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Structural Heart Interventions During COVID-19

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Abstract: The spread of Coronavirus Disease 2019 (COVID-19) pandemic across the globe and the United States presented unprecedented challenges with dawn of new policies to reserve resources and protect the public. One of the major policies adopted by hospitals across the nations were postponement of non-emergent procedures such as transaortic valve replacement (TAVR), left atrial appendage closure device (LAAC), MitraClip and CardioMEMS. Guidelines were based mainly on the avoidable clinical outcomes occurring during COVID-19 era. As our understanding of the SARS-CoV-2 evolved, advanced cardiac procedures may safely continue through careful advanced coordination. We aim to highlight the new guidelines published by different major cardiovascular societies, and discuss solutions to safely perform procedures to improve outcomes in a patient population with high

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acuity of illness during the COVID-19 pandemic era. (Curr Probl Cardiol 2022;47:100934.)

Introduction

On January 21, 2020, the Centers for Disease Control and Prevention (CDC) confirmed the first case of Coronavirus Disease 2019 (COVID-19) in the United States (US), and by March 11, 2020, the World Health Organization (WHO) had declared the outbreak a global pandemic. As the pandemic continues to rage around the world, the US alone has thus far recorded 33,257,768 confirmed cases and 597,727 deaths due to COVID-19, the disease caused by the SARS-CoV-2 virus reflecting the severity of the virus.[1] Based on these figures, the case-fatality rate currently lies at 1.8%, however this percentage is likely to fluctuate as disease prevalence and death rate change over time.[2] The spread of SARS-CoV-2 is known to be facilitated by close person-to-person contact, and exposure to respiratory droplets is recognized as the predominant route of transmission.[3-5] Evidence also suggests that airborne spread of viral particles is a possible, albeit infrequent, mode of SARS-CoV-2 transmission.[3-6] In response to uncertainties about COVID-19 severity, transmissibility, and appropriate infection control at the onset of the pandemic, non-emergent medical treatments in the US were temporarily delayed to limit further transmission.

The postponement of non-emergent procedures has impacted an already frail population of patients with structural heart diseases and multiple comorbidities that prevented beneficial procedures such as transaortic valve replacement (TAVR), left atrial appendage closure device (LAAC), MitraClip and CardioMEMS. Studies have demonstrated that TAVR improves health-related quality of life in high surgical risk patients with severe aortic stenosis.[40] MitraClip decreases heart failure hospitalization and mortality in patients with symptomatic heart failure with grade 3-4+ mitral regurgitation (MR).[36] CardioMEMS lowers rates of heart failure hospitalization and all cause hospitalizations,[41] while the LAAC device decreases risk of stroke in patients with non-valvular atrial fibrillation.[42]

The diversion of resources in response to the pandemic resulted in unavailability of ICU beds, personal protective equipment, and reassignment of hospital staff, which hindered the execution of these structural heart interventions. The overall landscape of the Covid-19 pandemic has led to the publication of a variety of recommended guidelines by several cardiology societies and groups regarding the prioritization of structural heart interventions. Specifically, patients deemed to be high risk for

clinical deterioration have been prioritized, while other less urgent cases have been postponed.[9-11] In our paper, we summarize the outcomes of structural heart procedures in the COVID-19 pandemic era, and proffer solutions to safely reinstitute these procedures without overwhelming the limited available resources. We also aim to highlight the patient population with high acuity of illness who should receive these non-emergent procedures to improve clinical outcomes during a pandemic.

Structural Heart Interventions during the COVID-19 Pandemic

Aortic stenosis is a slowly progressing disease which remains largely silent. It rapidly advances after the onset of symptoms and significantly increases the risk of sudden cardiac death. With a prevalence that varies from 0.2% between ages 50 and 59 years and up to 10% by the 8th decade, it remains a leading cause of cardiovascular mortality in the elderly population.[21] Although the most common clinical presentation includes heart failure, syncope and angina, elderly patients may present with decreased exercise tolerance and gastrointestinal bleeding due to platelet dysfunction or arteriovenous malformation. The onset of symptoms, however small, constitute clinically significant stenosis and a prompt need for intervention. Untreated symptomatic aortic stenosis is estimated to have a two-year mortality rate of 50%-68% with most patients dying from congestive heart failure.[22]

