Axillary Lymphadenopathy after Pfizer-BioNTech and Moderna COVID-19 Vaccination: MRI Evaluation

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Background: COVID-19 vaccination-related axillary lymphadenopathy has become an important problem in cancer imaging. Data are needed to update or support imaging guidelines for conducting appropriate follow-up.

Purpose: To investigate the prevalence, predisposing factors, and MRI characteristics of COVID-19 vaccination-related axillary lymphadenopathy.

Materials and Methods: Prospectively collected prevaccination and postvaccination chest MRI scans were secondarily analyzed. Participants who underwent two doses of either the Pfizer-BioNTech or Moderna COVID-19 vaccine and chest MRI from June to October 2021 were included. Enlarged axillary lymph nodes were identified on postvaccination MRI scans compared with prevaccination scans. The lymph node diameter, signal intensity with T2-weighted imaging, and apparent diffusion coefficient (ADC) of the largest enlarged lymph nodes were measured. These values were compared between prevaccination and postvaccination MRI by using the Wilcoxon signed-rank test.

Results: Overall, 433 participants (mean age, 65 years ± 11 [SD]; 300 men and 133 women) were included. The prevalence of axillary lymphadenopathy in participants 1–14 days after vaccination was 65% (30 of 46). Participants with lymphadenopathy were younger than those without lymphadenopathy (P = .001). Female sex and the Moderna vaccine were predisposing factors (P = .005 and P = .003, respectively). Five or more enlarged lymph nodes were noted in 2% (eight of 433) of participants. Enlarged lymph nodes greater than or equal to 10 mm in the short axis were noted in 1% (four of 433) of participants. The median signal intensity relative to the muscle on T2-weighted images was 4.0; enlarged lymph nodes demonstrated a higher signal intensity (P = .002). The median ADC of enlarged lymph nodes after vaccination in 90 participants was 1.1 × 10⁻³ mm²/sec (range, 0.6–2.0 × 10⁻³ mm²/sec), thus ADC values remained normal.

Conclusion: Axillary lymphadenopathy after the second dose of the Pfizer-BioNTech or Moderna COVID-19 vaccines was frequent within 2 weeks after vaccination, was typically less than 10 mm in size, and had a normal apparent diffusion coefficient.

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With the mass COVID-19 vaccination rollout worldwide, vaccination-related lymphadenopathy has become an important problem for patients, clinicians, and cancer researchers. Vaccination-related lymphadenopathy is a frequent imaging finding typically observed in the axilla ipsilateral to the vaccinated site after administration of COVID-19 vaccines, and it can present as a diagnostic dilemma in cancer imaging. It can lead to underdiagnosis or overdiagnosis and undertreatment or overtreatment, as well as heightened anxiety for the patient (1,2).

Society of Breast Imaging, the RSNA, and others have proposed recommendations addressing vaccination-related lymphadenopathy seen on images (2–6). The RSNA recommended that imaging should be scheduled before the first vaccination dose or at least 6 weeks after the final vaccination dose, whenever possible (2). Society of Breast Imaging recommended a follow-up examination in 4–12 weeks for unilateral axillary lymphadenopathy in women vaccinated in the previous 4 weeks (3). On the other hand, Wolfson et al (6) have recently insisted that screening mammography should not be delayed after COVID-19 vaccination.

Recommendations in the early days of 2021 were provisional, and more appropriate management strategies for vaccination-related lymphadenopathy are needed in both the general population and high-risk patients with cancer (1). The RSNA recommended reporting morphologic, functional, and metabolic features of lymphadenopathy encountered at imaging following vaccination (2), and it is necessary to establish criteria for interpreting these features. Scientific investigation into vaccination-related lymphadenopathy is paramount to revise guidelines for conducting proper follow-up and final assessment of lymphadenopathy, as well as avoiding unnecessary imaging and invasive procedures.

To date, large cohort studies relevant to imaging of COVID-19 vaccination-related axillary lymphadenopathy have been broadly divided into two categories. The first comprises studies in patients with malignancies, including men and women, in which...
Informed that their clinical, laboratory, and imaging data would be stored in a database and used for research purposes. Written informed consent was obtained from all participants. The questionnaire included COVID-19 vaccination information. A total of 1078 consecutive participants who participated in the comprehensive health screening program and underwent MRI from June to October 2021 were considered for inclusion in this study (Fig 1). Among them, 630 participants received two doses of a messenger RNA COVID-19 vaccine (Pfizer-BioNTech or Moderna). Those who lacked vaccination information, were vaccinated in both arms, or did not undergo prevaccination MRI were excluded. Those with a past or current medical history of diseases that may cause axillary lymphadenopathy were excluded. Those with a past history of COVID-19 were also excluded. Consequently, 433 participants were included in the study (Table).

