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Lessons for Treating Structural Heart Patients during the COVID-19 Pandemic and Beyond

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ABSTRACT

Background: We sought to compare characteristics and outcomes of structural heart disease (SHD) patients treated during the regional peak of the Coronavirus Disease 2019 (COVID-19) pandemic ("COVID era") compared with historical controls. During the COVID era, elective SHD procedures at Beth Israel Deaconess Medical Center were canceled but urgent cases were still performed. We enacted several practice changes in an effort to minimize complications, prevent COVID transmission, and decrease hospital stay during the pandemic.

Methods: Baseline characteristics and outcomes were collected on all patients who underwent SHD procedures during the COVID era and compared with patients treated during the same time period in 2019.

Results: Compared with SHD patients treated during 2019 (N = 259), those treated during the COVID era (N = 26) had higher left ventricular end diastolic pressure (LVEDP; 28 vs. 21 mmHg, p = 0.001), and were more likely New York Heart Association class IV (26.9% vs. 10.0%, p = 0.019), but had a lower rate of bleeding/vascular complications (0% vs. 16.2%, p = 0.013), a lower rate of permanent pacemaker implantation (0% vs. 17.4%, p = 0.019), and a greater proportion of patients were discharged on postoperative day 1 (POD#1; 68.2% vs. 22.2%, p < 0.001).

Conclusion: Practice changes employed for patients treated during the COVID era were associated with fewer vascular complications, a greater proportion of patients discharged on POD#1, and a lower rate of pacemaker implantation despite more severe illness. As a result, we plan to continue these practices in the post-COVID era.

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Introduction

The Coronavirus Disease 2019 (COVID-19) pandemic has had a considerable impact on health-care operations around the world. Hospitals have experienced rises in critically ill patients, increased need for personal protective equipment (PPE), and concerns about overall hospital capacity. In order to care for COVID-19 patients during the pandemic, elective cardiovascular procedures were placed on hold in compliance with government policies, Center for Medicare & Medicaid Services (CMS) recommendations, and major society guidelines.

Patients with cardiovascular disease are known to fare worse with COVID-19. However, patients with structural heart disease (SHD) can also face increased morbidity and mortality while awaiting their procedure, particularly if the illness evolves and becomes clinically unstable. To help guide decisions about which patients should undergo a procedure during the COVID-19 pandemic, the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions released a consensus statement to guide triage decisions. This document recommended prioritizing patients with the highest burden of symptoms, particularly patients who were unable to be discharged due to refractory heart failure attributable to their SHD.

These considerations all factored into our practice at the Beth Israel Deaconess Medical Center (BIDMC) during the regional peak of the pandemic. We sought to investigate the characteristics of SHD patients treated during the COVID-19 pandemic whose clinical features were felt to be too urgent to defer treatment. We also examined the impact of changes implemented in the care of SHD patients during the peak pandemic at our institution.

Materials and methods

This investigation is a retrospective cohort study of patients who underwent a transcatheter aortic valve replacement (TAVR) or percutaneous mitral valve intervention (PMVI) at a single tertiary care academic medical center in Boston, Massachusetts, USA, during the first regional peak of COVID-19 pandemic (3/15/2020 through 6/1/2020). COVID era patients were compared with SHD patients treated during 2019 at the same institution.
During the pandemic, all SHD patients awaiting a procedure were closely monitored by the SHD team through a weekly call and episodic telehealth visits. Patients meeting criteria for an urgent procedure were rapidly identified, referred for a virtual visit to discuss an intervention, and then promptly scheduled. Clinical urgency was determined by the heart team, using such factors as escalating symptoms (New York Heart Association [NYHA] class III–IV), recent hospitalization for acute heart failure or inability to be discharged from the hospital due to heart failure, drop in left ventricular ejection fraction (LVEF), very high aortic transvalvular gradients (mean gradient >60 mm Hg or peak velocity >5 m/s), or syncope.

In order to comply with governmental regulations, minimize resource utilization, and protect patients and team members, several other practice changes were implemented in the COVID era. New measures included systematic COVID-19 testing pre-procedure, a separate “clean” hospital entry pathway for COVID negative SHD outpatients (pre- and post-procedure), reduction in the procedural team to only allow essential members in the room, acute recovery of patients in the procedure room by the same team, extended recovery in an isolated COVID-19 area, and early next-day discharge when feasible. In order to ensure adequate hemostasis and early discharge, we began performing routine completion angiograms and vascular ultrasounds in all cases. We reasoned that this would both be beneficial to the patient and also beneficial to staff by preventing a later-manifesting vascular complication that would require a return to the procedure suite/operating room and exposure risk to a second procedure team.

