Adverse events associated with cardiac stents: A manufacturer and user facility device experience database analysis

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ABSTRACT

Aim: The present study was conducted to determine the adverse events (AEs) associated with cardiac stents reported to the Food and Drug Administration manufacturer and user facility device experience (MAUDE) database.

Materials and methods: The authors reviewed the cardiac stents related AEs reported to MAUDE from July 14, 2014, to June 30, 2024. Analyses of details collected are presented.

Results: MAUDE received a total of 500 unique cardiac stents related adverse events. Of 500 cases, MAUDE classified 213 instances (41.9%) as Failure to Advance, 35 (7.07%) as Patient device incompatibility. Of the 500 cases, 215 adverse events (44.61%) were reported in the year 2023.In these adverse events, 141 cases (61.30%) were identified in male and 89 cases (38.70%) were reported in female. In 500 instances US reported 163(33%) of adverse events followed by IN which reported 158(31.98%) AEs. Of 500 reported adverse events, 71

instances were reported in the age group of 71-80, 59 instances were reported between the age group of 61-70 requiring additional medical care.

Conclusions: Use of cardiac stents carries a degree of risk to patient's safety, if not properly used. MAUDE data is one of the reliable sources of AE. The findings from study reiterate that more in-depth analysis of AE of cardiac stents is needed. Until then operator needs to take all precautions to avoid AE when using cardiac stents.

Keywords: MAUDE, Cardiac Stents, Adverse Events

INTRODUCTION

A medical device can be any instrument, apparatus, implement, machine, appliance, implant, and reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose. Today, there are an estimated 2 million different kinds of medical devices on the world market, categorized into more than 7000 generic devices groups[1].

A stent is a medical device designed as a cylindrical metal mesh that is used to restore normal fluid flow when bodily fluids, such as blood or biliary fluids, are obstructed within blood vessels, gastrointestinal tracts, or other passageways. By inserting the stent into a narrowed or blocked area, it helps to alleviate the obstruction. Stents are generally categorized into two types: vascular stents, which are used in blood vessels, and non-vascular stents, which are used in other bodily systems[2]. Among these, coronary stents are particularly crucial for the revascularization process in patients suffering from coronary artery disease. The National Cardiovascular Data Registry (NCDR) is a group of registries maintained by the American College of Cardiology Foundation. These registries are used by a diverse constituency to improve the quality and outcomes of cardiovascular care, to assess the safety and effectiveness of new therapies, and for research. In 2014, NCDR CathPCI recorded over 667,000 percutaneous coronary interventions (PCIs), with more than 90% involving stent placements[2]. This registry encompasses over 90% of PCI-capable hospitals in the United States. According to the Medical Devices Rules of 2017 in India, cardiac stents are classified

as Class D devices, representing the highest risk category. This classification includes devices that are vital for life and could potentially cause significant harm if they malfunction[3].

In recent years, the U.S. Food and Drug Administration (FDA) has increasingly adopted a life-cycle regulatory approach for medical devices, which provides the agency with greater flexibility in setting premarket clinical trial requirements. This approach emphasizes ongoing post-market surveillance to continually evaluate and reassess the safety and effectiveness of devices[4,5]. Concerns have emerged regarding coronary stents, including issues such as late stent thrombosis associated with drug-eluting stents (DES), increased thrombosis and myocardial infarction risks linked to bioresorbable vascular scaffolds, and in-stent restenosis, which involves progressive narrowing due to vascular remodeling and neointimal hyperplasia, as reported by NCDR. Understanding the frequency and nature of these stent-related adverse events is crucial, as many patients will live with these implanted devices for extended periods[6,7,8].

