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JACC REVIEW TOPIC OF THE WEEK

Restructuring Structural Heart Disease Practice During the COVID-19 Pandemic



JACC Review Topic of the Week

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ABSTRACT

Patients with structural heart disease are at increased risk of adverse outcomes from the coronavirus disease-2019 (COVID-19) due to advanced age and comorbidity. In the midst of a global pandemic of a novel infectious disease, realitybased considerations comprise an important starting point for formulating clinical management pathways. The aims of these "crisis-driven" recommendations are: 1) to ensure appropriate and timely treatment of structural heart disease patients; 2) to minimize the risk of COVID-19 exposure to patients and health care workers; and 3) to limit resource utilization under conditions of constraint. Although the degree of disruption to usual practice will vary across the United States and elsewhere, we hope that early experiences from a heart team operating in the current global epicenter of COVID-19 may prove useful for others adapting their practice in advance of local surges of COVID-19. (J Am Coll Cardiol 2020;75:2974-83) © 2020 by the American College of Cardiology Foundation.



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atients with underlying cardiovascular disease (CVD) are at higher risk of both contracting the coronavirus disease-2019 (COVID-19) and having worse outcomes after infection (1,2). Cardiac complications of COVID-19 include myopericarditis, malignant arrhythmias, and biventricular heart failure (3). In the largest case series to date of over 44,000 COVID-19 patients from China, the case fatality rate was significantly higher in those with preexisting CVD (10.5% vs. 2.3%) (4). Patients with severe cases of COVID-19 frequently experience acute myocardial injury, as evidenced by elevated troponin levels, which is strongly associated with clinical deterioration (5) and increased mortality (6). Of patients with myocardial injury, prognosis is particularly poor for those with a prior history of CVD (7). Across nations, studies have also consistently demonstrated significantly higher case fatality rates in older persons (8-12), which may reflect an increased prevalence of comorbid conditions, as well as age-related declines in T- and B-cell function (13).

Although the current published data does not yet include specific descriptions of the impact of COVID-19 in patients with structural heart disease (SHD), it is reasonable to extrapolate that these patients are at high risk for adverse outcomes based on their advanced age and numerous comorbidities. In the absence of analytic outcomes data to guide evidencebased decision-making, reality-based considerations are necessary surrogates in formulating clinical pathways in the context of a global pandemic. The focus of these "crisis-driven" recommendations is: 1) to ensure appropriate, sensitive, and timely treatment of SHD patients; 2) to minimize the risk of COVID-19 exposure to patients and health care workers; and 3) to limit resource utilization under conditions of constraint. We draw heavily on our early experiences as a highvolume heart team at a large academic medical center in New York City, currently the global epicenter of COVID-19. Although the degree of disruption to usual practice will vary across regions in the United States and elsewhere due to differences in population density, rates of community spread, time to peak disease burden, and resource availability, we hope that early experiences from our center may prove useful for others adapting their practice in preparation for local COVID-19 surges.

ADAPTATIONS IN OUTPATIENT MANAGEMENT OF SHD

A ROADMAP FOR TRANSITIONING TO TELEMEDICINE. With widespread community transmission of COVID-19 throughout the United States, the overarching goal is to minimize the risk of COVID-19 exposure and to preserve limited resources such as anesthesia care, ventilators, intensive care unit (ICU) beds, and personal protective equipment (PPE). By early March 2020, COVID-19

inferit (FFE). By early March 2020, COVID-19 infection rates were rapidly increasing in New York, and in accordance with guidelines issued by our hospital administration, all elective procedures and surgeries were cancelled and nonurgent outpatient visits were discouraged. Patients scheduled for valve clinic visits over the next 2 months were offered the options to keep the original appointment but convert to a telemedicine encounter, or postpone until a future date when it becomes safer to have an in-person visit. There was clearly some self-selection bias, such that patients with greater symptoms generally agreed to an earlier telemedicine visit, whereas less symptomatic, more stable patients tended to prefer a delayed inperson visit.

