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Decline in the Volume of Structural Heart Procedures in the United States Due to the COVID-19 Pandemic

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Coronavirus Disease 2019 (COVID-19) has had an unprecedented impact on healthcare systems both globally and in the United States. To avoid unnecessary exposure to the staff, and to preserve limited resources, the Center for Disease Control recommended that institutions suspend elective medical procedures. As such, many structural heart procedures (SHP) were placed on hold throughout most healthcare systems. What constitutes an elective cardiac procedure, however, is not clearly defined. Moreover, COVID-19-associated delays in delivery of care have anecdotally been associated with adverse outcomes.¹ For example, delays in Transcatheter Aortic Valve Replacement (TAVR) have been associated with increased mortality in patients with severe aortic stenosis (AS).² Of all the structural heart interventions, TAVR represents the greatest number of interventions performed.

The extent of reduction in structural procedures due to the COVID-19 pandemic is unknown; however, its effect on ST-Elevation Myocardial Infarction (STEMI) volumes has been reported,³ with significant drops shown throughout the U.S. The assumption has been that parallel declines in SHP volumes would also occur. To evaluate for any potential drop in SHP volumes in the COVID-19 era, we quantified TAVR, MitraClip, and Watchman procedures from January 1, 2019, to April 30, 2020. Monthly data were collected from nine centers spread geographically across the United States: 1 - Delray Medical Center, Delray Beach, FL; 2 - Beaumont Hospital Royal Oak, Royal Oak, MI; 3 - Johns Hopkins University, Baltimore, MD; 4 - Abrazo Arizona Heart Hospital, Phoenix, AZ; 5 - UT Southwestern Medical Center, Dallas, TX; 6 - Dallas VA Medical Center, Dallas, TX; 7 - WellSpan York Hospital, York, PA; 8 - Shelby Baptist Medical Center, Alabaster, AL; 9 - The Christ Hospital, Cincinnati, OH (Figure 1a). As previously demonstrated for the evaluation of STEMIs,⁴ we used March 1, 2020 as the beginning of the COVID-19 period, based on the

social distancing recommendations set by the federal government. Similarly, the pre-COVID-19 period was established as the time frame between January 1, 2019 and February 29, 2020. The study was approved by the MetroWest Medical Center institutional review board. As the data collected was anonymized from multiple centers, informed consent was waived.

Of the SHPs included in this analysis, 52% were TAVRs. There was a relative reduction of 58% (95% confidence interval 0.4–0.7, p < 0.001) in SHPs during the COVID-19 era. An interrupted time series analysis was performed using a quasi-Poisson model. A level-and-slope model was chosen, with the change-in-slope parametrized as an interaction between time and onset of COVID-19. Adjustment for seasonality was done through a Fourier term. COVID-19 period (March 1-) was strongly associated with a significant decline in structural heart cases (Figure 1c; p < 0.001). The most common reason cited for TAVR or MitraClip performed during the COVID-19 period was refractory heart failure (Figure 1b).

These results should be examined against the backdrop of an exponential and consistent yearly rise in transcatheter structural procedures over the last several years. Although CDC guidelines on elective procedures could largely explain these findings, concerns for healthcare-associated COVID-19 may have also led to the avoidance of medical care by patients. Complications arising from delayed care in cardiac patients, especially those with heart failure, have been speculated.⁴ Heart failure is one of the most common manifestations of structural heart disease (e.g. AS and mitral regurgitation).⁵ Moreover, patients with untreated symptomatic AS are at an increased risk of sudden death. The true impact of this decline on patient outcomes will require future investigation. An ongoing multicenter registry of patients is examining the impact of such delays on clinical outcomes of patients with structural heart disease during this period.

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Figure 1. a. Location of participating sites for the study. b. Distribution of indications for the structural heart procedures (SHPs) in COVID-19 era. c. Seasonal adjusted representation of decline in SHPs.

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