

ORIGINAL ARTICLE

# Paclitaxel-Eluting versus Uncoated Stents in Primary Percutaneous Coronary Intervention

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## ABSTRACT

### BACKGROUND

Drug-eluting coronary-artery stents have been shown to decrease restenosis and therefore the likelihood that additional procedures will be required after percutaneous coronary intervention (PCI). We evaluated the use of a drug-eluting stent in patients undergoing PCI for acute myocardial infarction with ST-segment elevation.

### METHODS

We randomly assigned 619 patients presenting with an acute myocardial infarction with ST-segment elevation to receive either a paclitaxel-eluting stent or an uncoated stent. The primary end point was a composite of death from cardiac causes, recurrent myocardial infarction, or target-lesion revascularization at 1 year.

### RESULTS

Baseline clinical and angiographic characteristics in both groups were well matched. There was a trend toward a lower rate of serious adverse events in the paclitaxel-stent group than in the uncoated-stent group (8.8% vs. 12.8%; adjusted relative risk, 0.63; 95% confidence interval, 0.37 to 1.07;  $P=0.09$ ). A nonsignificant trend was also detected in favor of the paclitaxel-stent group, as compared with the uncoated-stent group, in the rate of death from cardiac causes or recurrent myocardial infarction (5.5% vs. 7.2%,  $P=0.40$ ) and in the rate of target-lesion revascularization (5.3% vs. 7.8%,  $P=0.23$ ). The incidence of stent thrombosis during 1 year of follow-up was the same in both groups (1.0%).

### CONCLUSIONS

Although the use of paclitaxel-eluting stents in acute myocardial infarction with ST-segment elevation reduced the incidence of serious adverse cardiac events at 1 year by 4.0 percentage points, as compared with uncoated stents, the difference was not statistically significant. (Current Controlled Trials number, ISRCTN65027270.)

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**P** RIMARY PERCUTANEOUS CORONARY INTERVENTION (PCI) is now considered the optimal approach to the management of myocardial infarction with ST-segment elevation when the procedure is performed expeditiously and at a high-volume center.<sup>1-5</sup> Stent implantation is associated with an improvement in both early and late outcomes, as compared with balloon angioplasty alone, predominantly as a result of a reduction in target-vessel revascularization.<sup>6,7</sup> Furthermore, drug-eluting stents have been shown to reduce in-stent restenosis (and therefore the need for repeated intervention) in a number of subgroups of patients.<sup>8,9</sup> Retrospective studies and one small, randomized trial have suggested that the use of drug-eluting stents is also beneficial in the setting of primary PCI.<sup>10-13</sup> We aimed to determine whether paclitaxel-eluting stents are superior to uncoated stents in the setting of primary PCI in terms of the rate of serious adverse cardiac events at 1 year.

## METHODS

### STUDY DESIGN

Our prospective, single-blind, randomized study, called the Paclitaxel-Eluting Stent versus Conventional Stent in Myocardial Infarction with ST-Segment Elevation (PASSION) trial, was performed at two centers in the Netherlands (Onze Lieve Vrouwe Gasthuis in Amsterdam and St. Antonius Hospital in Nieuwegein). The trial was entirely funded by the Department of Interventional Cardiology at Onze Lieve Vrouwe Gasthuis and was approved by the ethics committees at both institutions. All study participants provided oral informed consent, which was documented in the patients' clinical records. This approach to informed consent was explicitly approved by the ethics committee at each center.

### ENROLLMENT OF PATIENTS

We enrolled patients who were between the ages of 18 and 80 years if they had had an acute myocardial infarction with ST-segment elevation (>20 minutes of chest pain and at least 1 mm of ST-segment elevation in at least two contiguous leads or a new left bundle-branch block), reperfusion was expected to be achieved within 6 hours after the onset of symptoms, and the native coronary artery was considered to be suitable for pri-

mary PCI with stent implantation. We excluded patients if they had received thrombolytic therapy; the infarction was caused by in-stent thrombosis or restenosis; there was a contraindication to aspirin, clopidogrel, or both; patients were participating in another clinical trial; cardiogenic shock was evident before randomization; the neurologic outcome after resuscitation was uncertain; they had undergone intubation, ventilation, or both; there was known intracranial disease; or the estimated life expectancy was less than 6 months.