**Materials and Methods**

**Study Participants**

Institutional review board approval was obtained for this study. Our institution conducts a comprehensive health screening program that includes whole-body MRI. This program is an option to access the health care support service offered by HIMEDIC (Tokyo, Japan), which was established in 1994 with the aim of offering preventive medicine. The examinees were members, members’ families, and members’ acquaintances, who come annually for continuous health monitoring and medical support. Before participating in the program, examinees were informed that their clinical, laboratory, and imaging data would be stored in a database and used for research purposes. Written informed consent was obtained from all participants. The questionnaire included COVID-19 vaccination information. A total of 1078 consecutive participants who participated in the comprehensive health screening program and underwent MRI from June to October 2021 were considered for inclusion in this study (Fig 1). Among them, 630 participants received two doses of a messenger RNA COVID-19 vaccine (Pfizer-BioNTech or Moderna). Those who lacked vaccination information, were vaccinated in both arms, or did not undergo prevaccination MRI were excluded. Those with a past or current medical history of diseases that may cause axillary lymphadenopathy were excluded. Those with a past history of COVID-19 were also excluded. Consequently, 433 participants were included in the study (Table).
Image Analysis
In this study, axillary lymphadenopathy was defined as the presence of at least one enlarged axillary lymph node. An enlarged lymph node was defined as one on postvaccination MRI scans that was larger than the corresponding lymph node on prevaccination MRI scans and had a short-axis diameter greater than or equal to 5 mm. The enlargement of lymph nodes was visually assessed and, when noted, the short-axis and long-axis diameters were measured. The number of enlarged lymph nodes was counted. The largest enlarged lymph node was identified on postvaccination MRI scans, and the lymph node corresponding to the largest enlarged lymph node was identified on prevaccination MRI scans. The short-axis and long-axis diameters of the corresponding lymph node were also measured on prevaccination MRI scans.

Postvaccination chest MRI scans were independently reviewed by two board-certified radiologists (T.Y. and S.M., with 19 and 12 years of experience in chest MRI) for the evaluation of axillary lymphadenopathy ipsilateral to the vaccinated site based on side-by-side comparison with prevaccination MRI scans. Disagreement was solved by consensus. All cases of lymphadenopathy observed in this study were considered to be induced by COVID-19 vaccination because participants with a past or current medical history of diseases that may cause axillary lymphadenopathy were excluded from the study.

The relative signal intensity on T2-weighted images was obtained in the largest enlarged lymph node, per a previous publication (16). To measure the signal intensity of the largest enlarged lymph node, a circular region of interest was placed on the T2-weighted postvaccination MRI scan. The region of interest was also placed on the ipsilateral pectoralis minor muscle as the reference. The relative signal intensity on T2-weighted images was calculated by dividing the signal intensity of the lymph node by the signal intensity of the pectoralis minor muscle.

| Background Characteristics of Participants with and without COVID-19 Vaccination-related Axillary Lymphadenopathy |
|--------------------------------------------------|----------------------------------|----------------------------------|-----------|--------|
| Characteristic                                    | Overall (n = 433) | With Lymphadenopathy (n = 90) | Without Lymphadenopathy (n = 343) | P Value |
| Age (y)                                          | 65 ± 11            | 61 ± 10                        | 66 ± 10                        | <.001   |
| Sex*                                             |                     |                                 |                                 | .005    |
| M                                                | 300                | 51                             | 249                             |         |
| F                                                | 133                | 39                             | 94                              |         |
| Type of vaccine*                                 |                     |                                 |                                 | .003    |
| Pfizer-BioNTech                                  | 390                | 73                             | 317                             |         |
| Moderna                                          | 43                 | 17                             | 26                              |         |
| Time interval from second vaccination dose to MRI (d) | 56 (30–90)          | 24 (12–42)                     | 67 (42–96)                      | <.001   |
| Time interval between prevaccination and postvaccination MRI (d) | 364 (339–456)      | 357 (336–492)                  | 364 (341–452)                   | .42     |

Note.—Normally distributed data are means ± SDs and nonnormally distributed data are medians, with 25th–75th percentiles in parentheses. For continuous variables, the Wilcoxon rank-sum test was used to compare medians of the two groups. For categorical variables, the Fisher exact test was used to compare the two groups.

