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Is Postdilatation with a Noncompliant Balloon Necessary after Coronary Stent Deployment during Primary Angioplasty?

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Background: *Postdilatation (PD) with noncompliant balloon during elective percutaneous coronary intervention (PCI) is performed usually in clinical practice in order to optimize stent expansion. However, current knowledge about its use in patients undergoing primary PCI is controversial. This study aims to evaluate the angiographical and clinical results of PD in patients who underwent primary PCI with drug eluting stents (DESs).*
Methods: *A total of 405 consecutive patients (mean age 56.9 ± 12.3 years; 302 male) with ST elevation myocardial infarction were evaluated retrospectively. Patients received DES with or without predilatation according to physician's discretion. Eligible patients were divided into 2 groups based on PD procedure. The clinical end-points were death, target vessel revascularization (TVR) and stent thrombosis at 6 months after PCI. The angiographic end-points were postprocedural correct Thrombolysis in Myocardial Infarction (TIMI) frame count (cTFC), final TIMI flow, and myocardial blush grade (MBG).*
Results: *PD was performed in 214 patients (52.8%). Angiographical parameters such as TIMI flow, cTFC, and MBG did not differ after PD ($P > 0.05$). During 6-month follow-up, TVR and stent thrombosis rates were lower in the PD group (6 vs. 16, $P = 0.03$; and 3 vs. 10, $P = 0.04$, respectively). PD and diabetes were detected as independent predictors of MACE ($\beta = 0.52$, $P = 0.01$, and $\beta = -0.47$, $P = 0.02$; respectively).*
Conclusion: *Our study revealed that PD does not yield adverse effects on final angiographic parameters when performed during primary PCI. Besides PD seems to decrease probability of stent thrombosis and TVR.* (J Interven Cardiol 2013;26:325–331)

Introduction

Primary percutaneous coronary intervention (PCI) with the implantation of a drug-eluting stent (DES) is now widely preferred as the first-choice revascularization procedure in patients with acute ST elevation myocardial infarction (AMI).[1–3] Although angioplasty is evolving in terms of materials and techniques, acute and long-term complications, such as stent thrombosis and restenosis, have *not* been eliminated.[4–6] Several studies have identified stent underexpansion as a major risk factor for both restenosis and stent thrombosis; thus, optimization of the deployed stent is vital.[7–9] Dilatation with a noncompliant (NC) balloon after stent deployment, to provide optimal expansion, reduced the target vessel revascularization (TVR) rate and resulted in better angiographic results and clinical outcomes in patients undergoing elective PCI.[10–12] However, there is no consensus among interventional cardiologists regarding performance of postdilatation (PD) in primary PCI.[13,14] In this study, we sought to evaluate the effects of PD on postprocedural angiographical and 6-month clinical outcomes in patients who underwent primary PCI with a DES.

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Materials and Methods

Consecutive patients admitted to Bezmialem Foundation University, Faculty of Medicine Hospital with

AMI which underwent primary PCI from April 2011 to September 2012 were evaluated retrospectively (Fig. 1). Patients with acceptable angiographic result (<20% residual stenosis) by visual estimates after coronary stent deployment were included in the present study. Exclusion criterion was bypass graft occlusion. All patients received a DES directly or after predilatation in the infarct related artery (IRA) according to physician's discretion. Study population was divided into 2 groups according to PD procedure (group 1: patients with PD, group 2: patients without PD). The angiographic end-points were postprocedural corrected TIMI frame count (cTFC), final TIMI flow grade, and myocardial blush grade (MBG). The angiographic variables before and after the PD process were compared. Also, major adverse cardiac events (MACE) including death, TVR, and stent thrombosis at 1 and 6 months were evaluated. No scheduled follow-up angiography was indicated unless it was for patients with significant coronary lesions for PCI not related to the index coronary lesion, or patients with evidence of disease progression due to a new angina pectoris and/or objective evidence of ischemia. Stent thrombosis was defined according to the Academic Research Consortium definition as definite, probable or possible.[15] Stent thrombosis within 30 days was defined as early and after 30 days as late. All patients were informed about the study. The study was approved by the local Ethics Committee.

