Prevalence and Predictors of Coronary Artery Perforation During Percutaneous Coronary Interventions (from the ORPKI National Registry in Poland)

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Coronary artery perforation (CAP) is a rare but potentially life-threatening complication of percutaneous coronary intervention (PCI). With a growing number of PCIs in complex lesions, the problem of CAP becomes even more important nowadays. Data on CAP rates in Poland are lacking. Presented study is an analysis of 344,517 consecutive patients treated with PCI between 2014 and 2017. Data were gathered from the Polish National PCI Registry (ORPKI). During 4 years of data collection CAP was observed in 595 (0.17%) cases. Patients diagnosed with CAP were older (69 years Q1:63; Q3:78 vs 66 years Q1:60; Q3:75; p <0.001), more often female (44% vs 32%; p <0.001), with arterial hypertension (77% vs 71%; p = 0.002), and chronic kidney disease (8.9% vs 5.4%; p <0.001). In the CAP group, a higher rate of PCIs within chronic total occlusions (8.7% vs 2.3%; p <0.001) and saphenous vein graft lesions (2.7% vs 1.3%; p = 0.002), as well as rotational atherectomy procedures (2.2% vs 0.4%; p <0.001) was observed. Patients with CAP had higher rate of no-reflow phenomenon (5.5% vs 0.5%; p <0.001) and greater periprocedural mortality (4.2% vs 0.5%; p <0.001). In conclusion, our study confirms that CAP is more common during complex PCI procedures in high-risk patients. CAP occurrence is associated with worse immediate outcomes including increased periprocedural mortality. **(Am J Cardiol 2019;124:1186−1189)**

Coronary artery perforation (CAP) is a rare, however potentially life-threatening complication of percutaneous coronary interventions (PCI) which can rapidly lead to death secondary to cardiac tamponade. Previous studies report a rate of CAP of up to 1%.[1−6] Older age, female gender, the presence of calcified, tortuous lesions, and use of rotational atherectomy have been identified as risk factors of CAP.[2,6] Data about the rates of CAP in Polish population are lacking. This study aimed to examine the prevalence, procedural characteristics and predictors of CAP in an all-comers contemporary population in Poland.

Methods

The presented study is an analysis of prospectively collected data from consecutive PCI procedures between 2014 and 2017, stored through electronic case report forms in a database of National PCI Registry (ORPKI) operated by the Jagiellonian University Medical College in Krakow and endorsed by the Polish Association of Cardiovascular Interventions of the Polish Cardiac Society. ORPKI is a national registry collecting data on all PCI procedures performed in Poland.[7−9] For this analysis data on 344,517 consecutive procedures were retrieved from the database. The study included both stable angina and acute coronary syndrome patients. Patients' demography, baseline clinical characteristics, angiography, and PCI details as well as periprocedural pharmacotherapy were analyzed. CAP was defined as evidence of extravasation of dye or blood from the coronary artery during or following the PCI procedure. CAP was assessed by PCI operators but not by core-lab. Information on presence or absence of CAP was collected in the database.

Standard descriptive statistics were used in the analysis. Quantitative variables were described with median with interquartile range (for non-normal distribution of data). Categorical variables were presented as counts and percentages. Normality was assessed by the Kolmogorov-Smirnov-Lillifors test. Equality of variances was assessed using the Levene's test. Differences between groups were compared using the Student's or the Welch's *t* Test depending on the equality of variances for normally distributed variables. The Mann-Whitney *U* test was used for non-normally distributed variables. For categorical (nominal and dichotomous) variables the Pearson's chi-squared or the Fisher's exact test if 20% of cells had expected

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Table 1
Demography and baseline clinical presentation