Conducting a comprehensive new patient evaluation for SHD remotely is labor-intensive and presents challenges for elderly patients who may lack sophisticated knowledge of technology and access to a device with a streaming video camera. Family members or friends who would otherwise assist with setting up devices and navigating unfamiliar applications are now isolated from elderly patients and can no longer be relied upon to provide on-site technical support. An integrated team is therefore necessary to facilitate telemedicine, and multiple interactions with the patient are needed prior to the scheduled visit with the physician to streamline the actual encounter. Office staff must obtain images of the most recent prior echocardiogram and guide patients through the process of downloading and registering the telemedicine application. The preferred application at our institution is MyChart (Epic, Verona, Wisconsin), because it provides a secure Health Insurance Portability and Accountability Act (HIPAA)-compliant interface that is compatible with Epic (Verona, Wisconsin), an

ABBREVIATIONS AND ACRONYMS

COVID-19 = coronavirus disease-2019

CVD = cardiovascular disease

ICU = intensive care unit

PPE = personal protective equipment

SHD = structural heart disease TAVR = transcatheter aortic valve replacement

The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the *JACC* author instructions page.

electronic medical record platform. A physician assistant obtains a detailed medical history, reconciles medications, and sets expectations so patients understand in advance that all elective procedures are currently postponed. An hour prior to the telemedicine visit, a medical assistant calls to ensure that the patient is logged on to the application in a quiet, appropriate space. In instances where an unstable internet connection or other technical limitations prevent a patient from successfully using MyChart, we have used FaceTime and web conferencing applications such as Zoom to facilitate a video encounter. A video encounter offers distinct advantages over a phone call alone, as it enables subjective assessments of frailty and dyspnea, and a limited evaluation of volume status. Albeit imperfect, a web camera pointed at a patient's legs can convey the severity of peripheral edema. When all else fails, a phone call substituted for a video visit will still allow some degree of patient assessment and be acknowledged for coverage by Medicare. Similarly, there is coverage of subsequent, brief patientinitiated telephone or online communications with a health care provider, termed "virtual check-ins" (14).

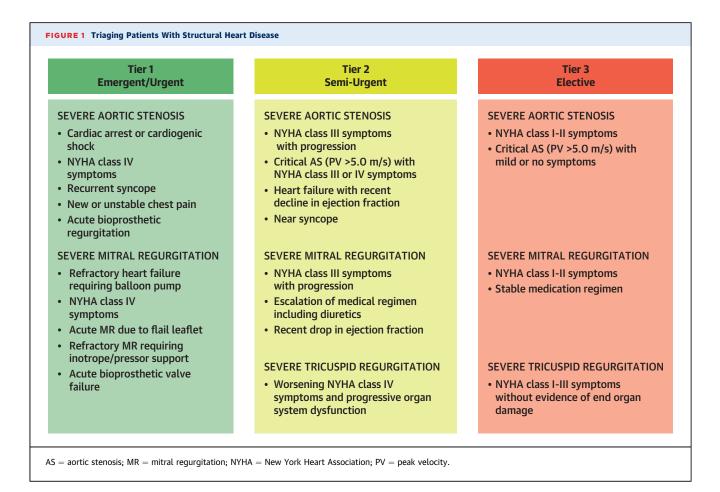
The ability to deliver such remote services was facilitated by the decision from the Centers for Medicare & Medicaid Services, effective March 6, 2020, to temporarily expand Medicare coverage for telemedicine using a wider range of communication tools, including smartphones, enabling beneficiaries to receive many health services without incurring the risks of leaving their homes. The ability to convert nearly any evaluation by the heart team to a telemedicine encounter was further enhanced by a temporary Centers for Medicare & Medicaid Services waiver of state-specific licensing requirements allowing physicians to evaluate patients residing in neighboring states (14). In addition, the Health and Human Services Office for Civil Rights waived penalties for providers acting in good faith who perform telemedicine visits using broadly available technologies like FaceTime that are not HIPAA-compliant.

As the vast majority of patient-physician interactions during the COVID-19 pandemic will transition to a remote interface, clear communication is critical to ensure that patients continue to receive high-quality cardiac care. Patients must be given specific instructions on how to self-monitor symptoms at home and when to call the clinic or consider an emergency department evaluation. Expectations should be conveyed regarding the frequency of follow-up with the medical team and the anticipated timeframe of eventual structural intervention. Given the fluidity and changing dynamics of the current crisis, cases may need to be postponed multiple times and for several months. Frequent, transparent communication will give patients confidence that their care is not being neglected. In the event that heart team members are reassigned to new roles staffing COVID-19 units, or they themselves become sick, contingency plans for coverage of outpatient responsibilities should be ensured.

