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RESEARCH ARTICLE

Evaluation of Late-Term Effects of BNT162b2 mRNA COVID-19 Vaccine on Myocardial Perfusion by Myocardial Perfusion Scintigraphy

BNT162b2 mRNA COVID-19 Aşısının Miyokardiyal Perfüzyon Üzerindeki Geç Dönem Etkilerinin Miyokardiyal Perfüzyon Sintigrafisi ile Değerlendirilmesi

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ABSTRACT

Objective: This study aimed to investigate the late-term effects of the BNT162b2 mRNA COVID-19 vaccine on myocardial perfusion using myocardial perfusion scintigraphy (MPS).

Materials and Methods: A retrospective analysis was conducted on 181 procedures involving pharmacological stress and rest single-photon emission computed tomography (SPECT) MPS performed between September 2020 and September 2023 in participants aged 18–70 years. Participants were divided into two groups: those who received the BNT162b2 mRNA vaccine (n=93) and those who did not (n=88). Individuals with prior cardiac surgery, severe valvular disease, atrial fibrillation, or other significant comorbidities affecting myocardial function were excluded. Demographic data, cardiovascular risk factors, and MPS parameters (end-diastolic volume [EDV], end-systolic volume [ESV], ejection fraction [EF], summed stress score [SSS]) were compared between groups.

Results: No significant intergroup differences were observed in age, sex, or cardiovascular risk factors ($p > 0.05$). The mean SSS was 2.54 ± 3.69 in vaccinated and 2.78 ± 4.15 in unvaccinated individuals ($p = 0.453$). Mean EF values between the vaccinated and unvaccinated groups were 64.27 ± 7.85% compared to 62.16 ± 9.79% ($p = 0.11$). No significant differences were observed in EDV (74.91 ± 18.63 ml vs. 77.18 ± 23.66 ml; $p = 0.48$) and ESV (27.58 ± 11.24 ml vs. 30.65 ± 15.69 ml; $p = 0.14$). No statistically significant difference was found in the frequency of ischemic MPS findings between the vaccinated and unvaccinated groups (34% vs. 35%; $p = 0.89$).

Conclusion: No adverse effects of the BNT162b2 mRNA vaccine on late-term myocardial perfusion or left ventricular function were detected.

Keywords: Myocardial Perfusion Scintigraphy, BNT162b2 mRNA Vaccine, Summed Stress Score, Cardiovascular Safety

ÖZET

Amaç: Bu çalışma, miyokard perfüzyon sintigrafisi (MPS) kullanarak BNT162b2 mRNA COVID-19 aşısının miyokard perfüzyonu üzerindeki geç dönem etkilerini araştırmayı amaçlamıştır.

Gereç ve Yöntemler: Eylül 2020 ile Eylül 2023 tarihleri arasında 18-70 yaş arası katılımcılarda farmakolojik stres ve istirahat tek foton emisyon bilgisayarlı tomografi (SPECT) MPS içeren 181 hasta üzerinde retrospektif bir analiz gerçekleştirilmiştir. Katılımcılar iki gruba ayrılmıştır: BNT162b2 mRNA aşısı olanlar (n=93) ve olmayanlar (n=88). Önceden kalp cerrahisi geçirmiş, şiddetli kalp kapak hastalığı, atriyal fibrilasyon veya miyokardiyal fonksiyonu etkileyen diğer önemli komorbiditeleri olan bireyler çalışma dışı bırakıldı. Demografik veriler, kardiyovasküler risk faktörleri ve MPS parametreleri (diyastol sonu hacmi [EDV], sistol sonu hacmi [ESV], ejeksiyon fraksiyonu [EF], toplam stres skoru [SSS]) gruplar arasında karşılaştırıldı.

