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Orijinal Araştırma / Original Article

The Early-Term Adverse Effects in Healthcare Personnel after CoronaVac Vaccination

CoronaVac Aşısı Sonrası Sağlık Personelinde Erken Dönem Olumsuz Etkileri

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Abstract

Objectives: Among the various Covidien-19 vaccine, Sinovac vaccination program in Turkey is carried out by coronavac vaccine developed by Chinese firms. Our aim was to determine the early side effects of CoronaVac vaccine in Turkish healthcare professionals.

Material and Method: Volunteer healthcare personnel vaccinated with CoronaVac were evaluated four weeks after the first dose. Demographic, clinical characteristics, and post-vaccination side effects were recorded. Statistical analysis was performed with SPSS 15.0 software.

Results: The study was conducted with 516 volunteers. The mean age was 34.53±7.80 years, and the majority of the participants (58.1%) were women. The most common occupational nursing (34.8%) and smoking rate in the study was 27.1%. Approximately one third (31%) of the participants had a previous COVID-19 infection and antibody positivity (27.9%). The most common side effects were determined to be arm pain (55.8%) followed by headache (24.8%), fatigue (18.6%) and joint pain (7.8%). On the third day after vaccination, the diagnosis of COVID-19 was reported in one person. Four (0.8%) stated that they took a break from their daily routine due to syncope and one person due to COVID-19.

Conclusion: In this study, no life-threatening side effects were reported in the early period after CoronaVac. Among the early side effects of CoronaVac vaccine in our study, the most common side effects were Arm soreness, Headache, Fatigue and Joint pain. We argue that it is important to use multi-layered and evidence-based strategies to raise the frequency of vaccination and to address the concerns and ownership of the vaccine in relation to the COVID-19 vaccine. In order to minimize widespread information pollution and hostility associated with vaccination, healthcare professionals should lead and strongly support vaccination programs.

Keyword: CoronaVac, COVID-19, vaccination, SARS-CoV-2, side effects

Öz

Amaç: Çeşitli Covidien-19 aşıları arasında Türkiye'deki Sinovac aşılama programı, Çinli firmalar tarafından geliştirilen coronavac aşısı ile yürütülmektedir. Amacımız CoronaVac aşısının Türk sağlık profesyonellerinde erken yan etkilerini belirlemekti.

Gereç ve Yöntem: CoronaVac ile aşılanan gönüllü sağlık personeli, ilk dozdan dört hafta sonra değerlendirildi. Demografik, klinik özellikler ve aşılama sonrası yan etkiler kaydedildi. İstatistiksel analiz SPSS 15.0 yazılımı ile yapıldı.

Bulgular: Çalışma 516 gönüllü ile gerçekleştirilmiştir. Ortalama yaş 34.53±7.80 yıl olup, katılımcıların çoğunluğu (%58.1) kadındır. Çalışmada en büyük meslek grubu hemşirelerdi(%34.8) ve sigara içme oranı %27,1 idi. Katılımcıların yaklaşık üçte biri (%31) daha önce bir COVID-19 enfeksiyonuna ve antikor pozitifliğine (%27.9) sahipti. En sık görülen yan etkilerin kol ağrısı (%55.8) olduğu, ardından baş ağrısı (%24.8), yorgunluk (%18.6) ve eklem ağrısı (%7.8) olduğu belirlendi. Aşılamadan sonraki üçüncü günde bir kişide COVID-19 teşhisi konuldu. Dördü (%0,8) senkop, bir kişi ise COVID-19 nedeniyle günlük işlerine ara verdiklerini belirtti.

Sonuç: Çalışmamızda CoronaVac aşısının erken yan etkileri arasında en sık görülen yan etkiler Kol ağrısı, Baş Ağrısı, Yorgunluk ve Eklem ağrılarıydı. Gönüllülerimizde hayatı tehdit eden herhangi bir yan etki görmedik. Aşılama sıklığını artırmak ve COVID-19 aşısıyla ilgili endişeleri gidermek için çok katmanlı ve kanıta dayalı stratejiler kullanmanın önemli olduğunu düşünüyoruz . Aşılamayla ilgili yaygın bilgi kirliliğini ve düşmanlığı en aza indirmek için sağlık profesyonelleri aşı programlarına liderlik etmeli ve güçlü bir şekilde desteklemelidir.