Data Collection. Demographical characteristics including age, gender, presence of diabetes mellitus (DM), hypertension (HT), hypercholesterolemia, smoking, family history of cardiovascular disease and PCI history of patients fulfilling the inclusion criteria were obtained from medical records. The localization of myocardial infarction (MI) determined from admission 12-lead ECGs. Blood values that were determined at the time of admission to the emergency department and on a daily basis during patient stay in the hospital were recorded from medical reports.

Procedures and Post-Intervention Medications. Angiographic data of the patients were evaluated from catheter laboratory records. All procedures were performed according to the standard interventional technique via a femoral approach. In all cases, nonionic low-osmolality contrast media was used and contralateral artery was injected first. The IRA flow was graded according to the TIMI classification. Angiographic images were reviewed by two blinded experienced interventional cardiologists. TIMI flow (0–III), MBG (0–III), and cTFC on coronary angiography were evaluated according to protocol described by Gibson et al.[16–18] Patients received DES implantation directly or after predilatation in the IRA at 12–14 atm. The use of glycoprotein IIb/IIIa receptor antagonists and thrombus aspiration catheter was obtained from medical records. All patients received pre-PCI 300 mg aspirin, 600 mg clopidogrel PO, and IV 100 U/kg bolus

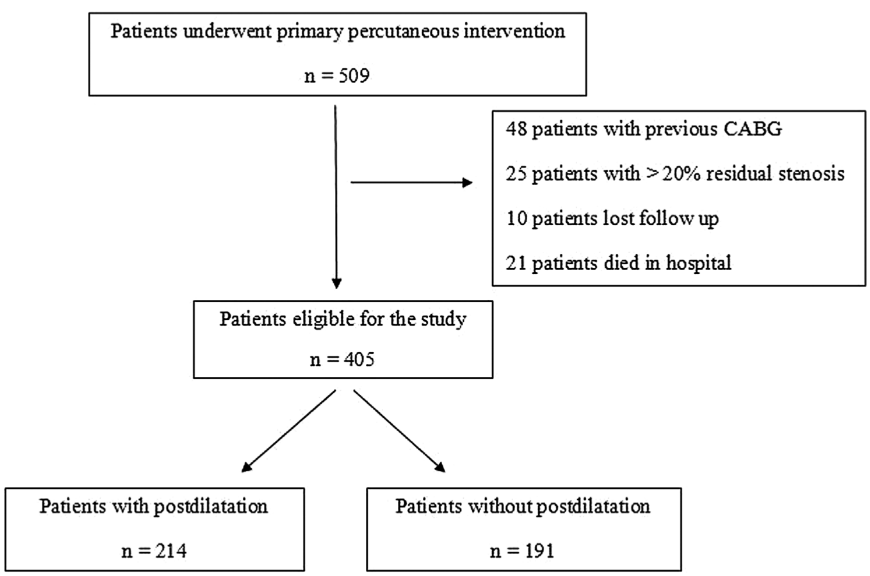

Figure 1. Flow chart of the patients enrolled in the study.

dose of unfractionated heparin followed by aspirin 100 mg and clopidogrel 75 mg PO daily. Dual antiplatelet therapy was recommended for at least 1 year.

