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Subclinical myocardial assessment after BNT162b2 messenger RNA COVID-19 vaccination in adolescents with chronic heart disease: a speckle-tracking echocardiography study

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Abstract

Purpose: Case reports of the development of perimyocarditis in adolescents and young adults after BNT162b2 messenger RNA (mRNA) COVID-19 vaccination have raised concerns about the cardiac side effects of the vaccine. The aim of the study was to evaluate clinical follow-up and subclinical myocardial function after mRNA COVID-19 vaccine in adolescents with chronic heart disease. *Methods:* Forty-one adolescents aged 12–18 who were followed up at paediatric cardiology clinic between December 2021 and May 2022, and who had received two doses of the Pfizer-BioNTech COVID-19 mRNA vaccine were included in the study. The patients were evaluated five times in total – before the vaccination, one week after receiving the first dose, one month after receiving the first dose, one week after receiving the second dose, and one month after receiving the second dose. Cardiac assessment for all patients included an electrocardiogram, transthoracic echocardiography, and two-dimensional speckle-tracking strain echocardiography for left ventricular subclinical myocardial function. *Results:* The mean age of the adolescents was 16.2 ± 1.5 years, and 56% (n = 23) were male. There was no statistically significant difference in patients' echocardiographic measurements including left ventricular global longitudinal strain and electrocardiogram parameters including PR, QRS, and QTc intervals through the follow-up. Seven patients reported cardiac complaints at post-vaccination follow-up visits, but laboratory and echocardiographic evidence of cardiac involvement was not observed. *Conclusions:* Based on the results of our study, the mRNA COVID-19 vaccine did not cause impairment in subclinical myocardial function assessed by speckle-tracking echocardiography in adolescents with chronic heart disease.

Coronavirus 2, which causes the coronavirus disease (COVID-19), reached pandemic levels in March 2020. Repeated COVID-19 waves worldwide have placed an enormous burden on global health systems, with more than 615 million documented infections and more than 6.5 million deaths as of September 2022.[1] The successful timely development and global distribution of COVID-19 vaccines have played an important role in limiting the severity of the disease and overcoming the pandemic.

At the beginning of the pandemic, it was thought that, unlike in adults, COVID-19 disease in children was asymptomatic or mild. However, it was found that it could cause a serious disease called multisystem inflammatory syndrome in children, which requires intensive care and can result in death.[2,3] In addition, with the mutation of the virus, the clinical course began to change, and severe cases began to be seen at a higher rate in children, as in adults.[4,5] Therefore, vaccinating children is as important as vaccinating adults.

With the administration of the COVID-19 vaccine to young adults and children around the world, speculation about side effects began to emerge. It was claimed that there was an increase in cases of myopericarditis, especially in young adults, after BNT162b2 messenger RNA (mRNA) COVID-19 vaccination.[6] This was supported in the literature, which caused great concern.[7,8,9] Given the concerns about the safety of the COVID-19 vaccine and the lack of data regarding children with chronic heart disease, studies evaluating the safety profiles of vaccines are needed. To date, there is no prospective study evaluating the effect of COVID-19 vaccines on cardiac functions in adolescents. In this study, we investigated possible adverse cardiac events and subclinical myocardial functions after COVID-19 vaccination in an adolescent population under follow-up at a paediatric cardiology outpatient clinic. The investigation includes comprehensive cardiac evaluation, speckle-tracking strain imaging, and follow-up.