Bulgular: Yaş, cinsiyet veya kardiyovasküler risk faktörlerinde gruplar arasında anlamlı bir fark gözlenmedi ($p > 0,05$). Ortalama SSS, aşılananlarda 2,54 ± 3,69 ve aşılanmayanlarda 2,78 ± 4,15 idi ($p = 0,453$). Aşılanan ve aşılanmayan gruplar arasındaki ortalama EF değerleri sırasıyla %64,27 ± 7,85 ve %62,16 ± 9,79 idi ($p = 0,11$). EDV (74,91 ± 18,63 ml vs. 77,18 ± 23,66 ml; $p = 0,48$) ve ESV (27,58 ± 11,24 ml vs. 30,65 ± 15,69 ml; $p = 0,14$) arasında anlamlı bir fark gözlenmedi. Aşılanan ve aşılanmayan gruplar arasında iskemik MPS bulgularının sıklığı açısından istatistiksel olarak anlamlı bir fark bulunmamıştır (34% vs. 35%; $p = 0,89$).

Sonuç: BNT162b2 mRNA aşısının geç dönemde miyokardiyal perfüzyon veya sol ventrikül fonksiyonu üzerinde herhangi bir olumsuz etkisi tespit edilmemiştir.

Anahtar Kelimeler: Miyokard perfüzyon sintigrafisi, BNT162b2 mRNA Aşısı, Toplam Stres Skoru, Kardiyovasküler Güvenlik.

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INTRODUCTION

Coronavirus disease 2019 (COVID-19) is one of the most highly transmissible infectious diseases worldwide, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus (1). During the early phase of the COVID-19 pandemic, preventive strategies were limited to the use of face masks, social distancing, and isolation of infected individuals. Subsequently, messenger RNA (mRNA)-based vaccines developed by Pfizer-BioNTech and Moderna were introduced and effectively employed to mitigate the global health crisis. These vaccines induce an immune response against SARS-CoV-2, either preventing infection or reducing disease severity. The rapid development and widespread administration of mRNA vaccines have played a crucial role in controlling the pandemic. However, as these vaccines were developed under emergency use authorization, ongoing concerns persist regarding their potential long-term cardiovascular effects (2–4). Reported cardiovascular adverse events following vaccination include myocarditis, pericarditis, arrhythmia, and thromboembolic complications, although the overall incidence of these conditions remains low (5–9). Myocardial perfusion scintigraphy (MPS) is an extensively used non-invasive functional imaging method for evaluating blood flow to the heart muscle. This technique is particularly effective in detecting myocardial ischemia, scarring, or other perfusion abnormalities (10).

In Türkiye, the BNT162b2 mRNA vaccine, developed by Pfizer-BioNTech, has been extensively administered. While the short-term cardiovascular effects of mRNA vaccines are relatively well known, their late-term effects on myocardial perfusion remain poorly understood. The aim of this study is to compare the late-term effects on myocardial perfusion between individuals who received the BNT162b2 mRNA vaccine and those who did not, using the MPS imaging method. The findings of this study may provide a better understanding of the late-term cardiovascular effects of the BNT162b2 mRNA vaccine.

MATERIALS AND METHODS

Research Methodology

This retrospective analysis encompassed patients aged from 18 to 70 years old who received MPS with pharmacologic stress and rest single-photon emission computed tomography (SPECT) from September 2020 to September 2023. The study was conducted in accordance with the Declaration of Helsinki. This study was approved by the Necmettin Erbakan University Ethics Committee (decision number: 2025/5625) on March 7, 2025.

The inclusion and exclusion criteria for participant selection in this study are outlined below.

Inclusion Criteria

• Referred for MPS due to clinical indications, including chest pain, dyspnea, or abnormal exercise stress test results suggestive of suspected coronary artery disease (CAD).

• Known vaccination status for the BNT162b2 mRNA vaccine (vaccinated or unvaccinated).

• Minimum interval of 6 months (180 days) between the last BNT162b2 vaccine dose and MPS for vaccinated patients.

Exclusion Criteria

• Confirmed atherosclerotic CAD (documented by angiography, coronary CT angiography, or history of myocardial infarction).

• History of heart failure, pulmonary thromboembolism, severe chronic obstructive pulmonary disease, malignancy, or renal failure.

• Prior cardiac surgery, severe valvular disease.

• Receipt of COVID-19 vaccines other than BNT162b2.