Anahtar Kelimeler: CoronaVac, COVID-19, aşılanma, SARS-CoV-2, yan etkiler

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INTRODUCTION

The clinical features of Coronavirus-19 (COVID-19) disease, caused by the SARS-CoV-2 virus that wasfirst described in Wuhan, China,have a wide spectrum ranging from simple flu-like symptoms to severe acute respiratory syndrome.[1]

There is an urgent need for an effective vaccine against COVID-19 to control and alleviate the burdenof pandemic on healthcare. Scientists globally started research studies for vaccine development since the beginning of the pandemic.[2]

The CoronaVac (Sinovac, China) vaccine, developed by using an established technique of inactivating the virus chemically, is used for mass inoculation against COVID-19 in Turkey.[3] Some studies have already reported that the CoronaVac has a favorable safety profile and provides immunogenicity. The results of the first phase 1/2 trial showed that the inactivated coronavirus vaccine had a good tolerability and increased the humoral immunity in people aged 18-59 years.[4-6]

Vaccination has been widely accepted as an effective way of lessening the burden of infectious diseases by medical authorities. Nevertheless, the efficiency of vaccination is directly dependent on the acceptance by the public.[7] The public suspicion and anxiety about the safety and efficacy of the vaccines have a negative impact on the vaccination programs and might develop into vaccine opposition in extreme circumstances.[8] Research studies for evaluating the public confidence in COVID-19 vaccinations found a reduction in the rates of intention to be vaccinated by a potential vaccine in general.[9-13]

There is a direct link between the confidence in the safety and efficacy of vaccines and the trust felt for healthcare personnel, the health system, and policymakers of vaccination programs according to public needs.[14]

The first tier of COVID-19 vaccination in Turkey consisted of healthcare personnel. Our purpose was to identify the early-term adverse effects of CoronaVac in Turkish healthcare personnel.

MATERIAL AND METHOD

This study was conducted on volunteered healthcare personnel who were in the first tier of people for COVID-19 vaccination launched on January 14, 2021, in Turkey. The volunteered health personnel administered with the initial dose ofCoronaVac (Sinovac, China) had been evaluated four weeks after vaccination. The signed informed consent of all participants and the study was carried out with the permission of Harran University Clinical Researches Ethics Committee (Date: 15.03.2021, Decision No: HRU/21.06.36) which was in compliance with the principles of the Declaration of Helsinki.

The demographics (age, gender, height, weight, profession) and the clinical properties (the presence of chronic diseases, previous COVID-19 infection, SARS-CoV-2 antibody positivity) were recorded. The post-vaccination adverse effects, either local (swelling/redness at the injection site, soreness/pain in the ipsilateral arm of injection) or systemic (fever, allergic rash, fatigue, nausea, vomiting, headache, syncope, joint/muscle pain, loss of appetite/smell/taste, dyspnea, cough, flu-like symptoms) were noted. Open-ended questions like the development of COVID-19 after the vaccination and the discontinuation of daily routines due to adverse effects were also questioned.

The healthcare personnel who did not volunteer and who had active COVID-19 were excluded from the study.

Statistical Analysis

Statistical analysis was performed using the SPSS 15.0 for Windows (SPSS Inc., Chicago, IL, USA). Descriptive statistics of continuous variables were shown as mean and standard deviation (SD) values while numbers and percentages were used to show the categorical data.

RESULTS

The study was completed with 516participants with a mean age of 34.53±7.80 years. The majority of the participants were female (58.1%), and nursing(n:180) was the most common (34.8%) healthcare profession in the study. Almost one-third of the participants (27.1%) were smokers, and 2.3% were past smokers. The most common chronic disease was found to be asthma in 12 participants. It was found that 160 people in the study had previous COVID-19, and 27.9% of the participants had antibodies against COVID-19. The demographics and the clinical characteristics of the study participants are shown in **Tables 1** and **2.**

The most commonly reported post-vaccination adverse effect (n:288, 55.8%) was the pain on the vaccination site . The following adverse effects included headache (n:128, 24.8%), fatigue (n:96, 18.6%), and joint/muscle pain (n:40, 7.8%). The development of COVID-19 infection in the post-vaccination 3rd day was reported in only one participant. Five people, one of whom with the COVID-19 and four of whom had syncope, reported the discontinuation to dailyroutines. Thereported adverse effects were summarized in **Table 3**.

