Drug-Eluting Versus Bare Metal Stents in Patients With ST-Segment–Elevation Myocardial Infarction

Eight-Month Follow-Up in the Drug Elution and Distal Protection in Acute Myocardial Infarction (DEDICATION) Trial

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Background—Implantation of drug-eluting stents (DES) limits the rate of coronary restenosis in most patients with coronary artery disease, but data are scarce with regard to their use in patients with ST-segment–elevation myocardial infarction and in connection with distal protection of the microvascular perfusion during primary percutaneous coronary intervention.

Methods and Results—We randomly assigned 626 patients referred within 12 hours from symptom onset of an ST-elevation myocardial infarction to have a DES or a bare metal stent implanted in the infarct-related lesion with or without distal protection during primary percutaneous coronary intervention. Quantitative coronary angiography was performed during the index treatment and 8 months later. The primary end point was loss of the lumen diameter in the infarct-related lesion induced by neointimal proliferation. Patients were comparable with regard to baseline demographic and angiographic characteristics. The mean late lumen loss was significantly lower in patients treated with a DES (0.06 mm; SD, 0.66 mm) than in patients who had a bare metal stent implanted (0.47 mm; SD, 0.69 mm; \(P<0.001\)). The rate of the composite end point of cardiac death, recurrent myocardial infarction, and target lesion revascularization was 8.6% in the DES group versus 14.4% in the bare metal stent group (\(P=0.03\)). Cardiac death occurred in 4.2% and 1.6% of the patients (\(P=0.09\)) and stent thrombosis occurred in 2.0% and 2.6% (\(P=0.72\)), respectively.

Conclusion—Implantation of DES improves the angiographic outcome and need for repeat revascularization without increasing the short-term risk of stent thrombosis but has a tendency to increase cardiac death in patients with ST-segment–elevation myocardial infarction. (Circulation. 2008;118:1155-1162.)

Key Words: angioplasty § coronary disease § myocardial infarction § restenosis § stents

Primary percutaneous coronary intervention, including stent implantation, has become the treatment of choice in patients with ST-segment–elevation myocardial infarction when performed within 12 hours after the onset of symptoms, even if it involves transporting the patient from a referring hospital, provided it can be performed within 90 minutes after first medical contact.1–4 Drug-eluting stents (DES) improve the angiographic and clinical outcomes in most patients. However, only a few larger randomized studies have been undertaken to evaluate the effect and safety of the use of DES in patients with ST-segment–elevation myocardial infarction,5–7 and the clinical results of these trials have not been consistent. In addition, inclusion criteria were rather strict in previous trials.

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Abrupt closure of an epicardial coronary vessel usually occurs in a large vessel and in an area of a vulnerable plaque with necrotic lipid cores and low-grade stenosis,8 and the vascular response to implantation of a DES in such an area...
could be considerably different from the response occurring in a smaller vessel and a high-grade stable lesion. Late angiographic evaluation after implantation of DES compared with bare metal stents (BMS) in patients with ST-segment–elevation myocardial infarction has been reported in only a few patients.

The present study was designed to evaluate whether implantation of DES currently used for other categories of patients with coronary artery disease reduces neointimal proliferation in the infarct-related lesion and thereby improves clinical outcome compared with BMS in a rather unselected group of patients with ST-segment–elevation myocardial infarction. Because it was unclear whether protection of the microcirculation during primary percutaneous coronary intervention improves outcome,10–12 patients were also randomized to treatment with or without distal protection using a filter wire system.

Methods

Study Design and Patients
The Drug Elution and Distal Protection in ST-Segment–Elevation Myocardial Infarction (DEDICATION) trial was a randomized study evaluating the effect of implantation of DES or BMS with or without distal protection during primary percutaneous coronary intervention conducted at 2 high-volume invasive cardiology centers in Denmark. The study protocol was approved by the local ethics committees, and all patients gave written informed consent before inclusion.

