Evaluating Coronary Drug-Eluting Stent Complications: A Manufacturer and User Facility Device Experience Database Analysis

Kakani Subhash[1], Pramod Kumar A[2], Deeksha.S[2], Ajoshson John[2], Jeesa George[2], Ritanya.S[2], S Shreevathsa[2]

[1]Independent Researcher

[2]Department of Pharmacy Practice, Faculty of Pharmacy, M. S. Ramaiah University of Applied Sciences, Bengaluru-560054, Karnataka, India

Corresponding Author:

Ms Jeesa George

Assistant Professor,

Department of Pharmacy Practice,

M S Ramaiah University of applied sciences,

Bangalore, 560054

Abstract

Introduction: A coronary drug-eluting stent (DES) is a small, metal mesh tube that's coated with medicine to help prevent blood clots from forming in an artery. DESs are used to treat coronary artery disease by reopening and maintaining narrowed arteries. The objective of this study is to describe adverse events related to DES.

Methods: The authors reviewed the coronary drug eluting stents related adverse events (AEs) reported to MAUDE from Jan 1, 2020, to Nov 1, 2024.

Results: A review of 2,500 cases from the MAUDE database (January 1, 2020 to November 1, 2024) identified key trends in device-related and patient-related adverse events. Of the device issues, 776 were classified as "Adverse Event without Identified Device or Use Problem," and 677 involved "Material Deformation." Additionally, 1,325 patient-related reports cited "No Clinical Signs, Symptoms, or Conditions," while 310 were linked to "Vascular Dissection." The SYNERGY brand accounted for the highest number of incidents

(345). Gender distribution revealed 735 male and 238 female reports, with the 61-70 age group having the most adverse events (310), followed by the 71-80 age group (221). Geographically, 468 events were reported in the United States and 441 in India. A total of 2,123 devices were operated by healthcare professionals.

Conclusion: The study highlights the prevalence of adverse events associated with coronary drug-eluting stents, emphasizing the need for on-going surveillance and improved safety measures. The findings highlight the need for further investigation to improve device performance, patient outcomes, and reduce risks.

Keywords: MAUDE, Coronary drug eluting stents, adverse events

Introduction

Medical devices are indispensable components of modern healthcare, serving critical functions in diagnosing, preventing, monitoring, and treating diseases [1]. Their range spans from basic tools like thermometers to advanced technologies such as robotic surgical systems and implantable devices[2]. A medical device is defined as any instrument, apparatus, machine, software, implant, reagent, or material intended for medical use in diagnosis, treatment, monitoring, or prevention of disease [1].

Coronary artery disease (CAD) continues to be a major global cause of morbidity and mortality [3]. The introduction of coronary drug-eluting stents (DESs) has transformed CAD management by reducing restenosis and improving long-term outcomes [4,5]. DESs are metallic scaffolds coated with antiproliferative drugs that inhibit neointimal hyperplasia, helping prevent re-narrowing of the artery [6,7]. Despite their proven benefits, DESs are associated with potential risks, including thrombosis, mechanical failure, and deployment-related complications [8,9].

The Manufacturer and User Facility Device Experience (MAUDE) database, maintained by the U.S. Food and Drug Administration, serves as a key post-market surveillance tool, capturing both mandatory and voluntary reports of device-related adverse events . Analyzing these reports provides real-world insights into device performance, patient safety issues, and emerging complications that may not appear during clinical trials [1]. This study aims to

systematically analyze adverse events associated with coronary DESs reported to the MAUDE database between January 1, 2020, and November 1, 2024, to identify trends, highlight potential safety concerns, and support future improvements in clinical practice and device design.

Despite the widespread use of DESs in the management of coronary artery disease, concerns regarding device-related complications such as stent thrombosis, restenosis, and delayed endothelial healing persist. Post-marketing surveillance plays a critical role in identifying rare and long-term adverse events that may not be captured during pre-approval clinical trials. The Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database serves as a valuable repository for real-world safety data on medical devices. However, there remains a need for systematic analysis of reported adverse events associated with DES to better understand their frequency, nature, and clinical implications, thereby contributing to improved patient safety and regulatory decision-making. The present study aims to evaluate the adverse events associated with coronary drug-eluting stents reported in the MAUDE database, with a focus on characterizing the types, outcomes, and potential trends of these events to enhance understanding of their safety profile in real-world clinical practice.

Methods

A retrospective analysis was performed using the MAUDE database to identify all reports related to coronary drug-eluting stents (DESs) submitted between January 1, 2020, and November 1, 2024. The search strategy incorporated device product codes (NIQ) along with coronary DES-specific keywords to ensure comprehensive retrieval of relevant cases. Each retrieved report was systematically reviewed and categorized according to the type of adverse event—classified as either device-related or patient-related—along with manufacturer brand, patient demographic details such as age and gender, geographic location of the event, and the occupation of the reporter, including whether the report came from a healthcare professional. Descriptive statistics were applied to summarize the frequency, characteristics, and distribution of reported events, and trends were evaluated where data permitted, particularly across different DES brands and patient age groups.

