

## Multi-Center Experience of Coronary Artery Perforation During Percutaneous Coronary Intervention: Clinical and Angiographic Characteristics, Management, and Outcomes Between 2010 and 2020

### ORIGINAL INVESTIGATION

#### ABSTRACT

**Background:** Coronary artery perforations are one of the most feared, rare, and catastrophic complication of percutaneous coronary intervention. Despite the remarkable increase in coronary angiography and percutaneous coronary intervention, there is no large database that collects coronary artery perforation for the Turkish population. Our study aimed to report our experience over a 10-year period for clinical and angiographic characteristics, management strategies, and outcomes of coronary artery perforation during the percutaneous coronary intervention at different cardiology departments in Turkey.

**Methods:** The study data came from a retrospective analysis of 48 360 percutaneous coronary intervention procedures between January 2010 and June 2020. A total of 110 cases who had coronary artery perforation during the percutaneous coronary intervention were found by angiographic review. Analysis has been performed for the basic clinical, angiographic, procedural characteristics, the management of coronary artery perforation, and outcome of all patients.

**Results:** The coronary artery perforation rate was 0.22%. Out of 110 patients with coronary artery perforation, 66 patients showed indications for percutaneous coronary intervention with acute coronary syndrome and 44 patients with stable angina pectoris. The most common lesion type and perforated artery were type C (34.5%) and left anterior descending (41.8%), respectively. The most observed coronary artery perforation according to Ellis classification was type III (37.2%). Almost 52.7% of patients have a covered stent implanted in the perforated artery. The all-cause mortality rate of coronary artery perforation patients in the hospital was 18.1%.

**Conclusion:** The observed rate of coronary artery perforation in our study is consistent with the studies in this literature. However, the mortality rates related to coronary artery perforation are higher than in other studies in this literature. Especially, the in-hospital mortality rate was higher in type II and type III groups due to perforation and its complications. Nevertheless, percutaneous coronary intervention should be done in selected patients despite catastrophic complications.

**Keywords:** Coronary artery perforation, in-hospital mortality, 1-year mortality

#### INTRODUCTION

Many studies have investigated coronary artery perforations (CAPs) as one of the most feared, rare, and catastrophic complications of percutaneous coronary intervention (PCI).<sup>1-4</sup> According to previously published studies, the incidence of CAP is 0.1%-3%.<sup>4-6</sup>

Turkey is a developing country, and its population reached 83.15 million people in 2020. Approximately 450 000 coronary angiography (CAG) procedures are performed per year, and the number of PCIs is increasing from day to day in Turkey.<sup>7</sup> Despite the remarkable increase in CAG and PCI, there are no large data about CAP in the Turkish population.

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The first aim of our study was to report our experience over a 10-year period for clinical and angiographic characteristics, management strategies, and outcomes of CAP during PCI at different cardiology departments in Turkey. The second aim was to compare our data with the existing literature.

## METHODS

### Study Design and Patients

This study was a multicenter, retrospective analysis of 10-year PCI data of patients treated from January 2010 to June 2020. During this period, 120 254 CAG procedure records were analyzed in 5 high-volume centers. It is approximately 5%-10% of all CAG procedures in Turkey. A total of 48 360 PCI procedures were identified from the database of all participated hospitals. A total of 110 cases who had CAP during PCI were detected by a retrospective review of the interventions according to international classification disease codes. The International classification disease code number of CAP was T81 (complications of procedures not elsewhere classified), and subgroup was T81.535A (perforation due to a foreign body accidentally left in the body following heart catheterization). The study included patients with a diagnosis of an ST-segment elevation myocardial infarction (STEMI), non-ST segment elevation myocardial infarction (NSTEMI), unstable angina pectoris (UAP), and stable angina pectoris.<sup>8</sup> Three physicians performed retrospective analyses of basic clinical, angiographic, procedural characteristics, management of CAP, and outcome of all patients. All CAP patients were followed up for 1 year through hospital visits, public health centers, and electronic medical records. Our study was approved by the Ethical Committee of the Faculty of Medicine at Celal Bayar University (June 29, 2020, No. 84) and has been performed per the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

### Definition and Classification of Coronary Artery Perforation

Coronary artery perforation was defined as the evidence of extravasation of dye or blood from the coronary artery during or following the PCI procedure using the British Cardiovascular Intervention Society's definition criteria. It was determined either by angiographic appearances consistent with dye outside the vessel lumen or by echocardiographic evidence of pericardial effusion.<sup>3</sup>

## HIGHLIGHTS

- Despite the remarkable increase in coronary angiography and percutaneous coronary intervention, there are no large data about coronary artery perforation (CAP) in the Turkish population.
- This study is the first study to report experience over a 10-year period for clinical and angiographic characteristics, management strategies, and outcomes of CAP during percutaneous coronary at different cardiology departments in Turkey.
- Also, we compared our data with the existing literature.

The severity of perforations was graded using the Ellis classification as follows: class I points out an extraluminal crater without extravasation; class II points out pericardial/myocardial blush without contrast jet extravasation; class III points out extravasation through more than 1 mm perforation, and class III/CS (IV) points out extravasation into a cardiac chamber or coronary sinus.<sup>1</sup> Pericardial effusion obtained by fluoroscopy or echocardiography, sudden drop in systolic arterial blood pressure (<90 mm Hg), the occurrence of pulsus paradoxus, and diastolic collapse of the cardiac chambers were accepted as cardiac tamponade.<sup>9</sup>

### Procedural Characteristics

Baseline clinical characteristics, including risk factors for coronary artery disease, 12-lead electrocardiograms, diagnoses of patients, previous drug treatment, biochemical markers, and an indication of PCI, were registered. The elevation of troponin I or creatine kinase muscle/brain more than 5 times the upper limit of normal value within 24 hours of PCI was defined as periprocedural myocardial infarction.<sup>10</sup> Culprit vessel and lesion location of all cases were obtained by detailed angiographic analysis. Lesion type was defined according to the American College of Cardiology/American Heart Association (ACC/AHA) classification.<sup>11</sup> Angiographic characteristics of lesions in culprit coronary artery such as tortuosity, calcification, chronic total occlusion, and lesion length were noted.<sup>12</sup> Mechanisms of CAP occurred by pre- or post-dilatation with the balloon, wire exit, stent implantation, and type of guidewire used were also recorded. In-hospital adverse events like cardiac tamponade, acute stent thrombosis, major bleeding, cardiogenic shock, reinfarction, cerebrovascular accident, coronary artery bypass grafting (CABG) due to PCI complication, and death were obtained from hospital records and Death Record System. Adverse events that developed within 1-year of follow-up were also registered. Bleeding requiring blood transfusion and retroperitoneal bleeding was defined as major bleeding. The management of CAP during PCI such as pericardiocentesis, balloon inflation, covered stent implantation, coil embolization, administration of protamine sulfate, or emergency CABG was also reported.

