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Aşılama Sonrası Sürenin COVID-19 ile Yatan Hastaların Radyolojik ve Laboratuvar Bulgularına Etkisi

The Effect of Post Vaccination Time on the Radiological and Laboratory Findings of Inpatients with COVID-19

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ÖZ

Giriş: COVID-19 (Coronavirus Disease 2019) enfeksiyonu, aşılanmış/aşılanmamış bireylerde asemptomatik/semptomatik olarak ortaya çıkmaktadır. Bu çalışmada, CoronaVac/BNT162b2 mRNA aşısı olan hastalarda ikinci doz aşıdan sonra geçen süreye göre toraks BT (bilgisayarlı tomografi) şiddeti ile laboratuvar bulguları arasındaki farklılıkların değerlendirilmesi amaçlandı.

Yöntem: Mart 2021 ile Aralık 2021 tarihleri arasında Mersin Şehir Eğitim ve Araştırma Hastanesi COVID-19 servislerinde yatan 40 yaş üstü 221 SARS-CoV-2 (severe acute respiratory syndrome coronavirus-2) PCR pozitif/torasik BT uyumlu hasta dahil edildi. Çalışmaya alınan hastalar ikinci doz CoronaVac/BNT162b2 mRNA aşısı yapıldıktan sonra ≤1 ay, 1-3 ay, 3-6 ay ve ≥6 ay olarak gruplandırıldı. Hasta bilgileri, ilk başvurudaki toraks BT ve laboratuvar değerlerine retrospektif olarak hasta dosyalarından ve hastane bilgi sisteminden ulaşıldı.

Bulgular: Tüm hastalarda ikinci doz aşıdan sonra pozitifliğin gelişmesi için medyan süre 111 (CI: 93-132) gündü. BNT162b2 mRNA aşılı grupta toraks BT ve laboratuvar değerleri açısından gruplar arasında anlamlı fark bulunmadı (p>0,05). CoronaVac aşısı olan grupta aşı sonrası pozitiflik gelişme süresi ile toraks BT toplam şiddet puanı arasında çok zayıf düzeyde pozitif korelasyon tespit edildi (r=0.148; p=0.048).

Sonuç: CoronaVac aşılı hastalarda ikinci dozdan sonraki süre arttıkça akciğer tutulum derecesinin arttığı, BNT162b2 aşılı hastalarda süre arttıkça fark olmadığı gösterilmiştir. Araştırma, daha geniş hasta grupları ve hastalık ilerlemesinin izlenmesi ile genişletilebilir. .

Anahtar Kelimeler: COVID-19, hastalık şiddeti, Sars-CoV-2, Aşı

ABSTRACT

Objective: COVID-19 (coronavirus disease 2019) infection occurs asymptomatically/symptomatically in vaccinated/unvaccinated individuals. This research aimed to evaluate the differences between thoracic CT (computed tomography) severity and laboratory findings in patients with CoronaVac/BNT162b2 mRNA vaccine, according to the time elapsed after the second dose of vaccine.

Method: Between March 2021 and December 2021, 221 SARS-CoV-2 (severe acute respiratory syndrome coronavirus-2) PCR positive/thoracic CT compatible patients over the age of 40 hospitalized in the COVID-19 services of Mersin City Training and Research Hospital were included. Patients included in the study were grouped as ≤1 month, 1-3 months, 3-6 months, and ≥6 months after receiving the second dose of CoronaVac/BNT162b2 mRNA vaccine. Patient information, thoracic CT and laboratory values at the first admission were obtained retrospectively from patient files and hospital information system.

Results: The median time to develop positivity after the second dose of vaccine in all patients was 111 (CI: 93-132) days. In the BNT162b2 mRNA-vaccinated group, no significant difference was found between the groups in terms of thoracic CT and laboratory values (p>0.05). In the CoronaVac-vaccinated group, a very weak positive correlation was found between the development time of positivity after vaccination and the thoracic CT total severity score (r=0.148, p=0.048).

