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Research Article

Comprehensive Assessment of Adverse Events Following CoronaVac Immunization: A Population-based Study in Turkey Between January and August 2021

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Abstract

Objective: The principal aim of this study was to rigorously assess the incidence and characteristics of adverse events following the administration of CoronaVac, an inactivated viral vaccine, which was one of the first pandemic vaccines to gain regulatory approval for emergency use in Turkey and is among the most widely administered vaccines globally for containment of the COVID-19 pandemic.

Methods: We conducted a longitudinal, population-based study of individuals who received two doses of the CoronaVac vaccine at intervals of 0 and 28 days between January 14, 2021, and August 1, 2021. This study employed a prospective design to collect and analyze data on adverse events occurring within a one-month follow-up period after the first and second dose administration.

Results: The cohort comprised 2,446 individuals, with a gender distribution of 51.2% females and 48.8% males, with an average age of 43.54 ± 15.90 years. The incidence of adverse events was 19.5% following the first dose and decreased to 15.6% after the second dose. Notably, females demonstrated a statistically higher rate of adverse events than males for both the first and second doses. Concurrently, individuals with comorbidities such as hypertension and diabetes exhibited significantly fewer side effects than those without comorbidities. The most commonly reported adverse events included arm pain, injection site pain, and fatigue. Only a small percentage of individuals required medical intervention and no hospitalizations were attributed to vaccine-induced adverse effects.

Conclusion: Given that all reported adverse events were of mild-to-moderate severity and completely resolved, it can be provisionally concluded that the vaccine has an acceptable safety profile. However, for a more definitive interpretation of the vaccine's long-term safety, further studies with extended follow-up periods are imperative.

Keywords: Adverse Effects; Comorbidity; CoronaVac; COVID-19; Epidemiology; Gender Variability; Longitudinal Study Pandemics; Vaccine

Introduction

The pandemic caused by "Coronavirus Disease 2019" (COVID-19) has impacted tens of millions of people worldwide since its declaration by the World Health Organization on March 11, 2020, leading to substantial economic losses [1]. Comprehensive measures such as hygiene protocols, frequent handwashing, avoiding face-to-face contact, wearing masks, avoiding crowds, and stringent isolation have been adopted across countries to mitigate viral transmission. However, these measures alone have proved insufficient in curbing the pandemic, compelling accelerated global efforts in vaccine development. Subsequently, vaccine production transpired at an unprecedented rate to alleviate the increasing burden of COVID-19 [2,3]. Historically, vaccination has been the most cost-effective and efficient method for halting the spread of infectious diseases. In the case of COVID-19, vaccination is considered a viable approach to rapidly eradicate the pandemic [4]. Although the controlling power of vaccines has been validated in numerous scientific studies, public hesitation toward vaccination remains a concern due to rapid vaccine development, distrust in scientific research on adverse effects, and vaccine skepticism [5]. This reluctance poses a significant public health risk, making it crucial to investigate the potential side effects of pandemic vaccines and educate hesitant individuals.

Vaccine administration in Turkey commenced on January 14, 2021, prioritizing healthcare workers and high-risk groups. CoronaVac, developed by Sinovac Life Sciences, was the first vaccine introduced in Turkey. It is an inactivated viral vaccine obtained from African green monkey kidney cells (Vero cells) inoculated with SARS-CoV-2 (CZ02 strain). Each vial contains 0.5 mL of an aluminum hydroxide diluent with an antigen equivalent to 600 Spike Units (equal to 3 µg) of inactivated full virion SARS-CoV-2 [6,7]. Research has indicated that a two-dose regimen of CoronaVac offers 67.7% protection against symptomatic COVID-19. Efficacy wanes over time post-vaccination and varies with age [8]. However, its protective impact on severe COVID-19 and mortality is significantly higher than its preventive effect against the disease [8]. Several studies have established that adverse events related to CoronaVac are minimal and of acceptable severity [9,10]. In this study, we aimed to evaluate the Adverse Effects of Post-CoronaVac vaccination (AEFIs) in individuals vaccinated at our hospital.

The present introduction offers a foundation for our research but also raises several intriguing questions for future academic discussions. For example, issues surrounding vaccine hesitancy may require a multidisciplinary approach that includes behavioral psychology, sociology, and public policy alongside medical science. Furthermore, as the pandemic evolves, the long-term efficacy and safety of vaccines such as CoronaVac may necessitate further studies. Therefore, the depth of scientific inquiry into these areas is crucial.

Materials and Methods

Study Design

The study was designed as a retrospective analysis, incorporating participants who received the CoronaVac vaccine between January 14, 2021, and August 1, 2021, at the Vaccine Clinic of Afyonkarahisar Health Sciences University. At the pandemic vaccine clinic, the vaccine was administered intramuscularly on days 0 and 28 in the deltoid region of the left arm. Data regarding adverse effects after the first dose were collected when the participants returned for their second dose. Furthermore, one month after the second dose, participants were contacted via telephone to document any adverse effects, thus reinforcing the longitudinal aspect of the study. Records from pandemic vaccine clinics were used in this study.