* Data are numbers of participants.
To measure the apparent diffusion coefficient (ADC) of the largest enlarged lymph node, regions of interest were placed on diffusion-weighted images obtained with $b$ values of 800 and 0 sec/mm$^2$ at postvaccination MRI and the ADC was calculated. When the corresponding lymph node on prevaccination MRI scans had a short-axis diameter greater than or equal to 5 mm, the relative signal intensity on the T2-weighted image and the ADC were obtained similarly. The change in the ADC was calculated as postvaccination ADC minus prevaccination ADC.

**Statistical Analysis**

Continuous variables are presented as means ± SDs for normally distributed data and medians with 25th–75th percentiles for nonnormally distributed data, as appropriate. Interreader agreement was evaluated with Cohen $\kappa$ statistics. For continuous variables, the Wilcoxon rank-sum test was used to compare the medians of the COVID-19 vaccination-related axillary lymphadenopathy group and the non-lymphadenopathy group (Table). For categorical variables, the Fisher exact test was used to compare the two groups (Table). For paired continuous variables, the Wilcoxon signed-rank test was used to compare related data. Excel (Microsoft) and JMP Pro version 16.0.0 (SAS Institute) were used to conduct analyses. $P < .05$ was considered indicative of a statistically significant difference.

**Results**

A total of 433 participants, including 300 men and 133 women (mean age, 65 years ± 11 [SD]) were evaluated. Background characteristics of the participants are demonstrated in the Table. Interreader agreement for the presence or absence of lymphadenopathy was substantial ($\kappa = 0.63$).

Overall, COVID-19 vaccination-related axillary lymphadenopathy was observed in 90 of 433 participants (21%) in this study. Participants with lymphadenopathy were significantly younger than those without lymphadenopathy (mean age, 61 years ± 10 vs 66 years ± 10; $P < .001$). Lymphadenopathy was significantly more common in women than men (39 of 133 [29%] vs 51 of 300 [17%], $P = .005$). Lymphadenopathy was more common in those who received the Moderna vaccine than in those who received the Pfizer-BioNTech vaccine (17 of 43 [40%] vs 73 of 390 [19%], $P = .003$). Participants with lymphadenopathy underwent postvaccination MRI significantly earlier after vaccination than participants without lymphadenopathy (median, 24 days [25th–75th percentile, 12–42 days] vs 67 days [25th–75th percentile, 42–96 days]; $P < .001$).

Figure 2 demonstrates the number of participants with and without COVID-19 vaccination-related axillary lymphadenopathy according to the number of days after the second vaccination dose. The prevalence of lymphadenopathy in participants at 1–14, 15–28, 29–42, and 43–56 days after vaccination was 65% (30 of 46), 40% (22 of 55), 29% (16 of 55), and 18% (11 of 62), respectively.

**Figure 3:** (A) Scatterplot shows the number of enlarged lymph nodes according to the number of days after COVID-19 vaccination. Five or more enlarged lymph nodes were noted in eight of the 433 participants (2%), and those in six of the eight participants were noted 1–14 days after vaccination. (B) Scatterplot shows the short-axis diameter of the largest enlarged lymph node according to the number of days after COVID-19 vaccination. Only four of the 433 participants (1%) had enlarged lymph node greater than or equal to 10 mm in the short axis. (C) Scatterplot shows the long-axis diameter of the largest enlarged lymph nodes according to the number of days after COVID-19 vaccination.
The prevalence of lymphadenopathy was less than 10% 57 days or more after vaccination. Participants demonstrated lymphadenopathy as late as 109 days after vaccination in this cohort.

Figure 3A shows the scatterplot of the number of enlarged lymph nodes according to the number of days after vaccination. Shortly after vaccination, participants tended to have more enlarged lymph nodes. The median number of enlarged lymph nodes was two (25th–75th percentile, 1–2). Five or more enlarged lymph nodes were noted in eight of the 433 participants (2%), and enlarged lymph nodes were noted 1–14 days after vaccination in six of those eight participants.

Figure 3B shows the scatterplot of the short-axis diameter of the largest enlarged lymph node according to the number of days after vaccination, and Figure 3C shows that of the long-axis diameter. Shortly after vaccination, participants tended to have larger enlarged lymph nodes. The median short-axis diameter of the largest enlarged lymph node was 6 mm (25th–75th percentile, 6–8 mm), and the median long-axis diameter was 9 mm (25th–75th percentile, 8–11 mm). Only four of the 433 participants (1%) had enlarged lymph nodes greater than or equal to 10 mm in the short axis.

