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Unilateral Axillary Lymphadenopathy after the Inactivated SARS-COV-2 (CoronaVac) Vaccine: Ultrasonographic Imaging

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Background: Currently, unilateral clinical and subclinical axillary adenopathy cases associated with the Pfizer-BioNTech and Moderna vaccines are increasingly reported. However, only one study on axillary adenopathy due to the CoronaVac vaccine is published.

Aims: To present the incidence, severity, and ultrasonographic findings of axillary adenopathy that developed in healthcare professionals in Turkey after they were vaccinated with CoronaVac against coronavirus disease-19.

Study Design: A prospective study.

Methods: In Turkey, the first dose of the CoronaVac vaccine for coronavirus disease-19 was administered to healthcare professionals on January 14, 2021, and the second dose on February 11, 2021. This study covered the period from January 21, 2021 (1 week after the first dose), and April 15, 2021 (9 weeks after the second dose). Individuals who had a history of COVID-19 more than 3 weeks after vaccine doses, systemic disease, and diagnosis and treatment history of breast cancer were excluded. The axillary lymph nodes of the vaccinated and contralateral arms were evaluated in 101 volunteer healthcare professionals using axillary ultrasonography.

Results: A significant difference was found in the cortical thicknesses of the lymph nodes between the vaccinated and contralateral axilla after both the first *(*p < 0.01)* and second *(*p < 0.01)* doses. Accordingly, the rates of subclinical lymphatic hyperplasia on the vaccinated side were 25.7% (n = 26/101) after the first and 31.1% (n = 28/90) after the second dose. Lymph nodes with pathological appearance based on a reduced echogenic hilum with marked cortical thickening were found only in 2.2%. Among the 39 cases in which antibodies (immunoglobulin G and immunoglobulin M) were measured, the antibody level was classified as <10 and ≥10. No statistically significant difference was found in the cortical thickness of the axillary lymph nodes between patients with high antibody levels (≥10) and those with low antibody levels (<10) *(p > 0.05)*.

Conclusion: In this study, clinical signs of axillary lymph node hyperplasia were not detected after vaccination with CoronaVac. Mild and diffuse thickening of the CoronaVac vaccine-induced lymph nodes was more common than pathological and palpable lymph nodes.

INTRODUCTION

Currently, with the increase in the vaccination rate worldwide against coronavirus disease-19 (COVID-19), unilateral axillary adenopathy cases reported in breast imaging after vaccination are also increasing.[1-6] Rare cases of unilateral axillary adenopathy detected by various imaging methods have been reported after vaccination applied to the upper extremity against viruses, such as seasonal influenza, Bacillus Calmette-Guérin, human papillomavirus, and H1N1.[7-9]

To date, unilateral axillary adenopathy cases after vaccination with Moderna and Pfizer-BioNTech vaccines for COVID-19 have been reported, which were first started to be widely administered.

In individuals who received the Moderna vaccine for COVID-19, ipsilateral axillary lymphadenopathy has been reported as the second most common side effect after local pain. For the population aged 18-24 years, this condition has been reported in 11.6% after the first and 16.0% after the second dose. For those aged >65 years, this rate is lower after the second dose at 8.4%. Similarly, a higher incidence of axillary adenopathy has been observed in individuals vaccinated with the Pfizer-BioNTech vaccine than those who were administered a placebo (64 versus 6 patients).[10-12] Unilateral axillary adenopathy rates reported in association with Moderna and Pfizer-BioNTech vaccines are for clinically detected painful and palpable lymph nodes. However, the incidence of subclinical lymph node reactions is predicted to be higher than these rates.

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In Turkey, the CoronaVac vaccine was first administered to all healthcare professionals. In this study, we aimed to present the frequency of unilateral axillary adenopathy and ultrasonographic (US) findings after the administration of the CoronaVac vaccine. Since unilateral axillary adenopathy is now increasingly encountered during imaging because of mass vaccination, increasing one's knowledge and awareness of this issue is extremely important to ensure correct diagnosis and properly guide patients.

