Decrease in Reported Rates of Catheter Ablation-Related Adverse Events During the COVID-19 Pandemic

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Abstract

Because the coronavirus disease 10 (COVID-19) pandemic has significantly altered cardiovascular care, we sought to investigate whether the number of reports of adverse events attributed to percutaneous catheter ablation devices changed over the course of the pandemic, specifically examining three medical device classes: cardiac ablation percutaneous catheters; cardiac ablation percutaneous catheters for treatment of atrial fibrillation; and cardiac ablation percutaneous catheters for treatment of atrial flutter. Using data from the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database, we compared weekly reported rates of adverse events for each device during the year immediately preceding the pandemic (March 2019-March 2020) to those during the first year of the pandemic (March 2020-March 2021). We report a 19% decrease in reported malfunctions related to cardiac ablation percutaneous catheters during the pandemic compared to pre-pandemic. We further report a 23% decrease in reported malfunctions related to cardiac ablation percutaneous catheters for atrial fibrillation during the pandemic compared to pre-pandemic. Finally, we report a 25% decrease in reported injuries related to cardiac ablation percutaneous catheters for atrial flutter during the pandemic compared to pre-pandemic.

Introduction

Adverse event reporting is essential for post-market surveillance and risk assessment of medical devices, and can also serve as an indicator of overall care patterns and device utilization. We have previously communicated that the COVID-19 pandemic was associated with a significant 46% decrease in weekly reported deaths attributed to implantable cardioverter defibrillators (ICDs), and a significant 27% decrease in weekly reported injuries attributed to coronary drug-eluting stents.[1] In addition, we have shown that the COVID-19 pandemic was associated with significant shifts in reported adverse events for valve replacement and repair, in particular a 27% decrease in weekly reported injuries attributed to non-allograft tissue heart valves.[2] This report assesses the impact of the COVID-19 pandemic on the number of weekly reports of adverse events attributed to three FDA cardiovascular medical device classes: cardiac ablation percutaneous catheters; cardiac ablation percutaneous catheters for treatment of atrial fibrillation; and cardiac ablation percutaneous catheters for treatment of atrial flutter.

Materials and 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.[3] We filtered the MAUDE data by device and adverse event type, examining 'malfunction', 'injury', and 'death' reports with the filter 'Cardiac Ablation Percutaneous Catheter' for cardiac ablation percutaneous catheters; the filter 'Catheter, Percutaneous, Cardiac Ablation, For Treatment Of Atrial Fibrillation' for cardiac ablation percutaneous catheters for atrial fibrillation treatment; and the filter 'Catheter, Percutaneous, Cardiac Ablation, For Treatment Of Atrial Flutter' for cardiac ablation percutaneous catheters for atrial flutter treatment. Since the World Health Organization officially declared

COVID-19 a pandemic on March 11th, 2020,[4] we chose to record the number of reports given each week over the course of two years: March 2019-March 2020, and March 2020-March 2021. For clarity, March 2020-March 2021 will be herein called 'pandemic data' or 2020-21, and March 2019-March 2020 will be called 'pre-pandemic data' or 2019-20. We performed paired t-tests for the differences between weekly reported adverse event types for each event type.

