RESEARCH ARTICLE / *Araştırma Makalesi*

Evaluation of Demographic Characteristics and Treatment of Patients Who Developed Iatrogenic Coronary Artery Perforation due to Percutaneous Coronary Intervention: Single Center Experience

Perkütan Koroner Girişime Bağlı İyatrojenik Koroner Arter Perforasyonu Gelişen Hastaların Demografik Özelliklerinin ve Tedavilerinin Değerlendirilmesi: Tek Merkez Deneyimi

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Abstract

Objective The aim of this study was to evaluate the demographic characteristics, frequency of perforation, clinical characteristics, treatment strategies and outcomes of patients who developed coronary artery perforation (CAP) during a percutaneous coronary intervention (PCI).

Materials and Methods Patients who CAP during a PCI between January 2015 and January 2020 were included in the study. In this five-year period, 25 out of 10,794 patients who underwent PCI developed CAP. Outcomes were classified as cardiac tamponade, requiring urgent revascularization by bypass or PCI, in-hospital mortality, and 30-day mortality.

Results In our study, frequency of CAP during PCI was 0.23%. Seventeen patients (68%) were male. The mean age of the patients was 62,52 ± 9.60 years. Eight patients had diabetes, 17 patients had hypertension and 5 patients had a history of chronic kidney disease. According to the Ellis classification system; rates of Ellis types I, II, III, and III-CS were 8 (32%), 9 (36%), 7 (28%), and 1 (4%), respectively. In 12 patients, tamponade was observed, and 7 of these patients underwent pericardiocentesis immediately, while 4 patients underwent pericardiocentesis on their follow-up (>24 hours). In three patients, type I perforation was initially unnoticed and tamponade was observed during follow-up. Six patients died in the hospital. In remaining patients, no mortality was observed within 30 days. In our study, the rates of adverse events for Ellis types I, II and III/III-CS, were as follows: cardiac tamponade, 12%, 20%, and 16%, respectively; emergency surgery, 0%, 4%, and 0% respectively; and death, 12%, 4%, and 8%, respectively.

Conclusion Although CAPs are very rare, they have quite a high mortality. Interventional cardiologists should be aware of the risk for Ellis type 1 perforations, especially, because they may not be noticed during the PCI. These data should be evaluated by studies conducted with larger numbers of patients.

Keywords Coronary artery perforation; percutaneous coronary intervention; graft-coated stent

Öz

Amaç *Bu çalışmanın amacı perkutan koroner girişim sırasında koroner arter perforasyonu gelişen hastaların demografik özelliklerini, sıklığını, klinik özelliklerini, tedavi stratejilerini ve sonuçlarını değerlendirmektir.*

Gereç ve Yöntemler *2015 ocak ve 2020 ocak ayları arasında perkütan koroner girişim yapılması sırasında koroner arter perforasyonu gelişen hastalar çalışmaya dahil edildi. Perkütan koroner girişim yapılan 10794 hastanın 25 tanesinde koroner arter perforasyonu gelişti. Kardiyak tamponad, acil perkütan veya baypas ile revaskülarizasyon gereksinimi, hastane içi ve 30 günlük mortalite sonlanım noktaları olarak belirlendi.*

Bulgular *Çalışmaya dahil edilen hastaların ortalama yaşı 62,5 ± 9,60 olup 17'si (%68) erkek idi. Sekiz hastada diyabet, 17 hastada hipertansiyon, 5 hastada kronik böbrek hastalığı öyküsü mevcuttu. Perkütan koroner girişim sırasında koroner arter perforasyonu gelişme sıklığı %0,23 idi. Ellis sınıflamasına göre 8 (%32) hastada Ellis tip I, 9 (%36) hastada Ellis tip II, 7 (%28) hastada Ellis tip III ve 1 (%4) hastada Ellis tip III-CS koroner arter perforasyonu gözlendi. On iki hastada tamponad gözlenmiş olup bu hastalardan 7 tanesine hemen, 4 tanesine ise takiplerinde (>24 saat) perikardiyosentez yapıldı. Üç hastada tip I perforasyon başlangıçta fark edilmemiş olup takipleri sırasında tamponad gözlendi. Bizim çalışmamızda 12 (%48) hastada kardiyak tamponad, 1 (%4) hastada acil cerrahi gereksinimi, 6 (%24) hastada ölüm gözlenmiştir. Ellis sınıflaması tip I, II ve III/III-CS gore bakıldığında sırasıyla kardiyak tamponad %12, %20 ve %16, acil cerrahi gereksinimi sırasıyla %0, %4 ve %0 iken ölüm sırasıyla %12, %4 ve %8 bulunmuştur. Kalan hastalarda 30 gün içinde ölüm gözlenmedi.*

