Original Research

Outcomes of COVID-19 Vaccination–Related Incidental Axillary Adenopathy in Women Undergoing Breast MRI

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Abstract

Objective: To assess the frequency, management, and early outcomes of COVID-19 vaccine–related adenopathy on breast MRI.

Methods: This IRB-exempt retrospective study reviewed patients who underwent breast MRI following COVID-19 vaccine approval in the U.S. from December 14, 2020, to April 11, 2021 (N = 1912) and compared patients who underwent breast MRI the year prior to the pandemic, March 13, 2019, to March 12, 2020 (N = 5342). Study indication, patient age, date of study, date and type of vaccination(s), time difference between study and vaccinations, lymph node–specific and overall management recommendations, and outcomes of additional examinations were recorded. Differences in the final assessment categories between the subjects scanned pre-pandemic and post-vaccine were compared using the Fisher exact test.

Results: Vaccine-related adenopathy was mentioned in 67 breast MRI reports; only 1 in the pre-pandemic group. There were no clinically relevant differences in patient demographics between groups. There was a statistically significant increase in BI-RADS 0 assessments between the pre-pandemic and post-vaccine approval groups—0.8% (45/5342) versus 1.8% (34/1912) (P = 0.001) and BI-RADS 3 assessments—6.5% (348/5342) versus 9.2% (176/1912) (P < 0.0001). Of the 29 patients who underwent additional imaging (range, 2–94 days following MRI) and the 2 patients who underwent biopsy, 47% (31/66), none were found to have malignant adenopathy.

Conclusion: COVID-19 vaccination is associated with transient axillary adenopathy of variable duration. This leads to additional imaging in women undergoing breast MRI, so far with benign outcomes, and this may affect audits of outcomes of MRI.

Key words: COVID-19; lymphadenopathy; high-risk breast MRI; vaccination.

Introduction

The U.S. Food and Drug Administration granted emergency use authorization of the first two COVID-19 vaccines, by Moderna (mRNA-1273, Moderna Inc., Bethesda, MD and Cambridge, MA) and Pfizer-BioNTech (BNT162b2, Pfizer/BioNTech, New York, NY and Mainz, Germany), in December 2020. Since then, radiologists worldwide have observed numerous cases of regional, most often axillary lymphadenopathy ipsilateral to the vaccine site. Other immunizations, including influenza, human papilloma virus, bacillus Calmette–Guerin, anthrax, measles, and smallpox vaccines, can occasionally elicit transient adenopathy.
Rarely, vaccines cause transient adenopathy on imaging, best documented on fluorodeoxyglucose-18 PET-CT (2,4,5). However, based on experience to date, the mRNA COVID-19 vaccines elicit incidental axillary lymphadenopathy on radiologic imaging more frequently than other vaccines. Clinical trial data for both mRNA COVID-19 vaccines demonstrate they are highly immunogenic, commonly causing local and systemic reactions. Over 85% of clinical trial patients experienced local reactions at the injection site, and over 75% reported systemic reactions (6). Axillary swelling or tenderness was reported in 10% of recipients of the Moderna vaccine in the clinical trial within seven days of the first vaccine dose and 14% following the second dose (6). Rates of axillary symptoms were even higher among younger patients for the Moderna vaccine—11.6% after the first dose and 16% after the second dose in those aged 18 to 64 years versus 6.1% after the first dose and 8.4% after the second dose in those aged ≥65 years (7).

With the goal of avoiding unnecessary biopsies and additional imaging, multiple organizations issued guidelines for managing incidental adenopathy on breast imaging after COVID-19 vaccination based on early experience (8). The Society of Breast Imaging expert opinion panel on January 2021 recommended a Breast Imaging Reporting and Data System (9) (BI-RADS) 0 assessment for unilateral adenopathy on screening mammogram, followed by a BI-RADS 3 assessment on the diagnostic imaging if the COVID-19 vaccine was within four weeks of the mammogram and a recommendation for follow-up breast imaging four to 12 weeks after the second dose (10). Other groups, such as the breast imaging radiologists at the Massachusetts General Hospital, took a less conservative approach, suggesting that incidental unilateral axillary adenopathy within six weeks of COVID-19 vaccination on screening studies may be deemed benign (11). Most early guidelines were not based on clinical data.

