Lymphadenopathy subsequent to Covishield (ChAdOx1 nCoV-19) Coronavirus virus vaccine: ultrasound findings and clinical implications

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Abstract

Introduction: Post anti-COVID-19 vaccine lymphadenopathies have been recently described in literature, from different parts of the world. Although there have been studies on lymphadenopathy following mRNA vaccines, there is a paucity of studies on lymphadenopathy following inactivated viral vaccines, such as Covishield.

Aim: In this study, we explored lymphadenopathy subsequent to Covishield vaccine in terms of its various ultrasound parameters in the Indian population.

Methods: This hospital-based longitudinal study was conducted among 50 adult beneficiaries of Covishield vaccine. Sociodemographic details and relevant clinical history were recorded using a semi-structured performa. Detailed ultrasound (USG) examination of the bilateral axillae was done on the day of vaccination and after 6–12 days post-vaccination. Vaccine beneficiaries were evaluated for the presence of any vaccine-associated lymphadenopathy and described the presence, number, size, morphology, cortical thickness, and presence or absence of echogenic hilum.

Results: Out of total (63) lymph nodes evaluated sonologically, majority (80.9%) of lymph nodes showed the features of benign lymphadenopathy. However, 12.6% (8/63) lymph nodes showed diffusely thickened cortex with preserved central echogenic hilum, 4.76% (3/63) lymph nodes showed eccentric cortical thickness with preserved hilar pattern, while only one lymph node showed diffuse cortical thickening with loss of central echogenic hilum.

Conclusion: With an increase in vaccination coverage, clinicians are likely to confront increasing cases of vaccine-associated axillary lymphadenopathy. Therefore, they should exercise care, that contemporary anti-COVID-19 vaccination can present an aetiology of axillary lymph nodes with suspicious USG features.

Keywords: COVID-19, Covishield, vaccine lymphadenopathy, ultrasound

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was carried out, and the development of vaccines was undertaken on a priority basis. Within a short span of time, a number of candidate vaccines were available for public use, making the emergency use of anti-COVID-19 vaccines, the fastest rollout of vaccines for a disease in the history of mankind.3

The initial vaccines which were in the fray were mRNA vaccines by Pfizer and Moderna, Oxford-AstraZeneca Covishield (ChAdOx1 nCoV-19 or AZD1222), and Gamaleya Research Institute of Epidemiology and Microbiology (Sputnik V) introduced in different parts of the world.4,5 In India, Covishield and indigenously developed Covaxin (BBV152) were the vaccines which were predominantly used. Vaccination drive against COVID-19 was launched in India on 16 January 2020.6 Till 31 March 2022, 11.35 billion doses of vaccines have been given around the world. India alone by this period, has completed 1.84 billion doses of vaccines. Subsequent to the use of anti-COVID-19 vaccines for public use, there have been some cases of lymphadenopathy reported. Moreover, present-day studies have reported cases of unilateral axillary and supraclavicular adenopathy associated with various anti-COVID-19 vaccines. Lymphadenopathy has been reported as 0.3% and 1.1% of Pfizer-BioNTech and Moderna vaccines, respectively.7,8 As vaccination has progressed, there have been increased instances of regional adenopathy reported, as an incidental finding in different imaging modalities. Ultrasound (USG) examination represents the first-line imaging method due to its speed, availability, low cost and repeatability.9,10 Incidentally detected post anti-COVID-19 vaccine in supraclavicular and axillary lymph nodes may imitate pathological lymph nodes.

Although there have been studies on lymphadenopathy following mRNA vaccines, there is a dearth of studies on lymphadenopathy following inactivated viral vaccines, such as Covishield. To the best of our knowledge, there have been no studies in this regard in the Indian population. Therefore, in this study, we explored lymphadenopathy subsequent to Covishield vaccine in terms of its various USG parameters. We evaluated vaccine beneficiaries for the presence of any vaccine-associated lymphadenopathy and described the presence, number, size, morphology, cortical thickness, and presence or absence of echogenic hilum.

Methodology

Study population and setting
This is a hospital-based longitudinal study conducted in the month of August 2021 at the radiology department of a tertiary medical institution in North India. We included 50 recipients of Covishield vaccine who gave their consent for the study and satisfied the inclusion and exclusion criteria. Systematic random sampling was followed for the selection of the study participants and every 10th beneficiary who underwent vaccination at the Covid vaccination centre of the institute was screened for eligibility and included after written informed consent.