Figure 4A shows the scatterplot of the relative signal intensity on T2-weighted images of the largest enlarged lymph node according to the number of days after vaccination, and Figure 4B shows that of the ADC. Although the relative signal intensity seemed to be low in later days after vaccination, it had little connection to the number of days after vaccination. The ADC had no relationship to the number of days after vaccination. The median relative signal intensity on T2-weighted images of the largest enlarged lymph node was 4.0 (25th–75th percentile, 3.5–5.6) and the median ADC was $1.1 \times 10^{-3}$ mm$^2$/sec (25th–75th percentile, 0.9–1.4 $\times 10^{-3}$ mm$^2$/sec).

Eleven of the 90 participants with axillary lymphadenopathy had the corresponding lymph node with a short-axis diameter greater than or equal to 5 mm on prevaccination MRI scans. Figure 4C demonstrates the changes in relative signal intensity on T2-weighted images of the largest enlarged lymph node before prevaccination and postvaccination MRI, and Figure 4D demonstrates the changes in ADC values. The largest enlarged lymph node on T2-weighted images at postvaccination MRI demonstrated a higher relative signal intensity than the corresponding lymph node on T2-weighted images at prevaccination MRI ($P = .002$). Lastly, the median apparent diffusion coefficient (ADC) of enlarged lymph nodes was $1.1 \times 10^{-3}$ mm$^2$/sec (range, 0.6–2.0 $\times 10^{-3}$ mm$^2$/sec), thus the ADC remained within normal range.

**Discussion**

We evaluated 433 participants (mean age, 65 years ± 11), including 300 men and 133 women. The prevalence of axillary lymphadenopathy in participants 1–14 days after vaccination was 65% (30 of 46). Participants with lymphadenopathy were significantly younger than those without lymphadenopathy (mean age, 61 years ± 10 vs 66 years ± 10; $P < .001$). Lymphadenopathy was significantly more common in women than men (39 of 133 [29%] vs 51 of 300 [17%], $P = .005$). Lymphadenopathy was more common in those who received the Moderna vaccine than in those who received the Pfizer-BioNTech vaccine (17 of 43 [40%] vs 73 of 390 [19%], $P = .003$). Five or more enlarged lymph nodes were noted in 2% (eight of 433) of participants, and enlarged lymph nodes greater than or equal to 10 mm in the short axis were noted in 1% (four of 433). The median relative signal intensity on T2-weighted images of the largest enlarged lymph node was 4.0 (25th–75th percentile, 3.5–5.6). The largest enlarged lymph node on T2-weighted images at postvaccination MRI demonstrated a higher relative signal intensity than the corresponding lymph node on T2-weighted images at prevaccination MRI ($P = .002$). Lastly, the median apparent diffusion coefficient (ADC) of enlarged lymph nodes was $1.1 \times 10^{-3}$ mm$^2$/sec (range, 0.6–2.0 $\times 10^{-3}$ mm$^2$/sec), thus the ADC remained within normal range.
We observed an overall prevalence of COVID-19 vaccination-related axillary lymphadenopathy of 21%. The prevalence of lymphadenopathy in participants at 1–14, 15–28, 29–42, and 43–56 days after vaccination was 65%, 40%, 29%, and 18%, respectively. Wolfson et al (6) also recently evaluated the number of patients with and without lymphadenopathy in terms of days after vaccination and observed a high prevalence of lymphadenopathy early after vaccination. The prevalence has ranged from 3% to 44% in other studies (6,11,14,15). Differences likely relate to the study population, definition of lymphadenopathy, time delay after vaccination, and method to evaluate lymphadenopathy.

Given the rate of decrease of lymphadenopathy over 29–56 days, postponing nonurgent imaging examinations of the chest is recommended (2–4). In particular, within 1–14 days after vaccination a high prevalence of lymphadenopathy may cause many false-positive results for malignancy and heighten the anxiety of patients. Recommendations and guidelines should be revised for the most appropriate duration of postponement and follow-up strategies based on accumulated knowledge, including our results.

Participants with lymphadenopathy were younger than those without lymphadenopathy in this study. This is compatible with the clinical trial of the Moderna vaccine (17) and a recent report by Horvat et al (15).

Lymphadenopathy was significantly more common in women than in men. This is compatible with the previous study by Nishino et al (11). This predominance in women may indicate that they are more hypersensitive to COVID-19 vaccines, just as women are more likely to develop delayed localized cutaneous reactions to the Moderna vaccine (so-called “Moderna arm”) and experience symptoms of hypersensitivity to other vaccines (18,19).

Lymphadenopathy was more common in those who received the Moderna vaccine than in those who received the Pfizer-BioNTech vaccine. This is also compatible with the clinical trials (17,20) and previous imaging studies (6,11).