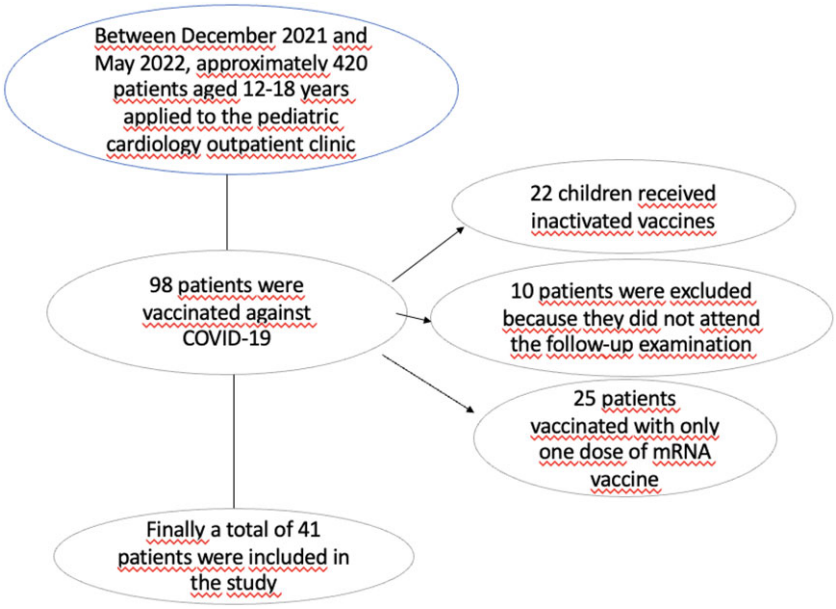

Figure 1. Flow chart of the study.

Materials and methods

Forty-one children aged 12–18 who were followed up between December 2021 and May 2022 at the paediatric cardiology outpatient clinic and who had received two doses of the COVID-19 mRNA vaccine (Pfizer-BioNTech) were included in the study. The patients were evaluated five times in total – before vaccination, one week after the first dose, one month after the first dose, one week after the second dose, and one month after the second dose. Patients who were not vaccinated, who received an inactivated vaccine, or who did not receive a second dose of the mRNA vaccine were excluded from the study. The flow chart of the study is shown in Figure 1. Cardiac evaluation for all patients included an electrocardiogram, two-dimensional transthoracic echocardiography, and speckle-tracking strain imaging. This study complies with the Declaration of Helsinki, the study protocol was approved by the local Ethics Committee (reference numbers 2021/1716), and all patients' families gave written informed consent to participate in the study.

Transthoracic echocardiography

Echocardiographic examination was performed using a S70 system (Philips) equipped. Standard views were used from the parasternal long-axis, short-axis, and the apical four-chamber views. Chamber quantification and flow velocities were obtained using pulsed and continuous-wave Doppler techniques as proposed according to the American society of echocardiography recommendations.[10]

Two-dimensional speckle-tracking echocardiography

Commercially available software (TOMTEC Imaging Systems, Munich, Germany) was used to obtain two-dimensional speckle-tracking echocardiography at frame rates between 40 and 80 frames/sec. Left ventricle global longitudinal strain analysis was performed with AutoStrain function in the standard 2-, 3-, and 4-chamber apical views by averaging the peak systolic strain in all segments (Fig 2).

Electrocardiography

A standard resting 12-led electrocardiogram examination was recorded for all patients. All electrocardiograms were taken at a rate of 25 mm/s and an amplitude of 10 mm/mV. Electrocardiograms were analysed for type of heart rhythm, heart rate, PR, QRS, and QT intervals. The QT interval corrected (QTc) for heart rate (n) was calculated using Bazett's formula ($QTc = n/\sqrt{RR}$).[11]

Statistics

All statistical tests were conducted using the Statistical Package for the Social Sciences 26.0 for Windows (SPSS Inc., Chicago, IL, USA). The Kolmogorov–Smirnov test was used to analyse the normality of the data. Continuous data are expressed as mean ± standard deviation, and categorical data are expressed as percentages. A chi-square or Fisher's exact test was used to assess the differences in categorical variables between the groups. A Student's t-test or the Mann–Whitney U-test was used to compare unpaired samples as needed. The primary analysis used ANOVA to compare all reported data for parametric variables, whereas the Kruskal–Wallis test was used for comparison among non-parametric variables between groups. Significance was assumed at a two-sided $p < 0.05$.

Results

A total of 41 adolescents with a mean age of 16.2 ± 1.5 years (56% male; n = 23) with a body mass index of 21.7 ± 2.9 kg/m^2 and who received two doses of the mRNA vaccine were included in the study (Table 1). The diagnoses of the 41 patients included in the study are as follows: three cases of mild pulmonary stenosis, two cases of pulmonary stenosis with balloon valvuloplasty, seven cases of previous acute rheumatic fever, six cases of mitral valve prolapse, one case of operated Fallot, four cases of a bicuspid aortic valve, one case of hypertrophic cardiomyopathy, one case of left ventricular myocardial non-compaction, two cases of ventricular extrasystoles, one case of vasovagal syncope, two cases of closed patent ductus arteriosus, one case of an operated atrioventricular septal defect, one