Inclusion and exclusion criteria
Adult beneficiaries coming for Covishield vaccine were included according to the sampling strategy after briefing them about the study process and procedures and taking consent. Adults with significant axillary lymphadenopathy detected by USG on the day of vaccination or with the history of any malignancy or pulmonary/systemic disease which could result in axillary lymphadenopathy, were excluded. In case the 10th person did not satisfy the eligible criteria, the next beneficiary was assessed for eligibility, and included. The process was continued till the recruitment of the study participants was completed. Sociodemographic details and relevant clinical history were recorded using a semi-structured performa.

Imaging modality
USG was performed using Alpinion E-cube i7 machine. Patient was positioned supine on the examination table. Detailed examination of the bilateral axillae was done on the day of vaccination and after 6–12 days post vaccination. USG images of each patient were assessed for the presence and level of lymph nodes, their number, size, morphology, cortical thickness, and the presence or absence of echogenic hilum. All necessary protocols were adhered to during the procedure.

Statistical analysis
Data were entered into MS Excel and analysed using IBM SPSS Statistics for Windows, Version 20.0 (IBM Corp., Armonk, NY). Frequency was expressed using proportion and percentages.
Normally distributed data were presented as mean (±SD), and categorical variables as frequency (%). Categorial variable (lymphadenopathy) was compared with the sociodemographic variables using Chi-square test/ Fisher’s exact test. A p-value was assessed at significance level of less than 0.05.

**Ethical permission**
The study was approved by the Institute Ethics Committee vide letter number IEC/AIIMS/BTI/133. All necessary protocols were adhered to and confidentiality was maintained throughout the study. Participants were briefed about the objectives of the study before being enrolled in the study, and informed written consent was taken.

**Results**
A total of 50 beneficiaries were included in the study and 63 lymph nodes in total were evaluated. Participants were near equally distributed in the youngest (18–30 years) 18 (36%) and elderly 19 (38%) years age group. About three-fourths, 38 (76%) of the participants were males. Five beneficiaries had a previous positive history (at least 3 months before) of Covid infection. Nearly two-thirds 32 (64%) of the participants had associated comorbidities (hypertension, diabetes, obesity, and liver disease). However, 11 (22%) of the study participants reported lymphadenopathy on the day of vaccination. Majority, 38 (76%) of the participants were diagnosed with lymphadenopathy on USG 1 week following vaccination. Among those in whom lymphadenopathy was found, majority 25 (65.7%) showed multiple lymph nodes (Table 1).

Out of total (63) lymph nodes evaluated sonologically, majority (80.9%) of lymph nodes showed features of benign lymphadenopathy, that is, well-defined oval shape, uniformly thin cortex with preserved central echogenic hilum which formed bulk of the node [Figure 1(a)]. About 12.6% (8/63) lymph nodes showed diffusely thickened cortex with preserved central echogenic hilum [Figure 1(b)], 4.76% (3/63) lymph nodes showed eccentric cortical thickness with preserved hilar pattern [Figure 1(c)] while only 1.5% (1/63) of lymph nodes showed diffuse

**Table 1.** Frequency distribution of the characteristics of vaccinated individuals in the study (N=50).

| Variable                                         | N (%)   |
|--------------------------------------------------|---------|
| **Age group (years)**                            |         |
| 18–30                                            | 18 [36] |
| 31–60                                            | 13 [26] |
| >60                                              | 19 [38] |
| **Sex**                                          |         |
| Male                                             | 38 [76] |
| Female                                           | 12 [24] |
| **History of COVID-19 infection**                |         |
| Yes                                              | 5 [10]  |
| No                                               | 45 [90] |
| **Comorbidities**                                |         |
| Yes                                              | 18 [36] |
| No                                               | 32 [64] |
| **Lymphadenopathy (reactive) on the day of vaccination** |         |
| Yes                                              | 11 [22] |
| No                                               | 39 [78] |
| **Lymphadenopathy after 1 week of vaccination**  |         |
| Yes                                              | 38 [76] |
| No                                               | 12 [24] |
| **Multiple lymphadenopathy (n=38)**              |         |
| Yes                                              | 25 [65.7] |
| No                                               | 13 [34.3] |
| **Lymph node characteristics on USG (n=63)**     |         |
| Oval with uniformly thin cortex and preserved echogenic hilum | 51 [80.9] |
| Diffuse cortical thickening with preserved echogenic hilum | 8 [12.69] |
| Diffuse cortical thickening with loss of central echogenic hilum | 1 [1.58] |
| Eccentric cortical thickness with preserved echogenic hilum | 3 [4.76] |
cortical thickening with loss of central echogenic hilum [Figure 1(d)].