### PROCEDURES

We administered aspirin (at a dose of 100 to 500 mg) and clopidogrel (300 mg) when patients first arrived at the hospital. A glycoprotein IIb/IIIa receptor blocker was administered at the discretion of the operator. A bolus of 10,000 IU of unfractionated heparin was administered before the procedure.

Coronary angiography was performed through either the radial or the femoral artery. The target segment was filmed in at least two orthogonal planes after the intracoronary administration of 100 to 200  $\mu$ g of nitroglycerin; quantitative coronary angiography was then performed. The use of thrombectomy devices and predilatation balloons was at the operators' discretion.

As soon as the length and diameter of the stent had been chosen, patients were randomly assigned to receive either a paclitaxel-eluting stent (Taxus Express2, Boston Scientific) or an uncoated stent (Express2 or Liberté, Boston Scientific) in a 1:1 ratio, with the use of permuted blocks of 50. Assignment to study groups was performed with the use of sealed envelopes. Patients, referring physicians, investigators responsible for obtaining follow-up information, and interventionalists performing repeated procedures were all unaware of treatment assignments.

Stents were deployed with a minimum pressure of 12 atm. If dissection or incomplete coverage of the lesion occurred, additional stents of the same type as the assigned stent were used. Final angiography was performed to obtain views similar to those obtained before the procedure. Epicardial blood flow in the infarct-related artery before and after stent implantation was determined according to the Thrombolysis in Myocardial Infarction (TIMI) classification.<sup>14</sup>

**FOLLOW-UP**

We prescribed 80 to 100 mg of aspirin daily for life and 75 mg of clopidogrel daily for at least 6 months. During each patient's hospital stay, we recorded all adverse events; during follow-up visits at 30 days and at 12 months, we recorded all serious adverse cardiac events (death from cardiac or noncardiac causes, recurrent myocardial infarction, revascularization of the target lesion or target vessel, and coronary-artery bypass grafting [CABG]), as well as interventions to nontarget vessels.

**STUDY END POINTS AND DEFINITIONS**

Drs. Laarman and Suttrop adjudicated all end points of the study in a blinded fashion. The primary end point was the first occurrence of a serious adverse cardiac event at 12 months, including death from cardiac causes, recurrent myocardial infarction requiring hospitalization, and ischemia-driven revascularization of a target lesion. The secondary end points of the study were revascularization of a target lesion and a composite of death from cardiac causes or recurrent myocardial infarction.

All deaths were considered to have been from cardiac causes unless a noncardiac cause could be identified. Recurrent myocardial infarction was defined by the development of either pathological Q waves lasting at least 0.4 second in at least two contiguous leads or an increase in the creatine kinase level to more than twice the upper limit of normal with an elevation of the creatine kinase MB isoenzyme. A creatine kinase level of more than five times the upper limit of normal was required for the diagnosis of myocardial infarction after bypass surgery. Patients who still had an elevation in cardiac enzymes received a diagnosis of reinfarction if there was an increase of at least 50% from the previous measurement.

Revascularization of the target lesion was defined as ischemia-driven PCI of the target lesion owing to restenosis or reocclusion within the stent or in the adjacent 5 mm of the distal or proximal segments and included CABG involving the infarct-related artery. Stent thrombosis was defined by the angiographic documentation of either vessel occlusion or thrombus formation within, or adjacent to, the stented segment. Stent thrombosis was categorized as acute (occurring within 24 hours after the procedure), subacute (occurring 1 to 30 days after the procedure), or

late (occurring more than 30 days after the procedure).

**STATISTICAL ANALYSIS**

We calculated that a total of 262 patients would be required in each group, using a two-sided test for differences in independent binomial proportions with an alpha level of 0.05, for the study to have a statistical power of 90% to detect a reduction in the primary end point from an anticipated event rate of 21.7% in the uncoated-stent group to 10.9% in the paclitaxel-stent group, a relative reduction of approximately 50%. This assumption was based on the results of the TAXUS-II trial of the Taxus Express2 paclitaxel-eluting stent.<sup>15</sup> Given the differences in the nature and design of that study and our study (primary vs. elective PCI and no angiographic follow-up), 10% was added to the number of patients. Allowing for attrition, the required study population was determined to be 620 patients.

