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ANALYSIS OF ADVERSE EVENTS ASSOCIATED WITH RENAL STENTS: A REVIEW OF THE MAUDE DATABASE

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ABSTRACT

Background: The present study was conducted to determine the adverse events (AEs) associated with renal stents reported to the Food and Drug Administration manufacturer and user facility device experience (MAUDE) database. **Materials and methods:** The authors reviewed the renal stents related AEs reported to MAUDE from Jan 1, 2014, to Oct 30, 2024. Analyses of details collected are presented. **Results:** The MAUDE database reported 604 AEs related to renal stents. Of these, 79 were classified as "Adverse Event without Identified Device or Use Problem," and 68 involved "Device Dislodged or Dislocated." The highest incidence occurred in the 65-79 age group (47%), followed by 50-64 (20.9%) and 80+ (20%). More events were reported in females than males. Common patient issues included "No Consequences or Impact" (191) and "No Clinical Signs or Symptoms" (124). The U.S. reported the most events (207), followed by Switzerland (47). Outcomes showed 286 events required intervention, with 218 evaluated by the manufacturer, and most events were due to device malfunction (263) and injury (319). **Conclusion:** Renal stents pose risks to patient safety if not properly managed. MAUDE data highlights AEs, underscoring the need for further analysis. Until more studies emerge, operators must exercise caution, follow best practices, and raise awareness to enhance patient education and support informed decision-making during procedures.

KEYWORDS: MAUDE, Adverse events, renal stents.

INTRODUCTION

Medical devices are essential tools in modern healthcare, playing a vital role in diagnosing, preventing, monitoring, treating, and alleviating various medical conditions. These devices range from simple instruments like thermometers to advanced systems such as robotic surgical tools and artificial organs. The continuous advancement in medical technology has significantly improved patient care, surgical precision, and disease management.[1]

A medical device is any instrument, apparatus, machine, software, implant, reagent, or material used in medical settings to diagnose, treat, monitor, or prevent diseases and medical conditions. Unlike pharmaceutical drugs, medical devices exert their effects primarily through physical or mechanical means rather than biochemical action. Regulatory agencies such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and World Health Organization (WHO) play a crucial role in the classification and regulation of these devices to ensure their safety, efficacy, and performance before approval for clinical use.[2,3]

Renal artery stenosis (RAS) is a clinically significant condition characterized by the narrowing of one or both renal arteries, most commonly due to atherosclerosis or fibromuscular dysplasia. RAS is recognized as an

important cause of secondary hypertension and may result in ischemic nephropathy, progressive renal dysfunction, and cardiovascular complications if left untreated.[4] Prompt diagnosis and effective management are therefore essential to preserve renal function and reduce adverse cardiovascular outcomes.[5]

Renal artery stenting has emerged as a minimally invasive therapeutic intervention aimed at restoring renal blood flow and improving blood pressure control in patients with significant RAS. Compared with surgical revascularization, percutaneous renal artery stenting offers advantages such as shorter hospital stay, lower perioperative morbidity, and faster recovery.[6] Indications for renal artery stenting include resistant hypertension, declining renal function, recurrent flash pulmonary edema, bilateral renal artery stenosis, and stenosis affecting a solitary functioning kidney.[7]

Despite its therapeutic benefits, renal artery stenting is associated with several potential complications and adverse events (AEs). Reported complications include stent dislodgement, restenosis, thrombosis, embolization, arterial dissection, and renal artery rupture, all of which may compromise procedural success and negatively affect patient outcomes.[8,9] Procedural complications may also increase the risk of hospitalization, repeat interventions, and deterioration in renal function.[10]

To improve post-market surveillance of medical devices, the U.S. FDA established the Manufacturer and User Facility Device Experience (MAUDE) database, a publicly accessible repository containing reports of device-related adverse events submitted by manufacturers, healthcare professionals, and patients.[11] The MAUDE database serves as an important resource for identifying device-related safety concerns, evaluating real-world device performance, and detecting emerging trends associated with medical device complications.[12]

Although several studies have evaluated the clinical efficacy of renal artery stenting, there remains limited large-scale evidence specifically assessing AEs associated with renal artery stents in real-world clinical practice. Moreover, complications related to device malfunction and procedural failure continue to raise concerns regarding patient safety and long-term outcomes.[13,14] Therefore, the present study was conducted to systematically review AEs associated with renal artery stents reported in the FDA MAUDE database over a ten-year period, with the objective of identifying patterns, assessing safety concerns, and highlighting areas requiring further clinical attention and post-market surveillance.[15,16]

MATERIAL AND METHODS

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 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 AEs, versions provided by the manufacturers, and conclusions drawn from the reported incidents.