Conclusion: It has been shown that as the time after the second dose increases in CoronaVac vaccinated patients, the degree of lung involvement increases, and there is no difference as the duration increases in BNT162b2 vaccinated patients

Keywords: COVID-19, disease severity, Sars-CoV-2, Vaccine

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INTRODUCTION

In December 2019, a new coronavirus named Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) emerged in Wuhan city of China's, which was described by the World Health Organization as the cause of the Coronavirus Disease 2019 (COVID-19) pandemic. The clinical diagnosis of COVID-19 was made primarily by clinical symptoms and some auxiliary diagnostic methods such as nucleic acid detection and immunological tests. Studies have shown an increase in leukopenia/leukocytosis, lymphopenia, aspartate aminotransferase (AST), alanine aminotransferase (ALT), lactate dehydrogenase (LDH), ferritin, d-dimer, C-reactive protein (CRP), sedimentation rate levels in COVID-19. Thoracic computed tomography (CT) is a highly sensitive method for rapid diagnosis and monitoring of disease progression in patients (1). Being over 50 years of age, comorbidities, shortness of breath, chest pain, cough, lymphopenia, and increased indicators of inflammation have been shown to be risk factors for severe/critical COVID-19 pneumonia, and it has been stated that severe/critical COVID-19 patients had significantly higher thoracic CT scores than other patients (2).

Effective and safe COVID-19 vaccines were needed to contain the pandemic. Studies have shown that inactivated COVID-19 CoronaVac (Sinovac Life Sciences, Beijing, China) and BNT162b2 (Pfizer–BioNTech) mRNA vaccines are safe and effective. Considering the BNT162b2 mRNA and CoronaVac vaccine efficacy, a gradual decrease was observed in the post-vaccination time, but it was stated that the effectiveness continued (3-5).

In our country, CoronaVac vaccine started to be applied as of January 2021 and BNT162b2 vaccine started to be applied as of April 2021. This research aimed to evaluate the differences between thoracic CT severity and laboratory values according to the time elapsed after the second dose of CoronaVac/BNT162b2 mRNA vaccine in inpatients diagnosed with COVID-19.

MATERIALS AND METHODS

SARS-CoV-2 PCR positive/thoracic CT COVID compatible inpatients over 40 years old in Mersin City Training and Research Hospital wards isolated for COVID-19 between March 2021 and December 2021 were grouped according to the elapsed time (≤1 month, 1-3 months, 3-6 months, and ≥6 months) after receiving two doses of CoronaVac vaccine (Sinovac Life Sciences, Beijing, China)/BNT162b2 mRNA (Pfizer–BioNTech), one month apart. The patients included in the research had not had a previous COVID-19 infection. The patients included in the study were followed in inpatient services. They were not patients followed in intensive care. A total of 221 patients were evaluated. The degree of lung involvement in thoracic CT was determined by the radiology specialist using the total severity score (6).

Additional diseases (hypertension (HT), diabetes mellitus (DM), cardiovascular system disease (CVSD), lung diseases (asthma/chronic obstructive pulmonary disease COPD)), cerebrovascular accident (CVA), chronic kidney disease (CKD), acute kidney failure (AKF)), vaccination status, thoracic CT and laboratory values (d-dimer, ferritin, CRP, ALT, LDH, procalcitonin, fibrinogen, platelet count, leukocyte count, lymphocyte count, Cr) of the patients at the time of first admission to the hospital were obtained retrospectively from patient files and hospital information system. Patients under the age of 40, patients without laboratory tests and thorax tomography, and patients who died after receiving a single dose of vaccine were not included in the evaluation. Informed consent form was obtained from the patients.

Statistical analysis

Statistical analyses were performed using the IBM SPSS 20.0 program (IBM, NY, USA). The Kolmogorov Smirnov test was performed for the normality analysis of the parameters. Mann-Whitney-U and Spearman correlation tests were used for non-normally distributed results, and differences between groups were analyzed using the chi-square test. p value of 0.05> was considered significant.

RESULTS

Of the patients included in the research, 114 (51.6%) were female and 107 (48.4%) were male. The mean age of the patients was 70.1±11.1 years. The mean age was 70.1±11.4 years in females and 70.1±10.8 years in males. As additional diseases, 180 (81.5%) patients had HT, 109 (49.3%) patients had DM, 97 (43.9%) patients had CVSD, 80 (36.2%) patients had lung diseases, 18 (8.1%) patients had CKD, 68 (30.8%) patients had CVA and 16 (7.2%) patients had AKF.