### Statistical Analysis

Statistical analyses were performed using IBM Statistical Package for the Social Sciences V25 (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0.IBM). Continuous variables were presented as mean + standard deviation and also categorical variables were presented as the frequency and percentage. Pearson  $\chi^2$  test or Fisher's exact tests of independence assessment were used to determine the relationship between categorical variables. The Student's *t* test was used to compare the means between 2 independent groups. The Mann-Whitney *U* test was used to compare differences between 2 independent groups when the dependent variable is either continuous or not normally distributed. Kruskal-Wallis *H* test was used for more than 2 independent groups for independent continuous variables. Pairwise comparisons were evaluated via Dunn's test. All statistical hypothesis tests performed under 2-tailed type 1 error assumption and *P* < .05 showed statistical significance.

**Table 1. Total Percutaneous Coronary Intervention, Coronary Artery Perforation, and Indication for Procedure**

PCI and CAP	n	%
Total number of CAG	120.254	100
Total number of PCI	48.360	40.2
Total number of CAP	110	0.22
<b>Indication of PCI for CAP patients</b>		
Unstable angina pectoris (UAP)	17	15.7
Non-ST-segment elevation myocardial infarction (NSTEMI)	23	21.1
ST segment elevation myocardial infarction (STEMI)	26	22.9
Stable angina pectoris (SAP)	44	40.3

PCI, percutaneous coronary intervention; CAG, coronary angiogram; CAP, coronary artery perforation.

## RESULTS

During the 10-year study period, the CAP rate across the 5 centers was 0.22% (Table 1).

### Baseline Clinical Characteristics

Of 110 CAP patients, the indication for PCI was acute coronary syndrome (ACS) in 66 patients (STEMI with 26 patients, NSTEMI with 23 patients, and UAP with 17 patients) and SAP with 44 patients (Table 1). The mean age of the study population was  $68 \pm 12$  years, and 37.6% of them were female. Smoking ( $P < .001$ ) and body mass index (BMI) ( $P = .014$ ) were statistically significant between males and females. Smoking prevalence and median BMI were higher in males than females. Other baseline clinical characteristics were similar (Table 2).

### Electrocardiogram and Baseline Angiographic Characteristics

A total of 96 patients had sinus rhythm on admission. Percutaneous coronary intervention was performed via the femoral artery in 82 (74.3%) of all CAP patients; 72 patients had 2 or more vessel lesions. The left anterior descending (LAD) artery was the target vessel in 55 patients for PCI. The most common lesion type was type C (34.5%). In-stent restenosis was present in 17 (15.4%) patients. Percutaneous coronary intervention procedure was performed because of a chronic total occlusion in 25 (22.7%) patients. Significant tortuosity and moderate to severe calcification were observed in 37 (33.6%) and 34 (30.9%) patients, respectively.<sup>13</sup> The mean Syntax score of all CAP patients was  $15.2 \pm 6.9$ . The most common perforated artery was LAD (50%). The most frequent CAP location belonged to the middle or distal part of the vessel (65.4%) (Table 3).

### Procedural Characteristics

The median vessel diameter was 3.0 [2.0-4.5] mm. The most frequent CAP according to the Ellis classification was type III (37.2%) and the second most frequent CAP was type II (33.6%). Coronary artery perforation more frequently occurred during post-dilatation (41.8%) and was predominantly due to non-compliant balloon (33.6%). Vessel to oversized balloon ratio for post-dilatation was approximately 0.7 and

high-pressure inflation. Besides this, most of the guidewire-related perforations belonged to type I, with 16 patients (76.2%). Balloon-related perforations were presented as type III, with 24 patients (42.9%), and stent-related perforations were presented as type III, with 17 (54.8%) patients. Most frequently, guidewire-related perforations occurred due to the use of hydrophilic guidewires. Stent implantation was the cause of CAP in 31 patients (28.2%) due to oversized stents. In our patient group, there was no CAP case due to cutting balloon or using atheroablative device (Table 4). All CAP patients received diagnosis during PCI except 2 type II patients. Two patients had hemodynamic instability due to cardiac tamponade in the coronary care unit after PCI. They were taken to the CAG unit again and CAPs were observed in CAG.

### Clinical Course

Pericardial effusion was detected in 67 (60.9%) CAP patients, and 36 (32.7%) patients were presented as cardiac tamponade. Periprocedural myocardial infarction was diagnosed in 11 (10.0%) patients. Cardiogenic shock was recognized in 24 (21.8%) CAP patients during PCI. Cardiopulmonary resuscitation was performed in 20 (18.1%) of 110 CAP patients. The periprocedural mortality rate of CAP patients was 9.0% (Table 5).

