

Analysis of Deaths Reported for Percutaneous Cardiac Ablation Catheter Devices

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Abstract - Cardiac ablation is a widely used intervention for cardiac arrhythmias. Indications for cardiac ablation include atrial fibrillation, atrial flutter, supraventricular tachycardia, and idiopathic ventricular tachycardia. While cardiac ablation is a valuable method for curing arrhythmia, the procedure carries significant risks. This study aimed to analyse the number of deaths attributed to percutaneous cardiac ablation catheters over the decade from 2011 to 2021, using data from the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database. Reported deaths attributed to percutaneous cardiac ablation catheters rose significantly in 2014. Since then, deaths attributed to percutaneous cardiac ablation catheters have remained relatively constant, with approximately 40 to 50 deaths reported yearly from 2014 to 2021. Importantly, reported deaths attributed to this class of devices are almost entirely driven by ablation devices manufactured by Biosense Webster, including the Thermocool® Smarttouch® catheter. Biosense Webster catheters accounted for 92% of reported deaths attributed to all percutaneous cardiac ablation catheters from 2011 to 2021. These results suggest a need for increased innovation, continuous improvement, and greater competition and choice within this class of devices. The study further characterized the causes of death attributable to percutaneous cardiac ablation catheters from 2011 to 2021. The data reveal that the most frequent causes of death are cardiac tamponade (25.5%), esophageal or atrio-esophageal fistula (22.5%), and cardiac arrest (16.0%). Other important causes of death following cardiac ablation include hypotension, stroke, cardiac perforation, embolism, ventricular fibrillation, dissection, shock, hemorrhage, and hypovolemia.

Keywords: cardiac ablation, arrhythmia, adverse events, percutaneous, catheter, medical device, tamponade, fistula

1. Introduction

Cardiac ablation is a minimally invasive procedure for treating cardiac arrhythmias, including atrial fibrillation, atrial flutter, supraventricular tachycardia, and idiopathic ventricular tachycardia. The goal of cardiac ablation is to create a myocardial lesion of predictable size and depth, thereby interrupting and blocking aberrant electrical signals in the heart while minimizing complications. Cardiac ablation is typically performed by identifying the source of the abnormal electrical signal, guiding a catheter to the target site, and scarring the tissue via either heat or cold. Radiofrequency ablation catheters apply heat to destroy tissue, while cryoablation catheters apply extreme cooling to destroy tissue (Fig. 1). While cardiac ablation is an effective intervention for arrhythmia, the procedure carries risks, particularly when the ablation creates lesions that are larger than the intended size, leading to off-target tissue destruction. The Food and Drug Administration (FDA) has approved several cardiac ablation catheters, including the J&J Biosense Webster Thermocool® Smarttouch® catheters, Medtronic DiamondTemp™ and Medtronic Arctic Front™ catheters, St. Jude TactiCath™ catheters, and Boston Scientific Blazer™ and Boston Scientific Intellanav™ catheters. The FDA Manufacturer and User Facility Device Experience (MAUDE) database, lists adverse reports from manufacturers, distributors, clinicians, and other voluntary reporters and is publicly accessible [1]. The goals of this study are to characterize the number of reported deaths associated with cardiac ablation catheters in the United States from 2011-2021, identify the catheters that are most frequently associated with reported deaths, and describe the causes of death during cardiac ablation procedures. This analysis can help identify opportunities for improvement of cardiac ablation devices to maximize patient outcomes and minimize serious adverse events.