The median time to develop positivity after the second dose of vaccine in all patients included in the research was 111 (CI: 93-132) days. The effects of vaccine types on thoracic CT severity and the differences in laboratory values (d-dimer, ferritin, CRP, ALT, LDH, procalcitonin, fibrinogen, platelet count, leukocyte count, lymphocyte count, creatinine) according to the time elapsed after the second dose of vaccine are shown in Table 1.

There was no effect of gender on CT severity and laboratory values in patients ≤1 month and ≥6 months. Ferritin (131.0/240.6, p=0.005) and Cr (1.1/1.2, p=0.018) were found to be lower in females in the group 1-3 months after the second dose of vaccination. In the 3-6 months group, ferritin (117.5/479.1, p<0.001), ALT (26.0/41.4, p=0.020), LDH (273.9/329.3, p=0.010) were lower in women, and platelet count (264.8/214.6, p=0.049) was higher in women.

Table 1. Differences in Thorax CT Severity and Laboratory Values of Vaccine Types According to the Time Elapsed After Two Doses of Vaccination

Time After 2nd Dose	Vaccine Type		Age	Total Severity Score	D-Dimer	Ferritin	CRP*	ALT*	LDH*	Procalcitonin	Fibrinogen	Platelets	Leukocyte	Lymphocyte	Cr*
<1 month	CoronaVac (n=32)	Median	70.10	5.50	0.88	186.50	4.90	21.50	245.00	0.03	531.00	209.50	8.48	1.54	0.99
		SD/ IQR	±7.5	1.25-11.75	0.65-1.63	63-257.5	1.19-9.58	15.3-36.8	221-344	0.015-0.09	437.5-683.3	174.8-309	5.47-10.96	0.98-1.99	0.82-1.21
	Biontech (n=6)	Median	58.50	7.00	0.98	316.30	2.50	21.00	266.50	0.00	498.50	207.00	7.00	1.50	1.00
		SD/ IQR	±10.8	3.25-11.25	0.49-3.13	201.4-434.2	1.0-10.1	13.0-46.7	237-277.5	0.0-0.15	434.5-665.3	178.3-287.5	5.75-11.2	1.0-2.1	1.0-1.4
	P value		**0.03**	0.68	0.92	0.10	0.68	0.83	0.95	**0.01**	0.77	0.89	0.68	0.63	0.26
1-3 months	CoronaVac (n=46)	Median	70.5	5.00	0.77	142.00	4.70	21.50	239.00	0.03	539.00	215.50	6.90	1.50	0.95
		SD/ IQR	±11.0	0.0-10.0	0.50-1.33	55.6-283.9	0.94-9.87	15.0-32.5	216-300	0.01-0.07	432.2-657.7	179.0-299.5	5.3-8.9	1.06-1.94	0.79-1.2
	Biontech (n=11)	Median	63.3	7.00	0.94	227.30	12.10	26.00	255.00	0.05	618.00	213.00	9.00	1.50	1.00
		SD/ IQR	±12.5	1.0-11.0	0.46-8.23	96.3-278	2.0-18.0	17-35	218-320	0.0-1.0	408-723	203-270	6.0-12.3	1.0-2.0	0.72-1.0
	P value		0.08	0.42	0.40	0.52	0.05	0.32	0.37	0.87	0.32	0.57	0.07	0.61	0.41
3-6 months	CoronaVac (n=50)	Median	73.0	5.5	0.82	156.7	3.53	24.5	275.0	0.10	498.5	211.0	8.59	1.08	1.01
		SD/ IQR	±8.5	2.0-11.0	0.50-1.34	51.0-323.5	1.86-12.6	17.7-34.7	241.0-335.2	0.04-0.40	458.0-639.3	166.0-282.5	6.23-11.72	0.79-1.56	0.71-1.17
	Biontech (n=16)	Median	57.2	8.5	0.49	181.1	4.5	36.5	304.5	0.0	512	236.5	8.5	1.0	1.0
		SD/ IQR	±8.1	6.0-12.0	0.32-1.16	90.4-348.7	1.25-9.75	17.5-41.8	234.0-359.8	0.0-0.0	443-641	177.0-328.5	5.25-10.67	1.0-2.0	1.0-1.0
	P value		**<0.001**	0.067	0.121	0.540	0.670	0.252	0.776	**<0.001**	0.928	0.411	0.369	0.258	0.620
>6 months	CoronaVac (n=51)	Median	75.8	8.0	1.18	159.7	5.0	19.0	307	0.0	487	224	8.0	1.0	1.0
		SD/ IQR	±10.7	3.0-13.0	0.69-2.18	71.6-384.0	3.0-11.0	12.0-26.0	245-371	0.0-0.0	433-624	172-284	6.0-11.0	1.0-1.0	1.0-1.0
	Biontech (n=9)	Median	59.9	8.0	0.59	118.6	5.0	25.0	315.0	0.0	475.0	226.0	8.0	1.0	1.0
		SD/ IQR	±8.9	5.0-10.0	0.33-1.57	68.3-741.8	2.0-10.5	14.5-65.5	281.0-326.5	0.0-0.0	422.0-611.5	173.5-340.5	6.0-9.0	1.0-1.5	1.0-1.0
	P value		**0.001**	0.686	0.096	0.909	0.983	0.149	0.860	0.128	0.828	0.627	0.458	0.776	0.524