A ROADMAP FOR CANCELING AND REPRIORITIZING STRUCTURAL HEART PROCEDURES. Any intervention that is unlikely to directly affect clinical care or outcomes over the next 2 to 3 months should be considered elective and be postponed. This includes procedures such as left atrial appendage occlusion and closure of atrial septal defects and patent foramen ovales, which are unlikely to affect short-term morbidity and mortality. Similarly, interventions for tricuspid regurgitation, which are currently possible only as part of clinical trial investigations, should generally be deferred unless local COVID-19 burden is low and resources are not constrained. The rationale for deferring elective procedures should be discussed with patients and documented in the medical record.

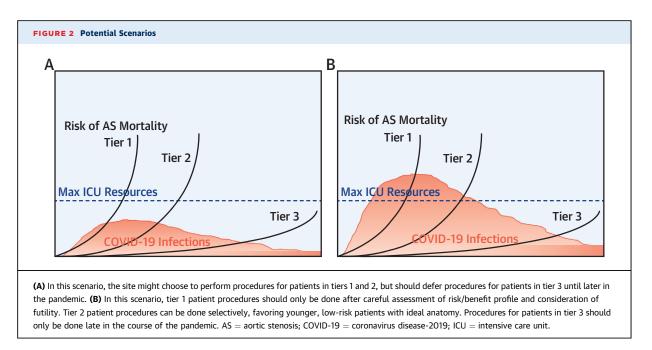
In contrast, for patients with an imminent risk of mortality, threat of irreversible clinical consequences (e.g., permanent organ system dysfunction), or likelihood of rapidly worsening symptoms that could provoke hospitalization, an intervention can be deemed emergent or urgent based on the acuity and severity of risk (Figure 1). Most emergent cases will be hospitalized patients in whom worsening hemodynamic compromise and impending multiorgan failure require an intervention within hours or 1 to 2 days. Examples would be cases of severe aortic stenosis (AS) with cardiogenic shock requiring inotropes or vasopressors and severe mitral regurgitation (MR) with refractory heart failure requiring an intra-aortic balloon pump. Examples of urgent cases of the highest risk strata (tier 1) would include hospitalized patients who cannot be safely discharged without a procedure, such as a patient with AS admitted with refractory heart failure, or an outpatient at high risk for decompensation in the next 2 weeks, such as a patient with AS with recurrent syncope. These tier 1 patients should be treated during the hospitalization or within 1 week, whereas urgent patients of lower risk (tier 2) and elective cases (tier 3) can be triaged for treatment over the subsequent months as outlined below.

Outpatients can be triaged based on a previous heart valve clinic visit or telemedicine evaluation into 1 of 3 categories based on the following considerations and examples:



- 1. *Emergent/Urgent, Tier 1:* defined as the highest-risk cases requiring a procedure within days (i.e., emergent) or 1 to 2 weeks (i.e., urgent)
 - a. Severe AS with New York Heart Association (NYHA) class IV symptoms
 - b. Severe AS with recurrent/refractory heart failure requiring hospitalization, particularly in patients with a history of reduced or recent decline in left ventricular ejection fraction (LVEF)
 - c. Severe AS with recurrent syncope
 - d. Severe AS with new, unstable chest pain syndrome
 - e. Acute severe bioprosthetic aortic regurgitation with heart failure refractory to pharmacotherapy
 - f. Severe MR with heart failure refractory to pharmacotherapy (e.g., new flail leaflet or ruptured chord) requiring hospitalization
 - g. Severe AS or severe MR in the setting of an acute coronary syndrome refractory to pharmacotherapy
- 2. *Semi-Urgent, Tier 2:* defined as cases at high risk of clinical deterioration over the next 1 to 2 months, thus requiring close monitoring at weekly intervals and an intervention within 1 to 2 months