We enrolled patients with chest pain of >30-minute duration who had a cumulated ST-segment elevation of >4 mm in at least 2 contiguous leads of the ECG, provided that they were >18 years of age and had a high-grade stenosis or occlusion of a coronary artery without excessive tortuosity or calcification prohibiting advancement of a filter wire to the distal vascular bed of the vessel. We did not distinguish between patients who were admitted directly to the tertiary unit with laboratory facilities or via a referring hospital as long as they presented to the catheterization laboratory within 12 hours from symptom onset. Exclusion criteria were previous myocardial infarction in the target vessel area, development of cardiogenic shock before enrollment, culprit lesions in an unprotected left main coronary artery, gastrointestinal bleeding within 1 month, pregnancy, known renal failure, life expectancy <1 year, and linguistic problems.

Randomization and Study Procedures
Patients were pretreated with 300 to 500 mg aspirin, 300 to 600 mg clopidogrel, and 10,000 IU unfractionated heparin as soon as transportation to the catheterization laboratory was arranged. A β-blocker was administered at the discretion of the transportation team according to blood pressure and heart rate. If there was no contraindication, patients were treated with a glycoprotein IIb/IIIa receptor blocker on arrival at the catheterization laboratory. Coronary angiography was performed, and the culprit lesion was identified. A guidewire was advanced through the highly stenosed or occluded lesion, and if the peripheral vascular bed was not visible, dilatation with a 1.5- to 2.0-mm-diameter balloon was allowed to visualize the coronary artery distal to the lesion. Central telephone (simple) randomization was performed by computerized assignment stratified with regard to sex and the presence of diabetes. Patients were randomly assigned to treatment with or without distal protection and to receive a DES or a BMS in the infarct-related lesion. All stents were implanted under high pressure (>12 atm). Implantation of >1 stent of the same kind was allowed to cover the entire lesion. Both operator and patient were aware of the assigned treatment.

Follow-Up Schedule
Patients were examined during and after the index procedure with ST-segment monitoring, cardiac markers, and echocardiography. At discharge, patients received a daily dose of a statin, clopidogrel (for 12 months), and aspirin (indefinitely). A β-blocker was administered in the absence of contraindications, and an angiotensin-converting enzyme inhibitor was given in case of reduced (<45%) left ventricular ejection fraction. Clinical follow-up was performed at 1 and 6 months to evaluate symptoms of restenosis and the occurrence of major adverse cardiac and cerebral events. Angiographic follow-up was scheduled at 8 months. A clinically driven angiography performed 4 to 8 months after the index treatment replaced the scheduled angiography. Target lesion revascularization (TLR) was indicated in cases of recurrent angina and a diameter stenosis >50% or a diameter stenosis >70% if the patient had no angina.

Quantitative Coronary Angiography Analysis
Angiograms of the infarct-related lesion were acquired immediately after the index procedure and 8 months later using identical projections. Quantitative analysis was performed with the MEDIS computerized edge-detection system by operators blinded to treatment assignments. The minimal lumen diameter was recorded within the stent margins (in-stent) and 5 mm proximally and distally to the stent (in-lesion). The reference diameter was determined with an interpolated edge-detection technique. Late lumen loss was calculated as the difference between the minimal lumen diameter immediately after the index procedure and at 8 months. Diameter stenosis was calculated as follows: (1–minimal lumen diameter/reference diameter)×100%. A diameter stenosis >50% was characterized as a binary restenosis.

Study End Points and Definitions
The primary end point of the study was the late lumen loss in the infarct-related lesion as determined by quantitative coronary angiography (see above). Secondary end points were the rate of major adverse cardiac events occurring within 8 months after treatment (cardiac death, nonfatal recurrent myocardial infarction, and TLR), development of binary restenosis, clinically driven TLR, and target vessel revascularization.

A recurrent myocardial infarction was defined as a total creatine kinase elevation ≥2 times the upper limit of normal with a concomitant increase in creatine kinase-MB concentration in the presence of an acute coronary syndrome, and reinfarction was present if the recurrent myocardial infarction could be related (by ECG or angiography) to the target vessel. Stroke was defined as the development of disabling neurological symptoms and objective findings lasting >24 hours. Clinically driven TLR was defined as percutaneous or surgical revascularization of the target lesion in the presence of recurrent angina and a significant stenosis/occlusion of the infarct-related lesion. Nonclinically driven TLR was allowed in the absence of angina when the diameter restenosis was >70%. Target vessel revascularization was defined as revascularization either in the target lesion or in an area remote from the target lesion in the same coronary artery. The Clinical Events Committee adjudicated all serious events and stent thromboses according to current definitions.

