



Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.

VIEWPOINT

Triage Considerations for Patients Referred for Structural Heart Disease Intervention During the COVID-19 Pandemic



An ACC/SCAI Position Statement

Pinak B. Shah, MD,^{a,b} Frederick G.P. Welt, MD,^{a,c} Ehtisham Mahmud, MD,^{d,e} Alistair Phillips, MD,^{f,g} Neal S. Kleiman, MD,^{a,h} Michael N. Young, MD,^{a,i} Matthew Sherwood, MD, MHS,^{a,j} Wayne Batchelor, MD,^{a,j} Dee Dee Wang, MD,^k Laura Davidson, MD,^{a,l} Janet Wyman, DNP, APRN,^{a,k} Sabeeda Kadavath, MD,^{a,m} Molly Szerlip, MD,^{d,n} James Hermiller, MD,^{d,o} David Fullerton, MD,^{f,p} Saif Anwaruddin, MD,^{a,q}
on behalf of American College of Cardiology and the Society for Cardiovascular Angiography and Interventions

ABSTRACT

The coronavirus disease-2019 (COVID-19) pandemic has strained health care resources around the world, causing many institutions to curtail or stop elective procedures. This has resulted in an inability to care for patients with valvular and structural heart disease in a timely fashion, potentially placing these patients at increased risk for adverse cardiovascular complications, including CHF and death. The effective triage of these patients has become challenging in the current environment as clinicians have had to weigh the risk of bringing susceptible patients into the hospital environment during the COVID-19 pandemic against the risk of delaying a needed procedure. In this document, the authors suggest guidelines for how to triage patients in need of structural heart disease interventions and provide a framework for how to decide when it may be appropriate to proceed with intervention despite the ongoing pandemic. In particular, the authors address the triage of patients in need of transcatheter aortic valve replacement and percutaneous mitral valve repair. The authors also address procedural issues and considerations for the function of structural heart disease teams during the COVID-19 pandemic. (J Am Coll Cardiol Intv 2020;13:1484-8) © 2020 by the American College of Cardiology Foundation.

This paper is being published simultaneously in *Catheterization and Cardiovascular Interventions* and *JACC: Cardiovascular Interventions*.

From the ^aAmerican College of Cardiology Interventional Cardiology Section Leadership Council, Washington, DC; ^bDivision of Cardiovascular Medicine, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts; ^cCardiovascular Division, University of Utah Health, Salt Lake City, Utah; ^dSociety for Cardiovascular Angiography and Interventions, Washington, DC; ^eDivision of Cardiovascular Medicine, University of California-San Diego, San Diego, California; ^fAmerican College of Cardiology Cardiac Surgery Team and Leadership Council, Washington, DC; ^gThe Heart, Vascular, and Thoracic Institute, Cleveland Clinic, Cleveland, Ohio; ^hCardiovascular Division, Houston Methodist Hospital, Houston, Texas; ⁱCardiovascular Division, Dartmouth-Hitchcock Medical Center, Geisel School of Medicine at Dartmouth, Lebanon, New Hampshire; ^jDivision of Cardiology, Inova Heart and Vascular Institute, Fairfax, Virginia; ^kHenry Ford Health System, Center for Structural Heart Disease, Wayne State University School of Medicine, Detroit, Michigan; ^lBluhm Cardiovascular Institute, Feinberg School of Medicine, Northwestern University, Chicago, Illinois; ^mDepartment of Cardiovascular Medicine, University of Arkansas for Medical Sciences, Little Rock, Arkansas; ⁿBaylor Scott and White, The Heart Hospital Plano, Plano, Texas; ^oAscension Medical Group, Indianapolis, Indiana; ^pDivision of Cardiothoracic Surgery, University of Colorado School of Medicine, Denver, Colorado; and the ^qCardiovascular Division, The Hospital of the University of Pennsylvania, Perelman School of Medicine, Philadelphia, Pennsylvania. Dr. Shah is a proctor for Edwards Lifesciences; and has received educational grants from Edwards Lifesciences, Medtronic, and Abbott. Dr. Welt is a site principal investigator for a multicenter trial supported by Medtronic; and is on the advisory board for Medtronic. Dr. Mahmud is a consultant for Abiomed, Medtronic, and Boston Scientific; and chairs multiple data and safety monitoring boards. Dr. Kleiman has received research grants from Medtronic; and serves on steering committees for the PROTECTED TAVR study, sponsored by Boston Scientific, and the PORTICO NG study, sponsored by Abbott. Dr. Sherwood is a consultant

