



Cervical and Axillary Lymphadenopathy After Administering mRNA BNT-162b2 Vaccine Against COVID-19: Clinical and Sonographic Findings, Outcomes of Short-term Follow-up

COVID-19'a Karşı Uygulanan mRNA BNT-162b2 Aşısı Sonrası Servikal ve Aksiller Lenfadenopati: Klinik ve Sonografik Bulgular, Kısa Dönem Takip Sonuçları

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ABSTRACT

Introduction: Vaccination plays an important role in all strategic actions against the COVID-19 pandemic. Despite the high safety and efficacy of vaccination, side effects of the vaccines may also occur. The purpose of this study was to evaluate the clinical and sonographic findings and short-term results of cervical and axillary lymphadenopathy after the BNT-162b2 mRNA vaccine.

Materials and Methods: The patients who received at least one dose of BNT-162b2 mRNA vaccine between July-September 2021 and were detected to have ipsilateral axillary and cervical lymphadenopathy related closely to the vaccination period, were included in the study. Clinical characteristics, sonographic findings of lymphadenopathies, and short-term results were analyzed retrospectively.

Results: A total of 13 patients [six females (46.2%), seven males (53.8%)] were evaluated in the present study. Mean age of the patients was 41.9 years (min-max= 20-56). Median time-lapse between vaccination and presentation to hospital was six days, and seven (53.8%) patients presented with symptoms and findings after the first dose, and six patients (46.2%) after the second dose. Three (23.1%) axillary lymphadenopathies, and 10 (76.9%) cervical lymphadenopathies were detected. Sonographic examination revealed lymphadenopathies predominantly oval morphology (69.2%), asymmetric cortical thickening (61.5%), and hilar-type vascularization (69.2%). Mean time of regression was found 19.2 days (min-max= 10-35).

Conclusion: Ipsilateral cervical and axillary lymphadenopathies may occur because of vaccines against COVID-19. The sonographic findings of these lymphadenopathies may not be distinguished clearly from malignant lymph nodes; and for this reason, close clinical and radiological follow-up would be appropriate to elucidate the process.

Key Words: Lymphadenopathy; Ultrasound; BNT-162b2 mRNA vaccine; Adverse event; Follow-up

ÖZ

COVID-19'a Karşı Uygulanan mRNA BNT-162b2 Aşısı Sonrası Servikal ve Aksiller Lenfadenopati: Klinik ve Sonografik Bulgular, Kısa Dönem Takip SonuçlarıUmur Anıl PEHLİVAN¹, Mehmet TORUN²¹ Van Başkale Devlet Hastanesi, Radyoloji Kliniği, Van, Türkiye² Van Başkale Devlet Hastanesi, Genel Cerrahi Kliniği, Van, Türkiye

Giriş: COVID-19 pandemisine karşı tüm stratejik yöntemler arasında aşılama, önemli bir rol oynamaktadır. Aşılamanın yüksek güvenlik ve etkinliğine rağmen, aşılardan yan etkileri de ortaya çıkabilir. Bu çalışmanın amacı BNT162b2 mRNA aşısı sonrası servikal ve aksiller lenfadenopatinin klinik ve sonografik bulgularını ve kısa dönem sonuçlarını değerlendirmektir.

Materyal ve Metod: Temmuz-Eylül 2021 tarihleri arasında en az bir doz BNT162b2 mRNA aşısı uygulanan ve aşılama dönemi ile yakın ilişkili ipsilateral aksiller ve servikal lenfadenopatisi saptanan hastalar çalışmaya dahil edildi. Klinik özellikleri, lenfadenopatilerin sonografik bulguları ve kısa dönem sonuçları retrospektif olarak analiz edildi.