Variable	Coronary artery perforation		p	OR (95% CI)	p
	NO (n = 343,922)	YES (n = 595)			
Age (years) (Q1; Q3)	66 (60; 75)	69 (63; 78)	<0.001	1.28* (1.19−1.38)	<0.001
Female	32%	44%	<0.001	1.67 (1.42−1.96)	<0.001
Weight (kg) (Q1; Q3)	80 (70; 90)	77 (69; 86)	<0.001	0.98 (0.98−0.99)	<0.001
Active smoker	19.4%	22.3%	0.069	1.2 (0.99−1.45)	0.07
Arterial hypertension	71%	77%	0.002	1.34 (1.11−1.63)	0.002
Chronic kidney disease	5.4%	8.9%	<0.001	1.70 (1.28−2.26)	<0.001
Prior CABG	6.3%	9.1%	0.006	1.48 (1.20−1.96)	0.006
Prior PCI	36.6%	36%	0.72	0.97 (0.82−1.14)	0.73
Prior stroke	3.3%	6.5%	<0.001	2.05 (1.48−2.84)	<0.001
Indication for PCI			0.049		
STEMI	26.3%	27.7%		1.07 (0.90−1.29)	0.43
NSTEMI	19.9%	24.2%		1.29 (1.07−1.55)	0.01
Unstable angina pectoris	28%	23.9%		0.80 (0.66−0.97)	0.02
Stable angina pectoris	25%	23.4%		0.91 (0.75−1.10)	0.34

* For each 10 years, CABG = coronary artery bypass grafting; PCI = percutaneous coronary intervention; STEMI = ST elevation myocardial infarction; NSTEMI = non-ST elevation myocardial infarction.

count <5 were used. Both univariate and multivariate logistic regression analyses were performed to identify predictors of CAP. Results are presented as odds ratios (OR) with an associated 95% confidence interval (CI). The level of statistical significance was set at p <0.05. All analyses were calculated with JMP, Version 14.0.0 (SAS Institute Inc., Cary, North Carolina).

Results

During 4 years of data collection, CAP was observed in 595 (0.17%) patients undergoing PCI. Patients diagnosed with CAP were older, more often women, with arterial hypertension and chronic kidney disease (Table 1). Angiography and PCI details are presented in Table 2. In the CAP

Table 2
Procedural characteristics

Variable	Coronary artery perforation		p	OR (95% CI)	p
	NO (n = 343,922)	YES (n = 595)			
Result of angiography			<0.001		
1-vessel disease	47%	35%		0.65 (0.54−0.79)	<0.001
LMCA disease	0.3%	0.2%		0.52 (0.19−1.38)	0.19
MVD	47%	55%		1.78 (1.41−2.23)	<0.001
MVD and LMCA disease	6%	10%		2.30 (1.53−3.46)	<0.001
Procedural details					
Chronic total occlusion	2.3%	8.7%	<0.001	4.14 (3.11−5.50)	<0.001
Rotational atherectomy	0.4%	2.2%	<0.001	5.28 (3.04−9.17)	<0.001
Femoral access	29%	34%	0.003	1.29 (1.09−1.53)	0.003
TIMI 0 or 1 before PCI	35%	48%	<0.001	1.71 (1.45−2.01)	<0.001
TIMI 3 after PCI	93.7%	68.6%	<0.001	0.15 (0.12−0.17)	<0.001
No-reflow during PCI	0.5%	5.5%	<0.001	11.26 (7.9−16)	<0.001
BVS implantation	1.3%	2.3%	0.03	1.76 (1.04−3)	0.04
Contrast dye (ml) (Q1; Q3)	150 (120; 200)	200 (150; 280)	<0.001		
Radiation dose (Gy) (Q1; Q3)	0.8 (0.4; 1.4)	1.4 (0.8; 2.3)	<0.001		
ASA during PCI	57%	67%	<0.001	1.55 (1.29−1.87)	<0.001
Clopidogrel during PCI	50%	49%	0.66	0.96 (0.81−1.14)	0.66
Ticagrelor during PCI	27%	33%	0.006	1.31 (1.08−1.59)	0.006
Prasugrel during PCI	0.82%	0.65%	1.0	0.79 (0.25−2.45)	0.68
UFH during PCI	89%	93%	0.017	1.46 (1.07−2.00)	0.02
GP IIb/IIIa during PCI	13%	17%	0.004	1.42 (1.12−1.80)	0.004
Periprocedural mortality	0.5%	4.2%	<0.001		
Cardiac arrest during PCI	0.6%	7.1%	<0.001		

LMCA = left main coronary artery; MVD = multi vessel disease; TIMI = thrombolysis in myocardial infarction; PCI = percutaneous coronary intervention; BVS = bioresrobable vascular scaffold; Gy = Grey; ASA = acetylsalicylic acid; UFH = unfractionated heparin; GP = glycoprotein.