Because of the high lifetime risk of breast cancer among most patients undergoing breast MRI, adenopathy on this modality presents a unique challenge. Occult breast cancers, defined as breast cancers presenting as unilateral adenopathy without a breast finding on mammography or US, are rare, representing <1% of all breast cancer diagnoses (12). A meta-analysis of occult breast cancers found that a primary in-breast lesion can be identified by MRI in most patients—an average 72% of cases (13). Nevertheless, it is important to recognize and differentiate between occult breast cancer with axillary malignancy and vaccine-related adenopathy. Thus, evidence-based guidelines are necessary to optimize management. The objective of our study was to assess the frequency of vaccine-related adenopathy on breast MRI, as well as the associated BI-RADS assessments and management recommendations for patients, in a pre-COVID-19 pandemic cohort and a post-vaccine cohort.

**Methods**

This retrospective Health Insurance Portability and Accountability Act–compliant study was given exempt status by the human subjects’ institutional review board at our institution. Informed consent was waived.

Final BI-RADS assessments from all breast MRIs (including full protocol MRIs and abbreviated MRIs for supplemental screening) performed at our institution from the date of the first COVID-19 vaccine administration, December 14, 2020, to April 11, 2021 (N = 1912) were obtained from our hospital’s electronic medical record (Epic, Epic Systems, Madison, WI). These outcomes were compared with final BI-RADS assessments from all breast MRIs from the year prior to the pandemic, March 13, 2019, to March 12, 2020 (N = 5342). The year prior to the pandemic was chosen to avoid comparing studies that may have been affected by the COVID-19 pandemic–related suspension of routine imaging from mid-March to May 2020 at our institution. Data also included second interpretations performed at outside institutions in both cohorts.

All breast MRI reports were queried through a radiology-specific search engine for mention of vaccination-related adenopathy (Montage, Montage Health Systems, Philadelphia, PA). Search terms included “COVID-19,” “vaccine,” “vaccination,” “vaccine + adenopathy,” “vaccine + lymphadenopathy,” “vaccination + adenopathy,” and “vaccination + lymphadenopathy.” Using these search terms, 78 studies were identified in the post-vaccine cohort and 1 study in the pre-pandemic cohort. Study indication, patient age, date of study, date and type of vaccination, time difference between study date and most recent vaccination, lymph node–specific management recommendations, overall BI-RADS assessments, and outcomes of additional examinations, if any, were obtained from the medical record.

At our institution, breast MRIs were performed at 13 centers and interpreted by 33 radiologists with between one and 31 years of post-residency experience. Examinations were interpreted by fellowship-trained or equivalent (defined as

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**Key Messages**

- Only 3.5% (66/1912) of studies performed following COVID-19 vaccination approval included comments on vaccine-related adenopathy, compared with 0.02% (1/5342, influenza) from the comparison year (P < 0.0001).
- COVID-19 vaccination–related adenopathy contributed to increased follow-up imaging in patients undergoing breast MRI (BI-RADS 0, 1.8% vs 0.8%, P = 0.001; BI-RADS 3, 9.2% vs 6.5%, P < 0.0001).
- While our study did not identify unexpected malignant adenopathy in the setting of suspected vaccine-related adenopathy on breast MRI, larger studies are needed to confirm our results.

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a minimum of five years of clinical experience in breast imaging interpretation) using the terminology of the BI-RADS atlas. The studies were not double read.

The original clinical study interpretation made by the interpreting radiologist’s assessment of the presence of adenopathy was used for study purposes. Studies were not secondarily reviewed by the authors. Criteria for adenopathy were based on the judgement of the interpreting radiologist alone.

Studies were performed using a breast specific 16-channel coil on 1.5T MRI systems from several different imaging vendors (Siemens Sola, Siemens, Erlangen, Germany; Siemens Espree, Siemens, Erlangen, Germany; and GE Signa, GE Healthcare, Chicago, IL). Full protocol MRIs included the following sequences: localizer sequence, axial T1 non-fat-saturated, axial T2-weighted short tau inversion recovery (STIR), axial T1 fat-saturated, three axial dynamic post-contrast T1 fat-saturated (imaging at injection, 90 seconds after injection, and 6.5 minutes after injection), and diffusion-weighted imaging. Three subtraction imaging sequence were created from the post-contrast images. Sagittal reformatted imaging was created from the second post-contrast imaging. Maximum intensity projections were created from all three subtraction sets. Abbreviated MRIs included the following sequences in the axial plane: axial STIR, T1 fat-saturated, one post-contrast T1 fat-saturated imaging (imaging 20 seconds after injection), and diffusion-weighted imaging. MultiHance (gadobenate dimeglumine) (Bracco Diagnostics, Princeton, NJ) was injected at 2 mL·s⁻¹ (0.1 mmol·kg⁻¹) followed by a 20-mL saline flush for all studies. All studies were interpreted on the same type of workstation (sectra, SECTRA, Linkoping, Sweden).