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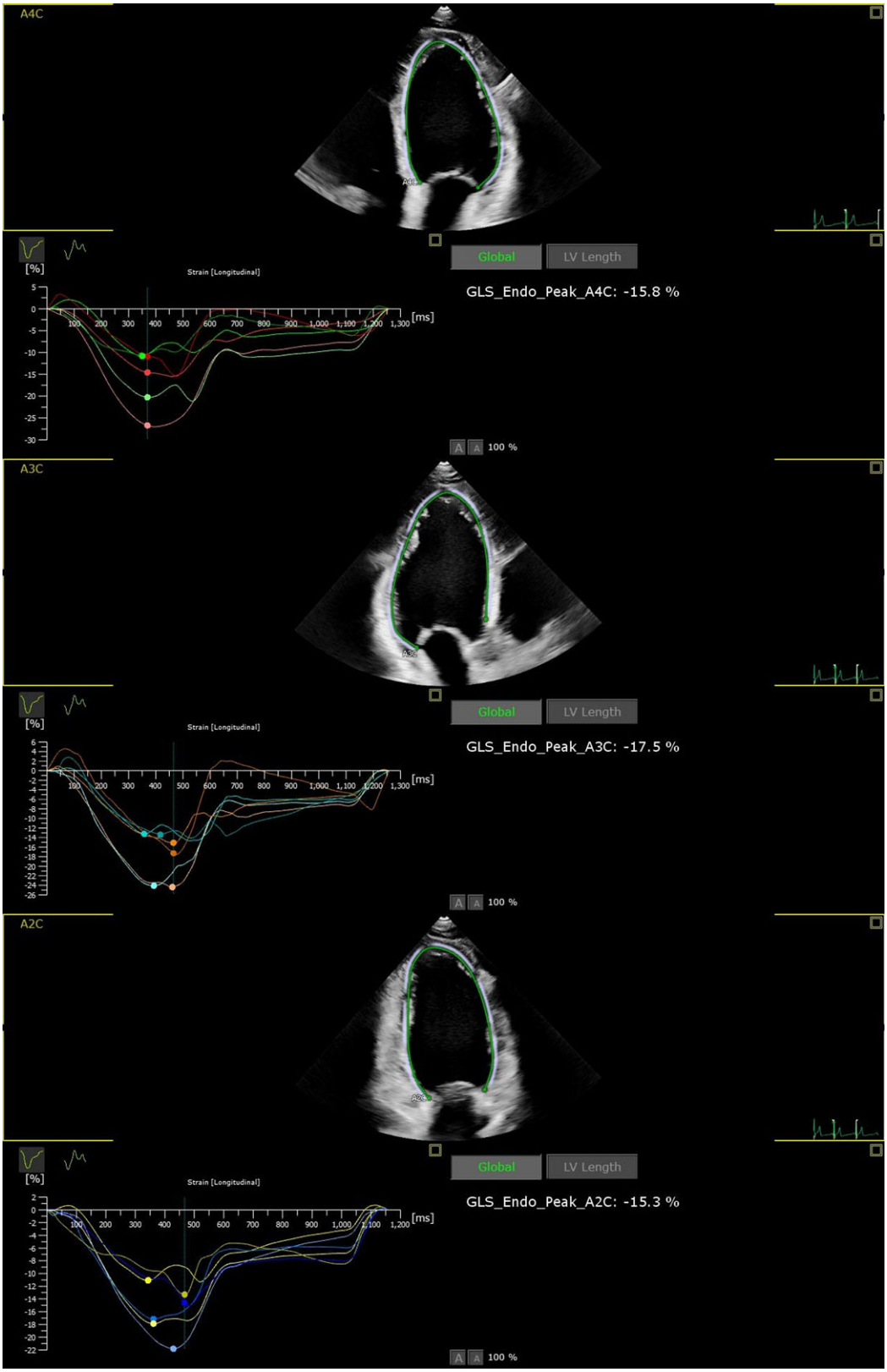

Figure 2. The figure shows the strain values and curves obtained from the left ventricular apical 2-, 3-, and 4-chamber views.

case of an operated subaortic membrane, one case of stented coarctation of the aorta, one case of an operated ventricular septal defect and subaortic membrane, one case of a small ventricular septal defect, one case of a ventricular septal defect and pulmonary atresia, three cases of small atrial septal defects, and one case of a transcatheter closured atrial septal defect.

