Coronary Artery Perforation and Tamponade — Incidence, Risk Factors, Predictors and Outcomes From 12 Years’ Data of the SCAAR Registry —

Jan Harnek, MD, PhD; Stefan James, MD, PhD; Bo Lagerqvist, MD, PhD

Background: The incidence and short- and long-term outcomes of coronary artery perforation (CAP) are not well described.

Methods and Results: We analyzed the characteristics and the short- and long-term outcomes of CAP among 243,149 patients undergoing percutaneous coronary interventions (PCI) from 2005 until 2017 in the national Swedish registry. We identified 1,008 cases of CAP with an incidence of 0.42%. Major adverse event rates were significantly higher in patients with CAP than non-CAP (P<0.001). The 1-year mortality rate was 16% vs. 5.5%, respectively, and the 12-year mortality rate was 52% vs. 34%. The restenosis rate was 5.2% vs. 3.1% and 17% vs. 9%, respectively. The target lesion revascularization rate was 4.2% vs. 2.6% and 10.5% vs. 7%. The stent thrombosis rate was numerically higher, 1.5% vs. 0.8% and 4.5 vs. 2.8%, with no stent thrombosis cases for equine pericardial stent grafts. Among the patients with tamponade a large proportion of cases occurred at the late stage (215/1,008, 21%), and most were not recognized in the cath-lab (167/215, 78%). The mortality rate for late tamponade was similar in patients suffering acute tamponade at 1 year (25.6% vs. 27%) or at 12 years (54% vs. 58%).

Conclusions: CAP is associated with an early high excess in morbidity and mortality but with low risk of additional adverse events in the long term. Late tamponade is as deadly as acute tamponade.

Key Words: Coronary complications; Coronary perforation; Percutaneous coronary intervention; Tamponade

The incidence of coronary artery perforation (CAP) and/or tamponade in patients undergoing percutaneous coronary interventions (PCI) is proportional to the complexity of the procedure, ranging from 0.2–0.4% in non-complex lesions,1,2 to 1.4–4.1% in chronic total occlusions (CTO).3–5 In contemporary registries the 1-year all-cause mortality after CAP is 18–35%, which is 2–3-fold higher than in patients without CAP.6–8 Predictors of CAP have been found to be age, female sex, atherectomy devices, hydrophilic wires, oversized balloons and/or stents, and excessive post dilations, as well as complex procedures such as calcified lesions, previous coronary artery bypass grafting (CABG), and CTO.6–8,9 Perforations based on their angiographic appearance were classified by Ellis et al into tree classes.6 However, this risk stratification may be insufficient because almost 21–25% of CAP cases are not recognized during the procedure, but afterwards in the ward as tamponade.6–8 A fatal outcome of CAP directly correlates with development of tamponade and concurrent arrhythmias with a high need for emergency pericardiocentesis.6–8 There may be differences in the clinical presentation, because a perforation with acute tamponade is likely caused by oversized balloons and a stent in the proximal arteries, whereas distal perforations are likely caused by distal guidewire exits in smaller arteries and many are missed in the catheter laboratory (cath-lab) only to be disclosed as late tamponade in the ward. It is unknown if there are differences in outcomes between acute and late tamponade after a perforation.

We report the incidence, risk factors, and short- and long-term (12 years) outcomes of CAP from the perspective of clinical relevance depending on the occurrence of a perforation and whether it was accompanied by acute or late tamponade.

Methods

Data were collected between 1 May 2005 and 23 January 2017 from the Swedish Coronary Angiography and Angioplasty Register (SCAAR), which is an integrated part of the Swedish Web-system for Enhancement and Development of Evidence-based care in Heart Disease Evaluated According to Recommended Therapies (SWEDHEART), with at least 1 year of follow-up. Data in the SCAAR are recorded online through a web interface for all consecutive patient data from every center (n=30) performing PCI in
Table 1. Baseline Characteristics of the Study Patients