Statistical Analysis
The Pearson chi-square test was used for all variables in Table 1 unless otherwise noted. Analyses for Table 1 were performed using SPSS Software, version 23.0 (SPSS, Inc., Chicago, IL, USA). Differences in the final assessment categories between the subjects scanned pre-pandemic and post-vaccine were compared by using the Fisher exact test. A P-value of less than 0.05 was considered to indicate a statistically significant difference. All statistical tests were two-sided and performed by using Stata 14.2 software (Stata, College Station, TX).

Results
In the post–vaccine approval group, 1912 breast MRI examinations were performed. In the pre-pandemic group, 5342 breast MRI examinations were performed. There were no statistically significant differences in patient characteristics (Table 1). There were minimal statistically significant differences between assessment of fibroglandular tissue (FGT) and background parenchymal enhancement (BPE) in both cohorts (Table 1).

There were no statistically significant differences in BI-RADS 1, 2, 5, or 6 final assessments between both groups (P = 0.41, P = 0.55, P = 0.49, and P = 0.28, respectively) (Table 2). There was, however, a statistically significant increase in overall BI-RADS 0 assessments between the post-vaccine and pre-pandemic groups of 1.8% (34/1912) versus 0.8% (45/5342), respectively (P = 0.001) and BI-RADS 3 assessments, 9.2% (176/1912) versus 6.5% (348/5342) (P < 0.0001). There was also a statistically significant difference in BI-RADS 4 assessments, 14.3% (273/1912) post-vaccine versus 10.9% (581/5342) pre-pandemic (P < 0.0001).

A total of 79 studies that included mention of the queried search terms were found. Of the these, 12 were excluded as the findings discussed in the report were not secondary to vaccination. A total of 67 studies were found to include mention of vaccination and adenopathy (66 in the post-COVID-19 vaccination approval group and one in the pre-COVID-19 pandemic group). Within the post-vaccine approval group, 3.5% (66/1912) of studies included comments on assumed vaccine-related adenopathy, compared with 0.02% (1/5342, influenza) from the comparison year (P < 0.0001). The remaining studies were from COVID-19 vaccinations (n = 64) (Figure 1), one from a varicella vaccination, and one from a pneumococcal vaccination. In the post–vaccine approval group, the management recommendation regarding vaccine-related adenopathy matched the overall study recommendation for 52 patients (Table 3). Vaccination-related adenopathy accounted for 24% (8/34) of the overall BI-RADS 0 recommendations and 17% (30/176) of overall BI-RADS 3 recommendations.

In 14 patients within the post-vaccine approval group, the overall BI-RADS study recommendation was driven by in-breast findings. Thus, the vaccine-related adenopathy specific recommendation differed from the overall BI-RADS study recommendation. Biopsy (BI-RADS 4) of a separate finding was recommended in 5 patients; within this subset, vaccine-related adenopathy was recommended for additional imaging in 4 patients (BI-RADS 0, n = 1; or BI-RADS 3, n = 3) and was deemed benign in 1 patient (BI-RADS 2). Management of known malignancy (BI-RADS 6) was recommended for 9 patients; within this subset, vaccine-related adenopathy was deemed benign in seven patients (BI-RADS 1 or 2), was recommended for short-term follow-up in one patient (BI-RADS 3), and was recommended for biopsy in one patient (BI-RADS 4).

The majority, 77% (51/66), of MRIs that mentioned vaccination-related adenopathy were performed in women who were at high risk for breast cancer or who had a current or past breast cancer diagnosis. Other indications included staging of recently diagnosed malignancy (13.6%, 9/66), abbreviated MRI screening for women with dense breasts (10.6%, 7/66), follow-up of a probably benign lesion (6.1%, 4/66), further evaluation of a symptom (6.1%, 4/66), and to assess neoadjuvant response (1.5%, 1/66).
The Moderna and Pfizer-BioNTech vaccines were given with near-equal frequency in our study population (37.8% (25/66) and 36.3% (24/66), respectively). Two non–COVID-19 vaccines were assumed to result in vaccine-related adenopathy (1 shingles and 1 pneumonia). Vaccine manufacturer was unknown for 22.7% (15/66) of patients with lymphadenopathy.
MRIs in patients with vaccine-related adenopathy were performed within days of a first or second vaccination, but also two months following second vaccination, with an average of 13.6 days following first vaccination (range, 4-29 days; n = 18) and 20.9 days following second vaccination (range, 1-66 days; n = 39). There were nine patients who did not have documented vaccination dates at the time they underwent breast MRI.

