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Original article

Outcome of prolonged balloon inflation for the management of coronary perforation

Kentaro Meguro (MD, PhD)*, Hiroshi Ohira (MD), Toshiyuki Nishikido (MD), Masaki Fujita (MD), Toshiya Chinen (MD), Tatsuo Kikuchi (MD), Kentaro Nakamura (MD, PhD), Takehiko Keida (MD)

Department of Cardiology, Edogawa Hospital, Tokyo, Japan

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ABSTRACT

Background: Coronary perforation (CP) is a rare, sometimes lethal complication of percutaneous coronary intervention (PCI).
Objectives: The purpose of this study was to review the cases of CP and to investigate the management after CP.
Methods: A total of 3469 PCIs were performed in our institution from April 1999 to April 2008. All CP cases were identified from our computerized database.
Results: Thirty patients were identified as having CP (0.86%). According to the Ellis classification, we determined the grade of perforation as type I in 17 cases (56%), type II in 2 cases (7%), and type III in 11 cases (37%). Most CPs were caused by wires (53%), while balloons, stents, and atherectomy devices were responsible for 7%, 37%, and 3%, respectively. Wire caused only 1 case of type III CP (6%), while stent caused 9 type III CPs (82%, $p < 0.01$). Four patients (36%) with type III CP required urgent coronary artery bypass graft surgery (CABG), while no patient with type I/II CP required it ($p < 0.01$). Prolonged balloon inflations were effective for 8 cases out of 11 stent CPs, however, the ballooning duration was significantly longer than that in wire and balloon CP (44 ± 37 min vs. 21 ± 13 min, $p < 0.05$).
Conclusions: Stent CP often causes type III CP and one third of type III CP required urgent CABG. Although stent CP required longer balloon inflations for the management, prolonged balloon inflation might be useful for the management even in the stent CP.

Introduction

Coronary perforation (CP) with percutaneous coronary intervention (PCI) occurs only rarely, but sometimes is a lethal complication [1–5]. There is no consensus about the optimal treatment of patients with CP; commonly used treatment options include prolonged balloon inflation, placement of a covered stent graft (CSG), pericardiocentesis, or urgent coronary artery bypass graft (CABG) surgery. CP is one of the indications for emergent CABG, however, urgent CABG in CP is associated with high mortality [6].

Although the CSG may be a reliable and highly effective treatment option for sealing CPs complicating PCIs [7], CSG does not have good prognosis in middle-term outcomes [8,9]. Besides, no studies about the usefulness of prolonged balloon inflation for CP have been reported.

The purpose of this study is to gain information about the incidence, management, and outcome of CP and to investigate the effectiveness and feasibility of prolonged balloon inflation for the management of CP in the contemporary era.

Materials and methods

Data from all patients who had CP as a complication of PCI at our institution from April 1999 to April 2008 were analyzed retrospectively from our computerized database. The type of perforation was classified according to the criteria proposed by Ellis et al. [1]. Type I CP is defined by the development of an extraluminal crater without extravasation, type II CP by a pericardial or myocardial blush without contrast jet extravasation, and type III CP by extravasation through a perforation of a cavity spilling into an anatomic cavity. All patients received dual antiplatelet therapy, aspirin 81–100 mg and clopidogrel 75 mg once a day or aspirin 81–100 mg once a day and ticlopidine 200 mg twice a day orally. Heparin bolus of 100 units/kg body weight was initially given. Periodic IV bolus of heparin was also given to keep activated clotting time value between 250 and 350 s throughout the procedure. No GP IIb/IIIa inhibitor was used in

* Corresponding author at: Department of Cardiology, Edogawa Hospital, Higashikoiwa 2-24-18, Edogawa-ku, Tokyo 133-0052, Japan. Tel.: +81 3 3673 1221; fax: +81 3 3673 1229.
E-mail address: meguro@med.email.ne.jp (K. Meguro).

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our institution. This study was approved by our hospital's Human Clinical Study Committee.

All descriptive data are expressed as the mean ± SD and Student's *t*-test was used to compare the variables. Categorical variables were compared using Fisher's exact test. A value of $p < 0.05$ was considered statistically significant. All calculations were performed using SPSS 19 software (SPSS Inc., Chicago, IL, USA).

