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Side effects and perceptions following Sinopharm COVID-19 vaccination

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A R T I C L E   I N F O

Article history:
Received 13 June 2021
Revised 4 August 2021
Accepted 5 August 2021

Keywords:
COVID-19 vaccine
Sinopharm COVID-19 vaccine
Sinopharm BBIBP-CorV
Side effects
Chronic diseases
United Arab Emirates

A B S T R A C T

Objectives: Vaccines are one of the best interventions developed for eradicating COVID-19. This study aimed to provide evidence on Sinopharm COVID-19 vaccine side effects.

Methods: A cross-sectional survey study was conducted between January and April 2021 to collect data on the effects of the COVID-19 vaccine among individuals in the United Arab Emirates. Demographic data, vaccination and the response of people unwilling to take the COVID-19 vaccine were reported.

Results: Side effects post first vaccine dose of normal injection site pain, fatigue and headache were more common in participants aged ≤49 years versus >49 years, while pain at the vaccination site, fatigue, lethargy, headache and tenderness were the most common side effects post second dose in both groups. All side effects for both doses were more prevalent among participants aged ≤49 years. Side effects were more common in females compared with males for both doses. The most common reason for being unwilling to take the COVID-19 vaccine was that vaccines are not effective.

Conclusion: Post-vaccination side effects for the first and second doses were mild and predictable, and there were no hospitalization cases; this data will help reduce vaccine hesitancy.

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Introduction

SARS-CoV-2, causing COVID-19 (Habas et al., 2020), has spread fast worldwide, resulting in various levels of illness. On March 11, 2020, it was announced that SARS-CoV-2 is a worldwide pandemic, and it is with us to this day (Lai et al., 2020). Although numerous therapeutic medications have been presented to resist COVID-19, they remain supportive and require more randomized control studies to determine their efficacy and potency. (Coronavirus disease (COVID-19) 2021, Trivedi et al., 2020).

Vaccines are one of the best interventions developed for eradicating COVID-19, saving millions of lives annually. Moreover, the best option remains an effective, safe vaccine without severe adverse reactions. The lack of effective and approved COVID-19 treatment has triggered a vaccine development race, with 259 COVID-19 vaccine projects underway from November 11, 2020. The rapid creation of vaccinations has increased the risk of vaccine safety issues (Haidere et al., 2021, Petousis-Harris, 2021).

Several candidate COVID-19 vaccines were developed from diverse platforms. One of these was the BBIBP-CorV vaccine (also known as the Sinopharm COVID-19 vaccine) which was made by the Chinese state-owned pharmaceutical business Sinopharm in China and adopted by the United Arab Emirates (UAE) (Zhang et al., 2021). Sinopharm COVID-19 vaccine is an inactivated vaccine that introduces a dead copy of SARS-CoV-2 into the body by a two-dose schedule, with 14 or 21 days between the 2 doses. By inserting the vaccine dose intramuscularly, the dead antigens from the virus are employed to make antibodies that prepare the immune system for future attacks by the virus. (Xia et al., 2021). The traditional inactivated whole-virus vaccines do not lead to clinical disease. In this technology, the inactivated viruses maintain their ability to replicate in vivo with mild or no symptoms (Forni and Mantovani, 2021).

Phases 1 and 2 of the clinical trials for the Sinopharm COVID-19 vaccine were carried out in China over 1 trial for each phase. A total enrolment of 640 participants showed that the vaccine triggered a COVID-19 neutralizing antibody response with a low rate of adverse reactions. The most common side effects were fever and pain at the site of injection and fever; however, these were
mild and self-limiting and did not require treatment (Sharma et al., 2020). Phase 3 was carried out over 4 trials in the following countries: the UAE, Bahrain, Egypt, Jordan, Peru and Argentina, with a total 69,000 people enrolled. The UAE approved the vaccine on December 9, 2020; the UAE announced that the vaccine was 86% efficacious, according to the interim results of its phase 3 trial (Xia et al., 2021).