The majority of patients who were recommended for additional imaging or biopsy have undergone follow-up studies to date (64.6%, 31/48) (Figure 2). All patients who were recommended for additional imaging were also recommended for targeted axillary US. Of the 43 patients recommended for targeted axillary US, 17 were evaluated as benign/negative, 9 were recommended for an additional short-term follow-up US, 1 was recommended for biopsy (with subsequently benign pathology), and 16 had not returned for additional imaging. Of the five patients recommended for biopsy, three were not performed because on the day of biopsy the US revealed benign or probably benign findings, and one was performed as a sentinel lymph node biopsy with benign results.

In patients who were recommended for an axillary US after breast MRI, a negative/benign assessment was more likely when imaging was performed six or more weeks after the second vaccination. Studies with benign/negative (BI-RADS 1 or 2) assessments were performed, on average, 60.9 days from second vaccination, compared with studies with probably benign (BI-RADS 3) assessments being performed an average of 42.4 days after second vaccination.

**Discussion**

COVID-19 vaccination is associated with ipsilateral axillary adenopathy on imaging, including mammography and breast

| BI-RADS 0 | Pre-Pandemic Cohort (N = 5342), n (%) | COVID-19 Vaccine Cohort (N = 1912), n (%) | P-value |
|-----------|--------------------------------------|---------------------------------------------|---------|
| BI-RADS 1 | 45 (0.8)                             | 34 (1.8)                                   | 0.001*  |
| BI-RADS 2 | 903 (16.9)                           | 307 (16.0)                                 | 0.41    |
| BI-RADS 3 | 2085 (39.0)                          | 731 (38.2)                                 | 0.55    |
| BI-RADS 4 | 348 (6.5)                            | 176 (9.2)                                  | <0.0001*|
| BI-RADS 5 | 581 (10.9)                           | 273 (14.3)                                 | <0.0001*|
| BI-RADS 6 | 29 (0.5)                             | 13 (0.4)                                   | 0.49    |
| Unknown  | 823 (15.4)                           | 211 (11.1)                                 | 0.28    |

P-values in bold denote significance.

**Figure 1.** Sequential MRIs from a 29-year-old woman with a known left breast estrogen receptor–positive, human epidermal growth factor receptor (HER2-neu) overexpressed invasive ductal carcinoma. The patient received COVID-19 vaccinations (Pfizer) in her right arm in late January and mid-February, 2021. Sequentially obtained MRIs as part of a clinical trial revealed vaccine-related adenopathy (arrow) and surrounding soft tissue edema (arrowheads) after first dose (A), continued adenopathy three days after the second vaccine with improvement of edema (B), decrease in size of adenopathy one month after the second vaccine (C), and near complete resolution at three months following the second vaccine (D). Abbreviation: STIR, short tau inversion recovery.
MRI. Management of this finding is controversial, as early guidelines, including those issued by the Society of Breast Imaging, are not yet validated by robust clinical data. In addition, recommendations for management on breast imaging have primarily focused on women who are at average risk undergoing screening mammography. Axillary adenopathy on breast MRI in the setting of recent COVID-19 vaccination poses a unique challenge, as this cohort of patients is at higher risk of breast cancer. Our study represents a large retrospective analysis of the time course and outcomes of assumed lymphadenopathy secondary to COVID-19 vaccination in a high-risk population and in women undergoing supplemental MRI for high breast density.

Our two cohorts were well matched in age, race, and body mass index. There were some statistically significant differences in assessment of FGT and BPE between both cohorts. Neither FGT nor BPE likely has any clinical impact on interpreting the presence or absence of adenopathy, as evaluation of the axilla is not limited by FGT or enhancement of breast tissue.

The results of our study demonstrate higher rates of unilateral axillary adenopathy that is assumed to be secondary to vaccination on breast MRI in the era of COVID-19 vaccination (3.5% of studies, compared to just 0.02% in the pre-pandemic cohort). Our study also found an increase in BI-RADS 0, BI-RADS 3, and BI-RADS 4 assessments secondary to this finding, which may affect future audit outcomes. This shift has resulted in additional targeted axillary USs and an increase in biopsies performed for axillary adenopathy.

Our results are consistent with early data showing high rates of adenopathy secondary to COVID-19 vaccination. Recent studies have found vaccine-related adenopathy in 13% of patients who were recently vaccinated and underwent PET-CT (14), 44% of patients who were vaccinated and underwent mammography (15), and 9% of patients who were vaccinated and underwent chest CT because of thoracic malignancy (16). Our rate of vaccine-related adenopathy is lower than these studies because we included all patients who underwent MRI, regardless of vaccination status.