For patients with new left bundle branch block or prolonged PR interval without right bundle branch block, instead of prolonged in-hospital monitoring, these patients were discharged with mobile outpatient cardiac telemetry with strict trigger parameters (including drop in heart rate and increase in PR and/or QRS intervals). Next day phone calls were made to all patients to assess their well-being and adjust their medications if needed.

Basic demographic data, patient characteristics, procedural details, and in-hospital outcomes were collected. Vascular and bleeding outcomes were reported using the standardized Valve Academic Research Consortium (VARC)-24 and Bleeding Academic Research Consortium (BARC)5 definitions. Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) scores were calculated using the STS website6 and Transcatheter Therapeutics (TVT) TAVR In-Hospital Mortality Risk scores were calculated using equations from the American College of Cardiology/Transcatheter Therapeutics (ACC/TVT) website.9 Baseline conduction disease was defined as right or left bundle branch block, sinus node dysfunction, or any degree of AV block. Procedure duration was defined as the difference between the patient’s arrival time in the procedure room and the patient’s departure time from the procedure room. This study was approved by the hospital’s institutional review board; requirement for informed consent was waived.

Statistical analysis was performed using JMP/14 software (SAS Institute Incorporated, Cary, North Carolina, USA) and STATA/13 (StataCorp LLC, College Station, Texas, USA). Comparisons of frequencies across categorical variables were done using the Chi-squared test or Fisher’s Exact test. Continuous variables were tested for normality using the Shapiro-Wilk method. Non-normally distributed variables were compared using the non-parametric Wilcoxon test. Descriptive statistics of summary data are presented as median [interquartile range] or number (percentage), as appropriate. Since the two groups were numerically unbalanced, we also compared outcomes using a propensity matched analysis with inverse-probability weighting based on age, STS score, gender, NYHA class, high or extreme risk status, LVEF, baseline conduction disease, and serum creatinine (Table). Further details of this analysis are available in the Supplementary Appendix.

**Results**

A total of 259 SHD patients (230 TAVRs and 29 PMVIs) underwent a procedure during the historical control period (1/1/2019 to 12/31/2019), and 26 during the COVID era (22 TAVRs and 4 PMVIs). All patients who met clinical urgency criteria were treated. No procedures were canceled or postponed due to patient or staff COVID status. Patients treated during the COVID era were younger compared with the historical control period (76 [68–82] vs. 81 [75–87], \( p = 0.004 \); Table 1). A greater proportion of COVID era patients were NYHA class IV compared with their 2019 counterparts (26.9% vs. 7.0%, \( p = 0.019 \)). Patients in the COVID era were more often inpatients which were unable to be discharged, compared with patients treated during 2019 (26.9% vs. 10.0%, \( p = 0.019 \)). TAVR patients treated during the COVID era had a higher mean LVEDP (28.0 [19.8–37.5] vs. 21 [16–26] mmHg, \( p = 0.001 \); Table 2). Procedure duration was longer in the COVID era compared with the historical control period (137 [110–180] vs. 110.5 [96–137.5] min, \( p = 0.001 \); Table 1). Patients undergoing TAVR were more likely discharged on postoperative day 1 in the COVID era than in 2019 (68.2% vs. 22.2%, \( p < 0.001 \); Table 2).

There were no differences in STS-PROM score, surgical risk category, TVT predicted in-hospital mortality, baseline conduction disease, LVEF, or mean aortic valve gradient of TAVR patients between COVID era patients and those treated in 2019. There were also no differences in overall length-of-stay, length-of-stay post procedure, or in-hospital mortality among both groups (no in-hospital mortality events in either group).

There were fewer patients who experienced a major vascular complication or bleeding event in the COVID era compared with those treated in 2019 (0% vs 16.2%, \( p = 0.013 \); Table 1). No TAVR patients required a new permanent pacemaker (PPM) in the COVID era, compared with 17.4% during 2019 (\( p = 0.019 \); Table 2). When matching based on age, STS score, gender, NYHA class, high or extreme risk status, LVEF, baseline conduction disease, and serum creatinine, the differences in these outcomes remained significant across groups (Table 3).