Having administered over 2 million doses of the vaccine as of mid-January 2021, the UAE Ministry of Health reported the vaccine to be 100% effective in preventing mild and severe COVID-19 cases (China to run human coronavirus vaccine trial in UAE 2020, Development of an Inactivated Vaccine Candidate, 2021, Cyranoski, 2020, Zahid et al., 2021). Moreover, the World Health Organization (WHO) announced that most side effects of the Sinopharm COVID-19 vaccine in 3 clinical trials on 1667 participants aged 18–59 years were mild to moderate, with headache, fatigue, and injection site reactions being the most common (World Health Organization (WHO) 2021).

Published data to support adverse reactions to the Sinopharm COVID-19 vaccine are lacking. Only 2 studies focus on this vaccine (Hatmal et al., 2021, Jayadevan et al., 2021), and fear of the new vaccine is a driver of vaccine hesitancy (Riad et al., 2021).

Knowledge on what happens post-vaccination among the general population is still limited. Describing what to expect after the first and second dose of vaccination will help lessen apprehension about this type of vaccine, increase public confidence in vaccine safety, and accelerate the vaccination process against COVID-19 (Hatmal et al., 2021, Jayadevan et al., 2021). The results of this study will be reassuring to those who are fearful of the Sinopharm COVID-19 vaccine. Therefore, the goal of this study was to provide evidence on Sinopharm COVID-19 vaccine side effects after receiving the first and second dose, as approved by the UAE.

Methodology

Study design, setting and participants

This cross-sectional survey-based study was carried out from 10 January to 30 April 2021 to evaluate Sinopharm COVID-19 vaccine adverse reactions among residents in the UAE. The study utilized a self-administered online survey created on Google Forms which had been randomly delivered to individuals (aged ≥18 years) using social media sites (Facebook, Email and WhatsApp). Potential participants were directed to a webpage with a brief introduction to the aim and purpose of the study and instructions on how to complete the survey. Informed consent that included statements about voluntary participation and anonymity was sought from all the respondents prior to data collection by sending a standardized general invitation letter with the survey link to accept or decline participation in the study. Participants who declined consent were not permitted to open the survey and participate in the study, and participants could withdraw from the survey at any time in line with the World Medical Association Declaration of Helsinki Ethical principles (Aresté and Salgueira, 2013). Persons who clicked on the link were directed to Google Forms and, to avoid issues of missing data, they had to respond to all the questions or were unable to proceed to the next section of the survey. No incentive or compensation was given to participants (Elm et al., 2007).

Out of 1102 surveys received from respondents, 1080 participants aged ≥18 years, from different emirates and nationalities, were included in this study. The study sample included participants who were either vaccinated with the first dose or second dose of Sinopharm COVID-19 vaccine and those who did not receive any COVID-19 vaccine during the early peak of the vaccination campaign in the UAE. Individuals aged <18 years and non-residents in the UAE were excluded from this study as they were not permitted to receive any vaccine type in the UAE during the conduct of this study. Individuals who had received a COVID-19 vaccine other than Sinopharm were not included in the study, based on the study’s aims.

Survey and data collection

The survey was designed based on extensive literature searches and guidelines from the WHO, MOHAP, and the Abu Dhabi Department of Health (DOH) in the UAE on the expected adverse reactions post Sinopharm COVID-19 vaccine. The survey questions were multiple choice and were made available in English and Arabic (Xia et al., 2021, World Health Organization (WHO) 2021, COVID-19 Vaccine 2021). The survey was validated by a group of experts who provided feedback on the different items of the survey.

The survey was in three sections. The first section included 7 demographic questions on gender, age, marital status, education level, employment, nationality, and the region of residence. The second section reviewed participants’ chronic conditions such as: cancer, autoimmune diseases, chronic respiratory diseases, diabetes, hypertension, obesity, heart disease, allergic reactions to vaccination (any type of immediate allergic reaction to a vaccine or injectable therapy), receiving immunotherapy or inhibitor therapy, severe anemia (level less than 7.0 g/dl), liver diseases, and no chronic condition.