### Management of CAP

Coiling of the perforated coronary artery was performed in 1 patient (0.9%). Pericardiocentesis was required in 32 patients (29.1%). The most frequent treatment strategy was prolonged balloon inflation (60.0%). The covered stent was implanted in the perforated artery in 58 patients (52.7%). The most commonly used covered stent was Graftmaster (Abbott Vascular, Santa Clara, Calif, USA), and it was mostly implanted in Ellis type III. Intra-aortic balloon pump was used for 16 patients (14.5%). Coagulant agent (protamine sulfate) injection and blood transfusion were required in 7 (6.3%) and 21 patients (19.0%), respectively. A transient pacemaker was implanted in 26 patients (23.6%). Coronary artery bypass grafting was deemed necessary in 19 patients (17.2%). Thrombolysis in myocardial infarction III flow was accomplished in 65 patients (59.0%) during PCI. When the patient records were examined, it was seen that prolonged balloon inflation was applied as the initial strategy. If bleeding could not be controlled with balloon inflation, a graft stent was inserted. Pericardiocentesis was performed if cardiac tamponade occurred in the follow-up of patients whose graft stent could not be passed or if bleeding continued despite graft stent implantation. Patients whose bleeding continued after pericardiocentesis underwent surgery. Microcoil embolization was performed in 1 case (Table 5).

### Outcomes

The majority of the patients were taking dual antiplatelet therapy, including acetylsalicylic acid and clopidogrel (51.8%). The use of ticagrelor and prasugrel was seen in 21 (19.0%) and 9 (8.1%) patients, respectively (Table 5). A coronary angiogram was required in 16 CAP patients within 1 year after hospital discharge. Thirteen CAP patients were re-hospitalized due to myocardial infarction, and 9 of them were STEMI patients

**Table 2. Baseline Clinical Characteristics According to Sex**

Clinical variables	Female		Male		Test Statistics; P
	Mean ± SD	Med [Min-Max]	Mean ± SD	Med [Min-Max]	
Age	68.5 ± 11.9	68 [47.0-93.0]	67.7 ± 13.2	68 [33.0-91.0]	t = -0.330 P = .742
BMI	27.1 ± 3.3	27 [20.8-38.0]	28.2 ± 2.5	27.8 [21.6-33.9]	<b>U = 1017.0</b> <b>P = .014</b>
	<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>	
HT <sub>Yes</sub>	26	63.40	42	60.90	X <sup>2</sup> = 0.071 P = .790
No	15	36.60	27	39.10	
DM <sub>Yes</sub>	14	34.10	19	27.50	X <sup>2</sup> = 0.535 P = 0.464
No	27	65.90	50	72.50	
Smoking <sub>Yes</sub>	9	22.00	51	73.90	<b>X<sup>2</sup> = 28.007</b> <b>P &lt; .001</b>
No	32	78.00	18	26.10	
Family history of CAD <sub>Yes</sub>	20	48.80	41	59.40	X <sup>2</sup> = 1.179 P = .278
No	21	51.20	28	40.60	
Chronic renal disease <sub>Yes</sub>	4	9.80	12	17.40	X <sup>2</sup> = 1.206 P = .272
No	37	90.20	57	82.60	
Previous MI <sub>Yes</sub>	16	39.00	24	34.80	X <sup>2</sup> = 0.200 P = .655
No	25	61.00	45	65.20	
Previous PCI <sub>Yes</sub>	21	51.20	36	52.20	X <sup>2</sup> = 0.009 P = 0.923
No	20	48.80	33	47.80	
CABG <sub>Yes</sub>	4	9.80	9	13.00	X <sup>2</sup> = 0.267 P = .606
No	37	90.20	60	87.00	
<b>Pre-procedural drugs</b>					
Aspirin <sub>Yes</sub>	25	61.00	46	66.70	X <sup>2</sup> = 0.364 P = .546
No	16	39.00	23	33.30	
Clopidogrel <sub>Yes</sub>	7	17.10	21	30.40	X <sup>2</sup> = 2.420 P = .120
No	34	82.90	48	69.60	
Prasugrel <sub>Yes</sub>	0	0.00	3	4.30	X <sup>2</sup> = 1.833* P = .292
No	41	100.00	66	95.70	
Tikagrelor <sub>Yes</sub>	2	4.90	2	4.90	X <sup>2</sup> = 0.288* P = 0.628
No	39	95.10	67	97.10	
Beta-blocker <sub>Yes</sub>	24	58.50	36	52.20	X <sup>2</sup> = 0.420 P = .517
No	17	41.50	33	47.80	
ACE inhibitor <sub>Yes</sub>	5	12.20	19	27.50	X <sup>2</sup> = 3.548 P = .060
No	36	87.80	50	72.50	
ARB <sub>Yes</sub>	17	41.50	20	29.00	X <sup>2</sup> = 3.548 P = .060
No	24	58.50	49	71.00	
Statin <sub>Yes</sub>	23	56.10	45	65.20	X <sup>2</sup> = 0.906 P = .341
No	18	43.90	24	34.80	
Calcium channel blocker <sub>Yes</sub>	8	19.50	13	18.80	X <sup>2</sup> = 0.008 P = .931
No	33	80.50	56	81.20	
Nitrate <sub>Yes</sub>	15	36.60	19	27.50	X <sup>2</sup> = 0.986 P = .321
No	26	63.40	50	72.50	
Trimetazidine <sub>Yes</sub>	6	14.60	10	14.50	X <sup>2</sup> = 0.000 P = .984
No	35	85.40	59	85.50	
Ivabradine <sub>Yes</sub>	7	17.10	3	4.30	<b>X<sup>2</sup> = 5.039*</b> <b>P = .038</b>
No	34	82.90	66	95.70	

t, Student's t test; U, Mann-Whitney U test; X<sub>2</sub>, chi square test; \*X<sub>2</sub> exact test, P < .05 significance level. Bold denotes statistically significant variables.

SD, standard deviation; BMI, body mass index; DM, diabetes mellitus; HT, hypertension; MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; ARB, angiotensin receptor blocker.

in a 1-year follow-up. Eight of 13 patients were re-hospitalized due to myocardial infarction of CAP vessel. Ten patients were re-hospitalized with covered stent restenosis. Eleven of all patients had redo-PCI. Sixteen of the CAP patients had side branch occlusion, and a cerebrovascular event occurred in 8 CAP patients after discharge in 1 year. Also, major bleeding was treated with blood transfusion in 12 patients in 1 year (Table 6). The all-cause mortality rate of CAP patients was 19.1% in hospital, 20.0% in 30 days, 23.6% in 6 months, and 27.2% in 1-year follow-up (Figure 1). The most common mortality was in type III perforation group in hospital follow-up (66.6%) and in 1-year follow-up (63.3%) ( $P = .004$ ) (Figure 2).

