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Guidelines for Balancing Priorities in Structural Heart Disease During the COVID-19 Pandemic

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ABSTRACT

During the novel coronavirus disease 2019 (COVID-19) pandemic, many hospitals have been asked to postpone elective and surgical cases. This begs the question, "What is elective in structural heart disease intervention?" The recently proposed Society for Cardiovascular Angiography and Interventions/American College of Cardiology consensus statement is, unfortunately, non-specific and insufficient in its scope and scale of response to the COVID-19 pandemic.

We propose guidelines that are practical, multidisciplinary, implementable, and urgent. We believe that this will provide a helpful framework for our colleagues to manage their practices during the surge and peak phases of the pandemic.

General principles that apply across structural heart disease interventions include tracking and reporting cardiovascular outcomes, "healthcare distancing," preserving vital resources and personnel, shared decision-making between the heart team and hospital administration on resource-intensive cases, and considering delaying research cases.

Specific guidance for transcatheter aortic valve replacement and MitraClip procedures varies according to pandemic phase. During the surge phase, treatment should broadly be limited to those at increased risk of complications in the near term. During the peak phase, treatment should be limited to inpatients for whom it may facilitate discharge.

Keeping our patients and ourselves safe is paramount, as well as justly rationing resources.

Contents

Abbreviations: ACC, American College of Cardiology; AS, aortic stenosis; ASD, atrial septal defect; BAV, balloon aortic valvuloplasty; CAIC, Canadian Association of Interventional Cardiology; COVID-19, novel coronavirus disease 2019; ECMO, extracorporeal membrane oxygenation; EF, ejection fraction; ICU, intensive care unit; LAA, left atrial appendage; LOS, length of stay; MR, mitral regurgitation; NYHA, New York Heart Association; PFO, patent foramen ovale; PPE, personal protective equipment; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SCAI, Society for Cardiovascular Angiography and Interventions; TAVR, transcatheter aortic valve replacement; TEE, transesophageal echocardiography.

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1. Introduction

During the global novel coronavirus disease 2019 (COVID-19) pandemic, resources are being redirected toward treating patients infected with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). In order to meet the challenges of the pandemic, hospitals were directed to cease elective work, especially elective surgeries that utilize valuable ventilators and occupy intensive care unit (ICU) beds. Structural heart disease interventions, particularly transcatheter aortic valve replacement (TAVR) for symptomatic severe aortic stenosis (AS) and transcatheter mitral valve repair with a MitraClip (Abbott, Chicago, IL) for severe mitral regurgitation (MR), have important prognostic and symptomatic benefits. As the COVID-19 pandemic continues to linger, with possibilities of recurrent future spikes, guidelines are required for how and when to manage patients requiring these interventions.

The Canadian Association of Interventional Cardiology (CAIC) has published guidelines on performing coronary and structural cardiac interventions stratified by the time phase of the pandemic [1]. During periods of minor restrictions in regular services, TAVR is recommended only in patients with an increased risk of complications in the near term (i.e., low ejection fraction [EF], valve-in-valve with severe aortic regurgitation, recent hospitalization) with a short expected length of stay (LOS). MitraClip is recommended in patients with repeated heart failure admissions. During a time of major restrictions in services, TAVR and MitraClip procedures are only recommended for inpatients in whom these procedures would expedite hospital discharge. When there is an inability to provide services because of staff or resource limitations, then a complete cessation of TAVR and MitraClip procedures is recommended. At all time points, a complete cessation of the performance of atrial septal defect (ASD), patent foramen ovale (PFO), and left atrial appendage (LAA) closure procedures is recommended.

In a consensus statement from the Society for Cardiovascular Angiography and Interventions (SCAI) and the American College of Cardiology (ACC), the authors proposed performing TAVR to treat symptomatic severe AS in all inpatients if they had reduced EF secondary to AS, New York Heart Association (NYHA) class III/IV heart failure secondary to AS, or syncope secondary to AS [2]. The authors recommended treating outpatients with severe to critical AS if they had syncope due to NYHA class III/IV heart failure. Treatment could be considered in minimally symptomatic patients with echocardiographic measures consistent with very severe AS based on gradient and valve area. The authors recommended deferring treatment in asymptomatic patients with severe to critical AS but urged weekly remote check-in.