The coronavirus disease-2019 (COVID-19) pandemic has put an enormous strain on health care systems worldwide. Hospitals in China, Italy, Spain, and now the United States have experienced surges of critically ill patients with COVID-19, which has resulted in a dramatic depletion of hospital resources, infection of health care personnel, and critical shortages of vital resources, including personal protective equipment (PPE), ventilators, and intensive care unit (ICU) beds. Capacity has also become limited to provide care for patients with serious comorbid conditions in need of urgent care not related to COVID-19. To preserve PPE and prepare for the potential surge of COVID-19 patients to U.S. hospitals, the Centers for Medicare and Medicaid Services has asked for deferral of nonessential procedures and operations (1). Patients who are in need of structural heart disease (SHD) intervention constitute a particularly challenging group, as many of them have conditions that may be life threatening if intervention is inappropriately delayed. Therefore, decisions regarding the timing of SHD interventions must consider the risk of delaying the procedure, the risk for the patient of COVID-19 exposure outside of home shelter, and use of limited hospital resources. Compounding this challenge is the geographic variation in the peak of the pandemic within the United States and the significant delay in restoration of normal health care operations after the immediate threat has passed. The length of this delay is unknown but could be many months subsequent to the peak, which poses distinct challenges for rescheduling procedures. The purpose of this document is to provide a framework for SHD teams to triage patients in need of SHD intervention during the COVID-19 pandemic and to discuss evaluation and procedural considerations for these patients.

The general priorities are: 1) to minimize exposure to coronavirus for patients with SHD and the structural interventional team; 2) to maintain

high-quality and durable structural interventional outcomes in those who do require procedures during the pandemic; 3) to reduce the risk that these patients with SHD use resources that might be needed for patients with COVID-19; and 4) to prevent delay of intervention in patients at particularly high risk for clinical deterioration, heart failure, and death. It is understood that for any individual patient, 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.

TRANSCATHETER AORTIC VALVE REPLACEMENT

Given advanced age and comorbidities, many patients with severe symptomatic aortic stenosis (AS) are at increased risk for COVID-19 complications and death. However, multiple studies have also shown higher mortality among patients with severe symptomatic AS with a delay in treatment (2,3) over several months to years rather than weeks.

This writing group proposes the following for the timing of transcatheter aortic valve replacement (TAVR) for patients with severe AS during the COVID-19 pandemic.

SYMPTOMATIC SEVERE AS. For inpatients with severe symptomatic AS associated with a reduction in ejection fraction thought to be secondary to AS, presence of New York Heart Association functional class III or IV 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 class III or IV CHF symptoms or syncope due to AS.

ABBREVIATIONS AND ACRONYMS

CHF	= congestive heart failure
COVID-19	= coronavirus disease-2019
ICU	= intensive care unit
MR	= mitral regurgitation
PPE	= personal protective equipment
SHD	= structural heart disease
TAVR	= transcatheter aortic valve replacement
TEE	= transesophageal echocardiography
TMVR	= transcatheter mitral valve replacement