|                        | No CAP | Perforation | Acute tamponade | Late tamponade | P1   | Any CAP | P2   |
|------------------------|--------|-------------|-----------------|----------------|------|---------|------|
| n (%)                  | 242,141| 640         | 153             | 215            |      | 1,008   |      |
| Age (mean (SD))        | 67.4 (10.9) | 69.8 (10.0) | 72.9 (9.7)      | 71.5 (10.1)    | <0.001| 70.6 (10.0) | <0.001|
| Male sex               |        |             |                 |                |      |         |      |
| Hypertension           | 189,031| 503         | 125             | 173            | 0.131|         | 0.030|
| Diabetes, type unknown | 301    | 3           | 0               | 1              | 0.011|         | 0.005|
| Smoker                 | 24,061 | 60          | 9               | 15             | 0.006|         | 0.001|
| Smoking status         | 27,005 | 67          | 16              | 26             |      |         |      |
| Unstable CAD           | 147,158| 424         | 101             | 132            | 0.006| 657     | 0.001|
| Diabetes               | 134,692| 396         | 84              | 108            | 0.005| 588     | 0.033|
| Hypertension           |        |             |                 |                |      |         |      |
| Diabetes               |        |             |                 |                |      |         |      |
| Smoking status         |        |             |                 |                |      |         |      |
| Ex-smoker >1 month     | 59,533 | 275         | 57              | 83             | <0.001| 350    | <0.001|
| Smoker                 | 43,899 | 104         | 20              | 27             | 0.011| 137     | <0.001|
| Previous MI            | 72,732 | 241         | 51              | 58             | <0.001| 350    | <0.001|
| Previous CABG          | 24,259 | 116         | 11              | 10             | <0.001| 137     | <0.001|
| Ex-smoker >1 month     | 72,515 | 213         | 47              | 63             | 0.328| 323     | 0.160|
| Calculated BMI (mean (SD)) | 27.4 (4.4) | 27.1 (4.5) | 26.2 (4.3) | 26.25 (4.1) | <0.001| 26.8    | <0.001|
| Any stent treatment    | <0.001 |             |                 |                |      |         |      |
| Not stented            | 44,656 | 169         | 26              | 50             | 0.901| 245     | 0.243|
| Stented                | 197,375| 363         | 81              | 153            | 0.092| 597     | 0.592|

P1 value between groups. P2 value between patients with No CAP and Any CAP. BMI, body mass index; CAD, coronary artery disease; CABG, coronary artery bypass grafting; CAP, coronary artery perforation and/or tamponade; MI, myocardial infarction; PCI, percutaneous coronary intervention; SD, standard deviation; STEMI, ST-elevation MI.

Sweden. The internet-based system provides each center with immediate and continuous feedback on processes and quality-of-care measures. Automatic quality control is continuously performed on the SCAAR interface. The recording of clinical and angiographic data for each patient is indicated as complete and the case can be closed only if all the mandatory variables have been inserted. Monitoring and verification of registry data are performed annually at least 20%, normal blood flow and no serious complications.

Myocardial infarction (MI) was defined as any rehospitalization after the index procedure registered in the Swedish Register of Information and Knowledge about Swedish Heart Intensive Care Admissions (SWEDEHEART/CCU) with International Classification of Diseases codes I21 and I22.

Vital Data
Data were obtained from the Swedish National Population Registry. The merging of the registries was performed by the Uppsala Clinical Research Center, Uppsala University, Sweden, and approved by the local ethics committee at Uppsala University. Procedural death was defined at the

Sweden. The internet-based system provides each center with immediate and continuous feedback on processes and quality-of-care measures. Automatic quality control is continuously performed on the SCAAR interface. The recording of clinical and angiographic data for each patient is indicated as complete and the case can be closed only if all the mandatory variables have been inserted. Monitoring and verification of registry data are performed annually at least 20%, normal blood flow and no serious complications.

Myocardial infarction (MI) was defined as any rehospitalization after the index procedure registered in the Swedish Register of Information and Knowledge about Swedish Heart Intensive Care Admissions (SWEDEHEART/CCU) with International Classification of Diseases codes I21 and I22.

