Frequency and outcomes of MRI-detected axillary adenopathy following COVID-19 vaccination

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Abstract

Objectives To assess the frequency of ipsilateral axillary adenopathy on breast MRI after COVID-19 vaccination. To investigate the duration, outcomes, and associated variables of vaccine-related adenopathy.

Methods In this retrospective cohort study, our database was queried for patients who underwent breast MRI following COVID-19 vaccination from January 22, 2021, to March 21, 2021. The frequency of ipsilateral axillary adenopathy and possible associated variables were evaluated, including age, personal history of ipsilateral breast cancer, clinical indication for breast MRI, type of vaccine, side of vaccination, number of doses, and number of days between the vaccine and the MRI exam. The outcomes of the adenopathy were investigated, including the duration of adenopathy and biopsy results.

Results A total of 357 patients were included. The frequency of adenopathy on breast MRI was 29% (104/357 patients). Younger patients and shorter time intervals from the second dose of the vaccine were significantly associated with the development of adenopathy ($p = 0.002$ for both). Most adenopathy resolved or decreased on follow-up, with 11% of patients presenting persistence of adenopathy up to 64 days after the second dose of the vaccine. Metastatic axillary carcinoma was diagnosed in three patients; all three had a current ipsilateral breast cancer diagnosis.

Conclusions Vaccine-related adenopathy is a frequent event after COVID-19 vaccination; short-term follow-up is an appropriate clinical approach, except in patients with current ipsilateral breast cancer. Adenopathy may often persist 4–8 weeks after the second dose of the vaccine, thus favoring longer follow-up periods.

Key Points
- MRI-detected ipsilateral axillary adenopathy is a frequent benign finding after mRNA COVID-19 vaccination.
- Axillary adenopathy following COVID-19 vaccination often persists > 4 weeks after vaccination, favoring longer follow-up periods.
- In patients with concurrent ipsilateral breast cancer, axillary adenopathy can represent metastatic carcinoma and follow-up is not appropriate.

Keywords Vaccines · Pandemic · Lymphadenopathy · Magnetic resonance imaging · Breast neoplasms

Introduction

New challenges emerged from the devastating effects of the COVID-19 pandemic. The novel pathogenicity of the SARS-CoV-2 virus as well as its associated mortality and morbidity rate started a worldwide effort to find measures to remediate the disease and control the spread of infection [1]. The
development of vaccines that could reduce the infection rate and lethality of the virus brought hope to billions of people worldwide [2]. While the vaccination process has been viewed with great enthusiasm, constant monitoring is still necessary to detect possible adverse events from these new vaccines [3].

In December 2020, the Food and Drug Administration (FDA) in the USA authorized the emergency use of the first two COVID-19 vaccines, produced by Pfizer-BioNTech (BNT162b2) and Moderna (mRNA-1273), respectively [4, 5]. These vaccines present new biotechnology that consists of an injection of mRNA that is capable of inducing human cells to produce viral proteins that can be detected by the immune system, starting a reaction chain that ultimately leads to immune protection. The third vaccine to receive emergency use authorization by the FDA is produced by Janssen (Ad26.COV2.S) and has a different approach of triggering an immune response [6]. In this case, the immune response is mediated by an adenovirus encoding the coronavirus S protein that infects human cells. The aforementioned vaccines were subsequently approved for use in the European Union by the European Medicines Agency [7]. Other vaccines currently not available in the USA or European Union have different approaches, such as the injection of attenuated SARS-COV-2 particles [8].

Axillary lymph nodes are the most common site of metastatic infiltration from breast tumors [9, 10]. During the nationwide SARS-COV-2 vaccination campaign, a number of studies were published associating mRNA-mediated vaccines with axillary adenopathy [11–15]. Vaccine-related adenopathy may be confounded with malignant infiltration of axillary lymph nodes [16, 17]. This distinction is particularly difficult in patients with a diagnosis of current or previous breast cancer. A number of authors and medical associations have recommended short-term follow-up of patients with adenopathy ipsilateral to the arm that received the vaccination dose to ensure benignity [16, 18–24]. Nevertheless, little is known regarding the frequency and duration of imaging-detected adenopathy in patients after the COVID-19 vaccination [21].