• Active or recent (<6 months) COVID-19 infection.

The medical history, clinical and demographic data, vaccination status, vaccine type, number of doses, and vaccination dates for all participants were collected and recorded from patient interviews and the electronic medical record system.

Patient Grouping

The patients were classified into two groups according to their receipt of the BNT162b2 mRNA vaccination aimed at the SARS-CoV-2 virus: one group received the vaccine, while the other group did not.

Acquisition and Analysis of SPECT Images

The patients were instructed to cease the use of calcium channel blockers, beta-blockers, nitrates, and caffeine-containing medications 24 to 48 h prior to the MPS imaging. The MPS investigation was conducted following the directives established by the European Society of Nuclear Medicine (11). A same-day protocol was employed for the stress-rest SPECT imaging. This approach involved an initial conducting of pharmacologic stress imaging, followed by rest imaging around 4 h later on the same day. Adenosine was supplied intravenously at a dosage of 140 µg/kg/min for a duration of 6 minutes during the pharmacologic stress test (11). Technetium-99m-methoxyisobutylisonitrile (Tc-99m MIBI) was administered as an intravenous bolus at the end of the 3rd min of adenosine infusion. Stress SPECT images were obtained 45 min post-injection of Tc-99m MIBI. During stress imaging, 8–12 mCi of Tc-99m MIBI was injected, whereas 24–36 mCi was provided during rest imaging approximately 4 h after the initial radiopharmaceutical injection (11).

The SPECT examination employed a dual-head camera (Siemens Medical Solutions, Forchheim, Germany) equipped with a low-energy high-resolution collimator. Eight-frame overlays were used, and a pulse length acceptability threshold of 20% was created. The data were recorded in a 64 × 64 matrix. Image interpretation was performed both visually and quantitatively using the Cedars-Sinai Quantitative Perfusion SPECT software. The left ventricular (LV) ejection fraction (EF) and wall motion were acquired from gated images around 4h after the initial radiopharmaceutical injection.

Stress and rest images were evaluated in a double-blind manner by two experienced nuclear medicine specialists using a 17-segment model of the left ventricle and a five-point scale (0 = normal perfusion, 1 = slightly reduced, 2 = moderately reduced, 3 = significantly reduced, 4 = perfusion defect) (12). Interobserver agreement was evaluated using Cohen's Kappa

coefficient, yielding a Kappa value of 0.85 (95% CI: 0.79–0.91), indicating excellent reproducibility. In instances of discord between the two specialists, further consultation was obtained from additional professionals within the department, and all discrepancies were solved through a consensus.

Perfusion scores were calculated to assess myocardial perfusion abnormalities and their severity. The summed stress score (SSS) represents the sum of all perfusion defects noted on the stress image, the summed rest score (SRS) indicates the sum of all defects detected on the rest image, and the summed difference score (SDS) is calculated from the difference among the stress and rest values (13). The QGS software autonomously calculated left ventricular functional parameters, encompassing left ventricular end-diastolic volume (EDV), left ventricular end-systolic volume (ESV), and EF. The patients were classified into two groups: those with an SSS of 0–3 and those with an SSS of 4 or higher. In this study, images having an SSS of 4 or higher were classified as abnormal.

Statistical Analyses

The sample size was calculated using G*Power 3.1 software, assuming a medium effect size (Cohen's d = 0.5), a significance level of 0.05, and a statistical power of 80%. Accordingly, a minimum of 64 participants per group was required. In the present study, a total of 93 participants were included in the vaccinated group and 88 individuals were in the unvaccinated group, both exceeding the minimum sample size needed to maintain adequate statistical power.

Statistical processing and analysis were performed using SPSS 25.0 software. To evaluate the normal distribution of numerical data, histogram plots, skewness, kurtosis, and the Kolmogorov-Smirnov test were employed. According to these analyses, age, ESV, EDV, and EF followed a normal distribution, while SSS did not. The Student's t-test was employed for regularly distributed variables, whereas the Mann-Whitney U test was used for non-normally distributed data. The chi-square test was used for categorical data. Descriptive statistics were provided as counts and percentages for qualitative data, and as means ± standard deviations or medians for quantitative data. For all studies, a p-value below 0.05 was assumed to indicate statistical significance.