Results

A total of 2,500 adverse event reports involving coronary drug-eluting stents (DESs) were extracted from the MAUDE database for the study period, revealing a broad spectrum of device- and patient-related concerns. Among device-related adverse events, the most frequently reported category was “Adverse Event without Identified Device or Use Problem,” accounting for 776 cases (31%), indicating situations where no clear device malfunction or user error was established despite the occurrence of an adverse clinical outcome. This was followed by “Material Deformation” with 677 reports (27%), which typically involved stent distortion due to mechanical stress during deployment or after implantation Table 1.

Sl.No	Device Problem	Total number of Problem
1	Adverse Event Without Identified Device or Use Problem (2993)	776
2	Material Deformation (2976)	677
3	Failure to Advance (2524)	542
4	Device Dislodged or Dislocated (2923)	358
5	Difficult to Remove (1528)	179
6	Break (1069)	127
7	Difficult to Advance (2920)	72
8	Positioning Problem (3009)	64
9	Activation Failure (3270)	46
10	Improper or Incorrect Procedure or Method (2017)	46
11	Difficult to Advance	45
12	Fracture (1260)	40
13	Difficult to Remove	40
14	Material Rupture (1546)	38
15	Break	35
16	Activation, Positioning or Separation Problem (2906)	29
17	Material Separation (1562)	28
18	Device Damaged by Another Device (2915)	28
19	Inflation Problem (1310)	24
20	Leak/Splash (1354)	23
21	Detachment of Device or Device Component (2907)	21
22	Entrapment of Device (1212)	21
23	Deformation Due to Compressive Stress (2889)	16
24	Inflation Problem	15
25	Material Separation	14
26	Activation Failure	14
27	Obstruction of Flow (2423)	13
28	Failure to Deflate (4060)	12

29	Device Damaged by Another Device	12
30	Migration or Expulsion of Device (1395)	11
31	Burst Container or Vessel (1074)	11
32	Material Split, Cut or Torn (4008)	11
33	Deflation Problem (1149)	11
34	Positioning Failure (1158)	10
35	Improper or Incorrect Procedure or Method	10
36	Detachment of Device or Device Component	9
37	Stretched (1601)	9
38	Device-Device Incompatibility (2919)	9
39	Material Integrity Problem (2978)	9
40	Entrapment of Device	7
41	Migration (4003)	7
42	Leak/Splash	7
43	Deflation Problem	7
44	Difficult to Insert (1316)	6
45	Fracture	6
46	Positioning Failure	6
47	Use of Device Problem (1670)	6
48	Activation, Positioning or Separation Problem	6
49	Premature Activation (1484)	6
50	Stretched	5
51	Product Quality Problem (1506)	5
52	Defective Device (2588)	5
53	Difficult or Delayed Positioning (1157)	5
54	Contamination (1120)	4
55	Material Rupture	4
56	Fluid/Blood Leak (1250)	4
57	Patient Device Interaction Problem (4001)	4
58	Device-Device Incompatibility	4
59	Patient-Device Incompatibility (2682)	4
60	Contamination /Decontamination Problem (2895)	3
61	Device Contamination with Chemical or Other Material (2944)	3
62	Deformation Due to Compressive Stress	3
63	Difficult or Delayed Activation (2577)	3
64	Use of Device Problem	3
65	Obstruction of Flow	3
66	Physical Resistance/Sticking	2
67	Difficult to Insert	2
68	Positioning Problem	2
69	Product Quality Problem	2
70	Material Integrity Problem	2
71	Physical Resistance/Sticking (4012)	2
72	Material Too Soft/Flexible (4007)	2

73	Material Deformation (2976	2
74	Mechanical Problem (1384)	2
75	Loose or Intermittent Connection (1371)	2
76	Off-Label Use (1494)	2
77	Material Puncture/Hole (1504)	2
78	Packaging Problem (3007)	2
79	Malposition of Device (2616)	2
80	Wrong Label (4073)	2
81	Device Markings/Labelling Problem (2911)	2
82	No Apparent Adverse Event (3189)	2
83	Material Puncture/Hole	1
84	Material Twisted/Bent (2981)	1
85	Human-Device Interface Problem (2949)	1
86	Therapeutic or Diagnostic Output Failure	1
87	Defective Component	1
88	Failure to Fold (1255)	1
89	Patient Device Interaction Problem	1
90	Premature Separation	1
91	Malposition of Device	1
92	Unintended System Motion	1
93	Device Contaminated During Manufacture or Shipping (2969)	1
94	Component Missing	1
95	Migration	1
96	aterial Deformation (2976)	1
97	Difficult or Delayed Positioning	1
98	Loose or Intermittent Connection	1
99	Premature Activation	1
100	Off-Label Use	1
101	Material Twisted/Bent	1
102	Tear, Rip or Hole in Device Packaging (2385)	1
103	Adverse Event Without Identified Device or+B348:C348 Use Problem (2993)	1
104	Device Problem	1
105	Activation Problem (4042)	1
106	Component Misassembled (4004)	1
107	Delivered as Unsterile Product (1421)	1
108	Material	1
109	Material Frayed (1262)	1
110	Unintended Movement (3026)	1
111	Migration or Expulsion of Device	1
112	Unsealed Device Packaging (1444)	1
113	Peeled/Delaminated (1454)	1
114	Mechanical Problem	1
115	Material Split, Cut or Torn	1

