

Increase in Reported Deaths, Injuries, and Malfunctions for Transcatheter Aortic Valve Prostheses During the COVID-19 Pandemic

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Abstract

Shifts in care delivery during the COVID-19 pandemic, particularly from surgical aortic valve replacement to percutaneous aortic valve replacement, may have had adverse outcomes for patients. We analyzed data from the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database, to determine trends in reported malfunctions, injuries, and deaths for transcatheter aortic valve prostheses during the decade 2012 to 2021. We find that reported deaths attributed to transcatheter aortic valve prostheses more than doubled from the pre-pandemic year of 2019 to the pandemic year of 2020. Monthly reported deaths attributed to transcatheter aortic valve prostheses increased by 124%, from 25.0 monthly deaths in 2019 to 55.9 monthly deaths in 2020 ($p < 0.003$). The increased level of deaths persisted in 2021, with 58.3 monthly reported deaths in 2021; the overall increase in deaths from 2019 to 2021 was 133%. We find that reported injuries attributed to transcatheter aortic valve prostheses increased by 25%, from 297.8 monthly injuries in 2019 to 371.4 monthly injuries in 2020 ($p < 0.03$). Finally we find that reported malfunctions attributed to transcatheter aortic valve prostheses increased by 39%, from 40.1 monthly malfunctions in 2019 to 55.7 monthly malfunctions in 2020 ($p < 0.007$). These results suggest an overall increase in adverse events following transcatheter aortic valve prostheses during the pandemic, and indicate a pressing need for further research into short-term and long-term patient outcomes following transcatheter aortic valve prostheses.

Introduction

The pandemic brought about unprecedented challenges for healthcare, particularly for cardiovascular surgery. As public health professionals implemented measures to limit the spread of infectious disease, minimally invasive surgeries were favored over open surgeries, both to shorten hospital stays and preserve healthcare resources. These shifts in care delivery may have had adverse effects on patient outcomes, particularly for aortic valve prostheses. We have previously reported that the COVID-19 pandemic had divergent effects on valve replacement procedures, with an increase in adverse events for percutaneous aortic valve prostheses and a decrease in adverse events for non-allograft tissue valves (1). In the present study, we aimed to determine long-term patterns in adverse events for percutaneous aortic valve prostheses, and characterize pandemic-related shifts in the context of longer-term trends. We analyzed data from the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database, to determine trends in reported malfunctions, injuries, and deaths for transcatheter aortic valve prostheses during the decade 2012 to 2021.

Methods

We used the Food and Drug Administration (FDA) Manufacturer And User Facility Device Experience (MAUDE) database, which lists reports from manufacturers, distributors, clinicians, and other voluntary reporters and is publicly accessible (2). We filtered the MAUDE data by device and adverse event type,

examining ‘malfunction’, ‘injury’, and ‘death’ reports for all devices with the product code ‘NPT’ which is the FDA abbreviation for ‘percutaneous aortic valve prostheses.’ We analyzed adverse event reports for these devices from October 2012 to December 2021, as adverse events were first reported for percutaneous aortic valve prostheses in October 2012, and we were interested in the entire history of adverse event rates for percutaneous aortic valve prostheses. We performed paired t-tests for the differences between monthly reported adverse event types for each event type (death, injury, malfunction); we set $p < 0.05$ as the cutoff for statistical significance.

Results

Reported deaths attributed to transcatheter aortic valve prostheses more than doubled from the pre-pandemic year of 2019 to the pandemic year of 2020 (Figure 1). Monthly reported deaths attributed to transcatheter aortic valve prostheses increased by 124%, from 25.0 monthly deaths in 2019 to 55.9 monthly deaths in 2020 ($p < 0.003$). The increased level of deaths persisted in 2021, with 58.3 monthly reported deaths in 2021; the overall increase in deaths from 2019 to 2021 was 133%. Reported injuries attributed to transcatheter aortic valve prostheses increased by 25% during the pandemic year of 2020 (Figure 2); reported monthly injuries rose from 297.8 in 2019 to 371.4 in 2020 ($p < 0.03$). Reported malfunctions attributed to transcatheter aortic valve prostheses increased by 39% during the pandemic year of 2020 (Figure 3; reported monthly injuries rose from 40.1 in 2019 to 55.7 in 2020 ($p < 0.007$).