The number of CAG and PCI increased with time. As a result of this rising, the number of CAP increased with time (Figure 3).

**Table 3. ECG and Angiographic Characteristics**

Characteristics	n	%
<b>CAG</b>		
One vessel lesion	34	30.2
Two vessel lesions	42	38.6
Three vessel lesions	24	21.1
Four and more vessel lesion	10	9.1
<b>Perforated vessel</b>		
Left anterior descending (LAD)	55	50.0
Circumflex (Cx)	25	22.7
Right coronary artery (RCA)	30	27.3
<b>ACC/AHA lesion type</b>		
A	34	31.2
B	38	34.5
C	38	34.5
<b>In-stent restenosis</b>	17	15.4
<b>Chronic total occlusion</b>	25	22.7
<b>Significant tortuosity</b>	37	33.6
<b>Moderate/severe calcification</b>	34	30.9
<b>Bifurcation coronary lesion</b>	10	9.1
<b>Lateral branch</b>	13	11.8
<b>Distal artery lesion</b>	26	23.6
<b>None</b>	58	52.7
<b>Syntax score</b>	15.2 ± 6.9	
<b>Perforated coronary artery</b>		
Left anterior descending artery	46	41.8
Diagonal artery	9	8.1
Circumflex artery	17	15.4
Obtuse marginal artery	7	6.3
Right coronary artery	31	28.1
<b>CAP location</b>		
Side branch	17	15.4
Proximal	21	19
Mid	36	32.7
Distal	36	32.7

ECG, electrocardiography; CAG, coronary angiogram; ACC/AHA, American College of Cardiology/American Heart Association; CAP, coronary artery perforation.

## DISCUSSION

In our study, the incidence of CAP was found to be <1% (0.22%), and it was compatible with our study's domain literature.<sup>3-6,14,15</sup> According to the studies from literature, this is the largest study to consider CAP as a rare complication of PCI in Turkey retrospectively. Most of the CAP patients were in the ACS group (59.7%) in our study. Aykan et al<sup>16</sup> analyzed retrospectively 25 patients with CAP (0.02%) in Turkey. In addition to this, we could not find any local publication about CAP.

In this study, CAP occurred more frequently in males (62.0%) and younger people ( $68 \pm 12$  years), despite female and older age being defined as risk factors for CAP.<sup>17,18</sup> The male to female ratio was 1.6 (1.6/1.0) in our study, and this finding was consistent with the study of Mirza et al.<sup>19</sup> Sixty-eight patients (61.8%) had hypertension, similar to the findings of Lee et al<sup>20</sup> (59.6%). Also, hypertension was the most common factor among CAP patients (82%) in Shimony et al<sup>21</sup> study. Although the previous CABG was another risk factor for CAP during PCI, its rate was low (12%) in the current study. Thirty-three patients (30%) had diabetes mellitus, similar to the findings of Mirza et al.<sup>19</sup> Patients with developing CAP during PCI had higher risk factors, such as smoking (54.5%), hyperlipidemia (54.5%), family history of coronary artery disease (CAD) (55.4%), and previous PCI (51.8%). In addition to this finding, the use of clopidogrel before PCI and lower creatinine clearance was detected as modifiable risk factors for CAP developed during PCI. However, patients with chronic renal disease (14.5%) and clopidogrel use (25.4%) were lower in this study compared to the study of Doll et al.<sup>22</sup>

According to our results, 76 of 110 CAP patients had AHA/ACC lesion types B and C. The presence of significant vessel tortuosity (33.6%) and moderate/severe calcification (30.9%) was commonly associated with CAP development. According to the studies in literature, more calcified lesions have been treated and the rate of CAPs was even higher.<sup>23-25</sup> Another powerful predictor of CAP is the use of stiff guidewire during the treatment of chronic total occlusion (CTO) lesion.<sup>17,21</sup> The number of patients in our study with CTO was relatively low (22.7%). The low CTO perforation rates might be due to the selection of medical treatment or CABG options in CTO lesions in these centers. Although coronary artery diameter <2.5 mm is an important predictor of CAP, the coronary artery vessel diameter in 16 of 110 CAP patients was <2.5 mm in this study. Oversized balloon dilatation or stent implantation in bigger vessels could be the main cause of CAP in our study. The third most common cause of CAP was guidewire used in PCI. The literature reports that the use of hydrophilic wire is a significant cause of CAP, which is a similar result in our study.<sup>4,17,21</sup> Coronary artery perforation was observed commonly in STEMI among all acute coronary patients, and the most perforated coronary artery was LAD in the current study. However, the most frequent artery associated with CAP in previous studies was RCA.<sup>3,21</sup> The location of CAP in coronary arteries was in the middle (32.7%) and distal (32.7%) segments. It was similar to the findings of Nawale et al.<sup>14</sup> The possible reason for the occurrence of CAP in these parts of

