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Complications and failure modes of coronary embolic protection devices: Insights from the MAUDE database

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ORIGINAL STUDIES

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Complications and failure modes of coronary embolic protection devices: Insights from the MAUDE database

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Abstract

Background: There is limited data on complications associated with the use of coronary embolic protection devices (EPDs).

Methods: We queried the Manufacturer and User Facility Device Experience database between November 2010 and November 2020 for reports on coronary EPDs: Spider FX (Medtronic, Minneapolis, MN) and Filterwire EZ (Boston Scientific, Natick, MA).

Results: We retrieved 119 reports on coronary EPD failure (Spider FX n = 33 and Filterwire EZ n = 86), most of which (78.2%) occurred during saphenous vein graft interventions. The most common failure mode was inability to retrieve the EPD (49.6%), with the filter trapped against stent struts in 76.2% of the cases. Other device complications included filter fracture (28.6%), failure to cross (7.6%), failure to deploy (7.6%), and failure to recapture the filter (3.4%). Filter fracture (54.5 vs. 29.1%) and failure to recapture (9.1 vs. 2.1%) were more commonly reported, while failure to deploy the filter (0 vs. 10.5%) was less commonly reported with the Spider-FX.

Conclusions: The most common modes of failure of coronary EPDs are the failure of retrieval (49.6%), followed by the filter fracture (28.6%). When using EPDs, careful attention to the technique is essential to avoid failures and subsequent complications.

KEYWORDS
embolic protection devices, filters, Spider FX, Filterwire EZ

1 | INTRODUCTION

Distal embolization is a potential risk of percutaneous coronary intervention (PCI) that can lead to slow or no-reflow and acute vessel closure, potentially leading to acute myocardial infarction.[1,2] Embolization can occur at the time of lesion crossing, balloon inflation, or stent deployment. Distal embolization is most pronounced in lesions with a high plaque or thrombus burden, such as ST-segment elevation acute myocardial infarction (STEMI) culprit lesions and saphenous vein graft (SVG) lesions.[3]

Embolic protection devices (EPDs) can prevent or reduce the extent of distal embolization of debris or thrombus, potentially reducing adverse clinical outcomes. Randomized trials have shown beneficial effects of EPDs on SVG interventions.[3] EPDs have demonstrated no significant benefit when routinely used in STEMI,[4,5] although some reports suggest benefit, for example, in patients with attenuated plaque.[6,7] Currently, EPDs are primarily used in SVG PCI.[8] Data on the complications of coronary EPDs are limited.[9] Therefore, we examined the reports of coronary EPDs failure reported to the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) registry.

TABLE 1 Reports of the Spider FX and Filterwire EZ device failure in the MAUDE registry