Definitions. The cTFC, a quantitative method of assessing coronary artery flow, was evaluated on the 3 main coronary branches (LAD, left anterior descending coronary artery; LCX, left circumflex artery; RCA, right coronary artery), using the protocol described by Gibson et al.[17] It was defined as the number of cineframes required for contrast to reach a standardized distal coronary landmark. These landmarks were as follows: the first branch of the posterolateral artery in the RCA, the distal branch of the lateral left ventricular wall artery in the circumflex system, and the distal bifurcation known as the "moustache" in the left anterior descending artery. The corrected TFC (cTFC) was calculated by dividing the TFC of the LAD by 1.7. The cTFC was multiplied by a factor of correction to convert to a speed of 30 frame/s making direct comparison with earlier reports possible. In general, the cTFC in the LAD and in the LCx were assessed in right anterior oblique caudal view and the cTFC in the RCA was assessed in left anterior oblique cranial view. The MBG, an assessment of myocardial perfusion, was defined as follows: Grade 0, no myocardial blush or contrast density; Grade 1, minimal myocardial blush or contrast density; Grade 2, moderate myocardial blush or contrast density but less than that obtained during angiography of a contralateral or ipsilateral noninfarct-related coronary artery; Grade 3, normal myocardial blush or contrast density, comparable with that obtained during angiography of a contralateral or ipsilateral non-IRA.

Statistical Analysis. Statistical analysis of the study was performed by SPSS Version 19.0 software (SPSS, Inc., Chicago, IL, USA). Continuous variables were reported as mean ± standard deviations (SD) and categorical variables were expressed as percentages. The categorical and continuous variables between the 2 groups were compared using the χ^2 test and unpaired *t*-test, respectively. For correlation analysis, Pearson correlation test was used for analyzing data, which showed a parametric distribution, and Spearman correlation test for evaluating associations between data with nonparametric distribution. A multivariate linear regression analysis was done to assess the power of relationship between MACE and correlating variables. Step-by-step "backward" method was used for linear regression analysis. A two-sided P-value <0.05 was considered statistically significant.

Results

Baseline Characteristics. A total of 405 eligible patients were included in this study. Demographic characteristics of the patients (mean age 56.9 ± 12.3 years; 302 males, 103 females) were shown in Table 1. Patients were divided into 2 groups according to PD: group 1 contained patients in whom PD was performed (n = 214) and in group 2, PD was not performed (n = 191). There was no statistically significant difference in terms of age, gender, BMI, cigarette smoking,

Table 1. Demographic Characteristics and Laboratory Values of the Study Population

	Group 1 (n = 214)	Group 2 (n = 191)	P-Value
Age (years)	57.5 ± 11.8	56.4 ± 13.0	0.16
Gender (male) (%)	157 (73.4%)	145 (75.9%)	0.56
BMI (kg/m^2)	28.0 ± 4.6	27.3 ± 3.5	0.21
Current smoker (%)	88 (41.2%)	64 (33.5%)	0.11
Hypertension (%)	66 (30.8%)	58 (30.4%)	0.92
Diabetes mellitus (%)	40 (18.7%)	43 (22.5%)	0.34
Dyslipidemia (%)	106 (49.5%)	101 (52.9%)	0.44
Anterior MI	94 (43.9%)	104 (54.5%)	0.03
Heart rate (beats/min)	79.5 ± 17.7	83.5 ± 20.8	0.15
Systolic BP (mmHg)	120.6 ± 26.4	124.1 ± 27.5	0.06
Diastolic BP (mmHg)	72.7 ± 15.1	72.8 ± 15.4	0.16
Peak CK-MB (ng/dl)	147.1 ± 116.6	154.7 ± 109.6	0.10

BMI, body mass index; HR, heart rate; BP, blood pressure; WBC, white blood cell; LDL, low density lipoprotein; HDL, high density lipoprotein; CK-MB, creatine kinase isoenzyme-MB.