116	Difficult to Open or Remove Packaging Material (2922)	1
117	Positioning Problem (3009	1
118	Insufficient Information (3190)	1
119	Burst Container or Vessel	1
120	Difficult or Delayed Activation	1

Table 1: Device problems associated with coronary drug stents

Patient-related adverse events were dominated by the category "No Clinical Signs, Symptoms, or Conditions," comprising 1,325 cases (53%), suggesting that many reports documented adverse events that did not translate into observable clinical consequences. In contrast, more serious complications such as vascular dissection were reported in 310 cases (12%), highlighting an important risk associated with coronary interventions Table 2.

Sl.No	**Patient Problem**	**Total Number of Problems**
1	No Clinical Signs, Symptoms or Conditions (4582)	1325
2	Vascular Dissection (3160)	310
3	No Consequences Or Impact To Patient	298
4	Insufficient Information (4580)	139
5	Thrombosis/Thrombus (4440)	88
6	Angina (1710)	85
7	Myocardial Infarction (1969)	72
8	Restenosis (4576)	45
9	Device Embedded In Tissue or Plaque (3165)	38
10	Obstruction/Occlusion (2422)	36
11	Stenosis (2263)	36
12	Vascular Dissection	32
13	Ischemia (1942)	32
14	Cardiac Arrest (1762)	29
15	Intimal Dissection	27
16	Insufficient Information	25
17	Chest Pain (1776)	25
18	Foreign Body In Patient (2687)	23
19	Arteriosclerosis/ Atherosclerosis (4437)	22
20	Stroke/CVA (1770)	20
21	No Known Impact Or Consequence To Patient	20
22	Myocardial Infarction	18
23	Angina	17
24	Hemorrhage/Bleeding (1888)	15
25	Arrhythmia (1721)	13

26	No Patient Involvement	13
27	Non specific EKG/ECG Changes (1817)	12
28	Unspecified Tissue Injury	12
29	Perforation of Vessels (2135)	12
30	Heart Failure/Congestive Heart Failure (4446)	11
31	Death	11
32	Dyspnea (1816)	10
33	Obstruction/Occlusion	9
34	Pain (1994)	9
35	Thrombosis/Thrombus	8
36	Stenosis	7
37	Ventricular Fibrillation (2130)	7
38	Unspecified Heart Problem (4454)	7
39	Atrial Fibrillation (1729)	6
40	Cardiac Enzyme Elevation (1838)	6
41	Embolism/Embolus (4438)	6
42	Hemorrhage/Bleeding	6
43	Tachycardia (2095)	6
44	Low Blood Pressure/ Hypotension (1914)	6
45	High Blood Pressure/ Hypertension	6
46	Ventilator Dependent (2395)	5
47	Bradycardia (1751)	5
48		5
49	High Blood Pressure/ Hypertension (1908)	5
50	Cardiac Arrest	5
51	Cardiogenic Shock (2262)	5
52	Foreign Body In Patient	5
53	Perforation	4
54	Discomfort (2330)	4
55	Cardiac Arrest, No Clinical Signs, Symptoms or Conditions	4
56	Hematoma (1884)	4
57	Rupture (2208)	4
58	Hypersensitivity/Allergic reaction (1907)	4
59	Swelling/ Edema (4577)	4
60	Pericardial Effusion (3271)	4
61	Pneumonia	4
62	Cardiac Tamponade (2226)	3
63	Rash (2033)	3
64	Reocclusion	3
65	Perforation (2001)	3
66	Pulmonary Edema (2020)	3
67	Aneurysm (1708)	2
68	Device Embedded In Tissue or Plaque	2
69	Heart Block (4444)	2

70	Non specific EKG/ECG Changes	2
71	Low Blood Pressure/ Hypotension	2
72	Chest Pain	2
73	Hemorrhagic Stroke (4417)	2
74	Local Reaction (2035)	2
75	No Code Available	2
76	Headache (1880)	2
77	Thrombosis	2
78	Unspecified Eye / Vision Problem (4471)	2
79	Complaint, Ill-Defined	2
80	Atherosclerosis	2
81	Heart Failure	2
82	Diaphoresis (2452)	2
83	Failure of Implant (1924)	2
84	Hematoma	1
85	Transient Ischemic Attack	1
86	Insufficient information	1
87	Local Reaction	1
88	Bradycardia	1
89	Atrial Fibrillation	1
90	Stroke/CVA	1
91	No Information	1
92	Patient Problem	1
93	Pericardial Effusion	1
94	Cardiomyopathy	1
95	Appropriate Clinical Signs, Symptoms, Conditions Term / Code Not Available	1
96	Arteriosclerosis/ Atherosclerosis	1
97	Injury	1
98	Vessel Or Plaque, Device Embedded In	1
99	Unspecified Tissue Injury (4559)	1
100	nsufficient Information	1
101	Unintended Radiation Exposure (4565)	1
102	Dizziness (2194)	1
103	Vasoconstriction (2126)	1
104	Cardiomyopathy (1764)	1
105	Syncope/Fainting (4411)	1
106	Ischemic Heart Disease (2493)	1
107	Ischemia Stroke (4418)	1
108	Hypoxia (1918)	1
109	Hemoptysis (1887)	1
110	No Clinical Signs, Symptoms or Conditions (4582	1
111	Liver Damage/Dysfunction (1954)	1
112	Shock (2072)	1
113	Prolapse (2475)	1

