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Impact of COVID-19 on Management Strategies for Coronary and Structural Heart Disease Interventions

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Abstract

Purpose of Review The COVID-19 pandemic has created unprecedented challenges globally, with significant strain on the healthcare system in the United States and worldwide. In this article, we review the impact of COVID-19 on percutaneous coronary interventions and structural heart disease practices, as well as the impact of the pandemic on related clinical research and trials. We also discuss the consensus recommendations from the scientific societies and suggest potential solutions and strategies to overcome some of these challenges.

Findings With the limited resources and significant burden on the healthcare system during the pandemic, changes have evolved in practice to provide care to the highest risk patients while minimizing unnecessary exposure during elective surgical or transcatheter procedures.

Summary The COVID-19 crisis has significantly impacted the management of patients with acute coronary syndromes, chronic coronary syndromes, and structural heart disease.

Keywords COVID-19 · Pandemic · Cardiac procedures · Interventional cardiology · Structural heart disease · Cardiovascular disease

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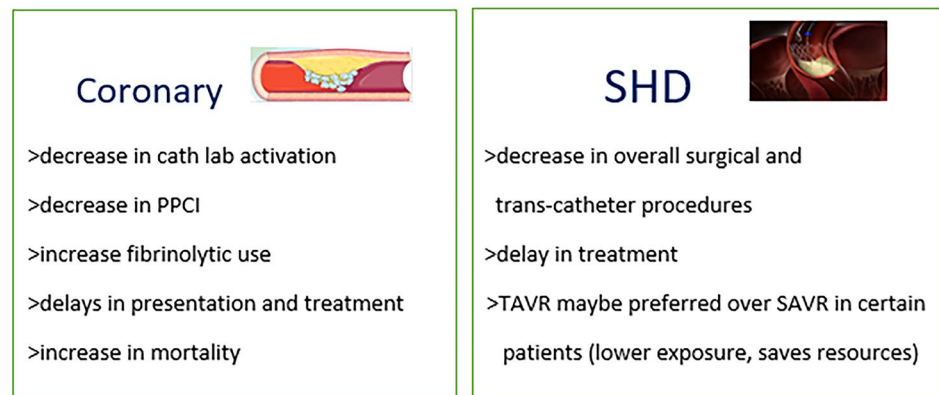
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Introduction

The novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes coronavirus disease 2019 (COVID-19), has resulted in a global pandemic with significant burden on the healthcare system in the United States (US) and worldwide [1–3]. This led to a dramatic depletion of hospital resources, exposure of health care personnel, and critical shortages of vital resources, including ventilators and intensive care unit (ICU) beds. This has created some limitations to provide care for patients with serious comorbid conditions in need of urgent care not related to COVID-19. This subsequently has led to system changes, including suspension of care for non-urgent conditions, transitioning to telemedicine clinics, and postponing elective procedures (Fig. 1) [1–3]. Moreover, many patients have been delayed in seeking medical care during the pandemic due to fear and uncertainty, which led to higher incidence of complications and late presentation of different pathological conditions, including myocardial infarction. Reports have shown excess death in the community from COVID-19 infection as well as other causes, which

Fig. 1 Summary of COVID-19 impact on coronary and structural heart disease (SHD) interventions. Abbreviations: primary percutaneous coronary intervention (PPCI), structural heart disease (SHD), transcatheter aortic valve replacement (TAVR), surgical aortic valve replacement (SAVR)

Impact of COVID-19 on Coronary and Structural Heart Disease Interventions



is likely attributed to the excessive strains on the healthcare system and delay in seeking care [4–6].

A large body of evidence has shown that patients with cardiovascular risk factors or established cardiovascular disease are at higher risk of experiencing severe COVID-19 illness requiring ICU care for advanced therapies such as mechanical ventilation, vasopressors for hemodynamic support, and mechanical circulatory support devices (MCS) including extracorporeal membrane oxygenation (ECMO) [2–6]. In addition, myocardial injury, due to underlying ischemia, acute thrombotic occlusion, or myocarditis, has been reported in up to 28% of hospitalized COVID-19-positive patients and is linked to higher mortality [1–3]. As such, management of cardiovascular patients in the COVID-19 era has evolved during the pandemic, especially when performing invasive cardiac procedures and potentially exposing healthcare staff in the setting of limited resources.