Statistical Analysis
The trial involved a factorial design evaluating the effect of treatment with versus without distal protection and implantation of DES versus BMS. With a power of 80% and a 2-sided type 1 error of 5%, 125 patients were needed in each group to detect a 0.25-mm increase in late lumen loss with an SD of 0.70 mm. With an expected 25% rate of patients lost to follow-up, 150 patients were needed in each arm of the study.

Differences in categorical variables were analyzed by the χ2 test or by Fisher’s exact test. Continuous variables were analyzed with the Mann–Whitney and Student t tests for unpaired samples. The Kaplan–Meier method was used to create survival estimates, and the log-rank test was used to test differences in these estimates. Interaction analyses...
were performed by Cox proportional-hazard models including an interaction variable. All probability values were 2 sided. The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

**Results**

**Patients**

Of 1687 screened patients, 626 were enrolled in the trial from May 2005 to November 2006 (Figure 1). Major reasons for exclusion were clinical instability, unconsciousness, unsuitable coronary anatomy, insufficient ST elevation, and participation in another study. The outcome of distal protection versus conventional treatment is published elsewhere.17

Patients in the 2 groups were well matched in terms of baseline clinical and angiographic characteristics (Table 1). The mean age was 63 years; 73% were men; ≈10% had diabetes; and the median duration from symptom onset to arrival in the catheterization laboratory was ≈3 hours 20 minutes. The left ventricular ejection fraction measured at discharge was comparable in the 2 groups. Glycoprotein IIb/IIIa receptor blockers were used in ≈95% of patients, and distal protection was used with success in ≈40% of the patients in each group (Table 2). All patients received the stent type that they were allocated to, except 3 patients in the DES group (2 were treated with balloon angioplasty alone, and 1 received a BMS) and 8 patients in the BMS group (5 were treated with balloon angioplasty alone, and 3 received a DES). The angiographic and clinical data for these patients were included in the groups to which they were randomly assigned. The diameter and length of the stented segment were similar in the 2 groups, and procedural success was high (Table 2). Of the stents implanted in the DES group, 47% were sirolimus-eluting (Cordis, NJ), 40% were paclitaxel-eluting (Boston Scientific, Natick, Mass), and 13% were zotarolimus-eluting stents (Medtronic, Calif). Among BMS, 38% were made of cobalt alloy (Vision, Abbott, Ill, and Driver, Medtronic), 39% were stainless steel stents from Boston Scientific, and 23% were miscellaneous stainless steel stents from Biotronik (Seoul, South Korea), Cordis, Guidant, Diegem (Belgium), Jomed (Helsingborg, Sweden), and Terumo (Tokyo, Japan). Patients who were excluded from the trial for the above reasons were slightly older, had a higher rate of diabetes and previous myocardial infarction, and had a longer duration of symptom onset to arrival, and 4% had lesions located in the left main stem or saphenous vein grafts (Table 1). As opposed to the included patients, 65% of the excluded patients received a DES, 20% received a BMS, and 15% were treated with balloon angioplasty only.

**Quantitative Coronary Angiography**

Follow-up angiography was performed in 84% of all patients and in 87% of those who were alive at follow-up. Only data from examined patients were used. Thus, no computations of missing data were performed. The minimal lumen diameter was similar in the 2 groups immediately after the index procedure but significantly larger at follow-up in the DES group (Table 3). Thus, the late lumen loss was 0.06 mm (SD, 0.66 mm) in the lesions of patients treated with a DES compared with 0.47 mm (SD, 0.69 mm) in patients who had received a BMS ($P < 0.001$). The diameter stenosis was less severe in the DES group at follow-up, and the rate of in-lesion binary restenosis was reduced accordingly, from ≈20% in the BMS to <10% in the DES group ($P < 0.001$). Similar results were found inside the stents (Table 3).