Coronary stents provide a valuable opportunity to analyze the effectiveness of using claims data to characterize adverse events related to medical devices, given their widespread implantation and the availability of detailed data sources linked to administrative claims. The FDA defines adverse events (AEs) as "any undesirable experience associated with the use of a medical product in a patient" [9,10]. The MAUDE (Manufacturer and User Facility Device Experience) database, managed by the FDA, serves as a comprehensive repository for reports of adverse events and device defects associated with medical devices. This database contains data from the last ten years of Manufacturer and User Facility Device Experience (MDR) reports and is updated monthly to include the most recent reports [10]. Although the primary public database typically contains data from the past five years, the FDA retains records of adverse events and device reports for a longer duration, with certain historical data available through direct contact with the FDA or specific FDA archives[11].

The aim of this study is to analyze and identify the adverse events (AEs) associated with cardiac stents as reported to the FDA's MAUDE database over a specific ten-year period. By reviewing the data, the authors aimed to provide insights into the frequency and types of complications related to cardiac stents, such as "Failure to Advance" and "Patient Device Incompatibility." The findings highlight the need for increased awareness of the risks involved in stent use, particularly among different demographics, including age and gender, and emphasize the importance of careful operator technique to minimize these risks.

Ultimately, the study advocates for a more comprehensive investigation into the safety profile of cardiac stents to improve patient outcomes.

MATERIALS AND METHOD

The U.S. FDA, a federal agency responsible for the oversight and approval of all health-related products and devices, maintains an open-access database known as MAUDE. This database compiles reports of adverse events (AEs) associated with devices approved by the FDA. According to FDA regulations, manufacturers and distributors are required to submit reports of AEs in a standardized narrative format within 30 days of the event. In addition, voluntary reports from healthcare professionals and patients are also accepted. The MAUDE database includes detailed narratives of the adverse events, versions provided by the manufacturers, and conclusions drawn from the reported incidents.

For the purposes of this study, adverse events related to the use of cardiac stents, identified by their unique product code (MAF) for cardiac stents, were extracted from the MAUDE database for the period spanning from July 14, 2014, to June 30, 2024. The collected data encompassed several key variables, including the year of reporting, type of event, country of occurrence, patient age, and patient sex. This information was meticulously categorized based on the specific device problems reported. The data were then entered into an Excel spread sheet for comprehensive analysis, and the results were subsequently compiled and presented. Descriptive statistics were conducted and presented. Simple cross-tabulations were used to explore the relationship between the adverse events (AEs) and the nature of reporting (voluntary/mandatory), as well as their applications (endodontics/periodontics/others).

RESULTS

A total of 500 adverse event (AE) reports related to cardiac stents were extracted from the MAUDE database within the designated timeframe. Upon classification by MAUDE, it was found that 213 cases, representing 41.9% of the total, fell into the category of "Failure to Advance." Additionally, 35 reports, or 7.07%, were identified as "Patient Device Incompatibility." There were 21 instances, accounting for 4.21%, where the adverse events did not specify a clearly identifiable device issue or usage problem. Furthermore, reports of material separation and improper or incorrect procedures or methods each constituted 2% of the total reports. A detailed overview of these trends is presented in Table 1.

Row Labels	Total Count of Device problem
Failure to Advance (2524)	176
Failure to Advance (2524)	37
Patient-Device Incompatibility (2682)	35
Adverse Event Without Identified Device or Use Problem (2993)	21
Material Separation (1562); Failure to Advance (2524)	13
Improper or Incorrect Procedure or Method (2017); Patient-Device Incompatibility (2682)	10
Defective Device (2588)	7
Improper or Incorrect Procedure or Method (2017)	7
Positioning Problem (3009)	6
Migration (4003)	5
Failure to Advance (2524); Device Dislodged or Dislocated (2923)	5
Positioning Failure (1158); Material Deformation (2976)	4
UNKNOWN	4