114	Unspecified Respiratory Problem (4464)	1
115	Movement Disorder (4412)	1
116	No Clinical Signs, Symptoms or Conditions (4582)Event Date 06/21/2023	1
117	Ischemia	1
118	Sepsis (2067)	1
119	Cancer (3262)	1
120	Low Cardiac Output (2501)	1
121	Dysphagia/ Odynophagia (1815)	1
122	Fistula (1862)	1
123	Restenosis (4576)Event Date 02/01/2019	1
124	Fever (1858)	1
125	Embolism/Embolus(4438)	1
126	Restenosis	1
127	Angina, Stenosis	1
128	Aneurysm	1
129	Material Deformation (2976)	1
130	Atrial Flutter (1730)	1
131	no Clinical Signs, Symptoms or Conditions	1
132	Ventricular Fibrillation	1
	Total	3129

Table 2: Patient problems associated with coronary drug stents

Manufacturer-specific analysis showed that the Synergy stent system accounted for the highest number of adverse event submissions, totaling 345 reports Table 3.

Sl.No	**Brand Name**	**Total no of Problems**
1	SYNERGY	345
2	SYNERGY XD	302
3	RESOLUTE ONYX RX	209
4	XIENCE SKYPOINT DRUG ELUTING CORONARY STENT DELIVERY SYSTEM	194
5	PROMUS PREMIER	160
6	RESOLUTE INTEGRITY RX	122
7	ONYX FRONTIER	103
8	XIENCE SIERRA EVEROLIMUS ELUTING CORONARY STENT SYSTEM	88
9	PROMUS ELITE	83
10	XIENCE ALPINE EVEROLIMUS ELUTING CORONARY STENT SYSTEM	75
11	XIENCE XPEDITION EVEROLIMUS ELUTING CORONARY STENT SYSTEM	71
12	PROMUS PREMIER SELECT	67

13	PROMUS ELEMENT PLUS	66
14	XIENCE XPEDITION 48 EVEROLIMUS ELUTING CORONARY STENT SYSTEM	54
15	XIENCE PRIME EVEROLIMUS ELUTING CORONARY STENT SYSTEM	51
16	SYNERGY MEGATRON	45
17	XIENCE SIERRAÂ¿	35
18	XIENCE SKYPOINTÂ¿	30
19	XIENCE XPEDITION	24
20	XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	23
21	XIENCE ALPINE	22
22	ONYX TRUCOR	16
23	XIENCE V EVEROLIMUS ELUTING CORONARY STENT SYSTEM	13
24	ENDEAVOR RESOLUTE RX	8
25	XIENCE PROA EVEROLIMUS ELUTING CORONARY STENT SYSTEM	8
26	ENDEAVOR RX	8
27	ELUNIR RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	6
28	XIENCE SIERRA	6
29	ORSIRO 3.5/40	6
30	XIENCE EVEROLIMUS ELUTING CORONARY STENT SYSTEM	6
31	XIENCE SKYPOINT	5
32	ENDEAVOR SPRINT RX	5
33	ORSIRO 3.5/30	5
34	XIENCE PROS EVEROLIMUS ELUTING CORONARY STENT SYSTEM	5
35	ORSIRO MISSION 2.75/22	4
36	ORSIRO 3.0/26	4
37	ORSIRO 2.5/40	4
38	ORSIRO MISSION 2.5/15	4
39	ORSIRO 3.0/18	4
40	ORSIRO MISSION (US) 3.5/15	4
41	ORSIRO MISSION 3.0/22	4
42	ORSIRO 3.0/35	4
43	ORSIRO 2.5/22	4
44	SYNERGYÂ¿ XD	4
45	ORSIRO 4.0/22	3
46	RESOLUTE ONYX OTW	3
47	ORSIRO 2.5/30	3
48	ORSIRO 2.25/18	3
49	ORSIRO MISSION 3.0/26	3
50	ORSIRO MISSION 2.5/22	3