For the purposes of this study, AEs related to the use of renal stents, identified by their unique product code (NIN) for renal stents, were extracted from the MAUDE database for the period spanning from Jan 1, 2014, to Oct 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 AEs and the nature of reporting (voluntary/mandatory), as well as their applications.

This study employed a retrospective descriptive design to evaluate AEs associated with renal artery stents reported in the FDA's MAUDE database. The MAUDE database compiles mandatory and voluntary reports from manufacturers, importers, user facilities, and healthcare professionals, providing post-market surveillance data for medical devices used in the United States.

Descriptive statistics were used to summarize the characteristics of the AEs. Frequencies and percentages were calculated for categorical variables. The data were stratified by age group, sex, event type, and geographic region to identify patterns and trends. No inferential statistics or comparative testing were performed due to the observational nature of the study and limitations inherent in the MAUDE reporting system.

RESULTS

A total of 604 AEs associated with renal artery stents were identified from the MAUDE database during the study period. Among these, 79 reports were categorized as "Adverse Event without Identified Device or Use Problem," while 68 cases involved device dislodgement or dislocation as shown in Table 1. The majority of reported events were related to patient injury (319 cases, 52.8%) and device malfunction (263 cases, 43.5%).

Table 1: Device Problem.

Device Problem	Count
Adverse Event Without Identified Device or Use Problem (2993)	77
Device Dislodged or Dislocated (2923)	68
Failure to Advance (2524); Device Dislodged or Dislocated (2923)	31
Insufficient Information (3190)	10
Difficult to Advance (2920); Device Dislodged or Dislocated (2923)	9
Premature Separation (4045)	9
Difficult to Remove (1528)	8
Break (1069)	8
Material Deformation (2976)	7
Leak/Splash (1354)	7
Difficult to Remove (1528); Failure to Advance (2524); Device Dislodged or Dislocated (2923)	7
Activation Failure (3270)	7
Leak/Splash (1354)	7
Improper or Incorrect Procedure or Method (2017); Device Dislodged or Dislocated (2923)	7
Difficult to Remove (1528); Failure to Advance (2524); Material Deformation (2976)	6
Difficult to Remove (1528)	5
Detachment Of Device Component (1104)	5
Premature Separation (4045)	5
Material Separation (1562)	4
Material Separation (1562)	4
Migration (4003)	4
Difficult to Advance (2920)	4
Device Operates Differently Than Expected (2913)	4
Premature Activation (1484)	3
Occlusion Within Device (1423)	3
Difficult to Advance (2920); Device Dislodged or Dislocated (2923)	3
Detachment of Device or Device Component (2907)	3
Failure to Advance (2524)	3
Material Rupture (1546)	3
Activation, Positioning or Separation Problem (2906)	3
Device Slipped (1584)	3
Improper or Incorrect Procedure or Method (2017); Failure to Advance (2524); Device Dislodged or Dislocated (2923)	3
Difficult to Remove (1528); Failure to Advance (2524); Material Deformation (2976)	3
Material Rupture (1546)	3
Migration or Expulsion of Device (1395)	3
Improper or Incorrect Procedure or Method (2017); Device Dislodged or Dislocated (2923)	3
Difficult to Remove (1528); Failure to Advance (2524); Device Dislodged or Dislocated (2923)	3
Failure to Advance (2524)	3
Migration or Expulsion of Device (1395)	3
Deflation Problem (1149); Difficult to Remove (1528)	3
Unintended System Motion (1430)	3
Off-Label Use (1494); Device Dislodged or Dislocated (2923)	2
Fracture (1260); Migration (4003)	2
Difficult or Delayed Activation (2577)	2
Difficult or Delayed Positioning (1157)	2
Activation Failure (3270)	2
Off-Label Use (1494)	2
Material Rupture (1546); Activation Failure (3270)	2
Off-Label Use (1494); Failure to Advance (2524); Device Dislodged or Dislocated (2923)	2
Obstruction of Flow (2423)	2

Common device malfunctions included deployment failure, incomplete stent expansion, structural fracture, and material degradation. These complications frequently occurred during the procedure and, in certain cases, resulted in aborted interventions or the need for device retrieval and replacement. Reported patient injuries ranged from minor vascular irritation to severe complications such as renal artery rupture, thrombosis,

embolism, and acute kidney injury, with some cases requiring prolonged hospitalization or additional surgical intervention.