Failure to Advance (2524); Material Deformation (2976)	3
Device Dislodged or Dislocated (2923)	3
Difficult to Remove (1528); Material Separation (1562); Failure to Advance (2524)	3
Difficult to Advance (2920)	3
Improper or Incorrect Procedure or Method (2017); Device Dislodged or Dislocated (2923)	3
Patient-Device Incompatibility (2682)	3
Off-Label Use (1494); Failure to Advance (2524)	3
Crack (1135)	3
Use of Device Problem (1670); Material Deformation (2976)	2
Material Deformation (2976)	2
Failure to Advance (2524); Deformation Due to Compressive Stress (2889)	2
Failure to Advance (2524); No Apparent Adverse Event (3189)	2
Material Separation (1562); Improper or Incorrect Procedure or Method (2017); Failure to Advance (2524)	2

Material Deformation (2976)	2
Positioning Failure (1158)	2
Failure to Advance (2524); Activation Failure (3270)	2
Material Separation (1562); Failure to Advance (2524)	2
Detachment of Device or Device Component (2907)	2
Off-Label Use (1494); Material Separation (1562); Failure to Advance (2524)	2
Failure to Advance (2524); Material Deformation (2976)	2
Improper or Incorrect Procedure or Method (2017); Patient-Device Incompatibility (2682)	2
Difficult to Advance (2524); Material Split, Cut or Torn (4008)	2
Difficult to Remove (1528); Difficult to Advance (2920)	2
Insufficient Information (3190)	2
Difficult to Remove (1528); Failure to Advance (2524)	2
Failure to Advance (2524); Improper or Incorrect Procedure or Method (2017); Failure to Advance (2524)	2

Failure to Advance (2524); Device Dislodged or Dislocated (2923); Material Separation (1562)	2
Patient-Device Incompatibility (2682); Adverse Event Without Identified Device or Use Problem (2993)	2

Table 1: Device problems associated with cardiac stents

When analyzing the distribution of adverse events over time, it was observed that the year 2023 had the highest reporting rate, with 215 cases, accounting for 44.61% of all reports. The subsequent year, 2022, recorded 162 reports, which represents 33.61% of the total. The year 2024 saw 97 reports, or 20.1%. Notably, only 2 reports were documented in 2009, while there was just one report for each year from 2010 to 2019. This annual reporting trend is illustrated in Table 2.

SL.NO	YEAR	NO OF EVENTS
1	2023	215
2	2022	162
3	2024	97
4	2009	2
5	2020	1
6	2019	1
7	2017	1
8	2014	1

Table 2: Adverse Events reported yearly on cardiac stents

In terms of patient demographics, the data indicated that 141 adverse events (61.30%) were reported among males, while females accounted for 89 events (38.70%), as depicted in Figure 1.

Figure 1: Gender analysis of adverse events associated with cardiac stents

Regarding the geographical distribution of reports, the United States emerged as the country with the highest incidence of adverse events, totaling 163 cases, which constitutes 33% of the overall reports. India followed closely with 158 reports, or 31.98%. Other countries reported varying numbers of events: Switzerland documented 56 cases (11.34%), Taiwan had 37 reports (7.49%), and Kazakhstan recorded 17 events (3.44%). Japan reported 12 cases, making up 2.43% of the total. Additionally, there were two reports each from Turks and Caicos, Spain, and Egypt. Notably, 17 reports did not specify the country of occurrence, as shown in Table 3.

SL.NO	COUNTRY	EVENTS
1	United states	163
2	India	158
3	Switzerland	56
4	Taiwan	37
5	South Korea	27
6	Japan	17
7	Brazil	5

8	Turks and Caicos Islands	2
9	Spain	2
10	Egypt	2
11	Tunisia	1
12	Thailand	1
13	Eswatini	1
14	Poland	1
15	New Zealand	1
16	Jamaica	1
17	Canada	1
18	Belgium	1
19	Not Available	17

Table 3: Country analysis of adverse events associated with cardiac stents

Analyzing the age distribution of the adverse events, it was noted that 71 cases were reported in the 71-80 age group, while 59 events were recorded in the 61-70 age group. This data indicates a higher prevalence of reported issues among older patients, who are likely to require additional medical care; Figure 2 illustrates a comparison of outcome parameters based on age in relation to the reported adverse events.