Vital Data
Data were obtained from the Swedish National Population Registry. The merging of the registries was performed by the Uppsala Clinical Research Center, Uppsala University, Sweden, and approved by the local ethics committee at Uppsala University. Procedural death was defined at the
Table 2. Procedural Characteristics

|                        | Perforation | Acute tamponade | Late tamponade | P1       | Any CAP | P2       |
|------------------------|-------------|-----------------|----------------|----------|---------|----------|
| n (%)                  | 242,141     | 640             | 153            | 215      | 1,008   | <0.001   |

Angiography findings

- Inconclusive or unknown: 1,582 (0.7) vs. 9 (1.4)
- Normal/atheromatosis: 11,874 (4.9) vs. 7 (1.1)
- 1-vessel disease: 107,439 (44.4) vs. 229 (35.8)
- 2-vessel disease: 66,114 (27.3) vs. 189 (29.5)
- 3-vessel disease: 41,071 (17.0) vs. 155 (24.2)
- LMT disease: 14,061 (5.8) vs. 51 (8.0)

Other abbreviations as in Table 1.

P1 value between groups. P2 value between patients with No CAP and Any CAP. AHA, American Heart Association classification; CTO, chronic total occlusion; DEB, drug-eluting balloon; FFR, fractional flow reserve; iFR, instantaneous wave-free ratio; IVUS, intravascular ultrasound; LAD, left anterior descending artery; LCX, left circumflex artery; LMT, left main trunk; OCT, optical coherence tomography; RCA, right coronary artery. Other abbreviations as in Table 1.
HARNEK J et al.

for rehospitalization for a new MI, restenosis, TLR, ST, redo-PCI and MACE (major adverse cardiac events, defined as death, restenosis, new MI, TLR, ST, Redo-PCI) at 1 year after the index procedure and during the 12 year study period were collected.

Perforation and Tamponade These adverse events were reported by the operator and registered both from the discretion of the operator.

Adverse Events Any complication, side-branch closure, perforation, tamponade in the cath-lab, tamponade in the ward, acute CABG, procedural and 1-month mortality were summarized. Furthermore, to observe the long-term outcomes of CAP, data
Coronary Perforation and Tamponade

The following covered stent grafts were used during the study period: Graftmaster RX Coronary Stent Graft (GM: Abbott Vascular Devices, Redwood City, CA, USA); the “Over and Under” (OU), balloon-expandable equine pericardium-covered stainless steel stent (Amnis Therapeutics, Or Akiva, Israel); the 2nd-generation equine pericardium-covered stent “Aneugraft” (Amnis Therapeutics); and the PK Papyrus polyurethane-covered cobalt-chromium-stent (Biotronic, Bülach, Switzerland). Their properties have recently been explained in detail.

Statistical Analysis

Baseline characteristics are summarized with means and standard deviations for continuous variables and frequencies and percentages for discrete variables. Cumulative event rates were estimated with the Kaplan-Meier method as time to event. All individually treated patients were followed until January 2018. Only P values < 0.005 were considered significant. Higher values up to 0.05 were considered hypothesis-generating.

A Forest plot was constructed based on logistic regression with the presence or not of CAP and entered as dependent variable, and the background and procedural factors were forced into the model. As the proportion of missing variables was low, we did not attempt any imputation of the data. Only 1,536 cath-lab (acute) and in the ward at discharge (late). Patients may have ≥ 1 complications and we divided the patients with CAP into the 4 groups: (1) any CAP (sum of subgroups 2–4); (2) perforation (in the cath-lab, without any drainable pericardial effusion) (3) acute tamponade (perforation in the cath-lab causing tamponade and an urgent need for pericardiotentesis); (4) Late tamponade (tamponade first detected in the ward caused by an unrecognized perforation in the cath-lab, including perforations in the cath-lab without acute tamponade).

All patients undergoing PCI during the study period were included in the analyses, including patients undergoing diagnostic procedures with the use of a coronary guide wire, such as imaging or for coronary physiology, and use of atheroablative devices. Treated segments using American Heart Association classifications are registered in the SCAAR. To gain further knowledge about CAP location, proximal or distal, we made a rough approximation and divided it into large arteries 1, 2, 3, 5, 6, 7, 11 and smaller arteries (all other segments), which corresponded to large segments 1, 2, 3, 11, 12, 13, 18 in the CASS classification. The definition was based on the severity of the consequences of the perforation. Large arteries (>3 mm) have a high risk of occluding significant side-branches, with greater effect on hemodynamic stability, a high risk of tamponade and cardiogenic shock and necessity for treatment with a stent graft.