Whereas the CAIC proposes a major scaling down of operations in a time-sensitive manner, the SCAI/ACC statement recommends treatment in a larger cohort of patients and voices comfort with deferring treatment only in asymptomatic patients. Many practical details for the heart team, the operators, and the hospital administration are understandably missing.

We recognize that this is an evolving situation in which guidelines need to be flexible and hospitals need to be nimble. The guidelines proposed in this manuscript attempt to provide cohesive guidance for structural heart disease treatment in the United States given our current knowledge of the COVID-19 pandemic and keeping in mind patient and healthcare safety and resource allocation (Fig. 1). Practical details, missing in the existing guidelines, are provided. The guidelines account for a prolonged phase of the pandemic, with potential future spikes in infection. Many questions remain unanswered. How do we maintain rapidly evolving guidelines that are uniform across all states and hospitals? Should we designate one hospital per city to continue servicing patients with structural heart disease during the COVID-19 pandemic era? What should be the criteria to select such an institution, and how do we protect that institution's services from being overrun by the COVID-19 response?

2. General principles

We believe it is vitally important that physicians track cardiovascular outcomes, especially when they are scaling down the interventions offered. In addition to recording and tracking this using Centers for Medicare and Medicaid Services (CMS) data, valve coordinators should keep a local log of patients and update these following weekly phone calls with patients. If there is a signal of increased death as a result of delaying treatment, then that should trigger an immediate reassessment of guidelines.

"Healthcare distancing" should be practiced in the catheterization laboratory during structural cases. Teams of operators, technicians, and nurses should be assigned, where possible, with minimal contact between teams. This may prevent a scenario in which all the structural operators in an institution are either sick or in quarantine because of exposure to SARS-CoV-2 and the hospital is unable to provide services. Such a scenario has the potential for cascading effects on cardiovascular surgery services, which would hamper an institution's ability to offer mechanical circulatory support, including extracorporeal membrane oxygenation (ECMO), in critically ill COVID-19 patients. Moreover, the number of healthcare workers in a procedure should be restricted to a minimum. Trainees may be reallocated to frontline services during peak times.

Preserving vital resources and personnel is important. This includes the use of ICU beds, ventilators, and anesthesiologists during and after the procedure. We will discuss the specifics of this for each procedure below. As the use of personal protective equipment (PPE) and ventilators ramps up in certain areas and hospitals, it is important to continue servicing patients with structural heart disease, as some hospitals continue to work at <50% of their capacity.

Decision-making on resource-intensive cases should be shared between the heart team and hospital management. If a procedure mandates the use of a ventilator, it is important that both the heart team and a high-level hospital administrator are involved in the decision-making.

Research cases may be considered for patients who require urgent treatment and still fit the study inclusion/exclusion criteria, while elective cases can be postponed until the worst of the pandemic is over. The treating team should strongly consider switching urgent cases to commercial therapies. Research cases require extra staff, including proctors, industry representatives, engineers, research nurse coordinators and, often, extra investigations and resource utilization. Monitoring bodies should consider relaxing protocol violations on follow-up visits and timeframes for structural heart disease research patients and allow telehealth follow-ups. Remote communication should be utilized more often, including guidance and proctoring. Vendors and specialists who are required to prepare the valve before deployment should be authorized to visit the hospital, wear adequate PPE, and leave as soon the procedure is complete.

Finally, each hospital should consider where it stands in the time course of the pandemic. Cutting down on cases too early may unnecessarily delay important procedures. This may also adversely impact the institution's financial health and impair its ability to operate effectively, procure extra supplies, and recruit additional staff. Conversely, continuing elective cases when the hospital is overrun with COVID-19 cases takes away vital resources, exposes patients and healthcare workers to unnecessary infection risk, and may overburden the system. We do not have clear evidence of when to resume services and need guidance from patterns in countries that have recovered from the pandemic.