*CRP: C-Reactive Protein, ALT: Alanine aminotransferase, LDH: Lactate dehydrogenase, Cr: Creatinine, SD: Standard lead, IQR: Interquartile range

In the CoronaVac-vaccinated group:

A significant difference was found in the total severity score values in thoracic CT between those who developed positivity 1-3 months after the second dose and those who developed positivity ≥6 months (5.7/8.5, p=0.018). There was no difference between the other groups (p>0.05).

A significant difference was found in the values of procalcitonin (0.28/0.52; p=0.001) and lymphocyte count (1.8/1.3; p=0.028) between ≤1 month and 3-6 months groups. There was a significant difference in the values procalcitonin (0.28/0.35; p=0.001), LDH (275.6/326.3; p=0.025), lymphocyte count (1.8/1.1; p=0.04) and Cr (1.0/1.4; p=0.034) between those who developed positivity for ≤1 month and ≥6 months. There was a significant difference procalcitonin (0.18/0.52; p<0.001), LDH (257.7/305.1; p=0.004), leukocyte count (7.6/10.2; p=0.011) and lymphocyte count (1.6/ 1.3; p=0.009) between 1-3 months and 3-6 months groups. A significant difference was found procalcitonin (0.18/0.35; p<0.001), LDH (257.7/326.3; p=0.001), d-dimer (1.26/2.27; p=0.047) and lymphocyte count (1.6 /1.1; p<0.001) between those who developed positivity for 1-3 months and ≥6 months. A significant difference was found procalcitonin (0.52/0.35; p<0.001), ALT (34.3/24.0; p=0.002) and d-dimer (3.05/2.27; p=0.029) between 3-6 months and ≥6 months groups.

As the post-vaccination time increased, a weak positive correlation was observed in LDH value (r=0.242, p=0.001). A very weak negative correlation was observed in lymphocyte count (r=-0.264, p<0.001).

LDH was higher in patients with lung disease (318.8/278.6; p=0.004). Fibrinogen (500.7/551.0; p=0.026) and Cr (1.16/1.19; p=0.010) levels were significantly lower in patients with CVSD. Platelet count was significantly lower in patients with ACF (178.8/250.5; p=0.004). Cr levels (2.42/1.07; p<0.001) and procalcitonin (0.47/0.33; p=0.025) were higher in patients with CKD. Lymphocyte count was lower in patients with CVA (1.27/1.50; p=0.016). No difference was found in those with HT and DM.

In the BNT162b2 mRNA-vaccinated group:

There was no difference between the groups in terms of thoracic CT and laboratory values (p>0.05). A significant difference was found in LDH (257.2/305.0; p=0.018) between the patients who developed positivity for ≤1 month and ≥6 months, there was a significant difference in procalcitonin (2.8/0.07; p=0.019) values between 1-3 month and 3-6 month groups, and a significant difference was found between procalcitonin (2.8/0.00; p=0.011) values between the patients who developed positivity for 1-3 months and ≥6 months.

Considering the relationship between thoracic CT total severity score and laboratory values of additional diseases in the BNT162b2 mRNA-vaccinated group, total severity score (5.2/9.2; p=0.008) was found to be lower in patients with lung diseases. Platelet count (263.6/214.8; p=0.019) was found to be higher in patients with HT. D-dimer (3.1/0.8; p=0.009), CRP (9.5/5.7; p=0.009) and fibrinogen (610.3/501.4; p=0.013) were found to be higher in patients with CVSD. Fibrinogen (740/533.3; p=0.014) and Cr (3.58/0.93; p=0.007) were found to be higher in those with CKD. No significant difference was found in patients with DM, AKF, and CVA.