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Table 1. General characteristics of the patients included in the study.

Variables	$n = 41$
Age (years) (mean ± SD)	16.2 ± 1.5
Gender (n, %)	
Female	18 (44%)
Male	23 (56%)
BMI (kg/m^2) (mean ± SD)	21.7 ± 2.9
BSA (m^2) (mean ± SD)	1.6 ± 0.2
Treatment (n, %)	
Beta-blocker	6 (15%)
ACE inhibitor	4 (10%)
Diuretics	3 (7%)
Acetylsalicylic acid	3 (7%)
Ca-channel blocker	1 (2%)

ACE: angiotensin-converting enzyme; BMI: body mass index; BSA: body surface area; Ca: calcium.

The heart rate, systolic and diastolic blood pressure, and the PR, QRS, and QTc intervals of the patients were similar at baseline, one week after the first dose, one month after the first dose, one week after the second dose, and one month after the second dose. No statistically significant changes were observed in conventional echocardiographic parameters and left ventricular global longitudinal strain during follow-up. Pericardial effusion was not observed in any patient during follow-up. The comparison of the electrocardiogram and echocardiographic parameters of the patients at baseline, one week after the first dose, one month after the first dose, one week after the second dose, and one month after the second dose are shown in Table 2.

A total of seven patients had cardiac complaints when questioned at follow-up visits: one patient with ventricular septal defect and pulmonary atresia had dyspnea in the first week after the first dose; one patient with vasovagal syncope had palpitations in the first month after the first dose; one patient previously diagnosed with acute rheumatic fever had mild atypical chest pain in the first week after the first dose; one patient with a bicuspid aortic valve had mild atypical chest pain in the first week after the second dose; one patient with ventricular extrasystoles had palpitations in the first month after both the first and second dose; one patient with an operated subaortic membrane had mild atypical chest pain in the first week after the first dose; one patient with mitral valve prolapse had palpitations in the first week after the second dose.

NT-pro-BNP and troponin values did not increase, and no pathological changes were observed in the electrocardiogram and echocardiographic parameters of these patients compared to before vaccination. Complaints were not serious and did not persist at follow-up. The demographic characteristics and NT-pro-BNP and hs-troponin-T values of the patients with cardiac complaints are shown in Supplementary Table S1.

Discussion

Forty-one adolescents who had received two doses of the mRNA vaccine were evaluated for cardiac side effects five times – before vaccination, one week after receiving the first dose, one month after receiving the first dose, one week after receiving the second dose, and one month after receiving the second dose. These evaluations revealed no statistically significant change in electrocardiograms or conventional and strain echocardiography parameters. None of the patients developed pericardial effusion during follow-up. Except for mild vaccine-related constitutional symptoms, only seven patients described cardiac symptoms at any of the follow-ups. No pathological increase in NT-pro-BNP and hs-troponin T values and/or electrocardiogram/echocardiographic evidence of cardiac involvement were observed in patients with cardiac complaints.

There is speculation that the incidence of perimyocarditis is increased after vaccination in young adults, and there have been cases of post-vaccine perimyocarditis.[6,7,8] This causes fear of vaccination in society and reduces vaccination rates. This decrease would be expected to be even more pronounced in young adults who already have chronic heart disease. Our paediatric cardiology outpatient clinic is an intensive clinic where a large number of patients with all types of acquired and CHD are evaluated. However, we observed that in this age group (12–18-year-olds), whose vaccination rate is already low in the community, the vaccination rate is even lower in patients followed up for heart disease due to concerns about cardiac side effects.

There are no studies that have prospectively evaluated the clinical or subclinical cardiac effects of the vaccine in adolescents. Studies on the risk of post-vaccination myocarditis have been conducted by retrospectively looking at the vaccination status of patients diagnosed with myocarditis.