	Overall (n = 119)	SPIDER-FX (n = 33)	FILTERWIRE-EZ (n = 86)	*p*-value
Coronary location				
Saphenous vein graft, n (%)	93 (78.2)	24 (72.2)	69 (80.2)	.37
Native, n (%)	14 (11.8)	6 (18.2)	8 (9.3)	.40
RCA, n (%)	9 (7.6)	5 (15.2)	4 (4.7)	.05
LAD, n (%)	3 (2.5)	1 (3)	2 (2.3)	.82
LCX, n (%)	1 (0.8)	0 (0)	1 (1.2)	.53
OM, n (%)	1 (0.8)	0 (0)	1 (1.2)	.53
Unknown, n (%)	12 (10)	3 (9.1)	9 (10.5)	.82
Modes of failure				
Failure of retrieval, n (%)	59 (49.6)	19 (57.6)	40 (46.5)	.28
Trapped against stent struts (total n = 59) (%)	45 (76.2)	8 (42.1)	20 (50.0)	.57
Filter fracture, n (%)	34 (28.6)	18 (54.5)	25 (29.1)	.01
Failure of crossing, n (%)	13 (7.6)	2 (6.1)	11 (12.8)	.29
Failure of deployment, n (%)	9 (7.6)	0 (0)	9 (10.5)	.05
Failure of recapturing, n (%)	4 (3.4)	3 (9.1)	1 (1.2)	.03
Management				
Successful catheter-based retrieval, n (%)	67 (56.3)	8 (24.2)	59 (68.6)	<.001
Snare, n (%)	12 (10.1)	5 (15.2)	7 (8.1)	.25
Rotational atherectomy to dislodge trapped filter, n (%)	1 (0.8)	0 (0)	1 (1.2)	.53
Guide extension catheter, n (%)	1 (0.8)	0 (0)	1 (1.2)	.53
Left inside patient, n (%)	38 (31.9)	18 (54.5)	20 (23.3)	<.001
Filter jailed with a stent, (total n = 38) (%)	20 (52.6)	9 (50.0)	11 (55.0)	.75
Surgical retrieval, n (%)	13 (10.9)	7 (21.2)	6 (7)	.02
Complications				
Stent deformation during retrieval, n (%)	34 (28.6)	4 (3.4)	30 (34.9)	.01
No reflow, n (%)	7 (5.9)	3 (9.1)	4 (4.7)	.35
Slow flow, n (%)	11 (9.2)	5 (15.2)	6 (7.1)	.17
Acute stent thrombosis, n (%)	1 (0.8)	1 (3)	0 (0)	.10
Coronary perforation, n (%)	2 (1.7)	0 (0)	2 (2.3)	.37
Coronary artery dissection, n (%)	3 (2.5)	1 (3)	2 (2.3)	.82
Hemodynamic collapse, n (%)	2 (1.7)	2 (6.1)	0 (0)	.02
Respiratory arrest, n (%)	2 (1.7)	1 (3)	1 (1.2)	.47
Embolized	13 (10.9)	5 (15.2)	8 (9.3)	.60
Microthrombi embolization, n (%)	4 (3.4)	1 (20)	3 (37.5)	.50
Femoral embolization, n (%)	2 (1.7)	1 (20)	1 (12.5)	.71
Abdominal embolization, n (%)	1 (0.8)	1 (20)	0 (0)	.18
Iliac embolization, n (%)	1 (0.8)	0 (0)	1 (12.5)	.41
Brachial embolization, n (%)	1 (0.8)	1 (20)	0 (0)	.18
Periprocedural MI, n (%)	10 (8.4)	2 (6.1)	8 (9.3)	.56
Stroke, n (%)	1 (0.8)	0 (0)	1 (1.2)	.53
Death, n (%)	1 (0.8)	0 (0)	1 (1.2)	.53
Outcome				
Successful intervention completed, n (%)	103 (86.6)	27 (81.8)	76 (88.4)	.34

Abbreviations: LAD, left anterior descending artery; LCX, left circumflex artery; MI, myocardial infarction; OM, obtuse marginal artery; SVG, saphenous vein grafts.

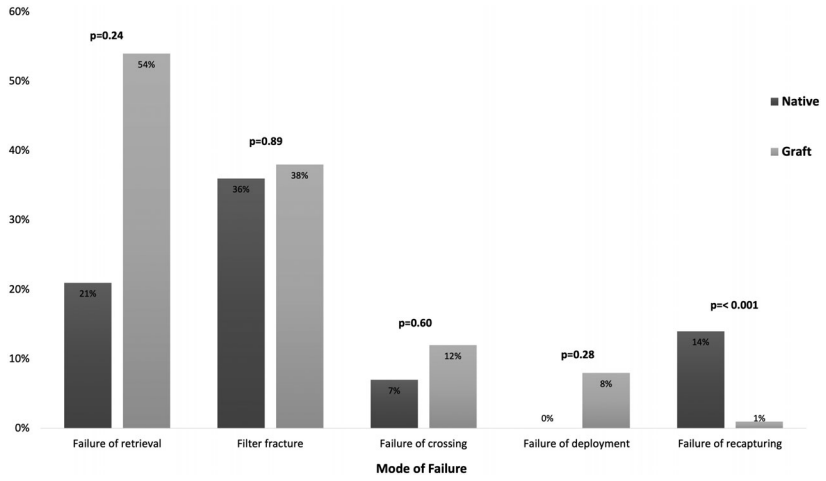

FIGURE 1 Modes of failures of coronary embolic protection devices as reported to the MAUDE registry. MAUDE, Manufacturer and User Facility Device Experience

2 | MATERIALS AND METHODS

The FDA's MAUDE database is an online database of adverse events caused by an approved medical device. Reporting to the MAUDE database is either mandatory (for manufacturers and device user facilities) or voluntary (for healthcare professionals, patients, and consumers). We searched the database from November 2010 to November 2020 for reports on coronary EPDs: Spider FX (Medtronic, MN) and Filterwire EZ (Boston Scientific, MA). The Spider FX device was the most recently approved in 2011. The Guardwire (Medtronic, Minneapolis, MN) and Proxis devices, although FDA approved, were omitted because they are not currently commercially available in the US.