Baseline data are presented as proportions or mean ( $\pm$ SD) values and were compared with the use of Student's *t*-test or the Wilcoxon rank-sum test for continuous variables and with Fisher's exact test for categorical variables. A two-sided *P* value of less than 0.05 was considered to indicate statistical significance.

We estimated the cumulative incidence rates of the primary and secondary end points at 1 year with the Kaplan–Meier method.<sup>16</sup> Data on patients who were lost to follow-up were censored at the time of the last contact. Relative risks were calculated by dividing the Kaplan–Meier estimated rate of an event at 1 year in the paclitaxel-stent group by the rate in the uncoated-stent group. The 95% confidence interval (CI) for the relative risk was calculated with the use of the standard errors from the Kaplan–Meier curve. The significance of differences in rates of the end points between treatment groups was assessed by the log-rank test. A Cox proportional-hazards model was used to adjust for baseline variables for calculation of an adjusted relative risk for the primary end point.

**RESULTS****BASELINE CHARACTERISTICS AND PROCEDURAL RESULTS**

We screened 1037 patients who had myocardial infarction with ST-segment elevation at the two

sites between March 28, 2003, and December 31, 2004. Of these patients, 619 were enrolled in the study; 310 were randomly assigned to the paclitaxel-stent group and 309 to the uncoated-stent group. The most common reasons for exclusion from the trial were an anticipated delay of more than 6 hours between the onset of symptoms and reperfusion, coronary anatomy that was not suitable for stent implantation, cardiogenic shock, and mechanical ventilation.

The baseline clinical characteristics of both groups were well matched (Table 1). The mean age was 61 years; 75.9% of the patients were men. The prevalence of diabetes mellitus was low

(11.0%). All patients received aspirin and clopidogrel before percutaneous coronary intervention. The time from the onset of symptoms to the first balloon inflation was approximately 3 hours in both groups.

The baseline angiographic characteristics are shown in Table 2. Approximately half the patients had multivessel disease, and in 50.1% of the cases, the left anterior descending coronary artery was the infarct-related artery. TIMI flow grade 2 or 3 was present in 29.3% of patients in the paclitaxel-stent group and in 28.4% in the uncoated-stent group. The majority of patients had an estimated lesion length between 10 mm and 19 mm.

**Table 1. Baseline Clinical Characteristics.\***

Characteristics	Paclitaxel-Eluting Stent (N=310)	Uncoated Stent (N=309)	P Value
Age — yr	61±12	61±13	0.91
Male sex — no. (%)	229 (73.9)	241 (78.0)	0.26
Diabetes mellitus — no. (%)	31 (10.0)	37 (12.0)	0.44
Hypertension — no. (%)	95 (30.6)	98 (31.7)	0.80
Hypercholesterolemia — no. (%)	72 (23.2)	86 (27.8)	0.20
Family history of CAD — no. (%)	125 (40.3)	110 (35.6)	0.25
History of smoking cigarettes — no. (%)	165 (53.2)	154 (49.8)	0.42
Previous PCI — no. (%)	14 (4.5)	13 (4.2)	1.00
Previous stent — no. (%)	5 (1.6)	6 (1.9)	0.77
Previous CABG — no. (%)	2 (0.6)	2 (0.6)	1.00
Previous myocardial infarction — no. (%)	14 (4.5)	18 (5.8)	0.48
Aspirin before PCI — no. (%)†	219 (70.6)	199 (64.4)	0.10
Clopidogrel before PCI — no. (%)†	118 (38.1)	109 (35.3)	0.50
Warfarin — no. (%)	4 (1.3)	2 (0.6)	0.69
Heparin before PCI — no. (%)†	67 (21.6)	54 (17.5)	0.22
Glycoprotein IIb/IIIa-receptor blocker (abciximab) before PCI — no. (%)	87 (28.1)	80 (25.9)	0.59
Thrombolysis — no. (%)‡	8 (2.6)	3 (1.0)	0.22
Nitrates before PCI — no. (%)	67 (21.6)	67 (21.7)	1.00
Beta-blockers — no. (%)	27 (8.7)	31 (10.0)	0.58
Calcium antagonists — no. (%)	10 (3.2)	8 (2.6)	0.81
Statins — no. (%)	25 (8.1)	42 (13.6)	0.03
Time from onset of chest pain to angioplasty — hr	3.00±1.70	2.97±1.80	0.86
Total ST-segment elevation — mm§	11±8	11±9	0.76

\* Plus-minus values are means ±SD. CAD denotes coronary artery disease.