Since its approval in 2011, TAVR has gradually become the standard of care for symptomatic patients with severe aortic stenosis who are intermediate or high surgical risk. In 2019, the FDA expanded its approval to include low surgical risk patients citing TAVR as less invasive as it involves smaller incisions and has a shorter recovery time when compared to open heart surgery.[23]

COVID-19 pandemic has placed an enormous burden on the healthcare system in the US and around the world. Hospital systems implemented large scale changes to accommodate for a surge in the number of cases with significant implications on wait times for patients with structural heart disease who are also at high risk due to their age and comorbidities. In one small study of 77 patients whose TAVR was deferred due COVID-19 pandemic, up to 10% of patients experienced a cardiac event within the first month and up to 35% of patients did so over the next three months.[24] Longer wait times for patients awaiting TAVR has been linked with increasing mortality and heart failure hospitalization.[25] This may be further exacerbated since the COVID-19 case

fatality rate is highest amongst elderly patients with preexisting cardiac condition.[26] Malasaire et al also observed that the probability of death in patients with severe aortic stenosis without TAVR intervention at 1, 3, 6, 12, and 24 months were of 3.8%, 10.4%, 23.3%, 27.5%, and 41.1% mortality, respectively, whereas a 30-day all-cause mortality rate for TAVR was postulated at 2.2%.[7,8]

Although the risk of hospital exposure to COVID 19 is still unknown, the risk of delaying the procedure should be balanced against the risk of contracting COVID-19 infection both before and after the procedure. Emerging evidence support similar outcomes of structural heart interventions performed before or during the era of COVID-19. A retrospective study at a single, tertiary care hospital in Israel compared TAVR outcomes between 59 patients during the COVID-19 era and 198 patients before the COVID-19 era.[29] The primary outcome revealed similar TAVR device success according to the Valve Academic Research Consoritum 2 (VARC-2) criteria (97% vs 93%, $P = 0.53$).[29] Additionally, there were no documented cases of COVID-19 at follow up.

Further outcomes of TAVR during the COVID-19 era were described by a Dutch single-institution cohort study of 71 patients. Procedural outcomes included vascular complications (11%), permanent pacemaker implantation (8%), stroke or TIA (7%), conversion to open surgery (1%), at least moderate paravalvular regurgitation (10%), hospitalization days (median of 5 with 4-7 IQR), and 30-day mortality (6%). COVID-19 testing before TAVR (35%) resulted in 0 positive tests. COVID-19 testing after TAVR (11%) resulted in 2 (3%) positive tests at 11 and 13 days postprocedure.[28] Both patients died due to COVID-19 at 14 and 16 days post-procedure.

Additionally, a series of 6 cases of patients undergoing TAVR with a same-day discharge protocol during the COVID-19 pandemic was described by Rai, et al.[38] Patients were discharged with remote cardiac monitoring and had follow up via telemedicine within 2 days, 2 weeks, and 30 days, revealing no post-procedural complications and significant symptomatic resolution. A case series of transcatheter mitral valve repair with clip in 2 patients with severe MR and cardiogenic shock during the COVID-19 era was outlined by Chitturi, et al.[39] Both patients underwent successful procedure, had mild residual MR confirmed with transthoracic echocardiography, and reported significant functional improvement (NYHA Class I and II) at 1-month follow up. One patient demonstrated evidence of an atrial septal defect intra-operatively requiring transcatheter closure with a septal occluder device.[39]

Recommendations For Structural Heart Interventions During COVID-19

There are various recommendations currently guiding clinicians in optimizing care to this patient population. The goals of each group center surround protecting patients and staff from unnecessary exposure to SARS-CoV-19, as well as preserving the already constrained health care resources.

The American College of Cardiology (ACC) and the Society for Cardiovascular Angiography and Interventions (SCAI) guidelines. The ACC and SCAI released a position statement recognizing increased mortality risk associated with delays in some structural cardiac intervention.[10] Their position statement suggests:

- TAVR should be performed in symptomatic severe aortic stenosis, hospitalized patients who have an increased risk of clinical deterioration. Symptomatic severe AS with high risk encompass those with NYHA class III or IV, syncope because of AS or those with low left ventricular ejection fraction.
- Close outpatient monitoring or urgent TAVR intervention is recommended in patients with mildly symptomatic severe AS (high mean gradient with small calculated valve area) with NYHA class I or II.
- They suggest delaying TAVR for 3 months or the restoration of elective procedures in patients with asymptomatic severe AS. This group of patients should have close outpatient monitoring via tele-health.
- They recommend minimalist approach, moderate conscious sedation and performing percutaneous coronary intervention (PCI) prior to TAVR only if the patient has additional symptoms secondary to CAD or would be of high risk for the TAVR procedure.