Analysis of patient demographics demonstrated that the highest proportion of AEs occurred in patients aged 65–79 years (47%), followed by those aged 50–64 years (20.9%) and ≥80 years (20%). Patients younger than 50 years accounted for approximately 12.1% of reported cases as shown in Figure 1. More AEs were reported in females than in males as shown in Figure 2. These findings are consistent with the increased prevalence of atherosclerotic RAS and higher procedural utilization among older adults.

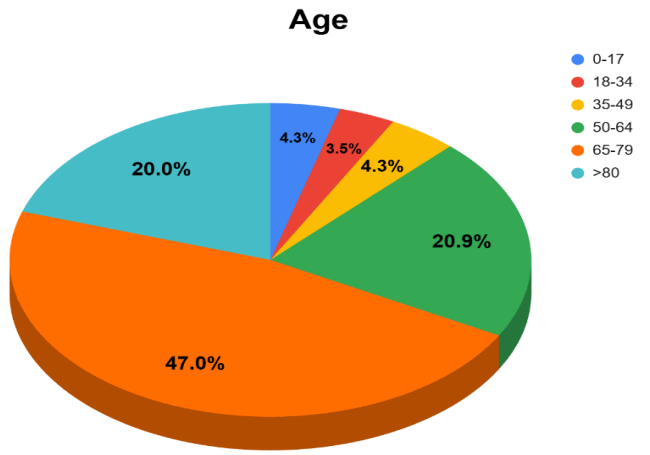

Figure 1: Age Demographics.

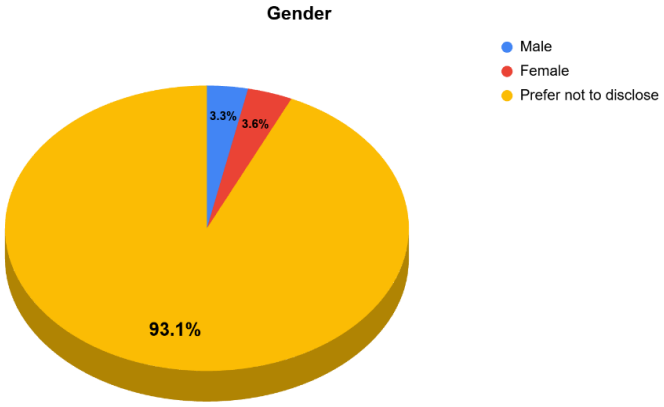

Figure 2: Gender Demographics.

Regarding patient outcomes, 191 events (31.6%) were reported as having no clinical consequences or impact, while 124 cases (20.5%) documented no clinical signs or symptoms despite the occurrence of a device-related issue. However, 286 events (47.4%) required additional medical or surgical intervention, including re-stenting, thrombolysis, or open surgical repair, indicating a substantial burden of morbidity associated with renal stent-related complications as shown in Table 2.

Table 2: Patient Problems.

Patient Problem	Count
No Consequences Or Impact To Patient (2199)	191
No Clinical Signs, Symptoms or Conditions (4582)	124
No Known Impact Or Consequence To Patient (2692)	32
Hemorrhage/Bleeding (1888)	31
Occlusion (1984)	26
No Code Available (3191)	26
Foreign Body In Patient (2687)	24
No Patient Involvement (2645)	23
Thrombosis (2100)	21
No Information (3190)	21