RESULTS

The study involved a total of 181 individuals. The average age of the participants was 54.94 ± 10.03 years, with 53% identifying as female and 47% as male. All vaccinated subjects had received a minimum of two doses of the BNT162b2 mRNA vaccine. No significant differences were observed in age, gender, or cardiovascular risk factors (hypertension, diabetes, smoking, and family history) among the two groups (p> 0.05). Table 1 shows the clinical and demographic features of the patients. Table 2 presents a comparison of the quantitative data obtained from MPS and myocardial perfusion patterns

Table 1. Clinical and Demographic Characteristics of the Participants

General Characteristics		Vaccine + (n=93)	Vaccine – (n=88)	pValue
Age (Years)	Mean ± SD	53.96±9.36	55.97±10.73	0.185
Gender	Male/Female	43/50	42/46	0.841
Hypertension	Yes/No	46/47	49/39	0.402
Smoking	Yes/No	29/64	25/63	0.684
Diabetes mellitus	Yes/No	26/67	23/65	0.783
Hyperlipidemia	Yes/No	11/82	9/79	0.64
Family history of CAD	Yes/No	46/47	51/37	0.252
Chest pain	Yes/No	81/12	78/10	0.615
Dyspnea	Yes/No	21/72	17/71	0.566
Abnormal Stress ECG Test	Yes/No	49/44	46/42	0.837

SD: Standard Deviation; ECG: Electrocardiogram; n: sample size

Table 2. Comparison of MPS Data and Perfusion Patterns between Groups

MPS DATA		Vaccine + (n=93)	Vaccine – (n=88)	pValue
ESV (mL)	Mean ± SD	27.58 ±11.24	30.65± 15.69	0.14
EDV (mL)	Mean ± SD	74.91 ± 18.63	77.18 ± 23.66	0.48
EF (%)	Mean± SD	64.27 ± 7.85	62.16 ± 9.79	0.11
SSS	Mean± SD	2.54 ± 3.69	2.78 ± 4.15	
	Median (IQR 25-75)	0 (0-6)	0 (0-7)	0.45
SRS	Median (IQR 25-75)	0 (0-2)	0 (0-2)	0.79
MPS Result	Normal/Ischemia (%)	61/32 (66/34)	57/31 (65/35)	0.89

MPS: Myocardial Perfusion Scintigraphy; EDV: End-diastolic volume; ESV: End-systolic volume; SSS: Summed Stress Score; SRS: Summed Rest Score; SD: Standard Deviation, EF:Ejection Fraction; IQR: Inter Quartile Range; mL: milliliter; n: sample size

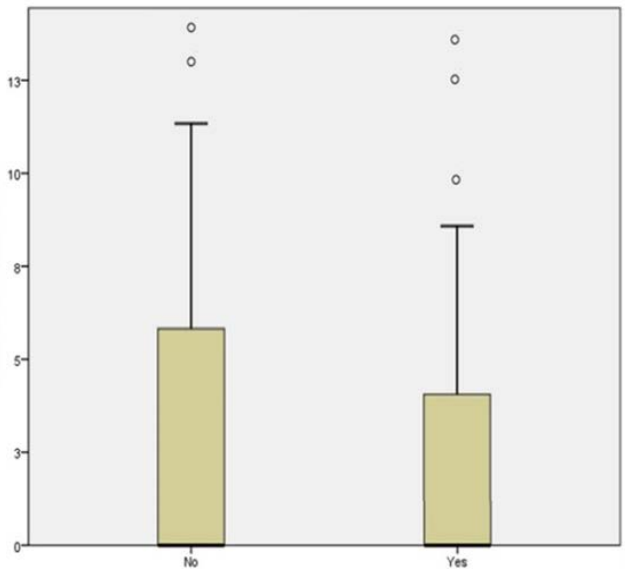

Figure 1. Distribution of Summed Stress Scores among vaccinated and unvaccinated participants.