There was no in-hospital mortality in either group. No nosocomial Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infections were reported among treated patients or SHD team members during the pandemic at our institution.
**Table 1.** Characteristics of patients undergoing structural heart procedures during the COVID-19 Pandemic compared with historical controls.

| Characteristics                               | COVID era (n = 26) | Historical controls (n = 259) | p-Value |
|-----------------------------------------------|--------------------|-------------------------------|---------|
| Age (years), median [IQR]                    | 76 [68–82]         | 81 [75–87]                   | 0.004   |
| NYHA Class IV, n (%)                         | 7 (26.9)           | 26 (10.0)                    | 0.019   |
| LVEF (%), median [IQR]                       | 59 [50–65.5]       | 60 [48–65]                   | 0.851   |
| Inpatients, n (%)                            | 7 (26.9)           | 26 (10.0)                    | 0.019   |
| Pre-procedure Cardiogenic Shock, n (%)       | 1 (3.9)            | 1 (0.4)                      | 0.175   |
| STS-PROM Score (%), median [IQR]             | 3.3 [1.9–5.7]      | 3.5 [2.2–5.6]                | 0.706   |
| High or extreme risk, n (%)                  | 15 (57.7)          | 149 (57.5)                   | 0.987   |
| Extreme risk, n (%)                          | 2 (7.7)            | 12 (4.6)                     | 0.371   |
| Procedure duration, (minutes), median [IQR]  | 137 [109.8–180]    | 110.5 [96–137.3]             | 0.001   |
| Contrast use (mL), median [IQR]              | 77.5 [42.5–103.8]  | 79 [55–100]                  | 0.590   |
| Radiation dose (mGy), median [IQR]           | 521 [338–700.5]    | 736 [383–1182.5]             | 0.067   |
| Length-of-stay (days), median [IQR]          | 1 [1–6.5]          | 2 [2–4]                      | 0.166   |
| Length-of-stay post procedure (days), median [IQR] | 1 [1–3.5]    | 2 [2–3]                      | 0.018   |
| Any Major Vascular or Bleeding Complication, n (%) | 0 (0)       | 42 (16.2)                    | 0.013   |
| In-hospital Death, n (%)                     | 0 (0)              | 0 (0)                        | -       |

IQR: Interquartile range; NYHA Class: New York Heart Association functional class; LVEF: Left ventricular ejection fraction; STS-PROM: Society of Thoracic Surgeons Predicted Risk Of Mortality; mL: milliliters; mGy: milli-gray.

**Table 2.** TAVR-specific procedural characteristics during the COVID-19 Pandemic compared with historical controls.

| Characteristics                               | COVID era (n = 22) | Historical controls (n = 216) | p-Value |
|-----------------------------------------------|--------------------|-------------------------------|---------|
| Failed bioprosthesis valve Indication, n (%)  | 6 (23.1)           | 19 (8.3)                      | 0.044   |
| TVT Predicted In-Hospital Mortality (%), median [IQR] | 1.9 [1.5–3.1]  | 2.3 [1.9–3.2]                 | 0.126   |
| Baseline LVEDP (mmHg), median [IQR]           | 28 [19.8–37.5]     | 21 [16–26]                    | 0.001   |
| Baseline Mean AV Gradient (mmHg), median [IQR] | 41 [36.5–59.5]   | 44 [37–54]                    | 0.973   |
| Baseline conduction defect, n (%)             | 12 (54.6)          | 109 (43.3)                    | 0.862   |
| New PPM, n (%)                                | 0 (0)              | 40 (17.4)                     | 0.019   |
| Discharged on POD#1, n (%)                    | 15 (68.2)          | 51 (22.2)                     | 0.001   |

TAVR: Transcatheter aortic valve replacement; IQR: Interquartile range; LVEDP: Left ventricular end diastolic pressure; AV: Aortic valve; PPM: Permanent pacemaker; POD: Post-operative day; TVT: Transcatheter Valve Therapeutics; mmHg: millimeter of Mercury.

**Table 3.** Adjusted outcomes comparison among patients who underwent SHD interventions in the COVID-era compared with historical controls.

| Characteristics                              | COVID era (n = 29) | Historical cohort (n = 259) | Difference in outcomes (p-Value) |
|----------------------------------------------|--------------------|----------------------------|---------------------------------|
| Major Vascular or Bleeding Complication, n (%) | 0                  | 42 (16.2)                  | < 0.001                         |
| New PPM, n (%)                               | 0                  | 40 (17.4)                  | < 0.001                         |
| Discharge on POD#1, n (%)                    | 15 (68.2)          | 51 (22.2)                  | < 0.001                         |

SHD: Structural heart disease; PPM: Permanent pacemaker; POD: Post-operative day.