Bulgular: Bu çalışmada toplam 13 hasta [altı kadın (%46.2), yedi erkek (%53.8)] değerlendirildi. Hastaların yaş ortalaması 41.9'du (min-maks= 20-56). Aşılama ile hastaneye başvuru arasındaki ortalama süre altı gündü ve yedi hasta (%53.8) ilk dozdan sonra, altı hasta (%46.2) ise ikinci dozdan sonra hastaneye başvurdu. Üç (%23.1) aksiller lenfadenopati, 10 (%76.9) servikal lenfadenopati saptandı. Sonografik incelemede lenfadenopatiler ağırlıklı olarak oval morfoloji (%69.2), asimetrik kortikal kalınlaşma (%61.5) ve hilar tip vaskülarizasyon (%69.2) özellikleri içeriyordu. Ortanca iyileşme süresi 19.2 gün olarak bulundu (min-maks= 10-35).

Sonuç: İpsilateral servikal ve aksiller lenfadenopatiler COVID-19'a karşı aşılardan dolayı ortaya çıkabilir. Bu lenfadenopatilerin sonografik bulguları malign lenf nodlarından net olarak ayırt edilemeyebilir ve bu nedenle sürecin aydınlatılması için yakın klinik ve radyolojik takip uygun olacaktır.

Anahtar Kelimeler: Lenfadenopati; Ultrason; BNT-162b2 mRNA aşısı; Yan etki; Takip

INTRODUCTION

The symptoms and findings of COVID-19 are quite non-specific ranging from asymptomatic processes to severe life-threatening pneumonia in infected individuals^[1]. Initially, COVID-19 was considered to be an isolated respiratory infection; however, it turned out to be a multisystemic disease over time^[2]. To control this multisystemic disease, periodic quarantines, various treatment strategies, and vaccine development projects were implemented globally. However, despite all these efforts, 258.164.425 cases and 5.166.192 deaths were reported worldwide because of COVID-19 when this article was prepared^[3]. Vaccination plays a very important role among the strategic moves in this respect^[4].

Although there are positive results on the safety and efficacy of vaccination, side effects regarding the vaccines may also be faced^[5,6]. After the approval of the vaccines by the United

States Food and Drug Administration, ipsilateral axillary and cervical lymphadenopathy cases were described after vaccine administration^[7-11]. These conditions cause anxiety in patients, and challenges for physicians in explaining this process, which has a wide spectrum of differential diagnosis^[5,12,13]. Axillary and cervical lymphadenopathies may be a manifestation of benign inflammatory/infectious processes as well as an indirect manifestation of breast and visceral malignancies^[14,15]. There are also articles in the literature from previous years on lymphadenopathies that develop after vaccinations^[16-18].

The purpose of the present study was to evaluate the clinical and sonographic findings along with short-term results of 13 patients who developed cervical and axillary lymphadenopathy after BNT-162b2 mRNA vaccine administration (Pfizer-BioNTech, Marburg, Germany).

MATERIALS and METHODS

This retrospective study had a single-center plan and was performed in accordance with the ethics standards of the Institutional Clinical Research Ethics Committee and with the 1964 Helsinki declaration. This study obtained approval from the Local Research Ethics Committee (Date: 24.11.2021, Decision No: 2021/21).

Patient Selection

A total of 13 patients were included in the study. The inclusion criteria for the study were: a) to apply to the hospital with axillary and cervical lymphadenopathy after BNT-162b2 mRNA vaccination (Pfizer-BioNTech, Marburg, Germany) between July and September 2021,

b) to be evaluated by ultrasound (US) at the time of application,

c) to be followed up clinically and/or by US for at least 30 days.

Those with any previously known oncological or hematological diseases were excluded from the study. In addition, those with any suspected findings or results about hematological, oncological, and rheumatological pathologies were also excluded.

Clinical, Sonographic Examination and Follow-up

The symptoms of admission during clinical examination, physical examination findings, and the day when the symptoms or findings were detected after the dose of the vaccine were recorded.