51	ORSIRO 3.0/40	3
52	ORSIRO 2.25/35	3
53	ORSIRO MISSION 3.0/15	3
54	ORSIRO 3.0/22	3
55	ORSIRO 2.75/30	3
56	ORSIRO 3.5/15	3
57	ORSIRO 2.25/13	3
58	ORSIRO MISSION 2.25/40	3
59	ORSIRO MISSION 3.0/30	3
60	ORSIRO 2.75/35	2
61	ORSIRO MISSION 2.5/30	2
62	XIENCE PRIME SV EVEROLIMUS ELUTING CORONARY STENT SYSTEM	2
63	ORSIRO 2.25/22	2
64	ORSIRO 2.25/26	2
65	ORSIRO MISSION	2
66	SYNERGY XD CORONARY STENT SYSTEM	2
67	ORSIRO 4.0/30	2
68	ORSIRO 2.25/30	2
69	ORSIRO MISSION (US) 2.75/40	2
70	PULSAR-18 6/60/135	2
71	ONYX FRONTIER 4.0 X 34 MM STENT	2
72	ORSIRO 2.25/15	2
73	ION	2
74	ORSIRO 2.5/15	2
75	ORSIRO MISSION 3.5/35	2
76	PROMUS ELEMENT	2
77	ORSIRO 2.75/18	2
78	SYNSIRO PRO 2.5/22	2
79	ORSIRO 2.5/18	2
80	ORSIRO MISSION 2.75/13	2
81	ORSIRO MISSION (US) 2.5/40	2
82	RESOLUTE ONYX	2
83	SYNSIRO PRO 2.75/18	2
84	ORSIRO 3.5/18	2
85	ONYX TRUSTAR	2
86	ORSIRO 4.0/26	2
87	ORSIRO MISSION 2.5/18	2
88	XIENCE PRO 48 EVEROLIMUS ELUTING CORONARY STENT SYSTEM	2
89	ELUNIRÂ¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	2
90	CORONARY DRUG-ELUTING STENT	2
91	RX XPEDITION EVEROLIMUS ELUTING CORONARY STENT SYSTEM	2

92	ORSIRO MISSION 2.25/18	2
93	ORSIRO 3.5/22	1
94	ORSIRO (US) 3.0/40	1
95	ORSIRO MISSION 3.0/35	1
96	BOSTON SCIENTIFIC SYNERGY	1
97	EVEROLIMUS ELUTING PLATINUM CORONARY STENT SYSTEM	1
98	ORSIRO (US) 2.75/40	1
99	ORSIRO 2.5/35	1
100	ORSIRO 3.5/9	1
101	SYNERGY XD MONORAIL CORONARY STENT SYSTEM	1
102	XIENCE SKYPOINT EVEROLIMUS ELUTING CORONARY STENT SYSTEM	1
103	ORSIRO MISSION 2.25/15	1
104	ORSIRO MISSION 2.75/18	1
105	XIENCE XPEDITION EVEROLIMUS ELUTING CORONARY STENT SYSTEM	1
106	ORSIRO MISSION (US) 2.25/13	1
107	ORSIRO MISSION (US) 3.5/18	1
108	ORSIRO 4.0/9	1
109	XIENCE PRO EVEROLIMUS ELUTING CORONARY STENT SYSTEM	1
110	RX XPEDITION	1
111	ORSIRO (US) 4.0/22	1
112	ORSIRO 3.0/13	1
113	SYNSIRO 3.0/22	1
114	PPROMUS PREMIER SELECT	1
115	ORSIRO MISSION 3.5/18	1
116	Brand Name	1
117	ONYX FRONTIERÂ¿	1
118	XIENCE SKYPOINT XIENCE DRUG ELUTING CORONARY STENT	1
119	BLUE/AVIATOR/PLUS 6X15/142P PK	1
120	MEDTRONIC RESOLUTE ONYX DES	1
121	ORSIRO MISSION (US) 4.0/15	1
122	ORSIRO (US) 2.5/13	1
123	ORSIRO MISSION 3.5/30	1
124	ORSIRO MISSION 3.5/22	1
125	ORSIRO (US) 3.5/40	1
126	ORSIRO (US) 2.25/13	1
127	ORSIRO 2.5/13	1
128	ORSIRO 2.75/15	1
129	ORSIRO (US) 2.25/18	1
130	METRONIC RESOLUTE ONYX DES	1
131	ORSIRO (US) 3.0/35	1

132	ORSIRO (US) 2.25/22	1
133	STENT XIENCE SKYPOINT 2.25MMX12MM RAPID EXCHANGE EVEROLIMUS ELUTING CORONARY	1
134	XIENCE ALPINE OTW EVEROLIMUS ELUTING CORONARY STENT SYSTEM	1
135	ORSIRO MISSION (US) 3.0/26	1
136	ORSIRO MISSION 2.25/26	1
137	ORSIRO MISSION (US) 3.5/26	1
138	XIENCE V	1
139	XIENCE PRIME BTK EVEROLIMUS ELUTING PERIPHERAL STENT SYSTEM	1
140	BIOFREEDOM DRUG COATED CORONARY STENT SYSTEM	1
141	SYNERGY XD- EVEROLIMUS PLATINUM CHROMIUM CORONARY STENT SYSTEM	1
142	ELUNIR-PERL RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	1
143	ORSIRO MISSION 2.75/40	1
144	ORSIRO MISSION 2.25/13	1
145	ORSIRO	1
146	MEDTRONIC ONYX FRONTIER DRUG ELU	1
147	ORSIRO MISSION (US) 3.0/40	1
148	SYNSIRO PRO 2.25/13	1
149	SYNSIRO PRO 3.0/18	1
150	ORSIRO MISSION 2.25/30	1
151	ORSIRO 2.75/22	1
152	XIENCE PRO EVEROLIMUS ELUTING RX CORONARY STENT SYSTEM	1
153	ORSIRO MISSION 2.5/35	1
154	ORSIRO MISSION 2.25/35	1
155	ORSIRO MISSION 4.0/13	1
156	ORSIRO MISSION (US) 2.5/15	1
157	SYNSIRO PRO 3.0/15	1
158	SYNERGY SHIELD	1
159	SYNSIRO PRO 3.5/40	1
160	SYNSIRO PRO	1
161	ONYX FRONTIER ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM CARDIAC STENT	1
162	ORSIRO 2.75/26	1
163	RESOLUTE ONYZ 2.00 X 30	1
164	ORSIRO MISSION 2.5/40	1
165	ORSIRO 3.5/35	1
166	BOSTON SCIENTIFIC SYNERGY XD STENT 3.00MM X 12MM	1