The following covered stent grafts were used during the study period: Graftmaster RX Coronary Stent Graft (GM: Abbott Vascular Devices, Redwood City, CA, USA); the “Over and Under” (OU), balloon-expandable equine pericardium-covered stainless steel stent (Amnis Therapeutics, Or Akiva, Israel); the 2nd-generation equine pericardium-covered stent “Aneugraft” (Amnis Therapeutics); and the PK Papyrus polyurethane-covered cobalt-chromium-stent (Biotronic, Bülach, Switzerland). Their properties have recently been explained in detail.

Statistical Analysis

Baseline characteristics are summarized with means and standard deviations for continuous variables and frequencies and percentages for discrete variables. Cumulative event rates were estimated with the Kaplan-Meier method as time to event. All individually treated patients were followed until January 2018. Only P values < 0.005 were considered significant. Higher values up to 0.05 were considered hypothesis-generating.

A Forest plot was constructed based on logistic regression with the presence or not of CAP and entered as dependent variable, and the background and procedural factors were forced into the model. As the proportion of missing variables was low, we did not attempt any imputation of the data. Only 1,536
patients (0.6%) were excluded from the logistic regression because of missing data. All analyses were conducted in SPSS ver. 24 (IBM Corp., Armonk, NY, USA) and R ver. 3.3.5 equipped with the survival, forest model and table one packages (www.r-project.org).

**Ethics Approval**
The study was approved by the regional Scientific Ethics Committee of Lund University. Because all patients were anonymized in the study (with their social security number substituted by a unique SWEDHEART specific ID-number) no informed consent was deemed necessary by the committee.

## Results

### Any Perforation and/or Tamponade

A total of 1,008 of 243,149 patients were diagnosed with a CAP during the 12-year observation period. Compared with patients without CAP, the affected patients were on average 3 years older and were 13% more often to be female. CAP patients had hypertension and hyperlipidemia significantly more often and a higher incidence of prior MI and CABG. A CTO was found in 25% of CAP patients. Among all CAP cases, 80% occurred in a B2/C lesion, 18% in a failed guidewire attempt, 20% in bifurcations, 76% were stented and in 17% a stent graft was used. Use of a rotablator or cutting balloon was rare (2% and 1%). Clinical baseline characteristics are shown in Table 1 and procedural characteristics in Table 2. Also in patients with a CAP as compared with those without, the number of stent grafts, stents, balloons and the total lengths of stents or stent grafts/patient, and side-branch closure were all significantly higher, which may well have been caused by the treatment of the CAP. Clinical adverse events during the procedure, at 1 month and at 1 year are shown in Table 3. Data were compared with all other non-CAP patients and adverse events, deaths, new MI, restenosis, ST, TLR, redo-PCI and MACE out to 11 years are shown in Figure 1 and Figure 2. Independent associations of CAP are shown in Figure 3. During the time period of the study the incidence of CAP was almost constant Figure 4, although procedural complexity Figure 4 increased numerically as the number of procedures increased from approximately 17,500/year in 2005 to 26,000/year in 2017 (data not shown). In the occurrence of a CAP complete revascularization were lower than for non-CAP patients (39% vs. 66%), as well as procedural success (69% vs. 95%, including 10% of diagnostic procedures).
Coronary Perforation and Tamponade

Long-term adverse events shown in the Kaplan-Meier curves (Figures 1, 2) demonstrate that most events occurred in the first year after the procedure, clearly visualized in the curves for death and MACE. Restenosis after a CAP in the treated segment was initially higher and continued to increase, reaching 17% at 11 years compared with 9% for non-CAP segments. ST in a perforated segment occurred more often the first month and continued to increase before it reached a maximum of 4.2% after 7 years, which is almost twice as high as the incidence in non-CAP segments.