Sonuç *Koroner arter perforasyonları çok nadir görülmesine rağmen mortalitesi çok yüksektir. Girişimsel kardiyologlar, özellikle perkütan koroner girişim sırasında gözden kaçabildiği için Ellis tip I perforasyonlara dikkat etmelidir. Bu verilerin daha çok hasta alınan çalışmalar ile değerlendirilmesi gerekir.*

Anahtar Kelimeler *Koroner arter perforasyonu; perkütan koroner girişim; greft kaplı stent*

INTRODUCTION

Coronary artery perforation (CAP), which can occur during percutaneous coronary interventions (PCI), is an extremely rare, life-threatening complication. The reported incidence of CAP during PCI is in the range of 0.2–0.6%; the incidence may rise up to 3% with transluminal extraction coronary atherectomy, directional coronary atherectomy, laser coronary angioplasty and high-speed mechanical rotational atherectomy.[1-4]

Cardiac tamponade due to CAP is the most frequent cause of mortality. Thus, interventional cardiologists need to be able to diagnose CAP quickly and know how to correctly treat it. The Ellis classification is the most commonly used classification for coronary artery perforations; this angiographic classification predicts the severity of the perforation as well as the risk of cardiovascular adverse events such as tamponade, myocardial infarction, cardiac surgery and mortality.[5] In this study, we aimed to evaluate the demographic characteristics, frequency of perforation, clinical characteristics, treatment strategies and outcomes of patients who developed CAP during a PCI.

MATERIALS and METHODS

Study design and population

The single-center, retrospective descriptive study was conducted with patients who developed CAP during PCI between January 2015 and January 2020. In this five-year period, 25 out of 10,794 patients who underwent PCI developed CAP. PCI indications, age, gender and demographic characteristics of the patients were collected. Patients applied to our outpatient clinic for a control examination. The in-hospital and 30-day follow-up information on clinical outcomes (e.g., cardiac tamponade, in-hospital death, 30-day mortality, and revascularization) were collected from electronic medical records or a registry data base or through a phone call, during which patients were asked about relevant end-point clinical events. Exclusion criterion was a lack of relevant patient-or procedural-related data. The study was approved by the Sakarya University Faculty of Medicine Ethics Committee (Ethics committee number: 71522473/050.01.04/119 Ethics Committee Approval Date: 04/04/2020).

Classification of coronary artery perforations, angiographic evaluation of the lesions, definitions, and angiography procedures CAP uses the Ellis classification system as follows: type I indicates the presence of an extraluminal crater without extravasation, type II indicates the presence of pericardial or myocardial blush without contrast jet extravasation, type III indicates the presence of contrast jet extravasation through frank (>1 mm) perforation, and type III cavity spilling (type III-CS) indicates the presence of contrast jet extravasation in any cardiac chamber or coronary sinus.[5] Lesion characteristics were categorized according to the American College of Cardiology (ACC) and the American Heart Association (AHA) lesion classification.[6] In addition, we evaluated the chronic total occlusion, the involved coronary artery, and the location of the lesion. The PCI was based on the following criteria: 1) residual stenosis of <30%, 2) coronary thrombolysis in myocardial infarction grade flow 3, and 3) an absence of dissection, thrombus or perforation after the procedure. The use of direct stenting, non-routine wire use, pre-dilation and post-dilatation were evaluated. In addition, prolonged balloon inflation and graft-covered stent treatments were assessed. The angiographic characteristics were further analysed by an independent interventional cardiologist.

Cardiac tamponade was identified in the presence of at least one of the following characteristics: 1) systemic hypotension (systolic blood pressure <90 mmHg) with evidence of paradoxical pulse by clinical assessment or by an invasive method; 2) evidence of pericardial effusion by echocardiography or angiography; and 3) diastolic collapse of the right ventricular free wall with echocardiographic evidence of significant respiratory variation of the transmitral Doppler velocity and/or dilated inferior vena cava with collapse during inspiration.