Table 1. Demographics of participants

Variables	Mean±SD / n (%)
Age (years)	34.53±7.80
Height (cm)	168.16±8.37
Weight (kg)	71.86±12.76
Gender	
Female	300 (58.1%)
Male	216 (41.9%)
Profession	
Physician	128 (24.8%)
Nurse	180 (34.8%)
Hospital security officer	32 (6.2%)
Medical secretary	72 (14%)
Hospital custodian	44 (8.5%)
Radiology technician	32 (6.2%)
Others	28 (5.4%)

Table 2. Clinical features

Variables	n (%)
Smoking	
Yes	140 (27.1%)
No	364 (70.5%)
Quit	12 (2.3%)
COVID-19disease history	
Yes	160 (31%)
No	356 (69%)
COVID-19 Antibody in serology	
Positive	144 (27.9%)
Negative	240 (6.5%)
Not tested	132 (25.6%)
Chronic Diseases	
Thyroiditis	8 (1.6%)
Rheumatoid disease	8 (1.6%)
Ulcerative colitis	4 (0.8%)
Diabetes mellitus	8 (1.6%)
Asthma	12 (2.3%)
Hypertension	4 (0.8%)
Chronic hepatitis	4 (0.8%)

Table 3. Post-vaccination adverse effects

	n (%)
Arm pain	288 (55.8)
Headache	128 (24.8)
Fatigue	96 (18.6)
Joint pain	40 (7.8)
Swelling at vaccination site	36 (7)
Fever	28 (5.4)
Flu-like symptoms	16 (3.1)
Sore throat	8 (1.6)
Dizziness	8 (1.6)
Allergic rash	8 (1.6)
Impaired taste	8 (1.6)
Vomiting	8 (1.6)
Loss of appetite	4 (0.8)
Dsypnea	4 (0.8)
Syncope	4 (0.8)
Cough	4 (0.8)
Others	5 (3.9)

DISCUSSION

In the first report of the Phase 1/2 trial of CoronaVac, all reported adverse effects were mild to moderate. The most common post-vaccination complaint was the soreness at the injection site in 9% of the study group, followed by fever (3%). Additionally, headache and mucocutaneous rash were more frequently observed in the group administered with a 6 µg dose of vaccine. No statistically significant difference in local and systemic adverse effects was observed between the placebo and the remaining groups. Serious side effects which were considered to be unrelated to the vaccination were reported in 2% of the participants.[2] Similarly in our study, no life-threatening early-term adverse effects to CoronaVac were observed in 526 healthcare personnel evaluated four weeks after the vaccination.

In our study, all adverse effects reported were in the range of mild to moderate. The frequency of arm soreness/ pain in our group was more frequent than reported by Wu et al. Similar to our results, Zhang et al. reported mild to moderate side effects in their study and tenderness at the injection site was the most commonly observed effect in their study. In our study the most commonly reported post-vaccination adverse effect (n:288, 55.8%) was the pain on the vaccination site. Zhang et al. also reported a case of acute allergic reaction, which had a good response to dexamethasone therapy.[15] In other studies on inactivated COVID-19 vaccine, post-vaccination effects were reported mild to moderate similar to ours.[4,5,16]

The mean age in our study was 34.53±7.80 years, but in the study of Zhang et al. it was 42.4±5.8 years.[15] Considerably, the age discrepancy between our study and the study of Zhang was due to the fact that our study group consisted of actively working healthcare personnel.

While the COVID-19 vaccine was presented to the public experiencing the pandemic-related psychological and physical stress, many conspiracy theories on COVID-19 pandemic and vaccines started to appear in the popular and social media.[9,10,17] The factors related to COVID-19 vaccine hesitancy are similar to those for previous vaccines such as the properties of the vaccines, the political factors, and the attitude and beliefs against vaccination.[18] The data from questionnaires revealed the public hesitancy regarding the efficacy of the vaccines and anxiety regarding the uncertainty of protection duration, safety, and side effects.[8,9,12]

In this study, it is noteworthy to report that the healthcare personnel who had previous COVID-19 (31%) and antibody positivity against SARS-CoV-2 (27.9%) were eager to be vaccinated. This kind of attitude is a definite indicator of pioneer roles the healthcare personnel have.

It is well-known since old times that the recommendations and actions of healthcare personnel result in higher vaccination rates in public. Still, the healthcare specialists are considered as the most trustworthy information source by the public.[19-21] Hence, in a recent questionnaire, participants quoted that the possibility of COVID-19 vaccine acceptance would be higher if the recommendation was made by healthcare providers.[13]

We consider the younger mean age and a small number of comorbidities in our study group as well as the unknown long-term adverse effects of the vaccine as the limitations of the current study. Further long-term studies with larger size and older age groups are required. In the current study, we wanted to emphasize the safety of inactivated coronavirus vaccine, CoronaVax.

CONCLUSION

No early-term life-threatening adverse effects after CoronaVac were reported in this study. We suggest that it is critical to use multi-tiered and evidence-based strategies to have the public embrace the idea and overcome the anxiety, and boost the frequency of COVID-19 vaccination. The healthcare personnel should pioneer and firmly support the vaccination programs to minimize the widespread information pollution and opposition to vaccination..

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Harran University Clinical Researches Ethics Committee (Date: 15.03.2021, Decision No: HRU/21.06.36).

Informed Consent: All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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