Results

A total of 3469 interventions were performed at our institution during the study period. We identified 30 patients with CP (0.86%). According to the Ellis classification, we determined the grade of perforation as type I CP in 17 cases (56%), type II CP in 2 cases (7%), and type III CP in 11 cases (37%) as shown in Table 1. No death was recorded among these cases in any grade of CP. Most cases of CP were caused by wires (16 cases, 53%), while balloons, stents, and atherectomy devices were responsible for 2 cases (7%), 11 cases (37%), and 1 case (3%), respectively. Most cases of wire perforation occurred with use of coronary hydrophilic wires (11 cases, 69%) or stiff wires made for chronic total occlusion (2 cases, 13%). Wire or balloon caused only 1 case of type III CP cases (6%), while stent caused 9 cases of type III CP (82%, $p < 0.01$).

A flow chart of treatment for CP is shown in Fig. 1 according to the Ellis classification. In most CP cases (97%), balloon inflations were performed except in 1 case of type I CP. All patients with types I and II CP and 64% of patients with type III CP were successfully managed by prolonged balloon inflation with or without pericardiocentesis without CABG. Incidences of cardiac tamponade and pericardiocentesis were 11% (2 cases out of 19) in types I and II CP and 27% (3 cases out of 11) in type III CP (ns). Seventeen cases out of nineteen (89%) in patients with types I and II CP were managed only by balloon inflation or follow-up, however, 5 cases in type III CP needed pericardiocentesis or CABG ($p < 0.05$). Covered stents were used in 2 cases, however, they could not manage CP because of unsuccessful delivery (1 case) and inadequate coverage (1 case) and these 2 CP cases required CABG. CABG was reserved for those patients who did not achieve hemostasis with conservative methods. Four patients (36%) with type III CP required urgent CABG surgery, while no patient with types I and II CP required it ($p < 0.01$).

Next, we compared the prognoses of CP when they were classified by devices that caused CP as shown in Table 2. While wire, balloon, and atherectomy CP required only 1 case of CABG out of 19 CP cases (5%), stent CP required 3 cases of CABG out of 11 CP cases (27%, ns). Incidences of cardiac tamponade, pericardiocentesis, or CABG were 16% (3 cases out of 19) in wire,

Table 1
Description of the coronary perforation cases.

	All, $N = 30$	Type I, $N = 17$	Type II, $N = 2$	Type III, $N = 11$	p-Value
Equipment causing the perforation					
Wire	16 (53%)	14 (82%)	1 (50%)	1 (9%)	0.000
Balloon	2 (7%)	1 (6%)	1 (50%)	0 (0%)	0.131
Stent	11 (37%)	2 (12%)	0 (0%)	9 (82%)	0.000
Atherectomy device	1 (3%)	0 (0%)	0 (0%)	1 (9%)	0.433
Outcome					
Death	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Tamponade	4 (13%)	2 (12%)	0 (0%)	2 (18%)	1.000
Treatment					
Follow-up only	1 (3%)	1 (6%)	0 (0%)	0 (0%)	1.000
Ballooning	29 (97%)	16 (94%)	2 (100%)	11 (100%)	1.000
Ballooning only	22 (73%)	14 (82%)	2 (100%)	6 (55%)	0.248
Pericardiocentesis	5 (17%)	2 (12%)	0 (0%)	3 (27%)	0.554
Covered stent	2 (7%)	0 (0%)	0 (0%)	2 (18%)	0.257
Urgent CABG	4 (13%)	0 (0%)	0 (0%)	4 (36%)	0.038

Data are expressed as number (percentage).
CABG, coronary artery bypass graft.