We defined axillary lymphadenopathy as the presence of at least one enlarged axillary lymph node at postvaccination MRI that was larger than the corresponding lymph node at prevaccination MRI. It is acknowledged that a single definition for lymphadenopathy is not widely agreed on (2). Because the prevalence and imaging characteristics depend on the definition of lymphadenopathy, we explicitly defined lymphadenopathy before we started the study. To detect true enlargement of lymph nodes, intranidividual comparison of cross-sectional images from two time points is the best method. We did not evaluate lymph nodes with a short-axis diameter less than 5 mm because they were too small to be evaluated properly considering the spatial resolution of MRI, especially diffusion-weighted imaging.

Enlarged lymph nodes demonstrated a higher signal intensity on T2-weighted images at postvaccination MRI. This presumably reflects an increase in water content due to immune reactions. A high signal intensity on T2-weighted images is not specific, and it may be limited in the differentiation of COVID-19 vaccination-related axillary lymphadenopathy from malignant lymphadenopathy.

The median ADC of enlarged lymph nodes in our study was 1.1 × 10⁻³ mm²/sec, with a range of 0.6–2.0 × 10⁻³ mm²/sec. Donners et al (21) have investigated the ADC of normal lymph nodes. According to their data, the median ADC of normal axillary lymph nodes is approximately 1.1 × 10⁻³ mm²/sec, with a range of 0.7–1.8 × 10⁻³ mm²/sec. Other studies showed that the ADC of metastatic axillary lymph nodes in patients with breast cancer was lower than that of benign axillary lymph nodes (16,22,23). Therefore, the ADC of enlarged lymph nodes induced by vaccination remained within the normal range, and this parameter is expected to be helpful in differentiating COVID-19 vaccination-related axillary lymphadenopathy from malignant lymphadenopathy.
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from malignant lymphadenopathy. A change in ADC may also be informative for differential diagnosis.

There were limitations in this study. It was conducted at a single institution in Japan and most participants were of Asian ethnicity. Only messenger RNA vaccines were included (Pfizer-BioNTech or Moderna). Study participants were older in age because seniors were prioritized for COVID-19 vaccinations in Japan. Only a subset of participants underwent evaluation of the changes in signal intensity on T2-weighted images and apparent diffusion coefficient of enlarged lymph nodes between prevaccination and postvaccination MRI.

In conclusion, the prevalence of COVID-19 vaccination-related axillary lymphadenopathy in participants 1–14 days after vaccination was 65%, with decreased prevalence over 4–8 weeks. Younger age, female sex, and the Moderna vaccine were predisposing factors. Enlarged lymph nodes demonstrated a higher signal intensity on T2-weighted images, while the ADC remained within normal range. These results provide important information needed to establish evidence-based guidelines for conducting proper follow-up and final assessment of axillary lymphadenopathy after COVID-19 vaccination, and to avoid unnecessary imaging and invasive procedures.

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Figure 5: Images in a 50-year-old man 10 days after COVID-19 vaccination. (A, B) Axial T2-weighted image (A) and diffusion-weighted image (B) obtained at postvaccination MRI demonstrate an enlarged lymph node (arrows) in the left axilla ipsilateral to the vaccinated site. (C, D) Axial T2-weighted image (C) and diffusion-weighted image (D) obtained at prevaccination MRI demonstrate the corresponding lymph node (arrowheads). The enlarged lymph node on the postvaccination MRI scans is obviously larger than the corresponding lymph node on the prevaccination scans. The enlarged lymph node on the T2-weighted image at postvaccination MRI demonstrates a higher signal intensity than the corresponding lymph node on the T2-weighted image at prevaccination MRI.
ensure any questions related to the work are appropriately resolved, all authors: literature research, T.Y., S.K., O.A.; clinical studies, T.Y., S.K., N.H.; experimental studies, S.M., S.K.; statistical analysis, T.Y., T.N., S.K.; and manuscript editing, T.Y., T.N., S.K., N.H., O.A.

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Figure 6: Images in a 53-year-old man 42 days after COVID-19 vaccination. (A, B) Axial T2-weighted image (A) and diffusion-weighted image (B) obtained at postvaccination MRI demonstrate an enlarged lymph node (arrow) in the left axilla ipsilateral to the vaccinated site. (C, D) Axial T2-weighted image (C) and diffusion-weighted image (D) obtained at prevaccination MRI demonstrate the corresponding lymph node (arrowhead). The enlarged lymph node on the postvaccination MRI scans is larger than the corresponding lymph node on the prevaccination scans. In this participant, the enlarged lymph node on the T2-weighted image at postvaccination MRI demonstrates isointensity relative to the corresponding lymph node on the T2-weighted image at prevaccination MRI.
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