**Table 4. Procedural Characteristics**

n	I 24	II 37	III 41	IIICS 8	Test Statistics; P
<b>Vessel diameter (mm)</b>	2.88 [2.00-4.50]	2.75 [2.50-4.00]	3.00 [2.00-4.00]	2.75 [2.25-3.50]	KW = 4.781, P = .092
<b>Guide wire type</b>					
<i>Floppy wire</i>	11 (19.0)	22 (37.9)	20 (34.5)	5 (8.6)	X <sup>2</sup> = 4.420, P = .610
<i>Hydrophilic wire</i>	9 (25.7)	12 (34.3)	13 (37.1)	1 (2.9)	
<i>CTO wire</i>	4 (23.5)	3 (17.6)	8 (47.1)	2 (11.8)	
<b>Balloon pre-dilatation</b>					
<i>Semi-compliant</i>	16 (20.5)	23 (29.5)	32 (41.0)	7 (9.0)	NA
<i>Non-compliant</i>	1 (20.0)	2 (40.0)	2 (40.0)	0 (0.0)	
<i>Cutting balloon</i>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
<b>Pre-dilatation semi-compliant balloon diameter (mm)</b>	2.0 [2-3]	2.0 [2-3]	2.5 [2.0-3.0]	2.0 [2.0-3.0]	KW = 1.192, P = .551
<b>Stent implantation</b>	35 (27.8)	41 (32.5)	40 (31.7)	10 (8.0)	NA
<b>Stent type</b>					
<i>BMS</i>	2 (9.1)	6 (27.3)	9 (40.9)	5 (22.7)	NA
<i>DES</i>	30 (30.3)	35 (35.3)	29 (29.3)	5 (5.1)	
<i>Bioabsorbable</i>	3 (60.0)	0 (0.0)	2 (40.0)	0 (0.0)	
<b>Stent number used in PCI</b>	1.0 [1.0-5.0]	1.0 [1.0-3.0]	1.0 [1.0-2.0]	1.0 [1.0-3.0]	KW = 0.320, P = 0.852
<b>Balloon post-dilatation</b>					
<i>Semi-compliant</i>	1 (25.0)	1 (25.0)	2 (50.0)	0 (0.0)	NA
<i>Non-compliant</i>	11 (26.2)	18 (42.8)	13 (31.0)	0 (0.0)	
<i>Cutting balloon</i>	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	
<b>Post-dilatation compliant balloon diameter (mm)</b>	3.0 [3.0-5.0]	3.0 [3.0-4.0]	3.5 [3.0-5.0]	NA	NA
<b>GbIIb-IIIa inh (+)</b>	7 (28.0)	9 (36.0)	8 (32.0)	1 (4.0)	X <sup>2</sup> = 1.232, P = .751
<b>GbIIb-IIIa inh (-)</b>	17 (20.0)	28 (33.0)	33 (38.8)	7 (8.2)	
<b>Covered stent (+)</b>	0 (0.0)	28 (48.3)	28 (48.3)	2 (3.4)	X <sup>2</sup> = 31.246, P < .001
<b>Covered stent (-)</b>	18 (34.6)	9 (17.4)	19 (36.5)	6 (11.5)	
<b>Covered stent diameter (mm)</b>	NA	2.92±0.22	3.05±0.30	NA	NA
<b>Perforation Reason</b>					
<b>Wire</b>					
<i>Floppy wire</i>	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	NA
<i>Hydrophilic wire</i>	12 (80.0)	3 (20.0)	0 (0.0)	0 (0.0)	
<i>CTO wire</i>	3 (60.0)	2 (40.0)	0 (0.0)	0 (0.0)	
<b>Balloon</b>	5 (8.9)	22 (39.3)	24 (42.9)	5 (8.9)	56 (50.9)
<b>Semi-compliant</b>					
<i>Pre-dilatation</i>	0 (0.0)	2 (50.0)	1 (25.0)	1 (25.0)	NA
<i>Post-dilatation</i>	3 (33.3)	3 (33.3)	1 (11.2)	2 (22.2)	
<b>Non-compliant</b>					
<i>Pre-dilatation</i>	0 (0.0)	2 (33.3)	4 (66.7)	0 (0.0)	NA
<i>Post-dilatation</i>	2 (5.4)	15 (40.6)	18 (48.6)	2 (5.4)	
<b>Stent</b>	1 (3.3)	10 (32.3)	17 (54.8)	3 (9.6)	P = .004

CTO, chronic total occlusion; BMS, bare metal stent; DES, drug eluting stent; PCI, percutaneous coronary intervention; KW, Kruskal-Wallis test; X<sup>2</sup>, chi square test; NA, non-available, P < .05

coronary vessels might be the tapered nature of the vessel diameter.

The most common CAP type was a type III perforation, and the second was type II perforation according to the Ellis classification.<sup>1</sup> This is in line with previous studies in the

literature.<sup>4,21</sup> Vessel diameter was larger in the type III perforation group than others. In addition to this, the number of balloon pre-dilatation, balloon pre-dilatation diameter, length, and pre-dilatation pressure was also higher in hydrophilic and CTO wires used group. The covered stent length and diameter were higher in the type III perforation group.