for Medtronic. Dr. Batchelor is a consultant for V Wave Medical and Abbott; and is on the Speakers Bureau for Boston Scientific, Medtronic, and Abbott. Dr. Wang is a consultant for Edwards Lifesciences, Materialise, and Boston Scientific; and received grant support from Boston Scientific. Dr. Wyman is a consultant for Edwards Lifesciences and Boston Scientific. Dr. Szerlip is a consultant and proctor for Edwards Lifesciences; is a consultant for Medtronic; and is a consultant and member of the Speakers Bureau for Boston Scientific. Dr. Hermiller is a consultant for Medtronic, Edwards Lifesciences, and Abbott. Dr. Anwaruddin is on the advisory board for Medtronic; is a consultant and proctor for Medtronic and Edwards Lifesciences; is on the steering committee for Boston Scientific; and is a proctor for V Wave Medical.

The views expressed in this paper by the ACC Interventional Council, SCAI, and ACC Cardiac Surgery Team and Leadership Council do not necessarily reflect the view of the *Journal of the American College of Cardiology* or *Catheterization and Cardiovascular Interventions*.

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: Cardiovascular Interventions* [author instructions page](#).

MINIMALLY SYMPTOMATIC SEVERE TO CRITICAL AS.

For patients with New York Heart Association functional class I or II 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 to date 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. 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. It is expected that some of these patients will develop worsening of their symptoms and will require the procedure to be performed more urgently during the pandemic. We recommend that the TAVR team convene virtually on at least a weekly basis to review the status of patients on the “waiting” list. A single interventional cardiologist and cardiac surgeon should assume a leadership position and be given the authority to arbitrate challenging cases. No triage system can accurately identify all patients who may be safely deferred; the triage system will need to be individualized to each medical center, institutional valve program, and patient population served, as well as the pandemic’s local impact.

PROCEDURAL CONSIDERATIONS FOR TAVR DURING THE COVID-19 PANDEMIC.

There should be no compromise in the quality of interventional care provided to TAVR patients during the COVID-19 pandemic. The majority of TAVR procedures can be performed using a minimalist approach, with moderate conscious sedation. Recent data from the TVT (Transcatheter Valve Therapy) Registry have shown a steady increase in the use of moderate sedation for TAVR, with improved safety and recovery (4,5). The majority of TAVR procedures do not require ICU recovery after the procedure, and this is important as critical care beds will be limited during the COVID-19 crisis in parts of the country. Percutaneous coronary intervention should be performed prior to TAVR only when coronary artery disease is contributing to the patient’s clinical presentation or would pose high risk for the TAVR procedure. Otherwise, percutaneous coronary intervention may be safely deferred (6,7).

TRANSCATHETER MITRAL VALVE PROCEDURES

PERCUTANEOUS MITRAL VALVE REPAIR. The majority of percutaneous mitral valve repair (edge-to-edge repair) can be safely deferred. The following groups of patients should be considered for treatment with edge-to-edge repair during the COVID-19 pandemic: 1) inpatients with severe functional mitral regurgitation (MR) (3+/4+) who cannot be safely discharged despite optimized guideline-directed medical therapy by a heart failure specialist; 2) outpatients with severe functional MR (3+/4+) with hospitalization for CHF within 30 days despite optimized guideline-directed medical therapy by a heart failure specialist; 3) inpatients with CHF and severe degenerative MR (3+/4+) due to acute valvular dysfunction (i.e., secondary to ruptured chord or papillary muscle rupture after myocardial infarction) who are at high risk for surgical mitral valve repair or replacement; 4) outpatients with severe degenerative MR (3+/4+) with hospitalization within 30 days despite optimized medical therapy who are high risk for surgical mitral valve repair or replacement; and 5) patients with either severe degenerative MR or functional MR who are in low-output, decompensated heart failure requiring ICU-level care for whom edge-to-edge device implantation might improve hemodynamic status for extubation and/or transfer out of the ICU setting.

It is the responsibility of the procedural team to keep in contact with patients who are deferred on a weekly basis to ensure that there has been no decompensation requiring earlier intervention.