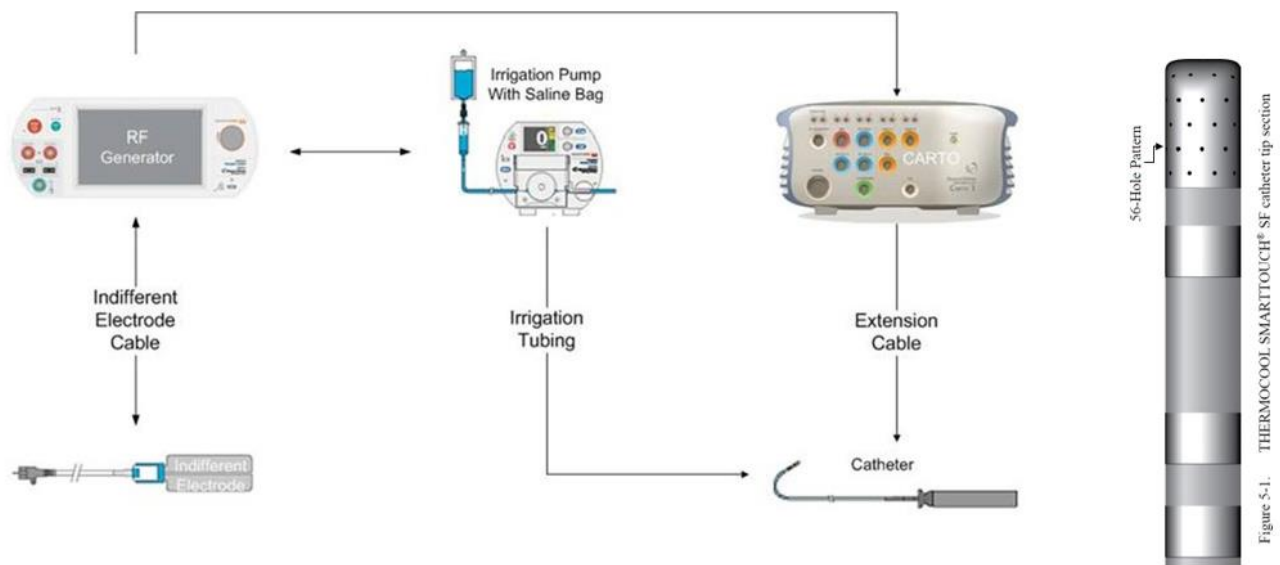


Fig. 1: Diagram of Thermocool® Smarttouch® ablation catheter from J&J Biosense Webster (Food and Drug Administration).

2. Methods

The Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database was searched using the search terms ‘Cardiac Ablation Percutaneous Catheter’ for the device and ‘Death’ for the event type over the time period from 2011 to 2021. The search therefore returned all instances of death reported for percutaneous cardiac ablation catheters during the decade. A total of 431 cases of death were found, and the device manufacturer and causes of death were recorded for each case.

3. Results

Analysis of the FDA MAUDE database reveals that the number of deaths associated with percutaneous cardiac ablation catheters increased significantly in 2014, more than doubling from 18 total deaths in 2013, to 43 total deaths in 2014 (Fig. 2). The yearly number of deaths associated with percutaneous cardiac ablation catheters fluctuated between 41 and 61 annual deaths from 2014 to 2021. Devices from the manufacturer J&J Biosense Webster, specifically Thermocool® Smarttouch® ablation catheters, were the main driver of deaths associated with percutaneous cardiac ablation catheters. J&J Biosense Webster ablation catheters accounted for 92% of reported deaths from all catheters in the decade 2011-2021.

The reported causes of deaths associated with percutaneous cardiac ablation catheters were analysed for the years 2011-2021. This analysis reveals that the most frequent cause of death associated with percutaneous cardiac ablation catheters was cardiac tamponade (Fig. 3). Cardiac tamponade results from penetration of the pericardium, leading to accumulation of fluid and blood in the pericardial sac. Tamponade is caused by accidental trauma during the ablation procedure; the build-up of fluid surrounding the heart eventually compresses the heart. Cardiac tamponade puts pressure on the heart and prevents it from filling properly, and ultimately manifests in a dramatically low blood pressure that can be fatal. Of 431 total deaths associated with percutaneous cardiac ablation catheters from 2011-2021, cardiac tamponade was identified in 25.5% of cases (Fig. 4). The second most frequent cause of death associated with percutaneous cardiac ablation catheters was atrio-esophageal fistula. An atrio-esophageal fistula is a dreaded complication of cardiac ablation; the complication occurs because of the anatomical position of the esophagus relative to the posterior wall of the left atrium [2]. The esophagus is most susceptible to injury when it is located close to the cardiac ablation target, and an injury to the esophagus can result in a perforation and fistula between the esophagus and the atrium. Of 431 total deaths associated with percutaneous cardiac ablation catheters from 2011-2021, esophageal fistula or atrio-esophageal fistula was identified in 22.5% of cases (Fig. 4).