Table 2. Angiographical and Procedural Characteristics of the Patients

	Group 1 (n = 214)	Group 2 (n = 191)	P-Value
MI localization (anterior/other) (%)	94/120 (43.9%)	104/87 (54.5%)	0.03
SYNTAX score	19.1 ± 7.5	17.7 ± 8.4	0.09
IRA			
LAD	94 (43.9%)	104 (54.5%)	0.03
LCX	55 (25.7%)	39 (20.4%)	0.14
RCA	65 (30.4%)	48 (25.1%)	0.17
Reperfusion time (minute)	223.1 ± 158.1	248.7 ± 162.9	0.15
Preprocedural TIMI flow grade			
0/1	160 (74.8%)	148 (77.8%)	0.84
2	45 (21.2%)	23 (11.9%)	0.08
3	9 (4.0%)	10 (5.3%)	0.23
Postprocedural TIMI flow grade			
0/1	5 (2.2%)	4 (0.8%)	0.12
2	49 (23.0%)	34 (18.6%)	0.14
3	160 (74.8%)	153 (80.6%)	0.41
Postprocedural MBG			
0/1	9 (3.9%)	10 (5.3%)	0.10
2	78 (37.3%)	57 (30.1%)	0.21
3	125 (58.8%)	123 (64.6%)	0.11
Postprocedural cTFC	15.4 ± 5.2	14.3 ± 5.9	0.24
Stent length (mm)	23.4 ± 6.2	20.5 ± 5.9	<0.01
Stent diameter (mm)	2.9 ± 0.4	3.1 ± 0.4	<0.01
Overlapping stents	10 (4.4%)	8 (3.5%)	0.54
Aspiration catheter usage (%)	23 (10.2%)	28 (12.4%)	0.23
Tirofiban usage (%)	19 (8.4%)	27 (11.9%)	0.11
LVEF (%)	41.3 ± 10.5	40.2 ± 9.3	0.90

Mean values ± standard deviation and n (%) were reported for continuous and categorical variables, respectively. MI, myocardial infarction; IRA, infarct-related artery; LAD, left anterior descending; LCX, circumflex; RCA, right coronary artery; TIMI, thrombolysis in myocardial infarction; cTFC, corrected TIMI frame count; MBG, myocardial blush grade; LVEF, left ventricular ejection fraction.

DM, or HT between the groups. Biochemical data were also not significantly different.

Angiographic and Procedural Characteristics. Angiographic and procedural characteristics are shown in Table 2. The LAD was the culprit artery in most patients in group 2 (94 vs. 104, $P = 0.03$). Postprocedural TIMI flow grade, cTFC, and MBG were similar in both groups, regardless of PD ($P > 0.05$). As a result of the greater number of LAD lesions in group 2, stents deployed were larger than those in group 1 (mean stent diameters, 3.1 ± 0.4 vs. 2.9 ± 0.4; $P < 0.01$). In contrast, mean stent length was greater in group 1 (23.3 ± 6.0 vs. 20.4 ± 5.9 mm; $P < 0.01$).

Clinical Follow-Up. At 30 days, patients were evaluated either at an office visit or via a telephone call (with the patient or the home physician) for assessment of their angina status and the recording of interim data, including MACE, coronary intervention, or clinical manifestations consistent with recurrent myocardial ischemia. Patients were also evaluated for their angina status and adverse cardiovascular events at 6 months (Table 3; Fig. 2). Control angiography was not scheduled during follow-up. Only symptomatic patients with significant ischemia detected either with treadmill exercise stress test, myocardial perfusion scintigraphy or dobutamine stress echocardiography underwent coronary angiography. Stent thrombosis occurred in 13 patients (3.2%); 3 in group 1 (2 patients with early and 1 with late stent thrombosis) and 10 patients in group 2 (6 patients with early and 4 with late stent thrombosis; $P = 0.04$). Patients in group 2 experienced more stent thrombosis at 6 months follow up (6 difinite, 3 probable, and 1 possible in group 2 vs. 2 definite and 1 probable in group 1; $P = 0.04$). TVR occurred in 22 patients; 6 in group 1 (3 patients with stent thrombosis, 3 with stent restenosis) and 16 patients in group 2 (10 patients with stent thrombosis, 6 with restenosis; $P = 0.03$). MACE occurred in 34 patients (17 in group 1 and 17 in group 2; $P = 0.49$). A multivariate logistic regression analysis