Table 3
Multivariate logistic regression model for predicting coronary artery perforation

	Odds ratio	Lower 95% CI	Higher 95% CI	p
Age (per 10 years)	1.17	1.08	1.27	<0.001
Female gender	1.48	1.24	1.76	<0.001
Weight (per 10 kg)	0.93	0.88	0.98	0.009
Previous CABG	1.42	1.07	1.89	0.02
Chronic kidney disease	1.38	1.03	1.84	0.04
Chronic total occlusion	4.07	3.05	5.42	<0.001
Rotational atherectomy	4.52	2.59	7.87	<0.001
Multivessel disease	1.69	1.35	2.13	<0.001

CABG = coronary artery bypass grafting.

group, we observed a higher rate of PCIs within chronic total occlusions and saphenous vein graft (SVG) lesions, as well as rotational atherectomy procedures. In univariate logistic regression analysis, rotational atherectomy during PCI as well as PCI of chronic total occlusion (CTO) were associated with a higher risk of CAP (Table 2). Implantation of bioresorbable scaffolds (BVS) was more common in the CAP group. Patients diagnosed with CAP had a higher rate of no-reflow phenomenon and greater periprocedural mortality (Figure 1). Age, female gender, previous coronary artery bypass grafting (CABG), presence of chronic kidney disease, multivessel disease, intervention in CTO as well as usage of rotational atherectomy during PCI were independent predictors of CAP in a multivariate logistic regression model (Table 3). Culprit lesion in SVG, mid-portion of the left anterior descending coronary artery and right coronary artery (regardless of the artery segment) were associated with the highest risk of CAP when analyzed according to PCI lesion location in a univariate logistic regression analysis (Table 4).

Discussion

The major finding of our study is that CAP is a relatively rare complication of PCI. We observed CAP in 0.17% of patients undergoing PCI. In a British study from 2017 on 39,115 patients, the rate of CAP was 0.37%.[2] Another study on 6,425 patients showed an incidence of CAP of 0.8%.[3] In

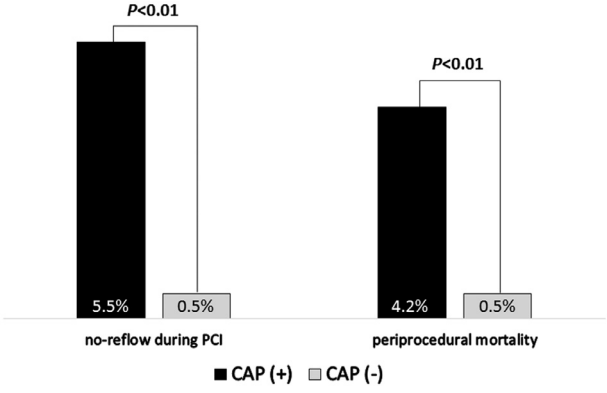

Figure 1. Periprocedural outcome. Patients diagnosed with CAP had higher rate of no-reflow phenomenon and greater periprocedural mortality.

Table 4
Perforation site according to coronary anatomy. Univariate logistic regression model

Variable	OR	Lower 95% CI	Upper 95% CI	p
Left anterior descending artery	0.96	0.79	1.16	0.65
Proximal	0.76	0.59	0.97	0.03
Mid	1.52	1.22	1.89	<0.001
Distal	1.64	0.96	2.79	0.07
1st Diagonal	0.64	0.32	1.28	0.21
2nd Diagonal	1.04	0.15	7.39	0.97
Circumflex artery	0.71	0.55	0.93	0.01
Proximal	0.72	0.49	1.06	0.10
Mid	0.75	0.53	1.06	0.10
Distal	1.19	0.66	2.17	0.56
1st ObtuseMarginal	0.78	0.48	1.25	0.30
2nd ObtuseMarginal	1.46	0.69	3.07	0.32
3rd ObtuseMarginal	1.01	0.14	7.2	0.99
Right coronary artery	1.26	1.05	1.52	0.01
Proximal	1.37	1.08	1.73	0.01
Mid	1.28	1.03	1.6	0.03
Distal	1.36	1.01	1.82	0.04
Saphenous vein graft	2.34	1.4	3.91	0.001