VALVE-IN-VALVE TRANSCATHETER MITRAL VALVE REPLACEMENT (TMVR).

Valve-in-valve TMVR is the only other transcatheter mitral valve intervention that is currently approved by the U.S. Food and Drug Administration. Because these procedures are resource intensive, they should be deferred until after the COVID-19 pandemic has adequately resolved, provided such mitral valve patients can be sufficiently managed on medical therapy in the interim. Valve-in-valve TMVR during the COVID-19 pandemic should be considered for patients with severe bioprosthetic mitral stenosis or MR who are inpatients with CHF or outpatients who have had hospitalizations for CHF within 30 days despite optimized guideline-directed medical therapy. Valve-in-ring TMVR and valve-in-mitral annular calcification TMVR are off-label procedures and pose much higher risk for complications that may prolong

hospitalization (8,9). These latter procedures should be generally avoided during the COVID-19 pandemic.

PARAVALVULAR LEAK CLOSURE

Paravalvular leak closure (particularly mitral) is generally a lengthy procedure and requires general anesthesia and transesophageal echocardiography (TEE). Patients with significant paravalvular leaks but with symptoms that can be managed medically should be deferred until after the moratorium on nonessential procedures has been removed. Patients who should be considered for paravalvular leak closure during the COVID-19 pandemic are inpatients with CHF and/or hemolysis.

OTHER SHD INTERVENTIONS

Other commonly performed SHD interventions include patent foramen ovale closure, atrial septal defect closure, left atrial appendage occlusion, and alcohol septal ablation for hypertrophic cardiomyopathy. These procedures treat conditions that rarely result in hospitalization or death without the procedure over the short term. For these reasons, these procedures should be deferred until it is deemed safe to resume performing nonemergent procedures in procedural suites.

INTRAPROCEDURAL IMAGING CONSIDERATIONS

To offset the risk for particulate aerosolization, pre-procedural TEE should be limited in use. If a patient is planned for an emergent percutaneous mitral valve repair procedure, on-table TEE will suffice in case planning at experienced centers. 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. The major aerosolization risk to the interventional imager and cardiac anesthesia team occurs during the initial intubation and any transesophageal probe manipulation thereafter in a nonintubated patient. In an already ventilated patient, care should be made that a high-efficiency particulate air filter is placed with the endotracheal tube to maximize safety of the SHD team at the head of the patient's bed. In the absence of sufficient PPE, alternative imaging modalities should be considered (intracardiac echocardiography if possible), as there is high risk for COVID-19 exposure with performance of TEE.

OUTPATIENT CLINICS

The SHD clinic is a vital entry point for patients with valvular heart disease and SHD into the health care system. In preparation for a procedure, patients require visits with multiple physicians and additional visits for imaging. Having patients make multiple trips to the hospital should be avoided during the COVID-19 pandemic to minimize the risk for virus transmission among inpatients, outpatients, and health care personnel. The SHD clinic should help coordinate visits for patients with SHD, and efforts should be made to use telemedicine for consultations. If a patient requires treatment during the COVID-19 pandemic, pre-procedural visits and imaging should be consolidated to a single hospital encounter prior to the procedure if possible. It will be important to maintain typical SHD clinic volumes with virtual visits during the pandemic so that preparations can be made to treat patients in need of SHD intervention as soon as possible once normal hospital operations are restored. Recently, the Society of Thoracic Surgeons/American College of Cardiology TVT Registry allowed the substitution of in-person visits with telephone or virtual visits for the 30-day and 1-year follow-up visits. Although some elements of these registries cannot be collected with remote follow-up, this will need to be addressed at a future date.

