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Complications and failure modes of covered coronary stents: Insights from the MAUDE database

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ABSTRACT

Background: Data on the mechanisms of failure of covered coronary stents [Graftmaster, PK Papyrus] are limited.
Methods: We queried the "Manufacturer and User Facility Device Experience" (MAUDE) database between August 2018 (when the PK Papyrus stent was FDA approved) and December 2020 for reports on covered coronary stents.
Results: We identified 299 reports in the MAUDE database (after excluding duplicates, peripheral vascular reports, and incomplete records) (Graftmaster $n = 225$, PK Papyrus $n = 74$). The most common mechanism of failure of covered stents was failure to deliver the stent (46.2%), followed by stent dislodgement (22.4%) and failure to seal the perforation (19.7%). Failure to deliver the stent was more often reported with Graftmaster compared with PK Papyrus (59.1% vs. 6.8%, $p < 0.001$). Stent dislodgement was more often reported with PK Papyrus compared with Graftmaster (75.7% vs. 4.9%, $p < 0.001$) and was managed by device retrieval or by crushing the stent.
Conclusions: The most common failure mechanisms of covered stents are failure of delivery, stent dislodgement, and failure to seal the perforation. Failure of delivery was more common with Graftmaster, while stent dislodgement was more common with PK Papyrus. Further improvements in covered stent design are needed to optimize deliverability and minimize the risk of complications.

1. Introduction

Coronary artery perforation (CAP) is a rare but potentially life-threatening complication of percutaneous coronary intervention (PCI) [1], most commonly occurring as a large vessel perforation [2]. It occurs in approximately 0.2–3% of all PCI procedures with a higher incidence in more complex lesions, such as chronic total occlusions [3] and calcified lesions requiring the use of atherectomy [4,5,6]. The incidence of CAP has not declined over time [7].

Covered stents can successfully seal large vessel CAP and some distal vessel perforation cases, [8] obviating the need for emergency cardiac surgery [9]. In the United States, two covered stents have received humanitarian device exemption by the Food and Drug Administration (FDA), the polytetrafluoroethylene (PTFE) covered Graftmaster stent (Abbott Vascular, Santa Clara, CA) and the polyurethane PK Papyrus stent (Biotronik, Lake Oswego, OR). We investigated the Manufacturer and User Facility Device Experience (MAUDE) database for reports on the failure of the aforementioned devices failure after approval of the PK Papyrus stent (Fig. 1).

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 registry is either mandatory (for manufacturers and device user facilities) or voluntary (for healthcare professionals, patients, and consumers). We

Abbreviation: MAUDE, Manufacturer and User Facility Device Experience database; CAP, coronary artery perforation; PCI, percutaneous coronary intervention.

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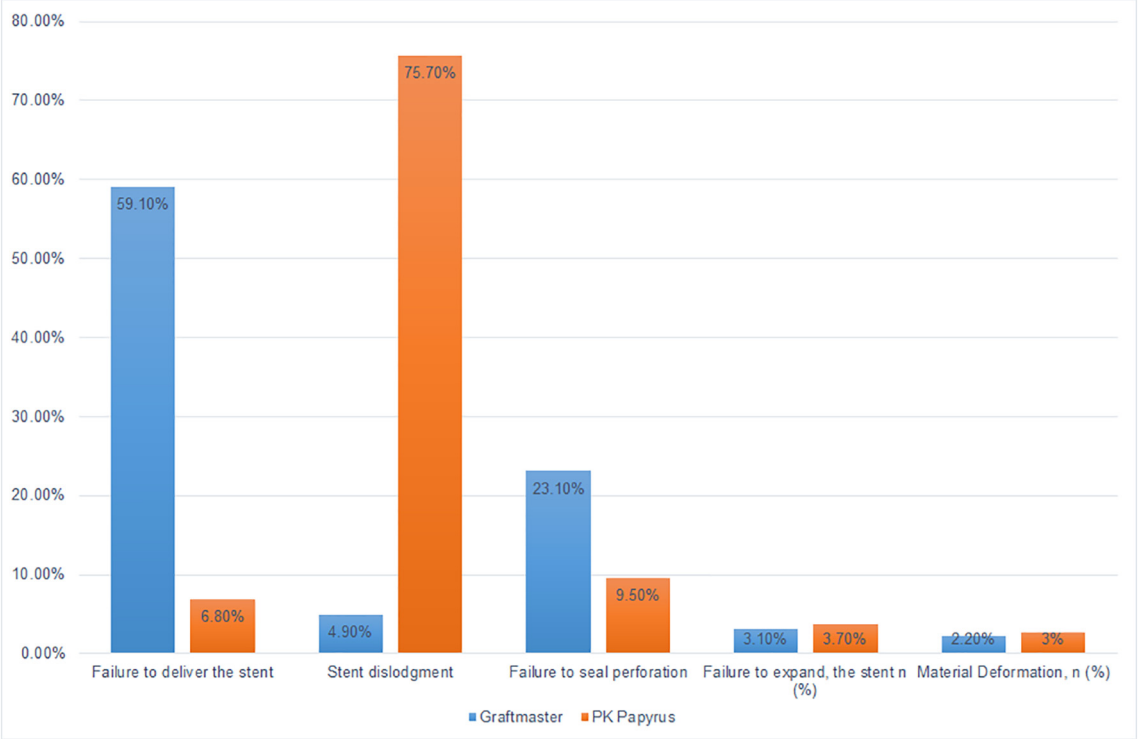