Baseline Factors Associated With CAP (Figure 3)

Significant associations of increased risk of CAP included higher age, female sex, previous smoker, CTO, direct stenting, no stenting, B2C lesions, rotablator, POBA, and unsuccessful wire-attempt. Significant associations of lower risk

Clinical Outcomes of CAP Patients

Among the 1,008 CAP patients, a perforation was diagnosed in the cath-lab in 83% (640+153+48/1,008) and an acute or late tamponade was diagnosed in 37% (153+215/1,008); 48 patients had a perforation in the cath-lab and developed a late tamponade in the ward. Side-branch closure was reported in 2.6% and treatment with emergency CABG occurred in only in 1.2%, both of which were significantly more frequent than for non-CAP patients (0.4% and 0%, respectively). Procedure-related, 1-month and 12-year mortality was 3.7%, 12.6% and 16%, respectively, compared with 0.1%, 2.6% and 5.5% for non-CAP patients. Other adverse events, such as new PCI, ST, restenosis, any TLR and MACE, occurred significantly more often as compared with non-CAP patients (Table 3). However, the incidence of re-hospitalization within 1 year for new MI was not higher.

Figure 3. Forest plot showing the strength of different variables associated with a coronary perforation with and without tamponade. CABG, coronary artery bypass grafting; CAD, coronary artery disease; FFR, fractional flow reserve; IFR, instantaneous wave-free ratio; IVUS, intravascular ultrasound; OCT, optical coherence tomography; STEMI, ST-segment elevation myocardial infarction.
cases caused by a diagnostic procedure the patients had a perforation in the cath-lab that did not lead to tamponade. **Acute Tamponade in the Cath-Lab** This group had the highest proportion of females (52%; 74/153) and the highest mean age (72.9 ± 9.7 years). Compared with the perforation and late tamponade groups, the CAP occurred in larger arteries, and required more stents/stent grafts and longer stents/stent grafts per segment. In this group direct stenting was frequent (41%; 63/153). Interestingly, left main trunk (LMT) disease was found in 7.9% before the treatment, but 9.8% of the patients had some repair performed within the LMT during the procedure because of the CAP. The inci-
Coronary Perforation and Tamponade

Table 4. Subanalysis of Type of Covered Stent Used

| Graftmaster | Over and Under | Aneugraft | PK Papyrus | P value |
|-------------|----------------|-----------|------------|---------|
| n (%)       | 130            | 28        | 26         | 41      |
| Death 1 year after procedure | 24 (18.5) | 14 (50.0) | 5 (19.2) | 7 (17.1) | 0.002 |
| Rehospitalized with MI within 1 year | 7 (5.4) | 1 (3.6) | 2 (7.7) | 6 (14.6) | 0.200 |
| New PCI within 1 year | 21 (16.2) | 4 (14.3) | 5 (19.2) | 11 (26.8) | 0.437 |
| Any ST within 1 year | 5 (3.8) | 0 (0.0) | 0 (0.0) | 4 (9.8) | 0.122 |
| Any in-stent restenosis within 1 year | 12 (9.2) | 5 (17.9) | 3 (11.5) | 3 (7.3) | 0.504 |
| Any TLR within 1 year | 12 (9.2) | 3 (10.7) | 3 (11.5) | 6 (14.6) | 0.806 |
| Any MACE within 1 year | 41 (31.5) | 19 (67.9) | 8 (30.8) | 16 (39.0) | 0.004 |

MACE, major adverse cardiac events including, death, redo-PCI, in-stent restenosis, ST, TLR and new MI. Other abbreviations as in Tables 1, 3.

Our study analyzed coronary perforations from the national and complete SCAAR database and found an incidence of 0.42% with a high risk for early death as well as a higher risk of restenosis, TLR, redo-PCI (all P<0.001) and ST (P<0.052). These events then leveled off and equaled patients without a CAP during 12 years’ follow-up.

Other novel findings were that late tamponade had equally poor prognosis as acute, despite differences in etiology, and that direct stenting was associated with a high risk of a CAP. Additional novel findings were that in CABG patient a CAP rarely resulted in an accompanying tamponade and that equine pericardium-covered type of stent grafts had no incidence of ST.