Y-axis: Summed Stress Score (SSS) **X-axis:** Vaccination Status (vaccinated and unvaccinated)

between the two groups.

No substantial differences were detected between the two groups in any of the analyses ($p > 0.05$). Despite the vaccinated group exhibiting a lower SSS, no statistically significant difference between the two groups was observed ($p > 0.05$). The boxplot illustrating the distribution of SSS between vaccinated and unvaccinated participants is presented in Figure 1.

As can be seen in the figure, although the median SSS value was slightly lower in the vaccinated group compared with the unvaccinated group, this difference did not reach statistical significance ($p = 0.45$; Mann–Whitney U test).

DISCUSSION

The effectiveness of mRNA vaccines against COVID-19 infection in reducing disease severity and preventing hospitalizations was previously strongly demonstrated by randomized controlled trials and real-world data (14, 15). However, as with any medical intervention, concerns arose about potential side effects, particularly those affecting the cardiovascular system. While short-term adverse effects, such as myocarditis and pericarditis, were extensively documented in the literature (2-9), the long-term cardiovascular consequences of mRNA vaccines remain insufficiently explored. MPS is a recognized, harmless imaging modality used to evaluate myocardial blood flow. It excels in detecting myocardial ischemia, scarring, and other perfusion abnormalities (10). However, despite its widespread application, its use in evaluating the long-term effects of mRNA vaccines on myocardial perfusion remains limited. To bridge this gap in the literature, in the present study, we compared myocardial perfusion patterns between individuals vaccinated with BNT162b2 and those who were not. To the best of our knowledge, the present study is the first to assess the late-term effects of the BNT162b2 mRNA vaccine on myocardial perfusion using MPS.

We found no significant differences in myocardial perfusion parameters, including the SSS, between the vaccinated and unvaccinated groups. This suggests that BNT162b2 does not exert a detrimental effect on myocardial perfusion in the long term. This result is particularly reassuring in the context of concerns surrounding the long-term cardiovascular safety of mRNA vaccines. This evidence also aligns with extensive observational data, such as that from Barda et al. (16) who reported that serious cardiovascular events were rare in a nationwide study of BNT162b2 administration. mRNA vaccines such as BNT162b2 have been crucial in the pandemic response by generating a strong immune response against SARS-CoV-2, therefore avoiding or alleviating illness severity. However, cardiovascular adverse events reported in previous studies (5–9, 17) reinforced the ongoing debate on the long-term cardiovascular safety of mRNA vaccines. These observations fueled debates about the late-term cardiovascular safety of mRNA vaccines. The mechanisms underlying these adverse effects remain poorly understood. A prevailing hypothesis predicts that the SARS-CoV-2 spike protein, produced in response to mRNA vaccination, interacts with angiotensin-converting enzyme 2 (ACE2) receptors, which are abundantly expressed in cardiovascular tissues (18). This interaction may trigger T-cell activation, potentially leading to myocardial damage by targeting both the vaccine-induced spike protein and cardiac antigens (19, 20). Furthermore, another study suggested that myocarditis following BNT162b2 vaccination may be linked to an inflammatory process (21). However, whether these mechanisms translate into long-term perfusion abnormalities remains uncertain, warranting further research.

Previous studies provided positive insights into the safety profile of mRNA vaccines, helping to alleviate public concerns about their rapid development during the COVID-19 pandemic (14,15,17). Adverse effects observed in the myocardium, particularly in the early post-vaccination period, were frequently associated with inflammatory responses and endothelial dysfunction (23-27). For instance, in a prospective study, Yamaji (28) found that endothelial dysfunction in relatively healthy individuals following vaccination is transient, resolving within 6 months without affecting vascular smooth muscle function. In our study, the lack of significant perfusion differences between the two groups may be attributed to the resolution of endothelial dysfunction and the preservation of vascular smooth muscle function, as previously demonstrated, considering that the interval between vaccination and MPS was at least six months (28). In addition, a Nordic (29) cohort study demonstrated that the late-term cardiovascular effects of BNT162b2 are minimal. Since our study involved a minimum interval of six months between vaccination and MPS, these findings may account for the lack of perfusion differences

observed between the two groups. While our findings suggest that BNT162b2 does not adversely affect myocardial perfusion in the late-term, questions remain about its cardiovascular safety in higher-risk populations, such as those with pre-existing endothelial dysfunction or coronary artery disease. These groups may be more susceptible to vaccine-related cardiovascular effects due to the underlying vascular pathology. Future research would be needed to explore these populations using advanced imaging techniques to detect subclinical changes.