† The drug was administered at presentation (before entry into the catheterization laboratory). All patients received aspirin and clopidogrel before PCI; those who had not received these agents before entry into the catheterization laboratory were given them at that time.

‡ A total of 11 patients received a thrombolytic agent before undergoing PCI, which was considered a protocol violation.

§ This category is the total of measured millimeters of ST-segment elevation in all 12 electrocardiographic leads.

The mean reference diameter was 3.13±0.43 mm in the paclitaxel-stent group and 3.20±0.47 mm in the uncoated-stent group.

The procedural characteristics were also well matched (Table 3). The average length of stents was 19 mm in both groups. Glycoprotein IIb/IIIa receptor blockers were used in three quarters of both groups (abciximab in all cases). TIMI grade 3 flow was established in 93.2% of patients in the paclitaxel-stent group, as compared with 96.1% of patients in the uncoated-stent group. The sizes of infarcts, reflected by the mean peak value of the creatine kinase MB isoenzyme, were similar (193±183 in the pacli-

taxel-stent group and 210±186 in the uncoated-stent group).

**EVENTS DURING THE FIRST 30 DAYS**

Events during the first 30 days after the intervention are shown in Table 4 and in Tables 1 through 9 of the Supplementary Appendix (available with the full text of this article at www.nejm.org). No significant differences were found between the two treatment groups. The cumulative incidence of serious adverse cardiac events at 30 days was 4.2% in the paclitaxel-stent group and 6.5% in the uncoated-stent group (P=0.21). Acute stent thrombosis (within 24 hours) occurred in one pa-

**Table 2. Baseline Angiographic Variables.\***

Variable	Paclitaxel-Eluting Stent (N=310)	Uncoated Stent (N=309)	P Value
Coronary artery disease — no. (%)			
1 Vessel	179 (57.7)	162 (52.4)	0.20
2 Vessels	82 (26.5)	100 (32.4)	0.11
3 Vessels	49 (15.8)	47 (15.2)	0.91
Infarct-related artery — no. (%)			
Left anterior descending artery	156 (50.3)	154 (49.8)	0.94
Left main stem	2 (0.6)	0	0.50
Right coronary artery	129 (41.6)	118 (38.2)	0.41
Left circumflex artery	18 (5.8)	32 (10.4)	0.04
Intermediate branch	3 (1.0)	4 (1.3)	0.72
Saphenous-vein graft	2 (0.6)	1 (0.3)	1.00
TIMI flow grade — no. (%)			
0	193 (62.3)	196 (63.4)	0.80
1	26 (8.4)	25 (8.1)	1.00
2	41 (13.2)	48 (15.5)	0.42
3	50 (16.1)	40 (12.9)	0.30
Lesion length — no. (%)			
0–9 mm	41 (13.2)	48 (15.5)	0.49
10–19 mm	201 (64.8)	188 (60.8)	0.36
20–29 mm	50 (16.1)	52 (16.8)	0.83
≥30 mm	18 (5.8)	21 (6.8)	0.62
Proximal tortuosity — no. (%)	17 (5.5)	17 (5.5)	1.00
Calcified lesion — no. (%)	28 (9.0)	19 (6.1)	0.22
Thrombus present — no. (%)	213 (68.7)	204 (66.0)	0.49
Reference diameter — mm	3.13±0.43	3.20±0.47	0.04
Mean luminal diameter — mm	0.15±0.35	0.17±0.38	0.60
Stenosis — %	94.8±13.2	94.0±14.6	0.48

\* Plus-minus values are means ±SD.