In the correlation analysis between post-vaccine positivity development time and thoracic CT total severity score, no correlation was found in the BNT162b2 mRNA-vaccinated group (r=0.93, p=0.557), while a very weak positive correlation was detected in the CoronaVac-vaccinated group (r=0.148, p= 0.048).

DISCUSSION

It was found that COVID-19 infection was evenly distributed between the genders and there were no significant demographic differences, with a mean age of 46.7 years. Compared with patients without any severe disease, patients with severe COVID-19 were significantly more likely to have hypertension, diabetes, as well as, chronic heart disease, lung disease, kidney disease and malignancy (7). In another meta-analysis, male patients aged 70 years and older were shown to have a higher risk of severe illness, ICU admission, and death from COVID-19 infection. (8). In our study, the age range of patients who developed positivity after the second dose of CoronoVac/ BNT162b2 mRNA vaccine was 70.1±11.1 years, and there was no difference in terms of gender. HT, DM, cardiovascular disease and lung diseases were the most common comorbidities in hospitalized patients. In a research conducted in our country, the seroconversion rates after two doses of CoronoVac vaccine were examined and on the 28th day after the second dose, total anti-spike and anti-nucleocapsid IgG were found to be effective by 92.9%, IgM by 15.2% and anti-S-RBD (reverse binding domain) IgG antibodies by 98.2%. However, it is stated that a third dose can be administered in people aged 50 and over and with additional disease (9). Another study found that the third dose of CoronaVac vaccine significantly increased antibody levels compared to the second dose, but the half-life of the neutralizing antibody was not as desired. Therefore, a fourth dose and annual vaccination may be considered in the SARS-CoV-2 vaccination strategy (10). In a research evaluating the effectiveness of vaccines, it was determined that the time to reach the protective threshold after the second CoronaVac dose was 26 to 31 days and the half-life of the SARS-CoV-2 antibody it caused was 57 days, and a 3.8-times increase in the maximum antibody concentration was observed with the addition of the third dose (11). In another study, it was shown that antibody titers against Wuhan/WH04/2020 and VOC strains peaked at 28 days after the first dose, and binding antibody against Wuhan/WH04/2020 Spike and RBD proteins was protective for at least one year. It has been found that vaccines delay reaching significant binding antibody levels in persons aged ≥60 years, remain at lower levels and decline earlier compared to persons aged 18 to 59 years (12). In our research, the total severity score on thoracic CT was found to be significantly higher in those who developed positivity ≥6 months after the second dose of CoronaVac vaccine than those who developed positivity 1 to 3 months later. In the correlation analysis between post-vaccine positivity development time and thoracic CT total severity score, a very weak positive correlation was detected in the CoronaVac-vaccinated group. In addition, a weak positive correlation was observed in LDH value and a very weak negative correlation in lymphocyte count as the post-vaccination time increased in the CoronaVac-vaccinated patients. It was thought that this might be due to the decrease in the protective effect of the vaccine as the post-vaccination time increased in the CoronaVac-vaccinated group.

BNT162b2 vaccine has been observed to be 95% effective in preventing COVID-19 and that it demonstrates similar vaccine efficacy

(usually 90%-100%) across subgroups by age, gender, race, ethnicity, body mass index, and presence of co-existing conditions (13). In a prospective study, healthcare workers who received BNT162b2 vaccine were followed for 6 months, and it was noted that antibody response was significantly reduced six months after receiving the second dose of BNT162b2 vaccine, especially in men, persons aged 65 years and older, and immunocompromised persons. The highest titers after the second dose of vaccine were observed between days 4 to 30 and a significant decrease in IgG level was observed each month, with the neutralizing antibody level falling rapidly during the first three months, with a relatively slow decline thereafter (14). In another research, the efficacy of the BNT162b2 vaccine was found to be negligible in the first two weeks after the first dose, increasing to 36.8% at the third week after the first dose, and peaking at 77.5% in the first month after the second dose. Efficacy was seen to accelerate after the fourth month, reaching approximately 20% at 5 to 7 months after the second dose, and then gradually decrease. However, strong protection against hospitalization and mortality was noted for 6 months after the second dose (15). Again, in a research conducted abroad, it was reported that antibodies peaked one month after two doses of BNT162b2 mRNA vaccine, followed by a decrease in antibody levels, and the antibody level decreased to 6.3% of the peak value four months after the second dose (16). In another research, it was stated that standard two-dose BNT162b2 mRNA vaccine provides protection in individuals who have not had a previous COVID-19 infection (17).