ST-Elevation Myocardial Infarction Care in the COVID-19 Era

Among COVID-19 patients with ST-segment elevation myocardial infarction (STEMI), emergent angiography might reveal a variety of findings including classic obstructive coronary artery disease (CAD), non-obstructive CAD, angiographically normal epicardial coronary arteries, and/or left ventricular dysfunction due to myocarditis or stress-induced cardiomyopathy [4–7]. In one of the earlier case series of 18 patients with COVID-19 presenting with STEMI, half of them underwent emergent coronary angiogram. Two-thirds had obstructive CAD. Myocardial injury in some of these patients has been attributed to plaque rupture, cytokine storm, hypoxic injury, coronary spasm, micro-thrombi, or direct endothelial or vascular injury [6].

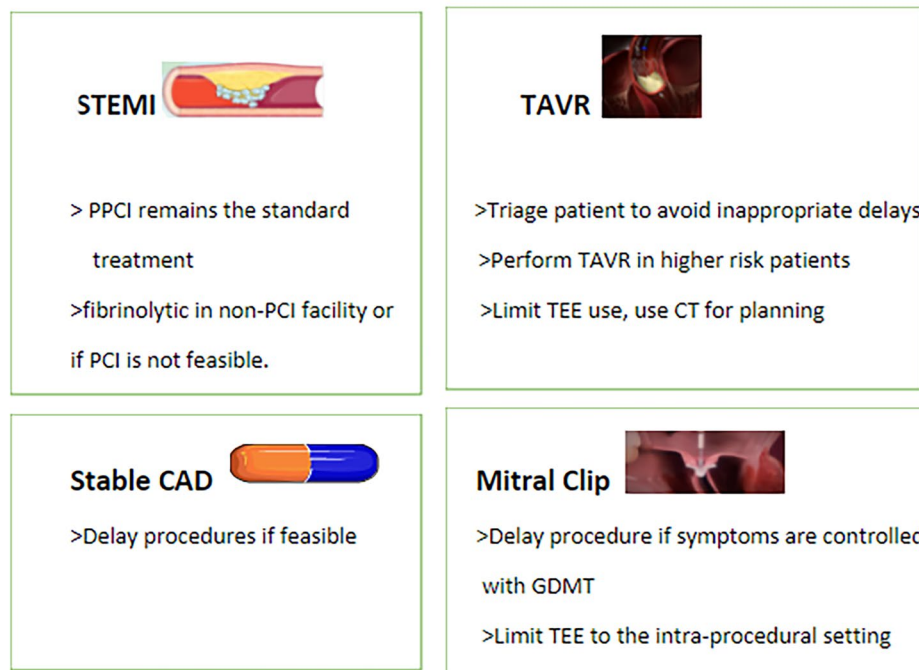
To minimize exposure among health care providers, some institutions and opinion leaders have advocated for

thrombolytic therapy as an initial mode of reperfusion, especially among relatively stable patients with inferior STEMI [6–8]. Indeed, some early reports showed a significant reduction in catheterization lab activation for STEMI [8–10]. Nevertheless, timely reperfusion with primary percutaneous coronary intervention (PPCI) remains the standard of care for STEMI patients per the current guideline recommendations [11•]. The American College of Cardiology (ACC) and Society for Cardiac Angiography and Interventions (SCAI) continue to recommend PPCI as the standard treatment of STEMI patients during the pandemic, with an expert team outfitted with personal protective equipment (PPE) in a dedicated cardiac catheterization laboratory room. A thrombolysis-based strategy may be entertained at non-PCI-capable referral hospitals or in specific situations where primary PCI cannot be executed or is not deemed the best option (Fig. 2). However, reports suggest a decline in PPCI volumes in the US and around the world [11•, 12, 13].

An analysis during the early phase of the COVID-19 pandemic showed an estimated 38% reduction in cardiac catheterization laboratory STEMI activations in the US, similar to other countries [9, 10, 11•, 12–15]. Another multi-center study from 18 European countries demonstrated a 19% reduction in PPCI for STEMI in March and April 2020 compared with similar months in 2019 [12]. Additionally, the pandemic was associated with a significant increase in door-to-balloon and total ischemic time, which could have contributed to the higher mortality noted during the pandemic [4–10, 11•]. Potential etiologies for the reduction in STEMI PPCI activations include avoidance of medical care due to social distancing or concerns of contracting COVID-19 in the hospital, STEMI misdiagnosis, conditions that mimic STEMI including myocarditis and stress cardiomyopathy among other conditions, and the increased use of pharmacological reperfusion during the pandemic [12–15].