Whereas the reference diameter of the target vessel in patients who had received a DES increased slightly from the index procedure to the 8-month follow-up, the opposite was recorded in patients who had a BMS implanted, with an
ensuing 10% difference in reference diameter in the 2 groups (P<0.001). There was no significant interaction between distal protection and stent type.

### Clinical Outcomes

The clinical outcomes of the 2 groups are outlined in Figure 2. Sixteen patients in the DES group versus 8 patients in the BMS group died during the 8-month follow-up period (P=0.14). Thirteen patients in the DES group versus 5 patients in the BMS group suffered a cardiac death (P=0.09). In the DES group, 1 patient died during the procedure, and 2 patients died of a malignant arrhythmia. The remaining 10 patients died as a result of cardiogenic shock or progressive heart failure; 4 of these patients died within 1 month after the acute myocardial infarction, and the Clinical Events Committee could not rule out that stent thrombosis occurred eventually in these 4 patients (accordingly, these 4 deaths were classified as probable stent thromboses). In the BMS group, 1 patient died during the procedure, 1 patient died of rupture of the myocardial wall, 1 suffered an arrhythmic death, and 2 developed progressive heart failure. Only 2 patients (1 in each group) died after 1 month. A major adverse cardiac event occurred in 28 patients (8.9%) in the DES group and in 45 patients (14.4%) in the BMS group (P=0.046), a difference that was driven by a marked difference in TLR (5.1% in the DES group and 13.1% in the BMS group; P=0.001). A significant albeit less pronounced difference was observed in clinically driven TLR (Figure 3). The corresponding rate of target vessel revascularization was 6.4% and 16.0%, respectively (P<0.001). Stroke occurred in 1.6% of patients with a DES and 1.0% of patients with a BMS (P=0.73).

Stent thrombosis occurred in 7 patients (2.0%) in the DES group and in 8 patients (2.6%) in the BMS group (P=0.72). Ten of the stent thromboses were definite, ie, verified angiographically. The 8-month mortality rate of patients not included in the trial was 13% with an overweight of in-hospital deaths.

### Discussion

Late lumen loss was significantly lower in the DES group compared with the BMS group and slightly less than in several other trials. In general, the restenosis level is somewhat smaller in ST-segment–elevation myocardial infarction patients than in patients with chronic stable disease, which is explained to some extent by the larger reference vessel in ST-segment–elevation myocardial infarction but also may be due to differences in the triggering of neointimal growth. In the present study, implantation of 3 different DES during primary percutaneous coronary intervention reduced neointimal proliferation as indicated by a smaller late lumen loss compared with that recorded in BMS during the succeeding 8 months. The rate of binary restenosis in the DES group

Table 1. Baseline Clinical Characteristics of the Patients and Lesions

<table>
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<th>Randomized</th>
<th>Nonrandomized</th>
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<tr>
<td></td>
<td>DES (n=313)</td>
<td>BMS (n=313)</td>
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<tr>
<td>Age, y</td>
<td>61.8</td>
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<tr>
<td>Male gender, %</td>
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<td>54.7</td>
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<td>Family history of CAD, %</td>
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<td>Previous PCI/CABG, %</td>
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<td>Door-to-balloon time, min*</td>
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<td>No. of diseased vessels, %</td>
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<td>Infarct-related artery, %</td>
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<td>RCA</td>
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<td>12</td>
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<td>LM/SVG</td>
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<tr>
<td>Baseline TIMI flow grade, %</td>
<td>65</td>
<td>70</td>
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<td>0–1</td>
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<td>30</td>
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</tbody>
</table>

Table 2. Procedural Results

| Use of GP IIb/IIIa inhibitor, n (%) | BMS (n=313) | DES (n=313) | P  |
| Visible thrombus, n (%)           | 304 (97)    | 299 (96)    | 0.21 |
| Filter wire used successfully, n (%)| 124 (40)    | 130 (42)    | 0.38 |
| Stent implanted, n (%)           | 311 (99)    | 308 (98)    | 0.29 |
| Stents per lesion, n             | 1.3 (0.62)  | 1.3 (0.62)  | 0.52 |
| Stented length, mm               | 22.2 (10.1) | 21.0 (9.4)  | 0.12 |
| Stent diameter, mm               | 3.54 (0.55) | 3.53 (0.53) | 0.84 |
| Maximum deployment pressure, mm Hg | 16.7 (3.7)  | 16.3 (3.7)  | 0.20 |
| TIMI grade III after procedure, n (%) | 282 (90)    | 281 (90)    | 1.00 |
| Procedural success, n (%)         | 308 (98)    | 310 (99)    | 0.73 |
| Left ventricular ejection fraction, % | 48.0 (10.4) | 47.3 (10.1) | 0.43 |
| Patients with LVEF ≤30%, %        | 20 (8.0)    | 18 (7.7)    | 0.85 |

