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COVID-19 Vaccine-Induced Subclinical Myopericarditis: Pathophysiology, Diagnosis, and Clinical Management

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ABSTRACT

The currently approved COVID-19 mRNA boosters carry a warning for acute, clinically apparent, vaccine-induced myocarditis. This serious condition has resulted in hospitalization and, in well-documented cases, fatalities. However, there is growing concern that long-lasting synthetic mRNA and persistent production of SARS-CoV-2 Spike protein may accumulate in the heart and cause cardiotoxicity over time. Additionally, subtler cardiovascular symptoms, which may not require immediate hospitalization, can also develop. Such symptoms include atypical or pleuritic chest pain, palpitations, intermittent arrhythmias, labile blood pressure with hyper- and hypotension and effort intolerance. Areas of inflammation found at autopsy too small to be detectable by cardiac magnetic resonance imaging have been associated with sudden death. Alarmingly, the initial presentation can include cardiac arrest with no premonitory symptoms. A thorough evaluation, including history of SARS-CoV-2 infections, the number and type of mRNA COVID-19 vaccines received, quantitative Spike protein antibody levels, ECG, imaging, and laboratory tests, form the cornerstone of initial assessment. Clinical and preclinical observations suggest combined oral administration of nattokinase, bromelain, and curcumin may support detoxification of the heart and cardiovascular system from Spike protein. The addition of colchicine and other targeted therapies may be essential in reducing myocardial and systemic vascular inflammation. These approaches hold promise to risk mitigation of sudden cardiac death in immunized individuals affected by subclinical COVID-19 vaccine induced myopericarditis.

Introduction

The COVID-19 pandemic has driven rapid development and deployment of genetic vaccines, notably the synthetic modified mRNA products, BNT162b2 and mRNA-1273, manufactured by Pfizer-BioNtech and Moderna, respectively. Significant controversy regarding COVID-19 mRNA vaccine safety has arisen based largely on postmarketing studies, autopsy studies, and careful reanalysis of the registrational trials that led to emergency use authorization of the products[1,2,3,4,5,6]. Nevertheless, it is estimated that 81% of Americans took one or more doses[7]. Among the myriad of safety concerns[8,9], subclinical myopericarditis following mRNA vaccination has emerged as an area of ongoing clinical research[10]. Subclinical myopericarditis refers to inflammation of the myocardium (heart muscle) and pericardium (the sac surrounding the heart) detected primarily through laboratory or imaging findings, without overt or pronounced clinical symptoms. Epidemiologists and cardiologists alike have voiced concern that subclinical vaccine-induced myopericarditis could explain changes in cardiac arrest rates at a population level[11,12,13,14,15,16].

Most cases of myocarditis are more accurately referred to as myopericarditis, as cardiac MRI often reveals concurrent pericardial involvement, such as thickening or effusion, alongside myocardial inflammation[17,18]. Symptoms may include chest pain, palpitations, or shortness of breath, but in subclinical cases, individuals remain asymptomatic, and the condition is usually detected through elevated biomarkers, electrocardiogram (ECG) changes, or imaging studies such as cardiac MRI[19].

In this paper, we synopsize key aspects of COVID-19 mRNA vaccine-induced subclinical myocarditis in terms of etiopathogenesis, epidemiology, diagnostic challenges, clinical care issues, policy implications, and future research directives. We outline a comprehensive evaluation protocol involving medical history, Spike protein antibody levels, ECG, imaging, and laboratory tests to assess vaccine-induced myopericarditis and related conditions. Our empirically supported approach to mitigating myocardial and vascular inflammation is aimed at reducing the elevated rates of sudden cardiac death observed in mRNA-vaccinated individuals with no other identifiable cause.

Etiology and Pathogenesis

The pathogenesis of myopericarditis is typically associated with viral infections, autoimmune conditions, or rare reactions to medications and vaccines[20]. In the context of COVID-19 vaccination, the mRNA-based vaccines have been most commonly associated with cases of vaccine-induced myopericarditis[21,22]. The exact mechanisms remain under investigation but are hypothesized to involve immune-mediated processes triggered by the mRNA vaccine's stimulation of the immune system to produce Spike protein antigens within the myocardium as well as in the systemic circulation[23].