Fig. 2 Summary of recommendations on coronary and structural heart disease (SHD) interventions during COVID-19 pandemic. Abbreviations: primary percutaneous coronary intervention (PPCI), ST-segment elevation myocardial infarction (STEMI), coronary artery disease (CAD), transcatheter aortic valve replacement (TAVR), trans-esophageal echocardiography (TEE), computed tomography (CT), guideline-directed medical therapy (GDMT)

Summary of Recommendations for Coronary and Structural Heart Disease Interventions During COVID-19 Pandemic



In a large retrospective cohort study of 80,449 patients hospitalized between January 2019 and December 2020 with out-of-hospital or in-hospital STEMI across 509 centers in the US, the investigators found no significant difference in the likelihood of undergoing PPCI by COVID-19 status in patients with out-of-hospital STEMI [16]. However, patients with in-hospital STEMI and COVID-19 were significantly less likely to receive invasive diagnostic or therapeutic coronary procedures than those without COVID-19. Among patients with out-of-hospital STEMI and COVID-19 vs. out-of-hospital STEMI without COVID-19, there was a significant difference in the rate of in-hospital mortality (15.2% vs. 11.2%, respectively; $P = 0.007$) [16]. Additionally, among patients with in-hospital STEMI and COVID-19 vs. in-hospital STEMI without COVID-19, there was a significant difference in the rate of in-hospital mortality (78.5% vs. 46.1%, respectively; $P < 0.001$) [16]. This further illustrates the significant impact of COVID-19 on the procedural and clinical outcomes of in-hospital STEMI patients across the US. In another large study from Sweden involving 86,742 patients with COVID-19, the investigators found that COVID-19 was an independent risk factor for acute myocardial infarction and ischemic stroke during follow-up, suggesting that acute thrombotic events are part of clinical picture of COVID-19 infection [17].

North American COVID-19 ST-Segment-Elevation Myocardial Infarction Registry

Given the paucity of data for managing COVID-19 patients with STEMI early in the pandemic, the SCAI and the Canadian Association of Interventional Cardiology (CAIC) in conjunction with the ACC Interventional Council have collaborated to create a multi-center observational registry, North American COVID-19 ST-Segment-Elevation Myocardial Infarction (NACMI) [1]. The primary objective of this registry was to create a multi-center database of patients presenting with ST-segment elevation or new left bundle branch block (LBBB) with a clinical suspicion of myocardial ischemia. Patients with COVID-19-positive or persons under investigation (PUI) were included. PUI were included in the registry because false-negative rates were up to 30% depending on the type of specimen collected [1]. As of December 6, 2020, 1185 patients were included in the NACMI registry (230 COVID-19-positive patients, 495 PUIs, and 460 control patients) [18]. COVID-19 positive patients were more likely Hispanic or Black, had a higher prevalence of diabetes mellitus and were more likely to present with cardiogenic shock. COVID-19-positive patients were less likely to receive invasive angiography (78% versus 100%; $P < 0.001$ relative to control patients) [16]. COVID-19-positive patients had lower rates of PPCI and higher rates of medical treatment

for STEMI compared to the control group (71% versus 93% for PPCI and 20% versus 2% for medical therapy; $P < 0.001$ relative to control patients). The primary outcome of the composite of in-hospital death, stroke, recurrent myocardial infarction, or repeat unplanned revascularization occurred in 36% of COVID-19-positive patients, 13% of PUIs, and 5% of control patients ($P < 0.001$ relative to control patients) [18]. Several studies reported an increased incidence of mechanical complications following acute myocardial infarction likely attributed to the delay in presentation during the pandemic [19, 20]. In this setting, it is important to note that PPCI should remain the default treatment for STEMI in COVID-19 patients. We, as physicians and as societies, should continue to educate patients with chest pain and those who are at risk for myocardial infarction to urgently seek care to avoid some of these complications.

Recent preliminary findings from the NACMI registry showed that MCSD use in COVID-19 patients with STEMI was associated with high mortality approaching 60%. The investigators found that MCSD use was in 13.3% of patients in the registry, with no difference between the COVID-19 and non-COVID patients. In those receiving MCSD, intra-aortic balloon pump was most frequently used. ECMO was more likely used among patients with COVID-19 (24% vs. 3%) [21].