MATERIALS AND METHODS

Study Design and Participants

In Turkey, the first dose of the CoronaVac vaccine was administered to healthcare professionals on January 14, 2021, and the second dose on February 11, 2021. This prospective study covered the period from January 21, 2021 (1 week after the first dose) to April 15, 2021 (9 weeks after the second dose). A total of 101 volunteer healthcare professionals (mean age, 36 years; age range, 22-56 years) who received the first dose of the CoronaVac vaccine through the deltoid were included in the study. After the first dose, both axillae of the volunteer healthcare professionals were evaluated by US, and the findings were recorded. Of the 101 volunteers who received the first dose, 11 could not participate in the study after the second dose because of personal reasons. Therefore, 90 volunteers who had received the second dose were evaluated with axillary US, and the findings were recorded. Furthermore, in 20 volunteers with significant axillary lymph node cortical thickening, a third axillary US was performed for follow-up 8-9 weeks after the second dose.

The exclusion criteria were as follows: individuals who had a history of COVID-19 more than 3 weeks after vaccine doses, systemic disease, and diagnosis and treatment history of breast cancer.

The study was approved by the ethics committee of our institution on February 10, 2021 (no. E2-21-143). All participants signed a voluntary consent form.

Axillary Ultrasound

Axillary US was performed in 101 volunteer healthcare professionals within 2-3 (mean, 18 days; range, 9-21 days) after the first dose of the CoronaVac vaccine and 90 participants within 2-3 weeks (mean, 8 days; range, 2-21 days) after the second dose (Table 1). The RS80A US system with Prestige (Samsung) and LM4-15B (4-15 MHz) linear array probe was used for the US, which was performed by two radiologists with 20 and 22 years of experience in axillary US. Both axillary lymph nodes of each volunteer were evaluated. After the administration of two vaccine doses, the cortical thicknesses of the largest and thickest lymph node were measured and recorded. Cortical thickness was classified as diffuse and asymmetrical. An increase in cortical thickness of >1 mm on the vaccinated side was considered significant. In participants with significant cortical thickening (>3.5 mm), follow-up US was applied to the axillary lymph node on the vaccinated side at 8–9 weeks after the second dose. Each participant was questioned to determine whether they had any complaints of palpable axillary lymph node swelling and pain. For participants who underwent antibody measurements, the antibody levels were classified as low (<10) and high (≥10), and the cortical thickening of the axillary lymph nodes was compared between these two groups to determine any significant difference.

Statistical Analysis

IBM SPSS Statistics for Windows version 25.0 (IBM Corp., Armonk, NY, USA) and Amos version 24.0 were used to analyze the data. Descriptive statistics of the collected data (arithmetic mean, standard deviation, median, first quartile, third quartile, number, and percentage) were calculated. Before the significance tests, continuous variables were examined with the Shapiro-Wilk test in terms of normality, one of the parametric test assumptions, and the Levene test in terms of the homogeneity of variances. Student's t-test was conducted to examine the differences between two samples consisting of different individuals for the data meeting parametric test assumptions. The paired-samples t-test was used to examine differences between two measurements dependent on an

TABLE 1. Demographic Data (First Dose n = 101, Second Dose n = 90)

			$\left(\begin{matrix}Mean \pm SD \\ [M\,(Q_1 - Q_2)]\end{matrix}\middle\vert\ n\ (\%)\right)$
Sex	Female		72 (71%)
	Male		29 (29%)
	Age		36.15 ± 9.07 [34 (28-44)]
First dose	US imaging day		18 ± 2.47 [18 (17-20)]
	Axillary lymph node of the vaccinated arm	Cortical thickness	2.51 ± 0.86 [2.4 (1.9-3)]
		Short axis	6.58 ± 2.03 [6.3 (5.33-7.8)]
		Long axis	16.04 ± 6.75 [15.1 (11.05-19.95)]
	Axillary lymph node of the contralateral arm	Cortical thickness	2.02 ± 0.77 [1.8 (1.5-2.4)]
		Short axis	5.97 ± 2.16 [5.7 (4.23-7.65)]
		Long axis	13.88 ± 6.97 12.55 (9.2-17.93)]
	Difference in the cortical thickness between the vaccinated and contralateral axillary lymph nodes		0.49 ± 0.93 [0.4 (-0.1 to 1.1)]
Second dose	US imaging day		8.08 ± 3.72 [7 (5.5-10.5)]
	Axillary lymph node of the vaccinated arm	Cortical thickness	2.83 ± 0.94 [2.7 (2.2-3.38)]
		Short axis	6.94 ± 1.85 [7 (5.7-8)]
		Long axis	16.8 ± 6.64 [16 (13-20.08)]
	Axillary lymph node of the contralateral arm	Cortical thickness	2.24 ± 0.8 [2.2 (1.7-2.7)]
		Short axis	6.22 ± 2.3 [6 (5-7.2)]
		Long axis	14.83 ± 6.35 [14 (10.2-18)]
	Difference in the cortical thickness between the vaccinated and contralateral axillary lymph nodes		0.59 ± 0.84 [0.5 (0.1-1.1)]