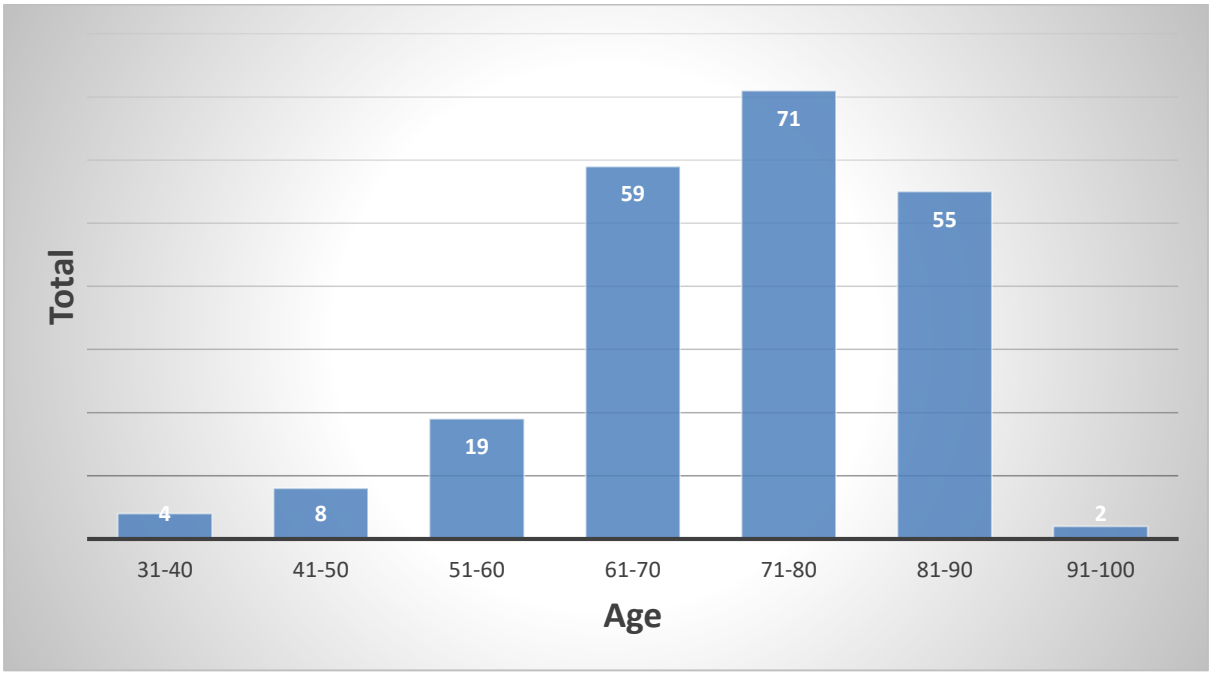

Figure 2: Age analysis of adverse events associated with cardiac stents

DISCUSSION

Adverse drug reactions (ADRs) associated with cardiac stents can include complications such as stent thrombosis, hypersensitivity reactions to the stent material, and bleeding related to antiplatelet therapy, all of which may significantly impact patient outcomes and require careful management. The study revealed a higher incidence of cases among older patients, indicating that this population may require additional medical care and closer monitoring.

Reports on device related malfunctions in existing literature are limited in scope. Two studies have been conducted on the adverse events caused by coronary stent placement were compared where both the studies stress on the role of imaging in stratifying risk. The study conducted by Sanket et al. discusses how Coronary Artery Calcium (CAC) imaging helps in identifying individuals at higher risk for coronary artery disease and guiding preventive measures [11].