Cases of myocarditis and pericarditis after COVID-19 vaccination have been reported, particularly after the second dose of the mRNA vaccine.[12,13] The first cases were recorded in male adolescents and young adults in the Israeli military.[14] In a retrospective medical record review conducted in Washington, Schauer et al. reported on thirteen 12–17-year-old patients, 12 of whom were male, who presented with symptoms of myopericarditis after receiving a second dose of the Pfizer vaccine.[7] The median time from receiving the second dose to symptom presentation was 3 days (range 2–4 days). All patients had sudden onset chest pain and elevated serum troponin levels. Seventy per cent had abnormal electrocardiogram findings (the most common ST elevation). The median length of hospital stay was 2 days (range 1–4 days), with no significant morbidity or mortality. The authors estimated a probable incidence of myopericarditis of 0.008% in 16–17-year-olds and 0.01% in 12–15-year-olds following the second dose, based on state immunisation rates.

After administering 2.8 million doses of the mRNA COVID-19 vaccine, the United States of America military reported that 23 patients experienced myocarditis.[6] All patients had significantly elevated cardiac troponin levels with acute onset chest pain within four days of receiving vaccine. Eighty-two per cent had abnormal electrocardiogram findings (most common ST elevation). While the observed number of myocarditis cases was small, the number was higher than expected among males after receiving a second dose. According to a report by the Israeli Ministry of Health, one in 3000 to one in 6000 men aged 16–24 who received the mRNA COVID vaccine developed myocarditis and pericarditis.[9] Ninety per cent of the cases in Israel appear to be men.

These cases support a possible causal relationship between vaccine administration and myocarditis. Because of this, the US FDA added a warning about the risk of myopericarditis and pericarditis to the fact sheet for the mRNA COVID-19 vaccine. The adjusted risk ratio for myocarditis and pericarditis events in children and young adults aged 16–24 was determined by the FDA to be

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Table 2. Electrocardiographic and echocardiographic measurements of patients according to vaccine doses during follow-up.

	Basal	1st dose/1st week	1st dose/1st month	2nd dose/1st week	2nd dose/1st month	p-value
SBP (mmHg)	117.5 ± 9.9	119.7 ± 12.1	118.8 ± 12.8	117.7 ± 11.8	121.1 ± 11.2	0.824
DBP (mmHg)	69.3 ± 6.3	70.1 ± 8.3	72.3 ± 6.4	72.4 ± 8.6	71.3 ± 7.2	0.775
Electrocardiogram parameters						
PR (ms)	135.8 ± 28.7	132.2 ± 31.5	137 ± 26.1	143.8 ± 26.8	140 ± 23	0.170
QRS (ms)	91.2 ± 8.8	95.6 ± 15.4	92 ± 13	96.4 ± 11.7	96.4 ± 12.4	0.632
QTc (ms)	390 ± 25.5	396 ± 18.2	396 ± 20.7	402.6 ± 17.9	394 ± 11.4	0.714
HR	73.0 ± 10.9	73.42 ± 10.1	74.15 ± 10.9	74.83 ± 11.9	77.17 ± 10.8	0.891
Echocardiographic parameters						
LV GLS (%)	−16.93 ± 2.5	−17.14 ± 2.1	−16.96 ± 2.9	−16.93 ± 2	−16.89 ± 2.6	0.876
LV EF (%)	69.57 ± 3.5	69.57 ± 3.4	69.11 ± 3.3	68.89 ± 3.8	69 ± 3.1	0.325
LVEDD (mm)	44.86 ± 4.8	44.75 ± 4.5	44.57 ± 4.5	44.36 ± 4.1	44.82 ± 4.3	0.375
RV (mm)	27.71 ± 4.9	27.79 ± 5	28.11 ± 5	27.29 ± 5.1	27.82 ± 5.4	0.108
LA (mm)	33.71 ± 3.6	33.75 ± 3.8	33.64 ± 3.9	33.71 ± 3.6	33.82 ± 3.9	0.977
RA (mm)	30.11 ± 3	29.79 ± 3.2	29.75 ± 3.5	29.86 ± 3.1	29.79 ± 3.3	0.382
sPAP (mmHg)	25.29 ± 6	25.89 ± 5.5	25.18 ± 6.3	25.11 ± 5.5	25.32 ± 6.2	0.781
E wave (cm/s)	66.64 ± 13.9	64.82 ± 12	65.89 ± 13.8	66.39 ± 14.5	66.39 ± 12.4	0.711
e' wave (cm/s)	9.04 ± 2.6	9.29 ± 2.4	8.86 ± 2.9	9.39 ± 2.7	8.93 ± 2.6	0.312
E/e' ratio	7.6 ± 1.3	7.22 ± 1.3	7.76 ± 1.3	7.27 ± 1.3	7.79 ± 1.7	0.105