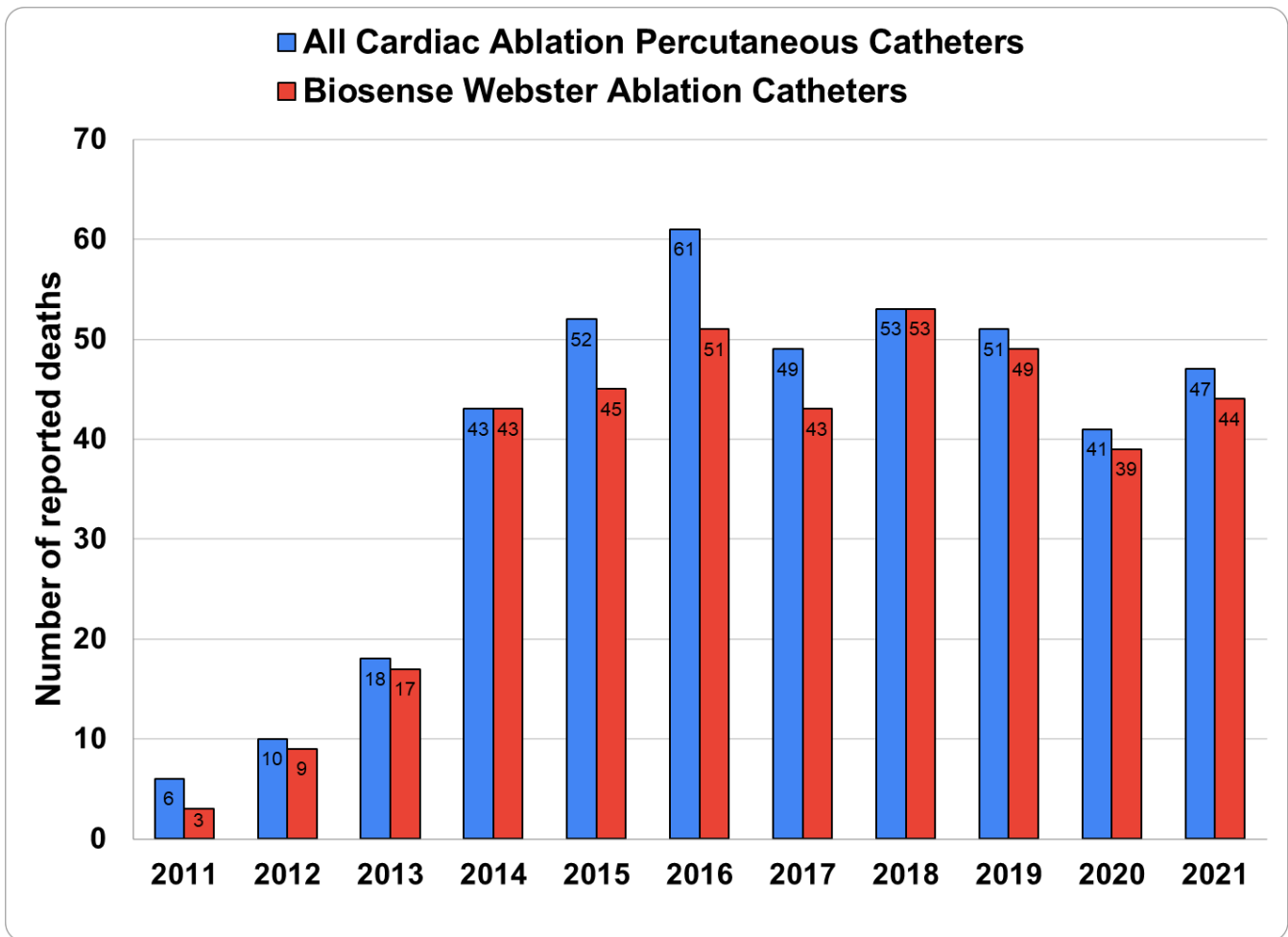


Fig. 2: Number of yearly reported deaths associated with percutaneous cardiac ablation catheters in FDA MAUDE database. The database was searched using the filters 'Cardiac Ablation Percutaneous Catheter' for product class and 'Death' for event type.

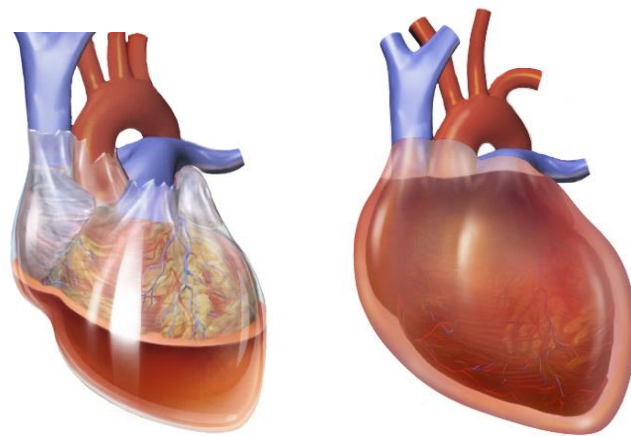


Fig. 3: Cardiac tamponade (Blaesen Medical).

