Original Investigation

COVID-19 Vaccine-Associated Subclinical Axillary Lymphadenopathy on Screening Mammogram

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Background: Women who received a COVID-19 vaccination may display subclinical unilateral axillary lymphadenopathy on screening mammography, which can appear suspicious for malignancy, leading to additional diagnostic evaluation.

Purpose: To evaluate the prevalence of subclinical unilateral axillary lymphadenopathy (sLAD) on screening mammogram in women who received either the first or second dose of the Pfizer-BioNTech (Pfizer) or Moderna COVID-19 vaccines compared to women who have not.

Materials and Methods: In this IRB-approved, HIPAA complaint study from 12/14/2020 to 4/14/2021, 1027 patients presented for screening mammography and met study inclusion criteria. Patients with history of baseline lymphadenopathy or prior cancer diagnosis were excluded.

Results: : Of the 1027 women, 43 were recalled for unilateral sLAD. 34 women received a COVID-19 vaccination ipsilateral to the sLAD (Pfizer n=19, 44.2%; Moderna n=15, 34.9%), 9 did not (20.9%). Incidence of unilateral axillary sLAD was significantly higher (p-value$<$0.01) in those who received a COVID-19 vaccination within approximately 7 weeks preceding screening mammogram. 13.2% of patients who received the Pfizer vaccine and 9.5% of patients who received the Moderna vaccine developed sLAD. Moderna's vaccine elicited a more robust reaction in the elderly (Moderna 63.7 years vs. Pfizer 59.7 years). For both vaccines, sLAD resolved on average 46.5 days after the last COVID-19 vaccine (p=0.44).

Conclusion: Women who have received either mRNA COVID-19 vaccines may benefit from scheduling their screening mammogram before vaccination or consider delaying screening mammography 8 weeks. While Pfizer may have an overall more robust immune response, Moderna may elicit a stronger immune response in elderly women.

Summary: Women who received a COVID-19 vaccination before screening mammography were significantly more likely to present with subclinical axillary lymphadenopathy than women who did not receive the vaccine.

Key Results: 13.2% of women who received a Pfizer-BioNTech vaccine exhibited subclinical axillary lymphadenopathy compared to 9.5% of those who received the Moderna vaccine. Only 1.2 % of those who did not receive a vaccine presented with subclinical unilateral axillary lymphadenopathy. The average time of resolution of the lymphadenopathy on diagnostic mammogram was 46.5 days overall, with Pfizer-BioNTech taking 50.7 days and Moderna 41.5 days.

Abbreviation: LAD lymphadenopathy, **sLAD** subclinical lymphadenopathy, **DM** diagnostic mammogram, **Pfizer** Pfizer-BioNTech

INTRODUCTION

This retrospective study aims to analyze the proportion of female screening mammography patients who develop subclinical unilateral axillary lymphadenopathy in response to receiving either the Pfizer-BioNTech (Pfizer) or Moderna COVID-19 vaccine, starting with the date the first COVID-19 vaccination was given in the United States, December 14, 2020, in order to determine if screening mammogram institutional guidelines should be updated to include COVID-19 vaccination status and timeline. This research will help guide clinical decision-making in regards to breast cancer screening in women who have received the COVID-19 vaccine in order to decrease the number of unnecessary diagnostic tests as more patients in the US receive these vaccines, or receive booster vaccinations in the future.

Unilateral axillary lymphadenopathy in the setting of uncertain etiology on a routine screening mammogram can be concerning for breast cancer, and warrants further diagnostic workup in the form of diagnostic mammography, ultrasound, biopsy, or a combination of these. However, this unilateral axillary lymphadenopathy can be a normal sign of

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