Ultrasound examinations were performed with Mindray DC-7 (Mindray Medical International Limited, Shenzhen, China) 5-10 MHz linear probe. Since several closely adjacent lymph nodes were detected in the localization where ultrasound scanning was performed, the largest lymph nodes were determined as the target lymph nodes. The localization, maximum size, morphology, cortex-hilum complex, and vascularity of the target lymph nodes were evaluated. In the follow-up, four patients were evaluated both clinically and with US. The other nine patients were evaluated only clinically. Relief in clinical symptoms and/or detecting more than 25% reduction in the largest size of the target lymph nodes on US

examination were considered recovery. The duration of recovery in the symptoms and findings of the patients in the follow-ups was recorded.

Statistical Analysis

The SPSS 23.0 Package Program was used for the statistical analyses of the data. Categorical measurements were summarized as numbers and percentages, continuous measurements as mean, standard deviation \pm minimum-maximum values.

RESULTS

A total of 11.922 BNT162b2 mRNA vaccines (Pfizer-BioNTech, Marburg, Germany), and 651 CoronaVac vaccines (Sinovac Life Sciences, Beijing, China) were administered in our region on the date when this study was conducted. None of the patients who received CoronaVac (Sinovac Life Sciences, Beijing, China) were observed to have axillary and cervical lymphadenopathy. However, there were 13 (0.11%) patients, with lymphadenopathy symptoms and findings, who received the BNT-162b2 mRNA vaccine (Pfizer-BioNTech, Marburg, Germany), and six of whom were females (46.2%) and seven (53.8%) males. Mean age of the patients examined was 41.9 years (min-max= 20-56). Mean age of the women was 46 (min-max= 37-48), and mean age of the men was 38.4 years (min-max= 20-56).

Seven (53.8%) patients after the first dose and six (46.2%) patients after the second dose applied with various symptoms such as cervical and axillary mobile palpable lesion, purulence in this localization, and tenderness in the area where the vaccine was administered. The symptoms were ipsilateral to the injection site in all patients, the symptoms were on the right side in one patient, and on the left side in the remaining 12 patients. Admission to hospital after vaccination ranged between three and nine days. Admission complaint was isolated painless mobile palpable lesion in 10 (76.9%) of our patients. Two of the remaining three patients had mobile palpable lesions accompanied by purulence and tenderness. Pain and a mobile palpable lesion were described by the other patient. Physical and US examinations revealed 3 (23.1%) axillary and 10 (76.9%) inferior cervical lymphadenopathies.

In addition, tenderness where the vaccine was administered, was detected in all patients. Sonographic evaluation revealed findings in favor of inflammatory processes in the neck compartments in one patient who had pain symptoms, and abscess formation accompanied by inflammatory processes in the neck compartments in two patients who described purulence.

Mean maximum size was 18 mm (min-max= 15-24) in the US examination for target lymphadenopathies. There was oval morphology in nine (69.2%), and round morphology in four (30.8%). Asymmetric cortical thickening was detected in eight (61.5%), symmetrical cortical thickening was found in three (23.1%), and absent hilum in two (15.4%). The color and power-mode Doppler examination of the target lymph nodes revealed no vascularity in two target lesions (15.4%) that were accompanied by abscess formation. Hilar-type vascularity was detected in nine (69.2%) of the remaining 11 target lymph nodes, and anarchic-type vascularity were detected in two (15.4%). All the findings are summarized in Table 1.

Percutaneous drainage was applied for lymphadenopathy in two abscess formations in which no vascularity was detected. The obtained material was purulent, and these two patients were administered amoxicillin plus clavulanate. Excisional biopsy was performed on patient seventh who had a 24 mm lymphadenopathy with round morphology and anarchic vascularity to exclude possible malignancy (Figures 1,2). The pathology result of the biopsy was reported as reactive lymphoid hyperplasia. In addition, breast US was performed on patient third, a female, who had anarchic vascularity and asymmetric cortical thickness lymphadenopathy for rule out breast pathology. Breast US was normal. Mammography, dynamic magnetic resonance imaging, and/or excisional biopsy were recommended; however, the patient denied all and preferred follow-up. It was observed that the symptoms and findings of this patient clinically regressed in 21 days.