Several studies provide strong biological plausibility for a causal relationship between the COVID-19 mRNA vaccinations and myocarditis. Upon autopsy of mRNA vaccinees, Krauson et al. isolated synthetic mRNA (Pfizer/Moderna) in the human heart, strongly indicating cardiac involvement[24]. Baumeier and colleagues found vaccine Spike protein in the hearts of young men suffering from vaccine myopericarditis[25]. Yonker et al. described unbound circulating Spike protein in blood of young persons hospitalized with COVID-19 vaccine-induced myopericarditis, while a vaccinated asymptomatic control group had appropriately neutralized Spike with anti-Spike antibodies[26]. Thus, the inflammation of myopericarditis appears to be secondary to locally present vaccine mRNA and Spike protein. The time course for myocardial accumulation of these factors is unknown but conceivably could occur over several years with chronic Spike protein circulation in the blood, myocardial perfusion, and deposition into the coronary arteries, capillary endothelium and the myocardial tissue.

Epidemiology, Risks, and Outcomes

Myopericarditis following COVID-19 mRNA vaccination is well-documented, occurring in all age groups for both genders. The majority of cases, however, have occurred in young males (<age 40) within a week after receiving the second dose[27]. A large Nordic study (n=23 million) found that mRNA vaccinations, particularly the second doses of BNT162b2 and mRNA-1273, were associated with higher rates of myocarditis in young men aged 16-24, with 5.55 and 18.39 excess events per 100,000 doses, respectively, compared to 1.37 excess events per 100,000 positive SARS-CoV-2 tests[28]. The mRNA vaccine-related myocarditis

events were four times higher for BNT162b2 and over 13 times higher for mRNA-1273 than infection-related myocarditis in this younger cohort, despite underreported infection rates potentially further lowering the true rate of infection amplifying the vaccine myocarditis incidence.

The incidence of subclinical myopericarditis is challenging to estimate, as it requires sensitive screening and is not associated with symptoms that would prompt clinical evaluation. Chiu et al found among 763 students a rate of 17.1% had at least one cardiac symptom after the second vaccine dose, mostly chest pain and palpitations[29]. Three prospective cohort studies have evaluated the incidence of subclinical myopericarditis after injection of synthetic mRNA. Mansanguan et al. reported an incidence rate of 2.3%, Buergin et al. reported an incidence rate of 2.8%, and a Pfizer-sponsored study yielded an estimated incidence rate of of 1.0%, though that study omitted daily cardiac troponin measurements[30,31,32]. It is reasonable to surmise that approximately 1-3% of COVID-19 mRNA vaccine recipients suffer some degree of myocardial injury per dose, thereby representing a profound concern for the short- and long-term health of younger vaccinees[33].

Population-level studies, such as cardiac MRI screening in selected cohorts, have identified a higher incidence of subclinical myocarditis than previously recognized, again mostly in adolescent and young adult males[34]. Nonetheless, most observational studies are ineffectual in this determination because they do not involve careful clinical examinations, imaging, and measurements of cardiac biomarkers in all subjects before and after vaccine administration. Without prospective monitoring of cardiac function, subclinical myopericarditis cases following COVID-19 vaccinations are grossly underreported in large cohort and surveillance studies.

Despite the mild outward or even asymptomatic appearance of subclinical myocarditis, many cases can involve severe cardiac fibrosis (scarring), leading to permanent heart muscle damage and a lifelong risk of fatal arrhythmias[35,36]. This damage may eventually progress to congestive heart failure and premature death[37]. Physical stress, such as vigorous exercise, may trigger cardiac arrest in younger adults with either clinical or subclinical myocarditis due to an adrenaline surge, potentially contributing to fatal outcomes[38].

Clinical Presentation of Subclinical Myopericarditis

Unlike overt myopericarditis, subclinical cases may lack obvious symptoms. **Figure 1** summarizes the broad clinical manifestations of vaccine-induced subclinical myopericarditis. Individuals usually do not experience severe chest pain, palpitations, or shortness of breath requiring hospitalization. However, more subtle cardiovascular symptoms develop that do not warrant acute hospitalization. Such symptoms may include atypical or pleuritic chest pain, palpitations, intermittent arrhythmias, labile blood pressure with hyper- and hypotension and effort intolerance[39,40].