Death (1802)	20
Ischemia (1942)	19
Stenosis (2263)	19
Vascular Dissection (3160)	15
Hematoma (1884)	12
Device Embedded In Tissue or Plaque (3165)	12
Pain (1994)	11
Renal Failure (2041)	10
Perforation (2001)	9
Rupture (2208)	8
Obstruction/Occlusion (2422)	7
Insufficient Information (4580)	7
Vessel Or Plaque, Device Embedded In (1204)	7
Pseudoaneurysm (2605)	7
Embolism (1829)	6
Blood Loss (2597)	6
Intimal Dissection (1333)	5
Embolism/Embolus (4438)	4
Collapse (2416)	4
Aneurysm (1708)	4
Calcium Deposits/Calcification (1758)	3
High Blood Pressure/ Hypertension (1908)	3
Arrhythmia (1721)	3
Impaired Healing (2378)	3
Infarction, Cerebral (1771)	3
Thrombosis/Thrombus (4440)	3
Failure of Implant (1924)	2
Sepsis (2067)	2
Respiratory Failure (2484)	2
Low Blood Pressure/ Hypotension (1914)	2
Hypersensitivity/Allergic reaction (1907)	2
Nausea (1970)	2
Multiple Organ Failure (3261)	2
Bacterial Infection (1735)	2
Stroke/CVA (1770)	2
Myocardial Infarction (1969)	2
Pneumonia (2011)	2
Unspecified Infection (1930)	2
Fever (1858)	1
Hemorrhage, Cerebral (1889)	1
Claudication (2550)	1
Embolus (1830)	1
Material Puncture/Hole (1504)	1
Cardiac Arrest (1762)	1
Malposition of Device (2616)	1
Discomfort (2330)	1
Appropriate Clinical Signs, Symptoms, Conditions Term / Code Not Available (4581)	1
Intracranial Hemorrhage (1891)	1
Rash (2033)	1
Adult Respiratory Distress Syndrome (1696)	1
Angina (1710)	1
Dizziness (2194)	1
Organ Dehiscence (2502)	1
Swelling (2091)	1
Spinal Cord Injury (2432)	1
Thrombus (2101)	1
No Code Available (3191	1

Pulmonary Embolism (1498)	1
Weakness (2145)	1
Vasoconstriction (2126)	1
Hematuria (2558)	1
Chest Pain (1776)	1
Injury (2348)	1
Wound Dehiscence (1154)	1
No Consequences Or Impact To Patient (2199	1
Fistula (1862)	1
Pneumothorax (2012)	1
Vomiting (2144)	1
Cardiogenic Shock (2262)	1
Paralysis (1997)	1
Inflammation (1932)	1
Test Result (2695)	1
Bradycardia (1751)	1
No Clinical Signs, Symptoms or Conditions (458	1
Extravasation (1842)	1
Respiratory Tract Infection (2420)	1
Paraplegia (2448)	1
Renal Disease, End Stage (2039)	1
Unspecified Vascular Problem (4441)	1

Geographically, the United States reported the highest number of adverse events (207 cases, 34.3%), followed by Switzerland (47 cases, 7.8%) as shown in Figure 3. Additional reports originated from Germany, the United Kingdom, Canada, Japan, and other countries, reflecting the widespread global utilization of renal artery stents and the importance of international post-market surveillance system.

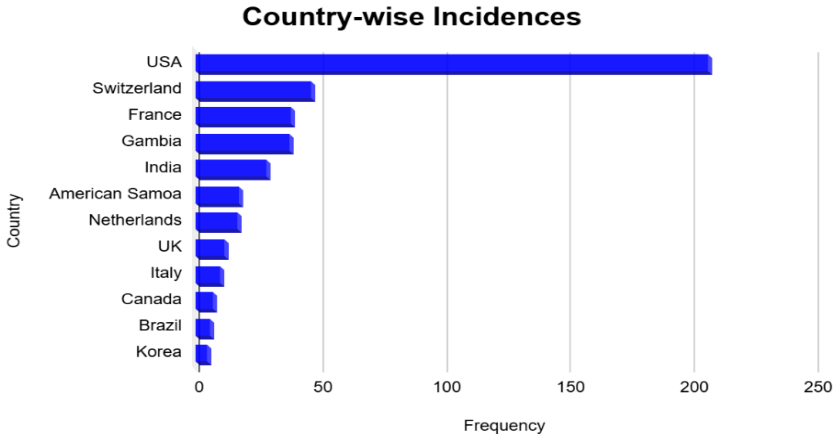

Figure 3: Country-wise Incidences.

Technical analyses of returned devices revealed issues such as mechanical fatigue, compromised radial strength, and balloon failure during deployment. Nevertheless, several investigations failed to establish a definitive root cause, highlighting the complexity of reproducing in vivo procedural conditions in laboratory settings.

An overall increase in AE reporting was observed over the ten-year study period, with a notable rise during the later years. This trend may be attributed to improved reporting practices, increased awareness regarding device surveillance, and the introduction of newer-generation stent systems with evolving safety profiles. Device malfunctions were more frequently associated with newer or modified product lines, suggesting the possibility of early post-market learning curves and the need for continued safety monitoring.