167	ABBOTT NEXT GENERATION DES 48	1
168	SYNERGY MEGATRON MONORAIL CORONARY STENT	1
169	ORSIRO MISSION 3.5/26	1
170	ORSIRO MISSION 2.75/15	1
171	ORSIRO MISSION (US) 3.0/30	1
172	ORSIRO MISSION 2.5/26	1
173	ORSIRO MISSION 3.5/13	1
174	ORSIRO MISSION (US) 4.0/13	1
175	ORSIRO MISSION 3.5/15	1
176	ORSIRO MISSION 2.75/30	1
177	ORSIRO MISSION 2.25/22	1
178	STNT COR 16 DIA4 PT CR EVERM SYNERGY XD	1
179	ORSIRO MISSION (US) 2.5/9	1
180	ORSIRO 2.75/9	1
181	ORSIRO MISSION 3.5/40	1
182	ORSIRO 4.0/13	1
183	STENT XIENCE SKYPOINT 2.75MMX23MM RAPID EXCHANGE EVEROLIMUS ELUTING CORONARY	1
184	ORSIRO 3.0/30	1
185	ORSIRO 2.75/40	1
186	ORSIRO 4.0/15	1

Table 3: Manufacture analysis of adverse events associated with coronary drug stents

Demographic trends indicated notable gaps in reporting, with gender unspecified in 1,527 cases; however, among the reports with available information, 735 events involved male patients and 238 involved female patients Figure 1.

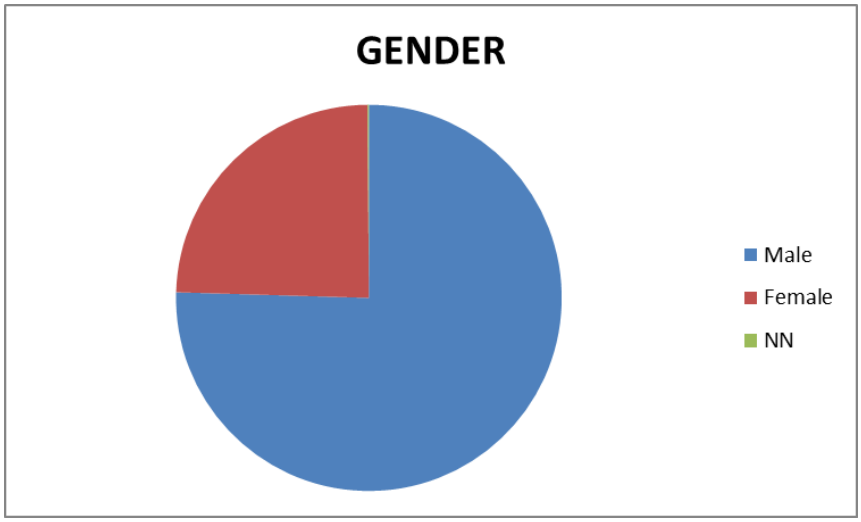

Figure 1: Gender analysis of adverse events associated with coronary drug stents

Age distribution data revealed that the 61–70-year age group had the highest number of reports (310 cases), followed by individuals aged 71–80 years (221 cases), aligning with the population most frequently undergoing percutaneous coronary interventions Figure 2.