- a. Severe AS with rapidly progressive or worsening NYHA class III symptoms (especially if reduced LVEF or peak transaortic jet velocity >5.0 m/s)
- b. Severe AS with heart failure and recent decline in LVEF or new-onset atrial fibrillation (especially if peak transaortic jet velocity >5.0 m/s)
- c. Severe MR with recent decline in LVEF and worsening NYHA class III symptoms despite optimal medical therapy
- d. Severe tricuspid regurgitation (TR) with worsening NYHA class IV symptoms and evidence of progressive organ system dysfunction (e.g., worsening kidney failure)
- 3. *Elective, Tier* 3: defined as cases with lower risk of deterioration if a procedure is postponed for 2 months or longer
 - a. Severe AS with NYHA class I to II symptoms (especially if normal LVEF)
 - b. Asymptomatic severe AS
 - c. Severe MR with NYHA class I to II symptoms on optimal pharmacotherapy
 - d. Severe TR with NYHA class I to III symptoms on medical pharmacotherapy

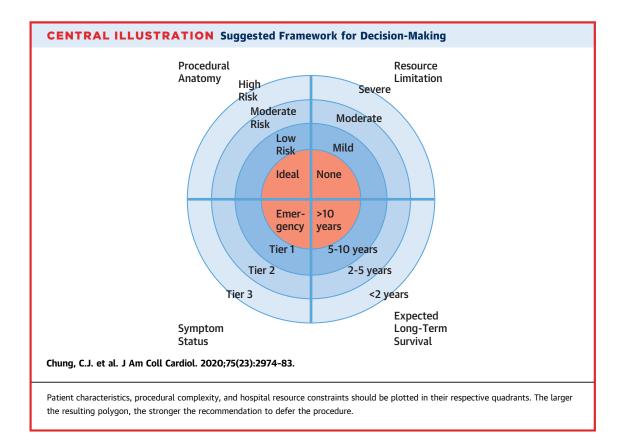


These tiers are not intended to be allencompassing but rather to provide illustrative case examples and general considerations to guide programs in prioritizing their own allocation of outpatient resources, such as time spent by staff communicating with patients. The degree to which individual programs are constrained in their ability to divert resources such as anesthesia care and ICU beds to their structural patients will be significantly affected by the local COVID-19 case burden. For instance, in geographic areas where the rate of increase in and overall case burden of COVID-19 is relatively low, there may be capacity to continue offering structural interventions to tier 1 patients throughout the pandemic, then to begin intervening on tier 2 patients as the disease burden tapers further (Figure 2).

At our center, all procedures that were originally scheduled for the next 2 months were canceled; the affected patients were subsequently categorized and reprioritized according to the previously listed criteria. Given the limitations of telemedicine, every new outpatient currently receives a follow-up call within 1 to 2 weeks of the initial encounter to ensure they are stable prior to scheduling future check-ins according to their tier of risk. Tier 2 patients receive weekly or biweekly check-in calls, whereas tier 3 patients receive check-in calls every 1 to 2 months. Tier 3 patients should be followed according to existing guidelines, when possible, but priority should still be given to minimizing both risk of exposure to COVID-19 and resource consumption. For instance, serial echocardiography in patients with asymptomatic severe AS can be performed less frequently than every 6 to 12 months if the patient remains asymptomatic.

Maintenance of close communication with patients is critical to ensure ongoing delivery of optimal cardiac care. A report from 1 Hong Kong hospital found a significantly longer time from symptom onset to first medical contact in patients presenting with STsegment elevation myocardial infarction from late January to mid-February 2020, possibly reflecting patients' fear of exposure to COVID-19 in the hospital (15). It is imperative that heart teams educate patients and referring physicians, and provide clear guidance on when to request phone consultations or urgent in-person evaluations to minimize avoidable morbidity and mortality due to delayed care. Clearly, this is a dynamic situation, and patients with clinical deterioration should be recategorized and reprioritized, as appropriate.