Perforations with tamponade have the second highest mortality and morbidity rates in contemporary PCI era. We found the incidence of a CAP was rare (0.42% in 243,149 Swedish patients) from 2005 till January 2017. It is in accordance with other contemporary registers that have reported 0.71%,2 0.37%,3 0.33%,7 3.9% and 0.34%.10 The mortality rates were for all CAP at 1 month (13%) and at 1 year (16%) were similar to the finding of others (11% and 18%),11 and 15%9. The 12-year all-cause mortality rate for patients with any CAP was 52%, which was significantly higher as compared with patients who did not suffer any CAP (24%).

Tamponade in relation to a CAP in contemporary large studies has been reported as 51%,2 14%,3 29%,5 14%,9 but none differentiated between outcomes of acute and late tamponade, despite suggested differences in etiology. We found that a CAP resulted in tamponade in 36% of cases. Of those, acute tamponade occurred in 15% and late tamponade in 21%.

Most perforations did not lead to acute tamponade, which may demonstrate the skill of the operators, who were able to treat and avoid development into such a serious complication. In such cases mortality and other MACE rates were slightly elevated in the initial phase, but reassuringly soon paralleled the events curves for non-CAP.

Perforation with acute tamponade is a rare and feared event. We can confirm that perforations with acute tamponade most often occur in large proximal arteries with an average minimal stent diameter >3 mm. The gravity of the situation is depicted in the high number of patients going into cardiogenic shock despite high use of hemodynamic-assist devices, intra-aortic balloon pump (IABP) and LUCAS, and patients undergoing emergency CABG.
Occurrence of late tamponade among all patients with a perforation has in prior publications been reported as high as 24.3% (37/150 patients), and 20.6% (43/149 patients). Late tamponade represented 21.3% (215/1,008) of our CAP cohort. The SCAAR register allowed us to distinguish between the types of CAP and we found that late tamponade was surprisingly serious, as mortality rates throughout the study period were almost as high as for perforations with acute tamponade and significantly higher than for perforations without tamponade. The results are serious, considering that the cause of the perforation is often a guidewire penetration in small and distal arteries. The majority of cases (78%; 167/215) were not recognized during the procedure. Only 4 (2.4%) of these patients received a stent graft; the rest was treated by other means. Considering the high mortality our data suggest that for patients with a CAP without acute tamponade in the cath-lab, but with a later development of a tamponade in the ward, vigilant therapy with pericardial drainage and possibly redo-PCI and perforation sealing may reduce the mortality rate.

We found female sex to be associated with CAP, which echoes contemporary registers and explanatory suggestions have been genetic, anatomic tortuosity and smaller arteries, and hormonal estrogen levels influencing coagulation factors and inflammatory parameters. Bifurcation lesions need special attention during PCI and have an increased risk of a CAP, which was pronounced in patients suffering acute or late tamponade. CTO stenting is associated with an inherent risk for a CAP because of the complex crossing techniques and artery sizing. The prevalence of CTOs (25%) in our study was similar to that for other studies and we too found that CTO was associated with the highest risk of a CAP. However, using intra-vascular ultrasound guidance in the treatment of CTO may prevent over-dilatation, as we found the prevalence of a CAP in this setting was lower.

A novel finding was that direct stenting was associated with a significant risk of CAP. It was performed in approximately 10% more cases of CAP than in non-CAP patients, and also in more women and mostly in the settings of ST-segment elevation MI (STEMI) and non-STEMI. Sizing in direct stenting can be difficult, and particular challenging when an artery is blocked by thrombus, heavily calcified or in a bifurcation, with the risk of over-dilation, which may lead to a CAP. ST has been reported by many authors to be increased after treatment of a CAP as compared with non-CAP. We found the risk only marginally and not significant elevated, driven by perforations without simultaneous tamponade, in which many CTOs were treated and with a high number of unsuccessful wire-attempts and unsuccessful procedures. It is well known that a suboptimal angiographic result with poor run-off is a nidus for ST. It is therefore remarkable that the equine pericardium-covered stents did not have any ST recorded, which suggests unique properties of the material, as noted previously. Many patients have been admitted for emergency surgery, in the older literature approximately 20–40%. A worldwide increase in the complexity of PCI procedures, including development of new techniques and better tools, has resulted in a reduction in the need for emergency surgery to 3–13%. In this study it was even more rare: 1.2%. We found a significantly higher incidence of a CAP in CABG patients but reassuringly the risk of treating a saphenous vein graft or arterial graft was not significantly different from non-CAP patients. The high incidence was only found in perforations without tamponade, which may be explained by pericardial tissue adhesion post-CABG.