Fig. 1. Failure mechanisms of covered stents as reported to the MAUDE registry.

searched the database from August 2018 (date of approval of Papyrus stent in the United States) to December 2020 for reports on the covered coronary stents failure (Fig. 2).

The database was last accessed on January 7th, 2021, by two independent reviewers (MZ and MM). The MAUDE database is publicly available and de-identified; therefore, no institutional review board approval was required for this study.

2.1. Outcomes and statistical analysis

The primary outcome of this study was the mechanisms of failure of covered stents. Secondary outcomes included clinical consequences of device failure. Categorical variables were described as numbers and percentages and were analyzed using Pearson's chi-square or Fisher's exact tests. A value of $p < 0.05$ was considered significant, and p-values are

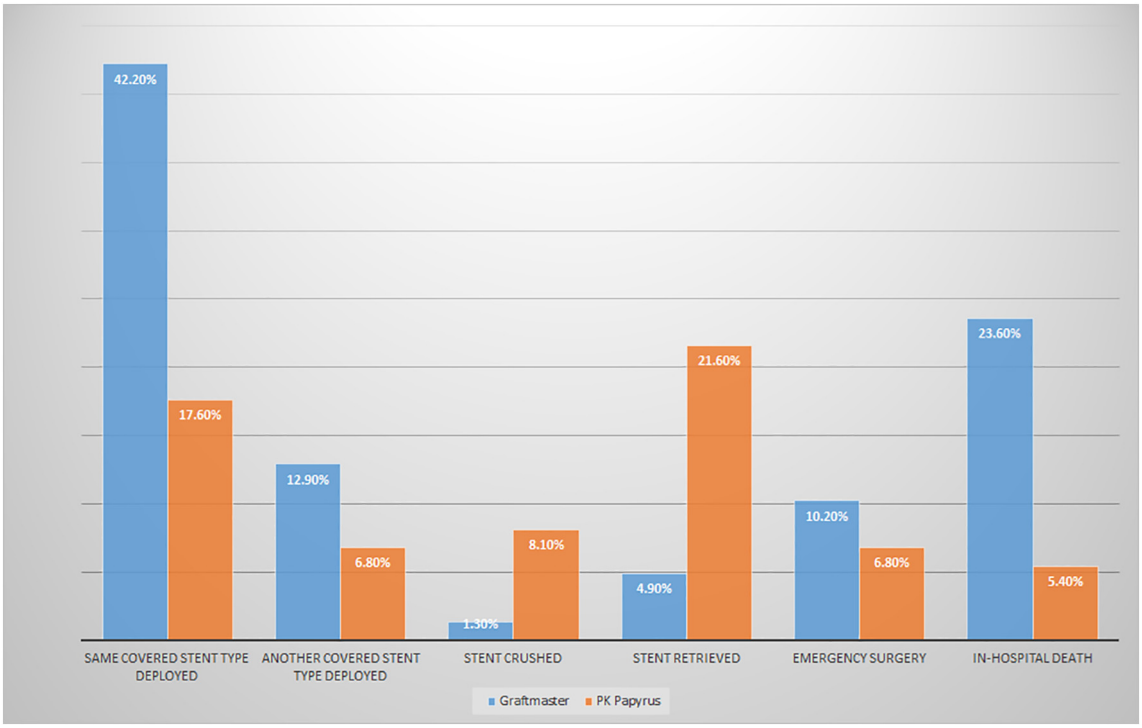

Fig. 2. Failure mechanisms of covered stents according to each stent type as reported the MAUDE registry.

two-sided where possible. All statistical calculations were performed with IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp (2017).

3. Results

A total of 422 reports were found during the study period. After excluding incomplete reports ($n = 12$), duplicate reports ($n = 45$), and reports in peripheral interventions ($n = 92$), our final cohort included 299 reports related to coronary covered stents failure. Of those, 225 reports were for the Graftmaster and 74 for the Papyrus stent (Table 1). Stent lengths and diameters were reported in most of the events. The most common diameter of the failed stents was 2.8 mm for the Graftmaster (50.7% of the reports) and 2.5 mm for the Papyrus (41.9% of the reports) (Table S1). The most common stent lengths were 19 mm (49.3%) and 15 mm (48.6%), for the Graftmaster and the Papyrus PK, respectively (Table S2).