Outcomes

Outcomes were classified as cardiac tamponade requiring urgent revascularization by bypass or PCI, in-hospital mortality, and 30-day mortality.

Statistical analysis

Statistical analyses were conducted using SPSS Statistics software version 16.0 for Windows (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as mean ± SD and categorical variables as percentages.

RESULTS

In our study, frequency of CAP during PCI was 0.23%. The mean age of the 25 patients included in the study was 62.52 ± 9.60, and 17 (68%) of the patients were male. Eight patients had diabetes, 17 patients had hypertension and 5 patients had a history of chronic kidney disease. The demographic characteristics of the patients are shown in Table 1.

Table 1. Baseline clinical characteristics of patient with coronary artery perforation

Age, (years)	62.52±9.60
Gender (male), n (%)	17, (68.00)
Hypertansion, n (%)	17, (68.00)
Diabetes mellitus, n (%)	8, (32.00)
Smoking, n (%)	11, (44.00)
Coronary artery disease, n (%)	8, (32.00)
Hyperlipidemia, n (%)	6, (24.00)
Renal impairment, n (%)	5, (20.00)

Eleven of the patients were referred to the catheter laboratory with an unstable angina pectoris/non–ST-segment elevation myocardial infarction (USAP/NON-STEMI) diagnosis; their intervention indications are shown in Table 2. When we looked at the distribution of the target lesion according to ACC/AHA classification, it was observed that 1 patient had type B1, 7 patients had type B2, and 12 patients had type C lesions. In 12 of the patients, the lesion was in the right coronary artery, and 11 of the lesions were in the midsection. Of the 25 patients, 5 had chronic total occlusion, and 19 had USAP/NON-STEMI and ST-segment elevation myocardial infarction (STEMI). The angiographic characteristics of the patients are shown in Table 3.

Table 2. Indication for percutaneous coronary artery intervention

Stable angina, n (%)	6, (24.00)
USAP/Non-STEMI, n (%)	11, (44.00)
STEMI, n (%)	8, (32.00)

USAP/Non-STEMI: Unstable angina pectoris/Non-ST-segment elevation myocardia linfarction, STEMI: ST-segment elevation myocardial infarction

Table 3. Angiographic characteristics of patient with coronary artery perforation

Treated vessel	
LAD, n (%)	7, (28.00)
LCX, n (%)	5, (20.00)
RCA, n (%)	12, (48.00)
SVG, n (%)	1, (4.00)
Lession location	
Osial/proximal, n (%)	9, (36.00)
Medial, n (%)	11, (44.00)
Distal, n (%)	5, (20.00)
Lession type	
B1, n (%)	1, (4.00)
B2, n (%)	7, (28.00)
C, n (%)	12, (48.00)
CTO, n (%)	5, (20.00)

LAD: Left anterior descending artery, LCX: Left circumflex coronary artery, RCA: Right coronary artery, SVG: Saphenous vein graft, American College of Cardiology (ACC) and American Heart Association (AHA) lesion type: B1, B2, C, CTO: Chronic total occlusion

According to the Ellis classification system, 8 (32%) patients had Ellis type I coronary perforation, 9 (36%) patients had Ellis type II, 7 (28%) patients had Ellis type III, and 1 (4%) patient had Ellis type III-CS coronary perforation. Pre-dilation in 12 patients, stenting in 2 patients, and post-dilation in 4 patients were responsible for the CAP. The CAP in six patients was caused by wires that are not used routinely. Treatments for the CAP included the conservative approach, prolonged balloon inflation and a graft-coated stent. In 12 patients, tamponade was

observed, and 7 of these patients underwent pericardiocentesis immediately, while 4 patients underwent pericardiocentesis on their follow-up (>24 hours). One patient underwent emergency CABG and surgical treatment to drain pericardial fluid. A graft-coated stent was inserted in five patients. Six patients died in the hospital. None of the remaining patients were hospitalized, and no mortality was observed within 30 days. The data on the type of CAP, the interventional operations causing the CAP, and the outcomes of the patients are shown in Table 4.