COVID-19 infection may cause myocardial damage through mechanisms such as cytokine-mediated inflammation or microvascular dysfunction, potentially impacting MPS findings. Although the present study excluded individuals with active or recent COVID-19 symptoms to minimize confounding, we cannot completely exclude the long-term myocardial effects of COVID-19 infection (13,18,30). Future research, including systematic documentation of COVID-19 history and serologic testing, would be needed to distinguish infection-related from vaccine-related cardiac effects. Furthermore, despite these data suggesting a positive assessment of BNT162b2's cardiovascular safety, the present study has several limitations. The one-center, retrospective study design and limited sample size (n = 181) may restrict generalizability of the findings. Furthermore, as a retrospective analysis, the present study is inherently limited in its ability to establish causal relationships and may be subject to selection bias, which should be considered when interpreting the results. Additionally, the study population consisted of individuals without previously known endothelial dysfunction, which may limit generalizability of the results to higher-risk populations. Although cardiovascular risk factors (e.g., high blood pressure, diabetes mellitus, dyslipidemia, cigarette smoking, age, gender, and family history) were similar between the vaccinated and unvaccinated groups, their potential impact on vaccine-related outcomes requires examination in larger cohorts.

Furthermore, due to the lack of documentation of booster doses in some patient records, we did not perform a comprehensive subgroup analysis based on the number of doses. Similarly, while the statistical methodology employed was sufficiently robust for primary comparisons, constraints inherent to the dataset and the moderate sample size limited the implementation of more sophisticated analytical techniques for subgroup evaluations. Consequently, a comprehensive investigation into potential heterogeneity and subtle patterns within these subgroups could not be conducted. Echocardiographic parameters were not systematically available due to the retrospective nature of the study; therefore, they were not included in the analysis to prevent selection bias. In addition, patients exhibiting ischemia identified using MPS were not routinely evaluated with coronary CT angiography or invasive coronary angiography due to the retrospective nature of the study. However, such complementary imaging could have provided valuable anatomical correlation. Future studies integrating MPS with coronary CT angiography or cardiac MRI are warranted to better delineate the etiology of perfusion abnormalities. Fronza et al. (31) demonstrated that cardiac MRI can assess subclinical effects in asymptomatic individuals post-mRNA vaccination. Finally, MPS's inability to directly evaluate microvascular function or subclinical inflammation suggests that subtle cardiovascular effects of the vaccine may have been overlooked. This suggests that complementary techniques, such as cardiac MRI, could prove valuable in future studies.

Despite the limitations outlined above, the present study makes a significant contribution to understanding BNT162b2's long-term cardiovascular safety and provides a reassuring perspective from a public health standpoint. The minimal impact of the vaccine on myocardial perfusion may support reliability of mRNA technology not only for combating COVID-19, but also for innovative applications such as cancer immunotherapy. This being said, in order to enhance the robustness of these findings, multicenter, prospective studies with extended follow-up periods would be necessary.

CONCLUSION

Unlike the short-term adverse effects of the BNT162b2 mRNA vaccine, in the present study, we focused on examining the long-term consequences on myocardial perfusion. No association was found between the BNT162b2 vaccine and increased myocardial ischemia. This result may help to alleviate concerns that the BNT162b2 mRNA vaccine could have a detrimental effect on myocardial perfusion in the long-term. It can be considered a reassuring finding, particularly in terms of public health. Further comprehensive and long-term studies would be needed to further strengthen the cardiovascular safety profile of mRNA vaccines.

DECLARATIONS

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