M, median; n, vaccinated person number; Q_1, first quartile; Q_3, third quartile; SS, standard deviation

individual. The Mann-Whitney U test was performed to examine differences between two samples consisting of different individuals and not meeting the parametric test assumptions. The Wilcoxon test was used to examine differences between measurements taken from two different regions of an individual. $P < 0.05$ was used as a criterion in the analysis of significance.

In this study, a power analysis was applied in a pilot study. As a result of the limitations of the power analysis through a pilot study, the statistical tests that can be used to perform statistical power analysis, sample size, level of significance, and direction of the research hypothesis were determined. In addition, information about test types, such as the number of independent variables for multiple regression analysis and number of groups for analysis of variance were determined. Then, using these values, power analysis was applied in a pilot study to each significance test for small, medium, and large effect sizes defined by Cohen. While performing the pilot study power analysis, statistical power values for each statistical significance test were obtained using the G*POWER program.

In the study, paired sample t-test was used to evaluate the vaccinated and unvaccinated arms separately and could not detect a difference in these measurement regions. In the analysis, the effect size was calculated as 0.50 (Cohen D = 0.50). Thus, a statistical power level of 80.3% was obtained for a minimum of 34 people. In line with these results, the analysis was conducted on a total of 34 people in a single group in the study.

RESULTS

Of the volunteer healthcare professionals who participated in the study, 72 (71.2%) were female and 29 (28.7%) were male (Table 1). A significant difference was found in the cortical thicknesses of the lymph nodes between the vaccinated and contralateral axilla after both the first and second doses (Table 2). The mean cortical thickness of the axillary lymph node was 2.4 mm (range, 0.8-5.4 mm) for the vaccinated side and 1.8 mm (range, 0.8-4.5 mm) for the contralateral side after the first dose, and 2.7 (range, 1-6.2 mm), respectively, after the second dose. Accordingly, a statistically significant difference was found between the cortical thickness of the vaccinated and contralateral axillary lymph nodes after both the first (t* = -4.859, $p = 0.001$) and second (t* = -6.154, $p = 0.001$) doses. After the first dose, the cortical thickness of the axillary lymph node of the vaccinated arm was 0.49 ± 0.93 units thicker than that of the contralateral one. After the second dose, the cortical thickness of the axillary lymph node of the vaccinated arm was 0.59 ± 0.84 units thicker than that of the contralateral axilla.

A difference of >1 mm in the cortical thickness between the vaccinated and contralateral axillary lymph nodes was considered to indicate a reaction (Table 3). Accordingly, the rate of subclinical lymphatic hyperplasia on the vaccinated side was 25.7% (n = 26/101) after the first and 31.1% (n = 28/90) after the second dose.

After the second dose, 15 of the 90 participants (16.6%) had diffuse mild cortical thickening and oval-shaped lymph nodes with a preserved echogenic hilum. Eleven (12.2%) participants had asymmetric cortical thickening, but their echogenic hilum was preserved and oval-shaped. Only two lymph nodes (2.2%) had significant asymmetric cortical thickening and reduction and displacement of the echogenic hilum. The number of lymph nodes with thickening ranged from 1 to 3, all located at Level 1.