All percutaneous mitral valves for severe MR should be postponed unless they fall in one of this category.[10]

- Patients who are hospitalized and can't be safely discharged, or who have at least one hospitalization for congestive heart failure (CHF) within 30 days because of severe functional mitral regurgitation (3+/4+) despite optimal medical therapy.
- Both inpatient or outpatients with CHF admission within 30 days who have severe degenerative acute mitral valvular dysfunction

because of ruptured chord or papillary muscle rupture and high risk for surgical mitral valve repair.
- Patients with decompensated heart failure with low output in whom mitral valve intervention might stabilize the patient enough for extubation, or improve patient's medical state.
- Valve-in-valve transcatheter mitral valve replacement (TMVR) should only be considered for patients who are hospitalized with CHF or hospitalized within 30 days with a diagnosis of CHF despite optimal medical therapy and have severe bioprosthetic mitral stenosis.

ASD closure, PFO closure. LAA closure, and alcohol septal ablation for hypertrophic cardiomyopathy should be deferred and are unlikely to affect short-term morbidity and mortality.

Paravalvular leak closure should only be considered in a hospitalized patient with CHF or hemolysis, otherwise medical management is encouraged until elective procedures are allowed.

Structural heart team should have the appropriate personal protective equipment during any intervention, minimize aerosolizing procedures, especially TEE by using alternative imaging modalities.[10]

Canadian Cardiovascular Society Guidelines and Canadian Association of Interventional Cardiology-Association Canadienne de Cardiologie d'intervention. They proposed performance of high risk TAVR (patients with low left ventricular ejection fraction, cases with severe aortic regurgitation (AR), recent hospitalization) with an expected short length of hospital stay during a period of minor restrictions in regular health service.[9] In contrast, during a period of major restrictions in health services, TAVR should be performed in limited inpatient cases to encourage hospital discharge. Mitral clips should be performed in patients with recurrent admissions due to heart failure during minor restrictions, and to expedite hospital discharge in the inpatient setting during major restriction of service**.** Overall, TAVR and Mitraclip procedures should be stopped if resources are limited, while patent foramen ovale (PFO) closure, left atrial appendage closure and atrial septal defect (ASD) closures should be discontinued at all stages of restriction.[9]

Other Recommendations

Mentias and Jneid recommend indications for TAVR based on three criteria: emergent, urgent or elective (summarized in Table 1). Emergent TAVR is reserved for patients with cardiogenic shock or acute refractory

Table 1. Summary of different guidelines on structural heart procedures during COVID-19

	Stratifications	TAVR	MITRACLIP
CCS/ CAIC-AAC[9]	By Phase of pandemic approach: Minor or major restrictions	- Minor restrictions: Only for patients with increased complication risk* - Major restrictions: Only for patients with repeated heart failure admissions	- Minor restrictions: Only for patients repeated heart failure admissions - Major restrictions: Only for patients with repeated heart failure admissions
ACC/SCAI [10]	Symptoms and disease severity approach	- Procedure recommended: • Symptomatic severe AS and hospitalized patients. • Symptomatic severe AS with NYHA III/ IV, syncope or low EF -Close monitoring or urgent TAVR: • Mild symptomatic severe AS with NHA I or II - Delaying for 3 mo with tele-health monitoring: • Asymptomatic severe AS	Only recommended for: • CHF admit within 30 d due to severe MR • Severe degenerative MR and high risk for surgical repair • Decompensated HFrEF, who MITRACLIP may improve state
AHA (Mentias and Jneid) [11]	Symptomatic approach: emergent, urgent (as soon as possible) or elective (postpone to 4-12 wk)	- Emergent: • Cardiogenic shock or acute refractory HF - Urgent: • Recent or recurrent HF exacerbation. • Recent or recurrent exertional syncope • Very severe AS with any symptoms - Elective: • Chronic angina or chronic fatigue • Patient with limited functional capacity • Severe asymptomatic AS	No recommendations
Chung et al. [12]	Risk of clinical decompensation: Tier 1: emergent/urgent (risk of decompensation within 2 wk) Tier 2: Semi-urgent (risk of decompensation in 1-2 mo) Tier 3: Low risk of decompensation >2 mo	Tier 1: Hospitalized patients with: • Cardiogenic shock with severe AS • Severe symptomatic AS Tier 2: • Severe AS with NYHA III, HFrEF or new atrial fibrillation Tier 3: • Asymptomatic severe AS with NYHA II-II and GDMT	Tier 1: Hospitalized patients with: • Cardiogenic shock with severe MR Tier 2: • Severe MR with NYHA III or HFrEF Tier 3: • Asymptomatic severe MR with NYHA I-II and GDMT

heart failure. Urgent criteria to perform TAVR as soon as possible is defined as:

- Recent or recurrent hospitalization due to heart failure.
- Recent or recurrent exertional syncope.
- Or very severe aortic stenosis (with mean gradient > 50 mm Hg, V max > 4.5 m's or AVA <0.75 m) in addition to any symptoms.[11]

Patients who meet elective criteria should postpone TAVR for 4-12 weeks, and these include:[11]

- Chronic angina, chronic fatigue or chest pain
- Patients with limited functional capacity
- Or severe asymptomatic AS

In addition, a large volume heart team institution within the epicenter of the global pandemic proposed clinical pathways in the management of structural heart disease. Cases were triaged based on the risk of clinical decompensation below[12] (summarized in Table 1).

- Tier 1 patients described as hospitalized patients with cardiogenic shock or heart failure requiring inotrope and/or vasopressors with either severe aortic stenosis or severe mitral regurgitation, who cannot be safely discharged without a procedure. Such patients should undergo emergent or urgent interventions due to the significant risk of hemodynamic compromise within hours to days.
- Tier 2 patients described as patients with severe AS with NYHA class III symptoms or heart failure and recent reduction in left ventricular ejection fraction; or new atrial fibrillation and severe mitral regurgitation (MR) with low new left ventricular ejection and NYHA class III. Such patients are at the risk of clinical decompensation within 1-2 months and classified as semi-urgent.
- Tier 3 patients described as patients with severe AS, MR or Tricuspid regurgitation (TR) with NYHA class I or II symptoms, on goal-directed therapy. Such patients are considered having a lower risk of decompensation if the procedure is delayed for over 2 months.
- Left atrial appendage occlusion, atrial septal defects or patent foramen ovale closure should be postponed for 2-3 months as they are unlikely to have a clinical complication for the delay.[12]

Summary of Recommendations for Mitral Clip Repair During COVID-19

Patients with Mitral Regurgitation were heavily affected during the Covid-19 pandemic in a multitude of ways. This included a delay in mitral valve repair (MitraClip procedures) for select patients, decrease in timely diagnosis and cardiovascular diagnostic testing, dilemmas in patient follow up and rescheduling for chronic MR, as well as an increase in financial burden.

The Journal of American Cardiology (JACC) set out new guidelines outlining management of Structural Heart Disease that is congruent with ACC/ SCAI recommendations. For MR, these guidelines emphasized that both inpatient and outpatients with severe functional or degenerative MR (3+/4+) on maximum GDMT or acute CHF hospitalization in the last 30 days (despite optimized GDMT) should be prioritized for surgery; whereas asymptomatic patients with chronic MR on optimized GDMT and no recent CHF exacerbations were considered elective procedures and safe to delay.[27] These patients were to be followed up weekly by the procedural team and managed with GDMT. Understandably, mitral valve repair with the MitraClip demonstrates increased risk of particular aerosolization due to requirement of TransEsophageal Echo (TEE) and ventilator use.[13]

These changes in guidelines reflects a serious concern for patients with asymptomatic degenerative chronic MR. Prior studies have demonstrated better postoperative prognosis and survival rates when LV EF remains $> 60\%$[33], LVESD $> 40\%$, and absence of new atrial fibrillation or pulmonary hypertension.[30-32] When patients progress to symptomatic severe MR (NYHA class III or IV preoperative), regardless of preserved left ventricular function, they have a worse postoperative prognosis.[34] It is also important to note an increase in sudden death when patients progress to symptomatic degenerative chronic MR.[35] This highlights the importance of not delaying surgical procedures in asymptomatic degenerative chronic MR patients during the Covid-19 pandemic.