An increase in the incidence of a CAP in approximately the same time period has been found by others (0.31–0.45%, 0.32–0.68%, 0.29–0.36%) and it has been speculated to be caused by the increased complexity of PCI procedures. We found the incidence to be almost constant, even though the crude number of complex procedures almost doubled from 2005 to 2017. That the complexity of procedures has not resulted in an increase in CAP may be explained by the considerable improvements in devices and their fast implementation by operators.

Entirely diagnostic procedures such as FFR/instantaneous wave-free ratio and optical coherence tomography have a significantly lower risk of CAP, indicating that such procedures are relatively safe. IVUS was used in the same percentage of CAP as in non-CAP procedures without any increased risk of CAP, contrary to prior publications, which have found an increased risk. Another baseline factor associated with a low risk for CAP was insulin-treated diabetes, a finding also noted by others. One explanation could be that patients with diabetes who underwent PCI were suitable and selected for the procedure and the more complex diabetic patients underwent CABG.

Patients having a significantly increased risk of CAP were older, female, have CTO or B2/C lesions and undergo procedures using a rotablator, a similar to finding to others.

**Study Limitations**

In an observational register study, the impact of unmeasured confounders cannot be excluded. Angiographic follow-up was only performed in symptomatic patients and images were not available for review. The sequential causal relation to an adverse event is not registered in the SCAAR. As an example, side-branch occlusion is probably associated with the treatment of a CAP by stent graft. Another example is cardiogenic shock, which would probably be caused by the hemodynamic compromise as a result of tamponade. Neither is it registered exactly how the CAP was treated, such as pericardial drains, ventilatory support etc.

Ellis class and pericardiocentesis are not registered in the SCAAR, but CAPs and tamponade are. Using CAP with or without tamponade should allow the reader to view the situation from the cath-lab perspective, so it can be easily placed into clinical perspective for estimating the outcome of CAP. From the adverse events it is obvious that most patients in the perforation group would be in Ellis class I or II. And equally clear that most patients in the acute tamponade group would be in Ellis class II or III. The shortcomings of the Ellis classes would be the very serious and often missed perforations emerging as late tamponade cases in the ward.

Large differences between the stent grafts were observed, and the relative low number of stent grafts used accumulated few events. Because of procedural confounders that we could not adjust for, it limits the robustness of any conclusion for specific graft types.

Data on cardiogenic shock and usage of LUCAS contained important information to the study, but unfortunately, these parameters first came into the SCAAR in 2009, and as new variables until fully implemented, both data-sets contained approximately 16% missing values.

Circulation Journal Vol.84, January 2020
Conclusions

CAPs with or without tamponade are rare but strongly associated with adverse events in the short-term, compared with procedures without these complications. Perforations resulting in late tamponade have poor outcomes and warrant proactive treatment. The 1-month all-cause mortality after a perforation is almost 5-fold increased initially, but if the patient survives after the first month the prognosis is good and almost equal to that for patients without a perforation or tamponade.

Acknowledgments

We express our gratitude to all Swedish PCI-hospitals and their staff for conscientiously and thoroughly filing every coronary procedure into the SCAAR database for the past 3 decades.

Disclosures

The authors have no conflicts of interest to disclose.