In our research, no significant difference was found between the groups vaccinated with BNT162b2 mRNA, between the thoracic CT and laboratory values, and in the correlation analysis between the development time of positivity after vaccination and the thoracic CT total severity score, no correlation was found in the BNT162b2 mRNA-vaccinated group. The reason for this may be due to the low number of patients vaccinated with BNT162b2 mRNA in SARS-CoV-2 PCR positive/thoracic CT COVID compatible patients over the age of 40 hospitalized in our hospital's COVID wards. We also thought that it could be concluded that those vaccinated with BNT162b2 mRNA were less hospitalized and that such vaccine could be more effective against COVID-19 infection. Interestingly, in our research, the total severity score was found to be lower in patients with a lung disease who received two doses of BNT162b2 mRNA vaccine. It was thought that COPD and significant fibrosis might cover the infiltration areas, causing the score to be lower. However, due to the small number of patients, it should be provided in larger patient groups.

In a meta-analysis of 11 studies comparing COVID-19 vaccine efficacy, it was stated that the BNT162b2 mRNA vaccine was more effective and has more efficacy in inducing neutralizing antibody response in individuals under 60 years of age than the CoronaVac inactivated vaccine (18). In another meta-analysis, it was determined that the BNT162b2 vaccine was more effective in preventing COVID-19 infection than the CoronaVac vaccine (19). In a research abroad, although the CoronaVac vaccine showed a high efficacy in preventing hospitalization and death in persons aged 60 years and older who hadn't had a previous COVID-19 infection, it was reported to have a lower efficacy compared to the BNT162b2 vaccine, and the vaccine efficacy tended to decrease significantly with age (20). In another study comparing the efficacy of vaccine types, it was reported that the BNT162b2 vaccine had the highest efficacy in the formation of anti-SARS-CoV-2 anti-RBD IgG antibodies. While the antibody level does not decrease until the seventh month in the mRNA vaccine and vector vaccine, it gradually decreases after the fourth month in the inactivated virus vaccine (21). Comparing the effect of two doses of CoronaVac and BNT162b2 vaccine on lung involvement and laboratory values between the groups in our research, it was found that there was no significant difference in terms of lung involvement, but there was a significant difference in procalcitonin in the ≤1 month and 3-6 month groups. No significant difference was found in terms of other laboratory values. In addition, the median time to develop positivity after the second dose of vaccine in all patients included in the research was 111 (CI: 93-132) days.

Limitations of the study

The limitations of our research are the unequal distribution of the patients included in the research, who were vaccinated with the CoronaVac and BNT162b2 vaccines, and the numbers in the groups separated in terms of duration. It was thought that this could be interpreted as the fact that patients hospitalized between March 2021 and December 2021 were generally vaccinated with CoronaVac vaccine or that patients vaccinated with BNT162b2 vaccine were less hospitalized in numbers. In addition, the progression of the COVID-19 infection could not be observed, since the degree of the lung involvement and laboratory values were taken at the time of first admission to the hospital. However, none of the patients included in the research was exitus.

Conclusion

It has been demonstrated that the degree of lung involvement increases as the time after the second dose increases in CoronaVac-vaccinated patients, and there is no difference in BNT162b2-vaccinated patients. However, this may be due to the small number of patients. Therefore, the research may be expanded with larger patient groups and monitoring of disease progression. It can be concluded that BNT162b2 vaccine is clinically more effective in preventing hospitalization, considering that the number of BNT162b2-vaccinated patients in COVID-19 wards is less and there is no significant difference in terms of lung involvement between the groups. For more precise results, it may be beneficial to follow the patients after the third and subsequent doses of vaccine and to increase the number of patients included in the research.

Ethics Committee Approval: This study was approved by Mersin University Non-Interventional Clinical Research Ethics Committee (Date: 20.04.2022, meeting no. 07 and Decision no: 286).

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