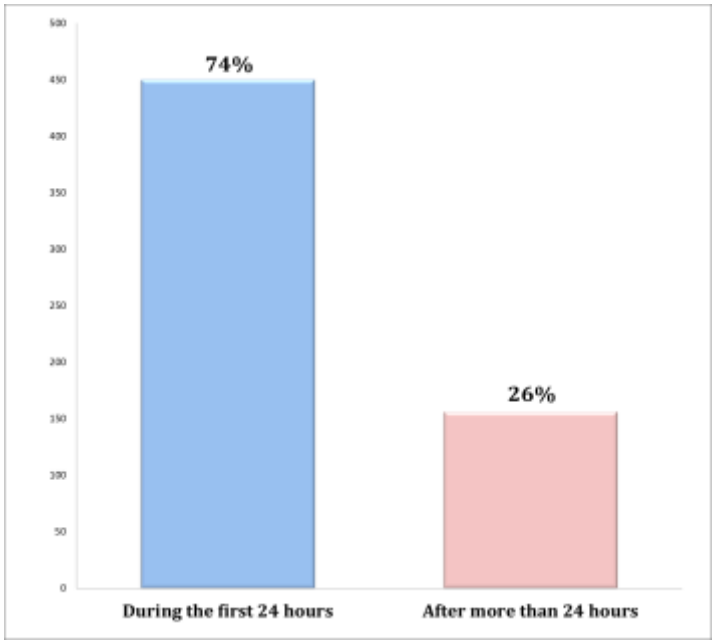

Figure 2: Distribution of the population according to time of side effects appearance.

Approximately 411(68%) vaccinated individuals developed side effects from the first dose, while 195 (32%) of the subjects were on the second dose (Fig. 3).

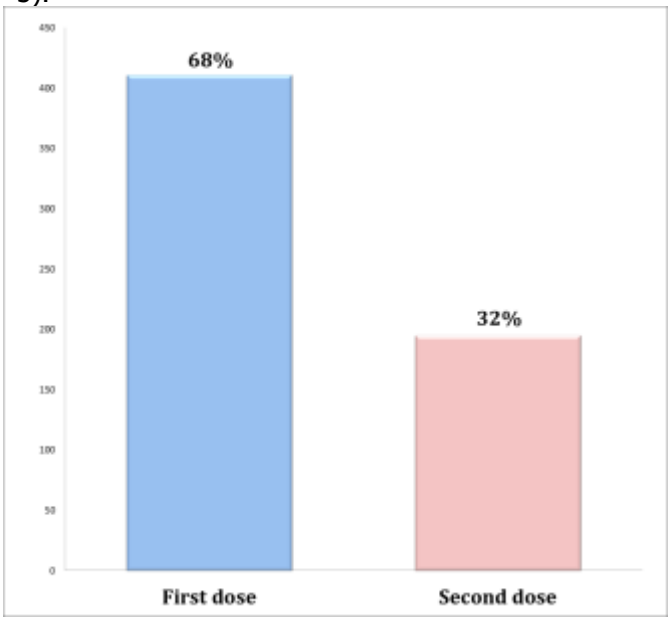

Figure 3: Distribution of the population according to recorded dose of vaccine.

No one who received the Sinopharm vaccine reported serious side effects or fatal complications during the study period (Fig. 4).

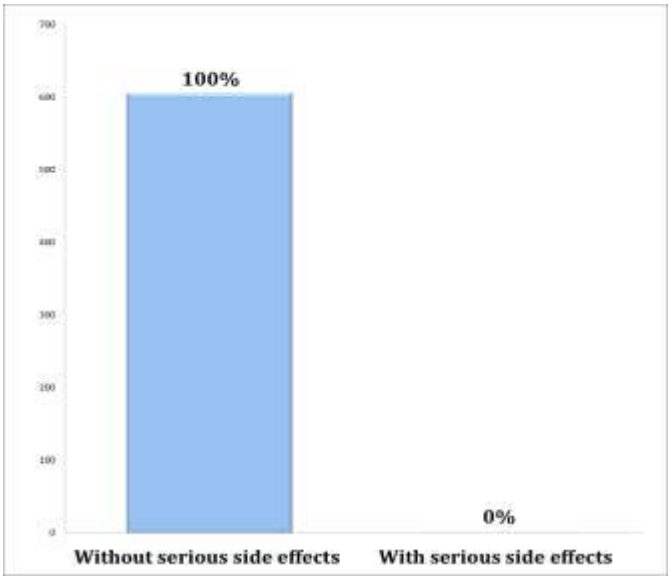

Figure 4: Distribution of the population according to serious side effects of vaccine.

Persons who received the vaccination from health workers amounted to 37 (6%) , compared to 596 (94%) from non-health workers (Fig. 5).