On univariate analysis, using Chi-square/Fisher’s exact test, only lymphadenopathy (benign/reactive) on the day of vaccination was found to be significantly associated with the presence of lymphadenopathy status post vaccination ($p=0.04$) (Table 2).

**Discussion**

Association of anti-COVID-19 vaccines with ipsilateral axillary lymphadenopathy is being increasingly described in literature. Conventionally, this vaccine is administered intramuscularly in left deltoid muscle. Axillary lymph nodes receive lymphatic drainage from ipsilateral breast, arm, thoracic wall and upper abdominal wall. Thus, any infective, inflammatory or mitotic aetiology involving the draining sites may result in ipsilateral axillary lymphadenopathy. Migration of locally activated antigens from injection site to draining lymph nodes results in vaccine-associated lymphadenopathy. These enlarged lymph nodes may be detected incidentally on screening or follow-up imaging of cancer patients. Whether these lymph nodes are benign or malignant pose a great diagnostic dilemma for clinicians and radiologists, thereby having a substantial impact on patient management strategy.
Table 2. Association between lymphadenopathy and other variables.

| Variable                                      | Lymphadenopathy present | Lymphadenopathy absent | p value |
|-----------------------------------------------|-------------------------|------------------------|---------|
| Age group (in years)                          |                         |                        | 0.63    |
| 18–30                                        | 15                      | 3                      |         |
| 31–60                                        | 9                       | 4                      |         |
| >60                                          | 14                      | 5                      |         |
| Sex                                           |                         |                        | 0.49    |
| Male                                          | 28                      | 10                     |         |
| Female                                        | 10                      | 2                      |         |
| History of COVID-19 infection                 |                         |                        | 0.37    |
| Yes                                           | 3                       | 2                      |         |
| No                                            | 35                      | 10                     |         |
| Comorbidities                                 |                         |                        | 0.82    |
| Yes                                           | 14                      | 4                      |         |
| No                                            | 24                      | 8                      |         |
| Lymphadenopathy on the day of vaccination     |                         |                        | 0.04*   |
| Yes                                           | 11                      | 0                      |         |
| No                                            | 27                      | 12                     |         |

*Significant, Fisher’s exact value.

USG is the modality of choice for evaluating axillary lymph nodes due to its high sensitivity and specificity. Various morphological features of lymph nodes have been described to distinguish benign versus malignant lymph nodes. Normal or benign lymph nodes show oval or lobulated shape with uniformly thin hypoechoic cortex measuring less than 3 mm in thickness. Benign lymph nodes show central echogenic hilum. Increase in lymph node size (>2 cm), round shape, loss of central fatty hilum and diffuse or focal cortical thickness >3 mm predict malignancy as cause of lymphadenopathy.

In literature, axillary lymphadenopathy as a side effect of vaccination, has been reported previously in few recipients of Bacillus Calmette-Guerin, influenza and human papilloma virus vaccine. Although the mRNA vaccines being used against COVID-19 are safe, but they are associated with few side effects. The most common side effect includes pain at injection site, fever, tiredness, headache and ipsilateral axillary lymphadenopathy. Axillary swelling ipsilateral to injection site has been reported in 11.6% and 16% of patients receiving first and second dose of Moderna COVID-19 vaccine. Incidence of ipsilateral axillary lymphadenopathy has been reported to be <1% for Pfizer-BioNTech and AstraZeneca vaccine and 0.1% for Janssen vaccine.

In our study, about 76% of patients showed ipsilateral axillary lymphadenopathy and 65.7% showed multiple lymph nodes. We found lymphadenopathy in every age group similar to study by Cocco et al., while another study reported increased incidence in younger age group (<40 years). In the study by Cocco et al., evaluating the multiparametric USG findings of
COVID vaccine-associated lymphadenopathy in 24 patients, 11 (45.8%) showed ipsilateral axillary lymphadenopathy and 13 patients (54.2%) showed supraclavicular lymphadenopathy. Majority of the patients (75%) showed benign lymph node features, while 37.5% of patients showed asymmetric cortical thickness. Granata et al. also demonstrated varying USG appearances of vaccine-associated lymphadenopathy. A study from the United States by Mortazavi et al. revealed lymph nodes with diffuse or focal cortical thickening in 29 (42.6%) cases and preserved hilar fat in one case. Necrotic lymph node appearing hypoechogenic with loss of blood flow has been described in a single case. Apart from the common nodal sites (axillary, supraclavicular), there have been reports of lymphadenopathy in atypical sites (infraclavicular, pectoralis major and nuchal) in a study by Cocco et al. It can be attributed to a robust immune system spreading along the lymphatics. They should be evaluated with concern in high-risk patients with history of neoplasia, to avoid misdiagnosis.