The last section was related to Sinopharm COVID-19 vaccine side effects. In the first section, participants had been asked about COVID-19 vaccination status to determine the scope of the rest of the questions. If the participant had received the vaccine, we asked about the number of doses administered and previous COVID-19 infection; then questions regarding side effects to vaccine first and second dose were asked separately based on each dose side effects, namely, normal/severe pain at the vaccination site, tenderness, redness, pruritus at the vaccination site, fever, headache, fatigue, nausea, diarrhea, cough, allergy, muscle pain, abdominal pain, back pain, and lightheart.

If the participant had not received any COVID-19 vaccine, a question was asked to clarify the reasons behind this. For pilot testing, the survey was passed randomly to 15 participants recently vaccinated who completed the survey after taking the 2 doses and were then excluded from the study. The Cronbach’s alpha test of internal consistency was used to evaluate survey reliability. The overall reliability was 0.81, indicating that the survey tool was reliable with good internal consistency (McLugh, 2012, Nunnally and Bernstein, 1994).

Sample size

The online Raosoft sample size calculator (Raosoft Inc., Seattle, WA, USA) was used to calculate the sample size of our study. Based on world meter elaboration of the latest United Nations data, the UAE population is approximately 10 million. Around 77.3% of the population had received at least one dose of the vaccine (according to the UAE supreme council for national security). We assumed the confidence level is 95%, the margin of error is 3%, and the response distribution is 50%. With a population of 7.7 million (vaccinated with at least one dose), the sample size recommended was 1067; the study included 1080 respondents meaning a convenience sample size was used (Sample size calculator, 2021, COVID-19 vaccines, 2021).

Statistical analysis

The Statistical Package for the Social Sciences version 22.0 (SPSS Inc. Chicago, IL, USA, 2013) was used to carry out descriptive statistics of 1080 participants for the demographic variables (gender,
age, education level, marital status, employment status, nationality and region of residence). In addition, health and chronic conditions, COVID-19-related anamnesis, such as vaccination status, previous infection, and the number of vaccination doses, and the reasons for participants’ vaccination hesitancy, were analysed. Data are presented in both frequencies and percentages.

In our study, the mean age was 37.2±13.1. Age was classified into 4 groups ranging from 18 to 80 years old. The median age of our sample, 49 years old, was selected to be a cutoff point to evaluate the difference in side effects between 2 groups of participants (≤49 vs >49) using a Chi-squared test. Similarly, a Chi-squared test was performed to assess the correlation between vaccine side effects and gender.

Results

Demographic characteristics

Table 1 shows the demographic data of participants: 760 (70.4%) were female, 320 (29.6%) male. The mean age was 37.22±13.1 years; 440 (40.7%) were single, 600 (55.6%) married, and 3.7% divorced or widowed. On education level, 644 (59.7%) held a bachelor’s degree, 288 (21.1%) a high school degree or below, and 180 (16.6%) a postgraduate degree. The majority (508, 47.1%) were employed, 232 (21.5%) unemployed and 304 (28.2%) were students. Most participants (856, 79.3%) were non-Emirati, 224 (20.7%) were Emirati. Many participants (52.9%) lived in Sharjah, 288 (26.7%) in Dubai and the rest (220, 20.3%) in the other Emirates.

Chronic conditions among the participants

Of 1080 participants, 780 (72.2%) were healthy, while 300 (27.8%) had chronic conditions. The most prevalent chronic conditions, as shown in Table 2, were diabetes 7.8% followed by hypertension 6.3%, while, respectively, 3.7%, 3.7%, 3.3%, 0.7%, 0.7%, 0.4%, 0.4%, and 0.4% suffered chronic respiratory disease, heart disease, obesity, cancer, severe anemia, autoimmune disease, severe allergies, were receiving immunotherapy, and had liver disease.

Relationship between the side effects of vaccination and age (≤49 years vs >49 years)

Table 3 compares COVID-19-related anamnesis of vaccinated individuals aged below and above 49. The study shows a significant difference in vaccination status between people who are ≤49 years and those who are >49 years.
years old and >49 years old (P=0.000), with participants aged >49 years more likely to be vaccinated (85%) compared with those ≤49 (75%). Differences in the number of doses between these 2 groups was not significant (P=0.0128). However, there was a significant difference between the 2 groups in whether participants had had COVID-19 infection previously (P=0.002), with those aged <49 more likely to have had a previous COVID-19 infection (16.6%).