In this study, we evaluated the frequency of ipsilateral axillary adenopathy following COVID-19 vaccination in patients who underwent breast MRI at a comprehensive cancer center. Additionally, we investigated possible variables associated with the incidence of adenopathy and the outcomes of patients with abnormal lymph nodes.

**Materials and methods**

**Population**

In this Health Insurance Portability and Accountability Act–compliant and Institutional Review Board–approved study, we retrospectively searched our database for patients who underwent breast MRI at our institution, a tertiary care cancer center, after receiving the COVID-19 vaccine. Consecutive cases within a 2-month period were queried from January 22, 2021, to March 21, 2021, starting from when the cataloging of the vaccination status began at our institution. The necessity for patient informed consent was waived by the Institutional Review Board. The exclusion criteria were as follows: (1) vaccine not received in the arm and (2) MRI study considered non-diagnostic due to the presence of artifacts. A total of 357 patients were included in our study sample. The flow of patient inclusion is presented in Fig. 1.

**Clinical information**

The health information system was queried for patients’ clinical information, including age, biological sex, and previous history of or current presence of known breast cancer. Clinical indication for breast MRI was also annotated and classified into a screening or diagnostic exam. COVID-19 vaccination history was also queried, including the type of vaccine, number of doses received before the MRI study, dates of the doses, and arm side that received the vaccine.

**Breast MRI**

Breast MRI reports were searched for information on the presence of abnormal axillary lymph nodes. Patients with abnormal lymph nodes ipsilateral to the arm that received one of the doses of the vaccine were considered positive for adenopathy. The presence of adenopathy was described by breast imaging specialist radiologists based on morphological features.

Fig. 1 Patient accrual diagram
including cortical thickening (> 3 mm), lack or effacement of a fatty hilum, size, decreased long/short axis ratio, or irregular contours. Patients with one or more abnormal lymph nodes were considered positive for adenopathy, even if additional normal-appearing lymph nodes were identified within the axilla. Patients with axillary adenopathy presumed to be vaccine-related were recommended for follow-up 4–8 weeks after the second vaccination dose following our breast imaging service recommendations at the time.

Outcomes

The outcomes of all patients were annotated on September 1, 2021. Patients with adenopathy for which follow-up was recommended were scheduled for a targeted axillary ultrasound to be performed at 4–8 weeks after the completion of the vaccination regimen. If for various reasons a breast MRI, PET-CT, or chest CT was performed before the follow-up ultrasound showing the decrease or resolution of the adenopathy, the follow-up ultrasound was considered unnecessary and canceled.

The nodal status on imaging follow-up of patients with adenopathy was annotated and classified into three categories: persistent, decreased, and resolved. Patients with persistent adenopathy were either recommended for an additional follow-up 4 weeks later or recommended for fine-needle aspiration (FNA) or core needle biopsy (CNB). Patients with current ipsilateral breast cancer who underwent sentinel lymph node biopsy were also cataloged and the results were annotated.

Statistical analysis

The results were expressed as medians and interquartile ranges (IQR) for continuous variables and proportions for categorical variables. Clinical, temporal, or vaccine-related characteristics such as age, presence of ipsilateral current breast cancer, history of ipsilateral treated breast cancer, clinical indication for breast MRI, type of vaccine, side (left or right) of vaccination, number of doses received before the MRI exam was one dose for 133/357 (37%) patients, two doses for 124/357 (35%) patients, one dose in each arm in 40/357 (11%) patients, and in 44/357 (12%) patients the type of vaccine was unknown. The vaccine was administered in the left arm in 268/357 (75%) patients, in the right arm in 69/357 (19%) patients, one dose in each arm in 12/357 (4%) patients, and in 8/357 (2%) patients the laterality was unknown. The number of doses received before the MRI exam was one dose for 173/357 (48%) patients and two doses for 184/357 (52%) patients. The median number of days was 26 days (IQR 14, 44) between the first dose of the vaccine and the exam date, 18 days (IQR 7, 29) between the second dose and the exam, and 15 days (IQR 8, 24) between the latest dose (either first or second dose) and the exam. Patient information is summarized in Table 1.