GP indicates glycoprotein; TIMI, Thrombolysis in Myocardial Infarction; and LVEF, left ventricular ejection fraction. Continuous variables are expressed as mean values (SD).
was of the same magnitude as that reported in the Trial to Assess the Use of the Cypher Stent in Acute Myocardial Infarction Treated With Balloon Angioplasty (TYPHOON), although the difference in diameter stenosis between the 2 groups at follow-up was less pronounced in our patients, probably reflecting the use of different types of stents. We implanted stents that were used contemporarily in our laboratories for patients without ST-segment–elevation myocardial infarction, and contrary to TYPHOON trial, patients with complex lesions such as ostial lesions, lesions in bifurcations, and lesions with a large thrombus burden were not excluded from the DEDICATION trial. The prevalence of diabetes among study patients, together with differences in location of the infarct-related lesions in the left and right coronary arteries, probably explains the differences in vessel size in patients included in our trial and those included in the TYPHOON and the Paclitaxel-Eluting Stent Versus Conventional Stent in Myocardial Infarction With ST-Segment Elevation (PASSION) trial. Although inclusion criteria were less strict in the DEDICATION trial, as reflected by a higher age of the patients and a higher rate of patients with complex lesions, the late lumen loss and the restenosis rate of patients who received a BMS were of the same magnitude as those reported in the Sirolimus-Eluting Stent Versus Bare-Metal Stent in Acute Myocardial Infarction (SESAMI) and TYPHOON trials.6,18 We also implanted more stents per patient and stented longer segments of the coronary arteries compared with the other trials. In addition, patients with poor left ventricular function (mean left ventricular ejection fraction, 47.5%) were included in the DEDICATION trial.

The acute hemodynamic condition during an acute myocardial infarction, including the possibility of general vasocostriction, implies a risk of suboptimal choice of stent size and deployment of stents in the infarct-related region.19 However, Spaulding et al6 did not find smaller vessel diameters during the acute procedure compared with those measured during a follow-up angiography 8 months after the primary percutaneous coronary intervention. Operators of the TYPHOON trial were discouraged from oversizing and postdilating the implanted stents with high pressure. On the
other hand, the residual stenosis in our patients was of the same magnitude as that reported in the TYPHOON trial but considerably higher than that in the PASSION trial despite a higher deployment pressure. Differences in stent properties and delivery systems, including the polymer of the DES, and different techniques to analyze the angiograms are plausible explanations of these differences. We found a general reduction in the target vessel reference diameter during the 8-month period succeeding the index procedure in patients who had a BMS implanted but not in those who received a DES. Longer-term follow-up of the patients will reveal the possible significance of this finding.

The limited in-stent neointimal proliferation in patients who received a DES resulted in a reduction in the composite end point of major adverse cardiac events from 14.4% to 8.6% \((P=0.04)\), driven mainly by a considerably lower rate of TLR. Tendencies toward higher TLR rates are usually found in patients who have a follow-up angiography performed routinely. However, the reductions in target vessel failure in those who are followed up clinically and those examined invasively seem to be of the same magnitude.\(^6\) Like in the TYPHOON trial, TLR in symptom-free patients was allowed in the present study in cases of severe \((>70\%)\) restenosis.

The death rate of the DEDICATION patients corresponded to that in the PASSION trial,\(^7\) although we observed a tendency toward a higher cardiac death in the DES group. A younger age of patients in the TYPHOON trial compared with that of our patients may account for the lower mortality rate in that trial. The rate of recurrent myocardial infarction and stroke was low and insignificantly different in our patient groups, which is in accordance with previous studies.\(^1,6,7,10\)

More patients developed cardiogenic shock or progressive heart failure in the DES group (10 versus 2 in the BMS group). On the other hand, a majority of the patients died in hospital, and it is hard to explain any impact of the drug released from the stents on the short-term clinical course.