Elective Coronary Procedures

As mentioned, with the advent of the COVID-19 pandemic in the US, resources have been reallocated and elective cases have been deferred to minimize the spread, altering the workflow of cardiac catheterization laboratories across the country for an extended period. To preserve resources, including PPE and hospital beds to care for COVID-19 patients, the Centers for Disease Control and Prevention recommended deferral of elective cardiac procedures early in the pandemic and during the third wave, including coronary angiography and PCI for symptom relief in chronic coronary syndromes [22].

Similarly, with the primary goal of reducing the risk of spread of COVID-19, protecting patients and healthcare teams while preserving access to necessary/emergency care, the National Health Service in the United Kingdom (UK) issued specialty guidance for the management of cardiology patients [23]. As a consequence, a study from England showed a 48.8% reduction in left main revascularization during the pandemic compared with previous years, with a shift towards PCI as the preferred strategy to minimize patients' exposure to the hospital environment and preserve ICU beds for COVID-19 patients. Post-procedural mortality remained the same in the both pre-COVID-19 and COVID-19 periods, suggesting that quality of outcomes was maintained during the pandemic [24].

Structural Heart Disease Interventions

Patients awaiting structural heart disease (SHD) interventions constitute a particularly challenging group, as many have conditions that might be life threatening if the intervention is inappropriately delayed [25•, 26–29]. Studies have shown a decline in surgical and transcatheter aortic valve procedures during the pandemic with potential increase in mortality [24, 25•, 26–29] (Fig. 1). In a single center study of 77 patients who were scheduled for TAVR in a tertiary center in the US, 28.6% of cases were canceled because of the pandemic. During the period in March and April 2020, 7.8% underwent urgent TAVR due to accelerating symptoms and 2.6% died [28]. Therefore, decisions regarding the timing of SHD interventions should consider the risk of delaying the procedure, the risk of COVID-19 exposure, and use of limited hospital resources. In this setting, some investigators developed a decision analysis model to evaluate 2 treatment strategies (i.e., prompt versus delayed transcatheter aortic valve replacement [TAVR]), for both low-risk and intermediate-risk patients with severe symptomatic aortic stenosis during the COVID-19 pandemic. The investigators found that prompt TAVR resulted in improved 2-year overall survival compared with delayed intervention for intermediate- and low-risk patients; as delayed treatment was associated with death and need for urgent/emergent TAVR during the waiting period. In contrast, when the probability of acquiring COVID-19 was significant ($> 55\%$ for intermediate-risk patients or 47% for low-risk patients), delayed TAVR was favored over prompt intervention [29].

The ACC/SCAI leadership issued a separate consensus to help cardiologists and structural interventionalists manage these patients with a focus on 4 main priorities: (1) minimize exposure to COVID-19 for SHD patients and the structural interventional team; (2) maintain high quality and durable structural interventional outcomes for those who require a procedure during the pandemic; (3) assure that these patients do not use resources that might be needed for COVID-19 patients; and (4) prevent delay of intervention for patients at particularly high risk for clinical deterioration, heart failure, or death (Fig. 2) [16]. Importantly, local clinical judgment based on the impact of the COVID-19 pandemic in the region and institution should ultimately guide the evaluation and treatment pathway given the geographic variation of COVID-19 impact in different regions [25•, 26].

Regarding TAVR, the ACC/SCAI writing group proposed timing for patients with symptomatic severe aortic stenosis (AS), minimally symptomatic severe to critical AS, and asymptomatic severe to critical AS (Table 1). Weekly telephone follow-up for patients with deferred procedures is recommended together with weekly virtual TAVR team meetings, including a single interventional cardiologist and