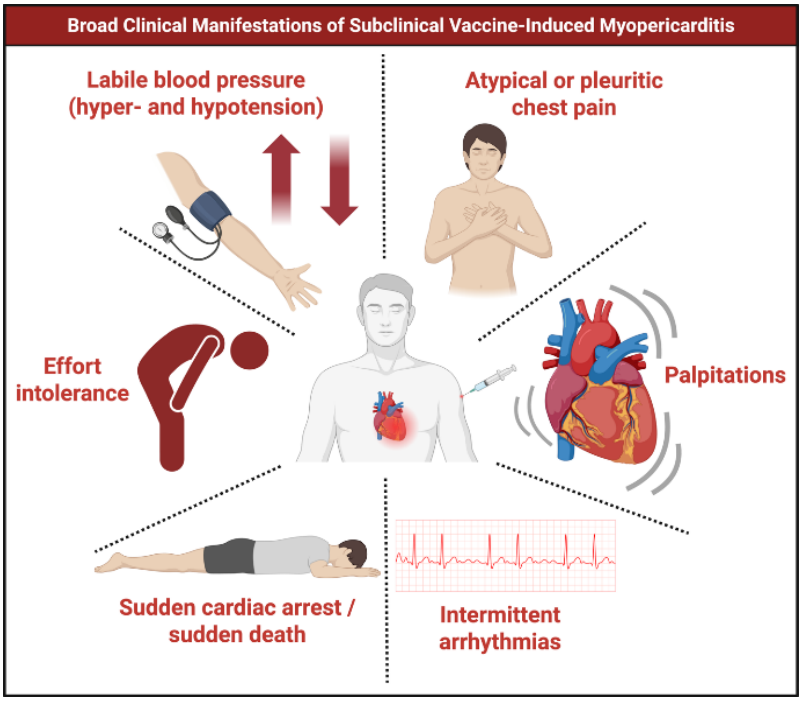

Figure 1. Broad Clinical Manifestations of Subclinical Vaccine-Induced Myopericarditis. This figure illustrates the broad spectrum of clinical manifestations associated with subclinical COVID-19 vaccine-induced myopericarditis. Unlike overt cases, affected individuals typically lack obvious symptoms such as severe chest pain or dyspnea. Instead, more subtle cardiovascular signs may appear, including atypical or pleuritic chest pain, palpitations, intermittent arrhythmias, labile blood pressure with both hyper- and hypotensive episodes, and effort intolerance. In certain cases, the first clinical presentation may be catastrophic, with sudden cardiac arrest or sudden death representing the most severe end of the continuum. These features underscore the importance of proactive screening and surveillance to identify subclinical cases early and prevent life-threatening outcomes. **Created with BioRender.com*

Subclinical myopericarditis may be suspected, identified, and supported by the following: 1) new symptoms arising shortly after mRNA vaccination, 2) labile blood pressure and heart rate (postural orthostatic tachycardia syndrome, or POTS), 3) elevated cardiac biomarkers (e.g., troponin I or T, BNP, galectin-3, d-dimer), 4) markedly elevated quantitative antibodies to Spike antigen, 5) presence of circulatory Spike protein, 6) presence of persistent vaccine mRNA in blood or tissue, 7) abnormal electrocardiogram (ECG) findings (e.g., ST-segment changes, arrhythmias), 8) imaging abnormalities (e.g., late gadolinium enhancement on cardiac MRI).

Any combination of these factors, particularly when observed in the context of recent mRNA vaccination, could aid in the detection of subclinical myopericarditis. In certain cases, however, the initial manifestation may be catastrophic, with sudden cardiac arrest or sudden death representing the most severe end of the clinical continuum of vaccine-induced subclinical myopericarditis. This possibility underscores the importance of proactive screening and surveillance to detect subclinical cases early, before they progress to life-threatening outcomes.

Diagnostic Tools and Criteria

Diagnosis of and risk stratification for subclinical myopericarditis typically depends on a combination of laboratory and imaging findings[41]:1) laboratory Tests: high-sensitivity troponin, BNP, galectin-3, d-dimer assays may reveal mild to moderate elevations, suggestive of myocardial injury, 2) electrocardiography: non-specific changes such as mild to moderate ST-segment or T-wave abnormalities may be present, 3) cardiac imaging: echocardiographic evidence of ventricular dysfunction and or pericardial effusion an cardiac MRI evidence of myocardial inflammation, with findings such as late gadolinium enhancement and edema. Large pericardial effusions warrant serologic testing for the antinuclear antibody and may require drainage[42].