Variable	Paclitaxel-Eluting Stent (N=310)	Uncoated Stent (N=309)	P Value
Stent size — mm	3.21±0.30	3.26±0.38	0.08
Stent length — mm	19±5.6	19±5.5	0.71
No. of stents implanted per patient	1.26±0.55	1.33±0.63	0.14
Maximal balloon inflation pressure — atm	15.84±2.94	15.73±2.94	0.70
Glycoprotein IIb/IIIa-receptor blocker after PCI — no. (%)	227 (73.2)	230 (74.4)	0.78
Final TIMI flow grade — no. (%)			
0	2 (0.6)	3 (1.0)	0.69
1	2 (0.6)	2 (0.6)	1.00
2	17 (5.5)	7 (2.3)	0.06
3	289 (93.2)	297 (96.1)	0.15
Reference diameter — mm	3.20±0.46	3.24±0.45	0.26
Luminal diameter — mm	3.15±0.47	3.13±0.57	0.66
Residual stenosis — %	3.03±6.6	4.66±12.1	0.04
Procedural success — no. (%)†	289 (93.2)	297 (96.1)	0.15
Maximum creatine kinase — U/liter	2046±2055	2244±2061	0.26
Maximum creatine kinase MB — U/liter	193±183	210±186	0.30

\* Plus-minus values are means ±SD.

† Patients in this category had TIMI flow grade 3 and were alive at hospital discharge.

tient (0.3%) in the paclitaxel-stent group. Subacute stent thrombosis occurred in one patient (0.3%) in the paclitaxel-stent group and in three patients (1.0%) in the uncoated-stent group.

#### 1-YEAR FOLLOW-UP

A total of 97.4% of patients in the paclitaxel-stent group and 98.1% of those in the uncoated-stent group underwent complete clinical follow-up. Events during the first year after the intervention are shown in Table 4 and in Tables 10 through 18 of the Supplementary Appendix. The cumulative incidence of the primary end point was 8.8% in the paclitaxel-stent group and 12.8% in the uncoated-stent group (relative risk, 0.69; 95% CI, 0.43 to 1.10;  $P=0.12$ ) (Fig. 1 and Table 4). Multivariate adjustment (which incorporated all the variables in Table 1, Table 2, and Table 3) did not substantially alter the estimate of the relative risk (relative risk, 0.63; 95% CI, 0.37 to 1.07;  $P=0.09$ ). The secondary end points are also shown in Table 4. Although trends were observed in favor of the paclitaxel-stent group, none of these differences were significant.

Late stent thrombosis occurred in one patient (0.3%) in the paclitaxel-stent group and in none

in the uncoated-stent group, a difference that was not significant. Clopidogrel was used for a median of 9 months (interquartile range, 6 to 12) in both groups; nine patients discontinued clopidogrel prematurely. None of these patients had a thrombotic event. The six patients with stent thrombosis were all compliant with the specified regimen at the time of the event.

#### DISCUSSION

Our study compared paclitaxel-eluting coronary-artery stents with uncoated stents for primary PCI during acute myocardial infarction with ST-segment elevation. The cumulative incidence of the primary end point — a composite of death from cardiac causes, recurrent myocardial infarction, and target-lesion revascularization at 12 months — was 8.8% in the paclitaxel-stent group and 12.8% in the uncoated-stent group. The adjusted risk ratio was 0.63, which was not statistically significant. There was also a trend in favor of the paclitaxel-stent group in the rates of individual adverse events, but no single end point reached statistical significance. In contrast, trials comparing these two types of stents in elective PCI have