It was observed after the short-term follow-up of the patients that the symptoms and findings were under control in all (Figure 3). Mean time of regression was found to be 19.2 days (min-max= 10-35).

DISCUSSION

Axillary and cervical lymphadenopathies can often be caused by inflammatory-infectious processes or they may rarely be the indication of malignant processes^[14,15]. Axillary and cervical regional lymphadenopathies, which were ipsilateral to the injection areas, were described previously because of mRNA vaccines that were developed against COVID-19, which is the most important agent at hand in the fight against the current pandemic^[7-11]. Although this was described in clinical studies, it is a source of concern for both patients and physicians since it involves a wide range of differential diagnoses^[5,12,13].

After the m-RNA vaccines that were developed against COVID-19, side effects were detected more commonly in young individuals (under 55 or 65 years old) and after the second dose^[12,13]. All 13 patients who were included in the present study, except for one, were under the age of 55, too. Seven of the patients described symptoms after the first dose, which contradicts the general data. Similar to these data, there were findings contradicting the expected general opinion. For example, in the study conducted by Cocco et al., 17 patients (70.8%), and in the case series of Mehta et al., three patients (75%) have been described to have symptoms and findings after the first dose^[11,15]. We believe that this may be because of the small size of our cases.

The detection time of any lymphadenopathy after mRNA vaccines developed against COVID-19 varies between 2-4 days. In general, lymphadenopathy is detected in the first 10 days in individuals administered with BNT-162b2 mRNA vaccine (Pfizer-BioNTech, Marburg, Germany) such as in our patient group. In this respect, the data obtained in the present study are in agreement with the expected application period. The lymphadenopathies that are associated with the mRNA-1273 vaccine (Moderna Inc., Massachusetts, USA) appear earlier than those associated with the BNT-162b2 mRNA vaccine (Pfizer-BioNTech, Marburg, Germany)^[12,13]. A comparison of these two vaccines could not be made in the present study because the mRNA-1273 vaccine (Moderna Inc., Massachusetts, USA) is not available in our country. However, a few

Table 1. The demographic, clinical, and radiological characteristics, and short-term follow-up findings of the patients who developed cervical and axillary lymphadenopathy after mRNA BNT-162b2 vaccine administration

Age	Gender	Presenta- tion symp- toms	Clinical findings	Vacc. dose	Vacc. type	Post- vacc. day	Lymp. mor- phology	Hilum and cortex assessment	Lymp vacular- ity	Lymph size (mm)	Treatment protocol	Antibio- therapy	Fol- low-up	Time of regres- sion (day)
1	F	Mobile palpable lesion	Sensitivity of vaccination zone	2 nd	Phiz-er-Bi-on-tech	5	Oval	Asymmetrical cortical thickening	Hilar	16	Follow-up	-	Clinical	18
2	M	Mobile palpable lesion, pain, purulation	Sensitivity of vaccination zone, abscess and deep neck inflammation	2 nd	Phiz-er-Bi-on-tech	7	Round	Hilum absent	None	19	Drainage, antibiotherapy and follow-up	Amoxicillin-clavulanate	Clinical and US	24
3	F	Mobile palpable lesion	Sensitivity of vaccination zone	2 nd	Phiz-er-Bi-on-tech	6	Oval	Asymmetrical cortical thickening	Anar-chic	17	Follow-up	-	Clinical	21
4	F	Mobile palpable lesion, pain, purulation	Sensitivity of vaccination zone, abscess and deep neck inflammation	1 st	Phiz-er-Bi-on-tech	9	Round	Hilum absent	None	20	Drainage, antibiotherapy and follow-up	Amoxicillin-clavulanate	Clinical and US	28
5	M	Mobile palpable lesion	Sensitivity of vaccination zone	2 nd	Phiz-er-Bi-on-tech	6	Oval	Asymmetrical cortical thickening	Hilar	15	Follow-up	-	Clinical	12
6	M	Mobile palpable lesion	Sensitivity of vaccination zone	1 st	Phiz-er-Bi-on-tech	5	Oval	Asymmetrical cortical thickening	Hilar	19	Follow-up	-	Clinical	15
7	F	Mobile palpable lesion, pain	Sensitivity of vaccination zone and deep neck inflammation	1 st	Phiz-er-Bi-on-tech	6	Round	Asymmetrical cortical thickening	Anar-chic	24	Surgical excision	-	Clinical and US	35
8	M	Mobile palpable lesion	Sensitivity of vaccination zone	2 nd	Phiz-er-Bi-on-tech	4	Oval	Symmetrical cortical thickening	Hilar	15	Follow-up	-	Clinical	10
9	M	Mobile palpable lesion	Sensitivity of vaccination zone	1 st	Phiz-er-Bi-on-tech	6	Oval	Asymmetrical cortical thickening	Hilar	18	Follow-up	-	Clinical	15
10	F	Mobile palpable lesion	Sensitivity of vaccination zone	2 nd	Phiz-er-Bi-on-tech	5	Oval	Symmetrical cortical thickening	Hilar	17	Follow-up	-	Clinical	19