3.1. Mechanisms of failure and clinical outcomes

The most common failure mechanism was failure to deliver the stent (138 reports, 46.2%). It was reported in 59.1% of the Graftmaster reports and 6.8% of the Papyrus PK reports. Stent dislodgement (67 reports, 22.4%) was more reported with PK Papyrus compared with the Graftmaster (75.7% vs. 4.9%) and was managed by device retrieval or crushing the stent. There were 58 reports of failure to seal the perforation (19.9%) with no difference in the incidence for each stent (52 reports (23.1%) for the Graftmaster and seven reports (9.5%) for the Papyrus PK) (Table 1).

Failure to achieve full expansion of the stent was found in 3% of reports, with no difference between stent types. Emergency surgery was reported in 9.4%, and death in 19.1%. In-hospital mortality was found to higher in the Graftmaster reports compared with the PK Papyrus reports (23.6% vs. 5.4%) (Table 1).

Table 1
Reports on coronary covered stents failure in the MAUDE registry.

	Overall (n = 299)	Graftmaster (n = 225)	PK Papyrus (n = 74)	P-value
Mechanism of failure				
Failure to deliver the stent, *n (%)*	138 (46.2)	133 (59.1)	5 (6.8)	<0.001
Device dislodgment, *n (%)*	67 (22.4)	11 (4.9)	56 (75.7)	<0.001
Failure to seal perforation, *n (%)*	59 (19.7)	52 (23.1)	7 (9.5)	0.110
Failure to expand the stent, *n (%)*	9 (3.0)	7 (3.1)	2 (2.7)	1.000
Material deformation, *n (%)*	7 (2.3)	5 (2.2)	2 (2.7)	0.684
Proximal shaft break, *n (%)*	1 (0.3)	1 (0.4)	0 (0)	–
Mid-shaft break, *n (%)*	6 (2.0)	6 (2.7)	0 (0)	–
Dissection or perforation, *n (%)*	3 (1.0)	3 (1.3)	0 (0)	–
No re-flow, *n (%)*	4 (1.8)	5 (1.7)	1 (1.4)	1.000
Used past expiration date, *n (%)*	7 (2.3)	7 (3.1)	0 (0)	0.199
Damaged prior to use, *n (%)*	2 (0.7)	2 (0.9)	0 (0)	–
Vessel ($n = 163$)				
Left main artery, *n (%)*	3 (1.0)	2 (0.9)	1 (1.4)	0.575
Left anterior descending artery, *n (%)*	128 (42.8)	112 (49.8)	16 (21.6)	< 0.001
Left circumflex artery, *n (%)*	40 (13.4)	29 (12.9)	11 (14.9)	0.695
Right coronary artery, *n (%)*	62 (20.7)	54 (24.0)	8 (10.8)	0.014
Vein graft, *n (%)*	14 (4.7)	13 (5.8)	1 (1.4)	0.201
Management				
Same stent deployed, *n (%)*	5 (1.7)	4 (1.8)	1 (1.4)	1.000
Same type of covered stent deployed *n (%)*	108 (36.1)	95 (42.2)	13 (17.6)	<0.001
Another type of covered stent deployed *n (%)*	34 (11.4)	29 (12.9)	5 (6.8)	0.205
Stent crushed, *n (%)*	9 (3.0)	3 (1.3)	6 (8.1)	0.008
Stent retrieved, *n (%)*	27 (9.0)	11 (4.9)	16 (21.6)	<0.001
Alternate management of perforation				
Treated with coils, *n (%)*	3 (1.0)	3 (1.3)	0 (0)	–
Balloon tamponade only, *n (%)*	41 (13.7)	39 (17.3)	2 (2.7)	0.001
Clinical outcomes				
IABP required, *n (%)*	4 (1.3)	4 (1.8)	0 (0)	0.575
ECMO required, *n (%)*	3 (1.0)	3 (1.3)	0 (0)	–
Pericardiocentesis, *n (%)*	2 (0.7)	2 (0.9)	0 (0)	–
Surgery, *n (%)*	28 (9.4)	23 (10.2)	5 (6.8)	0.492
Death, *n (%)*	57 (19.1)	53 (23.6)	4 (5.4)	<0.001

4. Discussion

Our study is the first to report the mechanisms of failure of covered stents after the PK Papyrus approval in the United States. Our findings can be summarized as follows: 1) the most common mechanism of covered stents failure was the inability to deliver the stent, followed by stent dislodgment, and failure to seal the perforation; 2) failure to deliver the stent was more reported with the Graftmaster stent; 3) stent dislodgement was more reported with the PK Papyrus stent and was managed by device retrieval or crushing the stent; and 4) In-hospital mortality was found to higher in the Graftmaster reports compared with the PK Papyrus reports.