Using traditional definitions of stent thrombosis, previous reports found a rate of stent thrombosis between 1% and 4% after implantation of BMS in patients with acute myocardial infarction.\(^20–22\) Thrombus burden in ST-segment myocardial infarction may predispose to stent thrombosis when DES are routinely used.\(^23\) We observed visible thrombus in almost 75% of the DEDICATION patients, although we did not distinguish between large and small thrombus burden. Stent thrombosis occurred in 11 patients in the DEDICATION study using the Academic Research Consortium definitions,\(^15\) and definite stent thrombosis was observed in 10 patients \((1.6\%)\), 7 of whom had a BMS. This rate of stent thrombosis is lower than that observed in the TYPHOON study,\(^6\) although we did not exclude patients with a large thrombus burden. On the other hand, our observation period was somewhat shorter than that of the TYPHOON and PASSION trials. Four of our patients \((all in the DES group)\) died within a month after the myocardial infarction. Because of considerable comorbidity in these patients, our Clinical Events Committee adjudicated these as events not necessarily related to \((probable)\) stent thrombosis in accordance with Cutlip et al.\(^15\) We observed only 1 case of possible late stent thrombosis \((in the BMS group)\). However, we will continue monitoring all our patients with regard to this serious side effect to which our patients with ST-segment–elevation myocardial infarctions might, at least theoretically, be predisposed. Accordingly, the importance of a high compliance to dual antiplatelet therapy for at least 1 year has been stressed to the patients.\(^24,25\)

A drawback of the present study is the lack of blinding of both patients and operators during the primary percutaneous coronary intervention. On the other hand, the angiographic analyses were performed by blinded investigators, and the Clinical Events Committee adjudicated the serious events without knowledge of the treatment sequence. In addition, the study was initiated, conducted, and interpreted completely by the investigators. A considerably higher death rate in the
excluded patients during the trial inclusion period reflects the limited comorbidity of those included in the trial. The impact of a higher age, higher frequency of diabetes and prior infarctions, acute occlusion of the left main stem or saphenous vein grafts, and considerably longer time to arrival from onset of symptoms contributed to a worsened prognosis of the excluded patients. It should be emphasized that only 83% of the included patients underwent reangiography and that the study was not powered to detect differences in clinical outcome. The results should be interpreted accordingly.

Conclusions

The present randomized study found a significant angiographic benefit and a lower rate of major adverse cardiac events after treatment with DES compared with BMS in a broad range of patients with ST-segment–elevation myocardial infarction. A tendency toward higher cardiac death in the DES group requires further monitoring of the patients.

Appendix


Sources of Funding

This work was supported by unrestricted grants from the Cordis/Johnson & Johnson, Medtronic, Abbott, and Boston Scientific companies.

Disclosures

None.

References


**CLINICAL PERSPECTIVE**

Primary percutaneous coronary intervention is the treatment of choice in patients with ST-segment–elevation myocardial infarction and <12 hours duration of pain, but whereas implantation of drug-eluting stents is known to reduce the development of restenosis in most patients, treatment of ST-segment–elevation myocardial infarction is considered an off-label indication of their use. We randomized patients with ST-segment–elevation myocardial infarction to have a drug-eluting or a bare metal stent implanted in their target vessel in connection with primary percutaneous coronary intervention and evaluated their angiographic and clinical outcome. We observed a reduction in the need for repeat revascularization in the drug-eluting stent group, reflecting a significant reduction in neointimal hyperplasia as determined by angiography. We also observed a tendency to an increased rate of cardiac death in the drug-eluting stent group that was not explained by a higher rate of stent thrombosis, a finding that warrants continued clinical follow-up of the patients.
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for the DEDICATION Investigators

_Circulation_. 2008;118:1155-1162; originally published online August 25, 2008; doi: 10.1161/CIRCULATIONAHA.107.758698

_Circulation_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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