

## MYOCARDITIS: EPIDEMIOLOGY, DIAGNOSIS, THERAPY

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**Abstract.** Myocarditis is an uncommon, potentially life-threatening disease that presents with a wide range of symptoms in children and adults. Viral infection is the most common cause of myocarditis in developed countries, but other etiologies include bacterial and protozoal infections, toxins, drug reactions, autoimmune diseases, giant cell myocarditis and sarcoidosis. Acute injury leads to myocyte damage, which in turn activates the innate and humeral immune system, leading to severe inflammation. In most patients, the immune reaction is eventually down-regulated and the myocardium recovers. In select cases, however, persistent myocardial inflammation leads to ongoing myocyte damage and relentless symptomatic heart failure or even death. The diagnosis is usually made based on clinical presentation and noninvasive imaging findings. Most patients respond well to standard heart failure therapy, although in severe cases, mechanical circulatory support or heart transplantation is indicated. Prognosis in acute myocarditis is generally good except in patients with giant cell myocarditis. Persistent, chronic myocarditis usually has a progressive course but may respond to immunosuppression.

**Keywords:** Protozoal infections, giant cell myocarditis and sarcoidosis, myocyte damage, heart failure, chronic myocarditis, immunosuppression.

**Intraduction**

In 1753, inflammation of the heart and the difficulty in discerning such was described by a physician, Jean Baptiste Senac in Versailles, France, in his work entitled *Traité des Maladies du Coeur* (Treatise on Disease of the Heart). The term myocarditis was ultimately coined by Joseph Freidrich Sobernheim in 1837; however, the use of this term included other cardiomyopathies that were previously undocumented including ischemic heart disease and hypertensive heart disease. It was not until the 1980s that the World Health Organization and the International Society and Federation of Cardiology attempted to differentiate between myocarditis and other cardiomyopathies. In general, myocarditis is identified as an inflammatory disease of the heart muscle cells and is pathologically identified by conventional histology and immunohistochemical techniques as an infiltration of mononuclear cells to the myocardium. Myocarditis can be acute, subacute, or chronic and may either involve focal or diffuse areas of the myocardium.

A recent update to the definition of myocarditis has been discussed by Caforio et al in defining myocarditis, using immunohistochemical data, as individuals who exhibit  $\geq 13$  lymphocytes/mm<sup>2</sup> including  $\leq 4$  monocytes/mm<sup>2</sup> with the presence of CD3-positive T lymphocytes  $\geq 7$  cells/mm<sup>2</sup>. This definition uses immunohistochemical data that require endomyocardial biopsy (EMB) collection and thus is limited to a relatively smaller cohort of patients or postmortem autopsy samples.

Moreover, although this definition of myocarditis has been widely accepted, it lacks information on the complexity of cellular infiltrates such as macrophage subtypes (classical/intermediate/nonclassical), effector (Th1/Th2/Th17), and regulatory (FoxP3+/CD4+) T-lymphocyte subtypes, and thus fails to differentiate a profibrotic response from a healing inflammatory response. Transcriptome-based analysis of biopsies may further our definition of myocarditis.

### **Epidemiology**

Before the Covid-19 pandemic, the estimated global incidence of myocarditis was 1 to 10 cases per 100,000 persons per year. The highest risk was among people between 22 and 44 years of age and among men. In the 35-to-39-year-old age group, the rate was 6.3 cases per 100,000 men and 4.6 cases per 100,000 women, with similar rates in the 20-to-44-year-old age group. The increased use of cardiac MRI has led to a gradual rise in the reported incidence of myocarditis in the United States, from 9.8 to 14.6 cases per 100,000 persons. Precise data on the burden of myocarditis are available only for selected clinical settings. For instance, the incidence of myocarditis among patients with heart failure varies from 0.6% to 5.0% according to age and region. Among patients with chest pain who were seen in the emergency department, 3% had acute myocarditis and pericarditis. A diagnosis of myocarditis was made on the basis of cardiac MRI in one third of patients with a previous diagnosis of acute myocardial infarction and nonobstructed coronary arteries. Autopsy studies in young people who died suddenly have shown a variable incidence of myocarditis. The incidence was 14% in the prospective registry of northeastern Italy. Among patients with advanced cancers who were treated with immune checkpoint inhibitors, the incidence was 1.18%. During the Covid-19 pandemic, 2.6 cases of definite or probable myocarditis and 4.1 cases of definite, probable, or possible myocarditis have been reported per 1000 patients hospitalized for Covid-19. Finally, analysis of currently available data on Covid-19 messenger RNA (mRNA) vaccine-related myocarditis suggests an overall incidence of 0.4 to 5.5 cases per 100,000 people in the United States and Israel. The Food and Drug Administration and the European Medicines Agency have recently estimated that the risk of myocarditis is about 1 case in 100,000 people vaccinated against Covid-19, with a higher risk among young males.