DBP: diastolic blood pressure; E: early diastolic transmitral flow; e': early diastolic tissue velocity; HR: heart rate; LA: left atrium; LV GLS: left ventricular global longitudinal strain; LV EF: left ventricular ejection fraction; LVEDD: left ventricular end-diastolic diameter; RA: right atrium; RV: right ventricle; SBP: systolic blood pressure; sPAP: systolic pulmonary artery pressure.

0.94 (95% confidence interval 0.59–1.52).[15] It has been predicted that mRNA vaccines may elicit a very high antibody response in a small subset of youth, thereby eliciting a multisystem inflammatory syndrome-like response in children.[16] Other putative mechanisms include anti-idiotype cross-reactive antibody-mediated cytokine expression and the induction of aberrant apoptosis in the myocardium resulting in myocardial and pericardial inflammation.[12]

Apart from these case series in which the vaccination status of patients presenting with myocarditis was questioned and other causes of myocarditis were excluded and associated with vaccination, there is no prospective study that monitors adolescents in terms of cardiac functions after vaccination. Of course, we did not aim to find a case of myopericarditis at our centre based on the incidence of post-vaccine myopericarditis; however, we did aim to investigate the clinical or subclinical cardiac side effects of the vaccine, including especially asymptomatic ones, with close follow-up.

In our study, there were a total of seven patients with cardiac complaints. Three of them complained of mild atypical chest pain that was not severe, did not require hospitalization, had no troponin elevation, and had no electrocardiogram changes. Four other patients described shortness of breath or palpitations. Again no increase in troponin or abnormal electrocardiogram findings was observed in these patients. Complaints were not serious and did not persist at follow-up visits. Since they already had concomitant cardiac diseases, it was natural to have these complaints when questioned.

Even in the absence of clinical arrhythmia, whether there was variability in PR, QRS, and QTc intervals was followed up serially with an electrocardiogram. There was no significant change in electrocardiogram parameters during the follow-up, including those with palpitations.

During follow-up, patients' echocardiographic parameters were similar to baseline. Subclinical myocardial functions were evaluated with strain echocardiography even if there was no change in conventional parameters. Ahmed et al. reported post-COVID-19 three children who presented with various systemic inflammatory symptoms but no obvious cardiac symptoms, all with normal left ventricular ejection fraction but reduced global longitudinal strain.[17] The global longitudinal strain is a cardiac tissue deformation index used to detect early changes in global function even before changes in ejection fraction are seen. Because this finding may indicate subclinical myocardial damage, it has been used in several studies on both short-term and long-term effects of COVID-19 on cardiac function.[18,19] However, in our study we did not detect a statistically significant decrease in global longitudinal strain at any follow-up after two doses of the vaccine. In addition, we did not encounter any vaccine-induced perimyocarditis cases at our centre, including cases excluded before or during the study.

The most important limitations of our study are that it is a single-centre study, and the study population is small. In addition, we did not measure troponin values if patients were asymptomatic at the follow-up visit. So far, all cases of post-vaccine myocarditis have had high troponin levels with a sudden onset of chest pain. Therefore, we evaluated the troponin value in patients with cardiac complaints. Measurement of subclinical myocardial function by strain echocardiography without cardiac MRI is another limitation of the study. Finally, the fact that most of the post-vaccine

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myocarditis cases have been observed in healthy adolescents and young adults and that we did not include healthy hearts can be considered as a limitation of the study.

Conclusion

Although larger and longer follow-up studies are needed to monitor vaccine-related adverse cardiac events, our study points to the safety of the mRNA COVID-19 vaccine in relation to clinical and subclinical cardiac function in a cohort of adolescents at a paediatric cardiology clinic.

Supplementary material. To view supplementary material for this article, please visit https://doi.org/10.1017/S104795112200422X

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Conflicts of interest. None.

Ethical standards. This study complies with the Declaration of Helsinki, and the study protocol was approved by the local Ethics Committee (reference number: 2021/1716).

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