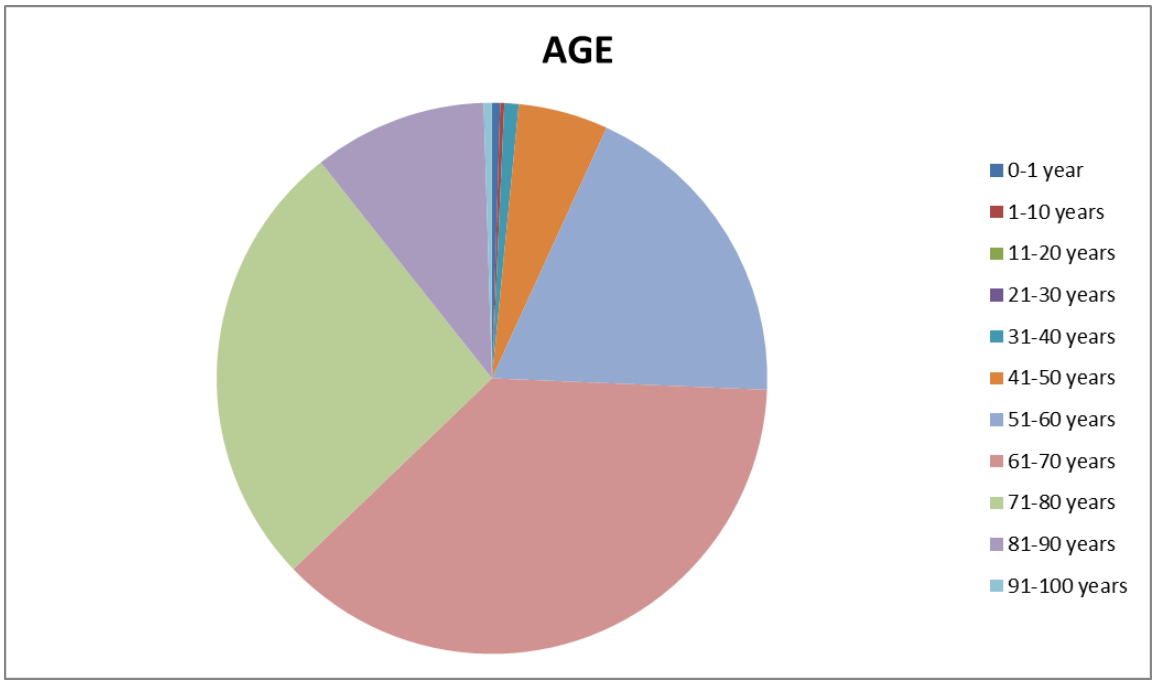

Figure 2: Age analysis of adverse events associated with coronary drug stents

Geographically, the largest number of adverse event reports originated from the United States (468 events), closely followed by India (441 events), reflecting substantial device utilization and reporting activity in these regions Figure 3.

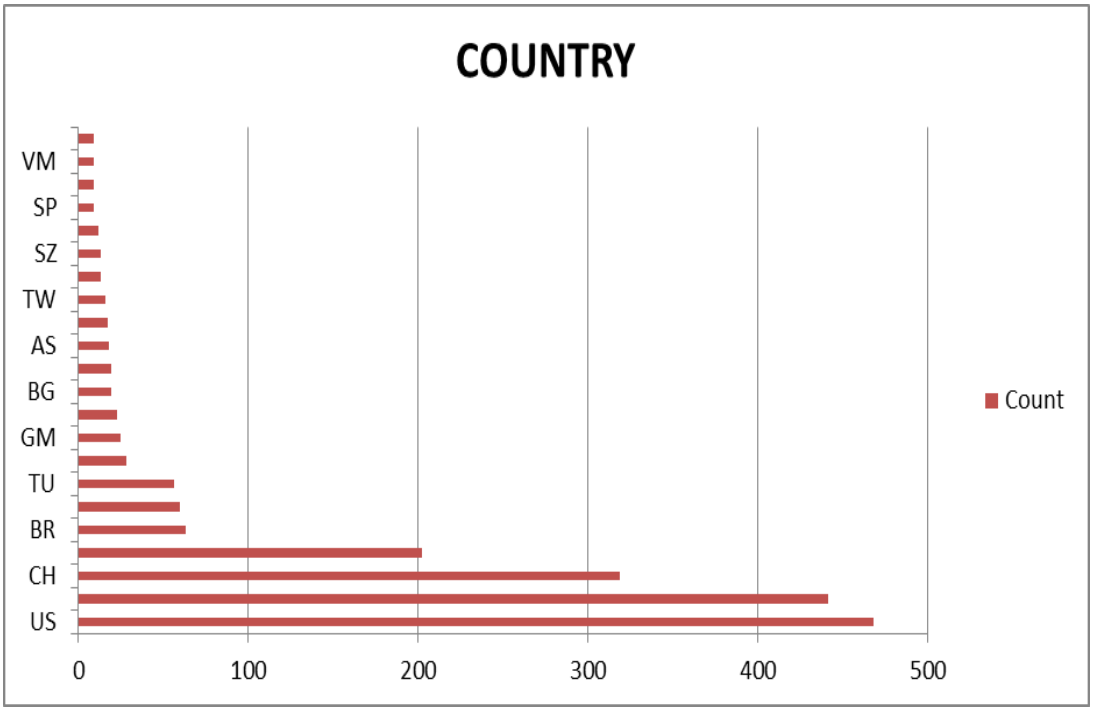

Figure 3: Country analysis of adverse events associated with coronary drug stents

Additionally, operator information indicated that 2,123 devices were reported as being handled by healthcare professionals, underscoring that most events occurred in formal clinical settings under trained supervision Figure 4.