Because these patients lack overt severe symptoms, diagnosis is often incidental or made in the context of research studies or screening protocols. However, recent evidence suggests that a more comprehensive risk stratification approach is warranted. A Spike Protein exposure history: Each SARS-CoV-2 infection or mRNA vaccination represents a cumulative exposure. A higher number of exposures correlates with greater risk of persistent Spike protein in circulation and myocardium.

Anti-Spike antibody concentration is prognostic and available in quantitative antibody assays (e.g., Roche Elecsys) serving as proxies for prior Spike exposure[43,44,45] Low titers (<1000 U/mL) suggest

lower risk, whereas persistently high titers (>1000 U/mL, sometimes >25,000 U/mL for years) indicate heightened risk[46].

Genetic testing is prudent to understand predisposition in high-risk patients or resuscitated cardiac arrest cases, genetic screening for ion channelopathies (e.g., SCN5A mutations) may identify inherited susceptibility[47].

Cardiac MRI with contrast demonstrating LGE indicates fibrosis. In other cardiomyopathies, late gadolinium enhancement ≥15% of the left ventricle has been predictive of sudden cardiac arrest and may serve as a high-risk marker here as well. Autopsy studies have indicated, however, that small patches of inflammation too small to be detected by cardiac MRI can be the presumed source of fatal re-entrant arrhythmias without the antecedent development of left ventricular dysfunction[11,48]. Thus a normal cardiac MRI does not rule out the presence of potentially lethal subclinical COVID-19 vaccine myopericarditis.

Risk modifiers include vaccine batch-to-batch variability, younger age, male sex, cumulative doses, and shorter intervals between doses should be incorporated into patient evaluation[49].

Collectively, this expanded diagnostic and risk stratification framework allows clinicians to identify patients with silent subclinical myopericarditis who might otherwise appear healthy, thereby facilitating early intervention and potentially preventing sudden cardiac arrest (**Figure 2**)[50].