The database was last accessed on December 15, 2020, by two independent reviewers (RM and MM). The MAUDE database is publicly available and de-identified; therefore, no institutional review board approval was required for this study. We compared the baseline characteristics and outcomes between the Spider-FX and Filterwire-EZ. We also compared outcomes in patients who had EPDs used in SVGs versus in native coronary disease.

2.1 | Outcomes and statistical analysis

The primary outcome of this study was the mechanisms of failure of coronary EPDs. Secondary outcomes included clinical consequences of device failure. Failure of retrieval of the EPD was defined as the failure to extract the filter intact from the vessel. Failure of recapture was defined as the inability to withdraw the filter in the retrieval catheter. Categorical variables were described as numbers and percentages. They were analyzed using Pearson's chi-square or Fisher's exact tests. A value of $p < .05$ was considered significant, and p-values are two-sided where possible. All statistical calculations were performed with IBM SPSS Statistics for Mac, Version 26.0. Armonk, NY: IBM Corp (2020).

2.2 | Results

A total of 677 reports were found during the study period. After excluding non-coronary (n = 455) and non-identifiable lesions (n = 113), our final cohort included 119 reports related to EPD failure during PCI. Of those, 33 reports were related to the use of the Spider FX (27.7%) and 86 to the Filterwire EZ (72.3%) (Figure S1). Most reports were during SVG PCI (78.2%), while native coronary artery PCI was 11.8%. We could not identify the target vessel in 10% of cases (Table 1).

2.3 | Mechanisms of failure and clinical outcomes

The most common failure mode was failure to retrieve the EPD (49.6%), with the filter trapped against stent struts in 76.2% of these cases. Other EPD complications included filter fracture (28.6%), failure to cross (7.6%), failure to deploy (7.6%), and failure to recapture the filter (3.4%). There was no difference in the incidence of failure of retrieval or crossing between the two filters. Spider-FX had higher reported incidence of filter fracture (54.5% vs. 29.1%, $p = .01$) and failure to recapture (9.1 vs. 2.1%, $p = .03$), but lower reported incidence of filter deployment failure (0 vs. 10.5%, $p = .05$) compared with the Filterwire-EZ (Figure 1).

Management of entrapment was with catheter-based retrieval in 57.1% of the cases, while surgical retrieval was needed in 10.9% of the reports. Successful catheter-based retrieval was reported in 66.3% of the Filterwire-EZ reports, and 34.4% of the Spider FX reports. Surgical intervention was reported in 21% of the Spider-FX cases and 7% of the Filterwire-EZ cases. The device was left in place in 31.9% of the cases, and jailed by a stent in 52.6% of them. The Spider FX was left in place in 54.5% of the reports compared with 23.3% for the Filterwire-EZ.

Stent deformation occurred in 28.6% of the reports, with a higher incidence with the Filterwire-EZ (34.9 vs. 3.4%, $p = .01$). Device embolization occurred in 10.9% of cases with no difference between both devices. The rates of slow flow and no-reflow were 9.2 and

TABLE 2 Subgroup analysis of clinical complication of embolic protection devices in native coronary artery versus vein graft interventions in the MAUDE registry