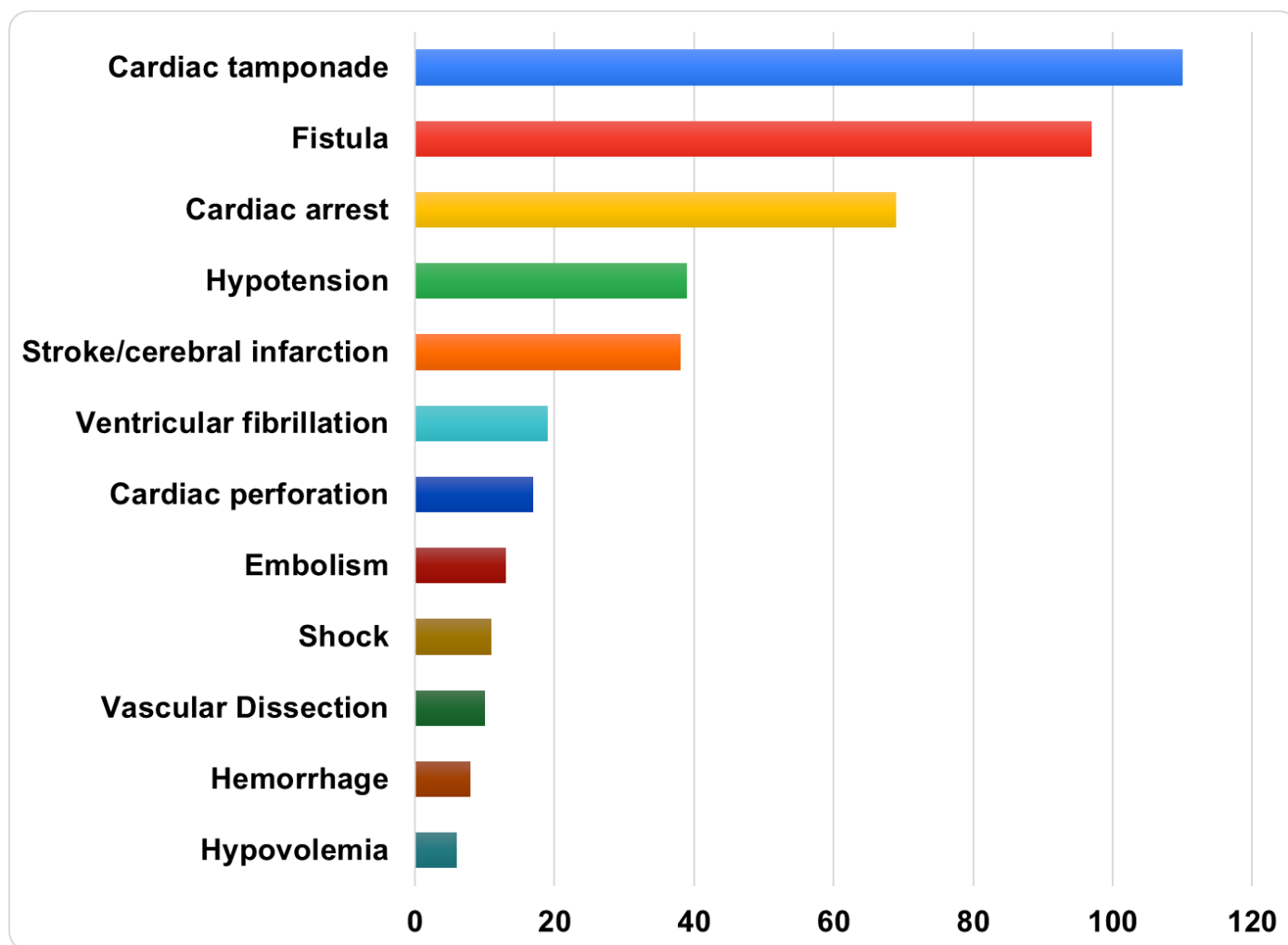


Fig. 4: Causes of death associated with percutaneous cardiac ablation catheters from 2011-2021 in FDA MAUDE database.

Cardiac arrest accounted for 16.0% of deaths associated with percutaneous cardiac ablation catheters in the decade from 2011 to 2021. Other important causes of death include hypotension, stroke, cardiac perforation, embolism, ventricular fibrillation, dissection, shock, hemorrhage, and hypovolemia.

4. Conclusion

According to FDA data, more than 80,000 deaths and 1.7 million injuries have been associated with all medical devices in the past decade from 2011 to 2021 [3]. It is therefore critical to understand trends in adverse event occurrence, along with underlying causes of injuries and deaths for medical devices. This study focused on cardiac ablation catheters, as these devices are widely used for the treatment of cardiac arrhythmias. In summary, this study reveals that reported deaths associated with percutaneous cardiac ablation catheters rose significantly in 2014. The cause of this increase is unclear. The increase in deaths may have been caused by changes in adoption of cardiac ablation devices from different manufacturers. Alternatively, the increase may have been caused by an increased volume of cardiac ablation procedures being performed; an increased volume of procedures will lead to an increase in the absolute number of adverse events. Another possible explanation is that there were changes in patient demographics in terms of age and underlying health conditions. Finally, the increase in reported deaths may have been caused by increased reporting of adverse events.

J&J Biosense Webster devices account for 92% of deaths associated with cardiac ablation percutaneous catheters in the decade 2011 to 2021. This finding signals the need for continued innovation, improvement, and competition in this class of

devices. The most frequent causes of death were cardiac tamponade, atrio-esophageal or esophageal fistula, and cardiac arrest. These findings can lend insights into possible avenues for design improvements, to reduce serious adverse events. One limitation of this study is that it focuses on adverse events for devices that are classified as 'Cardiac Ablation Percutaneous Catheter' in the FDA MAUDE database. The database also contains data for devices that are classified as 'Catheter, Percutaneous, Cardiac Ablation, For Treatment Of Atrial Flutter' and 'Catheter, Percutaneous, Cardiac Ablation, For Treatment Of Atrial Fibrillation.' Future work will incorporate data from these device classifications as well.

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