Several multidisciplinary expert groups released early recommendations suggesting that, in the setting of isolated axillary adenopathy ipsilateral to the site of recent (within six weeks) COVID-19 vaccination, and without a concurrent cancer diagnosis, the adenopathy may be deemed benign without need for additional imaging (17,18). Our early outcome results suggest supporting these recommendations for vaccine-related adenopathy on breast MRI. Although our study population was composed mostly of women at an elevated lifetime risk of breast cancer, all patients who completed additional imaging and/or lymph node biopsy were ultimately deemed benign. As our study is small with limited follow-up data, additional studies with larger patient populations and longer follow-up times are warranted to validate this recommendation. If a benign assessment is made in this high-risk population, clinical follow-up should be performed. If adenopathy persists on physical examination two months after vaccination, the patient should return for additional imaging. Finally, if any features of adenopathy are suspicious or if there are suspicious in-breast findings, biopsy should not be deferred. Additional studies could be performed to create a standardized criteria that would grade vaccine-related adenopathy and differentiate between potentially suspicious adenopathy.

Our results have important implications for the time course of MRI-detected adenopathy following COVID-19 vaccination. Although adenopathy was seen on MRI an average of two weeks following the first vaccine dose and three weeks following the second dose, it was also seen more than two months following the second dose. This suggests that vaccine-related adenopathy may persist on imaging well beyond the four to six weeks that was initially expected (10,11,17,18). Additionally, on follow-up imaging, nine patients had persistent adenopathy and were recommended for a second follow-up examination. Our study found that patients who were given a benign/negative assessment of their MRI-detected vaccine adenopathy on US were more likely to have been imaged two months after their last vaccine versus those who were imaged at a shorter interval. The

| Same Overall and Lymph Node BI-RADS (N = 52), n (%) | Differing Recommendations (N = 14) |
|--------------------------------------------------|----------------------------------|
| Overall BI-RADS, n (%) | Lymph Node–Specific BI-RADS, n (%) |
| BI-RADS 0 | 8 (15.4) | 0 |
| BI-RADS 1 | 1 (1.9) | 0 |
| BI-RADS 2 | 9 (17.3) | 0 |
| BI-RADS 3 | 30 (57.7) | 0 |
| BI-RADS 4 | 4 (7.7) | 5 (35.7) |
| BI-RADS 5 | 0 | 0 |
| BI-RADS 6 | 0 | 9 (64.3) |

Table 3. Overall BI-RADS Recommendations Versus Lymphadenopathy-Specific Recommendations in the Post-Vaccine Cohort
current Society of Breast Imaging guidelines recommend repeating imaging six to eight weeks following the second dose. Based on our data, a longer follow-up period is warranted, as adenopathy related to the COVID-19 vaccine can persist on imaging for more than two months post-vaccination.

Our study has limitations. The study was performed at a single institution. Like other retrospective studies, the study is limited by selection bias and variables that may influence the results. Based on the study design, we were unable to capture patients who underwent breast MRI following vaccination but did not have radiologic evidence of adenopathy. Thus, we could not calculate the true prevalence of adenopathy on imaging following COVID-19 vaccination. Further research could examine the relationship between the absence of lymphadenopathy on imaging and time since vaccination. Additionally, as studies were interpreted by multiple radiologists, we could not control for differences in reader sensitivity for adenopathy (ie, differences in readers’ thresholds for calling lymphadenopathy). Determination of the presence of adenopathy was based on the opinion of the interpreting radiologist—we did not independently measure lymph node size or evaluate lymph node morphology. There are likely additional MRI cases with mild, or borderline, lymphadenopathy that we were unable to capture in our data analysis. Finally, there were statistically significant differences in frequency of BI-RADS 3 and BI-RADS 4 assessments between the COVID-19 vaccination study time period and the prior comparison period that are not entirely explained by vaccine-related adenopathy. Additional biopsy recommendations or short-term follow-up recommendations may be secondary to pandemic-related delays in care or other variables. Our study design did not allow a full analysis of these differences. It is possible that individual reader variability, including differences in percentages of studies per reader between the two time periods, may contribute to these differences. However, our study design did not support a reader-based analysis. Finally, our larger study population included second interpretations of outside MRIs. It is possible that MRI parameters from outside institutions may influence the ability to detect axillary adenopathy.

**Conclusion**

In summary, our study represents an initial evaluation of vaccine-related adenopathy seen on breast MRI. Our results demonstrate that COVID-19 vaccination leads to additional imaging follow-up in women undergoing breast MRI, so far with all benign outcomes. Further research should be performed to determine whether vaccine-related adenopathy may be assessed as benign when first detected on MRI. Finally, our data demonstrate that adenopathy can be identified for at least two months following vaccination.

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Conflict of Interest Statement

None declared.

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