	Overall (n = 107)	Native coronary arteries (n = 14)	Vein grafts (n = 93)	*p*-value
Mode of failure				
Failure of retrieval, n (%)	53 (49.5)	3 (21.4)	50 (53.8)	.24
Trapped against stent struts (total n = 59) (%)	45 (42.1)	5 (35.7)	40 (43.0)	.60
Filter fracture, n (%)	40 (37.4)	5 (35.7)	35 (37.6)	.89
Failure of crossing, n (%)	12 (11.2)	1 (7.1)	11 (11.8)	.60
Failure of deployment, n (%)	7 (6.5)	0 (0)	7 (7.5)	.28
Failure of recapturing, n (%)	3 (2.9)	2 (14.3)	1 (1.1)	<.001
Management				
Successful catheter-based retrieval, n (%)	60 (56.1)	8 (57.1)	52 (55.9)	.93
Snare, n (%)	12 (11.2)	0 (0)	12 (12.9)	.15
Rotational atherectomy to dislodge trapped filter, n (%)	1 (0.9)	1(7.1)	0 (0)	.01
Guide extension catheter, n (%)	1 (0.9)	1 (7.1)	0 (0)	.01
Left inside patient, n (%)	35 (32.7)	4 (28.6)	31 (33.3)	.72
Filter jailed with a stent, (total n = 35) (%)	20 (52.6)	2 (50.0)	17 (54.8)	.71
Surgical retrieval, n (%)	11 (10.3)	2 (14.3)	9 (9.7)	.59
Complications				
Stent deformation during retrieval, n (%)	33 (30.8)	4 (28.6)	29 (31.2)	.84
No reflow, n (%)	7 (6.5)	0 (0)	7 (7.5)	.28
Slow flow, n (%)	11 (10.4)	0 (0)	11 (12)	.17
Acute stent thrombosis, n (%)	1 (0.9)	1 (7.1)	0 (0)	.10
Coronary perforation, n (%)	2 (1.9)	0 (0)	2 (2.2)	.58
Coronary artery dissection, n (%)	3 (2.8)	1 (7.1)	2 (2.2)	.29
Hemodynamic collapse, n (%)	2 (1.9)	0 (0)	2 (2.2)	.58
Respiratory arrest, n (%)	2 (1.9)	1 (7.1)	1 (1.1)	.11
Embolized	12 (11.2)	4 (28.6)	8 (8.6)	.02
Microthrombi embolization, n (%)	4 (30.8)	1 (25)	3 (37.5)	.71
Femoral embolization, n (%)	2 (15.4)	1 (25)	1 (12.5)	.77
Abdominal embolization, n (%)	1 (7.7)	0 (0)	1 (12.5)	.71
Iliac embolization, n (%)	1 (7.7)	0 (0)	1 (12.5)	.71
Brachial embolization, n (%)	1 (7.7)	0 (0)	1 (12.5)	.71
Periprocedural MI, n (%)	4 (30.8)	1 (25)	3 (37.5)	.71
Stroke, n (%)	0 (0)	0 (0)	0 (0)	*
Death, n (%)	1 (0.9)	0 (0)	1 (1.1)	.69
Outcome				
Successful intervention completed, n (%)	93 (86.9)	12 (85.7)	81 (87.1)	.88

Abbreviation: MI, myocardial infarction.

5.9%, respectively. Coronary perforation occurred in 1.7% of cases, while coronary dissection occurred in 2.5% of cases. The rates of death, stroke, and periprocedural MI were 0.8, 0.8, and 8.4%.

2.4 | Vein grafts versus native coronary disease

Coronary EPDs were primarily used in SVGs. Native artery interventions were more likely to be associated with failure to recapture the filter compared to SVG interventions (14.3 vs. 1.1%, $p < .001$). There was no difference in the incidence of retrieval failure, filter fracture, failure of crossing, or failure of deployment between SVG and native artery interventions. There was no difference in clinical outcomes between the two groups (Table 2).

3 | DISCUSSION

Our study is the first to report the modes of failure of coronary EPDs over a decade of use in the United States. The main findings of our

study can be summarized as follows: (1) coronary EPDs were primarily utilized in SVG PCI (78%) but are also sometimes used in native artery interventions; (2) the most common complication of coronary EPD use was retrieval failure (49%) followed by filter fracture (28.6%), which was in most cases managed by catheter-based retrieval or leaving the filter in place, with emergency surgery needed in 10.9% of the cases.

SVG PCI is associated with a high risk of MACE, primarily due to the risk of distal embolization. Although PCI of the corresponding native coronary is preferred to SVG PCI if feasible,[10] SVG PCI is still commonly performed. The SAFER trial demonstrated a significant benefit of EPD use in SVG PCI and formed the basis of current practice. Using an EPD in SVG PCI is recommended as class I in the US PCI guidelines. In contrast, it was recently downgraded to IIA in the European PCI guidelines based on data from observational studies.[11,12] The use of EPDs during SVG PCI has been shown to reduce the risk of distal embolization and MACE.[8] However, multiple studies have shown that EPD use during SVG PCI has been declining.[11,12] The decline in their use might indirectly lead to limited experience and higher complication rates.