### **Diagnosis**

The clinical features of myocarditis are varied. The spectrum includes asymptomatic patients who may have electrocardiographic abnormalities; patients with signs and symptoms of clinical heart failure and ventricular dilatation; and patients with symptoms of fulminant heart failure and severe left ventricular dysfunction, with or without cardiac dilatation. Patients may present with a history of a recent flulike syndrome accompanied by fever, arthralgias, and malaise. Laboratory tests may show leukocytosis, an elevated sedimentation rate, eosinophilia, or an elevation in the cardiac fraction of creatine kinase.

The electrocardiogram may show ventricular arrhythmias or heart block, or it may mimic the findings in acute myocardial infarction or pericarditis. The relations between these clinical and laboratory findings and the presence of myocarditis are obscure. Thus, the endomyocardial biopsy remains the gold standard for the diagnosis of myocarditis, despite its limited sensitivity and specificity.

However, the lack of association between biopsy evidence of myocarditis and the presence of autoantibodies in patients with clinical myocarditis, the paucity of positive biopsy findings in large cohorts of patients with suspected myocarditis, the potential discordance between clinical and histologic features of myocarditis, and the inherent limitation of histologic diagnosis suggest that the diagnosis of myocarditis should not be based on histologic findings alone. Rather, it is important to include other diagnostic tests, including assays for autoimmune serum or the induction of the major histocompatibility and intercellular adhesion molecules on cardiac myocytes, to identify patients with autoimmune myocarditis.

Creatine kinase levels are often elevated in myocarditis. In addition, recent studies demonstrate that measurement of serum levels of cardiac troponin T, troponin I, or both in patients in whom myocarditis is suspected on clinical grounds can provide evidence of myocardial-cell damage with a level of sensitivity that exceeds that of other enzymatic measurements and can be correlated with the results of immunohistologic assessments. Therefore, although the time window of detectability of creatine kinase, troponin I, and troponin T in patients with chronic heart failure remains to be defined, we recommend that these measurements be obtained in all patients with suspected myocarditis.

Because patients with systemic autoimmune diseases (e.g., scleroderma, lupus erythematosus, and polymyositis) can present with myocarditis, we measure the erythrocyte sedimentation rate and perform rheumatologic screening in patients with unexplained heart failure and signs and symptoms of connective tissue disease. These patients often present with a hypofunctional but relatively normal-sized ventricle and with hypoxia and exertional dyspnea that are disproportional to the degree of cardiac dysfunction. Recent studies also suggest that testing for the presence of viral genome in endomyocardial-biopsy specimens by PCR may provide diagnostic and prognostic information, as well as discriminating between autoimmune and viral myocarditis. For example, the persistence of enterovirus RNA in patients with dilated cardiomyopathy is a strong predictor of a poor prognosis. Furthermore, the presence of viral capsid protein in some patients with dilated cardiomyopathy may be a marker of persistent enterovirus infection. Not all investigators have been able to identify microbial persistence. Thus, assessment of the presence of viral genome remains largely investigational. However, we conduct serologic tests for HIV in all patients with suspected myocarditis, because early and effective therapy may improve overall survival and cardiac function.

### **Therapy**

Treatment for myocarditis comprises management of arrhythmias and heart failure according to conventional guidelines and cause-targeted therapy.