The study conducted by Francesco et al. examines how imaging helps in stratifying risk in heart failure patients, influencing treatment decisions and prognosis. They also point out the potential of imaging to improve patient outcomes. By providing detailed insights into cardiovascular conditions, these imaging techniques enable more tailored and effective interventions, potentially leading to better management of disease and improved patient outcomes [12]. Both studies address the limitations of current imaging methods. The study conducted Sanket et al. mentions limitations such as the inability of CAC imaging to capture non-calcified plaque and its dependence on patient characteristics and the study conducted by Francesco et al. discusses limitations related to imaging modalities in heart failure, such as challenges in interpreting results and the need for further research to optimize imaging techniques and their applications. The common themes of these studies include the impact of imaging on clinical practice, its role in risk stratification, potential benefits for patient outcomes, limitations of current techniques, and the need for integration into clinical guidelines and further research[12-14].

However there are some key differences in the studies which include as follows : The study conducted Sanket et al. focuses on the role of coronary artery calcium (CAC) imaging specifically for assessing and managing atherosclerosis and coronary artery disease (CAD) and discusses on how CAC imaging can be used to refine cardiovascular risk assessment and guide preventive strategies, emphasizing its application in primary prevention and risk stratification whereas in contrast the study conducted by Francesco et al. concentrates on

various cardiac imaging techniques used to assess heart failure, including echocardiography, cardiac MRI, and nuclear imaging and highlights how these imaging modalities help in diagnosing heart failure, evaluating its severity, and guiding treatment decisions, with a broader focus on heart failure management rather than just CAD[15-17].

Gjin et al., conducted a study on the prognostic value of coronary artery calcium score in patients with stable coronary artery diseases that examines the prognostic significance of CAC scores in patients with stable coronary artery disease (CAD), focusing on how CAC scores can influence disease management and predict outcomes in this population. It addresses how CAC scores can influence treatment decisions and monitoring in patients with stable CAD. The discussion covers how CAC scores can affect treatment decisions in stable CAD patients, including potential changes to existing treatment plans or more intensive monitoring based on CAC results. It focuses on limitations in the context of stable CAD, such as how CAC scoring might interact with other prognostic factors and the need for research to refine CAC scoring applications for stable CAD patients [18].

In contrast Rafael et al. conducted a study on long-term prognostic value of coronary artery calcium score in patients with intermediate risk of cardiovascular disease which evaluates the prognostic value of coronary artery calcium (CAC) scores in patients at intermediate risk for cardiovascular disease, particularly how CAC scores impact long-term outcomes and management. It discusses how CAC scoring can be used to guide preventive measures and interventions in patients at intermediate risk. The discussion includes how CAC scoring might lead to earlier intervention in patients at intermediate risk, aiming to prevent the development of CAD through lifestyle changes or medication and it also highlights limitations related to the use of CAC scoring for intermediate-risk patients, such as its role in predicting long-term outcomes and integrating with other risk factors [19].

Similarly two studies on Coronary stents contributing to adverse cardiovascular events were compared. The study conducted by Barash et al. centres on perioperative care, anaesthesia techniques, and their impact on surgical outcomes. It examines the relationship between anaesthesia management and postoperative complications, offering insights into optimizing patient care during surgery. It also emphasised on improving anaesthesia practices to enhance patient safety and outcomes in the surgical setting[20].

In contrast the study conducted by Helmut et al. focuses on cardiovascular outcomes related to stent placement, particularly focusing on the effectiveness of stents, risks such as stent

thrombosis, and the long-term impact on cardiovascular health. It elaborates on the management of cardiovascular patients undergoing stent procedures, including the importance of monitoring for complications like thrombosis and the role of antiplatelet therapy. Two studies have been conducted on the adverse events caused by coronary stent placement in newer generation cardiovascular evolution. The study conducted by Suwaidi et al focuses on the clinical use of stents, primarily their effectiveness in reducing restenosis and the need for emergency coronary bypass surgery[21-22].