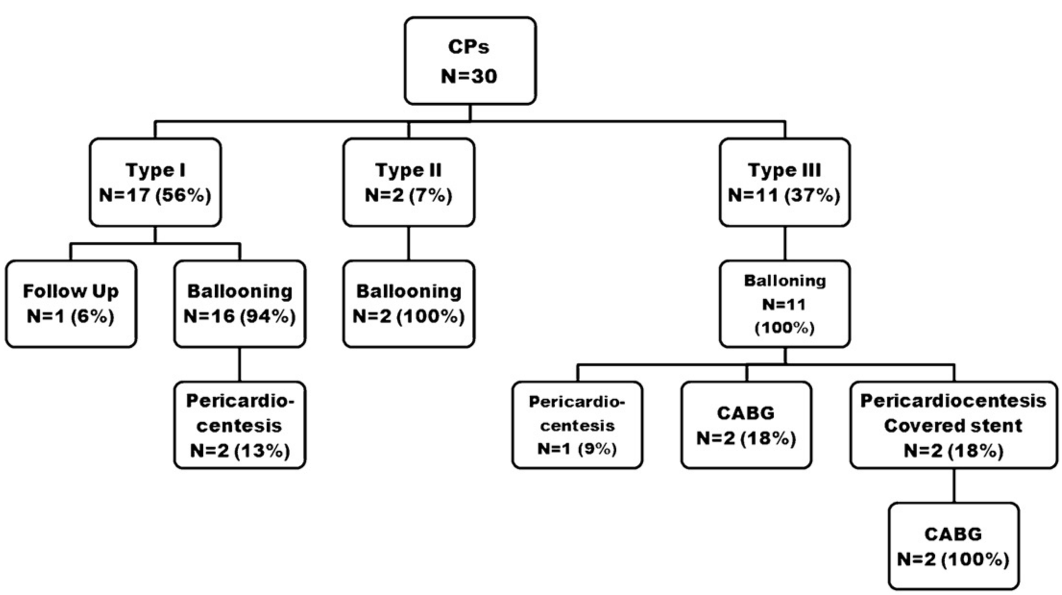

Fig. 1. Flow chart of the treatment for coronary perforation. CPs, coronary perforations; CABG, coronary artery bypass graft.

Table 2
The treatment and outcome of coronary perforations.

	All, $N = 30$	Wire, $N = 16$	Balloon, $N = 2$	Stent, $N = 11$	Atherectomy, $N = 1$	p-Value
Treatment						
Follow-up only	1 (3%)	1 (6%)	0 (0%)	0 (0%)	0 (0%)	1.000
Ballooning	29 (97%)	15 (94%)	2 (100%)	11 (100%)	1 (100%)	1.000
Ballooning only	22 (73%)	13 (81%)	2 (100%)	7 (64%)	0 (0%)	0.280
Pericardiocentesis	5 (17%)	1 (6%)	0 (0%)	3 (27%)	1 (100%)	0.106
Covered stent	2 (7%)	0 (0%)	0 (0%)	2 (18%)	0 (0%)	0.320
Urgent CABG	4 (13%)	1 (6%)	0 (0%)	3 (27%)	0 (0%)	0.534

Data are expressed as number (percentage).
CABG, coronary artery bypass graft.

balloon and atherectomy CP and 27% (4 cases out of 11, ns) in stent CP.

Prolonged balloon inflations were effective for 8 cases out of 11 stent CP cases (73%), while they were effective for 18 cases out of 19 cases of wire, balloon, and atherectomy device CP (95%, ns). Prolonged balloon inflations for the management of CP in most CP cases (86%) were performed using perfusion balloon to diminish myocardial ischemia. The ballooning duration for the management of CP in patients who were managed without CABG in stent CP was significantly longer than that in patients in wire and balloon CP (44 ± 37 min vs. 21 ± 13 min, $p < 0.05$). The ballooning duration for the management of CP in type III CP was also significantly longer than that in types I and II CP (48 ± 37 min vs. 20 ± 13 min, $p < 0.05$) as shown in Fig. 2.

Discussion

The results of the present study series suggest that CP during and after PCI was infrequent, however, severe perforation sometimes required pericardiocentesis or urgent CABG. Most stent CPs were classified as type III CP (82%) and often required pericardiocentesis or urgent CABG in contrast to wire CP, most of which were classified as type I CP (88%) and had good prognosis with only a few additional procedures. Although only a few papers [1] referred to the ballooning duration for hemostasis, we showed much longer prolonged balloon inflations were effective and indispensable for the management of severe CP.

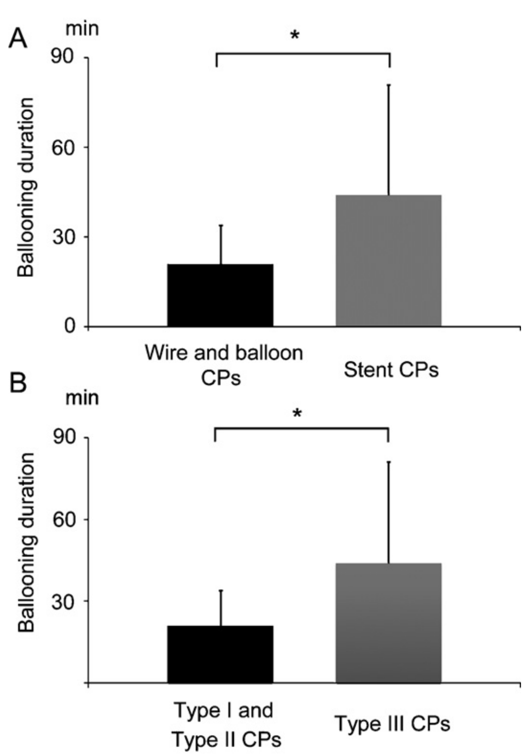

Fig. 2. Ballooning duration for the management of coronary perforations. (A) Ballooning duration compared between different devices and (B) ballooning duration compared between different types of coronary perforations, *$p < 0.05$; CPs, coronary perforations.