COVID-19 vaccination and adenopathy

There were 104/357 (29%; 95% CI: 25, 34) patients with ipsilateral axillary adenopathy after COVID-19 vaccination. Of these, 13/104 (13%) presented with adenopathy beyond 4 weeks following completion of vaccination. Patients with only one dose of the vaccine presented adenopathy between 4 and 30 days after the vaccine, while patients with two doses presented adenopathy between 1 and 62 days after the second dose of the vaccine. Younger age was statistically significantly associated with the development of adenopathy (p = 0.002). This was confirmed after false discovery rate adjustment (adjusted p value = 0.012). The median age of patients with adenopathy was 51 years (IQR 41, 59) in comparison with 57 years (IQR 46, 67) of patients without adenopathy. The presence of either a current ipsilateral breast cancer or a history of a treated ipsilateral breast cancer was not associated with the development of adenopathy (p = 0.087 and 0.5, 0.087 and 0.5, respectively).
Table 1  Patient characteristics, breast MRI details, and vaccine information

| Characteristics of patients                   | n (% ) |
|----------------------------------------------|--------|
| Patient median age = 55 years (range, 25–82) |        |
| Total number of patients                     | 357 (100) |
| Patient biological sex                       |        |
| Female                                       | 356 (99) |
| Male                                         | 1 (1)   |
| History of ipsilateral breast cancer         |        |
| Current cancer                               | 16 (4)  |
| Previous cancer                              | 57 (16) |
| Breast MRI technique                         |        |
| With contrast                                | 313 (88) |
| Without contrast                             | 44 (12) |
| Clinical indication for breast MRI           |        |
| Screening                                    | 219 (61) |
| Diagnostic                                   | 138 (39) |
| Type of vaccine                              |        |
| Pfizer-BioNTec                               | 175 (49) |
| Moderna                                      | 137 (38) |
| Janssen                                      | 1 (1)   |
| Unknown                                      | 44 (12) |
| Side of vaccine                              |        |
| Left arm                                     | 268 (75) |
| Right arm                                    | 69 (19)  |
| Bilateral                                    | 12 (4)  |
| Unknown                                      | 8 (2)   |
| Number of doses of the vaccine               |        |
| 1 dose                                       | 173 (48) |
| 2 doses                                      | 184 (52) |
| Median days between dose and breast MRI      |        |
| Days since the first dose                    | 26 |
| Days since the second dose                   | 18 |
| Days since the latest dose                   | 15 |

respectively). Of patients with concurrent ipsilateral breast cancer, 8/104 (8%) had adenopathy in comparison to 8/253 (3%) without adenopathy and among patients with a personal history of ipsilateral breast cancer, 14/104 (13%) developed adenopathy while 43/253 (17%) did not. Similarly, the clinical indication of the exam, either screening or diagnostic, was not associated with adenopathy (p = 0.9). Contralateral axillary adenopathy was not associated with COVID-19 vaccination and was only identified in patients with contralateral breast cancer and metastatic adenopathy.

A slightly larger proportion of patients who received the Moderna vaccine developed adenopathy 47/137 (34%) in comparison with the proportion of patients who received the Pfizer-BioNTec vaccine and who subsequently developed adenopathy 44/175 (25%), but this difference was not statistically significant (p = 0.12). Only one patient in our study population had received the Janssen vaccine, and this patient did not develop adenopathy. The comparison of types of vaccine between groups with and without adenopathy is demonstrated in Table 2.

Of the patients who received only one dose of the vaccine, 50/173 (29%) developed adenopathy; similarly, this finding was observed in 54/184 (29%) of patients who received two doses of the vaccine. No association was found between adenopathy and the number of doses of the vaccine prior to the MRI (p > 0.9). Likewise, the side where the vaccine was administered was not associated with adenopathy (p = 0.4).

The time between the second dose of the vaccine and the MRI exam was inversely associated with the development of adenopathy (p = 0.002). This was confirmed after false discovery rate adjustment (adjusted p value = 0.012). The time between the first dose or the latest dose and the exam were not associated with the development of adenopathy. The median time interval between vaccination doses and the presence of adenopathy on breast MRI exams are demonstrated in Table 3.