Table 4. Types of perforation-related devices, management and prognosis of patients with coronary perforation

	Type of coronaryperforation				
	Type I (n: 8)	Type II (n: 9)	Type III (n: 7)	Type III-CS (n: 1)	n, (%)
Device responsible for the perforation					
Floppy Guide Wire, n (%)	1	0	0	0	1, (4.00)
CTO Wire, n (%)	2	3	1	0	6, (24.00)
Predilatation, n (%)	4	4	4	0	12, (48.00)
Postdilatation, n (%)	0	2	2	0	4, (16.00)
Stent, n (%)	1	0	0	1	2, (8.00)
Clinicalmanagement					
Use protamin, n (%)	3	2	5	0	10, (40.00)
Prolonged inflated balloon, n (%)	3	9	7	0	19, (76.00)
Pericardiocentesis early, n (%)	0	4	3	0	7, (28.00)
Pericardiocentesis late, n (%)	3	0	1	0	4, (16.00)
Emergency surgery	0	1	0	0	1, (4.00)
Greft coated stent, n (%)	0	0	4	1	5, (20.00)
In-hospital prognosis and 30 days mortality					
Death, n (%)	3	1	2	0	6, (24.00)
Cardiac tamponade, n (%)	3	5	4	0	12, (48.00)
Death 30 Days, n (%)	3	1	2	0	6, (24.00)

CTO: Chronic total occlusion

DISCUSSION

In this study, while the incidence of CAP and pericardiocentesis rates were similar, mortality rates were higher than in previous studies. We also observed that most cases consist of chronic total occlusion and ACC/AHA type 2B/C lesions, and that the majority of patients were treated successfully.

The conditions that increase the risk of CAP can be grouped in three categories. The first are the characteristics of the patient and demographic characteristics such as female gender, advanced age, hypertension, chronic kidney disease, multi-vascular disease and coronary bypass history.[1,7-10] The second are the lesion characteristics, which include chronic total occlusion and ACC/AHA type B2 and type C lesions.[1] The third is defined by the materials used and the procedure. These include oversize balloon/stent, cutting balloon, non-routinely used hydrophilic/stiff wires, intravascular ultrasound catheter, transluminal extraction coronary atherectomy, directional coronary atherectomy, laser coronary angioplasty and high-speed mechanical rotational atherectomy.[10] Most of our patients had ACC/AHA type B2 or type C lesions and chronic total occlusion, and approximately two out of three of the CAPs developed due to the oversize balloon used in pre-dilation and post-dilatation. About one in four of the CAPs developed due to wires that are not used routinely.

During treatment, if the patient has been taking heparin, it can be inactivated with protamine; if the patient has been taking glycoprotein IIb/IIIa inhibitors, the medical treatment is regulated by platelet transfusion. Treatment options can vary depending on the extent of the perforation and the facilities of the laboratory. Especially in Ellis type I and II perforations, prolonged balloon inflation, a graft-covered stent and various embolizing agents can be used. In Ellis type III and III-CS perforations, however, a graft stent, handmade graft stent or surgical treatment is applied alongside prolonged balloon inflation. In addition, if the Ellis type III or III-CS perforation is in the distal or side branch, embolizing agents may be used. In all cases, the effusion should be performed with echocardiography, and pericardiocentesis or surgical drain of the pericardial fluid is recommended if tamponade is present. As the most common application, persistence can be occluded in 5–15 minutes.[11] Semi-compliant balloons are not recommended for more than 20 minutes due to potential myocardial damage. Perfusion balloons should be used if a balloon occlusion is planned for more than 20 minutes.[12] The dual catheter technique is frequently used, in which the balloon or stent balloon sent through the catheter by the first vascular access is inflated and allowed to stand in the lesion, and by using a second vascular access, the catheter is brought to the ostium of the vessel to save time. The first balloon is deflated, and the wire sent from the second catheter is advanced to the lesion's distal. The first balloon is inflated again when the second wire passes the lesion's distal. Then the graft stent through the second catheter is brought up to the stent coronary ostium. The first balloon is drawn into the catheter, and the catheter is slightly retracted. Then, the second catheter is inserted into the coronary ostium, and the graft stent is moved up to the lesion and implanted. This technique is also called the ping-pong technique.[13]