Follow-up US was performed in 20 participants with prominent cortical thickening for the follow-up evaluation at 8-9 weeks after the second dose. A significant decrease was found in the lymph node cortical thickness in 18 of these participants. Breast US was also undertaken in the remaining two participants without any decrease in cortical thickness. Of these two patients, a 24-year-old female healthcare professional presented with an oval-shaped, 8x6 mm hypoechoic lesion with an indistinct margin under the areola on the left breast. US-guided tru-cut biopsy and fine-needle aspiration biopsy (FNAB) were performed from this area and the left axillary lymph node (Figure 1). The pathology result of the breast was adenosis, columnar cell change, and fibrosis, and the left axillary lymph node was reported to be reactive. Concerning the other participant (a 34-year-old woman) without a cortical thickness decrease after 8 weeks following the second dose, no suspicious lesion was detected in the breast US. The FNAB cytology result of the axillary lymph node was reported as benign reactive (Figure 2).

Antibody [immunoglobulin (IgG) and IgM] measurements were available for 39 participants, who were divided into two groups as ≥10 (n = 25, 64.1%) and <10 (n = 14, 35.8%). No statistically significant difference was found between these two antibody groups in relation to the cortical thickness of the axillary lymph node on the vaccinated side (Table 4).

TABLE 2. Evaluation of the Difference in Cortical Thickness between the Vaccinated and Contralateral Axillary Lymph Nodes after the First and Second COVID-19 Vaccine Doses (n = 101)

		Vaccinated *M (Q^1-Q^3)*	Contralateral *M (Q^1-Q^3)*	T*/t*	P
Cortical thickness	First dose	2.4 (1.9-3)	1.8 (1.5-2.4)	**-4.859**	**0.001** [2]**
	Second dose	2.7 (2.2-3.38)	2.2 (1.7-2.7)	**-6.154**	**0.001** [2]**

*$p < 0.01$, **$p < 0.05$,
[1]Paired-samples t-test (*T**), [2]Wilcoxon test (t*)
M, median; Q_1, first quartile; Q_3, third quartile
In the comparison of differences between the groups, descriptive statistics are given as mean ± standard deviation or median (first–third quarter) values according to the normality distribution of data.

TABLE 3. Rates of Lymph Node Hyperplasia

		N	Over 1-mm difference in cortical thickness between the vaccinated and contralateral axillary lymph nodes	Percentage
Cortical thickness	First dose	101	26	26.7%
	Second dose	90	28	31.1%

n, number of participants who underwent axillary US after the first and second doses

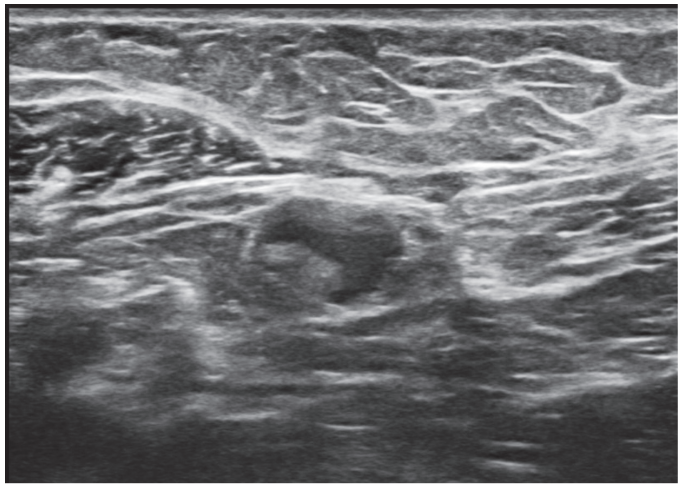

FIG. 1. Ultrasound image of a 24-year-old female healthcare professional obtained 10 days after the second dose of the CoronaVac vaccine administered through the left deltoid region, showing a 7x12 mm oval-shaped lymph node with 4.4 mm asymmetrical cortical thickening and small echogenic hilum (fine-needle aspiration biopsy result: benign reactive lymph node).