Table 4 presents the prevalence of general adverse reactions to the first dose of the Sinopharm COVID-19 vaccine in participants (≤49 years vs >49 years old). The table shows that overall 24.4% (26% vs 18.6%) did not have side effects. Common side effects among both age groups of participants were normal pain at the site of vaccination (42.2%), fatigue (12.2%) and headache (9.6%). The same table indicates a significant difference between the 2 age groups (≤49 years vs >49 years old) for severe pain at the vaccination site (P=0.023), nausea (P=0.010) and muscle pain (P=0.010). Of participants >49 years, 6.8% reported severe pain at the vaccination site compared with 1.4% among those aged ≤49. More participants aged >49 years reported nausea and muscle pain compared with participants aged ≤49 years, 0.5% vs 5.0% and 4.3% vs 13.6%, respectively.

The tables show no significant difference between the age groups in other side effects, namely normal pain at the vaccination site (P=0.999), tenderness (P=0.963), redness (P=0.452), induration and pruritus at the vaccination site (P=0.356), fever (P=0.631), headache (P=0.178), fatigue (P=0.429), cough and laryngitis (P=0.631), abdominal pain (P=0.324), back pain (P=0.054), laryngitis (P=0.631), and other symptoms (P=0.452).

In the second dose of the Sinopharm COVID-19 vaccine (≤49 years vs >49 years old), there was more prevalence of side effects than for the first dose (Table 5). Among the (≤49 years vs >49 years old) participants, 14% (15% vs 10%) did not have any post-vaccination symptoms. In both age groups, the most prevalent side effects of respondents were pain at the vaccination site (32.6%), fatigue (16.3%), laryngitis (13.7%), headache (10%), and tenderness (10%). The same table shows that there was a significant difference between both groups (≤49 years vs >49 years old) in fatigue (P=0.003), with no significant differences for other side effects.

**Relationship between the side effects of vaccination and gender**

Table 6 shows the prevalence of side effects post the first dose of Sinopharm COVID-19 vaccination among women and men. Our study included 760 females and 320 males. Women had more symptoms from the first dose than males (17% of females had no side effects vs 45% of males). There was a significant relationship between fatigue and gender (P=0.006); however, the results show no significant difference by gender for tenderness (P=0.194), redness (P=0.356), fever (P=0.891) and headache (P=0.434).

Table 7 presents the prevalence of side effects from the second dose of vaccination among females and males. Women had more side effects from the second dose than males (11.6% of females had no side effects vs 20% of males). Severe pain at the vaccination site (P=0.027) and fatigue (P=0.011) symptoms were significantly higher in females than males (10.5% vs 2.5% and 20.0% vs 7.5%), respectively. In addition, the table shows no significant difference by gender in the symptoms of normal pain at the vaccination site (P=0.482), tenderness (P=0.368), redness (P=0.834), fever (P=0.279) and laryngitis (P=0.053).

**Reasons reported by participants for not receiving a COVID 19 vaccine**

The three most common reasons reported by participants for unwilling to receive COVID-19 vaccine were: The vaccine is not effective (6.3%), in a category of people not authorized to take the
vaccine (5.2%), and believing that the vaccine has many side effects (4.4%). Participants also reported not having enough time to take the vaccine (3.7%), unavailability of the vaccine (3%), the vaccine not being approved by the WHO (1.5%), being afraid of needles (11%), and, the least common reason, waiting for another vaccine (0.4%) (Table 8).

**Discussion**

In August 2020, Trials 1 and 2 of the Sinopharm vaccine were completed and showed that the vaccine triggered a COVID-19 neutralizing antibody response with a low rate of adverse reactions. The most common adverse reactions were pain at the injection site and fever, but all were mild and self-limiting. Moreover, no treatment was required for any side effect (Xia et al., 2021). The UAE were among the first to conduct phase 3 clinical trials of the vaccine, which found the vaccine to have an 86% efficacy rate, according to interim results (Xia et al., 2021).