Ethical Approval

This study was approved by the Clinical Research Ethics Committee of Afyonkarahisar Health Sciences University (decision number 373, dated July 2, 2021).

Statistical Analysis

Descriptive statistical results are presented as frequency distributions in terms of numbers and percentages. The McNemar Chi-Square Test was used to assess the significance of the differences between the two doses. All analyses were performed using SPSS (version 24.0; IBM Corp., Armonk, NY, USA). Statistical significance was determined at a 95% confidence interval and 5% margin of error, denoted by $p < 0.05$. To compare the post-vaccination adverse effect rates between males and females, the Pearson Chi-Square Test was used.

Results

Demographics and Baseline Characteristics

In this study, adverse effects following immunization (AEFIs) were evaluated in 2,446 individuals who were vaccinated with CoronaVac. Of the participants, 51.2% were female, and 48.8% were male. The mean age was calculated to be 43.54 ± 15.90, with a range from 19 to 89 years. Four hundred and twenty-eight individuals (17.4%) presented with comorbidities.

Prevalence of Comorbidities

The most commonly observed comorbidities were hypertension (HT), accounting for 11.2%, and diabetes mellitus,

which was observed in 7.3% of the cohort. Notably, the rate of developing AEFIs was significantly lower in individuals with HT ($P < 0.001$) and diabetes ($P < 0.001$) than in those without these conditions. The distribution of all comorbidities is shown in Table 1.

Comorbid Condition	N	%
Heart Failure	21	0.9
Chronic Obstructive Pulmonary Disease	22	0.9
Malignancy	30	1.2
Rheumatologic Disease	12	0.5
Renal Insufficiency	28	1.1
Breastfeeding	0	0.0
Pregnancy	0	0.0
Hypertension	275	11.2
Diabetes Mellitus	178	7.3

Table 1: Distribution of Comorbid Conditions Among Vaccinated Individuals.

Incidence of AEFIs in Overall Cohort

In the analyzed cohort of 2,446 subjects vaccinated with the CoronaVac vaccine, the incidence of AEFIs following the first dose was 19.5% (n=477). Upon administration of the second dose, the rate declined to 15.6% (n=382). The observed difference in the AEFI rates between the first and second doses was statistically significant ($p = 0.0001$).

Gender-Specific Observations

Among those who received the first dose, 1,969 individuals (80.5%) reported no adverse effects, whereas 477 individuals (19.5%) experienced AEFIs. A gender-based analysis indicated that 66.2% of females reported AEFIs after the first dose, as opposed to 33.8% of males. The difference was statistically significant, with a chi-square value of 53.5 and a p-value of 0.0001. For the second dose, 2,064 individuals (84.4%) experienced no adverse effects, in contrast to 382 individuals (15.6%). Among those who experienced AEFIs after the second dose, 61.0% were female and 39.0% were male. Again, a statistically significant gender disparity was noted, with a chi-square value of 17.2 and a p-value of 0.0001.

Relationship Between AEFIs Following First and Second Doses

Additional analyses revealed that among those who did not experience AEFIs after the first dose, 211 (10.7%) reported AEFIs following the second dose. Conversely, among those who received AEFIs after the first dose, 171 (35.8%) reported AEFIs following the second dose. McNemar's test confirmed that the incidence of AEFIs after the second dose was significantly influenced by the presence or absence of AEFIs after the first dose (p=0.0001) (Table 2).

Side effect after vaccination	n (%) 1st dose/2nd dose	P*	Occurrence time (hour) Median (min-max) 1.dose/2. dose	n (%) 1st dose/2nd dose lasting for the first 24h	n (%) 1st dose/2nd dose lasting 72h	n (%) 1st dose/2nd dose lasting longer than 72h	n (%) requiring medical treatment 1.dose/2.dose
Fever	26 (1.1) /40 (1.6)	10001	1 (1-3) /1 (1-2)	15 (0.6) /29 (1.2)	4 (0,2) /2 (0,1)	-/2 (0,1)	13 (0.5) /4 (0.2)
Arm pain	139 (5.7) /139 (5.7)	0.0001	1 (1-2) /0 (0-2)	45 (1.9) /65 (2.7)	22 (0.9) /25 (1)	7 (0.3) /7 (0.2)	4 (0,2) /2 (0,1)
Pain at the injection site	59 (2.4) /80 (3.3)	0.055	1 (1-2) /0 (0-1)	25 (1.0) /36 (1.5)	4 (0.2) /20 (0.8)	6 (0,3) /2 (0.1)	1 (0) /1 (0)
Erythema, swelling, warmth at the injection site	51 (2.1) /26 (1.1)	0.002	1 (1-2) /1 (1-3)	9 (0.4) /32 (1.3)	4 (0.2) /6 (0.2)	-/-	8 (0.3) /3 (0.1)
Headache	64 (2.6) /42 (1,7)	0.026	1 (1-3) /1 (1-3)	44 (1.8) /27 (1.1)	4 (0,2) /3 (0,1)	1 (0) /1 (0)	15 (0.6) /12 (0.5)
Fatigu	65 (2.7) /71 (2,9)	0.656	1 (1-3) /0 (0-2)	28 (1.1) /23 (0.9)	16 (0.7) /18 (0.7)	5 (0.2) /7 (0.3)	1 (0) /2 (0,1)
Myalgia	39 (1,6) /27 (1,1)	0.169	1 (1-2) /2 (1-3)	23 (0.9) /10 (0.4)	4 (0.2) /12 (0.5)	-/-	2 (0,1) /3 (0,1)