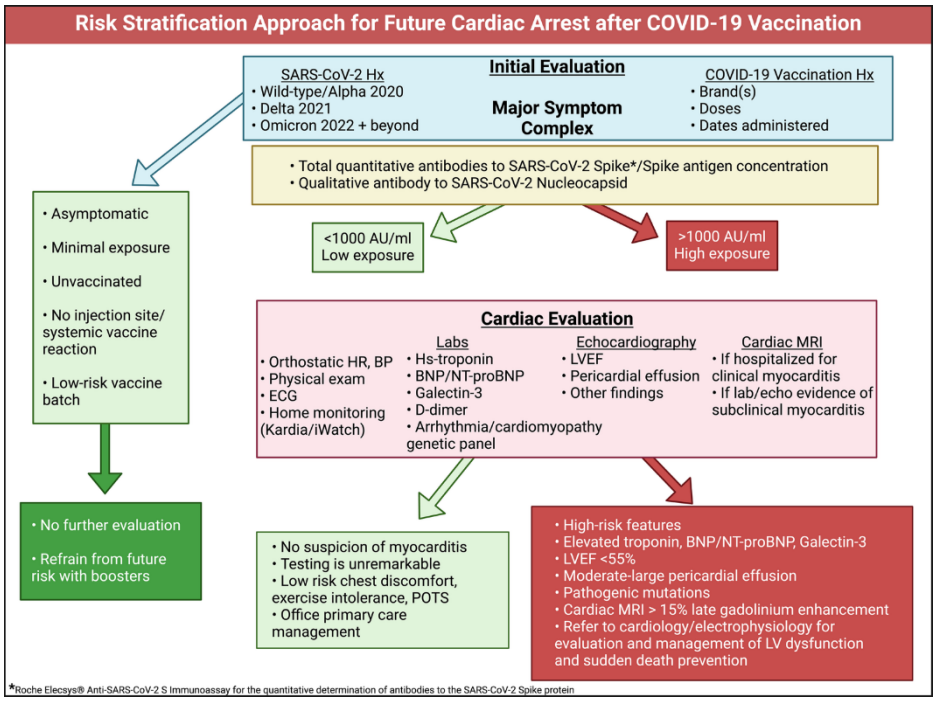

Figure 2: Risk Stratification Approach for Future Cardiac Arrest After COVID-19 Vaccination. Green boxes indicate clinical features, test results, and patients at lower risk. Red and pink boxes show tests and results indicating higher risk. Hx: History; AU/mL: Antibody units per milliliter; HR: Heart rate; BP: Blood pressure; ECG: Electrocardiogram; Hs-troponin: High-sensitivity troponin; BNP/NT-proBNP: Brain natriuretic peptide and N-terminal proBNP; LVEF: Left ventricular ejection fraction; POTS: Postural orthostatic tachycardia syndrome

**Figure reprinted from McCullough & Hulscher[40]. Permission to use this figure has been granted in accordance with the open access Creative Common CC BY-NC 4.0 license. Created with BioRender.com.*

Clinical Course and Prognosis

Most reported cases of vaccine-induced subclinical myopericarditis are self-limited, with normalization of biomarkers and imaging findings within weeks to months. It is critical to understand the importance of long-lasting tissue Spike deposition in this disease[51,52,53]. Resolution of this issue is potentially greatly assisted with Spike protein detoxification[54] combined with colchicine[55,56] over the course of a year or more. The proposed detoxification includes nattokinase 8000-16000 FU, bromelain 500-1000 mg, and curcumin 500-1000 mg daily (McCullough Protocol Base Spike Detoxification).™ Severe outcomes, such as persistent cardiac dysfunction or arrhythmias, are common and managed in accordance with current guidelines for subclinical cases.

Management Strategies

For subclinical cases, management is largely conservative, as patients are asymptomatic and recover spontaneously. Monitoring may include

follow-up biomarker testing and repeat cardiac imaging to confirm resolution. Recommendations may include: 1) temporary abstention from vigorous physical activity until biomarkers and imaging normalize and a reasonable period of detoxification has been performed, 2) Spike detoxification with oral nattokinase, bromelain, and curcumin[57] 3) colchicine 4) rapamycin (select cases)[58] Pharmacologic therapy is generally reserved for those with symptoms or evidence of significant inflammation or cardiac dysfunction. **Figure 3** outlines a schematic longitudinal approach for patients with subclinical vaccine-induced myopericarditis.