It emphasizes randomized trials and observational studies evaluating stents in diverse clinical situations. The discussion highlights the proven benefits of stenting over balloon angioplasty, but also addresses challenges like restenosis in complex lesions. The study conducted by borhani et al discusses the technological evolution of cardiovascular stents, focusing on advancements like drug-eluting stents (DES) and biodegradable scaffolds. It emphasizes material innovations to improve safety, reduce in-stent restenosis, and address long-term issues like thrombosis and hypersensitivity reactions caused by polymeric coatings. The study conducted by Suwaidi et al centers more on clinical outcomes and trial data related to stent effectiveness in real-world settings, while the study conducted by borhani et al dives deeper into the technological innovations and future developments of stent materials and designs, such as biodegradable polymers and drug-eluting mechanisms[23,24].

Two studies carried out by Yoshikawa et al. and Mieres et al. compare different generations of drug-eluting stents (DES) regarding adverse events and clinical outcomes. They discuss first-generation (DES-1) and second-generation (DES-2) stents and how their introduction changed the rates of complications such as stent thrombosis (ST) and target vessel revascularization (TVR). They focus on serious late adverse events such as stent thrombosis, spontaneous myocardial infarctions (MI), and death. They acknowledge that DES, despite advancements, still exhibit late-stage complications. Each of them uses randomized clinical trial (RCT) data to support their conclusions on the effectiveness and safety of different treatment options, including PCI (percutaneous coronary intervention) and coronary artery bypass graft (CABG) surgery. The study conducted by Mieres et al. has a more extensive focus on comparing DES with CABG, particularly stressing how CABG still has advantages in terms of long-term outcomes, especially regarding death and MI rates(n2). By contrast, the study carried out by Yoshikawa et al. concentrates more on comparing first- and second-generation DES without delving as deeply into CABG. It provides more detailed insights into the technical improvements in DES-2 designs (e.g., better polymers, reduction in stent

malposition) and how they have reduced adverse outcomes like stent thrombosis. This technical improvement is not as deeply explored in the first article, which sticks to the outcomes comparison between DES generations. In common both the studies share a common focus on drug-eluting stents and their complications, the study conducted by Mieres et al. takes a broader approach by comparing DES with CABG and discussing in greater detail the long-term issues specific to DES, like spontaneous MI and neo-atherosclerosis whereas the study conducted by Yoshikawa et al. focuses more narrowly on the comparison between different generations of DES and their stent-related adverse events[6,25].

In contrast another study carried out by Marei et al. provides a more molecular and bioengineering focus on how to induce endothelialisation of stents, especially in diabetic patients who face higher risks of thrombosis. It discusses innovative strategies like biofunctionalization of stents with coatings to enhance endothelial recovery, which could reduce in-stent thrombosis without the prolonged need for drug therapies. It highlights advances such as stents coated with CD34 antibodies to capture circulating endothelial progenitor cells, and biodegradable stents designed to naturally dissolve over time, minimizing the risk of late thrombosis[6,26].

The observations underscore the importance of robust post-marketing surveillance systems such as MAUDE in identifying potential safety signals that may not be fully captured during pre-market clinical trials. However, the interpretation of these data should be approached with caution due to inherent limitations of spontaneous reporting systems, including under-reporting, reporting bias, and incomplete clinical information. Despite these constraints, the study contributes valuable insights into device-related risks and reinforces the need for continuous monitoring, improved reporting practices, and clinician awareness to enhance patient safety outcomes.

CONCLUSION

It is crucial for healthcare providers to be thoroughly educated about the potential risks associated with these devices. Operators must receive comprehensive training to effectively address and manage any adverse events that may occur during or after the use of cardiac stents. It is essential that healthcare providers discuss the potential for such adverse events with patients prior to the procedure and obtain informed consent to mitigate medico-legal concerns. In the absence of additional strong evidence, the substantial volume of data

presented in this study will serve as a valuable reference point for understanding the adverse events linked to cardiac stents and guiding future clinical practice and research.

Conflicts of interest:

None of the authors had any financial or personal conflicts of interest.

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Data availability statement:

The data that support the findings of this study are available from the corresponding author, upon reasonable request.

Consent for publication

All authors reviewed the results and approved the final version of the manuscript.

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