Table 3. Clinical Outcomes of the Study Population at 6 Months Follow-Up

	All patients (n = 405)	Group 1 (n = 214)	Group 2 (n = 191)	P-Value
MACE	34 (8.4%)	17 (7.9%)	21 (5.2%)	0.49
Death	15 (3.7%)	8 (3.7%)	7 (3.7%)	0.10
Stent thrombosis				
Early	8 (2.0%)	2 (0.1%)	6 (3.1%)	0.15
Late	5 (1.2%)	1 (0.1%)	4 (1.7%)	0.18
Total	13 (3.2%)	3 (0.2%)	10 (4.8%)	0.04
TVR	22 (5.4%)	6 (3.3%)	16 (7.9%)	0.04

MACE, major adverse cardiac event; TVR, target vessel revascularization.

was performed with the variables that had found associated with MACE at 6 months (Table 4).

Discussion

The major finding of this study was that PD could be performed safely in patients with AMI. Additionally, it may reduce the risk of TVR and stent thrombosis, without increasing adverse cardiovascular events or mortality. Clinical studies have shown that DES implantation significantly reduces neointimal hyperplasia (NIH) and the need for repeated coronary revascularization, compared with bare metal stents.[4,5] Despite advances in stent technology and implantation techniques, both acute and long-term complications, such as stent thrombosis and restenosis, still occur.[11,12] Stent underexpansion has been defined as a major risk factor for both of these adverse events. Thus, stent optimization after deployment is crucial.[7–9] PD has been recommended to overcome these complications and provide optimal stent expansion in elective PCI.[10–12] However, there is no consensus among interventional cardiologists regarding performance of PD during primary PCI, due to limited data and a general lack of evidence.[13–14]

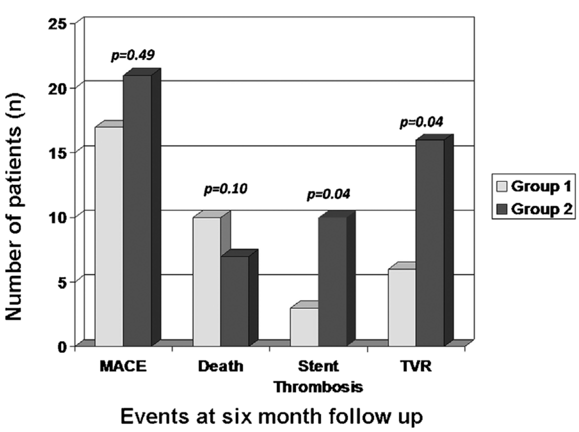

Figure 2. Percentage of clinical outcome measures at 6-month.

Ultrasonographic trials have demonstrated that incomplete stent expansion can occur even though semicompliant balloons carrying the stent were inflated to higher-than-normal pressures.[12] Various factors, such as heterogeneous stent expansion during implantation, dissolution of a thrombus behind stent struts in the setting of AMI, chronic stent recoil, and positive arterial remodeling, could be related to ISA in patients with AMI.[8,19,20] All of these factors may contribute to a higher incidence of ISA in patients presenting with AMI compared with those undergoing elective PCI.[21] On the other hand, oxygen free radicals that are released from leucocytes in AMI, may neutralize the vasodilatory effects of nitric oxide and increase vascular tone.[20] Also, the additional effects of coronary spasm, induced by the increased amount of circulating vasoconstrictors during AMI, may result in underestimation of the actual vessel diameter and the selection of a smaller stent.[21] Based on these findings, high-pressure NC balloon inflation after stenting would appear to have a beneficial role in patients presenting with AMI. Stent thrombosis and TVR were less common during follow-up in patients where PD was performed, which could be attributable to optimal stent expansion; however, there was no significant difference between the groups in terms of cardiovascular mortality in our study. Biswas et al.[14] recently evaluated the results of PD in 44% of 160 patients with AMI. They did not report any adverse effect of PD on angiographical and long-term clinical results in these patients. Favorable results with PD were explained by more frequent use of glycoprotein IIb/IIIa antagonists and a thrombus aspiration catheter (Export® catheter, Medtronic Corporation, Minneapolis, MN,

Table 4. Multivariate Logistic Regression Analysis for Variables Associated with MACE at 6 Months Follow-Up