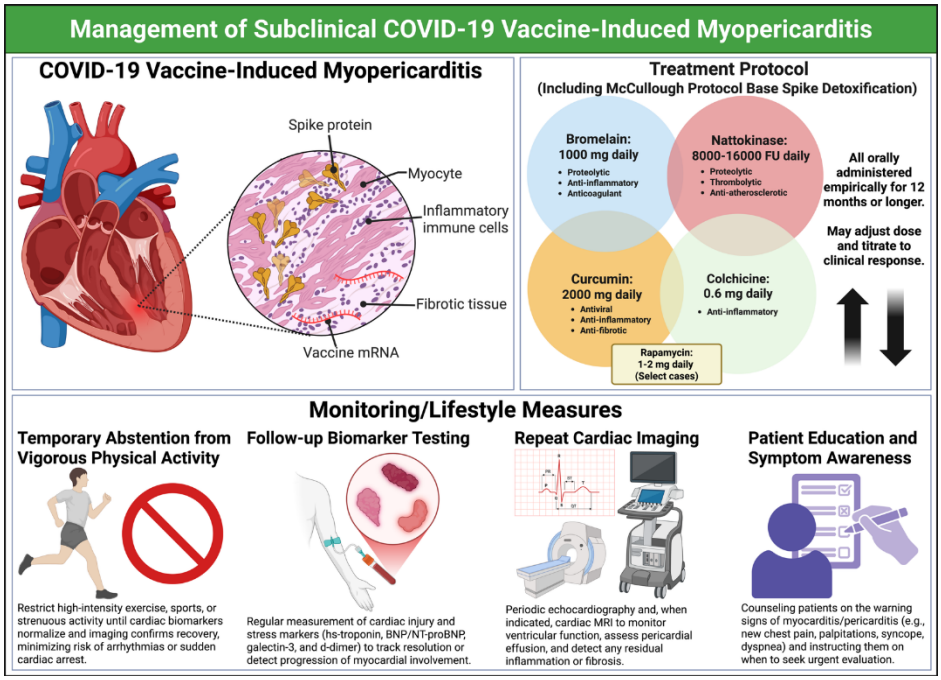

Figure 3. Management of Subclinical COVID-19 Vaccine-Induced Myopericarditis. This schematic summarizes a structured management approach to subclinical COVID-19 vaccine-induced myopericarditis. The lower panel emphasizes foundational monitoring and lifestyle measures, including temporary abstention from vigorous physical activity, serial biomarker testing, repeat cardiac imaging, and patient education regarding warning symptoms. The upper right panel illustrates pharmacologic strategies, beginning with the McCullough Protocol Base Spike Detoxification™ (nattokinase 8000–16,000 FU daily, bromelain 500-1000 mg daily, curcumin 500-1000 mg daily), combined with colchicine 0.6 mg daily, and in select cases, rapamycin 1–2 mg daily. All therapies are typically administered for 12 months or longer, with dose adjustment based on clinical response. **Created with BioRender.com*

Implications for Vaccine Policy

Recognition of subclinical myopericarditis has informed COVID-19 vaccine policy, particularly for young males with warnings in US Food and Drug Administration package inserts for Pfizer and Moderna mRNA vaccines. Some countries have recommended alternative dosing intervals, use of specific vaccine brands, or additional monitoring in higher-risk groups. Others have called for the complete market removal of COVID-19 vaccines to fully avoid any more cardiac injury on a population level[59].

Comparative Risks

The risk of myopericarditis from the mRNA inoculations is substantially higher and may be more severe than purported infection-associated cases[60,61]. COVID-19 vaccination, not SARS-CoV-2 infection, remains the main culprit in serious illness, hospitalization, and death after injection. Historically, no other group of vaccine products has represented such a clear, large-scale risk. An analysis of data from the Vaccine Adverse Event Reporting System (VAERS) indicated that myocarditis reports following the 2021 COVID-19 vaccine rollout from recipients were statistically at a 223 times greater volume than the average for all vaccines over the prior 30 years[62].

Research Gaps and Future Directions

Ongoing research aims to clarify: 1) true cumulative incidence of subclinical myopericarditis through population screening studies, 2) mechanisms underlying synthetic mRNA and Spike damage to the myocardium and the immune response leading to further cardiac involvement, 3) long-term outcomes of subclinical and mild clinical cases including heart failure and sudden death, 4) clinical, serological, and genetic markers of susceptibility. Continued surveillance and reporting

will help refine vaccine recommendations and ensure optimal safety.

Patient and Public Communication

Clear communication honoring the precautionary principle is essential to maintain vaccine safety and ensure individuals are aware of the potential risks, including sudden cardiac death. Health professionals should be vigilant in cases of subclinical myopericarditis, while encouraging Spike detoxification as a safe and easily implemented health care measure, at least until more research is completed.

Limitations

We recognize that large, prospective, blinded, triple-dummy, placebo-controlled trials will be required to make regulatory claims concerning one or more components of Spike detoxification. To our knowledge, no such trials have been proposed and budgeted let alone organized and started enrollment. As years continue to pass in the pandemic there is a greater need for empirical management with close clinical observations. Such a conclusive trial from funding to publication could take 5 to 20 years.

Conclusion

COVID-19 vaccine-induced subclinical myopericarditis may be more common than has been officially recognized, primarily occurring among younger males following mRNA vaccination. However, the true prevalence and incidence of subclinical cases is unknown due to lack of routine cardiac screening for functional complications post-vaccination in the general population. Persistent SARS-CoV-2 Spike protein accumulation in the heart may lead to subtle cardiovascular symptoms, cardiac arrest, or sudden death. Most cases resolve with Spike protein detoxification alone with some requiring colchicine. The theoretical benefits of vaccination continue to be far outweighed by the risks of subclinical vaccine myopericarditis. Ongoing research will further elucidate the mechanisms, true incidence, and long-term outcomes of this phenomenon, supporting safe and effective public health strategies and timely medical care.

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