Table 1 Summary of SCAI/ACC recommendations for TAVR based on severity of AS

Severity of AS	Recommendations
Symptomatic severe AS, New York Heart Association functional class III or IV	<ul style="list-style-type: none"> • For in-patients with severe symptomatic AS associated with a reduction in ejection fraction thought to be secondary to AS, congestive heart failure (CHF), or syncope secondary to AS, TAVR should be considered to decrease the risk for clinical deterioration, prolonged hospital stay, or repeat hospitalization • It would be reasonable to schedule TAVR for outpatients with severe to critical AS and CHF symptoms or syncope due to AS
Minimally symptomatic severe to critical AS, New York Heart Association functional class I or II	<ul style="list-style-type: none"> • For patients with CHF symptoms and quantitative measures of valve severity that indicate a critically tight valve, it is reasonable to consider either urgent TAVR or close outpatient virtual monitoring by the valve coordinator • Data are not robust enough to give firm recommendations, but features that warrant consideration of TAVR include particularly high peak or mean gradient, very small calculated aortic valve area, and very low dimensionless index
Asymptomatic severe to critical AS	<ul style="list-style-type: none"> • For truly asymptomatic patients, it is reasonable to postpone consideration of TAVR for 3 months or until after hospital operations resume elective procedures • Close outpatient monitoring, possibly via telehealth, should continue for all patients with severe AS • TAVR centers should establish a system that provides weekly telephone follow-up for patients whose procedures have been deferred

ACC American College of Cardiology, SCAI Society for Cardiac Angiography and Interventions, TAVR transcatheter aortic valve replacement, AS aortic stenosis

cardiac surgeon to discuss and manage these challenging cases [25•, 26].

Similarly, for other SHD interventions such as percutaneous mitral repair, transcatheter mitral valve replacement, paravalvular leak repair, the SCAI/ACC consensus document advised that the majority of these procedures should be deferred until after the COVID-19 pandemic has been relatively controlled, provided such patients can be sufficiently managed on medical therapy in the interim [25•]. To offset the risk for particulate aerosolization, the SCAI/ACC consensus document recommends that pre-procedural trans-esophageal echocardiogram (TEE) use should be limited [25•]. For any high-risk SHD procedure requiring interventional imaging support with TEE, emphasis must be placed on the availability of full PPE for the interventional imager, since the major aerosolization risk occurs during the initial intubation and probe manipulation in a non-intubated patient. In an already ventilated patient, the SCAI/ACC consensus recommends that a high-efficiency particulate air filter is placed with the endotracheal tube to maximize safety of the SHD team. In the setting of insufficient PPE, alternative imaging modalities should be considered, including intra-cardiac echocardiography or computed tomography whenever feasible [25•].

In the surgical field, hospitals around the country restricted the performance of elective surgery, including surgical aortic valve replacement (SAVR), to preserve ventilators, operating rooms, and ICU beds [27, 29, 30]. In this

regard, TAVR, especially minimalist TAVR, has evolved as an appropriate alternative with less impact on hospital (and particularly critical care) capacity than SAVR in the current time where resource utilization is of paramount importance [29, 30]. Some experts suggested alterations to the current evaluation of SAVR/TAVR practice during the COVID-19 crisis: with careful case selection, reviewing TAVR waiting list and triaging for high-risk patients (Table 2), reviewing SAVR waiting list and converting intermediate-risk patients to TAVR if appropriate, converting low-risk patients to TAVR with Heart Team consensus, avoiding TAVR work-up with TEE, use of coronary computed tomography instead of invasive coronary angiography in certain patients and efforts to make all tests in a single attendance for patients. Post-procedure, early safe discharge is recommended [25•, 27, 30]

Clinical Trials

Due to the considerable burden associated with COVID-19 infection, there has been a disruption of most clinical activities worldwide [31, 32]. With hospitals and health care centers overwhelmed with COVID-19 patients, access to hospitals poses a significant health risk to both research personnel and study participants. For this reason, many academic centers have suspended their research activities

Table 2 Suggested factors for triaging high-risk patients for TAVR during the pandemic

Relevant area	Suggested factors
Clinical	NYHA class IV symptoms or rapid recent deterioration Exertional syncope Previous/recent admission with decompensation (pulmonary edema/arrhythmia) Significant burden of comorbidity (coexistent cardiac disease; renal) Deteriorating renal function
Echo parameters	High peak and mean gradients Low aortic valve area Poor LV systolic function Severe coexistent MR
Computed tomography	Excessive aortic valve calcium score
Laboratory work-up	Significantly elevated NT-pro-BNP

TAVR Transcatheter aortic valve replacement, NYHA New York Heart Association, LV left ventricle, MR mitral regurgitation, BNP brain natriuretic peptide

during the pandemic except for trials which are considered of essential importance [31, 32].