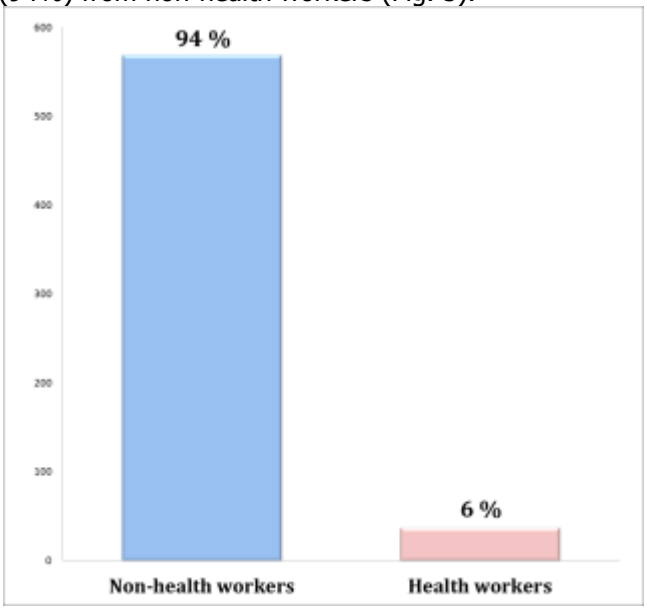

Figure 5: Distribution of the population as health workers or non-health workers

No deaths were recorded during the study period, as the mortality rate with the Sinopharm vaccine was (0%). All vaccinated people who had minor side effects were treated (table 2).

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Table 3: Final outcome of complaints regarding side effects of the Sinopharm vaccine

Final outcome	Frequency	Percentage%
Cure	606	**100**
Cure with disability	0	**0**
Case of fever need Follow-up	6	**1**
Death	0	**0**

During the study period, 7 people were comorbid with chronic diseases, although they were vaccinated without any noticeable complications. On the other hand, 6 people had received influenza vaccination and did not show any interactions (table 4).

Table 4: Comorbidity with chronic diseases or concomitant other vaccines.

Variables		Frequency	Complications
Chronic disease	Hypertension	4	Non
	Mellitus diabetes	3	Non
Concomitant influenza vaccination in the same year		6	Non

DISCUSSION

Sinopharm COVID-19 vaccine is a viral vaccine that is inactivated by destroying its genetic material either by chemicals, radiation, or heat. Once the viral replication capacity is impaired, viruses cannot replicate, but they can still stimulate the immune system to build antibodies to fight COVID-19[14,15]. Because the inactivated type of vaccine does not induce clinical symptoms, so in the Sinopharm COVID-19 technology, we see the emergence of mild or no symptoms [16, 17]. According to the results of this study, the most frequently reported side effects among participants were injection site pain, fever, and headache. No serious case was recorded among them. The findings of the study were supported by another study conducted by Al Khames Aga and Collagenous (2021), in which approximately 1,736 participants received 1 or 2 doses of the Sinopharm vaccine. Mild vaccine reaction was reported in 34.56% of participants, and it was greater for AstraZeneca and Pfizer vaccines than for Sinopharm. In addition, Sinopharm vaccine has shown less appearance of disadvantageous effects versus other vaccines [18].Also, the result of this study came in line with a cross-sectional survey of Saeed et al. (2021) in the United Arab Emirates. They found that the most frequent adverse events after vaccination were in sequence: injection site pain, lethargy, fatigue, and headache [19].In a comparative study by Abu-Halaweh and his group of the undesirable effects correlated with the Sinopharm and Pfizer vaccinations with 1,004 participants, and there was no respectable difference between the proportions of participants for both vaccines. However, Pfizer-vaccinated participants had remarkably higher frequencies of all adverse effects versus Sinopharm, with injection site pain being the most prevalent [20].
According to our results, only (0.5%) of the participants had experienced allergy symptoms after vaccination. It should be noted that allergic reactions to vaccines may be caused by ineffectual components (excipients) contributing to specific immediate IgE-mediated reactions [21]. Usually the intent of adding these substances to vaccines is to improve the following: stability, solubility, absorption, and taste. On the contrary, these excipients have the potential to induce to induce various allergic reactions ranging from mild local to life-threatening systemic [22]. It was noted in the current study that that the most cases of chronic health disorders among the vaccinated were hypertension (4 cases), followed by diabetes (3 cases), and this is consistent with a previous survey by Saeed et al. on the negative effects of the COVID-19 vaccine among 1080 individuals in the UAE. They observed that the generality chronic diseases among the Emirati participants were diabetes followed by hypertension [19].

CONCLUSIONS

Through the results, it was concluded that the side effects following vaccination with Sinopharm COVID-19 vaccine were mild, and there were no serious cases or required hospitalization, and this will help increase the acceptance of the vaccine. No deaths related to Sinopharm vaccine were recorded among the participants, which indicates a high level of safety related to this vaccine. The study recommends the necessity of providing health education programs

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through all social media about the importance of the vaccine in all our governorates.

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