**Table 4. Follow-up at 30 Days and 1 Year.\***

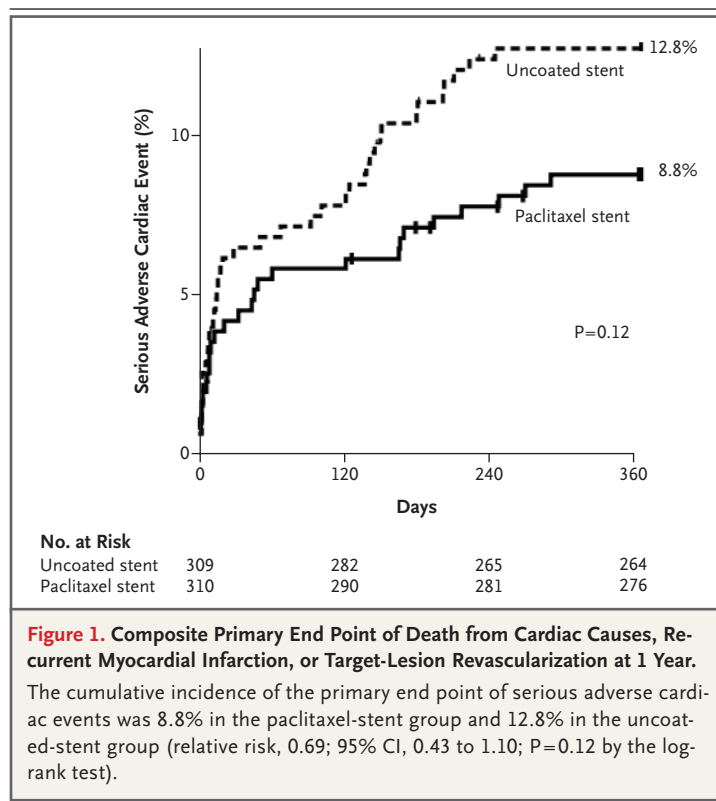
Variable	Paclitaxel-Eluting Stent (N = 310)	Uncoated Stent (N = 309)	P Value
	<i>no. of patients (%)</i>		
<b>Follow-up at 30 days</b>			
Complete data available	308 (99.4)	306 (99.0)	
Target-lesion revascularization	7 (2.3)	9 (3.0)	0.60
Recurrent myocardial infarction or death from cardiac causes	10 (3.2)	15 (4.9)	0.31
Composite of major adverse cardiac events	13 (4.2)	20 (6.5)	0.21
Death from any cause	8 (2.6)	13 (4.2)	0.27
Death from cardiac causes	8 (2.6)	13 (4.2)	0.27
Recurrent myocardial infarction	2 (0.7)	5 (1.7)	0.25
Stent thrombosis	2 (0.7)	3 (1.0)	0.65
Repeated PCI of target lesion	2 (0.7)	3 (1.0)	0.65
CABG of target vessel	6 (2.0)	6 (2.0)	0.99
<b>Follow-up at 1 year</b>			
Complete data available	302 (97.4)	303 (98.1)	
Target-lesion revascularization	16 (5.3)	23 (7.8)	0.23
Recurrent myocardial infarction or death from cardiac causes	17 (5.5)	22 (7.2)	0.40
Composite of major adverse cardiac events	27 (8.8)	39 (12.8)	0.12
Death from all causes	14 (4.6)	20 (6.5)	0.30
Death from cardiac causes	12 (3.9)	19 (6.2)	0.20
Recurrent myocardial infarction	5 (1.7)	6 (2.0)	0.74
Stent thrombosis	3 (1.0)	3 (1.0)	0.99
Repeated PCI of target lesion	6 (2.0)	10 (3.4)	0.29
CABG of target vessel	10 (3.3)	15 (5.1)	0.30

\* Cumulative incidences were estimated from the Kaplan–Meier curves at 30 days and 1 year and are not simple proportions.

consistently showed a significant benefit associated with the use of paclitaxel-eluting stents.<sup>8,9</sup>

There are a number of possible explanations for the difference between the results of this trial and those of previous studies. First, the trial power may have been insufficient. Event rates in the uncoated-stent group were much lower than those anticipated in our power calculations. The point estimate of the difference in the primary end point, if accurate, is clinically significant; a larger trial could have demonstrated statistical significance. However, the estimated relative reduction of serious adverse cardiac events by 31% is considerably smaller than that observed in previous trials with drug-eluting stents. This finding has consequences for the cost–benefit profile of these stents for the indication of primary PCI.<sup>8-13</sup> Second, the study design did not include angiographic follow-up. Recurrent stenosis observed during

routine follow-up angiography could have led to reintervention without symptoms or objective evidence of ischemia, thus increasing the event rate. In addition, after PCI for myocardial infarction, restenosis may have developed in some patients in the absence of ischemic symptoms, owing either to partial infarction or to a defective warning system. Third, there may have been a difference in response to vascular injury in the setting of primary PCI, as compared with that of more elective procedures. The literature, however, shows that angiographic and clinical restenosis after primary PCI remains an important issue.<sup>6,7</sup> Fourth, the study was performed in patients with relatively large infarct-related arteries in which there was a decreased risk of restenosis. Finally, continuing improvements in the design of stents and the lower thickness of struts may have been responsible for lower rates of restenosis in the un-



coated-stent group than in those reported previously.