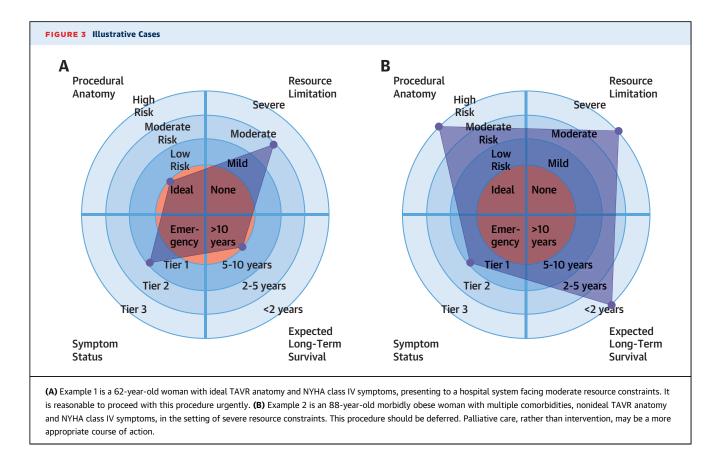
PATIENT SELECTION IN AN ENVIRONMENT OF RESOURCE CONSTRAINTS. As COVID-19 hospital admissions continue to increase, the demand for access to medical treatment is anticipated to outstrip existing resources across the United States. In the context of a pandemic, it is ethically permissible to limit access to procedures requiring disproportionate resource utilization and hindering the ability to mount an effective response to the pandemic (16). To ensure fair and consistent application of limited access, prospective guidelines for fair allocation of resources should be developed based upon maximizing the number of lives saved (utilitarianism), rewarding instrumental value (social usefulness), and prioritizing those who are worst off (17,18).



In the context of the current COVID-19 pandemic, members of the heart team must determine which patients are unlikely to derive sufficient benefit from an urgent procedure to warrant diversion of scarce resources, including anesthesia services, ICU beds, ventilators, and PPE. We propose that patients who are less likely to achieve meaningful improvement in health status, including those with advanced age, especially with associated frailty or dementia, should be deferred for structural heart procedures. Additionally, elderly patients with severe hemodynamic compromise and threatened multiorgan failure should generally not undergo salvage procedures. In making these challenging decisions, programs should weigh the patient's severity of presentation (as indicated by his or her tier), the expected benefit, the likelihood of an uncomplicated procedure, and the degree of resource limitation (Central Illustration and Figures 3A and 3B).

Similarly, surgical procedures, including valve repair or replacement, should be avoided whenever possible. In general, low-risk patients with severe AS who would normally be considered good candidates for surgery should instead be considered for transcatheter aortic valve replacement (TAVR), provided the anatomy is reasonable, especially in regions where hospitals are facing imminent surges in ICU occupancy.

When weighing whether and when to move forward with even an urgent structural heart intervention, preference should be given to patients with straightforward anatomy whose procedures can be performed with low or reasonable risk of complications and minimal resource utilization. For example, in TAVR candidates, this would include cases that can be safely performed under conscious sedation, with a low risk of vascular access complications or need for a permanent pacemaker, and a high probability of same- or nextday hospital discharge to home. MitraClip (Abbott, Abbott Park, Illinois) cases should generally be avoided, except in emergent or tier 1 cases, due to the increased risks to the procedure team associated with intubation and transesophageal echocardiography. Balloon aortic valvuloplasty (BAV) can be considered a temporizing or "bridging" procedure in select patients with severe AS, particularly those with unfavorable iliofemoral arterial access, suboptimal aortic valvular complex anatomy, or impaired renal function hindering the ability to obtain a TAVR computed tomographic angiogram (CTA). However, even careful planning cannot guarantee an absence of complications, particularly in elderly and frail



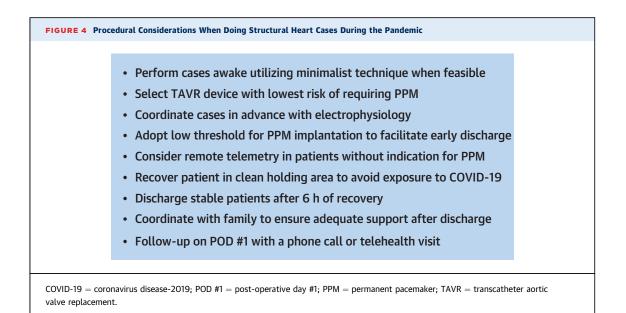
patients. Thus, higher-risk comorbid patients being considered for a BAV because they are not good candidates for a TAVR should also be considered for palliative care.

Once a decision is made to move forward with a structural procedure, pre-procedural testing should be streamlined to minimize the number of interactions with health care personnel. Echocardiograms performed within the past 6 months are generally sufficient and coronary angiograms (if necessary) should be performed at the time of the intervention. The only pre-procedural testing which is essential for TAVR is CTA performed within the past few years, as it enables assessment of vascular access, aortic valve anatomy, and overall procedural risk, which in turn guides the decision to move forward with the procedure. When possible, pre-procedural testing should be performed in outpatient settings where there is a lower risk of patient exposure to COVID-19.