* McNamer chi-square p

Table 2: Comparative Analysis of Adverse Events Following Administration of SARS-CoV-2 Vaccine: A Dose-Dependent Evaluation.

Categories of AEFIs

Fever

- **Incidence and duration**: After the first dose, 1.1% of the subjects reported fever, which increased to 1.6% after the second dose. Fever generally developed within one hour of vaccination and varied between 1-3 hours post-first dose and 1-2 hours post-second dose.
- **Prolonged Symptoms**: For first dose, 0.6% of patients continued to exhibit fever symptoms for the initial 24 h, whereas for the second dose, it was 1.2%. Over the first 72 h, prolonged symptoms were observed in 0.2% of patients post-first dose and 0.1% of patients post-second dose.
- **Medical Treatment**: Fever requiring medical treatment was reported in 0.5% of the post-first dose and 0.2% of the post-second dose.

Arm Pain

- **Incidence**: Both the first and second doses resulted in an arm pain incidence of 5.7%.
- **Prolonged Symptoms**: During first 24 h, symptoms persisted in 1.9% of individuals after the first dose and 2.7% after the second dose.
- **Medical Treatment**: Medical treatment for arm pain was necessary in 0.2% of the patients post-first dose and 0.1% of the patients post-second dose.

Pain at Injection Site

- **Incidence and Statistical Significance**: Pain at the injection site was reported by 2.4% of participants after the first dose and 3.3% after the second dose, a statistically significant difference with a p-value of 0.0001.
- **Prolonged Symptoms**: Symptoms lasting for 72 h were reported in 0.2% of patients post-first dose and 0.8% of patients post-second dose.

Other AEFIs

- **The injection Site Redness, Swelling, Heat Increase** were2.1% and 1.1%, respectively.
- **Headache**:2.6% post-first dose and 1.7% post-second dose.
- **Fatigue**:2.7% after the first dose and 2.9% after the second dose.
- **Myalgia**:1.6% after the first dose and 1.1% after the second dose.

Less Common AEFIs

- **Nausea**: Developed in 0.7% of the participants, with onset generally within the first hour.
- **Hypertension (HT)** was noted in only 0.3% of patients.
- **Dizziness**: Experienced by 0.4% of the participants.
- **No Medical Treatment Required**: No participant required medical treatment for nausea, HT, or dizziness.
- **Very Rare Symptoms**: Paresis, allergies, fainting, palpitations, and skin rashes, developed in very few participants (0.1% or less), with no medical treatment necessary.

Serious AEFIs

- Anaphylaxis was observed in only one patient who was successfully managed symptomatically in an outpatient setting. No serious AEFIs leading to hospitalization or death were reported.

Discussion

In the present study, we ascertained the incidence of Adverse Events Following Immunization (AEFIs) to be 19.5% after the first and second doses of the CoronaVac vaccine. None of the observed AEFIs were severe enough to preclude vaccination. Based on these data, it can be posited that the CoronaVac vaccine is safe for use. In a phase II randomized placebo-controlled trial conducted in China on an inactivated SARS-CoV-2 vaccine, the incidence rates of AEFIs were 27.3%, 19.3%, and 12% in the medium-dose, high-dose, and placebo groups, respectively, within 28 days post-immunization [11]. A phase 3 study of CoronaVac in Turkey also reported an AEFI incidence of 18.9%, corroborating the real-world data obtained in our study [10]. A separate study conducted on 1,628 healthcare workers in our country reported AEFI incidence rates of 18.4% and 15.6% after the first and second dose, respectively [12]. These findings are congruent with our results, lending further support to the safety profile of the CoronaVac.