Comparative outcomes analysis using propensity matching with inverse-probability weighting adjusted for STS score, New York Heart Association (NYHA) functional class, high or extreme risk status, left ventricular ejection fraction (LVEF), baseline conduction disease, and serum creatinine. Further details on this analysis are contained in the Supplementary Appendix.

**Discussion**

Although patients who underwent an urgent SHD procedure during the COVID era at our institution were more severely ill as demonstrated by higher NYHA classification and higher intra-procedural baseline LVEDP (Figure 1), their outcomes were similar to historical controls. Despite more severe illness, those treated during the COVID era had fewer bleeding or vascular complications, and fewer PPM implants, and a greater proportion were discharged on postoperative day 1. When adjusting for age, STS score, gender, NYHA class, high or extreme risk status, LVEF, baseline conduction disease, and serum creatinine, differences in these outcomes remained significant across the two groups.

We theorize several reasons for the above findings. With close symptom monitoring, patients needing an urgent procedure were identified adequately and treated before they could clinically decompensate further. Only one death occurred for a patient on the SHD waiting list – this patient had canceled his TAVR in the early COVID era due to fear of nosocomial exposure. A month later, he was admitted for sepsis and expired shortly thereafter (COVID test was negative).
Staffing during this time period was also more limited to a smaller group of attending physicians and a single interventional fellow and also from the nursing and technologist side to a smaller group of individuals. A more experienced group of operators and a set of staff more consistently working together than in the historical control period likely contributed to better outcomes.

Though we assert that patients had overall higher severity of illness during the COVID era as evidenced by higher LVEDP and a greater proportion of NYHA class IV, they were also slightly younger and this may have contributed to better outcomes.

Counterintuitively, procedure duration was longer during the COVID era but radiation exposure was less. This is very likely due to the exclusive use of our hybrid operating room during the COVID era, which has newer and more radiation-efficient X-ray technology. In the historical control group, many of the procedures were performed in an older catheterization laboratory which is less radiation-efficient. Procedure duration may have been longer during the COVID era due to our routine use of completion angiography and ultrasonography. Other potential factors that were unique to the COVID era such as bed availability did not affect procedure times since patients in both groups recovered in a post-procedure area.

In anticipation of early discharge, we began performing routine completion angiograms and vascular ultrasounds in all cases prior to departure from the procedure room. While this resulted in slightly higher contrast use than otherwise would be required and was associated with a longer procedure time, this practice led to the absence of any vascular complications or significant bleeding during the COVID era. Some patients had significant peripheral arterial disease, but no alternate access for TAVR was required during the COVID era.

Further, the use of outpatient mobile cardiac telemetry for patients at high risk of heart block post TAVR helped minimize the length of stay and was associated with an overall lower PPM rate. Of the seven TAVR patients in the COVID era (31.8%) discharged with mobile cardiac telemetry, two patients were found to require a change in their medications due to slow heart rates or prolonged PR interval on monitoring, but none required a PPM. Our approach to deciding on PPM implantation did not change. The reasons for our lower PPM rate during the COVID era are not entirely clear. It is possible that since a single TAVR team of our most experienced operators practiced during the COVID era, employing the latest techniques (e.g. more stringent use of the cusp-overlap technique for self-expanding valves), implants may have been higher, leading to less impingement on the conductions system.

As a result of these favorable outcomes during the COVID era, we have continued utilizing routine completion vascular ultrasonography and outpatient mobile cardiac telemetry since elective procedures have resumed.

In addition, the routine use of telehealth, including videoconferencing, enabled us to increase access to care despite being unable to see patients in the ambulatory clinic. We have continued to use this strategy in the post-COVID era for selected patients, particularly those elderly patients who live far away and for whom it is burdensome to travel for an in-person clinic visit.

**Conclusion**

Patients with SHD treated during the COVID era at BIDMC had higher severity of illness compared with those treated during 2019. Despite more severe illness, changes to our clinical protocols were associated with lower rates of vascular complications and an increased proportion of patients discharged the first postoperative day. Because of these improved outcomes, we have continued many of these practices after elective procedures have since resumed.
Limitations

The observational nature of our study limits the causal inference of our practice changes due to possible unmeasured confounding. Despite the use of statistical methodology to adjust for confounders (i.e. inverse-probability weighting), it is likely that there are other unaccounted variables. The impact of COVID on hospital operations, resource availability, and patient self-selection is impossible to fully capture in a statistical model.

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