If the vessel diameter is >2.5 mm, graft-coated stents can be used; biocompatible polymer polytetrafluoroethylene (PTFE)–coated stents are used most often. However, they are not preferred since they require very high pressure, are not flexible, lead to lateral branch occlusion, and have increased stent thrombosis and high restenosis rates. These stents can be difficult to pass through in diffuse calcific, tortuous vessels. Of the Ellis type III perforations, 91–93% are treated successfully with these stents.[14-16] PTFE-coated stents have 5.7% stent thrombosis and 29% stent restenosis rates, which are high compared to normal stents.[17] Surgery should be considered in CAPs that supply a large area and with the presence of a major side branch.New types of stents, such as a single layer of polyurethane on a single layer of stent material (e.g., Papyrus-covered stent, Biotronik,

Berlin, Germany) or a micro-porous ePTFE membrane on a single layer of stent material (e.g., BeGraft stent, Bentley, Hechingen, Germany) are much more flexible, thanks to reduced transition profiles.[18] In addition, the Papyrus-covered stent allows side branch passage by recanalization with stiff wires in case of a major side branch occlusion. In this way, balloon or stenting can be performed on the graft stent side branch.[19] In addition, Papyrus-covered stents and BeGraft stents can be simultaneously advanced through a 7F guiding catheter along with a different balloon and can be used as an alternative to the ping-pong technique. In large vessel perforations, complications can be managed successfully by using a handmade graft stent in the absence of a graft stent in the catheter laboratory.[20] A minimum distance of 4 mm is recommended on both sides of the CAP to ensure an adequate seal. We implanted a graft-coated stent in five of our patients.

Embolization methods, such as coil,[21] fat,[22] polyvinyl alcohol,[23] gelfoam,[24] N-butyl cyanoacrylate,[25] trombin injection,[26] microspheres,[27] glue,[28] and autologous blood clot,[29] can be applied as well as prolonged balloon inflation proximal to the site of the CAP. These agents are preferred in expendable arteries such as side branch and distal vessel perforations. Also, in the case of a perforation of a side branch, a graft-coated stent implantation can be considered in the main vessel at the side branch ostium for occlusion. Attention should be paid to non-target embolization when using these methods. In addition, the interventional cardiologist should look out for possible allergic reaction due to trombine. Surgery should be considered if these methods cannot be applied or if there is stenosis in other vessels. In our clinic, heparin was neutralized with protamine, and a conservative approach was applied, depending on the presence of side branch or distal perforations in the patient. Since there were no embolism therapeutic agents in our hospital, prolonged balloon inflation was performed on the lesion's proximal. In the case of aside branch perforation, prolonged balloon inflation was performed at the side branch ostium.

In some perforations, late tamponades can be observed 24 hours after the procedure;[30] this was the case in four of our patients. One of them was a type III perforation and was observed in follow-up after a graft-coated stent procedure. In the remaining three patients, type I perforation was initially unnoticed and dual anticoagulant treatment was carried out, and tamponade was observed during follow-up.

For Ellis types I, II and III/III-CS, the rates of adverse events have been recorded as follows: cardiac tamponade, 6–8%, 5–13%, and 20–63%, respectively; emergency surgery, 15–24%, 0–24%, and 50–60%, respectively; and death, 0–6%, 0–6%, and 19–21%, respectively.[5,31,32] In our study, the rates of adverse events for Ellis types I, II and III/III-CS, were as follows: cardiac tamponade, 12%, 20%, and 16%, respectively; emergency surgery, 0%, 4%, and 0% respectively; and death, 12%, 4%, and 8%, respectively. The high rates of tamponade and mortality in our Ellis type I perforations may be due to the fact that coronary perforations are not noticed during the procedure in some patients. Tamponade, emergency surgery, and low rates of mortality in Ellis Type III and Type III-CS perforations may be due to the ease of detection of these perforations and the immediate application of graft-coated stents in most of these patients.

Limitations

The single-center, retrospective nature of our study and limited number of patients are the limitations of this study.

CONCLUSION

Although CAPs are very rare, they have quite a high mortality. Interventional cardiologists should be aware of the risk for Ellis type I perforations, especially, because they may not be noticed during the PCI. Interventional cardiologists should be able to treat CAPs in the light of current data by considering the degree, the location of the coronary perforation and the availability of laboratory facilities.

The study was approved by the Sakarya University Faculty of Medicine Ethics Committee (Ethics committee number: 71522473/050.01.04/119 Ethics Committee Approval Date: 04/04/2020).

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