DISCUSSION

This study provides a comprehensive overview of AEs associated with renal artery stents reported in the FDA MAUDE database over a ten-year period. The findings demonstrate that although renal artery stenting remains an important minimally invasive intervention for the management of RAS, clinically significant complications continue to occur in real-world settings. The predominance of patient injuries and device malfunctions observed in this review highlights the continued need for

vigilant post-market surveillance and optimization of procedural practices.[13,16]

In the present analysis, the majority of AEs were related to either patient injury or device malfunction. Commonly reported device-related complications included deployment failure, incomplete stent expansion, structural defects, and device dislodgement. Similar findings have been reported in previous studies evaluating renal artery interventions, where procedural complications such as thrombosis, embolization, arterial dissection, and restenosis significantly affected patient outcomes.[8,10] These complications may compromise renal perfusion and lead to additional therapeutic interventions or prolonged hospitalization.

Device dislodgement and migration were among the frequently reported complications in the MAUDE database. Earlier studies have suggested that factors such as vessel tortuosity, heavily calcified lesions, improper device sizing, and operator-related technical difficulties may contribute to stent migration or embolization.[9] Such complications often require immediate retrieval procedures or repeat interventions, thereby increasing procedural morbidity and healthcare costs. Careful lesion assessment, accurate stent placement, and improved operator training may therefore help reduce these complications.

The highest proportion of AEs occurred among patients aged 65–79 years, which is consistent with the epidemiology of atherosclerotic RAS.[4] Elderly patients often present with multiple comorbidities including hypertension, diabetes mellitus, cardiovascular disease, and chronic kidney disease, all of which may increase procedural complexity and susceptibility to adverse outcomes.[7] Additionally, age-related vascular calcification and reduced arterial elasticity may contribute to procedural difficulties and increase the likelihood of vascular injury during stent placement.[11]

A substantial proportion of AEs required additional medical or surgical intervention, indicating the potential clinical significance of renal stent-related complications. Previous studies have demonstrated that severe complications following renal artery stenting may lead to acute kidney injury, renal infarction, prolonged hospitalization, or even mortality in high-risk patients.[5,13] The findings of the present study emphasize the importance of appropriate patient selection, procedural planning, and close post-procedural monitoring to minimize complications and improve clinical outcomes.

The United States reported the highest number of AEs in the MAUDE database, which may reflect the widespread utilization of renal artery stenting procedures as well as stringent FDA reporting requirements.[11] Variability in international reporting practices may partly explain the lower number of reports from other countries. Underreporting remains a recognized limitation of spontaneous reporting systems such as MAUDE and may contribute to underestimation of the true incidence of AEs associated with renal artery stents.[15]

An increase in AE reporting was observed during the later years of the study period. This trend may be attributed to increased awareness regarding device surveillance, greater emphasis on mandatory reporting systems, and the introduction of newer-generation stent technologies with evolving safety profiles. Similar reporting trends have been observed in studies involving other cardiovascular devices and post-market surveillance systems.[16-21]

Despite its strengths, the present study has several limitations. The MAUDE database relies primarily on passive surveillance and voluntary reporting, which may result in incomplete data, duplicate reports, reporting bias, and inconsistent clinical details.[15] Furthermore, the database does not establish a direct causal relationship between the device and the reported AE. Information regarding patient comorbidities, operator expertise, procedural techniques, and long-term follow-up outcomes is often unavailable. Therefore, the true incidence and severity of renal stent-related complications cannot be accurately determined solely from MAUDE data. Nonetheless, the database remains an important tool for identifying potential safety signals and guiding future research.[21-22]

Further prospective studies and multicenter registries are required to better evaluate the long-term safety and effectiveness of renal artery stents. Greater emphasis should also be placed on device innovation, operator training, procedural standardization, and careful patient selection to minimize adverse outcomes. Integration of real-world post-market surveillance data with clinical registries may further enhance understanding of device-related risks and support evidence-based clinical decision-making.

CONCLUSION

Renal artery stents, while beneficial in treating stenosis, present notable risks that must be carefully managed. This review of MAUDE data highlights the prevalence of device malfunctions, dislodgement, and patient injuries, with a significant impact on elderly populations and females. Increased awareness, improved procedural techniques, and enhanced patient education are crucial in mitigating these risks. Until further studies provide additional insights, healthcare providers must exercise vigilance, adhere to best practices, and ensure informed decision-making for optimal patient outcomes. It is essential that healthcare providers discuss the potential for such AEs 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 renal stents and guiding future clinical practice and research.

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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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