EPDs carry a risk of complications, such as entrapment,[11] leading to emergency cardiac surgery or death. Our study investigated the outcomes of the two currently available EPDs in the US: Spider FX and Filterwire EZ. The Spider FX consists of a nitinol mesh filter with pore sizes ranging from 70 to 200 μm with a distal floppy tip. It can be advanced after wiring the target lesion using any guidewire according to the operator's preference. The Filterwire-EZ is a steerable guidewire that is advanced across the target lesion, with a 110 μm pore size filter bag. For most sizes, both filters have similar crossing profiles (3.2 French).

In our analysis, the most common mode of EPD failure was failure to retrieve the filter, occurring in half of the reports. In >70% of the cases, the filter was trapped against stent struts. While not specified in the reviewed reports, buddy wires should never be used with EPDs, as inadvertent stent deployment over the buddy wire will lead to filter entrapment. To avoid filter entrapment, it is essential to avoid movement of the filter wire during and after stent deployment in addition to respecting the "landing zone" of each filter (> 40 mm for Spider and 25–35 mm for the Filterwire-EZ). When encountering difficulty in advancing the retrieval sheath through recently deployed stent, forceful advancement should be avoided, as it may result in filter movement and entrapment within the recently deployed stent. Instead, the stent may be post-dilated, and another retrieval catheter (such as the bend tip retrieval catheter) or a guide catheter extension may be used to remove the filter.

The second most common EPD failure mode was filter fracture (28%), which was noted in 18 (54%) of Spider-Fx reports and 25 (29%) of Filterwire EZ reports. Careful manipulation of the wire and filter avoiding excessive pulling are vital to avoid this complication. Catheter-based retrieval of the filter was successful in 57% of cases but with a lower incidence with the Spider-FX. In some cases, additional techniques were used, including rotational atherectomy or snaring. The device was left in place in 39% of cases. Surgical intervention was required in 10.9% of cases. EPD failure was associated with a low risk of death or stroke (<2%), vessel perforation or dissection (<5%), and slow or no-reflow (<15%).

Although prior studies have shown that routine use of EPDs in STEMIs of native coronary arteries does not improve outcomes,[13] EPDs were used in native vessel PCI in 13% of the reports. In our analysis, there was a significantly higher risk of failure to recapture the EPD in native vessel PCI (14.3 vs. 1.1%, $p < .001$). It might be reasonable to use EPDs in selective cases of native vessel PCI during STEMI with massive thrombus burden and anticipation of no-reflow. However, caution should be employed before their use, given slightly higher risk of recapture failure.

3.1 | Limitations

Our study is limited by selection bias resulting from the retrospective analysis of the MAUDE and the selective optional reporting by healthcare professionals. Second, the MAUDE database has several shortcomings, including the submission of incomplete or unverified reports. Third, the incidence of each device's mode of failure cannot be determined as the study lacks a denominator. Finally, a correlation between the device failure and clinical adverse events cannot be accurately determined.

3.2 | Conclusions

The most common modes of failure of coronary EPDs are failure of retrieval (49.6%) and filter fracture (28.6%). When using EPDs, careful attention to the technique is essential to avoid failures and subsequent complications.

CONFLICT OF INTEREST

Khaldoon Alaswad: consulting/speaker honoraria from Boston Scientific, Cardiovascular Systems Inc, Abbott Vascular, Teleflex. Mir Basir: Consulting/Speaker Abbott Vascular, Abiomed, Cardiovascular Systems, Chiesi, Zoll. Emmanouil Brilakis: consulting/speaker honoraria from Abbott Vascular, American Heart Association (associate editor Circulation), Amgen, Biotronik, Boston Scientific, Cardiovascular Innovations Foundation (Board of Directors), ControlRad, CSI, Ebix, Elsevier, GE Healthcare, InfraRedx, Medtronic, Siemens, and Teleflex; research support from Regeneron and Siemens; owner, Hippocrates LLC; shareholder: MHI Ventures. All other authors have nothing to disclose.

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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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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