**Table 5. Clinical presentation, Management, and Drugs of Outpatients**

	I n (%)	II n (%)	III n (%)	IIICS n (%)	n (%)	Test Statistics; P
<b>Clinical presentations</b>						
<i>Pericardial effusion</i>	0 (0.0)	28 (41.8)	36 (53.7)	3 (4.5)	67 (100)	$X^2 = 55.081, P < .001$
<i>Pericardial tamponade</i>	0 (0.0)	9 (25)	26 (72.2)	1 (2.8)	36 (100)	$X^2 = 31.886, P < .001$
<i>Periprocedural MI</i>	0 (0.0)	3 (27.3)	7 (63.6)	1 (9.1)	11 (100)	NA
<i>Cardiogenic shock</i>	0 (0.0)	2 (8.3)	22 (91.7)	0 (0.0)	24 (100)	$X^2 = 39.141, P < .001$
<i>CPR</i>	0 (0.0)	1 (5.0)	19 (95.0)	0 (0.0)	20 (100)	$X^2 = 34.926, P < .001$
<i>Periprocedural death</i>	0 (0.0)	1 (10)	9 (90)	0 (0.0)	10 (100)	NA
<b>Treatment strategy</b>						
<b>Prolonged balloon inflation</b>						
<i>Semi-compliant</i>	0 (0.0)	20 (40.0)	26 (52.0)	4 (8.0)	50 (100)	NA
<i>Non-compliant</i>	0 (0.0)	7 (43.8)	8 (50.0)	1 (6.2)	16 (100)	
<b>Covered stent</b>						
<i>Graftmaster</i>	0 (0.0)	11 (34.4)	20 (62.5)	1 (3.1)	32 (100)	NA
<i>PK Papyrus</i>	0 (0.0)	7 (63.6)	3 (27.3)	1 (9.1)	11 (100)	
<i>Aneugraft</i>	0 (0.0)	10 (66.7)	5 (33.3)	0 (0.0)	15 (100)	
<b>Coagulant agent</b>	0 (0.0)	2 (28.6)	4 (57.7)	1 (14.3)	7 (100)	NA
<i>Pericardiocentesis</i>	0 (0.0)	6 (18.8)	26 (81.2)	0 (0.0)	32 (100)	$X^2 = 39.517, P < .001$
<i>IABP</i>	0 (0.0)	1 (6.2)	15 (93.8)	0 (0.0)	16 (100)	$X^2 = 25.645, P < .001$
<i>Blood transfusion</i>	0 (0.0)	2 (9.5)	19 (90.5)	0 (0.0)	21 (100)	$X^2 = 31.748, P < .001$
<i>Micro coil</i>	0 (0.0)	1 (100)	0 (0.0)	0 (0.0)	1 (100)	NA
<i>Transient pacemaker implantation</i>	1 (3.8)	9 (34.6)	15 (57.6)	1 (3.8)	26 (100)	$X^2 = 9.409, P = .023$
<b>CABG</b>	1 (5.3)	2 (10.5)	14 (73.7)	2 (10.5)	19 (100)	$X^2 = 15.035, P = .002$
<b>Accomplished PCI</b>						
<i>No reflow</i>	0 (0.0)	3 (42.9)	4 (57.1)	0 (0.0)	7 (100)	NA
<i>TIMI I flow</i>	2 (25)	3 (37.5)	3 (37.5)	0 (0.0)	8 (100)	
<i>TIMI II flow</i>	5 (23.8)	8 (38.1)	7 (33.3)	1 (4.8)	21 (100)	
<i>TIMI III flow</i>	17 (26.2)	21 (32.3)	20 (30.7)	7 (10.8)	65 (100)	
<b>Post-procedural drugs</b>						
Aspirin	23 (25.8)	34 (38.2)	26 (29.3)	6 (6.7)	89 (100)	$X^2 = 14.655, P = .002$
Clopidogrel	14 (24.6)	20 (35.1)	19 (33.3)	4 (7.1)	57 (100)	$X^2 = 0.985, P = .826$
Prasugrel	3 (33.3)	4 (44.4)	2 (22.3)	0 (0.0)	9 (100)	NA
Ticagrelor	7 (33.3)	10 (47.6)	3 (14.3)	1 (4.8)	21 (100)	$X^2 = 6.991, P = .070$
Beta-blocker	20 (28.2)	28 (39.4)	18 (25.4)	5 (7.0)	71 (100)	$X^2 = 13.354, P = .003$
ACE inhibitor	8 (21.1)	17 (44.7)	10 (26.3)	3 (7.9)	38 (100)	$X^2 = 4.043, P = .260$
ARB	9 (50)	5 (27.8)	3 (16.6)	1 (5.6)	18 (100)	$X^2 = 10.593, P = .014$
Statin	21 (28.0)	28 (37.3)	21 (28.0)	5 (6.7)	75 (100)	$X^2 = 10.643, P = .013$
Calcium channel blocker	5 (27.8)	6 (33.3)	7 (38.9)	0 (0.0)	18 (100)	$X^2 = 1.931, P = .602$
Nitrate	10 (27.8)	18 (50)	7 (19.4)	1 (2.8)	36 (100)	$X^2 = 11.181, P = .010$
Trimetazidine	8 (53.3)	2 (13.3)	4 (26.7)	1 (6.7)	15 (100)	$X^2 = 10.568, P = .016$
Ivabradine	3 (50)	2 (33.3)	1 (16.7)	0 (0.0)	6 (100)	NA

CPR, cardiopulmonary resuscitation; IABP, intra-aortic balloon pump; CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction; ACE, angiotensin converting enzyme; ARB, angiotensin receptor blocker;  $X^2$ , chi square test; NA, non-available.

Also, balloon inflation and stent implantation were the most common perforation reasons in the type III group. Furthermore, post-dilation with non-compliant balloon was associated with balloon-related CAP. This might be due to

a mismatch of balloon and artery diameter or sliding of the non-compliant balloon from stented area to the non-stented area during PCI. Using a smaller balloon for pre-dilatation might be another problem. The use of an appropriate balloon