Outcomes

Of 104 patients with ipsilateral axillary adenopathy on breast MRI following COVID-19 vaccination, 74/104 (71%) had imaging follow-up performed at least 4 weeks after the second dose of the vaccine. All patients underwent an axillary ultrasound on follow-up, except for three who underwent PET-CT, two who underwent breast MRI, and one who underwent chest CT. In 8/74 (11%) patients, imaging follow-up performed at least 4 weeks after the second dose of the vaccine (ranging between 29 and 64 days after the last dose) demonstrated persistence of adenopathy. In 72/74 (97%) patients, the adenopathy was deemed resolved or decreased on follow-up, including 6 patients with persistent adenopathy on initial follow-up. Adenopathy was considered resolved in 57/74 (77%) patients (ranging between 31 and 130 days after vaccination) while in 15/74 (20%) patients, it was considered still abnormal but decreased in correlation with the breast MRI exam (ranging between 28 and 104 days after vaccination). Two patients were lost to follow-up after an axillary ultrasound performed more than 4 weeks after vaccination demonstrated persistence.

Table 2  Type of vaccine compared between patients with and without axillary adenopathy on breast MRI (p = 0.12)

| Type of vaccine | Adenopathy | No adenopathy | Total |
|-----------------|------------|---------------|-------|
| Pfizer-BioNTec  | 44 (25%)   | 131 (75%)     | 175   |
| Moderna         | 47 (34%)   | 90 (66%)      | 137   |
| Janssen         | 0 (0%)     | 1 (100%)      | 1     |
| Total           | 91         | 222           | 313   |
of adenopathy. The range of days after vaccination on imaging follow-up of patients with persistent, decreased, and resolved adenopathy is demonstrated in Table 4.

An interventional procedure was performed in 10/104 (10%) patients with adenopathy, including four FNAs, one CNB, and five sentinel lymph node biopsies (SLNBs). The results were positive for metastatic carcinoma in 3/104 (3%) patients, all of whom had concurrent ipsilateral breast cancer. These three patients represent 38% of a total of eight patients with axillary adenopathy and concurrent ipsilateral breast cancer. Two patients without ipsilateral breast cancer underwent FNA that yielded benign results. One additional patient had a previously diagnosed chronic lymphocytic leukemia and underwent an axillary CNB that yielded the same diagnosis.

**Discussion**

The frequency of ipsilateral axillary adenopathy on breast MRI following COVID-19 vaccination was 29%. Adenopathy was detected on MRI up to 62 days after the second dose of the vaccine. Younger patients were more prone to develop adenopathy. The type of vaccine, laterality of administration, and number of doses received before the exam were not associated with adenopathy. The number of days after the second dose of the vaccine was found to be statistically significant; patients who recently received the second dose of the vaccine were more likely to demonstrate adenopathy. Adenopathy resolved or decreased on follow-up in the majority of cases, but some patients demonstrated persistent adenopathy up to 64 days after the second dose of the vaccine. Metastatic adenopathy was only detected in patients with known ipsilateral breast cancer and in one patient with chronic lymphocytic leukemia.

The presence of ipsilateral axillary adenopathy on breast MRI after recent COVID-19 mRNA vaccination is very frequent, as observed in this study. On MRI, it was detected in the first week after the first dose of the vaccine and up to more than 8 weeks after the second dose. The frequency was found to be higher than on previous reports that noted the presence of clinically-evident adenopathy in 0.3% of patients who received the Pfizer-BioNTec vaccine and in up to 16% of patients who received the Moderna vaccine, in comparison with the 29% frequency observed in our study [11, 12, 14, 15]. This higher frequency may be because breast MRI allows for the detection of adenopathy that is not clinically apparent to the patient or physician on examination. On the other hand, our findings were less frequent than in a previous report on PET/CT by Cohen et al that identified hypermetabolic adenopathy in 46% of patients after the Pfizer-BioNTec vaccine [25]. Given the high proportion of patients who developed abnormal lymph nodes in our study, the finding of ipsilateral axillary adenopathy on breast MRI after recent COVID-19 mRNA vaccination should be considered probably benign in patients with negative breast imaging studies and with low suspicion for cancer recurrence. This result favors the recommendation for follow-up instead of an interventional procedure for these patients.

Younger patients were more likely to develop adenopathy than older patients. A previous report by the US Centers for Disease Control and Prevention (CDC) had also identified that young adult patients who received the Moderna vaccine were more prone to develop adenopathy [12]. In a study by Eifer et al on PET-CT after COVID-19 vaccination, age was also found to be inversely associated with increased rates of fluorodeoxyglucose (18F) uptake in ipsilateral axillary lymph nodes, corroborating our findings [26].