We compared groups of patients who had different grades of CP according to the Ellis classification. Patients who had type I or II CP had good prognoses with no cases of urgent CABG and only 2 cases of cardiocentesis. It seemed to be unusual that there were two cases of cardiocentesis in type I perforation. In both cases, the first manifestation of CP was cardiac tamponade, therefore, and we performed pericardiocentesis first. After the pericardiocentesis, contrast injection showed only extraluminal crater without extravasation and we considered CP had progressed spontaneously. In contrast, patients who had type III CP required 3 cases of cardiocentesis and 4 cases of urgent CABG. Type III perforations are obviously associated with higher complication rate including cardiac tamponade and CABG compared to type I or type II perforations. The frequency of adverse clinical outcomes relates to the severity of the CP. More severe perforations were associated with cardiac tamponade, high morbidity, and mortality as previously described [1,3,10,11].

In this series, wire perforation was the most common cause of CP as previously described [12], especially hydrophilic or stiff wires were responsible for 82% of wire perforations and 43% of all-cause CPs. The use of stiff extra supported and hydrophilic coronary guidewires to enable successful transit through the angulated, tortuous, or chronic total occluded lesions has led to an increase in the occurrence of wire perforations [4,12]. However, most cases of wire perforation appeared to be type I perforation and managed only by prolonged balloon inflation under the condition of heparin use. Prolonged balloon inflation (average 22 min) seemed to be effective for the management of wire perforations. Since atherectomy device caused only one case of CP in this series, the outcome of atherectomy device was not conclusive.

In agreement with previous reports [3,13], this analysis demonstrated that stent-induced CP resulted in type III CP, which often required pericardiocentesis, covered stent, and/or urgent CABG. Besides, the longer ballooning duration in the stent-induced CP cases, in which only prolonged balloon inflation were used for the hemostasis, was necessary for the management of CP (average 48 min). Although death was not documented in this series, stent-induced CP required more than prolonged balloon inflation and might have worse prognosis.

It was reported that covered stent graft is highly effective in sealing coronary perforations and the device was successful in achieving complete closure in most cases of CP [7,14]. In this series, we used covered stent graft for sealing in 2 CP cases after stent implantation, however, both cases could not be managed by covered stent and required urgent CABG. Different from other studies [3,11,15], we tried to manage the CP with prolonged balloon inflation. The percentage of covered stent use was relatively low (18%)

in type III CP compared to other reports (30–46.2%). Our findings did not make an objection to the usefulness of the covered stent for the nonsurgical treatment of CP. We used protamine in only one case of CP, although protamine is reported to be effective to stop the bleeding from CP by recovering the activating clotting time [16]. In some reports, it was reported that administration of protamine could cause acute thrombosis [17,18]. We considered the risk of acute thrombosis was high and the combination of CP and acute thrombosis seemed to be so critical [19,20] that we did not administer protamine in 29 cases. Although there were several reports describing the usefulness of subcutaneous tissue or autologus blood clotting for the treatment of CP [21,22], we did not use such techniques in the present study series.

Immediate placement of a perfusion balloon to minimize ischemia [23,24] and sealing in most of the perforations is one of the appropriate management techniques for CP [1]. Perfusion balloons were used in 86% of CP cases to complete the prolonged balloon inflations. Type III CP required an average of 48 min balloon inflation time to manage the CP and it was significantly longer than that in type I or type II CP. Type III CP often requires covered stent or urgent CABG for hemostasis (34–80%) [3,5,11,15], however, type III CP in our series required them in only 36% of cases. It was thought that prolonged balloon inflation for CP might be effective for hemostasis even in the type III CP cases. We also compared ballooning duration for the management of CP in stent-induced CP and other cases. Stent-induced CP required a longer time to achieve hemostasis in our series and it was partially because 82% of stent-induced CPs resulted in type III CP.

Limitations

Our study had a number of limitations. Consecutive patients who developed CP in a single center were studied retrospectively in this study. Because CP is a rare complication, our sample size was relatively low. The relatively low percentage of CPs requires caution when generalizing the findings from our study to all cases of CP. Whether the prospective application of prolonged balloon inflation will result in similar outcomes will require further study.

Conclusion

Stent CP often causes type III CP. Types I and II CP had good prognoses without any cases of urgent CABG surgery. Grade III CP often required urgent CABG surgery, however, no death was documented. Type III CP and stent CP required longer duration of prolonged balloon inflations for the management of CP. Since most cases of type III and stent CP were managed by prolonged balloon inflations by perfusion balloon, longer prolonged balloon inflation might be useful for the management of CP.

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