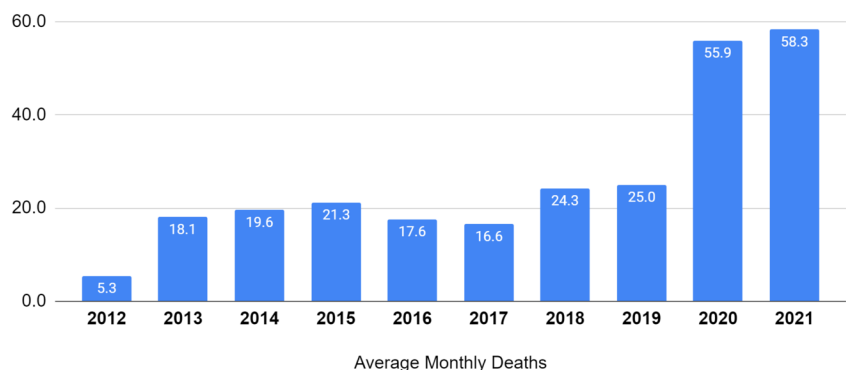


Figure 1. Reported injuries for percutaneous aortic valve prostheses in FDA MAUDE database.

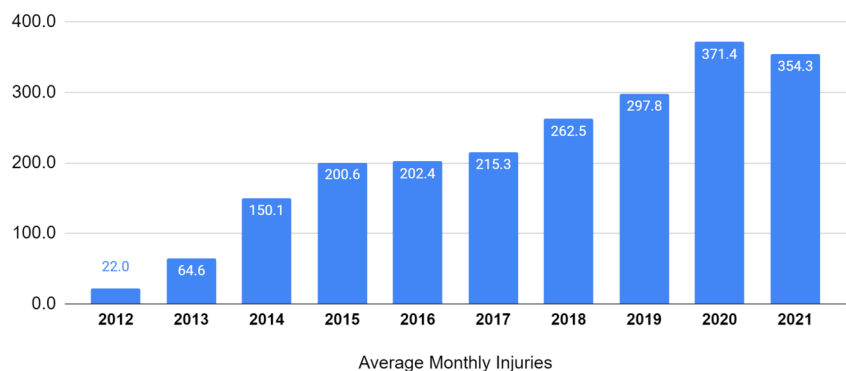


Figure 2. Reported injuries for percutaneous aortic valve prostheses in FDA MAUDE database.

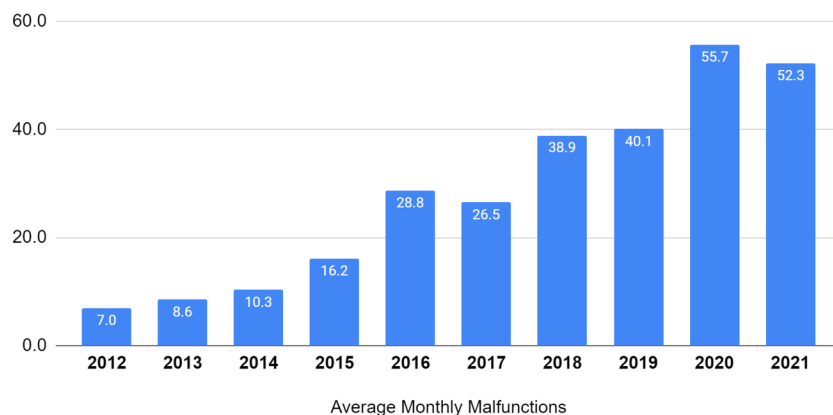


Figure 3. Reported malfunctions for percutaneous aortic valve prostheses in FDA MAUDE database.

Discussion

Reported deaths, injuries, and malfunctions attributed to percutaneous aortic valve prostheses rose dramatically during the COVID-19 pandemic years of 2020 and 2021. Reported deaths for percutaneous aortic valve prostheses rose 124% from 2019 to 2020, and rose 133% from 2019 to 2021; reported injuries for percutaneous aortic valve prostheses rose 25% from 2019 to 2020, and remained elevated in 2021; and reported malfunctions for percutaneous aortic valve prostheses rose 39% from 2019 to 2020, and remained elevated in 2021. These results suggest a need to re-evaluate transcatheter aortic valve replacement during the COVID-19 pandemic. Transcatheter aortic valve implantation was encouraged over surgical aortic valve replacement during the pandemic, as transcatheter interventions are associated with shorter hospital stays and a lower risk of contracting COVID-19 during hospitalization (3). However, the risk of transcatheter aortic valve replacement rises as the underlying disease progresses, making the procedure more challenging when patients wait longer (4). Surgical aortic valve replacement can provide excellent short-term and long-term results, with low morbidity and mortality, in low surgical risk patients (5). Future research should evaluate the long-term effects of pandemic-related changes in clinical decision-making for heart valve replacement.

References

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