Table 1. The demographic, clinical, and radiological characteristics, and short-term follow-up findings of the patients who developed cervical and axillary lymphadenopathy after mRNA BNT-162b2 vaccine administration

Age	Gender	Presentation symptoms	Clinical findings	Vacc. dose	Vacc. type	Post-vacc. day	Lymph. morphology	Hilum and cortex assessment	Lymph. vascularity	Lymph. level	Lymph. size (mm)	Treatment protocol	Antibio-therapy	Fol- low-up	Time of regres- sion (day)
11	42	M	Mobile palpable lesion	1 st	Phiz- er-Bi- on- tech	4	Oval	Asymmetrical cortical thickening	Hilar	Level 5	16	Follow-up	-	Clinical	15
12	37	F	Mobile palpable lesion	2 nd	Phiz- er-Bi- on- tech	6	Oval	Asymmetrical cortical thickening	Hilar	Level 5	16	Follow-up	-	Clinical	15
13	20	M	Mobile palpable lesion	1 st	Phiz- er-Bi- on- tech	3	Oval	Symmetrical cortical thickening	Hilar	Axillary	21	Follow-up	-	Clinical and US	28

F: Female, Lymph: Lymphadenopathy, M: Male, Morph: Morphology, US: Ultrasound, Vacc: Vaccine, Vasc: Vascularity.

cases were identified in the literature contradicting these generally accepted symptom onset times. Axillary and supraclavicular lymphadenopathies were also reported approximately two weeks after the use of the BNT162b2 mRNA vaccine (Pfizer-BioNTech, Marburg, Germany) and mRNA-1273 vaccine (Moderna Inc., Massachusetts, USA) [8,11,15]. However, some of these findings may have been detected later because they were detected incidentally. Thus, they could overestimate the onset time of symptoms and findings. On the other hand, atypical onset times could also be observed.

Level 4 and 5 cervical lymphadenopathies were detected at a rate of 76.9% in the present study. However, there are several other studies in the literature that have included pure supraclavicular, pure axillary, or both^[7-11]. In the study of Cocco et al., including patients who had involvement of both regions, an almost equal distribution (11 axillaries, 13 supraclavicular lymphadenopathies) has been reported, which is not in agreement with the present study^[11]. We believe that demonstrative data regarding the dominant involvement localization can only be obtained with larger case series and/or meta-analyses.