3. TAVR

Symptomatic severe AS carries an abysmal prognosis, with a 1- to 2-year mortality rate of 50% [3]. The patients who do worse when treated conservatively are those older than 80 years of age with chronic kidney disease, heart failure, EF <40%, pulmonary artery systolic pressure

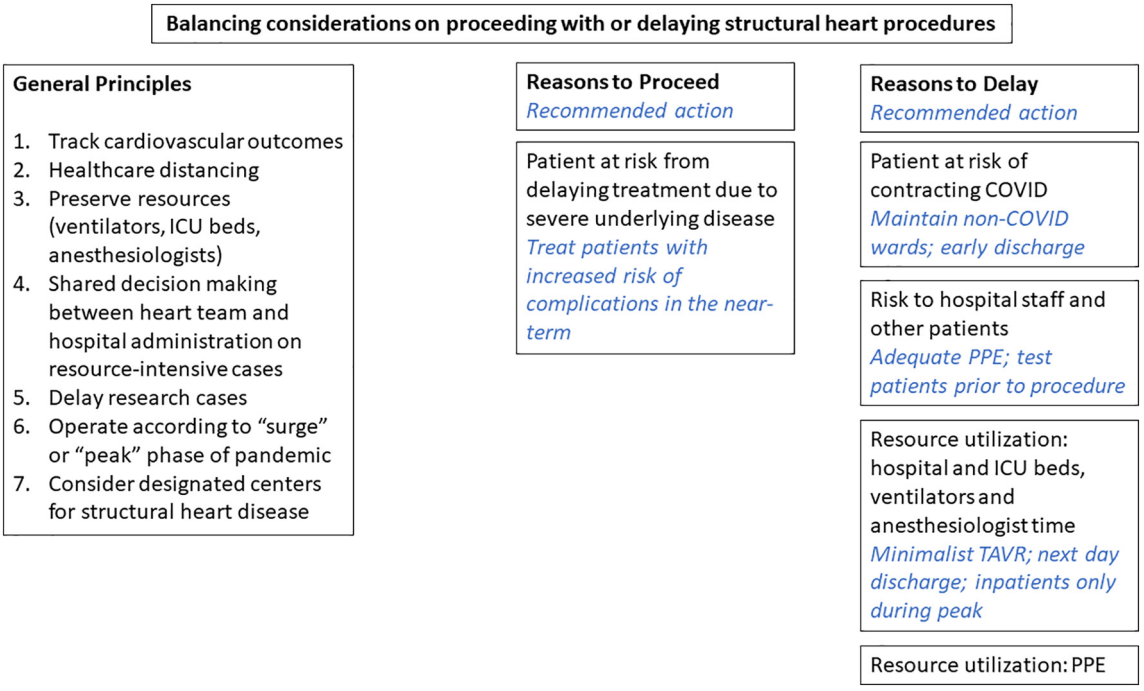

Fig. 1. General principles and risk-versus-benefit analysis for treating patients with structural heart disease during the COVID-19 pandemic. COVID - coronavirus disease. ICU - intensive care unit. PPE - personal protective equipment. TAVR - transcatheter aortic valve replacement.

>60 mmHg, and moderate or severe MR [4]. Information on patient outcomes during wait times for TAVR has been accrued from Ontario, where the mean wait time was 80 days from diagnosis to TAVR. These patients had a mortality rate of 2% and a heart failure admission rate of 12% at 80 days [5]. Predictors of poor outcomes on the waitlist included older age, low EF, valve-in-valve with aortic regurgitation, and prior heart failure admission [5].

Minimalist TAVR improves procedural efficiency and reduces LOS [6]. Predictors of next-day discharge include younger age, low creatinine, absence of atrial fibrillation, lower NYHA class and higher EF, and use of conscious sedation and transfemoral access [7,8]. Unfortunately, the patients who are most likely to be discharged the next day are generally not the ones who would benefit most from urgent TAVR; therefore, a careful balance needs to be struck.

We recommend the following:

1. Continue to perform TAVR for symptomatic severe AS in patients with increased risk of complications in the near term (i.e., old age, low EF, heart failure hospitalization, valve-in-valve with aortic regurgitation) during the "surge phase" of the pandemic.
2. Patients who can be delayed include those who are younger and mildly symptomatic with preserved EF and not in NYHA class III/IV. Valve coordinators should follow up with these patients weekly by phone to monitor their symptoms.
3. During the pandemic "peak," TAVR should only be performed in inpatients in whom the procedure will facilitate discharge from the hospital.
4. Where possible, TAVR should be performed via the transfemoral route. If there is a high risk for major vascular complications, for example, in borderline calcified and tortuous vessels, then consider delaying those cases.
5. Moderate conscious sedation should be used and be nurse-led to free up anesthesiologists and ventilators.
6. ICU admission post-procedure should be avoided.
7. A local algorithm for rhythm disturbances should be instituted to facilitate next-day discharge. This would include either electrophysiological study or remote rhythm monitoring for at-risk patients and weekly telephone calls for the first month.
8. Structural operators should be divided into teams to minimize potential exposures.
9. The number of healthcare workers should be limited to a maximum of five per case – one interventional cardiologist, one cardiothoracic surgeon, a running and recording nurse, a scrub technician, and a nurse for moderate sedation.
10. Teleclinics should be run for follow-up and for monitoring of patients who have had their procedures postponed.
11. All patients being admitted for a procedure should be tested for COVID-19, regardless of their signs or symptoms.
12. Strongly consider postponing TAVR in COVID-19-positive patients. This also avoids prolonged laboratory or computed tomography scanner down time after contact with a patient with COVID-19.
13. Each lab should develop PPE protocols for all laboratory staff. During the local peak of the pandemic, consideration should be made for all staff to wear N95 respirators and face shields for all cases because of the poor sensitivity of current COVID tests.
14. We do not recommend TAVR in patients with COVID-19 who are intubated. Balloon aortic valvuloplasty (BAV) may be considered in rare cases in which the severe AS is preventing ventilator weaning.
15. Case suitability should be determined by the heart team. If a ventilator, anesthesiologist, or ICU bed is required, the decision to proceed should be made in consultation with hospital management.
16. New patients should be screened in a virtual clinic, with risk stratification for urgent or delayed TAVR. Assessment that requires in-person contact should be skipped or delayed until the day of the procedure.
17. Coronary angiography should be performed at the time of TAVR to reduce the number of visits, with *ad hoc* percutaneous coronary intervention for high-grade proximal stenoses if deemed appropriate.
18. TAVR should be preferred over surgical aortic valve replacement because of the decreased length of stay and valuable resource utilization.
19. Regional centers for TAVR should be established during the "surge phase" of the pandemic, taking into consideration geographic coverage and center TAVR volumes. This would enable streamlined services for patients who need them while freeing up peripheral

hospitals to deal with the pandemic. Criteria for regional centers should be established by CMS using principles of just allocation of resources and patient access to care.

4. MitraClip

Many of the principles that apply to TAVR also apply to transcatheter mitral valve repair with the MitraClip. A few specific points are mentioned below.

1. Patients with increased risk of complications in the near term, particularly with repeated admissions for heart failure secondary to severe or moderate-to-severe primary MR that can be treated with a MitraClip, should be treated during the surge phase of the pandemic.
2. During the pandemic peak, inpatients with heart failure secondary to severe primary MR should be offered MitraClip therapy when it will expedite hospital discharge.
3. These procedures require transesophageal echocardiography (TEE), ventilator use, and an anesthesiologist, so careful case selection is necessary.
4. Attempting TEE under moderate sedation in patients with refractory heart failure is not recommended. There is no widespread experience using intracardiac echocardiography alone to guide MitraClip implantation.

5. ASD, PFO, and LAA closure

These procedures should be delayed until the pandemic has abated.

6. Conclusions

These are difficult times for everyone. Keeping our patients and ourselves safe, as well as justly rationing resources, is paramount. Different strategies are required during surge and peak times of the pandemic. Priority should be given to procedures that will facilitate discharge of patients. By collecting data and sharing experiences, we can optimize our response to the pandemic. Designated centers that continue structural heart disease intervention should be considered to provide safe services to our patients during the pandemic.

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Declaration of competing interest

Jaffar Khan – Proctor: Edwards Lifesciences, Medtronic.

Toby Rogers – Advisory Board: Medtronic; Consultant and Proctor: Medtronic, Edwards Lifesciences.

Ron Waksman – Advisory Board: Amgen, Boston Scientific, Cardioset, Cardiovascular Systems Inc., Medtronic, Philips, Pi-Cardia Ltd.; Consultant: Amgen, Biotronik, Boston Scientific, Cardioset, Cardiovascular Systems Inc., Medtronic, Philips, Pi-Cardia Ltd.; Grant Support: AstraZeneca, Biotronik, Boston Scientific, Chiesi; Speakers Bureau: AstraZeneca, Chiesi; Investor: MedAlliance.

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