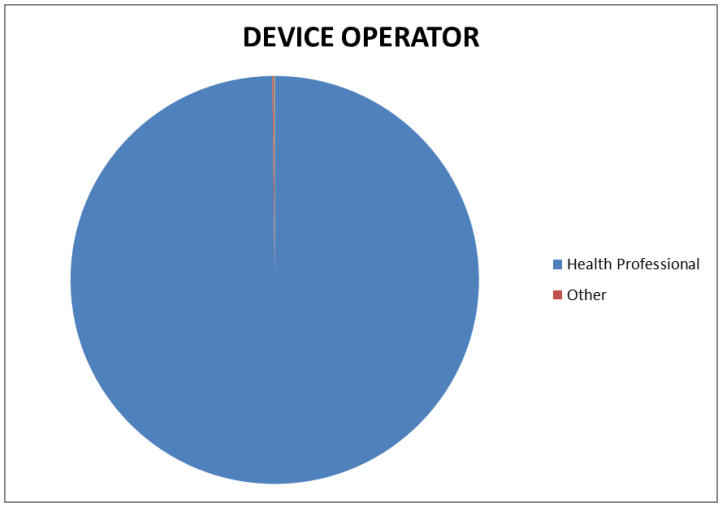

Figure 4: Device operator analysis of adverse events associated with coronary drug stents

Discussion

The analysis of 2,500 adverse event reports related to coronary drug-eluting stents (DESs) from the MAUDE database reveals patterns that both support and expand upon findings from recent clinical and post-market surveillance studies. The large proportion of cases categorized as "Adverse Event without Identified Device or Use Problem" is consistent with reports from contemporary DES registries, which show that many adverse outcomes occur in the context of complex patient profiles rather than discrete device malfunctions[11,12]. Recent literature similarly highlights that a significant share of DES complications arise from multifactorial causes—including vessel pathology, comorbidities, and procedural factors—rather than stent failure alone[12,13].

The high frequency of "Material Deformation" in this study aligns with newer analyses examining mechanical behavior of the latest-generation stent platforms. Several recent studies have reported that mechanical deformation, particularly longitudinal compression, continues to occur even in advanced cobalt-chromium and platinum-chromium stents[13,18]. This is particularly noted in challenging lesion subsets such as calcified or bifurcation lesions. Although manufacturers have introduced reinforced designs to reduce deformation susceptibility, real-world evidence—including the pattern seen in this study—indicates that such events remain clinically relevant[14,15].

Patient-related adverse events demonstrated an interesting distribution. Over half of the reports described "No Clinical Signs, Symptoms, or Conditions," echoing the trend in recent observational datasets where reported AEs do not necessarily correlate with clinical deterioration[14]. This reflects a broader shift in reporting behavior influenced by stringent regulatory expectations and automated manufacturer reporting systems[16,20]. However, the 12% incidence of vascular dissection observed in this study is notably higher than what is typically reported in controlled clinical trials, where rates are often below 3%[16,17]. This discrepancy is expected, as MAUDE captures high-risk, real-world cases that may not be represented in trial populations. Similar post-market analyses published in recent years have likewise shown higher rates of dissection, underscoring the importance of real-world surveillance for capturing complex procedural complications[16,17].

The Synergy stent appearing as the most frequently reported brand in this dataset may reflect its widespread global use rather than inherent device issues. Contemporary comparative

evaluations of major DES platforms note that SYNERGY, Xience, and Resolute Onyx are among the most commonly implanted stents worldwide. Therefore, higher reporting volume may correlate with market penetration. Several recent analyses of MAUDE stent data also reported brand distributions that mirrored market share[17].

Demographic trends in this study are consistent with global CAD patterns. The predominance of patient reports from those aged 61–80 years matches findings from multiple recent DES registries, where older adults constitute the majority of stent recipients due to the higher burden of atherosclerosis[18]. Similarly, the higher proportion of male patients reflects well-established epidemiological trends in CAD. The notable number of cases from India and the United States parallels global procedural statistics, with both nations being high-volume markets for coronary interventions and contributors to growing device-reporting infrastructures.

The finding that over 2,000 devices were handled by healthcare professionals aligns with previous research indicating that the majority of DES complications occur in formal clinical settings rather than due to user misuse[19,20]. Recent literature similarly emphasizes that even with improved stent design, adverse events remain influenced by lesion complexity, operator technique, and patient comorbidities[21]. This reinforces the importance of ongoing professional training, adherence to procedural guidelines, and utilization of intravascular imaging—now increasingly recommended in newer studies for optimizing stent deployment and reducing complications[22].

Overall, the trends identified in this analysis are consistent with contemporary findings from global DES safety literature. While device design advancements have reduced restenosis and thrombosis compared to earlier-generation stents[23], real-world data continue to reveal persistent risks related to mechanical behavior and patient-specific factors. The concordance between this study and recent international reports underscores the importance of complementary evidence from both clinical trials and post-market surveillance systems [24, 25,26]. Continued refinement in device engineering, procedural optimization, and standardized reporting practices will remain essential to improving safety and patient outcomes in the evolving landscape of coronary intervention.

Conclusion

The findings from this MAUDE database review reinforce the necessity of continuous post-market surveillance of coronary drug-eluting stents. A significant number of adverse events—especially those involving mechanical issues and vascular injury—highlight opportunities for improvement in device design, procedural training, and patient selection. Future studies should aim to correlate MAUDE data with clinical registries to provide a more comprehensive understanding of DES safety and performance. Until then, clinicians must remain vigilant in the use of these devices and contribute to accurate and timely reporting of complications to enhance patient safety.

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.

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