ADAPTATIONS IN THE CARDIAC CATHETERIZATION LABORATORY OR HYBRID OPERATING ROOM

MINIMIZING THE RISK OF COVID-19 EXPOSURE DURING STRUCTURAL HEART PROCEDURES. Guiding principles for structural interventions are similar to those that have been proposed for the treatment of patients with acute coronary syndromes (19). All patients should undergo clinical screening and expedited testing for COVID-19. To minimize the risk of exposure to COVID-19 and to conserve PPE, the treatment team should be limited to essential personnel and should not include trainees. We agree with recommendations from the American College of Cardiology Interventional Council and Society for Cardiovascular Angiography and Interventions that those who scrub for procedures should don PPE suitable for airborne precautions, including an N95 respirator and a face shield, given the risk of emergent intubation and need for cardiopulmonary resuscitation (20). Patients with unstable, deteriorating respiratory conditions should be intubated prior to transfer to minimize the risk of intubation in the cardiac catheterization laboratory. Use of high-flow nasal cannula and noninvasive positive pressure ventilation should be avoided, as they are associated with increased generation of infectious aerosols.

OPTIMIZING PROCEDURAL CHARACTERISTICS. TAVR should be performed with a modified minimalist approach, including use of conscious sedation,



avoidance of transesophageal echocardiography, and specific plans to minimize the length of stay in the hospital (21,22). Every effort should be undertaken to ensure a safe, expedited recovery and discharge to home (Figure 4).

ILLUSTRATIVE CASE EXAMPLE

A 61-year-old woman with multiple comorbidities and recent hospitalization for decompensated heart failure was referred for urgent evaluation of symptomatic severe AS with a Sievers Type 1 bicuspid aortic valve and preserved left ventricular function. She had a history of type 2 diabetes mellitus, coronary artery disease recently treated with percutaneous coronary intervention, and chronic obstructive pulmonary disease. She had presented to a local hospital with acute pulmonary edema requiring emergent intubation and aggressive diuresis. She was discharged within 2 days, but soon afterward, developed recurrent syncopal episodes. Importantly, testing for COVID-19 was negative.

Given her progressive symptoms and failure of medical management, there was consensus that she qualified as a tier 1 candidate for TAVR. There was consideration of direct hospital transfer; however, due to severe constraints on ICU availability and risk of exposure to COVID-19, expedited outpatient treatment was preferred. Under normal circumstances, given her young age and bicuspid anatomy, she would have been considered for surgical valve replacement. However, her anatomy was also reasonable for TAVR, so to avoid the increased risk of COVID-19 exposure with inpatient admission, as well as utilization of an ICU bed, the heart team agreed to proceed with TAVR as the preferred alternative, with a plan for same-day discharge.

The patient underwent transfemoral TAVR under conscious sedation with successful implantation of a 23-mm Evolut Pro + (Minneapolis, Minnesota) valve. She developed PR-interval prolongation and a new left bundle branch block after valve deployment. Current recommendations are to monitor such patients for 24 h, or at least overnight, with a temporary transvenous pacemaker in place (23). In anticipation of this possible scenario, however, there were preemptive discussions with electrophysiology colleagues to ensure their availability for immediate implantation of a permanent pacemaker in the cardiac catheterization laboratory to avoid an ICU admission. As such, a permanent dual-chamber pacemaker was implanted immediately with a plan to reassess the patient in 3 months and to explant her device if she is found not to require significant pacing. She was discharged home on the same day of the procedure to the care of her family, and is currently doing well without complications at 1 week postprocedure. Although not a typical cost-effective treatment strategy, it was felt to be appropriate in the current pandemic environment, balancing the needs of the patient with the overall needs of the general population.