Most studies have assessed post-vaccination adverse reactions of the Pfizer-BioNTech, Moderna, and AstraZeneca vaccines (El-Shitany et al., 2021, Chapin-Bardales et al., 2021, Kadali et al., 2021, Menni et al., 2021, Riad et al., 2021), while only 2 studies focus on the Sinopharm COVID-19 vaccine (Jayadevan et al., 2021, Hatmal et al., 2021). No published studies focus on Sinopharm COVID-19 vaccine side effects in the UAE to the author’s knowledge.

The finding of our study shows that the side effects of this vaccine appear to be mild. A quarter of participants reported they did not have any symptoms post the first vaccination shot while had mild symptoms following vaccination. For the second dose, 14% of participants did not report symptoms; however, the majority had mild and predictable side effects. None of the side effects were severe or required hospitalization. Our results were in line with a study in India where the frequency of experiencing symptoms following each dose of the vaccine was 24.4% (Sinopharm) (Jayadevan et al., 2021).

For the first dose of vaccination, the findings showed statistically significant differences in the prevalence of severe pain at the injection site, nausea and muscle pain, between the participants aged ≤49 vs >49. For the second dose, there was a significant difference between the 2 age groups in the prevalence of fatigue. Moreover, for both groups, the side effects for the second dose were normal pain at the vaccination site (42.2%), fatigue (12.2%), headache (9.6%), lethargy (9.2%), and muscle pain (6.3%). The reported symptoms in our study were similar to symptoms reported in the Phase 1/2 trial of the Sinopharm vaccine; WHO, DOH and MOH in the UAE reported that the most adverse reactions were injection site reactions, headaches and fatigue. They indicated that the most common systematic adverse reaction was pain at the injection site.
jejction site and fever, which were self-limiting and patients recovered; none of the symptoms was severe or required hospitalization [(COVID-19 Vaccine 2021, World Health Organization (WHO) 2021, Xia et al., 2021)].

Injection site pain is reported in several reports on vaccine side effects (El-Shitany et al., 2021, Hatmal et al., 2021 Jayadevan et al., 2021, Riad et al., 2021). Injection into a relaxed muscle leads to less pain compared with a tensed one; therefore, researchers recommend lowering the patient’s arm to be injected to reduce pain. In addition, vaccines in situ should be kept at a low temperature; the Sinopharm COVID-19 vaccine should be stored at normal refrigeration temperature. Injection without optimal warming may increase the probability of pain at the injection site (China State-Backed Covid Vaccine Has 86% Efficacy 2021, Hatmal et al., 2021, Riad et al., 2021).

The Food and Health Bureau of Hong Kong evaluation report on CoronaVac (another inactivated virus vaccine) reported that common adverse reactions (>10%) were injection site pain, headache, and fatigue (Food and Health Bureau (FHB) 2021).

The study of Riad and others among healthcare workers in Turkey found that injection site pain (41.5%), fatigue (23.6%) and headache (18.7%) were reported by more than 10% of the participants; this result was similar to our result for the Sinopharm COVID-19 vaccine (Riad et al., 2021). In our study, the younger adults (<49 years) were more frequently affected than older age groups (>49 years). Vaccine reactogenicity is known to correlate with transient elevation of inflammatory cytokines, suggesting that the vaccine reactogenicity declines with age, but it is not considered a reliable sign of a desirable immune response (Hervé et al., 2019). Similar results to ours are reported in various COVID-19 vaccine side effects studies (Jayadevan et al., 2021, Polack et al., 2020, Riad et al., 2021). Moreover, according to the Centers for Disease Control and Prevention, the side effects tend to be more noticeable after the first dose (Possible Side Effects After Getting a COVID-19 Vaccine 2021).

Similar to the findings of recently published studies (El-Shitany et al., 2021, Hatmal et al., 2021), we observed that the frequency of adverse effects to the second shot of vaccine was slightly higher than to the first dose except for nausea (1.5% vs 1.1% [first vs second dose]), allergy (1.1% vs 0.0%), cough (1.1% vs 0.7%), abdominal pain (1.85% vs 1.5%), and back pain (4.1% vs 3.0%). This finding could be interpreted on the basis of immune system response. The immune system could produce cytokines with an inflammatory effect on the blood vessels, muscles and other tissues; it may also produce flu-like symptoms that last for days after vaccination (Zhang et al., 2021).