The results of our study also differ from a series of retrospective analyses and one small, randomized trial evaluating the implantation of drug-eluting stents for myocardial infarction with ST-segment elevation.<sup>10-13</sup> Subgroup analysis of patients undergoing PCI with sirolimus-eluting stents for myocardial infarction in the Thoraxcenter Research Registry showed that the rate of serious adverse cardiac events at 300 days was reduced from 17.0% to 9.4% (P=0.02).<sup>11</sup> This pattern was repeated in a retrospective analysis from the Washington Hospital Center using the same stent type.<sup>12</sup> In the Single High-Dose Bolus Tirofiban and Sirolimus-Eluting Stent vs. Abciximab and Bare-Metal Stent in Myocardial Infarction (STRATEGY) trial involving 175 patients, the rate of death, reinfarction, or target-vessel revascularization at 8 months was reduced from 32% with an uncoated stent to 18% with a sirolimus-eluting stent.<sup>13</sup> These event rates are among the highest reported for any trial of PCI, and the reasons for the high event rates are not entirely clear, although most of the patients in the STRATEGY

trial underwent routine follow-up angiography and the mean reference-vessel diameter was considerably smaller than that in our trial. An additional feature of the STRATEGY trial was that by design, a different glycoprotein IIb/IIIa inhibitor was used in the two study groups, which confounded the interpretation of the comparison between the two types of stents.

We did not observe a difference in the rates of stent thrombosis between our two study groups, although the definition of stent thrombosis was conservative (since angiographic documentation was required). Acute or subacute stent thrombosis occurred in two patients (0.6%) in the paclitaxel-stent group and three patients (1.0%) in the uncoated-stent group. This incidence is low, given the thrombotic environment at the time of stent placement, the potential for suboptimal stent deployment in the setting of PCI for acute myocardial infarction, and decreased blood flow in a vessel that supplies infarcted myocardium. In a recent retrospective study from the Thoraxcenter, the incidence of stent thrombosis at 1 month (which was also defined on the basis of angiography) after primary PCI with the use of a paclitaxel-eluting stent was 2.9%.<sup>17</sup> We also found no evidence of an increase in the rate of late stent thrombosis, a topic that has recently caused concern.<sup>18</sup>

In this issue of the *Journal*, a report on the Trial to Assess the Use of the Cypher Stent in Acute Myocardial Infarction Treated with Balloon Angioplasty (TYPHOON) by Spaulding et al.<sup>19</sup> compares sirolimus-eluting stents with uncoated stents in primary PCI among 712 patients. The investigators report a significant difference in the primary end point (the composite of death from cardiac causes, recurrent infarction, and target-vessel revascularization at 1 year) in favor of sirolimus-eluting stents, as compared with uncoated stents (7.3% vs. 14.3%, P=0.004). Differences between the two trials — including the type of drug-eluting stent used, the study design (routine follow-up angiography was performed in a subgroup of patients in TYPHOON), primary end points, and inclusion and exclusion criteria — make it difficult to compare the outcomes of our trial with those of TYPHOON. It is worth noting, however, that the event rates in the two groups of patients in TYPHOON are not markedly different from those in our analysis.

In conclusion, our study did not show a significant benefit associated with the use of paclitaxel-eluting stents in primary PCI for acute myocardial infarction with ST-segment elevation, as compared with uncoated stents with the same design.

Dr. Laarman reports having served on the advisory board of Boston Scientific and having received lecture fees from Cordis,

Johnson & Johnson, and Medtronic; Dr. Dirksen, lecture fees from Boston Scientific; Dr. Kiemeneij, lecture fees from Terumo Medical and Cordis, Johnson & Johnson, and royalties from Boston Scientific; and Dr. Slagboom, consulting fees from Biotronik and lecture fees from Cordis, Johnson & Johnson. No other potential conflict of interest relevant to this article was reported.

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