2005 Ramana et al examined 4,886 patients undergoing PCI and confirmed diagnosis of CAP in 0.5% of cases.[4] In a Japanese study from 2002 on 7,449 patients, the rate of CAP was 0.9%.[5] A meta-analysis from 2011 of 16 studies involving 197,061 patients showed a pooled incidence of CAP of 0.43%.[6] Lower rate of CAP in presented analysis may be partially explained by lack of core lab angiograms analysis as well as by lack of out-of-cathlab data.

In our analysis patients with CAP were older, more often women, with chronic kidney disease and history of CABG, which is consistent with previous studies.[2,5,10] In presented analysis, in the CAP group we observed higher rate of PCIs involving CTO and SVG lesions and rotational atherectomy, which is also consistent with previous reports.[11–13] A study from 2016 on 527,121 patients showed that CTO lesions and rotational atherectomy are predictive of CAP (OR = 3.96; 95% CI 3.28 to 4.78; p <0.001 and OR = 2.37; 95% CI 1.8 to 3.11; p <0.001, respectively).[12] In 2017 Guttman with colleagues showed a growing incidence of CAP across study period: from 0.31% in 2005 to 0.45% in 2016. During the same time, the investigators observed an increase of PCIs involving CTO lesions and rotational atherectomy and in patients with a history of CABG and multivessel disease.[2] In presented study, patients diagnosed with CAP were more commonly treated with PCI with BVS implantation. In a study which included consecutive patients who underwent PCI in Poland in years 2014 to 2015, implantation of BVS was an independent predictor of CAP (OR = 6.728, 95% CI 2.39 to 18.91; p = 0.001).[14] Possibly, the recommended technique for BVS implantation, which included extensive lesion preparation and high pressure postdilatation may have contributed to higher rates of this complication. In our analysis, femoral access was more frequent in the CAP group. In contrast, femoral access is often preferable in hemodynamically unstable patients or during complex PCIs including PCIs of CTO lesions.

In presented study, patients with CAP had greater periprocedural mortality (4.2% vs 0.5%; p <0.001). In an analysis by Guttman et al the mortality rate in patients with CAP was 4.0%, however that study included a whole hospital course as opposed to our analysis which included only periprocedural data. Operator and cathlab preparation is crucial for rapid CAP treatment to prevent fatal outcomes. This includes rapid echocardiographic assessment with pericardiocentesis when indicated and immediate prolonged balloon inflation at the CAP site followed by stent or stentgraft implantation if necessary. In some cases, additional techniques like double catheter approach for bleeding limitation during stentgraft delivery or vessel embolization in persistent bleeding from distal perforation may be an option. This all underlines the value of operator education in CAP diagnostics and treatment. In presented study, some types of interventions like CTO, rotational atherectomy or SVG interventions were at high risk of CAP what emphasizes the importance of careful observation of angiography and patient clinical status during and after the procedure. In some cases, routine interval echocardiographic assessment may be indicated.

Our study has some limitations. First of all, the ORPKI database consists of data coming only from the cathlabs, thus follow-up was limited to periprocedural period. Long-term outcomes, data on further treatment and possible surgical interventions were not available. The data on antiplatelet/antithrombotic agents and other drugs administered before or after admission to the cathlab were not available, thus observed differences in use of these agents might be biased. Data about the severity and classification of CAP were not available. Subtle image of type 1 of CAP as well as lack of the data on out-of-cathlab diagnosis of pericardial effusion might cause an underestimation of this complication in our study.[15]

In conclusion, our study confirms that CAP is more common during complex PCI procedures in high-risk patients. CAP occurrence is associated with worse immediate outcomes including increased periprocedural mortality.

Disclosures

The authors have no conflicts of interest to disclose.

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