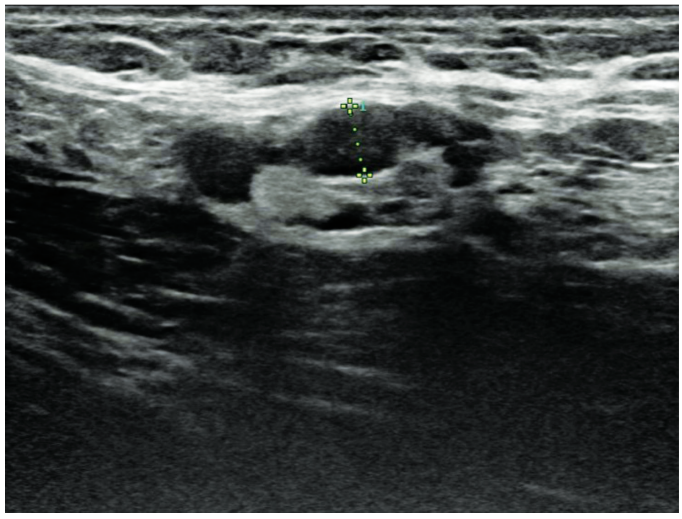

FIG. 2. Ultrasound image of a 34-year-old female healthcare professional obtained 4 days after the second dose of the CoronaVac vaccine through the left deltoid region, showing a 19x9 mm oval-shaped lymph node with 5.6-mm asymmetrical cortical thickening and a suppressed echogenic fatty hilum in the ipsilateral axillary region (fine-needle aspiration biopsy result: benign reactive changes).

DISCUSSION

Vaccination can cause temporary inflammation in the lymph nodes. **mRNA** vaccines such as Moderna and Pfizer-BioNTech are naturally immunostimulatory and are more immunogenic than other traditional vaccine technologies; therefore, they have a high potential of leading to lymphadenopathy development that can be detected on imaging.[13] By contrast, the CoronaVac vaccine against COVID-19 is an inactivated vaccine. In the phase 2 study of the CoronaVac vaccine, pain at the injection site was reported as the most common local side effect, but information on axillary adenopathy was not provided.[14,15] The incidence of fever after CoronaVac vaccination has been reported to be lower than viral-vectored vaccines or other COVID-19 vaccines based on DNA or RNA delivery.[14]

TABLE 4. Evaluation of the Vaccinated Axillary Lymph Node Cortical Thickness According to Antibody Levels after the First and Second Doses (n = 39)

Antibody levels		<10 (n = 14) *M (Q^1-Q^3)*	≥10 (n = 25) *M (Q^1-Q^3)*	T / z	P
Cortical thickness	First dose	2.9 (2.1-3.4)	2.2 (1.85-2.7)	-1.608	0.108[2]
	Second dose	2.94 ± 0.8	3.06 ± 0.94	-0.149	0.881[2]

*$p < 0.01$, **$p < 0.05$ *L*
[1]Student's t-test (*T*), [2]Mann-Whitney *U* test (*z*)
M, median; Q_1, first quartile; Q_3, third quartile
In the comparison of differences between the groups, descriptive statistics are given as mean ± standard deviation or median (first-third quarter) values according to the normality distribution of data.

The differential diagnosis of unilateral axillary adenopathy is broad and includes benign and malignant etiologies. The majority of malignant cases are caused by lymphoma or metastatic breast cancer. The most common causes of isolated axillary lymphadenopathy are benign reactive hyperplasia, inflammatory arthritis, and benign pathologies with infectious etiologies.[16] It is detected either by diagnostic US of patients presenting with unilateral adenopathy or enlarged lymph nodes or incidentally by mammography or breast magnetic resonance imaging.[16]

Mehta et al.[1] reported four cases of unilateral axillary adenopathy caused by Pfizer-BioNTech and Moderna vaccines and detected during routine breast imaging. With the widespread vaccination, the number of reported cases increased gradually. Recently, Prada et al.[6] published a series of 20 cases of supraclavicular lymphadenopathy that developed due to Pfizer-BioNTech and Moderna vaccines among healthcare professionals.

Granata et al.[17] published the US findings of lymphadenopathy caused by the Pfizer-BioNTech vaccine. In a sample of 18 cases, the authors detected laterocervical lymphadenopathy in 10 and axillary lymphadenopathy in 8.

A normal lymph node should have a reniform shape, a uniform hypoechoic cortex thinner than 3 mm, and an echogenic fatty hilum, and it should be well circumscribed. The presence of cortical thickening >3 mm, asymmetrical cortical thickening, irregular boundaries, or replacement or displacement in the fatty hilum is considered pathological.[18] In the current study, no palpable axillary lymph node was found, and the lymph node was observed to have an oval shape, a preserved echogenic hilum, and diffuse mild cortical thickening in most cases. Some of the participants (12.2%) had asymmetrical cortical thickening, but the echogenic hilum was still preserved and the lymph node was oval-shaped. Only two cases (2.2%) had significant asymmetrical cortical thickening and reduction in the echogenic hilum.