SHD TEAM PERSONNEL

SHD clinics and procedures are sustained through a multidisciplinary heart team process. This team consists of interventional cardiologists, cardiac surgeons, cardiac imaging specialists, anesthesiologists, and nurse specialists. Depending on the work flows and potential exposure both within the hospital (as rates of exposure-based infections to health care workers remain high during this pandemic) and outside the workplace, team members may need to be quarantined or treated for illness. This may lead to interruptions in scheduled cases depending on the length of absence. Consideration of clustered scheduling using designated teams may be helpful in addressing interruptions due to temporary absence of team personnel.

CLINICAL TRIALS

Strong consideration should be given for deferral of all clinical trial cases until after adequate resolution of the COVID-19 pandemic. This recommendation

should also be determined in accordance with institutional research policies, as several institutions have limited enrollment in clinical trials to only studies of lifesaving therapies during the pandemic. If patients being considered for clinical investigation become clinically unstable during the COVID-19 pandemic, they should be treated using commercially approved therapies. Continued follow-up of patients already enrolled and treated should be maintained.

CONCLUSIONS

The present COVID-19 pandemic has led heart teams to reprioritize many SHD interventions considering the ongoing surge of other critically ill patients. The current pandemic will require physicians to make

challenging decisions regarding the proper triage and deferral of patients as necessary. There remains significant uncertainty regarding the trajectory of the COVID-19 pandemic, but on the basis of the experience of other nations, the U.S. health care system must be prepared for a surge of critically ill patients in the coming weeks. A coordinated multidisciplinary effort needs to occur to safely defer and monitor patients with SHD requiring interventional therapies.

ADDRESS FOR CORRESPONDENCE: Dr. Pinak B. Shah, Cardiovascular Division, Brigham and Women's Hospital, 75 Francis Street, Boston, Massachusetts 02115. E-mail: pbshah@partners.org.

REFERENCES

- Centers for Medicare and Medicaid Services. Non-emergent, elective medical services, and treatment recommendations. Available at: <https://www.cms.gov/files/document/31820-cms-adult-elective-surgery-and-procedures-recommendations.pdf>. Accessed April 7, 2020.
- Elbaz-Greener G, Maish S, Fang J, et al. Temporal trends and clinical consequences of wait times for transcatheter aortic valve replacement: a population study. *Circulation* 2018;138:483-93.
- Elbaz-Greener G, Yarranton B, Qiu F, et al. Association between wait time for transcatheter aortic valve replacement and early postprocedural outcomes. *J Am Heart Assoc* 2019;8:e010407.
- Butala N, Chung M, Secemsky EA, et al. Conscious sedation versus general anesthesia for transcatheter aortic valve replacement: variation in practice and outcomes. *J Am Coll Cardiol Intv* 2020 Mar 16 [E-pub ahead of print].
- Hyman MC, Vemulapalli S, Szeto WY, et al. Conscious sedation versus general anesthesia for transcatheter aortic valve replacement: insights from the national ACC/STS TVT Registry. *Circulation* 2017;136:2132-40.
- Van Mieghem NM, van der Boon RM, Faqiri E, et al. Complete revascularization is not a prerequisite for success in current transcatheter aortic valve implantation practice. *J Am Coll Cardiol Intv* 2013;8:867-75.
- Kotronias RA, Kwok CS, George S, et al. Transcatheter aortic valve implantation with or without percutaneous coronary artery revascularization strategy: a systematic review and meta-analysis. *J Am Heart Assoc* 2017;6:e005960.
- Guerrero M, Urena M, Himbert D, et al. One-year outcomes of trans-catheter mitral valve replacement in patients with severe mitral annular calcification. *J Am Coll Cardiol* 2018;71:1841-53.
- Guerrero M, Vemulapalli S, Xiang K, et al. Thirty-day outcomes of transcatheter mitral valve replacement for degenerated mitral bioprostheses (valve-in-valve), failed surgical rings (valve-in-rings), and native valve with severe mitral annular calcification (valve-in-mitral annular calcification) in the United States. *Circ Cardiovasc Interv* 2020;13:e008425.

KEY WORDS COVID-19, MitraClip, structural heart disease, TAVR