Women were generally more likely to have side effects from vaccination than men; 83% of females reported side effects compared with 55% of males post first dose of vaccination, 98.5% females versus 80% males post second dose. Previous studies on COVID-19 vaccines have reported more side effects within females compared with males for both doses (El-Shitany et al., 2021, Jayadevan et al., 2021, Riad et al., 2021). According to the findings of the study on CoronaVac, local and systemic side effects were more prevalent after the second dose in females than males, which demonstrates the similar efficacy of this vaccine to Sinopharm (Riad et al., 2021).

The difference of side effects between genders reported for inactivated virus vaccines such as influenza, measles-mumps-rubella combination vaccine, attenuated Japanese encephalitis, and attenuated Dengue vaccines suggest that females have stronger immune responses and side effects are more frequent and more intense (Klein et al., 2010, Klein and Pekosz, 2014). In our study, 11% of participants had allergic symptoms post first vaccination dose.
while no cases for allergy were reported post second dose. This finding confirms that patients in this study with an allergic reaction to the first dose did not receive the second vaccination dose. There are no published data on the safety of the second dose of COVID-19 vaccine after an allergic reaction to the first dose, although one study indicated that anyone with an immediate allergic reaction history of any severity to any component of mRNA COVID-19 vaccines or to polyethylene glycol or polysorbate should not be vaccinated with the Pfizer-BioNTech or Moderna COVID-19 vaccine (Kounis et al., 2021).

Allergic reactions to vaccines not attributed to the active vaccine itself might be caused by inactive ingredients such as egg protein, gelatin, formaldehyde, thimerosal, or neomycin which contribute to specific immunoglobulin E-mediated immediate reactions. According to the European Medicines Agency, excipients are constituents of a medicinal form apart from the active substance; they are inert substances added to vaccines to improve stability, increase solubility, improve absorption, influence palatability, or create a distinctive appearance. Excipients can cause various clinical allergic reactions ranging from skin disorders to life-threatening systemic reactions (Caballero and Quirce, 2020).

Our study noted that the most prevalent chronic conditions among the UAE participants were diabetes (7.80%) and hypertension (6.30%). Our results are consistent with the Dubai Statistical Center study, which shows that UAE nationals have a high prevalence of diabetes and hypertension diseases. Furthermore, another study among patients with chronic disease in the UAE reported that 74.1% of individuals were diabetic (CDC 2020, Osama et al., 2011).

Recent studies have shown that COVID-19 vaccine hesitancy is variable. In New York, approximately 29% of residents claimed that they will refuse a vaccine, compared with 20% of Canadian residents, and 6% of residents in the United Kingdom. (Latimer, 2020, Henley, 2020). In our study, a few respondents reported that they did not want to receive the COVID-19 vaccine. The common reasons for indecision and rejection of COVID-19 vaccines were the individuals that the vaccine is ineffective, being a category of persons not authorized to take the vaccine, and being afraid of vaccine side effects (4.4%). Knowing what to expect post-vaccination will help in public education to dispel myths and lower apprehension about the Sinopharm COVID-19 vaccine. Similar reasons were reported in several studies. For example, in a study among individuals aged >18, the most common reasons for rejection of vaccine were that the participants did not think that the vaccine can be reliable as it is new and that COVID-19 infection is a biological weapon and the vaccine will serve those who produce this virus (Akarsu et al., 2021).

Conclusion
Fear of the unknown is a driver of vaccine hesitancy. This study showed that first and second dose post-vaccination adverse reactions of Sinopharm COVID-19 vaccine were common side effects that were mild, predictable, non-serious and non-life-threatening. To our knowledge, this is the first study dealing with the Sinopharm vaccine and evaluating the side effects among a UAE population, the results may help reduce public vaccine hesitancy.

Conflicts of interest
The authors declare no conflict of interest.

Funding
This research was funded by the University of Sharjah, UAE.

Ethical Approval
The study was approved by the Research Ethics Committee of the University of Sharjah in the UAE on 22/3/2021, with reference no. REC-21-02-09-07.

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