In regards to functional MR, GDMT is considered first line management and surgery is normally considered when patients remain symptomatic despite maximization of GDMT. However, more recently, studies such as the Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPT) trial show that early intervention has better patient outcomes for functional MR. The study highlights this by demonstrating a 50% all-cause death rate reported at 24-month follow-up in the

conservative therapy group when compared to device based treatment.[36] This equates to a 2% monthly fatality rate for each month delayed in patients with severe regurgitation and who qualify for elective early percutaneous edge-to-edge mitral repair. Giordano et al. further demonstrates this by providing data from selected centers showing a significant difference in 12 month survival for patients with secondary MR who were treated with invasive management (ie, MitraClip) vs those patients who were left untreated during the Covid-19 pandemic.[37]

By delaying repair, these patients are at risk for irreversible cardiac deterioration or sudden cardiac death.

Summary of Recommendations for Left Atrial Appendage Closure During COVID-19

Atrial Fibrillation is a condition that has continued to show increasing prevalence in our population over recent decades, whether due to improving diagnostic and preventative measures or purely due to higher incidence with our increasingly aging population.[14] Some estimates predict atrial fibrillation has a prevalence in as high as 2% of the population and as high as 13% in the elderly population, including those over 80.[14,15] This increasing incidence of atrial fibrillation has correlations with also-increasing use of oral anticoagulation for stroke prevention. These large numbers of patients with atrial fibrillation, however, also bring contraindications to oral anticoagulation. Sources vary based on inclusion criteria for contraindications to taking oral anticoagulation, but the presence of contraindications have been reported in anywhere from 13% to 18% of patients. Prior bleeding—whether gastrointestinal or intracranial in source—accounted for about one-third of these contraindications, according to the ORBIT-AF Registry.[16] When contraindications to oral anticoagulation are present, the question posits itself: does the benefit of anticoagulation for stroke prevention but including the risk of bleeding outweigh the risk of foregoing anticoagulation to face the higher risk of stroke?

Left atrial appendage closure with a WATCHMAN device showed non-inferiority to warfarin therapy in stroke prevention, which provides a legitimate option for patients with atrial fibrillation and contraindications to oral anticoagulation.[17] While pooled meta-analysis of the PREVAIL and PROTECT-AF trials at 5 years showed similar mortality and stroke prevention between groups, there was a benefit of a 1.7% rate of major bleeding in the left atrial appendage closure group versus 3.6% in the group receiving warfarin.[18] The ability to quickly schedule and complete

now routine procedures such as a left atrial appendage closure, however, became strained during the COVID-19 pandemic in 2020. The ACC and SCAI released reviews for structural heart disease practice in 2020 assessing and giving guidelines for triaging patients requiring valve replacements, but there is a lack of data on delays in Watchman device placement for atrial fibrillation during the pandemic.[12,29] These statements give guidelines on stratifying into tiers for how severe the valvular disorders are, which would be congruent with stratifying atrial fibrillation patients based on their CHA2DS2-VASc scoring. A CHA2DS2-VASc score of 5, for instance, correlates to a 10% risk of stroke, TIA, or systemic embolism over the course of a year.[19] Hence, extrapolation of Friberg's data leads us to expect that a 6-month delay in WATCHMAN device placement will on average lead to 5 thromboembolic events out of every 100 patients with contraindications to oral anticoagulation. One recently released retrospective study assessed same day discharge versus nonsame day discharge after WATCHMAN device implantation, and found no statistically significant difference in post-operative mortality or other complications evaluated.[20] These findings, along with the ACC recommendations for catheterization lab adaptations during the COVID-19 pandemic lead us to think that with appropriate stratification, WATCHMAN device placement is still feasible and likely still warranted during times of environmental and resource constraints.[12]

The exact CHA2DS2-VASc scores needed to place WATCHMAN candidates into a tier system has not been decided upon at this point, but with increasing scores, clinicians should weigh heavily on a case-by-case basis whether the procedure is indicated in a setting proven to be safe for patients even during the COVID-19 pandemic. Further studies looking at triaging of these procedures during the pandemic will be beneficial in the future when similar situations of limited resources overwhelm our healthcare system.

Conclusion

The decision to proceed with a structural heart procedure during the COVID-19 pandemic presents unprecedented challenges. However, delivering advanced cardiac care to patients can continue in a safe manner through care coordination and thorough planning. The guidelines for postponing elective procedures is based on the likelihood of significant, avoidable clinical outcomes occurring acutely in the postponement period. In the future, we hope to shed light on the ambiguity surrounding structural heart procedures such as TAVR, Mitraclip, Watchman, and

CardioMEMS during a pandemic by performing a retrospective analysis of procedural outcomes at our institution.

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