#### **Conventional Therapy**

Patients with hemodynamically stable heart failure should be treated with diuretic agents, angiotensin-converting-enzyme inhibitors, or angiotensin-receptor blockade and beta-adrenergic blockade. Additional treatment with aldosterone antagonists should be considered in patients with persistent heart failure despite adequate management. Whether early initiation of treatment should also be offered to patients with preserved LVEF in order to reduce inflammation, remodeling, and scarring remains uncertain.

Patients with hemodynamically unstable heart failure require inotropic agents. Treatment should be provided in an intensive care unit with respiratory and mechanical cardiopulmonary support facilities, and referral to a tertiary care center should be considered. In patients with cardiogenic shock who present with severe ventricular dysfunction that is refractory to medical therapy, mechanical circulatory support with ventricular assist devices or extracorporeal membrane oxygenation (ECMO) may be needed.

Since myocarditis can be a reversible disease, the main goals of treatment are biventricular unloading, adequate systemic and coronary perfusion, and venous decongestion, in an effort to prevent multiorgan dysfunction and provide a bridge to recovery, transplantation, or use of a durable assist device. Temporary devices, such as an intraaortic balloon pump, venoarterial ECMO, a rotary pump, or an intraaortic axial pump, should be considered.



The use of devices that reduce left ventricular afterload, such as a centrifugal or an intraaortic axial pump, alone or in combination with ECMO, is more likely to promote myocardial recovery than ECMO alone. In recent years, left ventricular unloading through a transcatheterially placed axial flow pump (Impella; Abiomed) has been shown to be a viable treatment option for patients with cardiogenic shock, both as the sole left ventricular support when right ventricular function is preserved and in combination with extracorporeal life support or with a right-sided Impella pump. In the absence of protocols for temporary mechanical circulatory support, the choice of device depends on local experience and on right ventricular function. If the patient cannot be weaned from mechanical circulatory support after 3 to 4 weeks, a durable left ventricular assist device or transplantation should be considered.

There are no specific recommendations for the treatment of arrhythmias and conduction disturbances in patients with myocarditis. After the acute phase, management should be in line with current guidelines on arrhythmia and device implantation. Since myocarditis is potentially reversible, a step-by-step approach is suggested during the acute phase. Pacing may be needed for complete atrioventricular block. Use of an implantable cardioverter–defibrillator should be deferred until the acute episode has resolved, generally 3 to 6 months after the initiation of the acute phase, and a wearable cardioverter–defibrillator can be considered as a bridge.

In competitive athletes, physical activity should be restricted during the acute phase of myocarditis and for a period of 3 to 6 months subsequently, according to the clinical severity and duration of the acute phase. After resolution, clinical reassessment is indicated before the athlete resumes competitive sport. Preparticipation screening should be performed every 6 months during follow-up.

### Conclusions

In the past 30 years, major progress has been made in our understanding of the regulation and diversity of cardiac inflammatory pathways implicated in the pathogenesis of myocarditis.

The medical community looks forward to the development of standardized treatment regimens for patients with acute myocarditis. Myocarditis remains an important clinical condition from perinatal to adult timeframes. Significant challenges remain in regards to firm diagnoses, clear management and treatment approaches, and ultimate consequences of acute disease. Viruses play an important role in causing myocarditis, yet their precise contributions are masked by varied clinical presentations and progression, and the widely varied type and quality of molecular tools and samples used to establish an association of the disease phenotype with certain cardiotropic viral agents. This scrambled situation in humans stands in contrast to the huge body of sterling work that has been conducted in *in vitro* and *in vivo* models wherein viruses and their mechanistic impact on host cells and immune systems has been documented elegantly. Similarly, many promising avenues of therapeutic intervention, pursued in model systems, have yet to be studied in humans given the relative infrequency of a viral heart disease diagnosis, the highly variable timepoint at which patients present after the initiation of their illness, and the near impossibility, to date, in establishing the actual onset of viral myocarditis in people.

A global approach to human studies is long overdue. A global cohort, with standardized clinical, imaging and immunovirological techniques, highly SOP-driven sample accrual, and a reset on our collective views of pathogenesis and disease course would open a new avenue for effective reduction in morbidity and mortality through supportive and pharmacological care.

Learnings from other human pathogenic viral conditions, caused by viruses that rarely cause human heart disease, may also spawn new approaches to prevention, detection, and intervention.

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