The patients who had a history of malignancy were not included in the present study. A history of malignancy has been defined in four patients in Cocco et al.'s study, and three patients in the study of Özitemiz et al.^[10,11]. Lymphadenopathies that occur after mRNA vaccine administration against COVID-19 will probably be a higher anxiety source in patients who have a history of malignancy than in the normal population. However, when unilateral axillary lymphadenopathy is detected within four weeks after vaccination, it may be beneficial to apply screening 4-12 weeks after the second dose of vaccine by questioning the vaccination history and saying that this may be a part of the vaccine-related immunization in line with the recommendations of the Society of Breast Imaging (SBI). Even, it is recommended that individuals with routine breast screening are screened before the first vaccination or 4-6 weeks after the second vaccination^[19]. Based on our current knowledge, there is not a consensus on

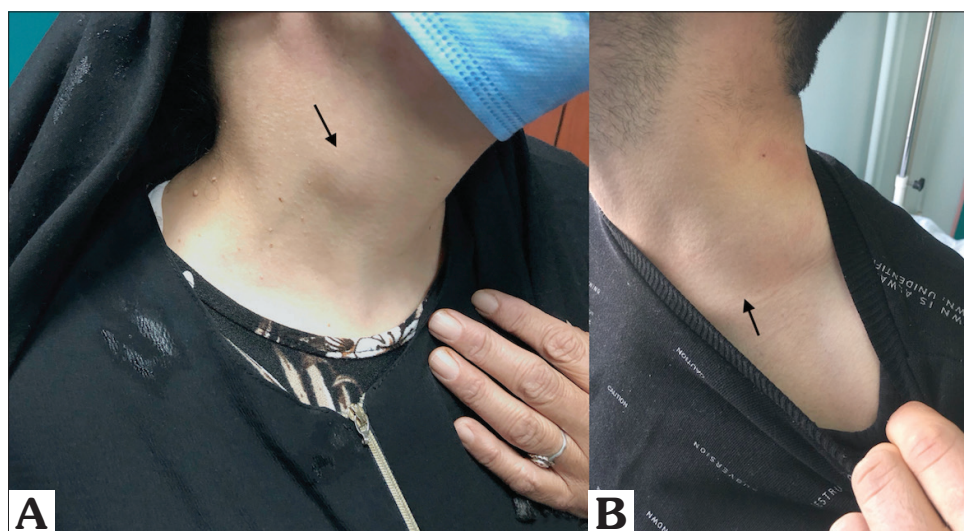


Figure 1. Level 4 and 5 cervical lymphadenopathies in patient 7th (A) and 9th (B) were detected at the time of physical examination.