References

1. Javaid A, Buch AN, Satler LF, Kent KM, Suddath WO, Lindsay J Jr, et al. Management and outcomes of coronary artery perforation during percutaneous coronary intervention. Am J Cardiol 2006; 98: 911 – 914.
2. Lemmert ME, van Bommel RJ, Diletti R, Wilschut JM, de Jaegere PP, Zijlstra F, et al. Clinical Characteristics and management of coronary artery perforations: A single center 11-year experience and practical overview. J Am Heart Assoc 2017; 6: e007049.
3. Danek BA, Karatasakis A, Tajti P, Sandoval Y, Karpmpaliotis D, Alaswad K, et al. Incidence, treatment, and outcomes of coronary perforation during chronic total occlusion percutaneous coronary intervention. Am J Cardiol 2017; 120: 1285 – 1292.
4. Kinnaird T, Anderson R, Ossei-Gerning N, Cockburn J, Sirker A, Ludman P, et al. Legacy effect of coronary perforation complicating percutaneous coronary intervention for chronic total occlusive disease: An analysis of 26 807 cases from the British Cardiovascular Intervention Society Database. Circ Cardiovasc Interv 2017; 10: e004642.
5. Guttmann OP, Jones DA, Gulati A, Kotecha T, Fayed H, Patel D, et al. Prevalence and outcomes of coronary artery perforation during percutaneous coronary intervention. EuroIntervention 2017; 13: e595 – e601.
6. Shimony A, Joseph L, Mottillo S, Eisenberg MJ. Coronary artery perforation during percutaneous coronary intervention: A systematic review and meta-analysis. Can J Cardiol 2011; 27: 843 – 850.
7. Kinnaird T, Anderson R, Ossei-Gerning N, Cockburn J, Sirker A, Ludman P, et al. Coronary perforation complicating percutaneous coronary intervention in patients with a history of coronary artery bypass surgery: An analysis of 309 perforation cases from the British Cardiovascular Intervention Society database. Circ Cardiovasc Interv 2017; 10: e005581.
8. Al-Lamee R, Lelasi A, Latib A, Godino C, Ferraro M, Mussardo M, et al. Incidence, predictors, management, immediate and long-term outcomes following Grade III coronary perforation. J Am Coll Cardiol Intv 2011; 4: 87 – 95.
9. Kinnaird T, Kwok CS, Kontopantelis E, Ossei-Gerning N, Ludman P, deBelder M, et al; British Cardiovascular Intervention Society and the National Institute for Cardiovascular Outcomes Research. Incidence, determinants, and outcomes of coronary perforation during percutaneous coronary intervention in the United Kingdom between 2006 and 2013: An analysis of 527 121 cases from the British Cardiovascular Intervention Society database. Circ Cardiovasc Interv 2016; 9: e003449.
10. Parch J, Seth M, Green J, Sutton NR, Chetcuti S, Dixon S, et al. Coronary artery perforations after contemporary percutaneous coronary interventions: Evaluation of incidence, risk factors, outcomes and predictors of mortality. Catheter Cardiovasc Interv 2017; 89: 966 – 973.
11. Ellis SG, Ajluni S, Arnold AZ, Popma JJ, Bittl JA, Eigler NL, et al. Increased coronary perforation in the new device era: Incidence, classification, management, and outcome. Circulation 1994; 90: 2725 – 2730.
12. Jernberg T, Attebring MF, Hambraeus K, Ivert T, James S, Jeppsson A, et al. The Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated according to Recommended Therapies (SWEDEHEART). Heart 2010; 96: 1617 – 1621.
13. Cutlip DE, Windecker S, Mehran R, Boam A, Cohen DJ, van Es GA; on behalf of the Academic Research Consortium. Clinical end points in coronary stent trials: A case for standardized definitions. Circulation 2007; 115: 2344 – 2351.
14. Alderman EL, Stadius M. The angiographic definitions of the Bypass Angioplasty Revascularization Investigation study (BARI). Coron Artery Dis 1992; 3: 1189 – 1207.
15. Kilic ID, Fabris E, Serdooz N, Ciazzio G, Foin N, About-Sherif S, et al. Coronary covered stents. EuroIntervention 2016; 12: 1288 – 1295.
16. Ioannidis JPA. The proposal to lower P value thresholds to .005. JAMA 2018; 319: 1429 – 1430.
17. Harnesk J, James S, Lagerqvist B. Very long-term outcome of coronary covered stents: A report from the SCAAR registry. EuroIntervention 2019; 14: 1660 – 1607.