A slightly larger proportion of patients who received the Moderna vaccine (34%) developed ipsilateral axillary adenopathy than patients who received the Pfizer-BioNTec vaccine (25%), but this difference was not statistically significant in our study. The number of doses received prior to the MRI exam was also not statistically significantly different between patients with and without adenopathy. The number of days after the second vaccine dose was significantly inversely associated with adenopathy while the number of days after the first dose was not. Since patients usually receive a second dose of the vaccine within 3 to 5 weeks after the first dose, these findings suggest that most patients who develop adenopathy after the first dose will sustain this finding until the date of the second dose. This is in contrast with previous reports that mentioned the resolution of clinically evident adenopathy in most cases in 10 days or less [11, 12]. On the

| Status of adenopathy | Number of patients | Range (days) |
|----------------------|-------------------|--------------|
| Persistent           | 8                 | 29–64        |
| Decreased            | 15                | 28–104       |
| Resolved             | 57                | 31–130       |
other hand, time after the second dose was, as expected, inversely associated with the presence of adenopathy, with a median of 14 days after the vaccine in patients with adenopathy in comparison with 20 days in patients without adenopathy.

For most patients who demonstrate vaccine-related adenopathy on breast MRI, this finding decreased or resolved on imaging follow-up within 4–8 weeks after the second dose of the vaccine, proving benignity. Yet, a significant portion (11%) of patients still demonstrated persistent adenopathy during this period. Given the frequency of persistent adenopathy 4–8 weeks after the second dose of the vaccine, follow-up periods that are equal to or greater than 8 weeks may be preferable to shorter follow-ups, in contrast with previous recommendations [16, 18–24]. Furthermore, in patients with persistent adenopathy 4–8 weeks after the second dose of the vaccine, an additional follow-up in 4 or more weeks may be preferable to an interventional procedure. This is in agreement with the European Society of Breast Imaging that recommended follow-up at least 12 weeks after COVID-19 vaccination when clinically indicated [27]. Future studies will clarify when an interventional procedure should be performed in patients without a suspicious breast lesion but with persistent adenopathy, as this can represent recurrence from a treated breast cancer, occult primary breast cancer, lymphoproliferative disorders, or metastatic disease from other solid tumors [28].

In our study sample, metastatic carcinomatous adenopathy was detected in only patients with current ipsilateral breast cancer. In patients with known ipsilateral cancer, adenopathy after the COVID-19 vaccination may represent malignant infiltration and biopsy should be recommended. Sampling is usually performed during surgery with SLNB but may be performed preoperatively in selected cases if clinically indicated. COVID-19 vaccination should not change the standard management of the axilla in patients with breast cancer as follow-up is not adequate for this population, in agreement with the European Society of Breast Imaging recommendations [27].

Our study is not devoid of limitations. First, we included only patients who received the vaccine in the first few months of the vaccination campaign. It is expected that in future studies, the frequency of adenopathy will decrease in populations who receive the second dose of the vaccine longer before an imaging exam. Second, only one patient in our population received the Janssen vaccine; thus, no conclusions could be made regarding this type of vaccine. Third, MRI images were not reviewed and the presence of adenopathy was based solely on the report. Lastly, follow-up was not standardized, with patients having a follow-up exam at different time points while a few were not followed at all.

In conclusion, ipsilateral axillary adenopathy after COVID-19 mRNA-based vaccination is a frequent event that was observed in 29% of patients after either the first or second dose. Younger patients are more prone to develop adenopathy while its frequency reduces as time goes by after the second dose of the vaccine. Adenopathy may often persist 4–8 weeks after the second dose of the vaccine, thus favoring follow-up periods that are equal to or greater than 8 weeks. Short-term follow-up is an appropriate clinical approach in most cases, except in patients with current ipsilateral breast cancer for which standard management of the axilla is still recommended.

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Declarations

Guarantor The scientific guarantor of this publication is Joao V. Horvat, MD.

Conflict of interest The authors of this manuscript declare relationships with the following companies: Dr. Kimberly N Feigin is a paid clinical advisor to Covera Health, Inc. The company had no participation in this study.

Statistics and biometry One of the authors (Varadan Sevilimedu) has significant statistical expertise.

Informed consent Written informed consent was waived by the Institutional Review Board.

Ethical approval Institutional Review Board approval was obtained.

Methodology

- retrospective
- observational
- performed at one institution

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