Turan et al.[19] evaluated axillary lymph nodes after the vaccination with CoronaVac. In their study, the mean cortical thickness of

vaccinated and contralateral side axillary lymph nodes (2.5 mm and 2.0 mm, respectively) was similar to our study (after the first dose 2.4-1.8 mm, after the second dose 2.7-2.2 mm). The values determined in that study and our study showed that the lymph node cortical thickening due to the CoronaVac vaccine was not very pronounced. Also, painful or palpable lymph node, which is common in mRNA vaccines, was not detected after CoronaVac vaccine in both studies.

In February 2021, Lehman et al.[20] documented how to approach patients with axillary adenopathy accompanied by a history of deltoid COVID-19 vaccination on the same side and they made some recommendations. According to these recommendations, if there is a history of COVID-19 vaccination within the previous 6 weeks and ipsilateral palpable axillary adenopathy developed after vaccination without breast signs or symptoms, the axillary lymph node is accepted as BI-RADS 2 and clinical follow-up is recommended.

In March 2021, the Society of Breast Imaging (SBI)[21] updated its recommendations for axillary adenopathy management after COVID-19 vaccination. Patients with a history of COVID-19 vaccination within the last 4 weeks, who have developed unilateral axillary adenopathy on the same side, are classified as BI-RADS 3, and a short-term follow-up (4-12 weeks after the second dose of the vaccine) is recommended. If axillary adenopathy continues, lymph node sampling is recommended for the exclusion of breast cancer or non-breast malignancy. In the present study, we evaluated 20 participants who had significant lymph node thickening after 8 or 9 weeks according to the control recommendation of SBI and performed FNAB on the axillary lymph node of two participants without regression. The cytology results of both cases were reported as benign reactive lymph nodes.

The limitations of this study include the small sample size, disproportionate distribution of sex, and US evaluation being performed on different days during the second or third week after vaccination. In the literature, post-vaccination lymphadenopathy develops in the axillary and neck region within 2-4 days (mean, 1-2 days) and continues up to an average of 10 days.[21] Unfortunately, in our study, it was not possible to evaluate the axilla with US in the first 4 days of vaccination. If we had performed this evaluation within this period, we could have measured more pronounced cortical thickening. However, none of the participants had any complaints of painful and palpable lymph nodes. Another limitation is the absence of US findings of axillary lymph nodes before vaccination. In addition, antibody measurements were not available for all participants; therefore, the relationship between the antibody level and cortical thickening was evaluated in a very limited portion of participants. We found no statistically significant difference between cortical thickening of the axillary lymph node between the high (≥10) and low (<10) antibody groups.

In our study group, unlike other COVID-19 vaccines, no clinically palpable and painful axillary lymph nodes were detected after vaccination with inactivated SARS-COV-2 vaccine (CoronaVac). Subclinical lymph node thickening detected by US was 26.7% after the first dose and 31.1% after the second dose. Mild and diffuse thickening was more common in the lymph nodes; 12.2% of the lymph nodes presented with a preserved echogenic fatty hilum accompanied by asymmetrical cortical thickening. Lymph nodes with pathological appearance based on a reduced echogenic hilum with marked cortical thickening were at a much lower rate (2.2%) than the results of other vaccines reported in the literature. Therefore, if there is a history of CoronaVac vaccination in pathologically suspicious lymph nodes with marked asymmetrical cortical thickening and a reduced or displaced hilum, a detailed examination of all findings of the breast should be undertaken in terms of malignancy since such thickening is not expected. If there is no suspicious finding, short-term follow-up (4-12 weeks) will be appropriate.

Ethics Committee Approval: The study was approved by the ethics committee of our institution on February 10, 2021 (no. E2-21-143).

Informed Consent: All participants signed a voluntary consent form.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Concept- E.E., ; Design- E.E., ; Data Collection or Processing- M.B.; Analysis or Interpretation- B.S.; Writing- A.Ö., E.Ö.

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