**Table 6. 1-Year Outcomes**

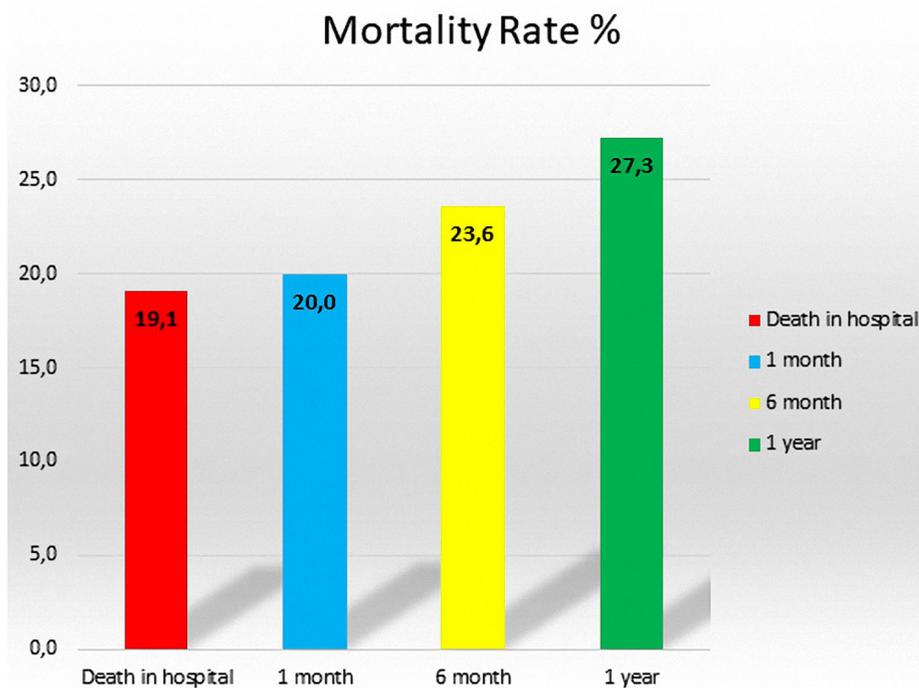
	I	II	III	IIICS	n
<b>CAG in 1 year</b>	2 (12.5)	5 (31.2)	7 (43.8)	2 (12.5)	$\chi^2 = 1.691, P = .639$
<b>Covered stent restenosis</b>	0 (0.0)	4 (40.0)	6 (60.0)	0 (0.0)	NA
<b>Side branch occlusion</b>	2 (12.5)	6 (37.5)	8 (50)	0 (0.0)	$\chi^2 = 3.004, P = .391$
<b>Re-hospitalization with myocardial infarction</b>	2 (15.4)	4 (30.8)	6 (46.2)	1 (7.6)	NA
<b>Cerebrovascular event</b>	1 (12.5)	2 (25)	5 (62.5)	0 (0.0)	NA
<b>Redo-PCI (+)</b>	2 (18.2)	3 (27.3)	5 (45.5)	1 (9.0)	NA
<b>Re-hospitalization with STEMI</b>	2 (22.2)	3 (33.4)	4 (44.4)	0 (0.0)	NA
<b>Bleeding</b>	1 (8.3)	3 (25.0)	8 (66.7)	0 (0.0)	NA
<b>Death</b>	2 (6.7)	8 (26.7)	19 (63.3)	1 (3.3)	$\chi^2 = 13.332, P = .004$
<i>In hospital</i>	1(4.8)	5 (23.8)	14 (66.6)	1 (4.8)	NA
<i>In first month</i>	0 (0.0)	1 (100)	0 (0.0)	0 (0.0)	
<i>In sixth month</i>	0 (0.0)	1 (25.0)	3 (75.0)	0 (0.0)	
<i>In first year</i>	1(25.0)	1(25.0)	2 (50.0)	0 (0.0)	

CAG, coronary angiogram; PCI, percutaneous coronary intervention; STEMI, ST segment elevation myocardial infarction;  $\chi^2$ , chi-square test; NA, non-available.

for vessel diameter before stent implantation can lead to a decrease in post-dilatation and perforation rates. For the optimal stent implantation, balloon to vessel ratio should be between 1 and 1.1.<sup>14</sup> Interestingly, balloon post-dilatation time and post-dilatation pressure were lower in the type III group than in other groups. This might be due to fast balloon inflation and balloon deflation during PCI. Using cutting and scoring balloons might be protective against CAP.<sup>3</sup> In this study, a cutting balloon was used in 1 of 110 CAP patients. High-pressure balloon inflation-related CAP was the most

common reason for CAP in the type II perforation group. Diminishing the aggressive use of oversized balloons and stents might decrease the rate of CAP.<sup>4</sup> The most common CAP cause was wire-related perforations in the type I group in our study. As a result, high-pressure balloon inflation, oversized balloons, and non-compliant balloons seemed to increase CAP development risk.

Clinically and angiographically, early diagnosis and treatment of CAP are critical for survival. The interventional



**Figure 1. Mortality rate (%): in-hospital, 1-month, 6 months, and 1-year.**

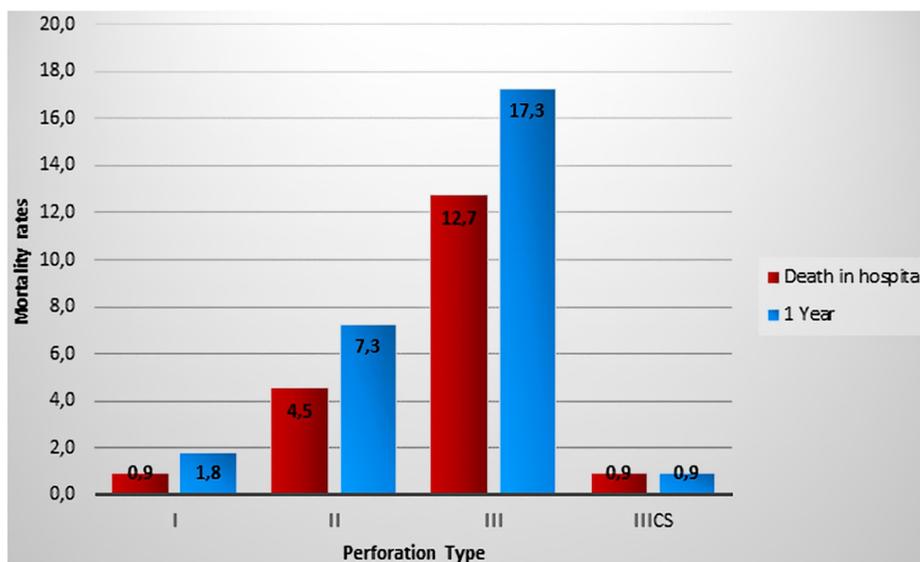


Figure 2. Mortality rate according to coronary artery perforation types: in-hospital and 1-year.

practice of the operator, the equipment of the center, the hemodynamic status of the case, and the perforation type determine the management of CAP. Even though there have been some strategies for the treatment of CAP, there is no consensus about treatment protocols. Also, the management of CAP may differ among institutions and even among invasive cardiologists in the same institution.<sup>6,23,26</sup> Coronary artery perforation treatment aims to seal the extravasation site and the reversal of hemodynamic collapse from pericardial effusion or cardiac tamponade.<sup>27</sup> Prolonged balloon inflation to seal the perforation is to maintain hemostasis. Brief and repeated contrast injections should be done to detect the residual extravasation. Prolonged balloon inflation was the most preferred treatment choice in this study, especially in patients with type III CAP. This approach might have been chosen more frequently since it may have allowed time for the next steps and quickly prevented further worsening of the hemodynamics. However, it should be kept in mind that this approach may lead to the development of distal ischemia in patients who had no collateral branches in coronary arteries.