This case illustrates several ways in which the COVID-19 pandemic necessitates deviation from usual practice in the provision of care to patients with SHD. First, the initial decision to avoid an inpatient transfer

	Stage of Pandemic			
		Early	Peak/Plateau	Late
Anticipated Number of Lases and Expected Impact on Hospital Resources	Low	 Continue outpatient visits Continue to perform cases Consider PPE* for all HCWs 	 Consider teleheath visits Continue cases but delay tier 3 patients (especially if COVID-19 negative) PPE for all HCWs 	 Continue outpatient visits Resume normal case schedule PPE for all HCWs or testing based use
	Moderate	 Early transition to telehealth Continue cases but consider delaying tier 2 patients Consider PPE for all HCWs 	 Telehealth visits only Continue tier 1 cases and selected tier 2 cases (favorable anatomy, younger age) PPE for all HCWs 	 Resume outpatient visits Resume cases with preference to tier 2 patients PPE for all HCWs or testing based use
	Severe	 Aggressive transition to telehealth Continue tier 1 and selected tier 2 cases PPE for all HCWs 	 Telehealth visits only Only perform selected tier 1 cases while avoiding extreme risk and futile cases PPE for all HCWs 	 Continue telehealth with slow restart of in-person visits As resources permit, restart tier 1 followed by tier 2 cases PPE for all HCWs or testing based use

PPE includes use of N95 respirators and face shields in addition to surgical gowns and gloves. HCW = health care workers; PPE = personal protective equipment.

was driven by the need for thoughtful resource allocation during a time of scarcity. Second, the decision to offer TAVR rather than surgery was heavily influenced by the need to reserve ICU capacity for critically ill COVID-19 patients and to minimize the patient's risk of nosocomial infection. Third, the decision to pre-emptively implant a permanent pacemaker rather than wait the usual time for monitoring arose from the aforementioned priorities. Each decision reflected an endeavor to provide optimal cardiac care in the context of a global health crisis. Regional variations in resource availability and the timing of COVID-19 surges will determine the extent to which other programs will need to limit resource utilization in the care of non-COVID-19 patients with SHD.

RECOMMENDATIONS ON RESTARTING STRUCTURAL PRACTICE: A STAGED RETURN TO NORMALCY

Once the severity of the COVID-19 pandemic begins to lessen, there will be a gradual release of strain on the health care system, allowing a staged return to normalcy. Although flattening of the curve should prevent some hospitals from being overwhelmed, this pandemic is likely to have a long "tail," and adjustments to usual practice will be necessary well into the foreseeable future. Until a vaccine becomes widely available, it will remain a priority to conduct outpatient services, pre-procedural testing and structural heart procedures following the general principles of social distancing and utilization of adequate PPE to minimize risk of COVID-19 transmission.

As outpatients at our center undergo evaluation and are categorized according to the framework delineated in Figure 1, they are maintained on a constantly evolving list reflecting the order in which cases will be performed as the health care system recovers. There is continual reassessment of tier 2 cases to ensure that high-risk candidates for intervention are not worsening to the point that procedural risk becomes excessive and the opportunity to derive meaningful benefit is lost. The goal is to intervene on tier 2 patients at the earliest reasonable time while continuing to minimize risk of exposure to COVID-19 and to exercise responsible stewardship of limited resources. Same-day or next-day discharge without ICU occupancy should be prioritized whenever possible. When this is not possible, patients should be admitted to an area with the lowest concentration of COVID-19 patients. In some instances, this may necessitate moving patients out of the hospital to an off-site facility dedicated to non-COVID-19 patients. In regions without a heavy burden of COVID-19 at the present time, it is reasonable to continue performing tier 1 and tier 2 cases, as long as they are not resulting in prolonged hospital stays and consuming disproportionate resources (Figures 2 and 5).

As the burden of COVID-19 on the health care system lightens further and increasing numbers of postponed cases are able to be performed, programs will need to find creative ways to alleviate the backlog of elective patients requiring procedures. In addition to structural cases, there will be a backlog of coronary and endovascular cases that will compete for limited time in the catheterization laboratory. There will also be a backlog of elective surgical cases competing for ICU resources. In many programs, expanded treatment hours including weekend schedules will become necessary to handle increased case numbers. Given significant geographical differences in COVID-19 burden and subsequent resource restrictions, patients with the means to do so may be advised to travel to other programs in less stressed health care environments. An important component to maintaining strong relationships with patients and referring physicians during this period of great uncertainty will be frequent, transparent communication and a sensitivity to patient needs and preferences. In the midst of an overwhelming crisis, it is difficult to chart a path to normalcy in the future. Although it remains unclear when the current pandemic will come to an end, when it does, heart teams across the country must be prepared to shift gears back to what they do best.

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