The SCAI consensus recommended with strong consideration the deferral of clinical trials until after resolution of the COVID-19 pandemic [25•]. As such, several institutions have limited enrollment to studies of lifesaving therapies during the pandemic. Moreover, some trials have been halted by the funding agencies, but others were left to continue at the discretion of the principal investigator [31]. For ongoing trials, follow-up has been hampered during the COVID-19 crisis. To limit unnecessary physical contact and to reduce exposure, visits to medical centers have been canceled or postponed, and remote follow-up via phone or virtual visits have been implemented [2, 3, 29]. As such, some trial protocols have been modified to prioritize data. The assessment of the primary outcome should ideally receive the highest priority, whereas secondary outcomes may be dropped or modified accordingly. [31].

Additional logistical challenges will likely affect research funding, as it is known that financial support to trials is often contingent to the achievement of pre-specified enrollment targets that will less likely be met during the COVID-19 pandemic. In this regard, the National Institutes of Health has issued a statement to address issues related to management of grants during the COVID-19 crisis [32]. These include (1) continued funding for salaries and benefits even when no work is performed and (2) milestone plans have been modified to accommodate the decrease in enrollment during the pandemic. The impact of COVID-19 on clinical trials will likely be proportional to the length of the pandemic and affect our scientific evidence in the next several years [31].

Potential Solutions

The COVID-19 pandemic has seemingly changed our healthcare system for the foreseeable future, especially with the recurrent waves and different variants [1–4]. With the significant strain on the healthcare system in the US and worldwide, there has been some adaptations on how to approach cardiac patients [33–36]. With the development of COVID-19 vaccine and maintaining procedural safety with pre-procedural COVID-19 testing, hospitals started ramping up their procedural volume gradually using local strategies [33–36]. To protect and provide confidence among health care workers and patients, systematic screening for COVID-19 symptoms (e.g., cough, fever, new anosmia or ageusia, dyspnea, diarrhea, or sore throat) and exposure to known cases should be performed routinely for all patients prior to hospital admission. Patients should also get tested with a single swab within 24–48 h of elective procedures and told to self-isolate until the procedure to avoid possible new exposure in the interim. Patients with symptoms and/or positive test results should have the elective procedures postponed [33–35].

Poulin and Pinto described a 4-week ramp-up strategy over 4 phases [33]. They recommended scheduling outpatients 2–3 days per week in the beginning (phase 1, 25% capacity), starting with urgent and emergent higher risk patients; severely symptomatic patients and those with long wait times (> 4 weeks), including symptomatic TAVR and mitral patients with declining ejection fraction and progressive symptoms evolving over the last month. They also recommended starting with patients at low risk for aerosolization and less likely to need ICU care. This is followed by phase 2 (50% capacity) for semi-urgent procedures for patients who are symptomatic and have been on the waiting list > 3 weeks. Phase 3 constitutes 75% of capacity and includes routine procedures. Phase 4 is the final phase and constitutes 110% of budgeted procedural cases. Clinical trial enrollment can be expected to resume in phase 4 [33].

Innovation and digital health have emerged as potential solutions to some of the challenges that we have encountered during the COVID-19 crisis. Remote telehealth monitoring, telehealth clinic visits, and patient education through social media have been implemented and shown to be beneficial to ensure ongoing continuity of care and health preservation strategies for those at higher risk of cardiovascular events [37–39]. There seems to be a great opportunity to combine innovative digital health and wearable technology such as remote electrocardiographic monitoring with embedded sensors and electrodes that can transmit real time physiologic data to monitoring centers [35]. Additionally, robotic PCI emerged as a promising strategy in experienced centers during a pandemic; as it facilitates procedural distancing, minimizes exposure risk, and decreases PPE cost [40, 41].

Conclusion

The COVID-19 pandemic has introduced unprecedented challenges and strain on the healthcare system in the US and worldwide. The impact of the pandemic on coronary and structural heart disease patients is particularly important since these patients are at high risk of deterioration if treatment is inappropriately delayed. Over the past 2 years, we have learned how the pandemic changed certain aspects in the management of cardiac patients. We have adopted strategies to focus our efforts on patients at higher risk of decompensation and/or worse prognosis in the short term. With the recurrent waves of infection and emergence of new strains, we need to continue to identify and fill the gaps which this pandemic has created in our care for these patients.

Compliance with Ethical Standards

Conflict of Interest VSM is a principal investigator for clinical trials with Edwards Life Sciences, Abbott, and GORE Medical. Dr. Elgendy has disclosures unrelated to this manuscript content including receiving research grants from Caladrius Biosciences, Inc. The other authors have nothing to disclose.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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