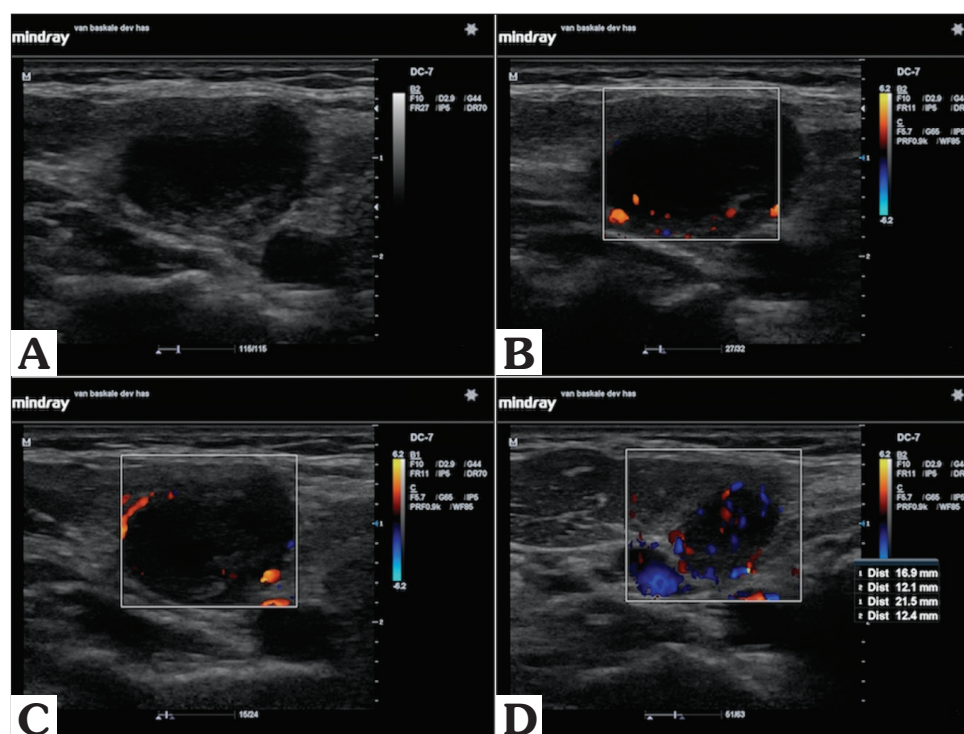


Figure 2. Target lymphadenopathy with nodular morphology and atypical anarchovascularity is seen in B mode (A) and color Doppler US (B,C) examination in patient 7th. One of the few lymphadenopathies that had similar morphology and vascular pattern in smaller size around this target lymphadenopathy is also shown (D).

cervical lymphadenopathies after the administration of the mRNA vaccine, which was developed against COVID-19, and we believe that a follow-up program would not be wrong in these cases,

which is similar to the recommendations of SBI. In support this hypothesis, no malignancies were identified in the cases followed up and even confirmed histopathologically, to the best of our

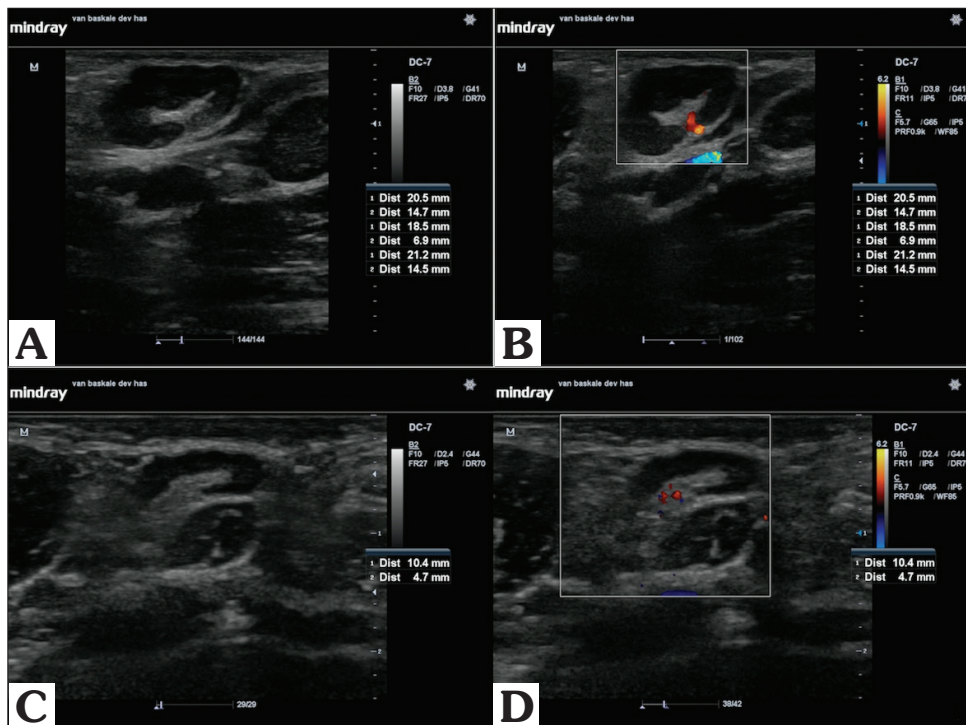


Figure 3. Target lymph node in Patient 13th that had symmetrical cortical thickening (A) and hilar type vascularity (B) at the time of diagnosis is seen. Regression findings in the target lymph node both in terms of size and morphology are seen in B mode (C) and color Doppler (D) US examination performed 28 days later (C,D).

knowledge at the time of writing of the present study.