Balloon-expandable polytetrafluoroethylene-covered stents have been found to show a significant effect in the treatment of CAP in the catheterization laboratory, preventing blood leakage, mainly in proximal and middle parts of major epicardial vessels without surgery support.<sup>22,28,29</sup> In our study, the covered stent strategy was the most preferred method in the treatment of CAP after balloon inflation. In convenient placement in calcified vessels, inadequate elasticity and higher restenosis rates are the main problems of covered stents.<sup>20</sup> Ten of 110 CAP patients (9.1%) accepted covered stent restenosis in 1 year in this trial, which is a lower rate than the findings of Lee et al.<sup>20</sup> Extended anti-platelet therapy might be required to avoid late stent thrombosis. In addition, the deployment of covered stents in distal and small vessels is more difficult. For this reason, polyvinyl alcohol, thrombogenic metallic coils, collagen foam, intra-arterial thrombin, or autologous fat tissue aspirated from the patient’s groin can be used to seal the perforation. Using these treatment strategies is efficient and low-cost for small and distal perforations.<sup>30,31</sup> In this study, therapeutic micro coil embolization was used in only 1 patient in the

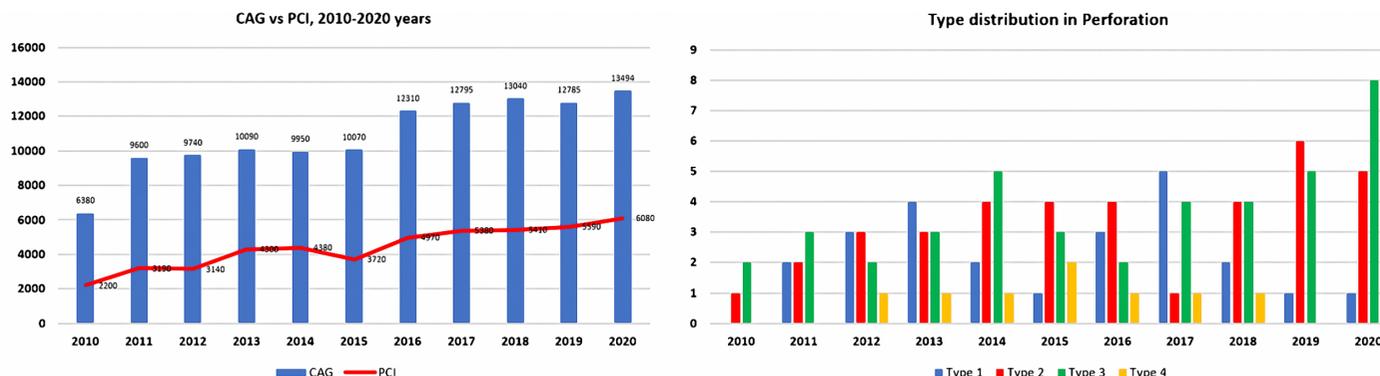


Figure 3. The number of CAG, PCI, and CAP according to years. CAG, coronary angiogram; CAP, coronary artery perforation; PCI, percutaneous coronary intervention.

type II perforation group and achieved sealing of the perforation site.

Pericardiocentesis is another important treatment method, especially in hemodynamically unstable CAP patients and in cardiac tamponade. Also, the morbidity and mortality rate of cardiac tamponade is higher, and pericardiocentesis is a life-saving procedure for CAP-related cardiac tamponade.<sup>9,27,31</sup> In the present study, pericardiocentesis was performed in the type II and type III perforation groups, and pericardiocentesis-related complications were not reported.

Requiring intra-aortic balloon pump, blood transfusion due to CAP, and transient pacemaker implantation during PCI were higher in the type III perforation group in our study. Nineteen CAP patients (17.2%) had CABG performed, and most of them were in the type III CAP group. Furthermore, 13 of 19 CAP patients (11.8%) belonged to emergency CABG. If graft stent or pericardiocentesis has not improved the hemodynamic instability, CABG should be undertaken without wasting time.<sup>32</sup> Long balloon inflation time, cardiac tamponade and hemodynamic instability, and delay in CABG may cause ischemia, ventricular arrhythmia, and congestive heart failure. In-hospital mortality was higher in type II and type III groups in this study due to these reasons. Also, in 1 year, the mortality rate was higher in type II and type III groups too. Rehospitalization with myocardial infarction was a major reason for 1-year mortality. Gastrointestinal or intracerebral bleeding due to longer use of dual antiplatelet therapy in patients with covered stents was another reason. Despite, the mortality rate was higher in type II and type III groups than in type I and type IV groups during hospitalization time, the mortality rate was decreasing in 1-year follow-up in type II and type III groups.

### Study Limitations

The solidity of the conclusions is directly related to the quality of data entered into the database. Additionally, the database may not include all records of type I perforation. Some physicians may not record type I perforation if the procedure is not problematic. Another limitation may be because of invasive imaging like optical coherence tomography or intravascular ultrasound to guide the complex PCI.

### CONCLUSIONS

Coronary artery perforation is not a common complication of PCI, and the rates of morbidity and mortality of CAP are high. The treatment strategy is determined by coronary anatomy, location of CAP, hemodynamic status, and cardiac surgery. This is the first study that points out the experience over a 10-year period regarding clinical and angiographic characteristics, management strategies, and outcomes of CAP during PCI in Turkey. In our study, the in-hospital mortality rate was higher in type II and type III groups than in type I and type IV groups due to perforation and its complications. Nevertheless, we propose that PCI should be done in selected patients despite catastrophic complications. It is even valid for highly trained physicians who may experience

CAP during PCI. However, the supply of covered stents has allowed physicians to perform more complex lesions and treat CAP in laboratories without cardiac surgery support. Even so, a surgical backup should not be forgotten.

**Ethics Committee Approval:** Ethical committee approval was received from the Ethics Committee of Celal Bayar University (approval no: June 29, 2020/84).

**Informed Consent:** Written informed consent was obtained from all participants who participated in this study.

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