Coronary perforations can be classified according to severity using the Ellis classification, with Type III perforations being ≥1 mm diameter with contrast streaming and cavity spilling [10]. Covered stents can help seal types II and III perforations in large vessels. In the United States until 2018, the Graftmaster stent was the only covered stent available. The Graftmaster is a balloon-expandable stent that consists of single PTFE layering between two coaxial 316 L stainless steel. The most recently FDA-approved covered stent is the PK Papyrus stent, which consists of an ultrathin (60 μm) strut cobalt-chromium design covered with polyurethane matrix [11].

In our analysis, inability to deliver the stent was the primary mechanism of failure accounting for 49% of reports and was more reported with Graftmaster. Poor deliverability is a known limitation of the Graftmaster stent, especially in calcified and tortuous vessels. The Graftmaster stent has a large crossing profile (1.63–1.73 mm) and two-stent layers, limiting its flexibility. The PK Papyrus has a lower crossing profile (1.18 to 1.55 mm) and single stent design covered on the abluminal side with a polyurethane layer, rendering it compatible with 5 Fr. guide up to 4 mm stents and 6 Fr. guide for the 4.5- and 5-mm stents. Previous observational studies have also reported shorter delivery times with PK Papyrus [12].

The second most common failure mechanism of covered stents was stent dislodgment, which was more reported with PK Papyrus. In the early experience of PK Papyrus, it was successfully delivered and sealed the perforation in 95.0% and 91.3% of cases, respectively [13], with only three cases of stent dislodgement (3.9%). Our study represents a real-life experience in the United States since the device's approval, and further investigation into the possible causes of the stent's easy dislodgement is warranted.

Previous observational studies have shown that PK Papyrus was associated with a lower risk of pericardial effusion, cardiac arrest, and emergency surgery than the Graftmaster [12,14]. There was no difference in the risk of emergency surgery or pericardiocentesis between both stents in our analysis. In-hospital mortality, however, was found to be lower in the PK Papyrus reports. This could be related to the high incidence of failure to deliver the Graftmaster stent, which can be disastrous in emergent situations. We could not assess the difference in long-term outcomes in both stents given the database limitations. A previous meta-analysis suggested a higher risk of stent thrombosis and in-stent restenosis with Graftmaster compared with the PK Papyrus stent [14].

The best treatment of CAP is avoidance, with proper balloon sizing and utilizing intravascular imaging. However, should a perforation occur, the operator should be well equipped to treat it effectively. Having covered stents available as well as understanding the limitations of the available devices is crucial. It is essential to have strong support and

possibly guide extensions in situations when perforation is anticipated (e.g., severely calcified vessels). Although lacking the denominator of all cases of perforations, the high incidence of in-hospital death in our study (20%) is alarming. It highlights the need for improved management of coronary perforations. Our study suggests that the PK Papyrus might be the preferred option in managing CAP, giving its better deliverability, albeit at the cost of a higher risk of dislodgment. Different measures should be taken to avoid dislodgement of the Papyrus PK stent, including guide extensions and avoidance of negative preparation of the stent.

4.1. Limitations

Our study is limited by the retrospective analysis from the MAUDE database with its inherent selection bias resulting from optional reporting by healthcare professionals. Second, the association between the device failure and clinical adverse events could not be adjudicated. Third, most of the variables are self-reported and could not be determined in each report. Fourth, the incidence of device failure cannot be determined as the study lacks a denominator. Finally, the classification of perforations, according to the Ellis classification, was not reported consistently and could not be analyzed.

4.2. Conclusions

The most common failure mechanisms of covered stents were the failure of delivery, stent dislodgement, and failure to seal the perforation. Failure of delivery was more common with the Graftmaster, while stent dislodgement was more common with the PK Papyrus stent.

CRediT authorship contribution statement

Michael Megaly: conceptualization, Development or design of methodology, statistical analysis, writing the initial draft.
Magi Zordok: data curation, development or design of methodology
Amgad Mentias: data curation
Yashasvi Chugh: data curation
Rupinder S Buttar: data curation
Mir B. Basir: critical review, commentary, and revision
M Nicholas Burke: critical review, commentary, and revision
Dimitrios Karmpaliotis: critical review, commentary, and revision
Lorenzo Azzalini: critical review, commentary, and revision
Khaldoon Alaswad: critical review, commentary, and revision
Emmanouil S. Brilakis: Conceptualization oversight and leadership responsibility for the research activity planning and execution, critical review, commentary, and revision

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Declaration of competing 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.

Lorenzo Azzalini: consulting/speaker honoraria from Abiomed and Teleflex.

M Nicholas Burke: Opsens Medical, speaker. Egg Medical and MHI Ventures, shareholder.

All other authors have nothing to disclose.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.carrev.2021.04.002.

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