Mean maximum size of the target lymphadenopathies of our patients was found to be 18 mm at admission. Although our findings were similar to the data reported by Mehta et al., they were slightly larger than the data reported by Cocco et al.^[11,15]. Target lymphadenopathies showed hilar-type vascularization (69.2%) dominantly oval morphology (69.2%) with asymmetric cortical thickening (61.5%). Aside from these findings, it must be kept in mind that lymph node that shows nodular morphology with anarchic vascularity (Patient 7th), which cannot be differentiated clearly from malignant lymph nodes, may also be faced. Since malignant processes were not ruled out in this particular case, excisional biopsy option was applied. The excised lymph node was interpreted as histopathologically reactive lymphoid hyperplasia. Axillary lymphadenopathy with asymmetric cortical thickening and anarchic type of vascularization was detected in another patient (Patient 3th), and

excisional biopsy was recommended. However, this patient preferred to be followed up and stated that the findings were under control after 21 days, and she did not want to come for follow-up after one month. Unfortunately, morphology of this lymphadenopathy could not be evaluated with follow-up US. Our data that were obtained from the morphological analysis of the target lymph node exhibited similar characteristics to the oval morphology that was described in Cocco et al.'s study (69.2% vs. 75%). Asymmetric cortical thickening was found as the dominant finding in our data that were obtained regarding the cortex-hilum complex of the target lymph node, which was also the case in Cocco et al.'s study but was detected to be at higher rates in our study, which is different (61.5% vs 37.5%). Our categorical group and the categorical group in the study of Cocco et al. differed in terms of the vascularization data of the target lymph node that were obtained with the color and power-mode Doppler. Cocco et al. have reported the incidence of central vascularity to be 45.8%,

both central and peripheral vascularity 50%, and isolated peripheral vascularity incidence of 4.2%. According to transform these data into the categorization in the present study, it would not be wrong to argue that they found an anarchic vascularity ratio is 4.2%, which is lower than the data of the present study^[11] (15.4% vs. 4.2%). It was noteworthy in our study that abscess formation developed in two target lymphadenopathies. We believe that this may possibly be because of the superposed infectious processes based on the low socioeconomic status of the region we live in. Two patients were admitted to hospital on the seventh and ninth days after their vaccination, respectively, which was interpreted to be adequate time for a superposed infection. The fact that the purulent materials that were obtained from these patients were not sent for culture (because of the inability to perform culture analysis in our hospital) was also a limitation of the present study.

All of the patients who were included in the present study showed improvement during the follow-up period, as in other similar studies reported in the literature. Although mean recovery time in our study was similar to that reported in the study of Fernandez-Prada et al., it was earlier than that reported in the study of Mehta et al. and Cocco et al.^[7,8,11]. However, sonographic follow-up was used for all four patients who were included in the study of Mehta et al., and for 12 patients in the study of Cocco et al., and we think that this period may be secondary to the late normalization of the sonographic findings. Unlike these studies, we were able to follow-up only four patients with US, and we think that a comparison with the results of these studies would not be accurate because surgical and percutaneous drainage were used in three of these four patients^[7,11].

CONCLUSION

In conclusion, ipsilateral cervical and axillary lymphadenopathies caused by the vaccines developed against COVID-19 may be encountered, which is the most important agent at hand in the fight against the pandemic. We experienced that sometimes the sonographic findings of these

lymphadenopathies may not be distinguished from malignant lymph nodes clearly; and for this reason, the close clinical and radiological follow-up would be appropriate to elucidate the process. However, if the findings persist, histopathological evaluation must be made use of to rule out possible malignant processes.

ETHICS COMMITTEE APPROVAL

This study was approved by Van Training and Research Hospital Clinical Research Committee (Date: 24.11.2021, Decision No: 2021/21).

CONFLICT of INTEREST

None of the authors had conflict of interest.

AUTHORSHIP CONTRIBUTIONS

Concept and Design: UAP, MT

Data Collection or Processing: UAP, MT

Analysis/Interpretation: UAP, MT

Literature Search: UAP, MT

Writing: UAP, MT

Final Approval: UAP, MT

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