	β Coefficient	Odds (95% CI)	P-Value	R^2
Age	−0.01	0.98 (0.95–1.03)	0.49	0.09
Diabetes	0.52	1.69 (1.13–2.52)	0.01	
Stent length	0.03	1.03 (0.97–1.10)	0.36	
Stent diameter	−0.90	0.41 (0.14–1.16)	0.09	
Postdilatation	−0.47	0.63 (1.00–0.94)	0.02	
Final TIMI frame count	0.06	1.06 (0.99–1.13)	0.08	
Final TIMI flow grade	−0.88	0.41 (0.16–1.05)	0.06	
Final MBG	−0.38	0.68 (0.21–2.15)	0.51	

Variables associated with MACE in the univariate analysis were included to the multivariate logistic regression model.
CI, confidence interval; MACE, major adverse cardiac events; TIMI, thrombolysis in myocardial infarction; MBG, myocardial blush grade.

USA). Zhang et al.[13] reported that the number of MIs and deaths *increased* with PD in patients with acute coronary syndromes (ST elevation and non-ST elevation MI). Distal embolization has been reported to be associated with worse outcomes. However, when the study was re-evaluated, it became clear that the increased mortality rates were not due to cardiovascular reasons alone. Patients in the PD group had significantly greater comorbidities. Complex (type C and ostial) lesions were significantly more common in the PD group. Although distal embolization was reported as the underlying mechanism, there was no reflow phenomenon and the percentages of TIMI II coronary flow were similar (2.7% vs. 2.1%, $P > 0.05$). Thus, as the investigators emphasized, the main reason for the increased mortality was unclear. In our study, there was no significant difference between the 2 groups in terms of angiographical results, such as final TIMI score, cTFC, or MBG. No reflow after PD was seen in only a small fraction of patients after PD (4 patients, 1.9%), which returned to TIMI grade II/III flow immediately after intracoronary nitroglycerin. Vasoconstriction induced by PD could explain the impaired coronary flow dynamics. Huang et al.[22] reported that deceleration of coronary flow during primary PCI was generally reversible and responded well to intracoronary administered vasodilatators. No reflow phenomenon due to distal embolization of the thrombus burden occurs immediately after predilatation or stent deployment in most cases. Thus, it seems unlikely that there would be no reflow after PD due to distal embolization of a thrombus. Furthermore, if PD is not performed, any thrombus present might dissolve, resulting in incomplete stent apposition, an important predictor of stent thrombosis. PD and DM were found to be independent predictors of MACE in our study. Previous studies reported that diabetic patients undergoing primary PCI experienced worse outcomes than nondiabetics. Similarly, in our study, patients with DM had higher rates of MACE. We suggest that the detrimental effect of DM in patients with AMI could be explained by multiple physiological and metabolic factors rather than stent underexpansion.

Limitations. This study had a small population size. It was not randomized, or controlled; rather, operators were free to perform PD according to the patient's clinical status and preprocedural angiographic findings. There was no significant difference in the baseline characteristics of the 2 groups. Lack of control angiography in all patients restricted us to evaluating angiographical outcomes at 6 months. Patients with a coronary bypass history were excluded, because evaluation of TIMI frame count in saphenous grafts was not feasible. We did not evaluate patients with bare metal stents, so our results cannot be generalized. All coronary angiogram images were assessed by 2 operators, who were not blinded to procedural details, which may have resulted in observer bias. Interobserver reproducibility showed substantial agreement for cTFC, TIMI flow grade, and MBG, with a weighted κ of 0.64 (0.480.79). Further studies are needed to evaluate whether our clinical outcome findings hold true in a larger study population over a longer follow-up period.

Conclusions

In conclusion, performance of PD in patients undergoing primary PCI did not adversely affect coronary blood flow. Moreover, it demonstrated favorable clinical outcomes at 6-month follow-up. These results suggest the feasibility of performance of PD by interventional cardiologists in patients with AMI.

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