Results

For devices classified as cardiac ablation percutaneous catheters, we found that there was a statistically significant drop in reported malfunctions from 2019-20 to 2020-21. On average, there were ˜1.6 fewer weekly reports of malfunctions attributed to cardiac ablation percutaneous catheters during the pandemic compared to the pre-pandemic year, a drop of 19% (P-value = 0.04) *(Figure 1).* We additionally examined the number of weekly reports of injuries attributed to cardiac ablation percutaneous catheters in the pandemic year versus the pre-pandemic year, and found no significant difference (P-value [?] 0.42). We then examined adverse event data for cardiac ablation percutaneous catheters for atrial fibrillation. We found that there were, on average, ˜1.8 fewer weekly reports of malfunctions attributed to cardiac ablation percutaneous catheters for atrial fibrillation during the pandemic compared to the pre-pandemic year, a drop of 23% (P-value < 0.02) *(Figure 2).* We further examined the number of weekly reports of injuries attributed to cardiac ablation percutaneous catheters for atrial fibrillation in the pandemic year versus the pre-pandemic year, and found no significant difference (P-value [?] 0.61) *(Figure 3)* . Finally, we analyzed adverse event data for cardiac ablation percutaneous catheters for atrial flutter. We found that there were, on average, ˜1.1 fewer weekly reports of injuries attributed to cardiac ablation percutaneous catheters for atrial flutter in the pandemic year compared to the pre-pandemic year, a drop of 25% (P-value < 0.02). We analyzed the number of weekly reports of malfunctions attributed to cardiac ablation percutaneous catheters for atrial flutter in the pandemic year versus the pre-pandemic year, and found no significant difference (P-value [?] 0.10).

Discussion and Conclusion

In summary, our examination of the FDA MAUDE database revealed significant decreases in reported rates of malfunctions associated with cardiac ablation percutaneous catheters, malfunctions associated with cardiac ablation percutaneous catheters for treatment of atrial fibrillation, and injuries associated with cardiac ablation percutaneous catheters for treatment of atrial flutter during the pandemic. There are several potential explanations for the observed decreases. One explanation is that fewer cardiac ablations were performed during the pandemic due to underdiagnosis and undertreatment, leading to fewer adverse events. A German study of 74 hospitals demonstrated a decline in hospital admissions for atrial flutter and atrial fibrillation during the early phase of the pandemic, with daily admissions declining from 77.5 admissions/day to 44.4 admissions/day.[5] The decline was even more evident for patients with no prior history of atrial flutter or atrial fibrillation; the daily admissions for this subset of patients declined from 41.1 admissions/day to 21.9 admissions/day.[5] The decrease in admission rates may have been accompanied by underdiagnosis of cardiac diseases causing only moderate to mild symptoms; a Danish nationwide registry reported a 47% lower incidence of patients with new-onset atrial fibrillation or atrial flutter during the pandemic in comparison to the prior year.[6] In a Polish study of a region inhabited by 4.6 million people, the number of patients hospitalized with atrial fibrillation or atrial flutter declined 60% during the nationwide pandemic lockdown in 2020, compared with the same period in the prior year.[7] In the same Polish population, the number of percutaneous ablation procedures declined 69% during the nationwide pandemic lockdown in 2020, compared with the same period in the prior year.[8] In an Italian survey of 104 physicians in 84 centers, 77.4% of centers reported a significant reduction in elective ablations during the pandemic.[9] In Spain, the Spanish Catheter Ablation Registry reported an 18% decline in ablations procedures during the pandemic year 2020 versus the prior year 2019.[10] In a study of the Health Episodes Statistics database of England, covering all 147 National Health Service (NHS) hospitals in England, the number of ablations for atrial fibrillation declined 83%, and all other ablations declined 64%, during three weeks of lockdown during the pandemic compared to the previous year.[11] Given the cardiovascular complications of COVID-19, it might be expected that hospital

admissions for atrial flutter or atrial fibrillation would increase, yet the opposite has been observed. Further investigation is needed to determine the extent of cardiovascular underdiagnosis and undertreatment during the COVID-19 pandemic

Disclosures

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Figure Legends

Figure 1. Weekly number of reported malfunctions attributed to Cardiac Ablation Percutaneous Catheters in FDA MAUDE database.

Figure 2. Weekly number of reported malfunctions attributed to Cardiac Ablation Percutaneous Catheters for Atrial Fibrillation in FDA MAUDE database.

Figure 3. Weekly number of reported injuries attributed to Cardiac Ablation Percutaneous Catheters for Atrial Flutter in FDA MAUDE database.