Interestingly, our study observed a lower frequency of AEFIs in individuals with hypertension (HT) and diabetes than in those without these conditions. Contrary to our findings, existing literature suggests a close relationship between AEFIs and comorbid conditions post-inactivated SARS-CoV-2 vaccination. For instance, individuals with diabetes were found to have a higher likelihood of experiencing post-vaccination fatigue ($p=0.049$) and flu-like symptoms ($p=0.013$) than their non-diabetic counterparts. Similarly, hypertensive participants were more likely to experience pain at the injection site ($p=0.013$), headaches/migraines ($p<0.001$), and fatigue/lethargy ($p=0.002$) [13]. Therefore, our study presents a contrast that warrants further investigation using larger and more comprehensive datasets.

Our study also revealed a statistically significant decrease in AEFI incidence following the second dose, which is consistent with the findings of Gümüş et al., where the general side effects were 37.2% and 28.7% after the first and second doses, respectively [14]. Similarly, the most frequently observed AEFI, localized pain at the injection site (15.7% and 11.6%, respectively), were in line with our data. Akar et al. reported first-dose AEFI rates of 31.3% and second-dose rates of 26.8% [15]. Compared with these rates, our study found lower incidences of AEFIs for both doses, but the declining trend after the second dose remained consistent with the literature.

The most frequently observed side effects in our study were arm pain, injection site pain, and fatigue. Almost all AEFIs commenced within the first 24 hours and diminished within a few days, rarely necessitating medical treatment. According to a review by the Hong Kong SAR Food and Health Bureau (FHB), the most common adverse reactions are pain at the injection site, headaches, and fatigue [16]. Similar observations were made in this study. Furthermore, the prevalence of fever, which is considered a less common AEFI, was consistent with the literature, being observed in 1.1% of cases after the first dose and 1.6% after the second dose [17]. Batı et al. reported arm pain (54.6%) and fatigue (39.2%) as the most common side effects after CoronaVac vaccination, consistent with our data [17,18].

Our study also noted sex differences in AEFI incidence, with women experiencing them more frequently [19]. This may be attributable to the higher immunogenic response that women exhibit to antigenic stimulation than men, which is supported by compelling clinical data illustrating gender-based variations in innate, humoral, and cell-mediated responses to viral vaccines [20].

Study Limitations

Sample Size and Generalizability: The study's limited sample size undermines its statistical power, making it difficult to generalize the findings to a broader population with varied demographics and medical histories.

Short Follow-Up Period: The brief follow-up duration in the study design may not capture long-term adverse effects or rare events that manifest over an extended time post-vaccination.

Lack of Gender-Specific Analysis: Although a higher incidence of AEFIs was noted among women, the study did not focus on gender-specific immunological responses, creating a knowledge gap in vaccine tolerability across genders.

These limitations of our research warrant further research involving larger cohorts, extended follow-up periods, and specialized gender-based studies to substantiate the current findings.

Conclusion

A Rigorous Assessment of CoronaVac's Safety Profile

Our study provides compelling empirical evidence that bolsters the safety profile of the CoronaVac COVID-19 vaccine. Across the study population, adverse events following immunization (AEFIs) were restricted to mild-to-moderate manifestations, with no incidence severe enough to necessitate discontinuation of the vaccination schedule. This observation is in alignment with prior peer-reviewed literature endorsing the safety of CoronaVac [21,22].

Key Findings

The most frequently observed AEFIs were localized arm pain, injection site discomfort, and transient fatigue. It is noteworthy that these AEFIs exhibited a higher prevalence among female participants, indicating the potential for gender-specific variations in vaccine tolerability.

Implications for Public Health Policy

Our findings are particularly significant for public health planning, offering a data-backed reassurance for the continuation of vaccination campaigns utilizing CoronaVac, especially in settings that require swift and effective immunization strategies. However, it is crucial to approach these conclusions with nuanced scientific caution. While our study offers valuable insights into the safety of CoronaVac, the limited scope necessitates further investigation. We recommend larger-scale, long-term studies that include more diversified demographic cohorts to validate our findings and elucidate any rare but severe AEFIs that may not have been captured in this study. Furthermore, ongoing post-marketing surveillance should be implemented to continually assess the vaccine's safety profile, particularly in the face of emerging SARS-CoV-2 variants. There is a need for a centralized repository of AEFIs associated with COVID-19 vaccines, including CoronaVac, to facilitate real-time safety assessments.

Recommendations for Gender-Specific Studies

The observed gender difference in AEFI incidence warrants dedicated studies to explore immunological mechanisms underlying this disparity. Such studies could shape the development of gender-adapted vaccination guidelines, thereby optimizing the risk-benefit ratio for each gender. In summary, while CoronaVac has demonstrated a predominantly mild-to-moderate AEFI profile and is substantiated by existing academic literature as a safe vaccine option against COVID-19, it remains essential to perpetuate rigorous, large-scale, longitudinal studies for a conclusive safety assessment.

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