Apart from USG, anti-COVID-19 vaccine-associated lymphadenopathy has also been detected on other imaging modalities, such as mammography, breast MRI and F-FDG-PET/CT posing a diagnostic conundrum.

According to fifth edition of BI-RADS, isolated unilateral axillary lymphadenopathy detected on screening mammography in the absence of history of any infectious/inflammatory cause is categorised as BI-RADS 0 and warrants additional imaging evaluation. In the absence of any infectious or inflammatory source in ipsilateral breast, it is categorised as BI-RADS 4 and warrants biopsy evaluation. Such increased incidence of vaccine-associated axillary lymphadenopathy has not been reported with any vaccination till date. Most subclinical cases of unilateral axillary
lymphadenopathy following anti-COVID-19 vaccination has been described in patients undergoing breast imaging.\textsuperscript{44,45} Therefore, this has led to subsequent recommendations from breast imaging societies. Society of Breast Imaging has given recommendations for the management of axillary lymphadenopathy in patients with recent anti-COVID-19 vaccination (Figure 2).\textsuperscript{46} Similar guidelines have been issued by European Society of Breast Imaging (Figure 3). It emphasises vaccine to be given in the contralateral arm or anterolateral thigh in patients with history of breast cancer.\textsuperscript{47}

The published literature so far is based on the clinical findings of axillary lymphadenopathy. Not all vaccine-associated axillary lymphadenopathy could be clinically evident so the incidence of vaccine-associated ipsilateral axillary lymphadenopathy would be much higher. Also, with the addition of third/booster dose, the cases of lymphadenopathy after vaccination are expected to rise. However, postvaccination lymphadenopathy may not pose significant concern to vaccinated individuals and should not deter the vaccination drive. However, they need to be kept in consideration, particularly in follow-up of malignancy patients.\textsuperscript{48} Clinicians must be vigil about the transient hypermetabolic regional lymph nodes and should evaluate the detailed vaccination history, without fail. Since most of these lymphadenopathies resolve spontaneously within 2 weeks, imaging modalities can be undertaken 4–6 weeks following vaccination as suggested by other studies.\textsuperscript{46,49} Observation for at least 6 weeks until resolution or short-term follow-up with USG with reassurance is recommended rather than immediate biopsy and change in treatment course, unless the patient has a medical emergency.

**Strengths and limitations of the study**

The single centre study with limited sample size and absence of long-term follow-up is one of the
critical limitations of the study. Also, pathological correlation was not established in our study. Nevertheless, to our knowledge, this is the first study in the Indian population evaluating lymphadenopathy subsequent to an inactivated anti-COVID-19 vaccine, Covishield. Even subclinical cases of lymphadenopathy were detected and characterised sonologically. This study adds to the growing body of literature about incident lymphadenopathy following anti-COVID-19 vaccinations that will guide clinicians in the management of patients, both with oncological disease and with patients with recently developing lymphadenopathy. Furthermore, prospective studies with a longer follow-up time and multicentric in approach can further substantiate the findings of our study.

**Conclusion**

With mass roll out of anti-COVID-19 vaccine and administration of booster doses, clinicians are likely to confront increasing cases of vaccine-associated axillary lymphadenopathy. Clinicians should exercise care, that a history of a recent anti-COVID-19 vaccine can present as an aetiology of axillary lymph nodes with suspicious USG features. Information regarding the vaccine type, site, dose and duration since vaccination should be collected prior to imaging. Patients with suspicious imaging findings should be kept on follow-up. Information regarding vaccine-associated lymphadenopathy should be disseminated to allay the recipient’s and clinician’s anxiety and avoid unnecessary biopsies, especially in cancer patients.

**Declarations**

**Ethical approval and consent to participate**

Ethical approval was obtained from the Institute Ethics Committee of AIIMS Bathinda, Punjab, India vide letter number IEC/AIIMS/BTI/133. Participants were briefed about the objectives of the study before being enrolled in the study, and informed written consent was taken.

**Consent for publication**

Not applicable.

**Author contributions**

**Soumya Swaroop Sahoo:** Formal analysis; Methodology; Supervision; Validation; Writing – review & editing.

**Navdeep Kaur:** Conceptualisation; Formal analysis; Investigation; Project administration; Resources; Software; Supervision; Writing – original draft; Writing – review & editing.

**Amandeep Kaur:** Conceptualisation; Formal analysis; Methodology; Writing – review & editing.

**Shivane Garg:** Investigation; Project administration; Software.

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**Availability of data and materials**

All the data supporting the findings of the study is available in form of tables and images within the article.

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